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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TREACE MEDICAL CONCEPTS, INC., Plaintiff, v. STRYKER CORPORATION and WRIGHT MEDICAL TECHNOLOGY, INC., Defendants.	Civil Action No. _____ **REDACTED DOCUMENT**

COMPLAINT AND DEMAND FOR TRIAL BY JURY

Plaintiff Treace Medical Concepts, Inc. ("Treace Medical"), by and through its undersigned counsel, as and for its Complaint for Patent Infringement, violations of the Sherman and Clayton Acts, violation of New Jersey's Antitrust Act, and Interference with Prospective Economic Advantage against Defendants Stryker Corporation and Wright Medical Technology, Inc. (collectively, the "Stryker Defendants"), alleges as follows:

NATURE OF THIS ACTION

1. Pursuant to Local Civil Rule 10.1, the address for the principal place of business for Plaintiff and each Defendant are as follows:

Treace Medical Concepts, Inc.
100 Palmetto Park Place
Ponte Vedra, FL 32081

Stryker Corporation
2825 Airview Boulevard
Kalamazoo, MI 49002

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

2. This is a civil action arising out of one or more of the Stryker Defendants' (a) patent infringement in violation of the Patent Laws of the United States, 35 U.S.C. §§ 271 and 281-285; (b) violations of Section 1 of the Sherman Act, 15 U.S.C. § 1; (c) violations of Section 3 of the Clayton Act, 15 U.S.C. § 14; (d) violations of New Jersey's Antitrust Act; and (e) interference with prospective economic advantage in violation of New Jersey law.

3. Founded in 2014, Treace Medical is a medical technology company with the mission of advancing the standard of care for the surgical management of bunion and related midfoot deformities. Treace Medical pioneered and patented the novel Lapiplasty® 3D Bunion Correction System®—a combination of instruments, implants, and surgical methods designed to

surgically correct all three planes of a bunion deformity and secure the unstable joint, addressing the bunion's root cause.

4. The United States Patent and Trademark Office has awarded Treace Medical numerous patents covering its inventions relating to instrumented bunion correction, including U.S. Patent No. 9,622,805 (the "'805 Patent"); U.S. Patent No. 10,874,446 (the "'446 Patent"); U.S. Patent No. 11,039,873 (the "'873 Patent"); U.S. Patent No. 11,116,558 (the "'558 Patent"); U.S. Patent No. 11,602,386 (the "'386 Patent"); U.S. Patent No. 11,602,387 (the "'387 Patent"); U.S. Patent No. 11,911,085 (the "'085 Patent"); U.S. Patent No. 11,937,849 (the "'849 Patent"); and U.S. Patent No. 11,950,819 (the "'819 Patent") (collectively, the "Asserted Patents").

5. The Stryker Defendants have infringed and continue to infringe, either literally or under the doctrine of equivalents, one or more claims of each of the Asserted Patents in violation of 35 U.S.C. § 271. Treace Medical brings this action, *inter alia*, to stop the Stryker Defendants' patent infringement.

6. In addition, Stryker Corporation has illegally foreclosed competition in a substantial portion of the market of bunion correction systems through rebate agreements and other misconduct that bundles these unique systems with other, unrelated product lines in violation of Section 1 of the Sherman Act, Section 3 of the Clayton Act, and Section 3 of the New Jersey Antitrust Act. Stryker Corporation's illegal acts have resulted in increased costs, decreased quality of patient care, and decreased adoption of life-changing surgical systems and procedures. Treace Medical brings this action to protect a competitive market where health care purchasing decisions are made on the merits of product effectiveness and price, rather than coercion of health care purchasing departments through large rebate payments in unrelated service lines.

THE PARTIES

7. Plaintiff Treace Medical is a Delaware corporation with its principal place of business at 100 Palmetto Park Place, Ponte Vedra, Florida 32081. Treace Medical owns the Asserted Patents.

8. Defendant Stryker Corporation ("Stryker") is a Michigan corporation with its principal place of business at 2825 Airview Boulevard, Kalamazoo, Michigan 49002. Stryker's Orthopaedics segment and Foot and Ankle business are located at 325 Corporate Drive, Mahwah, New Jersey 07430.

9. Defendant Wright Medical Technology, Inc. ("Wright") is a subsidiary of Stryker and is a Delaware corporation with its principal place of business at 1023 Cherry Road Memphis, Tennessee 38117. Stryker directly or indirectly owns 100% of the outstanding voting securities of Wright.

10. The Stryker Defendants have two later-developed offerings directed to addressing bunion deformities in the foot that are accused herein. First, on information and belief, Stryker and Wright own, control, manufacture, market, and/or sell the ORTHOLOC™ 2 LapiFuse™ Triplanar Correction System ("LapiFuse™ System" or "LapiFuse™ Procedure"). Second, Stryker owns, controls, manufactures, markets, and/or sells the PROstep® MIS Lapidus System ("PROstep® Lapidus System" or "PROstep® Lapidus Procedure").

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over Treace Medical's patent infringement claims under 28 U.S.C. §§ 1331 and 1338(a), because these claims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

12. This Court also has subject matter jurisdiction over Treace Medical's causes of action under federal antitrust laws, including Section 1 of the Sherman Act and Section 3 of the

Clayton Act, under 15 U.S.C. §§ 15 and 26, and 28 U.S.C. §§ 1331 and 1337. Further, this Court has subject matter jurisdiction over Treace Medical's related causes of action for violations of New Jersey's Antitrust Act and interference with prospective economic advantage under New Jersey law under 28 U.S.C. § 1367(a) because they are related to the federal antitrust claims such that they form part of the same case or controversy under Article III of the United States Constitution.

13. This Court has specific and general personal jurisdiction over both Stryker Defendants consistent with the requirements of the Due Process Clause of the United States Constitution and the New Jersey Long Arm Statute. As further detailed below, Stryker has established sufficient minimum contacts in this forum through its regular and established place of business at 325 Corporate Drive, Mahwah, New Jersey 07430, located in this District. In addition, on information and belief, both Stryker and Wright regularly do business in this District, both of their activities have targeted this District, and both have committed one or more acts complained of in this District, providing additional bases for the Court's exercise of personal jurisdiction over each Stryker Defendant. For example, the Stryker Defendants have committed and continue to commit acts of patent infringement in this District by, among other things, importing, making, using, offering to sell, and/or selling systems that infringe the Asserted Patents, and by contributing to and/or inducing the infringement of these patents by others. On information and belief, Stryker has also committed the anticompetitive acts complained of herein throughout the country, including in this District from its Mahwah "home to Stryker Orthopaedics."

14. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c), and 1400(b). On information and belief, both Stryker Defendants have committed acts of patent infringement in this District and in the State of New Jersey by, for example, making, using, offering to sell, and selling systems that infringe the Asserted Patents, and/or contributing to and/or inducing the

infringement of those patents by others. On information and belief, Stryker has also committed the anticompetitive acts complained of herein in this District. In addition, Stryker has a regular and established place of business in this District at 325 Corporate Drive, Mahwah, New Jersey 07430 (the "Mahwah facility"), a 48-acre site where Stryker houses research laboratories, manufacturing, warehouse, distribution, business and administration offices. Stryker is registered to do business in New Jersey and has appointed an agent for service of process in New Jersey, located at 820 Bear Tavern Road, West Trenton, New Jersey 08628.

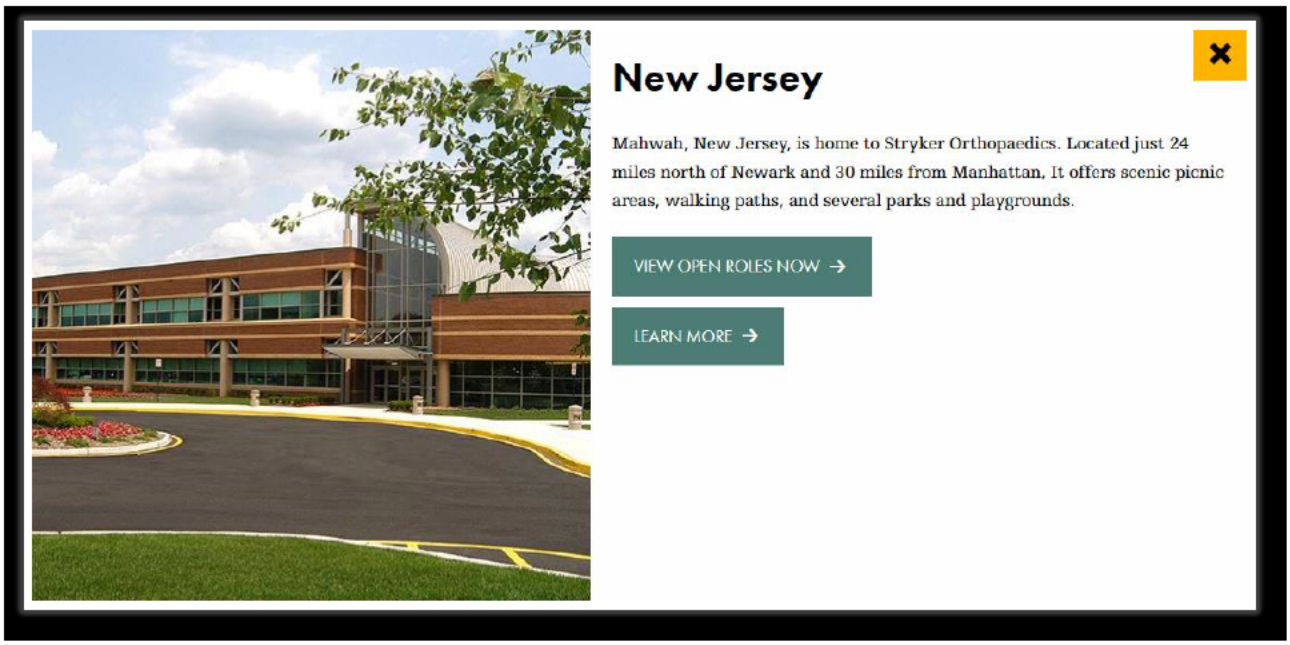
15. Likewise, Wright is registered to do business in New Jersey and has appointed an agent for service of process in New Jersey, located at Princeton South Corporate Center, Suite 160, 100 Charles Ewing Boulevard, Ewing, New Jersey 08628. On information and belief, Wright also has a regular and established place of business in this District at the Mahwah facility. The Mahwah facility is Wright's manufacture reporting address for U.S. Food and Drug Administration ("FDA") activities, including the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database.

16. On information and belief, the accused LapiFuse™ System is currently owned, controlled, manufactured, marketed, and/or sold by one or both Stryker Defendants. The LapiFuse™ System was originally owned, controlled, manufactured, marketed, and sold by Wright. Stryker acquired Wright on November 11, 2020. A LapiFuse™ System video animation on Stryker's website, available at https://www.stryker.com/us/en/foot-and-ankle/products/lapifuse.html, references both Stryker and Wright. On information and belief, the Stryker Defendants are acting in concert with each other to commit the acts complained of herein related to the LapiFuse™ System.

17. On information and belief, Stryker owns, controls, manufactures, markets, and/or sells the accused PROstep® Lapidus System.

18. On information and belief, the accused LapiFuse™ System and PROstep® Lapidus System are part of Stryker's Foot and Ankle business, which is a part of Stryker's Orthopaedics segment. Since 2021, Stryker and Wright have combined their foot and ankle product portfolio, including the accused systems, and advertise those accused systems from their Mahwah facility.

19. Stryker's Orthopaedics segment headquarters is located at 325 Corporate Drive, Mahwah, New Jersey 07430. As Stryker states on its "Careers" website at https://careers.stryker.com/locations (under "Our locations," "North America"), "Mahwah, New Jersey is home to Stryker Orthopaedics," as shown below:



20. A Stryker Career Blog provides the following further details, at https://www.strykercareersblog.com/post/5-reasons-to-join-stryker-in-mahwah-nj:

21. Stryker Orthopaedics also has a location at 165 East 9th Avenue, Unit F, Runnemede, New Jersey 08078.

22. Within Stryker's Orthopaedics segment, the Foot and Ankle business is also located in Mahwah, New Jersey, as shown in the image below from the "Contact Us" webpage of Stryker's website.

23. For the LapiFuse™ System, Stryker maintains a webpage with "information for healthcare professionals" at https://www.stryker.com/us/en/foot-and-ankle/products/lapifuse.html, which includes a "CONTACT" link. The "CONTACT" link directs to the contact information page for Stryker's Foot and Ankle business located in Mahwah, New Jersey, shown in the image above.

24. In addition, Stryker's Press Release announcing the launch of the PROstep® Lapidus System was issued from "Mahwah, N.J."

25. Further, Stryker's website invites prospective patients to "FIND A SURGEON" at https://patients.stryker.com/surgeons. When the "FIND A SURGEON" link is clicked, the prospective patient can select from doctors in New Jersey specializing in either "LapiFuse bunion correction" or "PROstep bunion correction." Wright's website also has a "FIND A PHYSICIAN" option in its patient-facing website at https://www.wright.com/patients, which redirects to Stryker's "FIND A SURGEON" search referenced above.

FACTUAL BACKGROUND

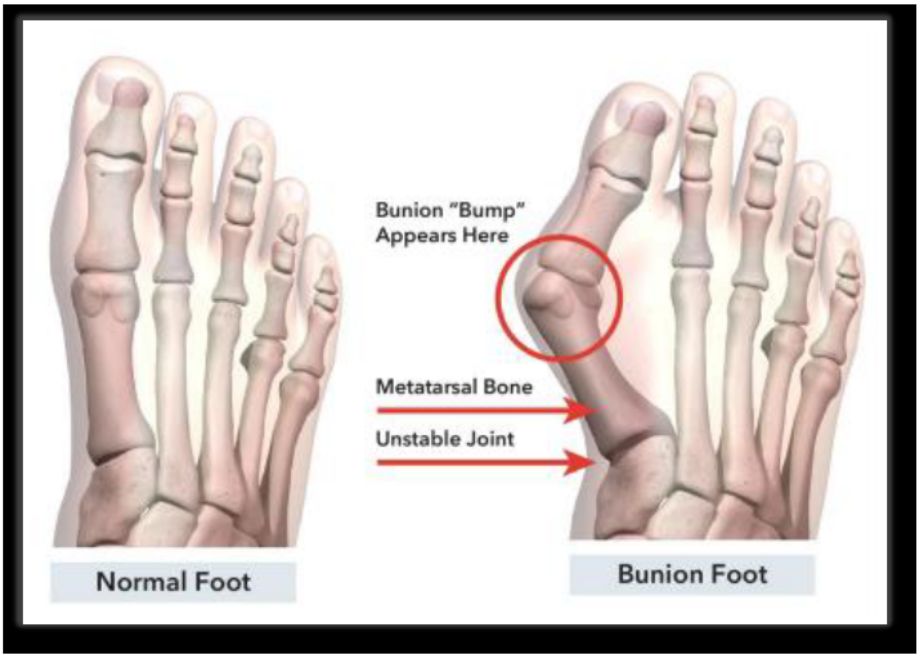
A. Treace Medical's Novel Lapiplasty® 3D Bunion Correction® System and Procedure

26. Treace Medical is the United States' leading designer, developer, and manufacturer of surgical instruments, implants, and methods focused on addressing the root cause of bunion deformities and related midfoot correction, including through its Lapiplasty® 3D Bunion Correction® System (the "Lapiplasty® System," "Lapiplasty® Procedure," or "Lapiplasty® System and Procedure"). The Lapiplasty® System includes unique procedural instrumentation and single-use implant kits to surgically correct bunion deformities with Treace Medical's novel surgical approach, the Lapiplasty® Procedure.

27. Bunions, the common name for hallux valgus deformities, are among the most commonly found forefoot problems and affect approximately 67 million Americans. Recognizable as a bump on the side of a big toe, bunions are not just a cosmetic problem. Bunions are a deformity of the bone structures within the foot that can result in painful disability that tends to worsen over time. Bunions can cause severe and debilitating pain, limited mobility, and greater risk of injury due to decreased stability. People with bunions also experience increased

susceptibility to other pathologies, such as hammertoes and arthritis of the joint, not to mention restrictions on footwear and the emotional burden related to the appearance of the bunion.

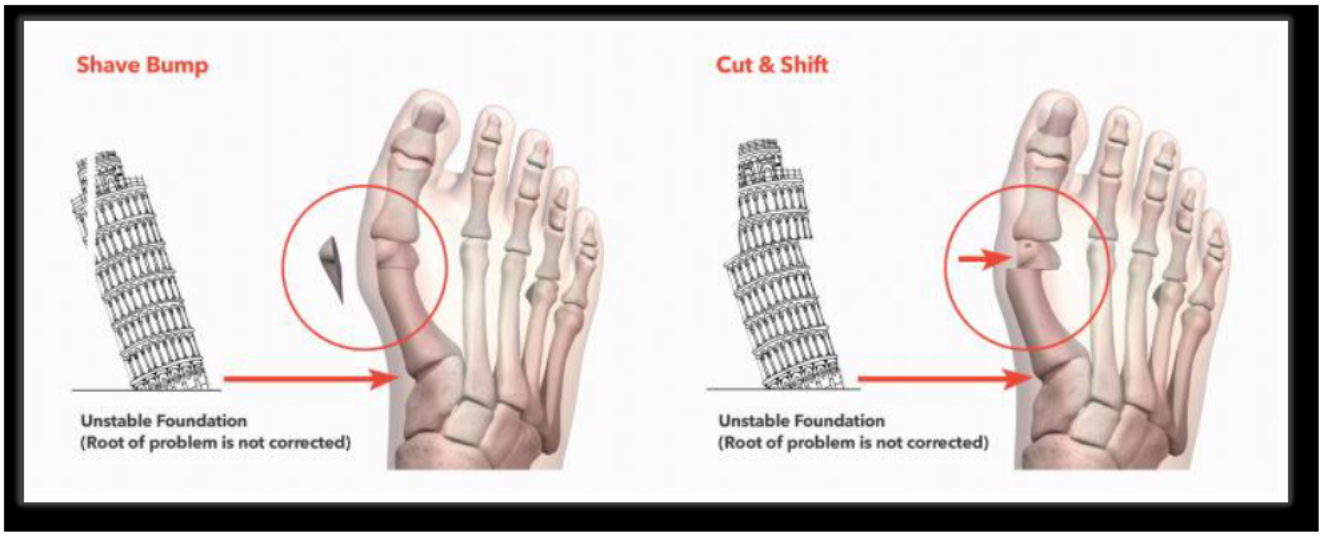
28. Bunions occur when an unstable joint in the middle of the foot causes a metatarsal bone on the big toe of the foot to rotate out of alignment, as illustrated below:



29. Bunions often progress to the point of requiring surgical intervention. Indeed, of the more than four million Americans who seek medical treatment for bunions each year, a quarter of those—over a million Americans—have a deformity or severity of condition that makes them a candidate for surgical bunion correction. Yet historically, these deformities regularly went untreated. When treated, two primary surgical approaches existed. Both traditional approaches produced mixed results and neither consistently addressed the deformity, which can present in three anatomical planes.

30. Under one traditional approach, the bunion "bump" is merely shaved off and the metatarsal bone of the big toe is cut in half and shifted over to reduce the appearance of the bunion. This cut and shift "osteotomy" technique mainly addresses the cosmetic bump and does not correct

the root cause of the deformity, creating an increased likelihood that the metatarsal bone will continue to drift out of position over time and the bunion will return. Recovery is also reported to require up to 6 weeks of non-weight bearing activity. This technique is illustrated below:



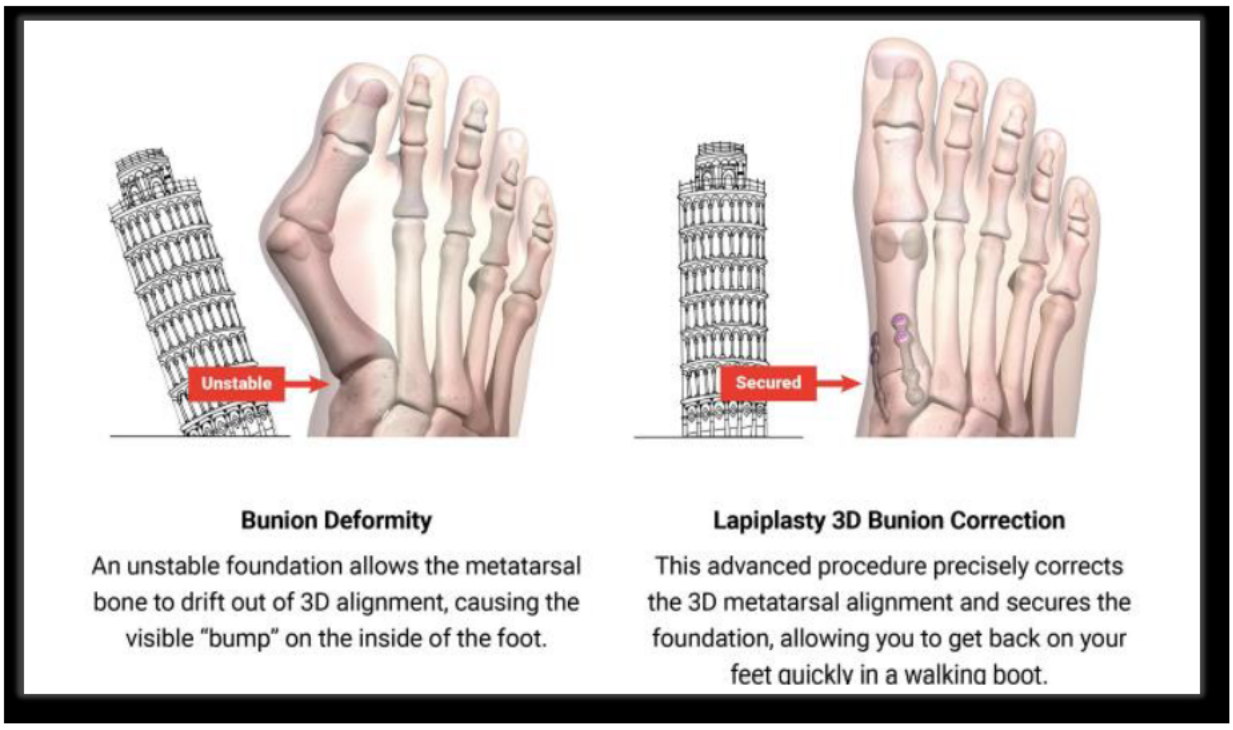
31. The second primary historical technique, known as a traditional Lapidus fusion, seeks to fuse the unstable joint, using a "freehand" surgical technique. The procedure involves removing a small slice of bone from the base of the metatarsal and the next bone, the medial cuneiform. The joint at the base of the metatarsal is then fused to help prevent the return of the deformity. This surgically difficult freehand approach results in inconsistent outcomes and is reported to involve a long period of recovery, requiring about 6 to 10 weeks of non-weight bearing activity.

32. Treace Medical, founded by John Treace in 2014, set out to solve the problems associated with the traditional approaches.

33. In 2015, Treace Medical introduced surgeons to a better way of surgically treating bunions—an instrumented bunion correction procedure later branded as the Lapiplasty® System and Procedure. Treace Medical and its team of surgeons and engineers invented an entire set of instrumentation, implants, and procedures that for the first time allowed surgeons to reproducibly

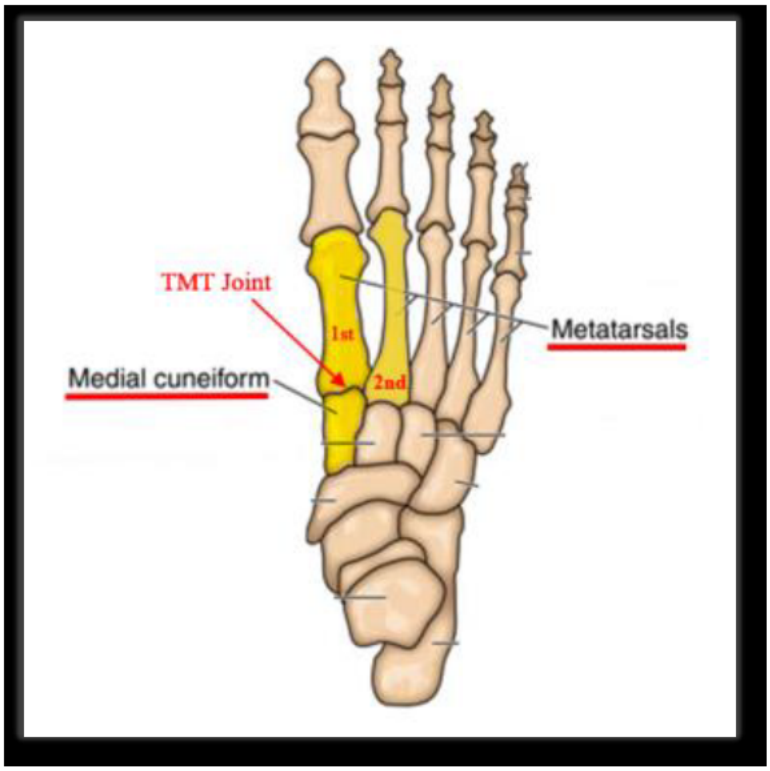
correct the bunion in up to three planes and restore the natural biomechanical structure of the foot, addressing the root cause of the deformity. With help from Treace Medical's procedural instrumentation, the Lapiplasty® Procedure realigns the entire metatarsal bone into its normal anatomical position in three planes, and then secures the unstable joint with fixation implants. Treace Medical's novel system and methods have led to improved patient outcomes, as demonstrated in multiple clinical studies. Among other advantages, Treace Medical's instrumented procedure allows for quick return to weight-bearing in a walking boot with low risk of recurrence.

34. A simplified illustration of Treace Medical's Lapiplasty® 3D Bunion Correction® is shown below:



35. The bones of the foot most relevant to Treace Medical's novel Lapiplasty® System and Procedure are the metatarsal and cuneiform bones. The first metatarsal bone, second metatarsal bone, and medial cuneiform bone (each highlighted in yellow in the figure below) and

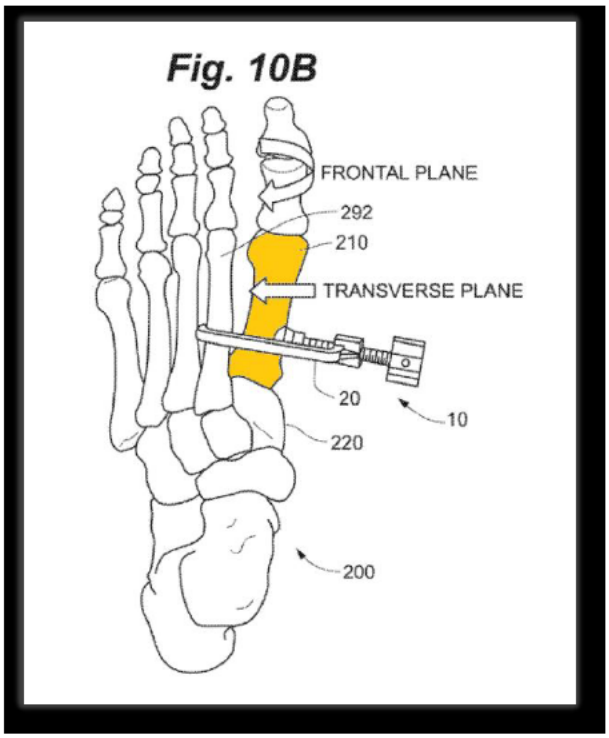
the joint (tarsal-metatarsal joint, or "TMT" joint) between the first metatarsal and medial cuneiform bones are the general focus of bunion surgery using Treace Medical's patented methods, instruments, and implants:



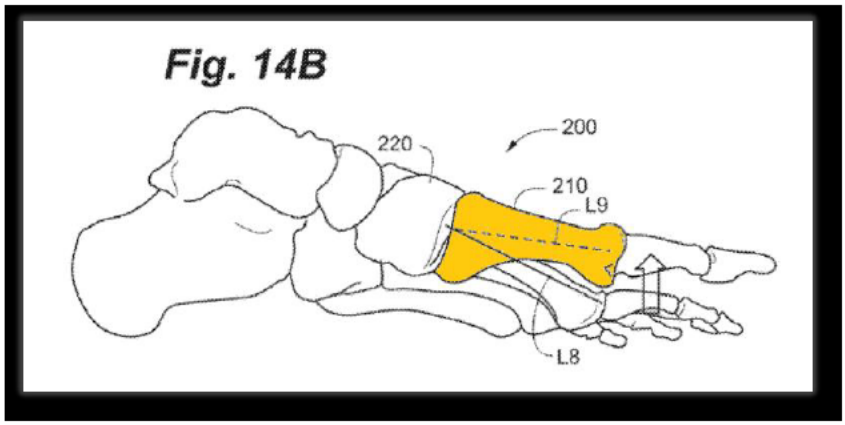
36. Treace Medical's surgical methods and instruments guide surgeons to restore the relative position and orientation of the first metatarsal bone with the medial cuneiform bone and the adjacent second metatarsal bone, and to permanently fix this restored position with implants that support the fusion of the first metatarsal bone to the medial cuneiform bone at the TMT joint.

37. Treace Medical's patented Lapiplasty® System and Procedure is the first to provide the ability to accurately and reproducibly correct bunion deformity in all three planes. For example, as demonstrated in the below image from Treace Medical's asserted '805 Patent, Treace Medical's Lapiplasty® System and Procedure uses instruments to correct the alignment of the first metatarsal in the transverse plane (from right to left direction in the figure below, to reduce an "intermetatarsal angle" between the first and second metatarsals). The Lapiplasty® System and

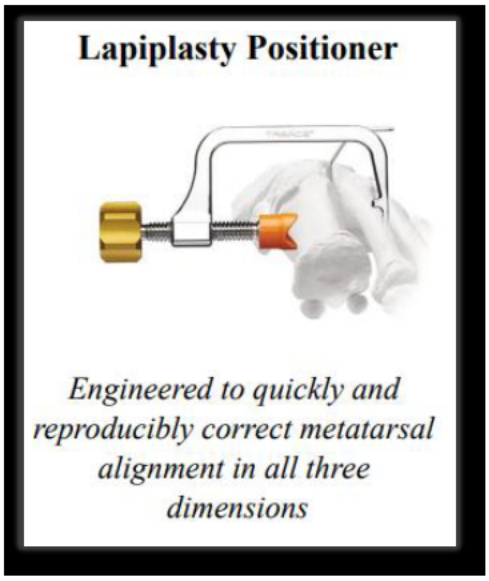
Procedure also corrects the alignment of the first metatarsal in the frontal plane (the first metatarsal, highlighted in yellow, is rotated about its axis):



38. In addition, Treace Medical's Lapiplasty® System and Procedure can correct bone misalignment in the sagittal plane, including correcting the alignment of the first metatarsal upward or downward. In the image below, a misalignment of the first metatarsal in the sagittal plane is shown with an arrow, reflecting that the first metatarsal (highlighted in yellow) is positioned upward (or "dorsally") compared to the other metatarsals in the foot. Correction with Treace Medical's Lapiplasty® System and Procedure moves the first metatarsal in a downward (or "plantarly") direction to align with the other metatarsals of the foot:

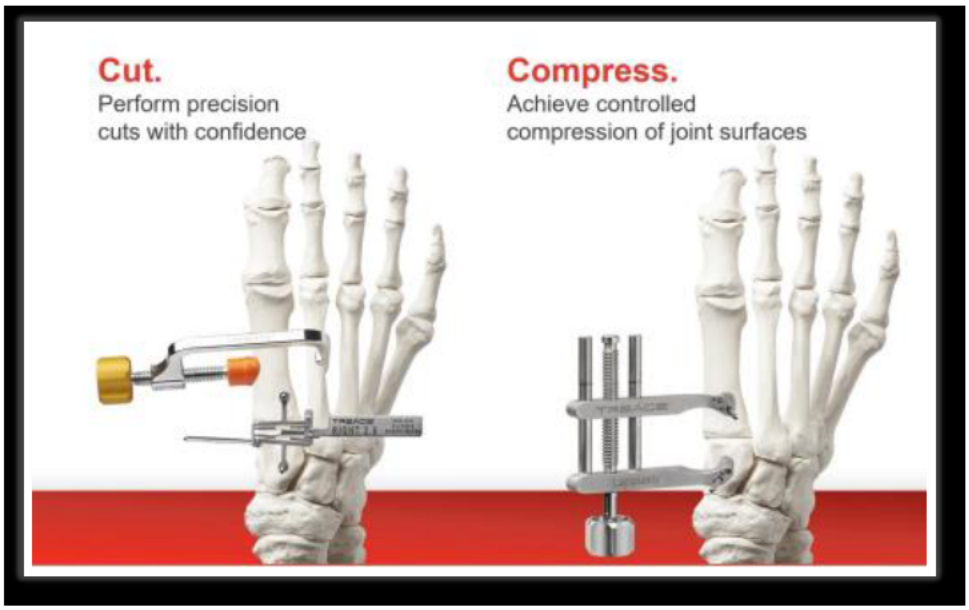


39. One key instrument used to accurately and reproducibly correct the position of the metatarsal bone for treatment of a bunion deformity in Treace Medical's Lapiplasty® System and Procedure is a bone positioning guide, commercially called the Positioner. Item 10 in Figure 10B above is one embodiment of a bone positioning guide. Treace Medical's commercial Lapiplasty® System Positioner is illustrated below:

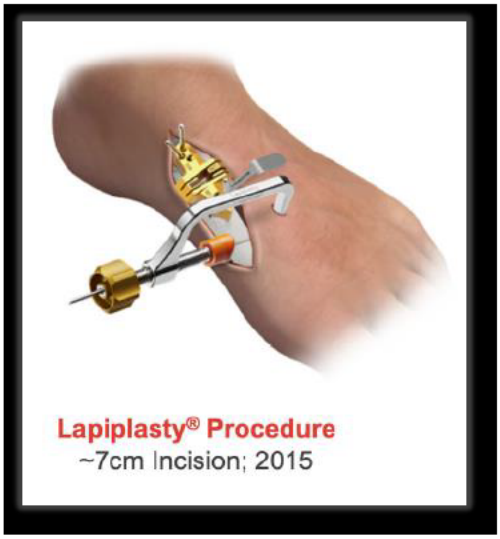


40. Treace Medical's Lapiplasty® System and Procedure also involves preparation of the ends of the medial cuneiform and first metatarsal for fusion, including cutting and then compressing the joint surfaces, as depicted in the image below. Preparing the bones is useful to facilitate flush contact between the bone surfaces and to present bleeding bone faces that can fuse

together, stabilizing the TMT joint. Treace Medical's patents describe that preparation of the joint can be done by using a tissue removing instrument, for example, a saw, rotary bur, or osteotome.

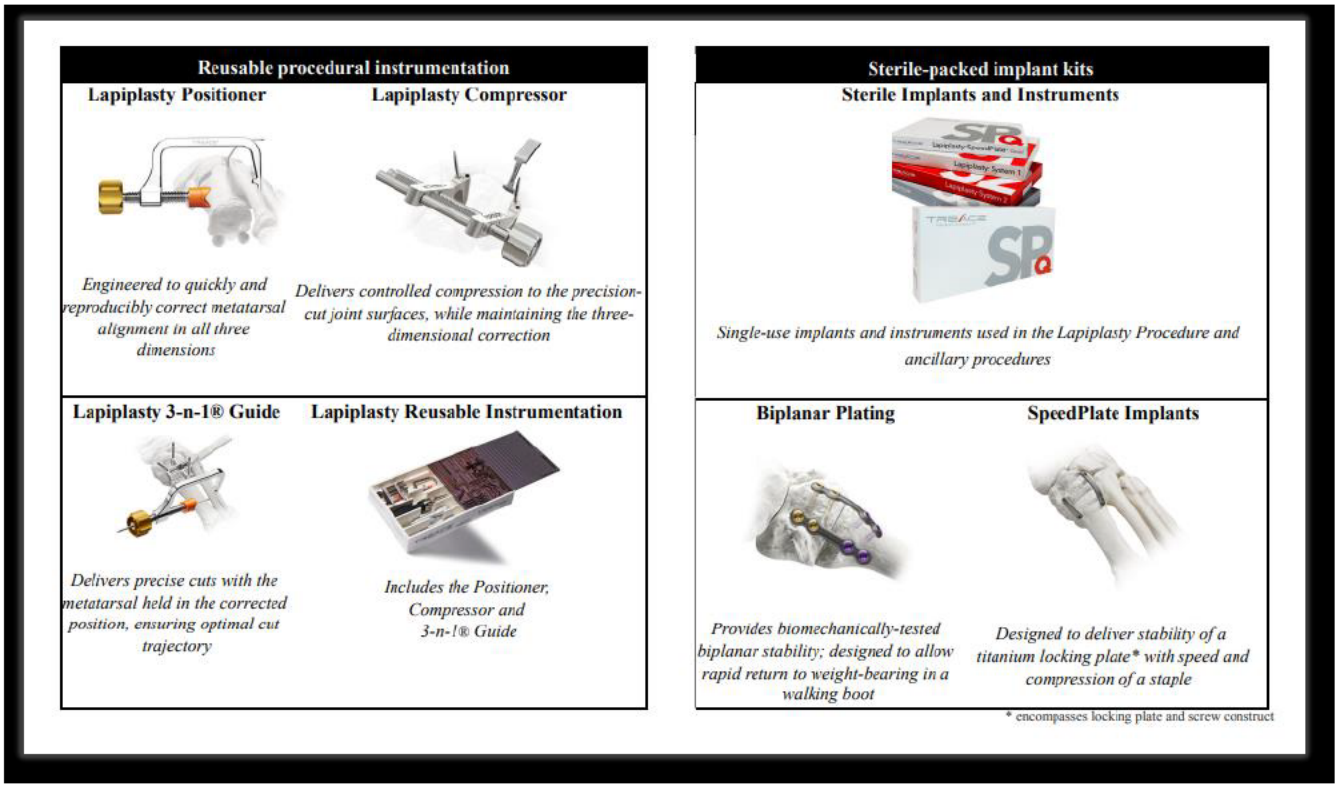


41. The Lapiplasty® System includes a cut guide that aids surgeons in making precise cuts at an optimal cut trajectory. Treace Medical's current commercial cut guide is shown in the image above as part of the "Cut" step. A prior version of the cut guide is depicted below:



42. Ultimately, the first metatarsal is fixed in an anatomically correct position and the TMT joint is secured by fixation devices, as illustrated below:

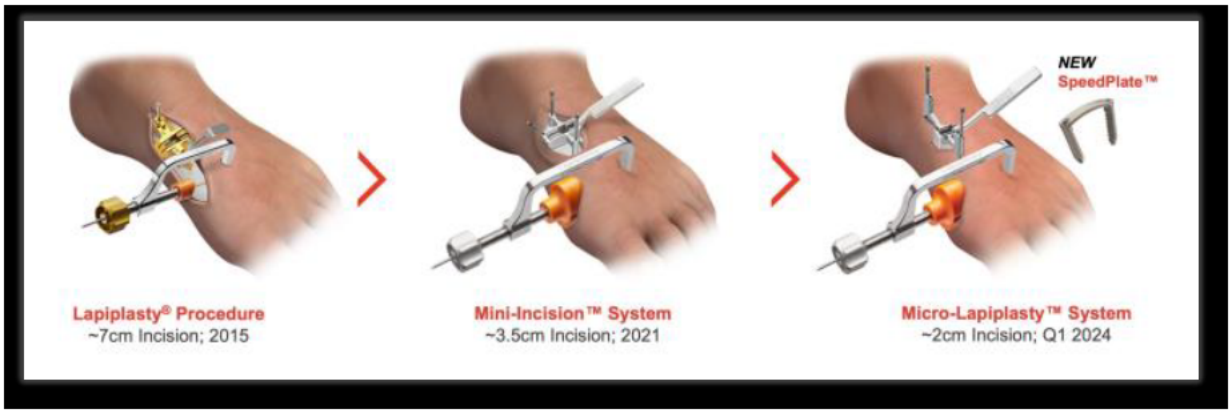
43. As described above, reusable instruments are used to guide the metatarsal re-positioning and joint preparation steps of the Lapiplasty® Procedure, while single-use implants such as staples or the above-depicted screws and bone plates fixate the corrected bone position. The reusable kit and single-use implant products of the Lapiplasty® System are illustrated below:



44. Compared to traditional methods, Treace Medical's Lapiplasty® System and Procedure allows for reproducible instrumented correction of bunion deformities for even the most severe bunion cases exhibited across the full patient population. This allows surgeons with varying degrees of expertise and specialization in bunion treatment to accurately and efficiently treat bunion deformities for successful patient outcomes.

45. Treace Medical is constantly innovating and improving its products, including updating its correction and compression instruments, cut guides, implants, or associated hardware every year since the Lapiplasty® System was introduced in 2015. Treace Medical can quickly introduce and propagate updates to its instruments, which are provided by Treace Medical representatives to surgeons for each surgery in a reusable instrument tray, thus providing immediate benefits of product improvements to surgeons and patients.

46. In 2021, Treace Medical launched a "minimally invasive" version of the Lapiplasty® System with the Lapiplasty® Mini-Incision™ System. Although the standard Lapiplasty® System and Procedure requires a limited number of cuts and reduced operating time, the Lapiplasty® Mini-Incision™ System allows the Lapiplasty® Procedure to be performed through reduced incision sizes. By early 2024, Treace Medical had also launched a version of the Lapiplasty® System with even smaller incisions called the Micro-Lapiplasty™ Minimally Invasive System, as well as its SpeedPlate™ implants that are aimed at enabling faster TMT joint fusion through smaller incisions. The three Lapiplasty® Systems are depicted below:



47. Treace Medical provides a variety of Lapiplasty® System options for surgeons and patients offered at differing price levels. Overall pricing for a particular procedure may further be affected based on the specific selection of implants and other system components. In this manner, Treace Medical is able to meet a customer's demand for a variety of price points related to particular purchasing and health insurance environments. Such price point flexibility provides cost-effective access to life-changing procedures to a wide spectrum of patients.

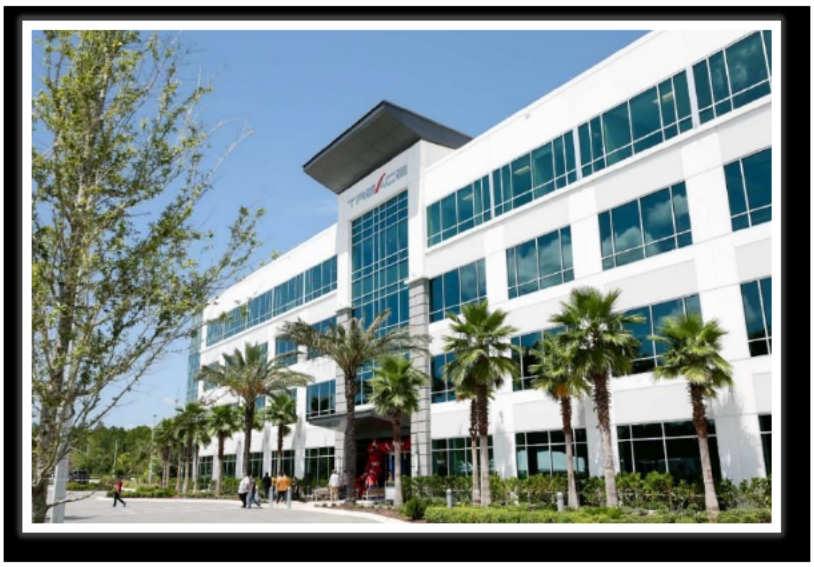
48. Treace Medical's surgical instruments, implants, and methods have received extensive industry praise. As a result, surgeons have increasingly chosen to change the way they treat bunions from traditional surgical methods to Treace Medical's instrumented technique.

B. Treace Medical's Lapiplasty® System and Procedure Created the Market for Instrumented TMT Bunion Correction

49. In March 2015, Treace Medical received 510(k) clearance for the first implants used with the Lapiplasty® System. Since then, and as Treace Medical continued to make instrument and implant improvements, more than 100,000 Lapiplasty® Procedures have been performed in the United States. The annual number of Lapiplasty® Procedures has grown from less than 2,000 procedures in 2017, to over 10,000 in 2020, and to nearly 30,000 in 2023, despite the adverse impact of the COVID-19 pandemic on elective procedures in 2020 and 2021.

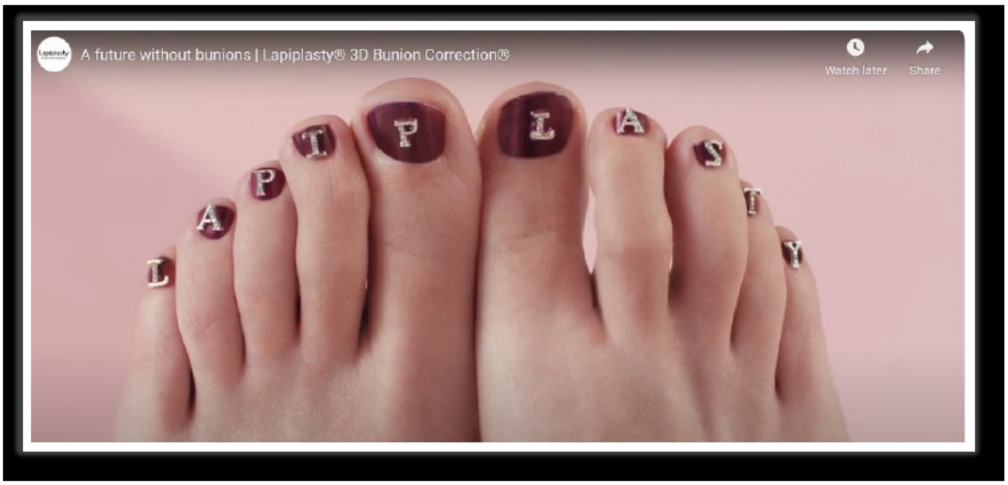
50. Treace Medical created and built up the market for instrumented TMT bunion correction systems and procedures that did not previously exist. Treace Medical has invested years of work and over $150 million educating surgeons and patients on its patented Lapiplasty® System and Procedure and its clinical benefits compared to traditional bunion correction techniques. Educational efforts include participation in numerous clinical studies and providing hands-on training to surgeons at Treace Medical's state-of-the-art on-site training center and at national, regional, and local medical education labs.

51. Treace Medical's state-of-the-art training facilities are located at its headquarters in Ponte Vedra, Florida. Treace Medical's headquarters is also the operations base for the company—which directly employs over 500 people in the United States:

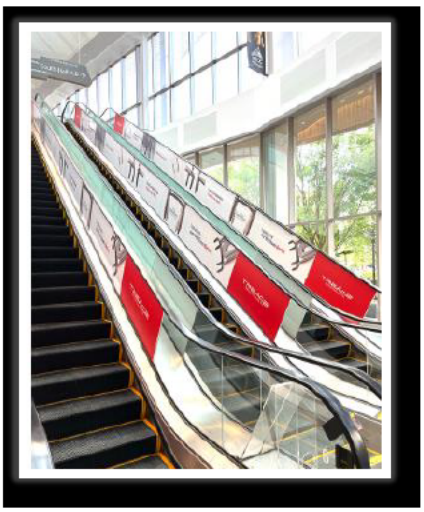


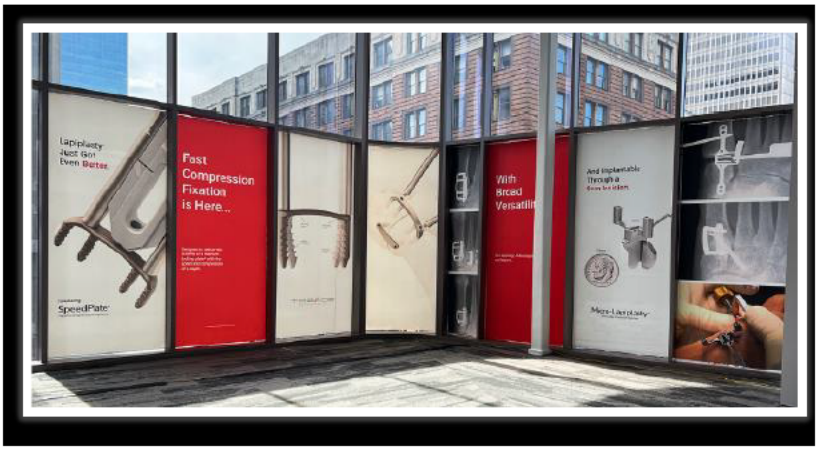
52. The Florida facilities include a simulated surgical lab where surgeons and medical students receive hands-on training:

53. Treace Medical has also created awareness of its patented Lapiplasty® System and Procedure through publications, websites, commercials, sponsorships, videos, conferences, surgical guides, and numerous other marketing and educational channels. For example, Treace Medical has established direct-to-consumer marketing of the Lapiplasty® System and Procedure at its https://www.lapiplasty.com/ website, in television commercials (as depicted below) shown during popular programs such as "The Bachelor," and as an official medical device partner of the Professional Pickleball Association. These direct-to-consumer advertisements prominently display Treace Medical's registered Lapiplasty® trademarks, provide educational resources to bunion sufferers, and support them in locating trained Lapiplasty® podiatric surgeons and orthopedic foot and ankle surgeons.



54. Treace Medical has been a lead sponsor and presenter at surgeon conferences such as those organized by the American College of Foot and Ankle Surgeons ("ACFAS") and the American Orthopedic Foot & Ankle Society ("AOFAS"). For example, at the 2023 AOFAS annual meeting, Treace Medical was among the top three sponsors, provided a grant for the Women's Leadership Awards, displayed a repeating video on the conference jumbotron, hosted simulated surgical workshops, ran a social media campaign with nearly 60,000 impressions and over 1,000 reactions, and had prominent display advertising at registration and entrances (shown below):





55. Of the over 10,000 estimated foot surgeons nationwide, over 3,000 surgeons are active users of the Lapiplasty® System and have been trained by Treace Medical to perform the procedure. Only surgeons who complete comprehensive training (almost always including a simulated surgery) are allowed to purchase the Lapiplasty® System or perform the Lapiplasty® Procedure. Treace Medical has also developed and released extensive training guides, videos, webinars, and other educational materials for surgeons and patients, which provide comprehensive training and a robust library of information about the Lapiplasty® System and Procedure and its benefits. This ongoing training educates Lapiplasty® System users and ensures that Lapiplasty® Procedures are performed by trained surgeons. Additionally, the supporting materials ensure surgeons have access to resources for addressing issues that may arise during a Lapiplasty® Procedure. As a result of the Lapiplasty® System's robust design and Treace Medical's surgeon education and quality control measures, the Lapiplasty® Procedure has low incidence rates of complications and has developed a well-earned reputation for quality and reproducibility.

56. Treace Medical's Lapiplasty® System and Procedure has received validation and acclaim in the academic and clinical communities, evidenced by 24 peer-reviewed journal publications and numerous successful clinical studies. Indeed, Treace Medical is the only company with an instrumented TMT bunion correction system with multicenter, prospective studies. These clinical publications demonstrate that the Lapiplasty® Procedure allows patients to quickly return to weight-bearing in a walking boot within 3 to 10 days. Further, these publications demonstrate meaningfully low rates of recurrence of bunion deformities. The studies also reflect a low rate of incidence of the bones not healing together (the "non-union rate"). Finally, this research suggests that the Lapiplasty® System and Procedure may result in a

significant decrease in post-operative bony and soft tissue width, visible as a slimmer foot, which is a factor in physician and patient satisfaction.

57. Treace Medical's data also reflects that surgeons typically increase their usage of the Lapiplasty® Procedure over time as they see improved clinical outcomes for their patients. For example, based on data gathered in December 31, 2023, a surgeon who has used the Lapiplasty® Procedure for one year performs an average of about 7 procedures per year, while a surgeon with 4 years of experience with the Lapiplasty® Procedure averages about 15 procedures per year, and a surgeon with 6 or more years of experience with the Lapiplasty® Procedure averages about 19 procedures annually.

58. Treace Medical's Lapiplasty® System includes reusable instrument trays with surgical guides as well as single-use implant kits for permanent bone fixation and fusion. For each surgery, a Treace Medical representative delivers the Lapiplasty® System consisting of a reusable instrument tray and a sterile kit, comprising all components needed for a Lapiplasty® Procedure. The Treace Medical representative is typically present during the procedure, and each representative undergoes extensive training on the Lapiplasty® System and Procedure, which enables the representative to provide useful information and guidance before, during, and after the procedure. Each sale of an implant kit, which incorporates the cost of the reusable instruments, corresponds to a single procedure.

59. Treace Medical has developed a robust, efficient, and cost-effective supply chain for producing and packaging all components of the Lapiplasty® System. Treace Medical estimates that its suppliers employ more than 500 employees servicing Treace Medical's manufacturing, production, and packaging needs. The Treace Medical supply chain includes alternative and backup suppliers for all system components, with each supplier meeting Treace Medical's

stringent quality standards. Treace Medical has achieved economies of scale with its suppliers such that those suppliers are able to provide favorable pricing to Treace Medical. In turn, Treace Medical passes such cost savings on to its customers with pricing that remains competitive.

60. If Treace Medical fully utilized its existing capacity, it could substantially and quickly increase its production and distribution of the Lapiplasty® System without incurring significant additional fixed costs or direct employee headcount, doubling its production and distribution within approximately six months. Treace Medical's supply chain could double its production and packaging of the Lapiplasty® System while its sales representatives in almost every United States metro area could oversee and service a doubling or more of Lapiplasty® Procedures with minimal, if any, increase in the number of sales representatives. Indeed, each additional Lapiplasty® Procedure increases Treace Medical's per-procedure margin. Further, Treace Medical's agreements with many of its suppliers include volume discounts that would further reduce per-procedure costs if production were to increase. Treace Medical has in the past and would continue to pass on a significant proportion of these cost savings to its hospital and surgical center customers and, indirectly via these customers, to their patients.

61. In less than a decade, Treace Medical has created and launched a groundbreaking, innovative surgical technology. Treace Medical is the undisputed leader in the instrumented TMT bunion correction market that it created, with Treace Medical achieving a compound annual revenue growth rate of 48.3% from 2020 to 2023.

62. Unfortunately, with Treace Medical's novel Lapiplasty® System and Procedure and associated commercial success, the Stryker Defendants have sought to capitalize on Treace Medical's pioneering technology for their own financial gain. After Treace Medical's Lapiplasty® System and Procedure created the instrumented TMT bunion correction market, the Stryker

Defendants came out with two offerings seeking to address bunion deformities in the foot: the ORTHOLOC™ 2 LapiFuse™ Triplanar Correction System, and the PROstep® MIS Lapidus System.

63. Although "copycat" competitors have acquired market share as the overall market has grown, Treace Medical wins when competing on the merits of efficacy, price, education, and service.

C. Treace Medical Has Protected Its Pioneering Bunion Correction System and Procedure with a Robust and Extensive Patent Portfolio

64. To protect its innovations, Treace Medical invested early on in a robust portfolio of utility patents.

65. Treace Medical filed its first patent applications related to the Lapiplasty® System and Procedure as U.S. Provisional Patent Application Nos. 62/024,546 and 62/192,319 on July 15, 2014. Treace Medical has over 65 granted U.S. patents, with an additional 24 foreign patents, and 85 pending U.S. patent applications. Treace Medical's patents cover core Lapiplasty®-related instrumentation and surgical techniques as well as other associated innovations.

66. The Stryker Defendants' LapiFuse™ System and PROstep® Lapidus System infringe several of these issued utility patents. Specifically, the Stryker Defendants' LapiFuse™ System infringes at least the following nine Asserted Patents: the '805 Patent; '446 Patent; '873 Patent; '558 Patent; '386 Patent; '387 Patent; '085 Patent; '849 Patent; and '819 Patent. The PROstep® Lapidus System, in turn, infringes at least the following three Asserted Patents: the '386 Patent; '085 Patent; and '819 Patent.

i. Treace Medical's Asserted Method Patents

67. Five of the Asserted Patents are directed to methods for performing instrumented TMT bunion correction surgery: the '805 Patent, '873 Patent, '558 Patent, '085 Patent, and '849 Patent.

68. The '805 Patent claims "[a] method of correcting a bunion deformity." The '805 Patent is directly infringed when the Stryker Defendants' LapiFuse™ System is used to perform or demonstrate a bunion correction surgery, as described in more detail in Count I below. The '805 Patent is titled "**Bone Positioning and Preparing Guide Systems and Methods**" and issued on April 18, 2017. The '805 Patent claims priority to a provisional patent application originally filed on August 14, 2015, and to a non-provisional utility application filed on December 28, 2015.

69. The '873 Patent claims "[a] method of correcting a bunion deformity." The '873 Patent is directly infringed when the Stryker Defendants' LapiFuse™ System is used to perform or demonstrate a bunion correction surgery, as described in more detail in Count III below. The '873 Patent is titled "**Bone Positioning and Preparing Guide Systems and Methods**" and issued on June 22, 2021. The '873 Patent claims priority to a provisional patent application originally filed on August 14, 2015, and a non-provisional utility application filed on December 28, 2015.

70. The '558 Patent claims "[a] method of correcting a bunion deformity on a foot." The '558 Patent is directly infringed when the Stryker Defendants' LapiFuse™ System is used to perform or demonstrate a bunion correction surgery, as described in more detail in Count IV below. The '558 Patent is titled "**Bone Positioning Guide**" and issued on September 14, 2021. The '558 Patent claims priority to provisional patent applications originally filed on July 14, 2015, and August 14, 2015, and to non-provisional utility applications filed on December 28, 2015, and July 14, 2016.

71. The ’085 Patent claims “[a] method of correcting a bunion deformity.” The ’085 Patent is directly infringed when either the Stryker Defendants’ LapiFuse™ System or Stryker’s PROstep® Lapidus System is used to perform or demonstrate a bunion correction surgery, as described in more detail in Counts VIII-IX below. The ’085 Patent is titled “**Bone Positioning and Preparing Guide Systems and Methods**” and issued on February 27, 2024. The ’085 Patent claims priority to a provisional patent application originally filed on August 14, 2015, and a non-provisional utility application filed on December 28, 2015.

72. The ’849 Patent claims “[a] method of performing a bunion surgery to correct an alignment between a first metatarsal and a first cuneiform.” The ’849 Patent is directly infringed when the Stryker Defendants’ LapiFuse™ System is used to perform or demonstrate a bunion correction surgery, as described in more detail in Count X below. The ’849 Patent is titled “**Bone Positioning and Cutting System and Method**” and issued on March 26, 2024. The ’849 Patent claims priority to a provisional patent application originally filed on July 15, 2014, and a non-provisional utility application filed on July 15, 2015.

ii. Treace Medical’s Asserted Apparatus and System Patents

73. The other four Asserted Patents are directed to instrumented TMT bunion correction apparatus or systems: the ’446 Patent, ’386 Patent, ’387 Patent, and ’819 Patent.

74. The ’446 Patent claims “[a] bone positioning guide for a bunion correction procedure.” The ’446 Patent is directly infringed by the making, sale, and offer for sale of the LapiFuse™ System, and by use of the LapiFuse™ System in a bunion correction surgery or demonstration, as described in more detail in Count II below. The ’446 Patent is titled “**Bone Positioning Guide**” and issued on December 29, 2020. The ’446 Patent claims priority to two provisional patent applications originally filed on July 14, 2015, and August 14, 2015, and to non-provisional utility applications filed on December 28, 2015, and July 14, 2016.

75. The ’386 Patent claims “[a] bone positioning guide for a bunion correction procedure.” The ’386 Patent is directly infringed by the making, sale, and offer for sale of either the LapiFuse™ System or the PROstep® Lapidus System, and by use of either the LapiFuse™ System or PROstep® Lapidus System in a bunion correction surgery or demonstration, as described in more detail in Counts V-VI below. The ’386 Patent is titled “**Bone Positioning Guide**” and issued on March 14, 2023. The ’386 Patent claims priority to provisional patent applications originally filed on July 14, 2015, and August 14, 2015, and to non-provisional utility applications filed on December 28, 2015, and July 14, 2016.

76. The ’387 Patent claims “[a] metatarsal correction system.” The ’387 Patent is directly infringed by the making, sale, and offer for sale of the LapiFuse™ System, and by use of the LapiFuse™ System in a bunion correction surgery or demonstration, as described in more detail in Count VII below. The ’387 Patent is titled “**Bone Positioning and Preparing Guide Systems and Methods**” and issued on March 14, 2023. The ’387 Patent claims priority to a provisional patent application originally filed on August 14, 2015, and a non-provisional utility application filed on December 28, 2015.

77. The ’819 Patent claims “[a] bone positioning system” including “a bone positioning guide,” “a tissue removing instrument,” and “a fixation device.” The ’819 Patent is directly infringed by the making, sale, and offer for sale of either the LapiFuse™ System or the PROstep® Lapidus System, and by use of either the LapiFuse™ System or PROstep® Lapidus System in a bunion correction surgery or demonstration, as described in more detail in Counts XI-XII below. The ’819 Patent is titled “**Bone Positioning Guide**” and issued on April 9, 2024. The ’819 Patent claims priority to provisional patent applications originally filed on July 14, 2015, and August 14, 2015, and to non-provisional utility applications filed on December 28, 2015, and July 14, 2016.

D. The Stryker Defendants' Knockoff Systems and Methods

78. On information and belief, Wright began working on its knockoff instrumented TMT bunion systems as early as fall of 2017. On or about September 2017, Stryker's current Medical Director for its Foot and Ankle division and Wright's former Chief Medical Officer, Hodges Davis, M.D., and his colleague Carroll Jones, M.D., both of whom were consultants of Wright and current Stryker consultants, attended a Lapiplasty® cadaveric demonstration lab presented by Treace Medical for their foot and ankle surgery practice at OrthoCarolina. In a follow-up conversation with John Treace, Treace Medical's CEO, founder, and Board Member, Dr. Jones asked for a Lapiplasty® Positioner (a key instrument in achieving reproducibility) but was informed by Mr. Treace that it could not be sold separately and that Treace Medical had "24 patents filed around the way we perform the Lapiplasty procedure and instrumentation involved." Dr. Jones responded "we'll have to make our own."

79. By 2019, it became well known that the Lapiplasty® System was gaining traction with surgeons and creating a rare new category of procedure, rather than merely iterating upon previous technologies and methods. At that time, Treace Medical had compiled data showing a potential annual market opportunity of more than $4.5 billion in sales for bunion treatments.

80. With information about the Lapiplasty® System and Procedure in hand, Dr. Davis, Dr. Jones, and a group of other consulting physicians subsequently helped to develop the knockoff LapiFuse™ System with Wright. Stryker then purchased Wright, and, as described further below, Stryker has and continues to leverage its dominant position in other products to coerce health system administrators into forcing the LapiFuse™ System on surgeons, even over those surgeons' objections due to their preference for Treace Medical's superior Lapiplasty® System and Procedure.

i. The Stryker Defendants [redacted] Prior to Launching Their Infringing Systems and Targeting Treace Medical's Market.

81. [redacted]

82. [redacted].

83. [redacted]

84. [redacted].

85. [redacted], on or about August 16, 2019, Wright published a Surgical Technique guide for what it referred to at the time as "Ortholoc™ 2 Lapidus Plating System with 3Di Technology." This Surgical Technique guide described a set of surgical instruments and their method of use that mirrored Treace Medical's Lapiplasty® System and Procedure. The currently accused LapiFuse™ System and Procedure is little changed from what is described in the August 2019 publication.

86. Soon after, on August 27, 2019, Patrick Fisher, Wright's then-President for Lower Extremities, sent a text message to John Treace, Treace Medical's CEO, founder, and Board Member. That text read, "JT—you may already know this but I wanted to give you a heads up that we are launching a new Lapidus correction system in a premarket trial in the next few weeks. You guys can't be the only ones running away with Lapidus!!"

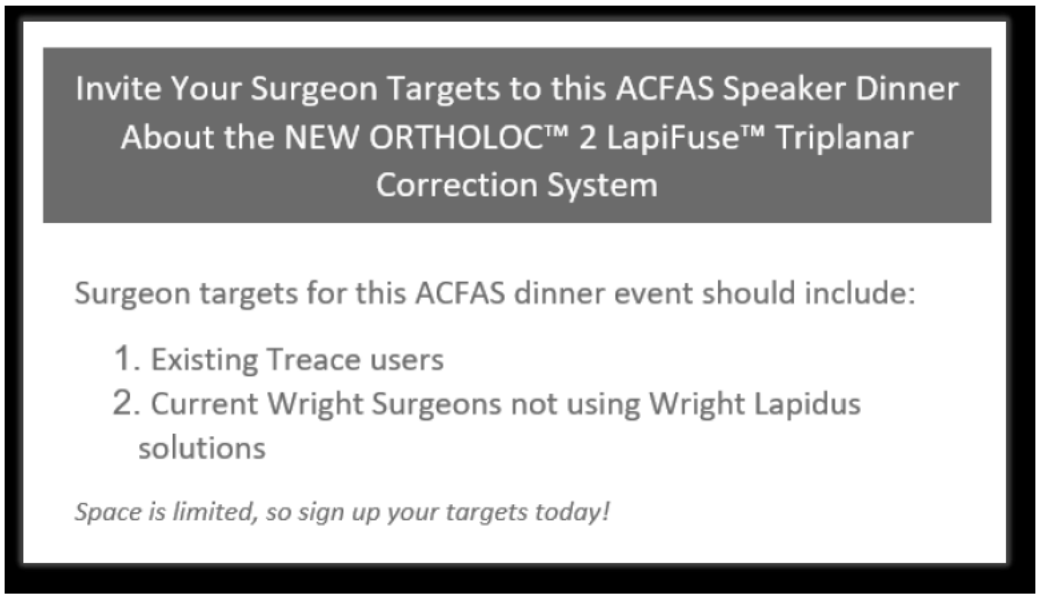
87. Only a few months later, on November 4, 2019, Stryker announced a definitive agreement to acquire Wright. Stryker completed its acquisition of Wright the next year, on November 1, 2020.

88. While the Stryker/Wright acquisition was ongoing, Wright held a National Sales Meeting in Las Vegas, Nevada, on February 8, 2020. As part of that meeting, Wright conducted a training session on the LapiFuse™ System where it displayed the below slides comparing Treace Medical's Lapiplasty® System to Wright's LapiFuse™ System:

89. On information and belief, [redacted] For example, one slide presented during its LapiFuse™ System launch included a "Targeting Plan" identifying the number of "Treace surgeons" and the breakdown by percentage of Doctors of Podiatric Medicine ("DPMs") vs. Medical Doctors ("MDs"), [redacted]

90. On February 10, 2020, Wright held an internal marketing meeting at which the below slide was presented announcing an ACFAS Speaker Dinner in connection with Wright's

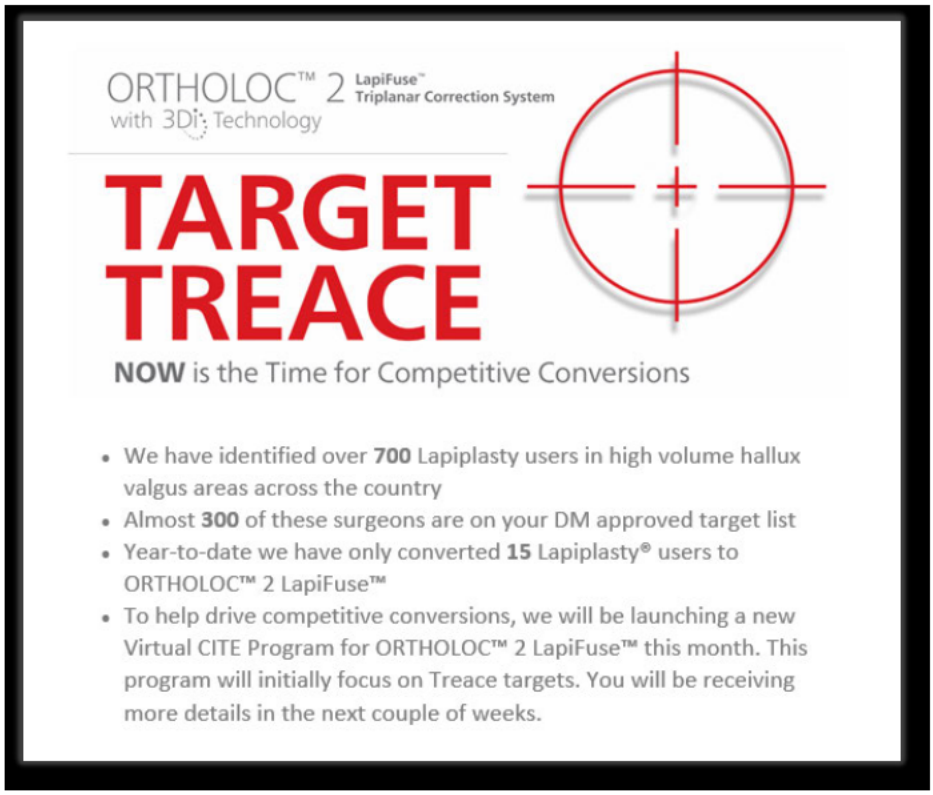
LapiFuse™ System. This slide explained that "[e]xisting Treace users" should be the first "Surgeon targets" for this dinner event.



91. The ACFAS annual meeting, which is the country's largest gathering of foot and ankle surgeons, was held from February 19-22, 2020. Wright officially launched its LapiFuse™ System at that conference. On information and belief, Wright invited a large number of Treace Medical users to attend a dinner during the ACFAS annual meeting. On information and belief, Wright's LapiFuse™ Procedure was discussed at this dinner.

92. On March 11, 2020, Wright further specifically targeted Treace Medical's potential customers by sending a marketing email with the subject "ORTHOLOC™ 2 LapiFuse™ is coming, the competition is coming up short." The email alleged that "Lapiplasty®… Has Come Up Short."

93. A later August 7, 2020, Wright sales email, reproduced in relevant part below, leaves no doubt as to Wright's scheme to specifically target Treace Medical. Wright encouraged its sales team to "target" and "convert" users of Treace Medical's Lapiplasty® System and Procedure to Wright's copycat system:



94. As noted in the image above, year-to-date as of August 2020, Wright had "only converted 15 Lapiplastly® users to ORTHOLOC™ 2 LapiFuse™." Faced with limited demand for the LapiFuse™ System on the product's merits, on information and belief the Stryker Defendants instead furthered their plan to free ride on Treace Medical's intellectual property and investments by engaging in improper and predatory business practices, described in more detail in Sections F-K below.

ii. The Stryker Defendants' Infringing LapiFuse™ System

95. The Stryker Defendants make, use, sell, and offer for sale in the United States an unauthorized copycat version of Treace Medical's Lapiplasty® System and Procedure that they have branded as the "ORTHOLOC™ 2 LapiFuse Triplanar Correction System." Stryker maintains an internet website at https://www.stryker.com/us/en/index.html where it advertises the

LapiFuse™ System. Wright also maintained an internet website at https://www.wright.com/ where it advertises the LapiFuse™ System that remains live to date.

96. Stryker promotes the LapiFuse™ System to patients at https://patients.stryker.com/LapiFuse and to surgeons at https://www.stryker.com/us/en/foot-and-ankle/products/LapiFuse.html. For example, at the surgeon-facing website, Stryker describes the LapiFuse™ System as a "[t]riplanar correction system." Mirroring Treace Medical's language, Stryker states that "[t]he LapiFuse bunion correction system was designed for predictable and reproducible triplanar corrections" and is "[d]esigned to increase fusion and lower recurrence rates."

97. Wright's website similarly promotes the LapiFuse™ System as providing "[p]redictable and reproducible triplanar correction" and touts a "[c]onsistent approach to IM angle [transverse plane] and sagittal plane correction, and frontal plane rotation," as depicted in an image on the website reproduced below, available at https://www.wright.com/footandankleproducts/ortholoc-2-lapifuse-triplanar-correction-system#/?playlistId=0&videoId=0:

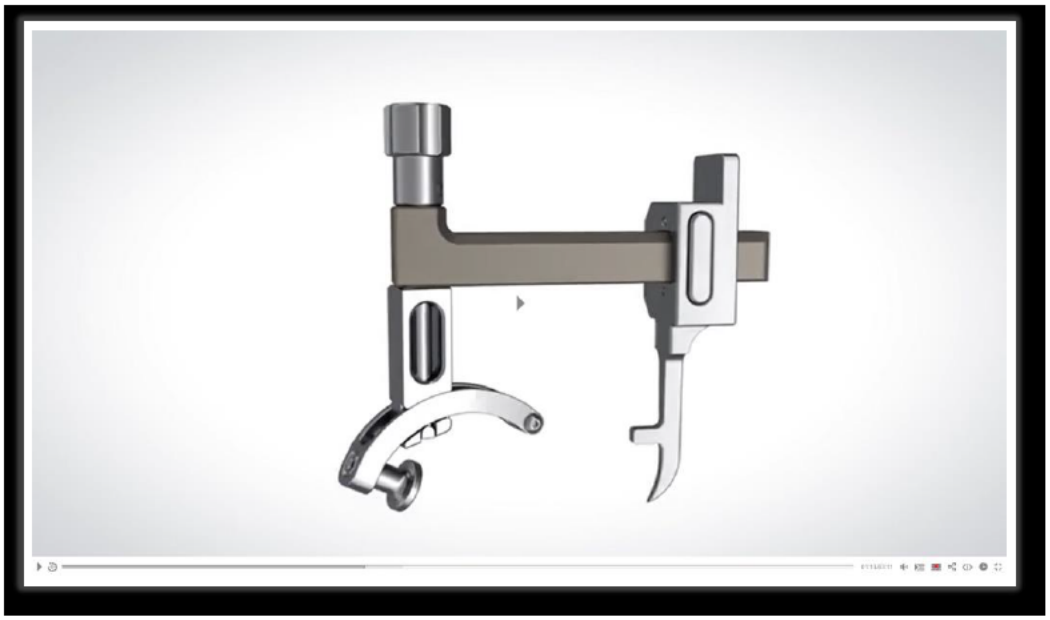
98. Both Stryker's and Wright's websites include a video animation instructing surgeons on the LapiFuse™ System and Procedure; the two videos are nearly identical (the

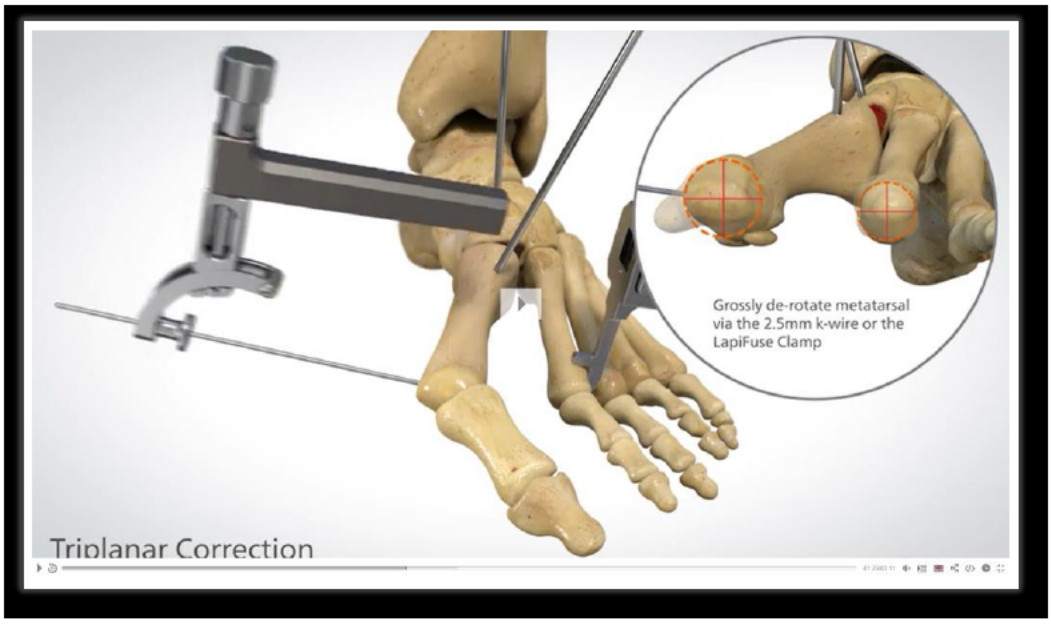
"LapiFuse Video").[1] The Stryker website states that "[t]his animation illustrates our triplanar correction system."

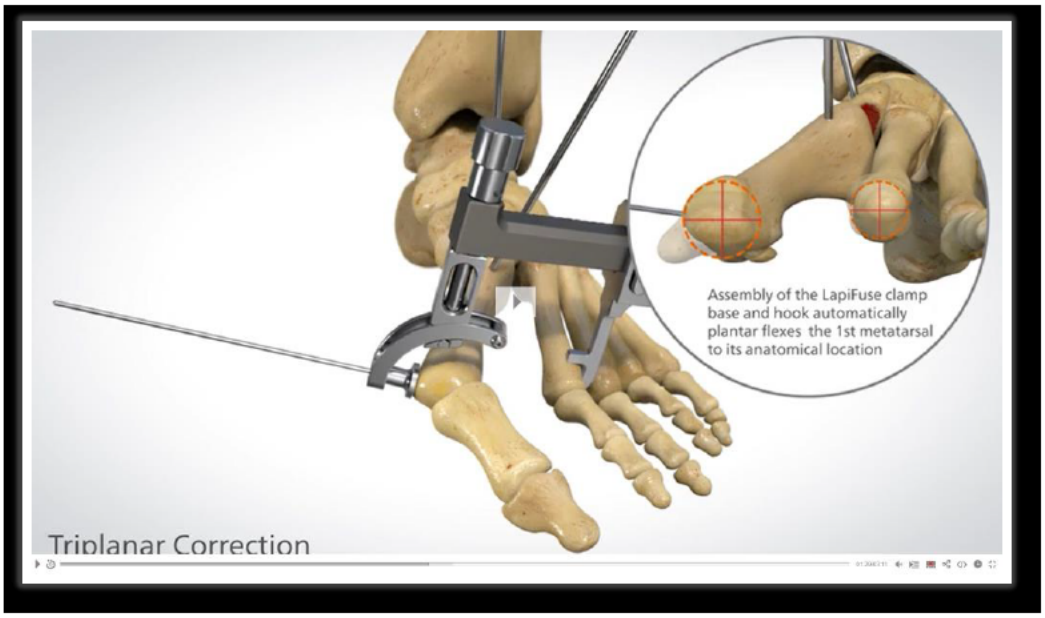
99. Wright also published an ORTHOLOC™ 2 LapiFuse™ Triplanar Correction System Surgical Technique (the "LapiFuse Brochure"), which is attached as **Exhibit 1** and is dated May 15, 2020.

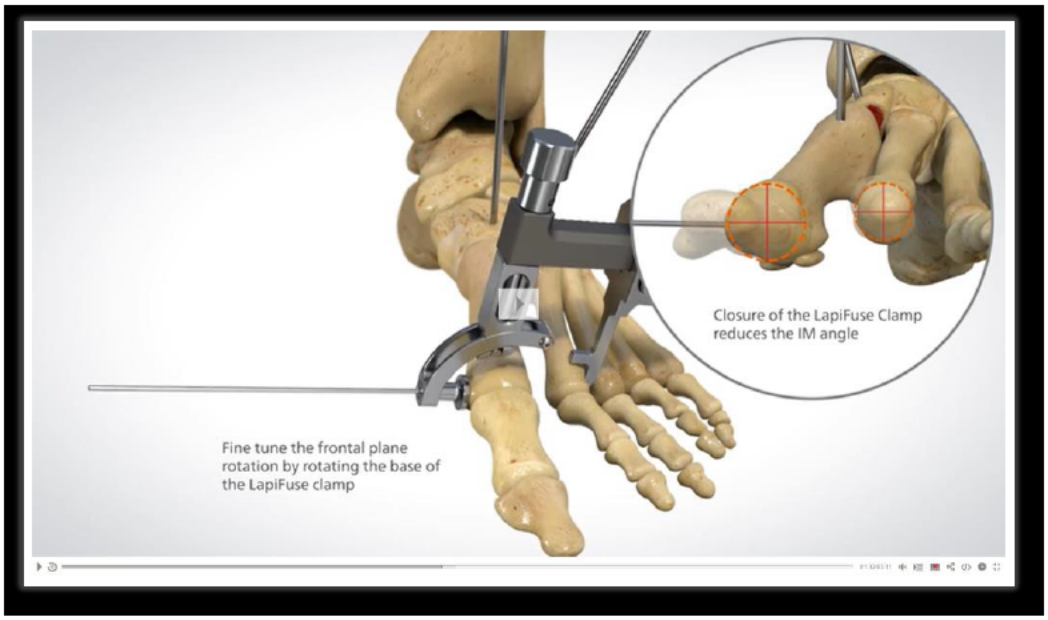
100. Just like Treace Medical's Lapiplasty® System and Procedure, the Stryker Defendants instruct "Triplanar Correction" in their LapiFuse™ Procedure, as demonstrated by the LapiFuse Video and LapiFuse Brochure. The Stryker Defendants instruct performing this correction using their dedicated instrument called the LapiFuse Clamp, as detailed in the series of images below from the LapiFuse Video. The first image depicts the LapiFuse Clamp in isolation. In the second image, the LapiFuse Video instructs "[g]rossly de-rotate the metatarsal via the 2.5mm k-wire or the LapiFuse Clamp," relating to de-rotating the first metatarsal in the frontal plane. Next, in the third image, the LapiFuse Video instructs "[a]ssembly of the LapiFuse clamp base and hook automatically plantar flexes the 1st metatarsal to its anatomical location," referring to sagittal plane movement. Finally, in the fourth image, the LapiFuse Video states that "[c]losure of the LapiFuse Clamp reduces the IM angle" and instructs "[f]ine tune the frontal plane rotation by rotating the base of the LapiFuse Clamp," referring to movement in the transverse plane and frontal plane, respectively.

[1] *Available at* https://www.stryker.com/us/en/foot-and-ankle/products/lapifuse.html ("LapiFuse Animation"); https://www.wright.com/footandankleproducts/ortholoc-2-lapifuse-triplanar-correction-system#/?playlistId=0&videoId=5 ("ORTHOLOC™ 2 LapiFuse™ Triplanar Correction System Animation"). The images provided herein are from the LapiFuse Video as available on Wright's website.



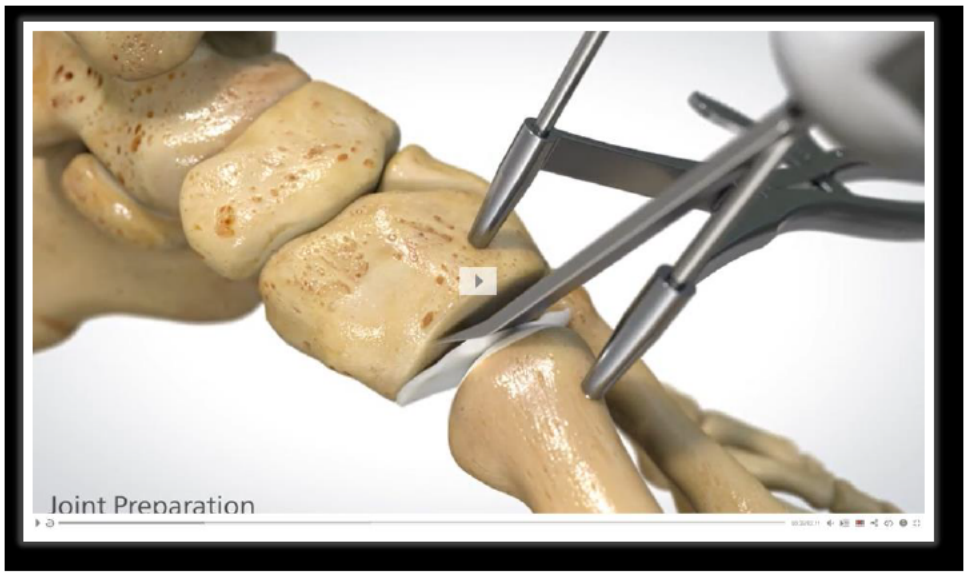

Grossly de-rotate metatarsal via the 2.5mm k-wire or the LapiFuse Clamp
Triplanar Correction





101. Just like Treace Medical's Lapiplasty® System and Procedure, the Stryker Defendants also instruct that surgeons prepare the TMT joint between the first metatarsal and medial cuneiform. The LapiFuse Brochure describes this step as "First Metatarsal Joint Distraction and Preparation." The LapiFuse Brochure and LapiFuse Video instruct joint preparation with surgical instruments (*e.g.*, an osteotome), as illustrated in the image below from

the LapiFuse Video. On information and belief, the identified tissue removing instruments are manufactured, sold, and provided by the Stryker Defendants.

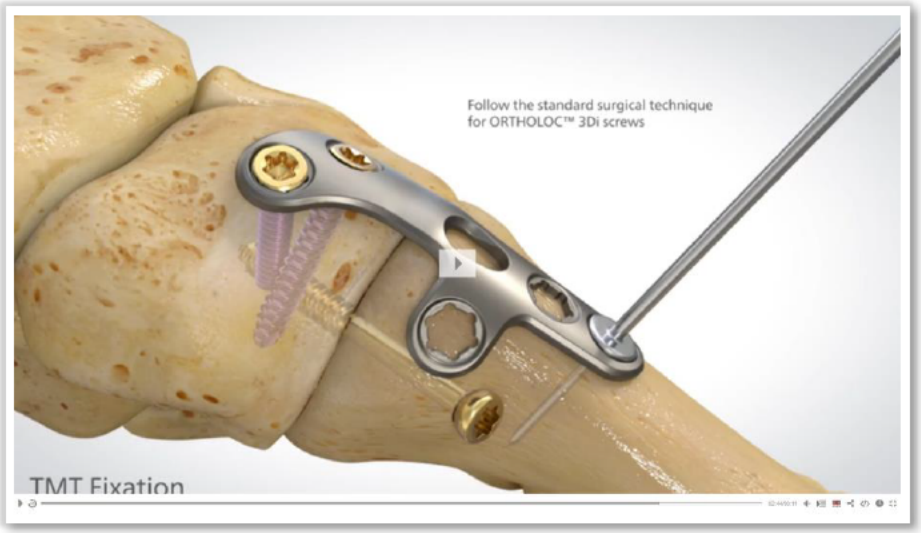


102. The Stryker Defendants also provide a cut guide to surgeons to assist with TMT joint preparation, just like Treace Medical's cut guide. A presentation the Stryker Defendants created for surgeons, titled "ORTHOLOC™ 2 with 3Di Technology: LapiFuse™ Triplanar Correction System" (the "LapiFuse Surgeon Presentation"), which is attached as **Exhibit 2** and on information and belief was shared in 2020, contains the following slide with text and images related to a "Joint Preparation Guide" including a "Cut Guide" to guide the surgeons' cuts of the first metatarsal and medial cuneiform:

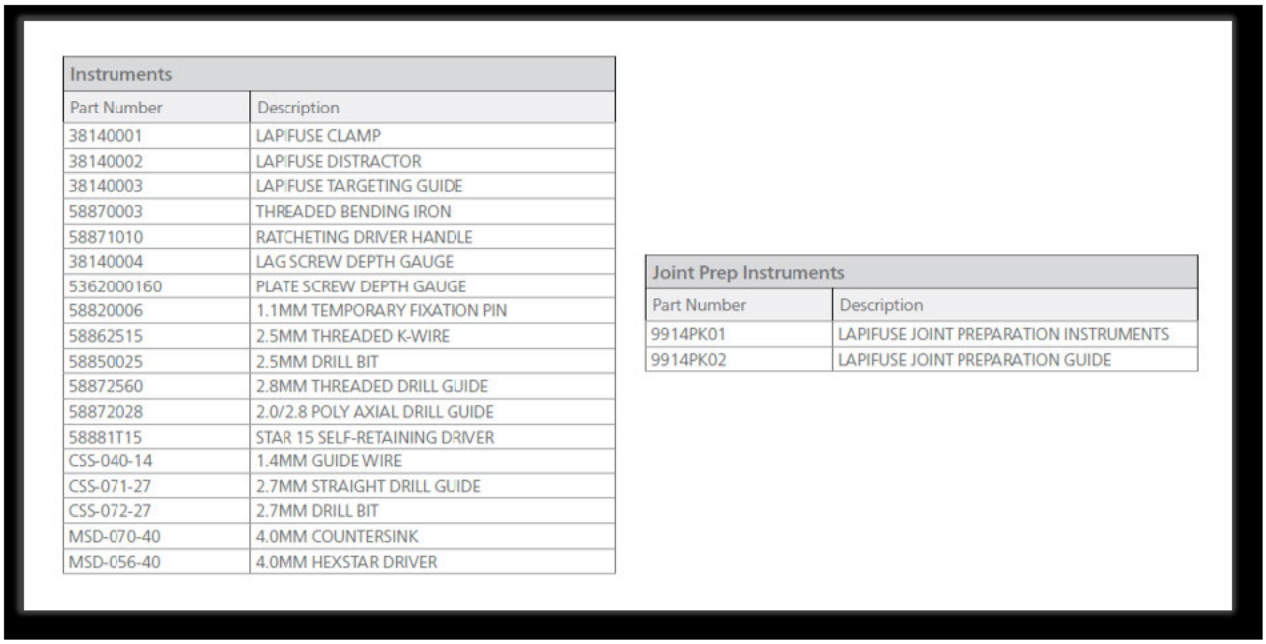
103. The LapiFuse Brochure also states under the "First Tarsometatarsal Joint Distraction and Preparation" step: "Alternatively, use the Joint Preparation Guide."

104. On information and belief, the Stryker Defendants have provided and continue to provide surgeons a cut guide for use with the LapiFuse™ System. These components are manufactured, sold, and provided by the Stryker Defendants and are designed for the LapiFuse™ System. On information and belief, the Stryker Defendants are careful not to publicly advertise their cut guide given its striking similarities to Treace Medical's patented Lapiplasty® System cut guides.

105. Further, just like Treace Medical's Lapiplasty® System and Procedure, the Stryker Defendants instruct fixating the moved position of the first metatarsal using implants (*e.g.*, plates and screws), as illustrated in the images below from the LapiFuse Video. These implants are manufactured, sold, and provided by the Stryker Defendants and are designed for the LapiFuse™ System.



106. The components of the LapiFuse™ System are illustrated in the images above and many are identified by part number in the LapiFuse Brochure, as reproduced below.



Instruments	
Part Number	Description
38140001	LAPIFUSE CLAMP
38140002	LAPIFUSE DISTRACTOR
38140003	LAPIFUSE TARGETING GUIDE
58870003	THREADED BENDING IRON
58871010	RATCHETING DRIVER HANDLE
38140004	LAG SCREW DEPTH GAUGE
5362000160	PLATE SCREW DEPTH GAUGE
58820006	1.1MM TEMPORARY FIXATION PIN
58862515	2.5MM THREADED K-WIRE
58850025	2.5MM DRILL BIT
58872560	2.8MM THREADED DRILL GUIDE
58872028	2.0/2.8 POLY AXIAL DRILL GUIDE
58881T15	STAR 15 SELF-RETAINING DRIVER
CSS-040-14	1.4MM GUIDE WIRE
CSS-071-27	2.7MM STRAIGHT DRILL GUIDE
CSS-072-27	2.7MM DRILL BIT
MSD-070-40	4.0MM COUNTERSINK
MSD-056-40	4.0MM HEXSTAR DRIVER

Joint Prep Instruments	
Part Number	Description
9914PK01	LAPIFUSE JOINT PREPARATION INSTRUMENTS
9914PK02	LAPIFUSE JOINT PREPARATION GUIDE

107. The LapiFuse Brochure also lists by part number the Stryker Defendants' implants for the LapiFuse™ System, including various "Lapidus" plates, locking screws, non-locking screws, and lag screws.

108. The vast majority of the components used in the LapiFuse™ System—including the LapiFuse Clamp, cut guide, tissue removing instruments, and fixation devices—have been designed specifically for the infringing LapiFuse™ Procedure, and, on information and belief, certain components are collectively packaged for that procedure. Accordingly, the Stryker Defendants sell and offer to sell components of the patented systems covered by the Asserted Patents that are used in practicing the surgical methods of the Asserted Patents through their sales of the LapiFuse™ System. These components are a material part of the inventions in the Asserted Patents. On information and belief, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, the Stryker Defendants knew that these components are especially made or especially adapted for use in an infringement of the Asserted Patents, as described further below. In addition, these components—many of which are labeled as "LapiFuse"

components—are not a staple article or commodity of commerce suitable for substantial non-infringing use. The only (and infringing) use of the LapiFuse™ System is depicted and described in the LapiFuse Video and LapiFuse Brochure discussed above.

109. As discussed in more detail in Counts I-V, VII-VIII, and X-XI, the LapiFuse™ System infringes the apparatus and system Asserted Patents; the LapiFuse™ System and Procedure infringe the Asserted Patents directed to surgical methods; and the surgical technique depicted in the LapiFuse Video and LapiFuse Brochure instructs, encourages, and assists surgeons to use the LapiFuse™ System to infringe those Asserted Patents. The Stryker Defendants also contribute to the infringement of the Asserted Patents by selling and offering to sell the LapiFuse™ System. The infringing LapiFuse™ System and Procedure seek to improperly profit from the inventions Treace Medical created almost a decade ago.

110. The LapiFuse™ System is an inferior knockoff of Treace Medical's Lapiplasty® System and Procedure. For example:

- The LapiFuse™ System was launched with a limited number of cases performed by a limited number of surgeons, and has never been validated as effective and repeatable in clinical studies;
- Of the two studies that the Stryker Defendants cite as supporting its LapiFuse™ claims, neither discusses procedures performed with the LapiFuse™ System: one (Galli) predates the development of the LapiFuse™ System by years and, as a biomechanical cadaver study using pins for fixation, did not test anything resembling the LapiFuse™ System fixation under relevant conditions; and the other (Walker, Harris) discusses Lapidus and osteotomy procedures generally that shorten the first ray, not the LapiFuse™ System;
- Surgeons forced to use the LapiFuse™ System report the occurrence of "rebound" or "bounceback" in the transverse plane compared to their experiences with the Lapiplasty® System and Procedure; and
- On the one hand, the Stryker Defendants rarely advertise use of cut guides with the LapiFuse™ System. On the other hand, on information and belief, the Stryker Defendants provide cut guides for the LapiFuse™ System. On information and belief, the result is surgeon confusion and inferior TMT joint preparation.

111. As a result of these deficiencies, surgeons forced to use the LapiFuse™ System over the Lapiplasty® System have reported poor surgical outcomes with the LapiFuse™ System that they do not believe would have occurred with the Lapiplasty® System and Procedure.

iii. Stryker's Infringing PROstep® Lapidus System

112. Stryker announced the launch of another knockoff product, its PROstep® MIS Lapidus System, on September 19, 2023. Stryker's announcement came over two years after Treace Medical's launch of Lapiplasty® Mini-Incision. Stryker promotes the PROstep® Lapidus System to both patients at https://patients.stryker.com/prostep and to surgeons at https://www.stryker.com/us/en/foot-and-ankle/products/prostep.html.

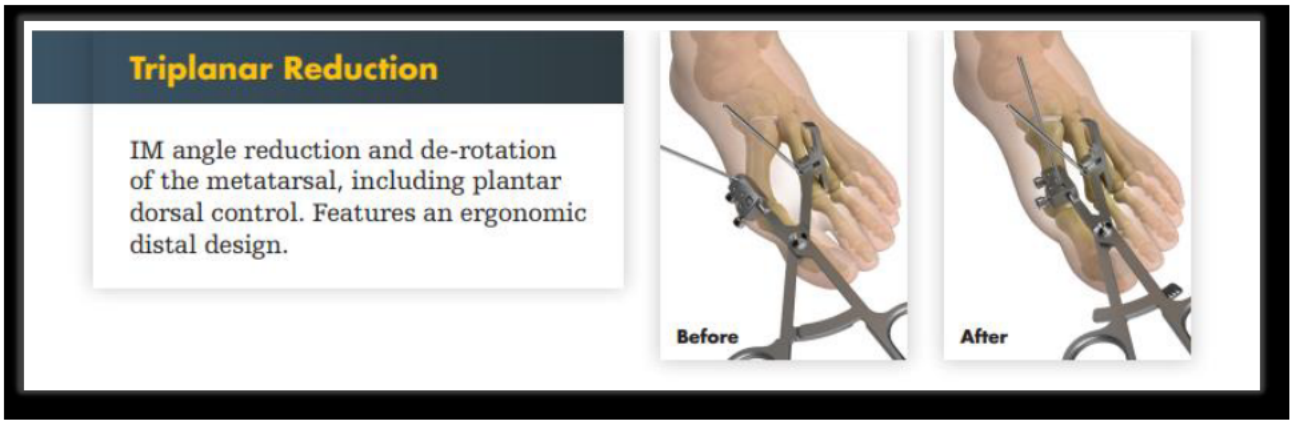
113. According to Stryker's "Sell Sheet" for the PROstep® MIS Lapidus System,[2] the PROstep® Lapidus System is "an internal fixation system intended for minimally invasive reduction of hallux valgus deformity and subsequent fusion of the first metatarsal cuneiform joint." Stryker instructs surgeons on methods to use the PROstep® Lapidus System in a variety of forms, including in a "PROstep MIS Lapidus Operative Technique" Brochure (the "PROstep Operative Technique Brochure" or "PROstep Brochure"),[3] and a video on Stryker's website titled "PROstep MIS Lapidus – Surgical Animation" (the "PROstep Video").[4]

114. Just like Treace Medical's Lapiplasty® System and Procedure, Stryker instructs an initial step of "Triplanar Reduction" using the PROstep® Lapidus System and technique, as depicted in the below image from Stryker's Sell Sheet:

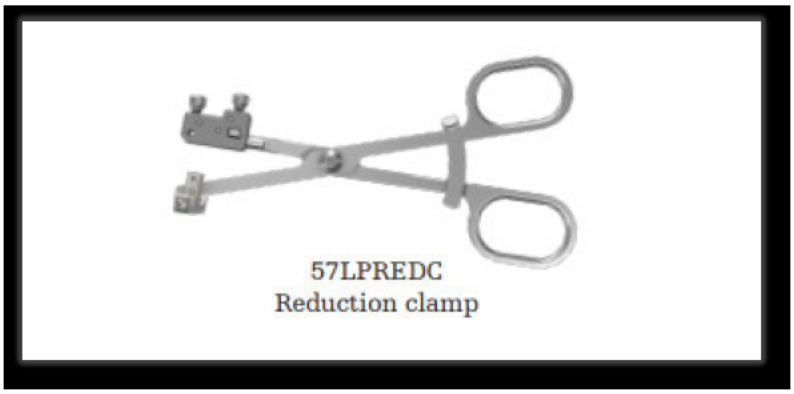
[2] *Available at* https://www.stryker.com/content/dam/stryker/foot-and-ankle/products/prostep/documents/PROstep%20MIS%20Lapidus%20Sell%20Sheet.pdf.

[3] *Available at* https://www.stryker.com/content/dam/stryker/foot-and-ankle/products/prostep/documents/PROstep%20MIS%20Lapidus%20Operative%20Technique.pdf.

[4] *Available at* https://www.stryker.com/us/en/foot-and-ankle/products/prostep/video-library.html ("PROstep MIS Lapidus - Surgical Animation").



115. Stryker's PROstep Operative Technique Brochure likewise instructs surgeons to perform "triplanar reduction" using Stryker's dedicated instrument called the Reduction Clamp, as detailed in the series of images below. The first image shows the Reduction Clamp in isolation. In the second image, Stryker instructs "[c]lose the clamp to reduce the IM angle," relating to movement of the first metatarsal in the transverse plane. The third image, in turn, instructs surgeons in "correction of rotation," referring to the frontal plane, and directs a surgeon to "adjust plantarflexion of the metatarsal by pulling it plantarly away from the clamp," to address correction in the sagittal plane.



Step 6: Reduction of the IM angle

Close the clamp to reduce the IM angle so that there is 1-2mm of space between the first and second metatarsal on X-ray.

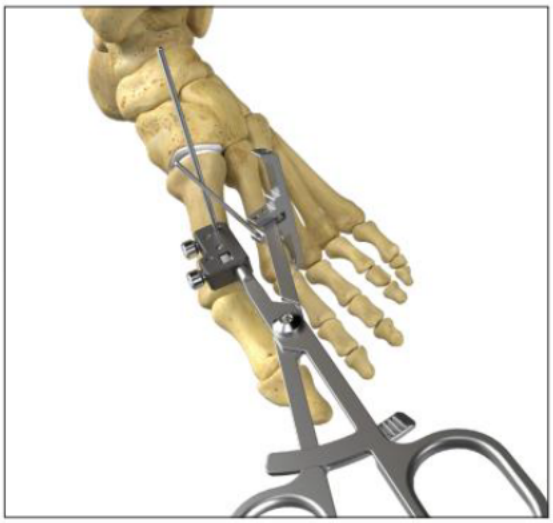


Figure 10
Reduction of the IM angle

Step 7: Additional correction of rotation

Using the 2mm wire in the 1st metatarsal as a joystick, achieve any additional desired supination correction of the 1st metatarsal. The sesamoids should be reduced under the first metatarsal head when viewed on AP X-ray.

Lock this correction by tightening the distal-most set screw (the set screw **not** in line with the 2mm wire), using the Reusable T20 Driver (57LPDT20) and the ratcheting handle (58871010).

After correction rotation, if additional IM correction is now achievable and necessary, the clamp may be closed further.

If needed, adjust plantarflexion of the metatarsal by pulling it plantarly away from the clamp. The first metatarsal head should be 2-3mm below the lesser metatarsal heads. Once aligned appropriately, tighten the more proximal set screw to fully secure the metatarsal in the corrected position.

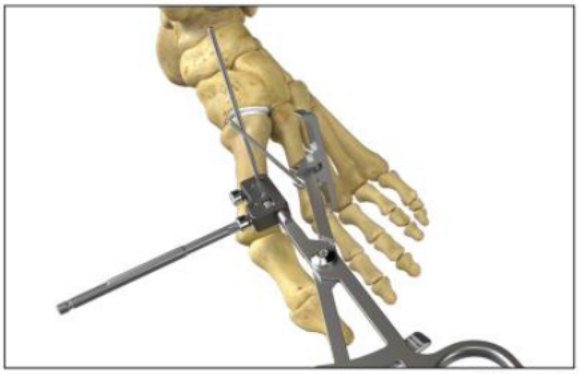


Figure 12
Additional correction of rotation

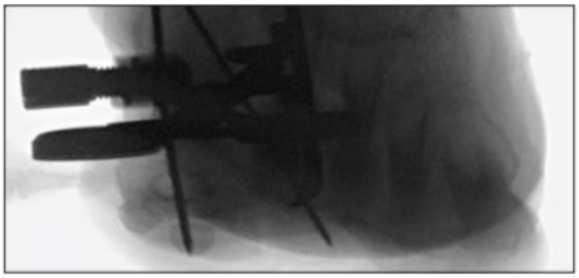
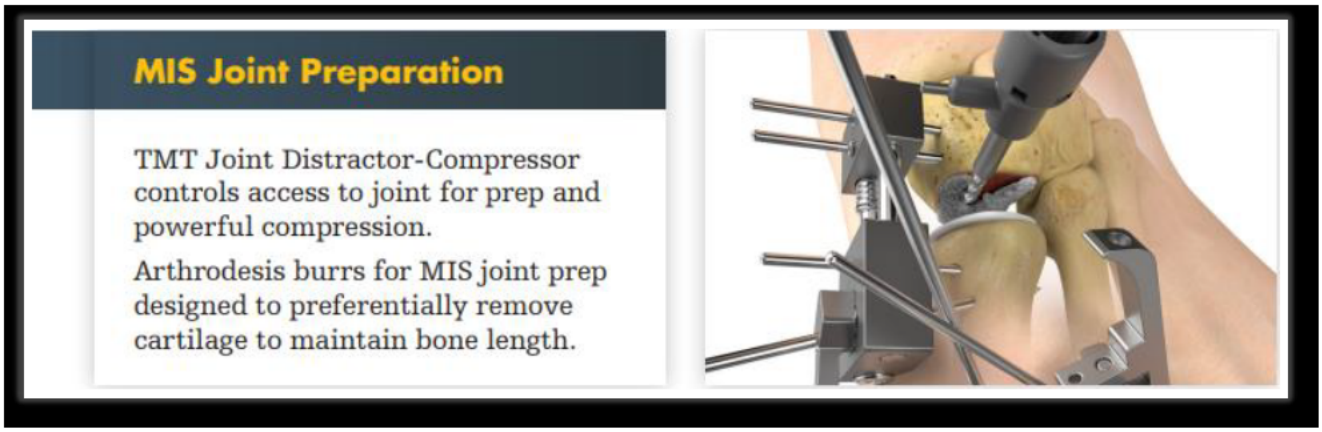


Figure 13
Reduced sesamoids

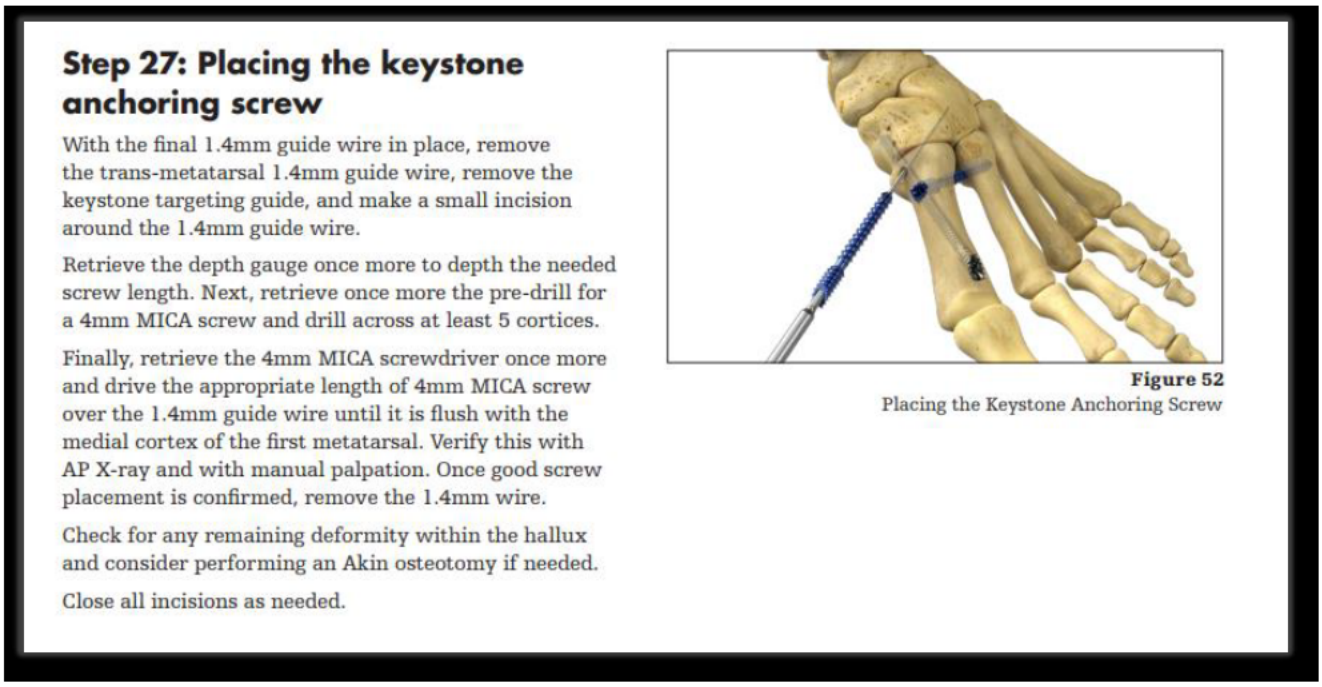
116. Just like Treace Medical's Lapiplasty® System and Procedure, Stryker instructs as a next step in its PROstep® Lapidus Procedure to prepare the TMT joint between the first

metatarsal and the medial cuneiform with surgical instruments (*e.g.*, a burr), as illustrated in the images below. The first image appears in the PROstep Sell Sheet and generally describes this step. The second image is an exemplary instruction on joint preparation from the PROstep Operative Technique Brochure. On information and belief, the identified tissue removing instruments are manufactured, sold, and provided by Stryker.



117. Ultimately, just like Treace Medical's Lapiplasty® System and Procedure, Stryker instructs fixating the moved position of the first metatarsal using implants (*e.g.*, screws), as illustrated in the images below. The first image appears in the PROstep Sell Sheet and generally

describes the fixation step of the PROstep® Lapidus Procedure. The second set of images illustrate an exemplary instruction on fixation from the PROstep Operative Technique Brochure. The identified implants are manufactured, sold, and provided by Stryker and are designed for the PROstep® Lapidus System.



118. The components of the PROstep® Lapidus System are identified by part number in the PROstep Brochure, including two kits: the PROstep MIS Lapidus Consumables Kit (Part No. 57LPKITA) and the PROstep MIS Lapidus Instrument Kit (Part No. 57LPKIT1). The PROstep Brochure's descriptions of the contents of each kit are reproduced below:

PROstep Consumable Instrumentation used in Lapidus procedure

Part no.	Description
57S1MI07	PROstep Instrument Pack
57KWPACK	PROstep MIS Lapidus K-wire Pack
58PM2SLV	Irrigation sleeve for primado 2
58TPXSLV	Irrigation sleeve for core 2
58CC3012	Cartilage burr – cylinder 3mm x 12mm
58SC3012	Sculpting burr – cylinder 3mm x 12mm
58CF4008	Cartilage burr – flame 4mm x 8mm

Part no.	Description
58RSPH40	Cortical burr – sphere
58RW3113	Cortical burr – wedge 3.1mm x 13mm
58FENAWL	Curved fenestration awl
57DRDEP5	Drill and depthing pack 5mm
DSDS10143	1.4mm MICA Wire
57S00030	Drill for 4mm MICA Screw
57S02025	Driver for 4mm MICA Screw

PROstep MIS Lapidus Reusable Instrument Kit

Part no.	Description
57LPREDC	Hallux valgus reduction clamp
57LPDT20	Reusable T20 driver
57LPDCPG	Dist-comp placement guide
57LPDSCP	Distractor-compressor
57LPDCSL	Dist-comp wire sleeve
57LPSTGL	Screw targeting guide left

Part no.	Description
57LPSTGR	Screw targeting guide right
57LPTP50	Chamfered tissue protector
57LPKTGL	Keystone targeting guide left
57LPKTGR	Keystone targeting guide right
58871010	Ratcheting AOQC handle

119. The PROstep Brochure also lists by part number Stryker's implants for the PROstep® Lapidus System, including various "PROstep MIS 4mm Chamfer Screws" and "PROstep MIS 4mm MICA Screws."

120. The vast majority of the components used in the PROstep® Lapidus System—including the Reduction Clamp, tissue removing instruments, and certain implants—have been designed specifically for the infringing PROstep® Lapidus Procedure, and, on information and belief, are collectively packaged for that procedure. Accordingly, Stryker sells and offers to sell components of the patented systems covered by the Asserted Patents that are used in practicing the surgical methods of the Asserted Patents through their sales of the PROstep® Lapidus System.

These components are a material part of the inventions in the Asserted Patents. On information and belief, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, Stryker knew that these components are especially made or especially adapted for use in an infringement of the Asserted Patents, as described further below. Further, these components—many of which are labeled as "PROstep" components—are not a staple article or commodity of commerce suitable for substantial non-infringing use. The only (and infringing) use of the PROstep® Lapidus System is depicted and described in the PROstep Sell Sheet, PROstep Operative Technique Brochure, and PROstep Video discussed above.

121. As discussed in more detail in Counts VI, IX, and XII, the PROstep® Lapidus System infringes the apparatus and system Asserted Patents; the PROstep® Lapidus System and Procedure infringe the Asserted Patents directed to surgical methods; and the surgical technique depicted in the PROstep Operative Technique Brochure instructs, encourages, and assists surgeons to use the PROstep® Lapidus System to infringe those Asserted Patents. Stryker also contributes to the infringement of the Asserted Patents by selling and offering to sell the PROstep® Lapidus System. The infringing PROstep® Lapidus System and Procedure seek to improperly profit from Treace Medical's inventions.

122. Although the PROstep® Lapidus System is a knockoff of Treace Medical's Lapiplasty® Systems, it is not a particularly good or high-quality knockoff. The deficiencies of the PROstep® Lapidus System compared to the Lapiplasty® System, Lapiplasty® Mini-Incision System, and Lapiplasty® Micro-Incision System are manifold. For example:

- The PROstep® Lapidus System and Procedure have no supporting clinical studies;
- The PROstep® Lapidus Procedure requires a large number of steps beyond the core steps described above, making the procedure longer and more involved;
- The PROstep® Lapidus System and Procedure requires use of instruments (such as a burr) that require more training; and

- The Reduction Clamp used in accordance with the PROstep® Lapidus Procedure obscures aspects of the procedure on fluoroscopy, including occluding the sesamoid bones and metatarsal head.

123. For ease of reference, Stryker and Wright's LapiFuse™ System and Stryker's PROstep® Lapidus System will be collectively referred to herein as the "Stryker TMT Bunion Systems."

E. The Stryker Defendants Had Notice of Treace Medical's Patents Prior to Launching Both Infringing Systems

124. As noted above, the Stryker Defendants launched the LapiFuse™ System in February 2020 and launched the later PROstep® Lapidus System in September 2023. Prior to both dates, Treace Medical provided notice of its patents and has continued to do so extensively up to the present.

125. First, as described above in Section D, the Stryker Defendants had direct knowledge of Treace Medical's patent portfolio as it existed at the time, when in 2017 Treace Medical informed a designer of Wright's LapiFuse™ System that it had patents and [redacted].

126. In addition, Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents to alert the industry and potential infringers, like the Stryker Defendants, to Treace Medical's issued patents and pending patent applications. Treace Medical's patent marking webpage states: "One or more implants, instruments, systems, and/or techniques associated with the product names below may be covered by claims in one or more of the United States Patents or Patent Applications as indicated[.]" The Asserted Patents are listed on Treace

Medical's patent marking webpage along with the associated patented articles in compliance with 35 U.S.C. § 287(a).

127. Treace Medical's packaging for reusable instruments and implants, and trays for reusable instruments, include notice of its marking website in accordance with 35 U.S.C. § 287(a) such as the following: "Pat. www.treace.com/patents", "See www.treace.com/patents", and "Covered by one or more patents."

128. Further, on information and belief, the Stryker Defendants' patent attorneys were aware of Treace Medical's patent portfolio. During the U.S. prosecution of the Stryker Defendants' patent applications, their patent attorneys acknowledged awareness of numerous Treace Medical patents and published patent applications and cited to family member patents of all but one of the Asserted Patents as follows:

- **'805 Patent**: The published application for the '805 Patent was cited by the examiner in a "Notice of References Cited" on July 26, 2024, relating to Wright's U.S. Patent Application No. 17/660,718.
- **'446 Patent**: The '446 Patent claims priority to (among other patents) U.S. Patent No. 9,936,994 (the "'994 Patent") and U.S. Patent No. 11,185,359 (the "'359 Patent"). The '994 Patent was cited in an "Information Disclosure Statement by Applicant" submitted to the USPTO by Stryker's patent attorneys on November 12, 2018, relating to Stryker's U.S. Patent Application No. 14/794,406. The published application for the '359 Patent was cited in an "Information Disclosure Statement by Applicant" submitted to the USPTO by Wright's patent attorneys on March 17, 2023, relating to Wright's U.S. Patent Application No. 17/660,718.
- **'873 Patent**: The '873 Patent claims priority to (among other patents) the U.S. Patent No. 10,045,807 (the "'807 Patent"). The published application for the '807 Patent was cited in an "Information Disclosure Statement by Applicant" submitted to the USPTO by Stryker's patent attorneys on November 12, 2018, relating to Stryker's U.S. Patent Application No. 14/794,406.
- **'558 Patent**: The '558 Patent claims priority to (among other patents) the '994 Patent, which was cited in an "Information Disclosure Statement by Applicant" submitted to the USPTO by Stryker's patent attorneys on November 12, 2018, as detailed above.

- **'386 Patent**: The '386 Patent claims priority to (among other patents) the '994 Patent, which was cited in an "Information Disclosure Statement by Applicant" submitted to the USPTO by Stryker's patent attorneys on November 12, 2018, as detailed above.

- **'387 Patent**: The '387 Patent claims priority to (among other patents) the '807 Patent and the '805 Patent. The published application for the '807 Patent was cited in an "Information Disclosure Statement by Applicant" submitted to the USPTO by Stryker's patent attorneys on November 12, 2018, as detailed above. The published application for the '805 Patent was cited by the examiner in a "Notice of References Cited" on July 26, 2024, as detailed above.

- **'085 Patent**: The '085 Patent claims priority to (among other patents) the '807 Patent. The published application for the '807 Patent was cited in an "Information Disclosure Statement by Applicant" submitted to the USPTO by Stryker's patent attorneys on November 12, 2018, as detailed above.

- **'819 Patent**: The '819 Patent claims priority to (among other patents) the '994 Patent, which was cited in an "Information Disclosure Statement by Applicant" submitted to the USPTO by Stryker's patent attorneys on November 12, 2018, as detailed above.

129. Treace Medical has also prioritized educating competitors and customers of its substantial and ongoing efforts to utilize patents to protect its investments in the instrumented TMT bunion correction market that it created. Treace Medical regularly issues press releases touting the issuance of its patents. By way of example:

- *Treace Announces Grant of Additional U.S. Patent on Instrumented Bunion Correction* (October 21, 2021): Announcing U.S. Patent No. 11,147,590, which is the parent to the asserted **'849 Patent**, and highlighting another patent in the same family as the '849 Patent, U.S. Patent No. 10,945,764. "The patent is an expansion of a portfolio filed during Treace's pathbreaking development work in the field with early priority dating back to 2014…. The new patent is the Company's 30th granted US patent (Treace also holds 6 patents granted outside the U.S.)."

- *Treace Announces Grant of U.S. Patent and Allowance of U.S. Patent Application on Bone Positioner Technology for Bunion Correction* (November 30, 2021): "The newly granted patent and allowed patent application expand Treace's comprehensive patent coverage on instrumented bunion correction techniques with particular emphasis on metatarsal bone positioning instrumentation, a product category Treace pioneered through its innovative development efforts."

- *Treace Announces Grant of U.S. Patent on Instrumented Bunion Correction* (January 19, 2022): "'We are pleased that the Patent Office continues to recognize the novel advances made by Treace. The addition of this recent patent grant further strengthens our intellectual property position and highlights our commitment to innovation in advancing the surgical

treatment of bunion patients,' said John T. Treace, CEO, Founder and Board Member of Treace."

- *Treace Files Patent Infringement Suit To Protect Lapiplasty® Bunion Technology* (March 28, 2022): "'Treace Medical . . . announced today that it filed a lawsuit against Fusion Orthopedics, LLC, alleging infringement of multiple patents related to Treace's Lapiplasty® 3D Bunion Correction™ system. … Mr. Treace added, 'We remain committed to protecting our proprietary technology and intellectual property, which drives our ability to continue to innovate solutions that benefit patients.'"

- *Treace Medical Expands Market Leading Global IP Portfolio For Bunion And Related Deformities* (April 19, 2023): "In 2023, Treace has filed 15 new United States patent applications and the [USPTO] has granted to the Company 7 utility patents. These granted patents are U.S. Patent Nos. 11,627,954, 11,622,797, **11,602,386**, **11,602,387**, 11,607,250, 11,596,443, and 11,583,323, relating to novel systems, devices, and methods for performing instrumented surgery for bunions and related deformities[.]." (Emphasis added for Asserted Patent.)

- *Treace Medical Concepts Reports Second Quarter 2024 Financial Results* (August 6, 2024): "Patent portfolio expands to 65 granted U.S. patents, with an additional 22 granted patents worldwide and 84 pending U.S. patent applications… Treace has pioneered and patented the Lapiplasty® 3D Bunion Correction® System – a combination of instruments, implants, and surgical methods designed to surgically correct all three planes of the bunion deformity and secure the unstable joint, addressing the root cause of the bunion and helping patients get back to their active lifestyles."

130. Likewise, Treace Medical regularly attends industry meetings and conferences, such as the ACFAS annual meeting and the AOFAS annual meeting. Treace Medical representatives are trained to discuss and do discuss that Treace Medical is the inventor of instrumented TMT bunion correction surgery and promote the fact that Treace Medical has strong patent protection on both the systems and procedures. For example, Treace Medical's '805 Patent issued well before Wright attended the February 2020 ACFAS to launch its LapiFuse™ System. In addition, Treace Medical's '446 Patent issued before Stryker attended the May 2021 ACFAS Vegas Scientific Conference to promote the LapiFuse™ System following the Wright acquisition. Similarly, Treace Medical's '386 Patent issued before Stryker attended the AOFAS annual meeting in September 2023 to debut its PROstep® Lapidus System.

F. Stryker's Manipulation of Integrated Delivery Networks and Bundled Service Line Agreements

131. On information and belief, Stryker, [redacted], concluded that [redacted], it would use its dominance in other product service lines to push the LapiFuse™ System on customers. By August 2020, the LapiFuse™ System had achieved only minimal traction, and on information and belief Stryker further focused on bundling the LapiFuse™ System within agreements for its unrelated trauma service line.

132. As discussed in more detail below, Stryker has a dominant market position in the service line for trauma implants ("trauma service line"), and leverages that dominant position by manipulating Integrated Delivery Networks ("IDNs") through bundled service line agreements and substantial "discounts" or "rebates" to coerce hospital systems to purchase Stryker's LapiFuse™ and PROstep® MIS Lapidus Systems rather than the Lapiplasty® System, despite those systems being unrelated to the trauma service line.

133. IDNs are groups of healthcare providers such as hospitals, ambulatory surgical centers, and other outpatient care facilities that collectively provide comprehensive and "integrated" customer care for virtually all types of procedures and healthcare needs. More than half of instrumented TMT bunion procedures nationwide are performed at an IDN-affiliated hospital or surgical center, with the vast majority of the remaining procedures performed by independently owned surgical centers, *i.e.*, that operate outside of IDNs.

134. IDNs include an administrative purchasing department that manages the supply chain for the facilities throughout its network. A medical equipment supplier such as Stryker or Treace Medical generally has to be "on contract" to conduct business within the hospitals and facilities of the IDN. Such a contract, in effect, ostensibly provides the supplier a "license" to

provide their products to departments and surgeons within the IDN. An IDN supply chain department will ultimately have numerous agreements and agreement types for particular products and purposes, including standalone agreements, bundled service line agreements, and agreements with group purchasing organizations ("GPOs").

135. IDNs often directly negotiate contracts with medical device and equipment suppliers for categories of products, often referred to as "service lines." Historically, only certain product categories have been subject to bundled service line agreements, such as the spine service line, trauma service line, and hip and knee implant service lines. Extremities including foot and ankle have not historically been covered by bundled service line agreements, due in large part to a diversity of suppliers and products within extremities, relatively rapid recent advances compared to other service lines, and the overall relative spend and potential cost savings compared to larger service lines such as spine and trauma.

136. Another source of IDN purchasing is through group purchasing organizations or "GPOs." Rather than the IDN negotiating directly with medical equipment suppliers, the GPO negotiates agreements that an IDN can adopt through its membership in the GPO. As a general matter, GPO agreements are utilized for commoditized medical devices and equipment. Stryker is well known in the industry as preferring direct negotiations with IDNs over selling through GPOs, particularly for the types of medical devices and implants at issue in the present action.

137. Where a service line is covered by a bundled service line contract, the IDN agrees on behalf of all of its facilities to purchase a certain percentage (typically 80%–90%) of specified products quantified by annual spend within those service lines from the contracted supplier. On-contract competitors to a bundled service line supplier can still sell products covered by the bundled service line agreement, but are collectively limited with all other such suppliers to the

remaining 10%–20%. An IDN may have different bundled service line suppliers for different service lines, or in some instances may commit to bundled service line agreements for multiple product groupings within a single service line.

138. Bundled service line agreements have frequently been a subject of scrutiny by antitrust lawsuits and competition authorities, particularly where multiple products or service lines are included within a single bundled service line agreement. Bundled service line agreements were first used by GPOs and raised a variety of issues relating to rebates, kickbacks, and loss of patient and physician choice. In response to such concerns, GPOs have developed best practices and procedures to promote transparency and open competition. Direct bundled service line agreements between medical device companies and IDNs are operated and structured differently for different companies, without governing standards, regulations, or centralized oversight.

139. One practice that has historically drawn particular scrutiny is bundled service line agreements that include multiple unrelated products from different service lines, which may allow a medical device supplier to leverage its market position in one service line into other areas. These practices draw even greater scrutiny where they target competitors unable to offer the full line of bundled products. Accordingly, even within a service line where there is a bundled service line agreement, specialty products are typically "carved out" of the bundled service line agreement altogether, meaning that those specialty products do not count against the required percentage to obtain the supplier rebate.

140. Many GPOs have explicit policies prohibiting bundles of unrelated products. For example, the GPO Premier's "Group Purchasing Code of Conduct" lays out an explicit policy of "No Bundling of Unrelated Products." A Government Accountability Office report similarly indicates that "all five GPOs reported that they did not bundle unrelated products," and the

Healthcare Group Purchasing Industry Initiative requires GPOs to disclose whether "the GPO permit[s] bundling of unrelated products or services from the same vendor or from different vendors… [and] [i]f so, under what circumstances would the GPO consider bundling to be appropriate?" In sum, GPOs have long understood that bundling of unrelated products raises substantial ethical and competition issues, and thus rarely if ever engage in such practices.

141. On information and belief, Stryker's primary competitor in the trauma service line—Johnson & Johnson (DePuy Synthes)—does not bundle unrelated products as Stryker does. As one court explained in an antitrust case against Johnson & Johnson:

> Beginning in the fall of 2003, J & J took steps to mitigate the effects of its bundled contracts on single product competitors. In determining threshold percentage discount requirements, J & J carved out purchases from competitors who did not offer a full line of products. For example, a GPO could purchase Applied trocars without jeopardizing its ability to qualify for discounts or achieve the maximum discount level.

142. Stryker's bundling of instrumented TMT bunion correction systems with its trauma service line, described in more detail below, includes no such carve outs.

143. Stryker has one of the most comprehensive medical product portfolios of all medical device companies and can supply multiple products under bundled service line agreements for multiple service lines. And within each of those service lines, Stryker can provide among the most comprehensive medical device and equipment offerings to reach the required spend percentage. Stryker has had particular success achieving agreements within its trauma service line, where, on information and belief, it has the highest percentage of direct agreements with IDNs of all suppliers.

144. The "carrot" of Stryker's bundled service line agreements with healthcare systems is a substantial rebate of 3%–5% on all purchases (often in the range of hundreds of thousands to over a million dollars) that Stryker pays to the IDN if the IDN achieves the required percentage of

purchases within the covered product service line(s). The "stick" is monitoring and enforcement of individual healthcare facilities' compliance with the bundled service line agreement. As part of the standard "request for proposal" or "RFP" process, Stryker identifies the products that are competitive with those covered by the bundled service line agreement by product number or "stock keeping unit" ("SKU"). Thus, for example, if a competitive SKU is identified as corresponding to a Stryker product within the bundled service line agreement, that product counts against the IDN's rebate-eligible percentage.

145. On information and belief, Stryker's bundled service line agreements allow Stryker to monitor and audit each IDN facility's progress towards the rebate-eligible purchase percentage, including receiving access to usage information for individual competitive products, often at a facility or surgeon level. On information and belief, Stryker holds regular meetings with IDN administrative staff to confirm progress or lack thereof toward rebate eligibility and to discuss usage of bundled service line and competitive products.

146. Because the rebate is received annually or semi-annually, it is not applied to directly reduce the price of procedures but rather can be used within the receiving department for a variety of purposes.

G. The Relevant Geographic Market

147. The relevant geographic market is the United States. All of Treace Medical's sales are presently in the United States and a majority of Stryker's sales are in the United States. The United States (as well as other countries) have unique legal and regulatory requirements for the design, manufacturing, and purchase of medical devices and equipment such as the devices at issue in this matter. Both Treace Medical and Stryker sell their products nationwide, as do most other competitors for instrumented TMT bunion correction systems.

H. The Relevant Product Markets

148. Stryker is a diversified medical technology company providing a wide range of medical devices, equipment, implants, services, and other technologies that are used throughout hospitals and operating rooms, and which "impact more than 150 million patients annually." Given that almost 75% of Stryker's annual revenue is in the United States, this constitutes a substantial portion of the United States population "impacted" by Stryker as a patient each year.

149. Stryker segments its business into "MedSurg and neurotechnology" and "orthopaedics and spine." Collectively, these products encompass nearly every aspect of surgical and hospital operations. Stryker's MedSurg and neurotechnology business includes business segments of instruments, endoscopy, medical, neurovascular, and neuro cranial. According to Stryker, orthopaedics and spine includes trauma, knees, hips, upper extremities (*e.g.*, hands, elbows, and shoulders), foot and ankle, spine, craniomaxillofacial, and sports medicine. The products at issue in this action are trauma implants from the trauma business segment and TMT bunion systems from the foot and ankle business segment.

150. Throughout its early history up and through the early 2000s, Stryker largely achieved growth and gained market share through in-house product development. More recently, however, Stryker has relied on acquisitions to fuel its growth into new product segments and to increase its market share in segments where it is already present. As stated in its most recent Form 10-K filed with the U.S. Securities and Exchange Commission, "[o]ur goal is to… maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions[.]" As Stryker's CFO has explained, "the piece that I know gets you excited, gets me excited, it's just we're a serial acquirer." As explained by Stryker's CEO Kevin Lobo, its philosophy over the last decade has been to achieve the top "category position" and be "absolute leaders" in all markets it participates in, which it has primarily achieved through acquisitions. Once Stryker acquires a technology, it relies upon

its sales and distribution network to capture market share with minimal additional product innovation.

151. Of more than a dozen recent acquisitions, Stryker's acquisition of Wright, completed in November 2020, is most relevant to the present action. Not only did Stryker gain access to Wright's (then floundering) LapiFuse™ System, but Wright went from an extremities-focused company to one with access to Stryker's full line orthopedic product mix and sales heft. True to its corporate strategy of growth through acquisition and leveraging of distribution, the resulting product mix combined Stryker's dominant but slow-growing trauma implant business with faster growing extremities products. For example, analysts and industry experts have explained that:

- "SYK Perceived as Far and Away Market Leader" in orthopedics, and is seeking to "sustain above-market sales growth and successfully drive margin expansion" by "shift[ing] revenue to the higher growth MedSurg/Extremities [businesses], now approaching 80% of sales[,]" based in part on a type of "contract that incentivizes higher volume usage of SYK implants."

- "I think that [the acquisition of Wright] was pretty huge. Stryker and Wright Medical had always been competing for those top five positions in terms of market share. If I'm honest, I was surprised that that deal was even able to go through because it did, in my mind, represent taking a massive, massive chunk of the market. Obviously, they're not playing in just the implant space. They're all over the entire surgical experience."

152. This provides Stryker with enormous leverage that it can wield during system-wide purchasing negotiations with IDNs, including to undermine, shutout, and limit healthcare providers' access to products from more innovative competitors such as Treace Medical that lack a full suite of products for entire service lines. The primary service line that Stryker has leveraged to coerce IDNs to include the Stryker TMT Bunion Systems in Stryker bundled service line agreements to the substantial exclusion of the superior Lapiplasty® System is its trauma service line.

i. Trauma Service Line

153. Within the medical field, the term "trauma" is generally understood to refer to traumatic bone injuries—typically fractures—that result from accidents, falls, sports injuries, assaults, or other forms of impact. Within the hospital supply chain, the trauma service line is generally understood to refer to a variety of implants that are used to repair such fractures and restore bone function in the context of providing emergency medical treatment. These implants are specially designed for particular anatomical locations or fracture types. For example, Stryker's recently launched Pangea plating system includes anatomy-specific implants (Humerus, Peripro Femur, Distal Femur, Proximal Tibia, Distal Tibia, Distal Fibula) and fracture-specific implants (Large Fragment, Small Fragment, and Mini Fragment).

154. Stryker's product portfolio includes products, including many commodity products, that encompass virtually every trauma product sub-category. Accordingly, Stryker is able to offer IDNs a comprehensive trauma bundle covering virtually all of the trauma needs of the healthcare facilities in an IDN. As discussed above, with IDNs these are typically bundled service line deals in which the healthcare facilities are required to purchase 80%–90% of certain products within the trauma service—as determined by SKUs of Stryker and competitors—to obtain a substantial rebate. Trauma is generally considered a "mature" product line with minimal growth opportunities.

155. The trauma market is highly concentrated, with a Herfindahl-Hirschman Index ("HHI") of over 2,350 for all trauma suppliers and over 3,400 for the four trauma suppliers that attempt to sell trauma service line product bundles. Stryker, along with DePuy Synthes, is one of two dominant suppliers in the trauma field, with Zimmer Biomet and Smith & Nephew both having market share of approximately 10%. Each of Zimmer Biomet and Smith & Nephew lack

significant product offerings for multiple products within the trauma service line, and thus, the ability to offer fully comprehensive product bundles.

156. As between the two dominant suppliers, DePuy Synthes primarily sells trauma products through GPOs, with undifferentiated products that are considered commoditized in the industry, with a lack of anatomic design, innovation, or creativity. Stryker, on the other hand, almost exclusively sells through bundled service line agreements with IDNs, with particularly dominant positions in key trauma product lines such as intramedullary hip screws (43% market share) and staple fixation (44% market share). Accordingly, Stryker's dominance within the trauma service line is exacerbated in sophisticated IDN settings involving direct purchasing by large hospital systems, where on information and belief it has bundled trauma service line agreements with 80% or more of IDNs.

157. In contrast to Stryker's comprehensive product offering within the trauma service line, Treace Medical does not sell any trauma service line products.

158. The trauma service line is a relevant product market distinct from other medical device product markets. Given the differences in the types of injuries treated by trauma implants compared to other types of surgery (*e.g.*, spine, soft tissue, foot and ankle, upper extremities, joint replacement, etc.), with limited exceptions trauma implants are not functionally interchangeable with devices, implants, and equipment for non-emergency or elective orthopedic surgeries or procedures. For example, Stryker's "Orthopaedics" landing page distinguishes "Trauma" from other types of orthopedic surgery markets such as "Craniomaxillofacial," "Foot and Ankle," "Joint Replacement," "Spine," "Sports Medicine," and "Upper Extremities." In public presentations such as a recent "OTA Podcast: Help Them Help You: Creating Orthopaedic Trauma Value Through a

Hospital Alliance - Sponsored by Stryker[,]" Stryker employees refer to trauma as a distinct service line.

159. The vast majority of trauma surgeons specialize in trauma surgery to the exclusion of other types of surgery such as spine, soft tissue, foot and ankle, upper extremities, and joint replacement. Trauma surgeons take a subset of specialized courses in medical school, have specialized residencies, and are typically part of a separate trauma department for administrative purposes.

160. Medical organizations and journals consider trauma procedures to be distinct from other surgical procedures, including other types of orthopedic procedures. For example, organizations dedicated to trauma care include the American Association for the Surgery of Trauma ("AAST"), the Eastern Association for the Surgery of Trauma ("EAST"), Western Trauma Association ("WTA"), and the International Association for Trauma Surgery and Intensive Care ("IATSIC"). Examples of specialty conferences for trauma surgery include the AAST Annual Meeting, EAST Annual Scientific Assembly, WTA Annual Meeting, IATSIC Congress, World Trauma Congress, and the Trauma, Critical Care and Acute Care Surgery Conference.

161. Trauma implants have no reasonably interchangeable substitutes, and there is no significant cross-elasticity of demand with other non-trauma surgical products, including within other orthopedic specialties such as foot and ankle, spine, craniomaxillofacial, sports medicine, joint replacement, or upper extremities. Because of many factors, including price, performance, value and safety, there are no other significant economic substitutes for trauma products. Even if surgical devices, implants, and equipment targeted to other types of surgery could be utilized in emergency trauma surgeries at similar prices, few if any surgeons would move from specialized trauma products to products within other general orthopedic specialties, based at least on their

training and familiarity with specialized trauma products and the substantial costs in surgeon training and procurement processes to obtain all of the needs of a functioning trauma department.

162. If a hypothetical monopolist were to become the only seller within the trauma service line in the United States, and if prior to that time these products were sold at competitive prices, the hypothetical monopolist could profitably charge a small but significant non-transitory increase in price (a "SSNIP") for the trauma service line. In other words, a hypothetical monopolist could permanently increase prices and do so profitably in a manner that would be significant and non-transitory, and that is not otherwise justified such as due to increased costs to the hypothetical monopolist. For example, the prices charged by a hypothetical monopolist within the trauma service line would not be disciplined by other orthopedic service lines such as foot and ankle, upper extremities, joint replacements, spine, or the like. Nor would healthcare providers be able to refuse to purchase or otherwise have negotiating power with such a hypothetical monopolist since trauma surgeries must be performed on an emergency basis at or near the time when the trauma occurs. Accordingly, the trauma service line is a separate relevant product market for antitrust purposes.

ii. TMT Bunion Systems

163. At the time of Stryker's acquisition of Wright, one of the fastest growing product lines within what Stryker referred to as the "fast growing extremities market" was instrumented TMT bunion surgery systems ("Instrumented TMT Bunion Systems" and "Instrumented TMT Bunion Procedures"). Sales of Instrumented TMT Bunion Systems had grown from essentially zero when Treace Medical launched the Lapiplasty® System in 2015 to $39,416,000 for Treace Medical alone in 2019 and $57,365,000 for Treace Medical alone in 2020. By 2024, the total market for Instrumented TMT Bunion Systems and components was estimated to be almost $500 million, with predictions of growth to over $650 million by 2030.

164. As described above, with its Lapiplasty® System and Procedure, Treace Medical developed and popularized Instrumented TMT Bunion Systems and Procedures, resulting in a substantial increase of life-changing procedures performed in the United States. Due to factors such as ease of use and reproducibility, Instrumented TMT Bunion Systems and Procedures have largely replaced traditional freehand Lapidus procedures (collectively with Instrumented TMT Bunion Systems and Procedures, "TMT Bunion Systems" and "TMT Bunion Procedures") and expanded the addressable market for life-changing bunion correction procedures. In other words, even with traditional non-instrumented freehand Lapidus procedures included within the overall market of TMT Bunion Systems and Procedures, the instrumented TMT bunion correction market created by Treace Medical makes up the vast majority of the market for TMT Bunion Systems and Procedures ("TMT Bunion Market").

165. TMT Bunion Systems and Procedures are distinct from other so-called bunion correction procedures such as first metatarsal distal osteotomies (*i.e.*, osteotomies performed further up the foot, closer to the big toe). Particularly since the introduction of Instrumented TMT Bunion Procedures, the standard of care is to only consider distal osteotomies for mild bunion conditions, while proximal osteotomies are now rarely performed and have been displaced almost entirely by Instrumented TMT Bunion Procedures. Distal osteotomies are performed in a manner more similar to other foot and ankle procedures, with minimal changes to bone positioning, shaving of the big toe, and use of screws or plates to hold changes to the bones of the big toe. In contrast, Instrumented TMT Bunion Procedures utilize specialty instruments to temporarily separate the first metatarsal bone from the medial cuneiform bone, move the first metatarsal relative to the medial cuneiform and second metatarsal in multiple planes, and fix the moved position with specialty implants such as plates, screws, or staples to hold the moved position and

promote fusion between the first metatarsal and the medial cuneiform. These instruments may include unique clamps for holding and moving bones relative to each other, cut guides for performing precision cuts of the first metatarsal and/or medial cuneiform, custom implants configured for the geometries of the first metatarsal and medial cuneiform, and in a number of systems such as the Lapiplasty® System, even custom blades, osteotomes, burrs, and K-wires to fit with complex foot geometries.

166. TMT Bunion Systems have no reasonably interchangeable substitutes, and there is no significant cross-elasticity of demand between these systems and other foot and ankle products or procedures such as hammertoe treatments, corrections to smaller toes, ankle arthroscopy, ankle replacement, ankle fusion, Achilles tendon repair, plantar fascia release, tarsal tunnel release, flatfoot reconstruction, or other foot and ankle repairs. Because of many factors, including price, performance, value and safety, there are no other significant economical substitutes for TMT Bunion Systems. TMT Bunion Systems generally do not use common or shared instruments with other foot and ankle surgeries, and foot and ankle surgeons knowledgeable of other foot and ankle procedures must undergo extensive training before they properly perform TMT Bunion Procedures.

167. Further, significant cross-elasticity of demand does not exist between TMT Bunion Systems and equipment used in other types of orthopedic surgical procedures such as upper extremities, spine, knees, hips, craniomaxillofacial, or trauma. With the exception of some power tools and a limited number of commodity components, TMT Bunion Systems do not use common or shared instruments and implants with trauma surgeries, since TMT Bunion System components are typically specific to the complex and unique mid-foot anatomy.

168. Instrumented TMT Bunion Procedures are performed almost exclusively by foot and ankle surgeons, the vast majority of whom specialize in foot and ankle to the exclusion of other anatomical regions. Foot and ankle surgeons take a subset of specialized coursework, have specialized residencies, and are typically part of a separate department for administrative purposes. And Instrumented TMT Bunion Procedures are almost exclusively researched and presented within organizations such as AOFAS, ACFAS, and the International Federation of Foot & Ankle Societies ("IFFAS"), and at specialty conferences for foot and ankle surgery including the AOFAS Annual Meeting, ACFAS Scientific Conference, IFFAS Triennial Meeting, and Podiatry Institute Conferences.

169. The type of procedure employed for bunion correction surgery is typically based on the severity of the deformity as determined from the hallux valgus angle and intermetatarsal angle, using measures such as the Coughlin-Mann classification. Distal osteotomies are generally considered only for a "Mild" severity of the hallux valgus deformity, while corrective procedures are required for "Moderate" and "Severe" conditions. Prior to the introduction of the Lapiplasty® System (the first Instrumented TMT Bunion System) to the market, surgeons performed bunion correction procedures for moderate to severe deformities using a "freehand" Lapidus procedure or proximal osteotomies (*i.e.*, osteotomies performed closer to the TMT joint than distal osteotomies). Now that Instrumented TMT Bunion Systems have become a standard of care, the overall number of correction procedures for moderate to severe bunion conditions has increased substantially and virtually all of these are TMT Bunion Procedures, as proximal osteotomies are significantly less effective and are now rarely performed. Most of these TMT Bunion Procedures are Instrumented TMT Bunion Procedures, and few if any surgeons would move from Instrumented TMT Bunion Systems to freehand Lapidus procedures due to the difficulty and unpredictability of the latter.

170. Few if any surgeons would move from performing TMT Bunion Procedures for major deformities to other bunion procedures such as osteotomies, since distal osteotomies are largely cosmetic procedures that fail to correct the underlying bone deformity and are recommended only for mild deformities, and proximal osteotomies are less effective for moderate to severe deformities and are now rarely performed at all.

171. If a hypothetical monopolist were to become the only seller of TMT Bunion Systems in the United States, and if prior to that time these products were sold at competitive prices, the hypothetical monopolist could profitably charge a small but significant non-transitory increase in price (a "SSNIP") for the TMT Bunion Systems. In other words, a hypothetical monopolist could permanently increase prices and do so profitably in a manner that would be significant and non-transitory, and that is not otherwise justified such as due to increased costs to the hypothetical monopolist. For example, the prices charged by a hypothetical monopolist of TMT Bunion Systems would not be disciplined by other procedures such as metatarsal distal osteotomies or proximal osteotomies. Nor would healthcare providers be able to refuse to purchase or otherwise have negotiating power with such a hypothetical monopolist, since they would otherwise have to forego actual bunion correction procedures entirely that are necessary for effective patient care. Accordingly, TMT Bunion Systems are a separate relevant product market for antitrust purposes.

172. Foot and ankle products have not historically been subject to bundled service line agreements for a number of reasons. First, foot and ankle products have traditionally included a diverse and specialized product mix provided by a large number of smaller specialty medical device companies such as Paragon 28, DJO Global, Medartis, Arthrex, and Integra LifeSciences. This is in addition to more fragmented product line offerings from Stryker, Zimmer, Smith &

Nephew, DePuy Synthes (Johnson & Johnson), and before its purchase by Stryker, Wright. Second, almost all foot and ankle surgeries are performed by Doctors of Podiatric Medicine or orthopedic surgeons ("MDs") who specialize in foot and ankle surgery. These foot surgeons traditionally were not direct IDN employees and had privileges to practice at multiple locations, such as multiple IDNs, multiple facilities within IDNs, and/or ambulatory surgical centers ("ASCs") that were not affiliated with IDNs. Accordingly, if an IDN attempted to force a surgeon to use a product that the surgeon did not prefer, the surgeon could perform the surgery elsewhere with the preferred product.

173. Despite only recently launching the Stryker TMT Bunion Systems, Stryker has already foreclosed a substantial portion of the market for TMT Bunion Systems from competitors such as Treace Medical almost solely via the improper and anticompetitive bundling of TMT Bunion Systems with its trauma service line. For example, on information and belief, within IDNs Stryker is either the first or second largest supplier of TMT Bunion Systems, despite Treace Medical's product leadership and approximately 5-year head start. As more IDN contracts come up for renewal and Stryker has additional opportunities to coerce IDN purchasing departments to include TMT Bunion Systems in their trauma service line bundles, Stryker's market share will only increase. Further, there is a significant trend of independent foot and ankle surgeons and practices being absorbed as employees by IDNs. For example, between 2012 and 2022, the share of physicians who work in private practices fell by 13 percentage points and a recent Stryker-sponsored podcast noted that this trend has continued. As this trend continues and accelerates, the percentage of surgeons unable to choose which TMT Bunion Systems to use, and instead forced to use the Stryker TMT Bunion Systems, will only increase.

I. Stryker's Anti-Competitive Acts

174. Treace Medical has invested over $150 million to create a new class of surgical procedure and system that has already improved over 100,000 lives. These investments include research and development to create and constantly improve customized instrumentation and components for the Lapiplasty® System, education of a substantial portion of the relevant surgeon population on performing the Lapiplasty® Procedure through live simulated surgical and other trainings, and education of the relevant patient population through multiple media channels. Treace Medical has protected those investments through development of a robust intellectual property portfolio, including over 65 granted U.S. utility patents, 24 granted foreign patents, nearly a hundred pending patent applications, and registered trademarks on its core Lapiplasty® 3D Bunion Correction® brand.

175. Treace Medical is entitled to enforce its intellectual property rights to protect and recover upon those investments. A primary purpose of intellectual property protection is to incentivize investments in innovative products though enforceable rights that prevent copyists from free-riding on an inventor's technology and branding. Absent enforceable intellectual property rights, well-heeled copyists such as Stryker could make it nearly impossible for innovative companies to recover their investments, drying up capital and investment in innovative companies such as Treace Medical such that life-changing technologies like the Lapiplasty® Procedure are never developed in the first place or delayed for years or decades.

176. Stryker has chosen the path of "efficient infringement," a strategy employed by dominant industry players in which they openly infringe and rely upon the costs and uncertainties of patent litigation, and a nearly unlimited ability to pay for those costs, to dissuade smaller competitors from bringing patent lawsuits at all and delay payment of a damages award for years, all while capturing market share with copycat products. As discussed in more detail in Sections D-

E, in this instance that strategy should fail—Stryker's infringement is simply too brazen and willful for an efficient infringement strategy to be allowed.

177. Stryker's anticompetitive playbook involves much more than efficient infringement. IDN supply chain practices may be complex, but it has long been recognized by GPOs and the courts that bundled purchasing agreements should not be leveraged to exclude innovative single or limited product suppliers like Treace Medical. Rather, both GPOs and other bundled service line suppliers have traditionally "carved out" such product categories, particularly where an entirely new product type is at issue. In the case of Stryker's trauma bundle, there should be nothing to "carve out," since the bundled product (here, TMT Bunion Systems) is not even a trauma product. But Stryker has turned these industry-standard practices on their head, by "pulling in" TMT Bunion Systems into its trauma service line bundle.

178. As Stryker's CEO Kevin Lobo has acknowledged, as of the mid-2010s Stryker was a relative newcomer to bundled purchasing due to its history with "niche" products, but through growth and acquisitions could "actually run the entire trauma service center and service line of a hospital[,]" such that its strategic shift to "total account conversions" was "now working." And it has worked well, with Stryker now a dominant player in trauma and particularly in bundled trauma agreements with IDNs.

179. While bundled purchasing arrangements and rebates may be appropriate *within* a mature service line such as trauma, Stryker's more recent attempt to pull in a new and innovative product line that is not even a trauma product within its trauma service line runs directly afoul of well-established industry practices and competition law. As discussed herein, Stryker has engaged in a course of interrelated anticompetitive acts that, independently and in combination, have foreclosed and truncated the competitive process for TMT Bunion Systems and Procedures. As a

result, healthcare purchasers are coerced to purchase Stryker TMT Bunion Systems that in fact cost these healthcare purchasers more when hidden costs, lower product quality, and bundled "rebates" attached to those purchases are considered. Patients and their insurers end up paying the same amount for procedures performed with the inferior Stryker TMT Bunion Systems, which are not selected for their merits by surgeons as part of a competitive process but are forced on surgeons and patients by Stryker's anti-competitive bundling of unrelated products. Accordingly, competitors such as Treace Medical have already been foreclosed from competition on the merits of price and product features in a substantial portion of the market for TMT Bunion Systems.

i. Exclusionary Bundling and Rebate Agreements for Unrelated Products

180. Wright and then Stryker initially had relatively little success in selling the LapiFuse™ System to hospitals and surgery centers before engaging in its anticompetitive bundling practices.

181. Prior to Stryker's trauma service line bundling and other conduct as described in this Complaint, Treace Medical had achieved substantial success in obtaining carve outs within numerous IDNs based on the unique and non-substitutable features of the Lapiplasty® System. Since Stryker began targeting Treace Medical with bundles, rebates, and other conduct at IDNs, Treace Medical has been foreclosed from competing on the merits at numerous IDNs.

182. Prior to Stryker's trauma bundling and other conduct as described in this Complaint, Treace Medical had made substantial headway in selling the Lapiplasty® System within the foot and ankle segment based on the unique and non-substitutable features of the Lapiplasty® System, and the fact that it was only competing with foot and ankle products. Since Stryker began targeting Treace Medical with trauma bundles, rebates, and other conduct at IDNs, that success also has slowed and, in some cases, reversed.

183. On information and belief, Stryker became aware of the enormous financial opportunity for Instrumented TMT Bunion Systems at least in part through [redacted]. On information and belief, Stryker decided at that time to aggressively pursue a plan to displace the Lapiplasty® System via Stryker's dominance in other product service lines and its IDN relationships, rather than on the respective merits and price of the Wright LapiFuse™ System versus the Lapiplasty® System.

184. In November 2019, Stryker announced the $4 billion purchase of Wright. As Stryker management explained at the time, "with Wright Medical, Stryker will be a leading player in the fast growing $5 billion extremities market." Acknowledging that Stryker and Wright were "highly complementary players in the fast-growing extremities market[,]" Stryker explained that "as we bring Wright Medical into Stryker, we will be a category leader in all segments of the $5 billion extremity market on a global basis, including foot and ankle."

185. A main purpose of the Wright acquisition was to expand from Stryker's traditional areas of strength such as trauma into the foot and ankle market, where Wright was better positioned. As Stryker explained at the time, "Wright Medical's portfolio fills additional gap[s] such as… differentiated foot and ankle technologies. Overall, we are excited about the opportunity to bring Wright Medical into our trauma and extremities orthopedics team[.]" One expert analysis discussed this "gap filling" from the perspective of effects on hospital system purchasing:

> As far as what I think is going to happen with that [Stryker and Wright] merger, I think that you're going to continue to see more and more of these single-vendor contracts that they're going to be able to secure. Typically, with single vendor contracts, you're looking at 80% of whatever hospital entity that you're signing the contract with, that they're agreeing to use your products 80% of the time. Obviously, the surgeons that are working within that hospital, they have their own ability to make choices about what products they use and what they think is going to be best for the patient.

> There is this interesting, I don't know, dynamic between the purchasing department and, we'll say, the money-focused individuals that are treating the hospital as a business, which it is, versus the surgeon that is trying to do what is best for their patient. I've heard a lot of complaining about, "Well, [m]y hospital is pushing me to use this product because that's what we have under contract."
>
> Typically, you'll see a 20% carve out that's for the smaller company. … With Stryker and Wright already being massive companies coming together and now just having an even more complete portfolio, I really feel like it's going to position them well to take over more of those contracts and to secure more of those procedures.

186. As one of the largest medical device companies having the broadest product portfolios, Stryker has trauma agreements with almost all IDNs in the United States that enter into such agreements, with trauma service line contracts at an estimated 80% or greater of IDNs nationally. While the percentages and the exact rebate mechanism may differ, virtually all of these Stryker "trauma" agreements identify product categories by SKU or surgery type, and require the IDN hospital to purchase at least 80% of products within those categories to access the substantial rebate, which is typically in a range of 3%–5%.

187. Stryker has been successful in forcing hospitals to accept TMT Bunion Systems bundled within its trauma service line, even though TMT Bunion Systems are not trauma products and even though neither TMT Bunion Systems nor other foot and ankle products have traditionally been included in bundled service line agreements at all, let alone within the trauma service line. For example, Stryker has included Instrumented TMT Bunion Systems in its "trauma" bundles at least at Ascension Health, Cleveland Clinic, Intermountain Health Care, and Lovelace Health System.

188. In other words, under these agreements every dollar spent on a non-Stryker TMT Bunion System, including the Lapiplasty® System, counts against the remaining 10%–20% *of trauma products* and potentially endangers the bundled discount for the entire trauma service line.

189. Stryker's anti-competitive bundling tactics have turned traditional hospital purchasing practices on their head, with Treace Medical being asked to compete with Stryker to bid on a trauma bundle in which Treace Medical does not have any products. On information and belief, these requests are due to Stryker presenting IDN purchasing departments with product bundles that include multiple unrelated product lines, including both the trauma service line and TMT Bunion Systems.

190. A large portion of the candidates for TMT Bunion Procedures are older and insured through Medicare. In many or most instances, Medicare does not reimburse bunion procedures through independent ASCs, with the result that the Medicare patient population is uniquely exposed to reduced quality of care, price distortions, and reduced output created by Stryker's anticompetitive tactics.

191. Not only are the Stryker TMT Bunion Systems inferior to Treace Medical's Lapiplasty® System and Procedure, but Stryker also fails to provide surgeons with comprehensive training and supporting medical resources such as those provided by Treace Medical. In part, this is based on Stryker free riding on surgeon training provided by Treace Medical when hospital administrative staff force Lapiplasty® trained surgeons to use the Stryker TMT Bunion Systems. Stryker also fails to provide its sales representatives, who typically cover a wide range of foot and ankle products, with the types of detailed training and information about Instrumented TMT Bunion Procedures given to Treace Medical representatives. In short, when administrators at healthcare facilities under contract with Stryker force their surgeons to use a Stryker TMT Bunion System instead of the surgeon's preferred choice of Treace Medical's Lapiplasty® System, those administrators are forcing surgeons to operate on patients with an inferior product supported by inferior training and resources.

192. On information and belief, Stryker's trauma service line agreements typically have an initial term of 3 to 5 years and can be extended for additional years. As a practical matter, these agreements often end up being extended multiple times. On information and belief, Stryker uses each new proposal, renewal, or extension to add TMT Bunion Systems within the bundled products comprising the trauma service line.

193. The above are just some examples of Stryker's anticompetitive bundling of TMT Bunion Systems within its trauma service line and its enforcement of those agreements, resulting in the coerced use of its inferior and more costly (when hidden costs or trauma rebates are considered) Stryker TMT Bunion Systems to the exclusion of competitive products, including the Lapiplasty® System. On information and belief, Stryker's agreements with IDNs, including but not limited to its trauma service line agreements, have confidentiality provisions that prevent the IDN or any of its employees from discussing Stryker's contracting and enforcement practices with third parties. That confidentiality shields from scrutiny many aspects of Stryker's bundling and rebate practices, including the terms of the bundled service line agreements, negotiations regarding those agreements, Stryker's means of including TMT Bunion Systems in the bundled service line agreements, and other related subject matter. Treace Medical has been told by IDN employees that non-disclosure agreements with Stryker prevent them from discussing the reasoning and rationale for declining to contract with Treace Medical or otherwise not allowing surgeons to use the Lapiplasty® System. Accordingly, on information and belief, and consistent with the displacement of the Lapiplasty® System by inferior Stryker TMT Bunion Systems where Stryker has trauma service line agreements, Stryker's anticompetitive practices are far more widespread than the specific instances described in the preceding paragraphs.

194. Surgeons and IDN administrative staff who have been willing to discuss the decision-making process and rationale have almost universally confirmed that bundling in the trauma service line was the primary basis for being forced away from permitting surgeons to use the Lapiplasty® System:

- One surgeon who performed 27 Lapiplasty® Procedures in the prior year was forced to switch to the LapiFuse™ System when their hospital system switched to a Stryker trauma service line bundle including the Stryker TMT Bunion Systems. Since the hospital system forced the LapiFuse™ System on the surgeon, he has performed no Lapiplasty® Procedures.

- A prominent surgeon in a prominent system has been aggressively hounded by IDN administration to use the LapiFuse™ System instead of the Lapiplasty® System, because the LapiFuse™ System is included in their trauma contract. They have been told to use the LapiFuse™ System despite not receiving any training on that system and despite repeated responses to hospital administration explaining the differentiated results of the Lapiplasty® System versus the LapiFuse™ System.

- A prominent surgeon and leader of a prominent foot and ankle organization scheduled a Lapiplasty® Procedure well ahead of time. On the morning of the surgery after the patient arrived, the surgeon was told he could not use the Lapiplasty® System and was forced to use the LapiFuse™ System, without any consultation regarding relative efficacy for the patient. The LapiFuse™ System was under a Stryker trauma contract.

- A large surgery group of 8-10 surgeons that had used the Lapiplasty® System for years was told they would no longer be allowed to use the Lapiplasty® System due to the IDN's trauma contract with Stryker.

195. In sum, Stryker has engaged in predatory, anticompetitive conduct by structuring its bundling and associated rebate program so that IDNs are effectively coerced by the structure of the Stryker trauma service line rebate programs to buy all TMT Bunion Systems from Stryker as well. If these IDNs do not comply, they are directly penalized by Stryker for purchasing a rival's products.

196. Stryker has engaged in tying and/or full line forcing, in that it has linked TMT Bunion Systems with other products in which it is dominant including its bundled trauma service line. More specifically, Stryker contracts with IDNs for the trauma service line are made

contingent on the IDNs agreeing to accept the non-trauma Instrumented TMT Bunion Systems as part of that service line. This practice enables Stryker to condition the availability and amount of discounts/rebates for the entirety of the trauma service line on the IDN's purchase of the Stryker TMT Bunion Systems. This tying arrangement forces customers to forego purchasing the Lapiplasty® System from Treace Medical or TMT Bunion Systems from other competitors.

197. Stryker has engaged in *de facto* tying by structuring its bundled service line rebates so as to effectively tie the trauma service line in which it is dominant to the IDN's purchase of Stryker TMT Bunion Systems, with the result that IDNs are induced to purchase all, substantially all, or significantly more of the Stryker TMT Bunion Systems and are penalized for purchasing the Lapiplasty® System or any other competitive systems.

198. Stryker has engaged in unlawful exclusive dealing and *de facto* exclusive dealing by conditioning its trauma service line rebates on an IDN's agreement to include Instrumented TMT Bunion Systems in its trauma bundles. Stryker's rebate program coerces the IDN's individual facilities to purchase all, substantially all, or significantly more of the Stryker TMT Bunion Systems and penalizes IDNs purchasing the Lapiplasty® System or other competitive systems.

199. In sum, Stryker has unlawfully leveraged its dominant position in the trauma service line, through its bundled service line agreements and its associated rebate programs, in a manner designed to coerce IDN customers to purchase all, substantially all, or significantly more of the Stryker TMT Bunion Systems and to penalize IDNs purchasing the Lapiplasty® System or other competitive systems, allowing Stryker to secure increasing market power in TMT Bunion Systems.

200. If Stryker is able to continue driving Treace Medical out of IDNs where surgeons have been using the Lapiplasty® System and Procedure, and preventing Treace Medical and other Stryker competitors from competing to sell their products within other IDNs, it will further foreclose a substantial portion of the TMT Bunion Market from competition on the merits.

201. The total exclusionary discount on the Stryker trauma service line significantly impacts an IDN's financial performance because of the high volume and total cost of the products within the trauma service line. Because Stryker has deliberately and intentionally structured its trauma service line agreements to include the non-trauma Stryker TMT Bunion Systems, IDNs can only obtain Stryker's proffered discount if they also purchase the Stryker TMT Bunion Systems. Competitors such as Treace Medical cannot offer a low enough price to offset the entire total bundled rebate and cannot profitably offer TMT Bunion Systems when competing with the trauma bundle because the total rebate on the trauma bundle far exceeds any reduction in price that could be available from an equally efficient Stryker competitor in TMT Bunion Systems.

202. On information and belief, Stryker is selling the Stryker TMT Bunion Systems below cost after allocating Stryker's rebate on the trauma bundle to sales of the Stryker TMT Bunion Systems. This is confirmed by surgeons who have not been permitted to purchase Instrumented TMT Bunion Systems from Treace Medical—a more efficient competitor with a superior product—because those sales are tied to rebates for trauma products. IDN purchasing departments have rejected offers by Treace Medical to sell the Lapiplasty® System at substantial discounts because Stryker has forced TMT Bunion Systems into the trauma bundle and tied them to the associated rebate program.

203. Stryker's trauma bundling practices exclude equally and more efficient competitors within the TMT Bunion Market, including Treace Medical. Stryker's bundling forecloses

competition on both price and product quality. Patients receive treatment with clinically inferior devices, while surgeons lose their ability to use the TMT Bunion Systems of their choice to offer patients the best possible surgical outcomes. Health insurers pay the same reimbursement rates without regard to the quality of the TMT Bunion System and results of the procedure, and will pay more over time when considering the additional costs of revision surgeries and costs associated with a suboptimal outcomes resulting from use of an inferior Stryker TMT Bunion System.

204. Stryker's trauma bundle creates a powerful disincentive for IDNs to buy TMT Bunion Systems from Stryker rivals, including Treace Medical, for reasons that have nothing to do with the relative merits of the competing products. IDNs who have committed to Stryker's trauma bundles would have difficulty terminating Stryker's bundled agreements as a practical matter. Competitors in trauma bundles such as DePuy Synthes, Smith & Nephew, and Zimmer have little ability to discipline Stryker's bundling practices, as evidenced by their limited market share of direct IDN bundled service line contracts for trauma bundles. By effectively forcing competitors, such as Treace Medical, out of and/or denying them access to IDNs through its bundled trauma agreements, Stryker can foreclose competition in a substantial and profitable portion of the market for TMT Bunion Systems. Such a situation poses a substantial long-term risk that Stryker can continue to sell the Stryker TMT Bunion Systems at supracompetitive levels in view of product quality and full system costs, with these true costs further concealed via bundled pricing.

205. Treace Medical and other competitors simply cannot match the total amount of the trauma rebate that Stryker attaches to the purchase of TMT Bunion Systems. On information and belief, for many IDNs the amount of the trauma rebate is greater than total TMT Bunion System sales.

206. The "true" pricing of the Stryker TMT Bunion Systems is demonstrated in portions of the market where Stryker is unable to leverage its trauma bundle, such as independent ASCs. ASCs typically specialize, and thus do not purchase a trauma bundle that Stryker can leverage. Thus, independent ASCs provide an example of competition on the merits, without Stryker's bundling practices.

207. This example of competition on the merits demonstrates that Treace Medical wins on cost and product quality in the absence of Stryker's anticompetitive tactics. ASCs generally receive lower reimbursement rates from insurers than hospitals and ASCs within IDNs, and thus have greater cost constraints. Yet, Treace Medical's Lapiplasty® System has a greater market share within these cost-constrained ASCs, while the Stryker TMT Bunion Systems have minimal market share.

208. Stryker's trauma bundling practices, in combination with Stryker's other anticompetitive conduct as described herein, have allowed Stryker to foreclose a large percentage of the overall TMT Bunion Market to competitors. Stryker's conduct forecloses competition, denies IDNs the choice of, and access to, better and more cost-effective surgical devices, and harms consumers in the form of ultimately higher prices and lower quality surgical devices.

ii. False and Misleading Conduct with Surgeons and Hospitals

209. To further its anti-competitive practices, and on information and belief, Stryker provides false and misleading information to surgeons and IDN staff in support of its trauma bundling scheme, which includes false or misleading claims about the clinical efficacy and cost of the Stryker TMT Bunion Systems.

210. On information and belief, Stryker misrepresents its products and pricing, creating false comparisons with the Lapiplasty® System pricing. On information and belief, when providing pricing of the Stryker TMT Bunion Systems to IDNs for consideration, Stryker quotes

a subset of components that often lack required implants, instruments, K-wires, drill bits, and other components for a complete Instrumented TMT Bunion Procedure. This pricing is then leveraged to offer an artificially "lower" price as part of its trauma bundles.

211. On information and belief, Stryker falsely or misleadingly represents that this quoted package of components is comparable to the Lapiplasty® System's full sterile kit and access to the instrument tray, which collectively include all of the necessary components for a surgery, including all implants. Under Stryker's "a la carte" model, actual procedures often require substantial additional payment for additional implants, K-wires, drill bits, and other components. In addition, in its advertisements and literature, Stryker largely fails to acknowledge or discuss the need for and pricing of cut guides associated with the Stryker TMT Bunion Systems. As a result of Stryker providing misleading and incomplete pricing information, and falsely comparing this pricing to the Lapiplasty® System pricing, IDN staff are left making uninformed decisions when Stryker includes the Stryker TMT Bunion Systems in its trauma bundles.

212. On information and belief, Stryker misrepresents the quality and function of the Stryker TMT Bunion Systems to IDN administrative staff as being "equivalent to," "the same as," or "as clinically effective as" the Lapiplasty® System. There is minimal clinical evidence to support these false, misleading, and potentially dangerous statements. On information and belief, numerous IDN purchasing departments have refused to consider Treace Medical products requested by their surgeons based on Stryker's false and misleading statements that there is no clinical differentiation between Stryker TMT Bunion Systems and the Lapiplasty® System. On information and belief, surgeons who were previously using the Lapiplasty® System were forced by hospital administrative staff to switch to Stryker TMT Bunion Systems based on hospital administrative staff's directives—informed by Stryker's false and misleading statements—that the

Stryker TMT Bunion Systems are as clinically effective as and interchangeable with Treace Medical's Lapiplasty® System. In this manner, these false statements are used by Stryker to support the improper inclusion of TMT Bunion Systems in its trauma bundles.

213. In its public-facing materials and in printed materials provided directly to hospital purchasing staff, Stryker usually avoids comparing the Stryker TMT Bunion Systems to the Lapiplasty® System. This is not surprising given that Stryker lacks clinical support for any comparative claims inconsistent with the at least 24 clinical studies that support the efficacy of the Lapiplasty® System and Procedure. For example, Stryker's reimbursement guides to hospitals do not include appropriate diagnosis codes for the actual medical condition, hallux valgus, that is corrected by a properly performed TMT bunion correction procedure. Rather, Stryker refers to the Stryker TMT Bunion Systems as products that merely perform "stabilization," "fixation," and "joint fusion."

214. Stryker's anti-competitive acts also include misleading and inaccurate public advertisements about the Stryker TMT Bunion Systems and the Lapiplasty® System. For example, during the AOFAS annual meeting held September 11-14, 2024, Stryker posted the following to LinkedIn to promote "the PROstep MIS portfolio":

215. The above advertisement asks surgeons to "[d]iscover how minimally invasive bunion surgery stacks up against Lapiplasty and explore the PROstep MIS portfolio by visiting Stryker booth #601 at AOFAS 2024." This statement is misleading as it is unclear whether Stryker is referring to Treace Medical's Lapiplasty® Systems or is improperly using the word "Lapiplasty" as referring to a type of procedure. This statement is false in that it implies that Lapiplasty® Systems do not include "minimally invasive bunion surgery" options, when in fact Lapiplasty® Mini-Incision™ has been on the market since 2021 and Lapiplasty® Micro-Incision™ has been on the market since 2023.

216. The above advertisement also asks viewers to "[c]lick here to see a summary of the study results: https://lnkd.in/eDYsmCeu." That summary, available at https://view.stryker.com/viewer/923d4c1119a4cddb12e19cbd287ffdc1, is barely over a page long and

provides results for a study conducted "at a single center between February 2020 – February 2022." Although Stryker's PROstep® MIS Lapidus System was not even launched until September 2023, its advertisement falsely implies that the study applies to the entire "PROstep MIS portfolio." Indeed, the QR code at the end of the summary links to PROstep MIS Lapidus products that had not launched at the time of the "study":

217. And the study summary itself is transparently misleading for additional reasons. The title of the study summary falsely implies that the study relates to all minimally invasive bunion surgeries—"Is Minimally Invasive Bunion Surgery Right For Your Practice" and "A Comparison… versus Minimally Invasive Techniques"—when in fact the only minimally invasive procedure addressed is cut-and-shift distal osteotomy. As is depicted in the upper right hand corner and described in the first paragraph of the summary, the procedures compared in the study were (1) cut-and-shift distal osteotomies (called "MISDTO" in the study); with (2) a vague reference to a "Lapiplasty® (modified Lapidus procedure, MLP)":

stryker

Case study: Is Minimally Invasive Bunion Surgery Right for Your Practice?

Summary: A Comparison of Post-Operative Patient Reported Outcome Measurements Following Bunion Surgery: Modified Lapidus Procedure versus Minimally Invasive Techniques

Madeline Bhend, BSc (Med), BS; Chase Gauthier, MD; Tyler Gonzalez, MD; J. Benjamin Jackson, MD, MBA

Study purpose

Minimally invasive surgery distal transverse osteotomy (MISDTO) and Lapiplasty® (modified Lapidus procedure, MLP) are surgical options for the treatment of hallux valgus. The purpose of this study was to compare postoperative outcomes, time to weight bear, and patient reported outcomes using the Patient Reported Outcome Instrumentation System (PROMIS) between the two surgical procedures.

Key highlights

- **MIS technique resulted in non-union rate of 2.6%** (compared to 13.6%for MLP procedure).
- **MIS technique resulted in no hardware failures** (compared to

218. Accordingly, from the summary it is clear that the study does not apply to the entire "PROstep MIS portfolio" or to "Minimally Invasive Bunion Surgery" and "Minimally Invasive Techniques" generally as Stryker states, but instead only to distal osteotomies, *i.e.*, not at the TMT joint. More importantly, the study fails to acknowledge that, particularly since Treace Medical's introduction of the Lapiplasty® System, surgeons do not consider the cut-and-shift distal osteotomies available in 2020–2022 adequate to treat moderate or severe bunion conditions. Accordingly, any differences in mobility, recovery, non-union rate, or time to weight bearing are most likely due to the underlying severity of the condition treated, not the system used to perform the surgery.

219. Finally, although the study summary refers to Lapiplasty® including the "®" symbol, a number of the purported "Lapiplasty®" procedures considered in the study were not Lapiplasty® Procedures at all and did not use the Lapiplasty® System, and instead were performed using other Lapidus systems and procedures. Stryker is thus improperly using Treace Medical's

"Lapiplasty®" trademark to falsely state that its study presents a direct comparison with Treace Medical's Lapiplasty® System and Procedure.

220. In sum, this public Stryker advertisement evidences the false narrative that, on information and belief, Stryker has employed with IDN staff to make incorrect and false comparisons with "Lapiplasty®," in support of bundling with unrelated trauma products.

iii. Stryker's Lack of Business Justification

221. Stryker lacks legitimate business justification for the above-identified anticompetitive practices, each of which is improper, and through which Stryker has unlawfully restrained competition and foreclosed a substantial portion of competition in the market for TMT Bunion Systems. Stryker could accomplish any legitimate business purposes it might have by less restrictive means, such as providing pricing discounts or other price-based incentives based on IDN purchasing of TMT Bunion Systems without inclusion in the trauma service line bundle.

J. Damage to Competition and Purchasers

222. Stryker's actions have damaged the market for TMT Bunion Systems by foreclosing a substantial portion of that market from competition, resulting in pricing distortions, reduced product quality, and damage to the competitive process. Stryker's acts create the danger of converting a growing and competitive market into a stagnant market in which normal competitive forces are unable to operate. Stryker's acts have diminished individual rivals' competitiveness by preventing competitors from obtaining economies of scale that could reduce prices, imposing barriers to entry for competitors, and reducing competitors' ability to discipline Stryker's anticompetitive behavior.

i. Supracompetitive Pricing

223. Stryker's anticompetitive conduct has resulted in supracompetitive prices, both when viewed through the lens of attribution of the annual value of Stryker's trauma rebates to the

Stryker TMT Bunion Systems as well Stryker's actual pricing for the Stryker TMT Bunion Systems. As discussed above, the Stryker TMT Bunion Systems are of a lower quality, and Stryker also misleads IDNs and surgeons about the actual pricing for its products. So not only are Stryker TMT Bunion Systems overpriced as "advertised" in view of their quality and effectiveness, but those prices are often only a portion of the total price for a particular procedure. If competitors such as Treace Medical were able to compete with Stryker on the merits of price and quality of TMT Bunion Systems, Stryker's pricing for the Stryker TMT Bunion Systems would be reduced. Rather than IDNs being restricted to the Stryker TMT Bunion Systems, competitors could compete on both price and product features, resulting in improved financial outcomes for healthcare facilities and improved patient outcomes.

ii. Inferior Results and Efficacy for Patients

224. Stryker's anticompetitive conduct has resulted in fewer product choices for surgeons and patients being forced to use inferior products with inferior support. Based on Stryker's dealings with IDN administration, surgeons are foreclosed from using the Lapiplasty® System that is superior to the Stryker TMT Systems. Stryker fails to provide equivalent training to surgeons and its sales representatives lack specialized training. In comparison to Stryker's lack of supporting clinical studies for the Stryker TMT Systems, through its years of work, Treace Medical has 24 clinical studies or papers specifically discussing the proven efficacy of the Lapiplasty® System and Procedure and improved patient outcomes.

225. Stryker's anticompetitive conduct has discouraged or has the potential to discourage competitors from improving and investing in their TMT Bunion Systems. With competitors increasingly left to compete in only a limited corner of the market left to them by Stryker, such as ambulatory surgery centers not within an IDN, Stryker has successfully starved companies of product sales income to fund future product innovation and investment.

226. Thus far, based on its role as the industry trailblazer and initial traction before Stryker's anticompetitive acts, Treace Medical has continued its investments and can cost-effectively meet increased demand for its products. But for Stryker's anticompetitive conduct, Treace Medical certainly could have sold more Lapiplasty® Systems. However, if Stryker is allowed to continue its anticompetitive conduct, Treace Medical will also be forced to reduce its investments in product improvements, education, and training over time.

227. As a result, hospital purchasers, the surgeons who operate at those hospitals, and the patients who get undifferentiated care have suffered from a lack of choice, inferior product designs, and limited product innovations and improvements. TMT Bunion Systems are predicted to eventually represent a more than $600 million market annually. Freed of Stryker's anticompetitive conduct, there would be ample market opportunity to support continued and ongoing product improvements and innovations by competitors in this market.

iii. Foreclosure of Competitors—Damage to Competitive Process

228. Stryker has engaged in anticompetitive acts that substantially foreclose competition in the market for TMT Bunion Systems, preventing IDN customers from having choices regarding available, better medical devices and healthcare solutions. By engaging in such anticompetitive conduct, Stryker forecloses competitors from reaching IDN purchasers with their offerings for Instrumented TMT Bunion Systems.

229. Stryker has leveraged its dominant position in the trauma service line to foreclose a substantial portion of the TMT Bunion Market. With each new agreement or renewal as its prior contracts come due for renewal, this market foreclosure grows as Stryker continues to make it impossible for TMT Bunion System competitors such as Treace Medical to compete on the merits within a substantial portion of the relevant market. Treace Medical has seen this repeatedly as it is forced out of or sees its cases diminished in hospitals and surgical centers where it previously

had a relationship and has faced ever-increasing roadblocks in breaking in with new IDN customers that would otherwise have been strong, primary customers.

230. This can be compared to the less than 50% of the market where TMT bunion surgeries are performed outside of IDNs, and thus Stryker has to compete on the merits of price and product rather than by bundling and rebate programs with its trauma service line. In this portion of the market, Treace Medical and other competitors have a much larger share of the market while Stryker's market share is significantly lower than its market share within IDNs.

231. In fact, reimbursements for TMT Bunion Procedures are less at these independent ASCs than in hospitals, and thus ASCs are more price sensitive than hospitals. Thus, the Lapiplasty® System wins over the Stryker TMT Bunion Systems where quality and pricing are most critical to purchasing decisions, further demonstrating that Stryker's actual product quality and cost are not the reason for its market share for IDN purchases of TMT Bunion Systems.

232. Treace Medical has been stymied by Stryker's anticompetitive conduct at numerous hospitals nationwide. The following are some examples of the many customers who told Treace Medical that they could not purchase the Lapiplasty® System or had their purchases limited because of Stryker trauma contracts: Ascension Health, Cleveland Clinic, Intermountain Health Care, and Lovelace Health System.

iv. Lack of Pro-Competitive Benefits

233. Stryker's conduct has no pro-competitive benefit or legitimate business purpose. Stryker's conduct does not improve its operating efficiency or deliver reduced costs or efficiencies to hospitals. Nor does Stryker's conduct improve patient safety or choice, reduce costs to patients, or otherwise provide any additional benefits to consumers. Stryker's conduct does not increase product quality, has not resulted in lower prices, and increases long term costs to patients and insurers through revision surgeries and other costs from sub-optimal surgical outcomes. Stryker's

pricing is misleading and is tied to the much larger trauma rebate. Accordingly, Stryker's effective pricing for the Stryker TMT Bunion Systems is well beyond competitive levels.

K. Antitrust Injury and Standing

234. Treace Medical has suffered losses as a direct consequence of the anticompetitive aspects of Stryker's conduct. Stryker has substantially foreclosed competition through its anticompetitive conduct as discussed above.

235. Stryker holds a dominant position in the market for the trauma service line and has used that position and anticompetitive business practices to foreclose competition in a substantial portion of the TMT Bunion Market. As a result, Treace Medical and other competitors in the TMT Bunion Market are being seriously impeded in competing on the merits of product and price in the largest portion of the TMT Bunion Market. Treace Medical's injuries are of the type the antitrust laws were intended to prevent and flow from that which makes Stryker's acts unlawful because Treace Medical is a direct competitor in the relevant market for TMT Bunion Systems. Stryker has prevented Treace Medical and other competitors from competing on an even playing field for TMT Bunion Systems within IDNs, effectively barring a substantial portion of surgeons and patients from having access to Treace Medical's superior and more cost-effective Lapiplasty® Systems.

236. As discussed above, many hospitals and surgeons have informed Treace Medical that they could not purchase the Lapiplasty® System because of trauma service line contracts with Stryker. Stryker's anticompetitive conduct forecloses a substantial portion of the TMT Bunion Market and prevents many surgeons from even considering Treace Medical's products and prevents patients from receiving the treatment they want.

237. Stryker's anticompetitive behavior has caused Treace Medical to lose profits from the sale of the Lapiplasty® System within IDNs. Stryker has damaged Treace Medical's goodwill

by making false and misleading claims of equivalency between the Lapiplasty® Systems and the Stryker TMT Bunion Systems, creating a false impression to IDN administrative staff and surgical staff that TMT Bunion Systems are commodity products, causing substantial reputational damage and loss of goodwill to Treace Medical.

238. All of Treace Medical's above-described losses are antitrust injuries—*i.e.*, losses proximately caused by the anticompetitive aspects and character of Stryker's unlawful conduct. The full extent of Treace Medical's losses will be demonstrated at trial.

239. Treace Medical has antitrust standing to bring the present claims for numerous reasons. As alleged above, Treace Medical has suffered antitrust injury. Treace Medical is a seller of TMT Bunion Systems and has lost profits on sales of its Lapiplasty® System. Moreover, Treace Medical has engaged and continues to engage in massive and trailblazing efforts to educate healthcare providers and patients of the substantial benefits of its Lapiplasty® Systems over alternatives. Treace Medical has and will continue to incur substantial losses as a direct result of Stryker's continuing anticompetitive practices as outlined herein. For their part, surgeons and patients are deprived of better, more cost-effective products as a result of the injuries to Treace Medical and to competition generally in the TMT Bunion Market.

240. Treace Medical is just the sort of disruptive competitor company that the antitrust laws were intended to protect. Treace Medical invented Instrumented TMT Bunion Procedures and invested over $150 million developing its products and educating surgeons, healthcare providers, and patients on the benefits of its Lapiplasty® System. Treace Medical effectively created a new standard of care that has already changed over a hundred thousand lives with long-term, cost-effective solutions compared to the prior painful and inconsistent standard of care with high long-term bunion recurrence rates (up to 78%) and low patient satisfaction. Stryker identified

and targeted Treace Medical as a disruptive competitor whose superior, cost-effective, and differentiated Lapiplasty® Systems and technology lead could prevent Stryker from winning customers on the merits in a new, fast-growing market. Stryker thus targeted its anticompetitive conduct specifically at Treace Medical as described herein. Allowing Stryker to succeed in using anticompetitive tactics to foreclose a substantial portion of the market from competition on the merits will discourage investment in differentiated medical device companies in the future, resulting in many life-changing medical devices never being developed in the first instance.

241. Treace Medical is well suited to promote the public policies underlying the antitrust laws. If Treace Medical is successful in stopping Stryker from unlawfully bundling TMT Bunion Systems with the trauma service line, Treace Medical will be able to compete on the merits of product, price, and intellectual property protection. Benefits will also flow to other innovative medical companies that lack comprehensive product lines, as suppliers with dominant positions in one service line will at least understand that there are substantial antitrust risks in exclusionary bundling with other unrelated product types. In fact, this has long been the understanding of GPOs and Stryker competitors such as Johnson & Johnson. Failing to put a stop to Stryker's anticompetitive conduct may encourage others to mimic its tactics to the detriment of product quality, competition, and prices, while the result of enforcement of these long-standing rules against Stryker will be a more competitive market for medical devices with more innovation and more cost-effective treatment.

242. Treace Medical is the most direct victim of Stryker's anticompetitive conduct. Treace Medical has developed the most sophisticated products, operations base, and supply chain in the TMT Bunion Market and has the greatest ability to deliver constant product innovations in

the most cost-effective manner. Treace Medical is uniquely positioned to deliver the most technically advanced bunion products at ever-decreasing price points.

243. Treace Medical is uniquely situated to raise and address Stryker's anticompetitive conduct and its anticompetitive effects. Treace Medical likely knows more about Stryker's anticompetitive practices than any other entity, as it has been "boots on the ground" since the Wright acquisition and launch of the LapiFuse™ System, and has witnessed first-hand the development and ever increasing usage of Stryker's anticompetitive bundling practices when it could not compete on the merits. As the company that invented and created Instrumented TMT Bunion Systems and the market for these systems, Treace Medical is uniquely motivated and interested in bringing a stop to these anticompetitive practices that also impact other competitors in the TMT Bunion Market, and likely in other medical device markets.

244. There is no significant risk of duplicative recovery or complex apportionment from allowing Treace Medical to bring these claims. Treace Medical's losses directly flow from the anticompetitive conduct that Treace Medical now challenges. There is no risk of an improper allocation of these losses among various claimants, nor any risk that Stryker will be ordered to pay the same damages twice if it is ordered to compensate Treace Medical for Treace Medical's antitrust injuries. This case does not involve other parties or "downstream" actors that would be competing for the same pool of profits garnered by Stryker's anticompetitive acts. Treace Medical's losses are not speculative, remote, or tenuously connected to Stryker's antitrust misconduct. In addition, Stryker's anticompetitive misconduct has directly and significantly harmed Treace Medical in the manner pleaded above and in the very market in which Stryker has committed its anticompetitive acts. Treace Medical therefore has antitrust standing to assert its present antitrust challenge against Stryker.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 9,622,805 BY LAPIFUSE™ SYSTEM
(Against Stryker Corp. and Wright Medical Tech., Inc.)

245. Treace Medical incorporates by reference Paragraphs 1-244 of this Complaint.

246. On April 18, 2017, the USPTO issued U.S. Patent Number 9,622,805 B2 ("**the '805 Patent**") to Treace Medical, listing inventors Robert D. Santrock, Paul Dayton, Daniel J. Hatch, W. Bret Smith, F. Barry Bays, Carlos Eduardo Gil, Sean F. Scanlan, Joe William Ferguson, and John T. Treace. The '805 Patent is titled "Bone Positioning and Preparing Guide Systems and Methods" and is directed to "[a] method of correcting a bunion deformity." A true and correct copy of the '805 Patent is attached to this Complaint as **Exhibit 3**. The '805 Patent remains in force and is assigned to Treace Medical. Treace Medical has owned the '805 Patent since it was issued and still owns the '805 Patent.

247. The '805 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

248. Stryker and Wright have made, used, offered for sale, sold, and/or imported into the United States medical instruments and implants used in performing bunion surgery. These medical instruments and implants are offered by Stryker and Wright for the use of the ORTHOLOC™ 2 LapiFuse™ Triplanar Correction System. The LapiFuse™ instruments and implants are identified in Stryker's and Wright's LapiFuse Video and LapiFuse Brochure, as detailed above.

249. Attached to this Complaint as **Exhibit 4** is a claim chart explaining how Stryker and Wright describe through the LapiFuse Video and LapiFuse Brochure the performance of the steps of exemplary claim 9 of the '805 Patent using the LapiFuse™ System and thereby instruct and encourage surgeons to perform the method of claim 9 and other claims of the '805 Patent ("**the '805 Claimed Method**"). On information and belief, Stryker and Wright continue to instruct and

encourage surgeons to perform the ’805 Claimed Method. On information and belief, Stryker and Wright have not instructed surgeons to perform the LapiFuse™ Procedure using the LapiFuse™ System in a non-infringing manner. The LapiFuse™ System has no substantial non-infringing uses.

Direct Infringement of the ’805 Patent

250. On information and belief, Stryker and Wright have directly infringed and continue to directly infringe, both literally and/or under the doctrine of equivalents, the ’805 Patent by using (*e.g.*, by performing actual or simulated surgical procedures) the LapiFuse™ System to perform the patented surgical method of the ’805 Patent in the United States in violation of 35 U.S.C. § 271(a), including within this judicial district, in a manner that infringes at least claim 9 of the ’805 Patent without a license from Treace Medical.

251. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the LapiFuse Video and LapiFuse Brochure using the LapiFuse™ System directly infringe the ’805 Patent.

252. On information and belief, surgeon consultants to Stryker and Wright, working at Stryker’s or Wright’s direction, tested and performed the ’805 Claimed Method using the LapiFuse™ System on Stryker’s and Wright’s behalf as part of developing the LapiFuse™ System and Procedure at least before the LapiFuse™ System was first offered for sale and sold in the United States.

253. In addition, surgeon consultants to Stryker and Wright, working at Stryker’s or Wright’s direction, perform the ’805 Claimed Method using the LapiFuse™ System as part of surgeon education both before and after the LapiFuse™ System was offered for sale and sold in the United States.

254. Stryker and Wright have created at least the LapiFuse Video and LapiFuse Brochure showing the LapiFuse™ System being used to perform the LapiFuse™ Procedure and thereby performing the ’805 Claimed Method. On information and belief, surgeons working on Stryker’s or Wright’s behalf and at Stryker’s or Wright’s direction, performed the ’805 Claimed Method using the LapiFuse™ System in connection with creating the LapiFuse Brochure, which demonstrates performance of the ’805 Claimed Method using the LapiFuse™ System.

255. Stryker and Wright also direct and/or control surgeons to perform the ’805 Claimed Method using the LapiFuse™ System because, among other things, Stryker and Wright condition receipt of benefits to surgeons on their performance of one or more steps of the ’805 Claimed Method, and establish that performance by, among other things, providing detailed instructions concerning the assembly of the LapiFuse™ System that, if not followed, will deprive the surgeons of the benefits they hope to obtain from the LapiFuse™ System and performing one or more steps of the ’805 Claimed Method. For example, Stryker and Wright advertise surgeons on their websites who, on information and belief, use the LapiFuse™ System as Stryker and Wright instruct in the LapiFuse Video and LapiFuse Brochure to perform the ’805 Claimed Method. On information and belief, the Stryker and/or Wright representative present in the operating room for each LapiFuse™ Procedure monitors and directs the surgeon and will only provide the surgeon components of the LapiFuse™ System if the surgeon performs one or more steps of the ’805 Claimed Method.

Induced Infringement of the ’805 Patent

256. On information and belief, Stryker and Wright have induced and continue to induce infringement of the ’805 Claimed Method in violation of 35 U.S.C. § 271(b).

257. Stryker and Wright have provided materials to hospitals and surgeons that demonstrate using the LapiFuse™ System to perform the ’805 Claimed Method. For example, the

LapiFuse Video and LapiFuse Brochure instruct, encourage, and assist surgeons to use the LapiFuse™ System in a manner that directly infringes the claims of the '805 Patent. On information and belief, Stryker and Wright sales staff, surgical site representatives, consulting surgeons, and public and non-public instructional materials similarly instruct and encourage surgeons to use the LapiFuse™ System in a manner that directly infringes the claims of the '805 Patent as depicted and described above and in Exhibit 4. On information and belief, Stryker and Wright distributed these materials to hospitals and surgeons with the intent to cause surgeons to use the LapiFuse™ System and Procedure to perform the '805 Claimed Method. Stryker and/or Wright representatives present in the operating room for each LapiFuse™ Procedure monitor surgeons' performance of the LapiFuse™ Procedure and, on information and belief, direct them to use the LapiFuse™ System for the LapiFuse™ Procedure to infringe the claims of the '805 Patent.

258. On information and belief, Stryker and Wright have provided such instructions and encouragement despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the '805 Patent and the resulting infringement thereof by surgeons Stryker and Wright so instructed.

259. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The '805 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® System and Procedure heading.

260. Stryker and Wright had knowledge of the '805 Patent at least as of 2019 [redacted] Any contention that Stryker and Wright

did not know that the acts Stryker and Wright actively induced constituted infringement of the '805 Patent would be based on willful blindness. On information and belief, Stryker and Wright were further on notice of Treace Medical's patent rights based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; Treace Medical's substantial publicity regarding its patent portfolio; and the citation of the '805 Patent as prior art to a Wright patent application. At a minimum, Stryker and Wright were on notice that they would need to conduct a right-to-use study that included reviewing Treace Medical's patents before releasing and promoting its LapiFuse™ System and Procedure.

261. On information and belief, Stryker and Wright know that their surgeon customers and surgeon consultants are performing the '805 Claimed Method using the LapiFuse™ System and Procedure and are directly infringing the '805 Claimed Method.

262. Stryker's and Wright's inducing acts, such as distribution of the LapiFuse Video, LapiFuse Brochure, and other instructional materials, to promote and demonstrate the LapiFuse™ System and Procedure, and instructing and encouraging surgeons to use the LapiFuse™ System in a manner consistent with that Procedure described above and in Exhibit 4 caused and are causing surgeons to use the LapiFuse™ System and Procedure in a manner that infringes the '805 Claimed Method.

Contributory Infringement of the '805 Patent

263. On information and belief, Stryker and Wright have contributorily infringed the '805 Claimed Method in violation of 35 U.S.C. § 271(c).

264. Stryker and Wright have made, used, offered for sale, sold, and/or imported into the United States medical instruments and implants used in performing the infringing LapiFuse™ Procedure, including at least the LapiFuse Clamp, tissue removing instruments, and implants.

265. On information and belief, surgeons have performed and are performing the LapiFuse™ Procedure using the LapiFuse™ System as instructed, assisted, and encouraged by Stryker and Wright in at least the LapiFuse Video and LapiFuse Brochure and by Stryker's and Wright's sales staff, surgical site representatives, and surgeon consultants, thereby directly infringing the '805 Claimed Method.

266. On information and belief, Stryker and Wright had actual knowledge of the '805 Patent and Treace Medical's infringement allegations at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint.

267. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because of Treace Medical's virtual marking through its internet website at https://www.treace.com/patents. The '805 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® System and Procedure heading.

268. Stryker and Wright had knowledge of the '805 Patent at least as of 2019 [redacted]. Any contention that Stryker and Wright did not know that the LapiFuse™ System is especially made or especially adapted for use in an infringement of the '805 Patent would be based on willful blindness. On information and belief, Stryker and Wright were further on notice of Treace Medical's patent rights based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS)

where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; Treace Medical's substantial publicity regarding its patent portfolio; and the citation of the '805 Patent as prior art to a Wright patent application. At a minimum, Stryker and Wright were on notice that they would need to conduct a right-to-use study that included reviewing Treace Medical's patents before releasing and promoting its LapiFuse™ System and Procedure.

269. Components of the LapiFuse™ System including at least the LapiFuse Clamp, tissue removing instruments, and implants are material components for use in practicing the '805 Claimed Method. These components are especially made for use in a manner that infringes the '805 Claimed Method. The LapiFuse™ System components are not staple articles or commodities of commerce suitable for substantial non-infringing uses. For example, the only known use of the LapiFuse Clamp is for the infringing uses as described above and in Exhibit 4. Further, the implants (bone plates and screws) include "LapiFuse" or "Ortholoc 3Di" in their product name, and the tissue removing instruments are sold in a "LapiFuse" joint preparation kit.

270. On information and belief, Stryker and Wright have provided materials to hospitals and surgeons, including the LapiFuse Video and LapiFuse Brochure, demonstrating the use of the LapiFuse™ System to perform the '805 Claimed Method. The distribution of these materials further shows that Stryker and Wright especially made the LapiFuse™ System to perform the '805 Claimed Method. Stryker and/or Wright representatives present in the operating room for each LapiFuse™ Procedure monitor surgeons' performance of the LapiFuse™ Procedure and, on information and belief, direct them to use the LapiFuse™ System for the LapiFuse™ Procedure to infringe the claims of the '805 Patent.

271. On information and belief, at a date prior to the filing of this Complaint and at least as of the date of the filing and service of this Complaint, Stryker and Wright have known that the LapiFuse™ System (including the LapiFuse Clamp, tissue removing instruments, and implants) were especially made for use in a manner that infringes the '805 Claimed Method and were directly infringing the '805 Claimed Method.

272. On information and belief, surgeons have in fact used and continue to use the LapiFuse™ System and Procedure in a manner that infringes the '805 Claimed Method.

Willful Infringement of the '805 Patent

273. Stryker and Wright have willfully infringed the '805 Claimed Method.

274. On information and belief, Stryker and Wright have infringed and continue to infringe the '805 Claimed Method with knowledge of Treace Medical's rights in the '805 Patent.

275. On information and belief, Stryker's and Wright's acts of infringement of the '805 Claimed Method have been and continue to be willful, deliberate, and egregious.

276. On information and belief, Stryker and Wright acted despite an objectively high likelihood that their actions constituted infringement of a valid patent claim and knew or should have known of this objectively defined risk of infringement.

Requested Relief for Stryker's and Wright's Infringement of the '805 Patent

277. Stryker's and Wright's misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters a permanent injunction prohibiting Stryker, Wright, and those acting on their behalf from infringing the '805 Patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the LapiFuse™ System for performing the '805 Claimed Method. Stryker's and Wright's misconduct has caused Treace Medical to suffer irreparable injury that is not adequately compensated for by remedies available at law. The balance of hardships

between the parties warrant a remedy in equity and the public interest would not be disserved by a permanent injunction.

278. Treace Medical is entitled to recover damages that would place Treace Medical as close as possible to the same financial position that it would have been in had Stryker's and Wright's infringement of the '805 Patent not occurred. Treace Medical is entitled to recover damages including all profits that it has lost as a result of Stryker's and Wright's sale of the LapiFuse™ System and the products used in the performance of instrumented TMT bunion correction procedures using the LapiFuse™ System. At a minimum, Treace Medical is entitled to a reasonable royalty on Stryker's and Wright's sales of the LapiFuse™ System and products used in the performance and practicing of the patented instrumented TMT bunion correction procedures using the LapiFuse™ System.

279. Treace Medical requests pursuant to 35 U.S.C. § 284 that damages awarded to it in this matter for Stryker's and Wright's willful infringement of the '805 Patent be increased to three times the amount found or assessed by the fact finder.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 10,874,446 BY LAPIFUSE™ SYSTEM
(Against Stryker Corp. and Wright Medical Tech., Inc.)

280. Treace Medical incorporates by reference Paragraphs 1-279 of this Complaint.

281. On December 29, 2020, the USPTO issued U.S. Patent Number 10,874,446 B2 ("**the '446 Patent**") to Treace Medical, listing inventors W. Bret Smith, Paul Dayton, Sean F. Scanlan, F. Barry Bays, Carlos Eduardo Gil, John T. Treace, Robert D. Santrock, Daniel J. Hatch, and Joe W. Ferguson. The '446 Patent is titled "Bone Positioning Guide" and is directed to "[a] bone positioning guide for a bunion correction procedure." A true and correct copy of the '446 Patent is attached to this Complaint as **Exhibit 5**. The '446 Patent remains in force and is assigned

to Treace Medical. Treace Medical has owned the '446 Patent since it was issued and still owns the '446 Patent.

282. The '446 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

283. Stryker and Wright have made, used, offered for sale, sold, and/or imported into the United States the ORTHOLOC™ 2 LapiFuse™ Triplanar Correction System. The LapiFuse™ System is exemplified in Stryker's and Wright's LapiFuse Video and LapiFuse Brochure, as detailed above.

284. Attached to this Complaint as **Exhibit 6** is a claim chart explaining how the LapiFuse™ System meets the elements of exemplary claim 1 of the '446 Patent. The LapiFuse™ System has no substantial non-infringing uses.

Direct Infringement of the '446 Patent

285. On information and belief, Stryker and Wright have directly infringed and continue to directly infringe, both literally and/or under the doctrine of equivalents, the '446 Patent by making, selling, offering for sale, and/or using (*e.g.*, by performing actual or simulated surgical procedures using) the LapiFuse™ System in the United States in violation of 35 U.S.C. § 271(a), including within this judicial district, in a manner that infringes at least claim 1 of the '446 Patent without a license from Treace Medical.

286. Stryker and Wright also direct and/or control surgeons to infringe the '446 Patent with the LapiFuse™ System because, among other things, Stryker and Wright condition receipt of benefits to surgeons on assembly and use of a device that infringes the '446 Patent, and establish that assembly and use by, among other things, providing detailed instructions concerning the assembly and use of the LapiFuse™ System that, if not followed, will deprive the surgeons of the benefits they hope to obtain from the LapiFuse™ System and assembly and use of a device that

infringes the ’446 Patent. For example, Stryker and Wright advertise surgeons on their websites who, on information and belief, assemble the LapiFuse™ System as Stryker and Wright instruct in the LapiFuse Video and LapiFuse Brochure to infringe the ’446 Patent. On information and belief, the Stryker and/or Wright representative present in the operating room for each LapiFuse™ Procedure monitors and directs the surgeon and will only provide the surgeon components of the LapiFuse™ System if the surgeon assembles and uses the LapiFuse™ System as provided by the ’446 Patent.

Induced Infringement of the ’446 Patent

287. On information and belief, Stryker and Wright have induced and continue to induce infringement of the ’446 Patent in violation of 35 U.S.C. § 271(b).

288. The LapiFuse Video and LapiFuse Brochure instruct, encourage, and assist surgeons to use the LapiFuse™ System in a manner that directly infringes the claims of the ’446 Patent. On information and belief, Stryker and Wright sales staff, surgical site representatives, consulting surgeons, and public and non-public instructional materials similarly instruct and encourage surgeons to use the LapiFuse™ System in a manner that directly infringes the claims of the ’446 Patent as depicted and described above and in Exhibit 6. Stryker and/or Wright representatives present in the operating room for each LapiFuse™ Procedure monitor surgeons’ use of the LapiFuse™ System and, on information and belief, direct them to assemble and use the LapiFuse™ System to infringe the claims of the ’446 Patent.

289. On information and belief, Stryker and Wright have provided such instructions and encouragement despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the ’446 Patent and the resulting infringement thereof by surgeons Stryker and Wright so instructed.

290. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The '446 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® Positioner heading.

291. To the extent Stryker and Wright contend that they did not know of the '446 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '446 Patent and that the acts Stryker and Wright actively induced constituted infringement of the '446 Patent. On information and belief, Stryker and Wright at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; Treace Medical's substantial publicity regarding its patent portfolio; and Stryker's and Wright's patent attorneys' citations to patents in the same family as the '446 Patent as prior art to Stryker and Wright patent applications.

292. On information and belief, Stryker and Wright have continued to distribute materials, including the LapiFuse Video and LapiFuse Brochure, to demonstrate the infringing use of the LapiFuse™ System. Continued distribution of these materials further shows that the LapiFuse™ System is especially made to infringe the '446 Patent.

293. On information and belief, Stryker and Wright know that their surgeon customers and surgeon consultants are performing bunion correction procedures using the LapiFuse™ System and are directly infringing the claims of the ’446 Patent.

294. Stryker’s and Wright’s inducing acts, such as distribution of the LapiFuse Video, LapiFuse Brochure, and other instructional materials, to promote and demonstrate the LapiFuse™ System, and instructing and encouraging surgeons to use the LapiFuse™ System in a manner consistent with that Procedure described above and in Exhibit 6, caused and are causing surgeons to use the LapiFuse™ System in a manner that infringes the claims of the ’446 Patent.

Contributory Infringement of the ’446 Patent

295. On information and belief, Stryker and Wright have contributorily infringed the ’446 Patent in violation of 35 U.S.C. § 271(c).

296. Stryker and Wright have offered for sale, sold, and/or imported into the United States medical instruments and implants that are part of the LapiFuse™ System, including at least components of the LapiFuse Clamp. These products are components of the apparatus covered by the ’446 Patent.

297. On information and belief, surgeons are assembling and using the LapiFuse™ System as instructed, assisted, and encouraged by Stryker and Wright in at least the LapiFuse Video and LapiFuse Brochure and by Stryker’s and Wright’s sales staff, surgical site representatives, and surgeon consultants, thereby directly infringing the claims of the ’446 Patent.

298. On information and belief, Stryker and Wright have provided components of a patented apparatus despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the ’446 Patent and the resulting infringement thereof by surgeons Stryker and Wright so instructed.

299. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The '446 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® Positioner heading.

300. To the extent Stryker and Wright contend that they did not know of the '446 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '446 Patent and that the LapiFuse™ System components are especially made or especially adapted for use in an infringement of the '446 Patent. On information and belief, Stryker and Wright at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; Treace Medical's substantial publicity regarding its patent portfolio; and Stryker's and Wright's patent attorneys' citations to patents in the same family as the '446 Patent as prior art to Stryker and Wright patent applications.

301. Components of the LapiFuse™ System, including at least the components of the LapiFuse Clamp, are material components of a patented apparatus claimed in the '446 Patent. These components are especially made for use in a manner that infringes the apparatus claimed in the '446 Patent. The LapiFuse™ System components are not staple articles or commodities of commerce suitable for substantial non-infringing uses. The only known use of the LapiFuse Clamp

is for the infringing uses in the LapiFuse™ System as described above and in Exhibit 6. Further, the implants (bone plates and screws) include "LapiFuse" or "Ortholoc 3Di" in their product name, and the tissue removing instruments are sold in a "LapiFuse" joint preparation kit.

302. On information and belief, Stryker and Wright have provided materials to hospitals and surgeons, including the LapiFuse Video and LapiFuse Brochure, demonstrating the infringing assembly of the LapiFuse™ System. The distribution of these materials further shows that Stryker and Wright especially made the LapiFuse™ System to infringe the '446 Patent. Stryker and/or Wright representatives present in the operating room for each LapiFuse™ Procedure monitor surgeons' use of the LapiFuse™ System and, on information and belief, direct them to assemble and use the LapiFuse™ System to infringe the claims of the '446 Patent with the awareness that the LapiFuse™ System (including components of the LapiFuse Clamp) have no substantial non-infringing uses.

303. On information and belief, at a date prior to the filing of this Complaint and at least as of the date of the filing and service of this Complaint, Stryker and Wright have known that the LapiFuse™ System (including components of the LapiFuse Clamp) were especially made for use in a manner that infringes the '446 Patent and were directly infringing the '446 Patent.

304. On information and belief, surgeons have in fact used and continue to use the LapiFuse™ System, thereby infringing the '446 Patent.

Willful Infringement of the '446 Patent

305. Stryker and Wright have willfully infringed the '446 Patent.

306. On information and belief, Stryker and Wright have infringed and continue to infringe the '446 Patent with knowledge of Treace Medical's rights in the '446 Patent.

307. On information and belief, Stryker's and Wright's acts of infringement of the '446 Patent have been and continue to be willful, deliberate, and egregious.

308. On information and belief, Stryker and Wright acted despite an objectively high likelihood that their actions constituted infringement of a valid patent claim and knew or should have known of this objectively defined risk of infringement.

Requested Relief for Stryker's and Wright's Infringement of the '446 Patent

309. Stryker's and Wright's misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters a permanent injunction prohibiting Stryker, Wright, and those acting on their behalf from infringing the '446 Patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the LapiFuse™ System. Stryker's and Wright's misconduct has caused Treace Medical to suffer irreparable injury that is not adequately compensated for by remedies available at law. The balance of hardships between the parties warrant a remedy in equity and the public interest would not be disserved by a permanent injunction.

310. Treace Medical is entitled to recover damages that would place Treace Medical as close as possible to the same financial position that it would have been in had Stryker's and Wright's infringement of the '446 Patent not occurred. Treace Medical is entitled to recover damages including all profits that it has lost as a result of Stryker's and Wright's promotion and sale of the LapiFuse™ System and component products. At a minimum, Treace Medical is entitled to a reasonable royalty on Stryker's and Wright's promotion and sales of the LapiFuse™ System and component products.

311. Treace Medical requests pursuant to 35 U.S.C. § 284 that damages awarded to it in this matter for Stryker's and Wright's willful infringement of the '446 Patent be increased to three times the amount found or assessed by the fact finder.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 11,039,873 BY LAPIFUSE™ SYSTEM
(Against Stryker Corp. and Wright Medical Tech., Inc.)

312. Treace Medical incorporates by reference Paragraphs 1-311 of this Complaint.

313. On June 22, 2021, the USPTO issued U.S. Patent Number 11,039,873 B2 ("**the '873 Patent**") to Treace Medical, listing inventors Robert D. Santrock, Paul Dayton, Daniel J. Hatch, W. Bret Smith, F. Barry Bays, Carlos Eduardo Gil, Sean F. Scanlan, Joe W. Ferguson, and John T. Treace. The '873 Patent is titled "Bone Positioning and Preparing Guide Systems and Methods" and is directed to "[a] method of correcting a bunion deformity." A true and correct copy of the '873 Patent is attached to this Complaint as **Exhibit 7**. The '873 Patent remains in force and is assigned to Treace Medical. Treace Medical has owned the '873 Patent since it was issued and still owns the '873 Patent.

314. The '873 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

315. Stryker and Wright have made, used, offered for sale, sold, and/or imported into the United States medical instruments and implants used in performing bunion surgery. These medical instruments and implants are offered by Stryker and Wright for the use of the ORTHOLOC™ 2 LapiFuse™ Triplanar Correction System. The LapiFuse instruments and implants are identified in Stryker's and Wright's LapiFuse Video and LapiFuse Brochure, as detailed above.

316. Attached to this Complaint as **Exhibit 8** is a claim chart explaining how Stryker and Wright describe through the LapiFuse Video and LapiFuse Brochure the performance of the steps of exemplary claim 1 of the '873 Patent using the LapiFuse™ System and thereby instruct and encourage surgeons to perform the method of claim 1 and other claims of the '873 Patent ("**the '873 Claimed Method**"). On information and belief, Stryker and Wright continue to instruct and

encourage surgeons to perform the '873 Claimed Method. On information and belief, Stryker and Wright have not instructed surgeons to perform the LapiFuse™ Procedure using the LapiFuse™ System in a non-infringing manner. The LapiFuse™ System has no substantial non-infringing uses.

Direct Infringement of the '873 Patent

317. On information and belief, Stryker and Wright have directly infringed and continue to directly infringe, both literally and/or under the doctrine of equivalents, the '873 Patent by using (*e.g.*, by performing actual or simulated surgical procedures) the LapiFuse™ System to perform the patented surgical method of the '873 Patent in the United States in violation of 35 U.S.C. § 271(a), including within this judicial district, in a manner that infringes at least claim 1 of the '873 Patent without a license from Treace Medical.

318. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the LapiFuse Video and LapiFuse Brochure using the LapiFuse™ System directly infringe the '873 Patent.

319. On information and belief, surgeon consultants to Stryker and Wright, working at Stryker's or Wright's direction, tested and performed the '873 Claimed Method using the LapiFuse™ System on Stryker's and Wright's behalf as part of developing the LapiFuse™ System and Procedure.

320. In addition, surgeon consultants to Stryker and Wright, working at Stryker's or Wright's direction, perform the '873 Claimed Method using the LapiFuse™ System as part of surgeon education.

321. Stryker and Wright have created at least the LapiFuse Video and LapiFuse Brochure showing the LapiFuse™ System being used to perform the LapiFuse™ Procedure and thereby performing the '873 Claimed Method. On information and belief, surgeons working on

Stryker's or Wright's behalf and at Stryker's or Wright's direction, performed the '873 Claimed Method using the LapiFuse™ System in connection with creating the LapiFuse Brochure, which demonstrates performance of the '873 Claimed Method using the LapiFuse™ System.

322. Stryker and Wright also direct and/or control surgeons to perform the '873 Claimed Method using the LapiFuse™ System because, among other things, Stryker and Wright condition receipt of benefits to surgeons on their performance of one or more steps of the '873 Claimed Method, and establish that performance by, among other things, providing detailed instructions concerning the use of the LapiFuse™ System that, if not followed, will deprive the surgeons of the benefits they hope to obtain from the LapiFuse™ System and performing one or more steps of the '873 Claimed Method. For example, Stryker and Wright advertise surgeons on their websites who, on information and belief, use the LapiFuse™ System as Stryker and Wright instruct in the LapiFuse Video and LapiFuse Brochure to perform the '873 Claimed Method. On information and belief, the Stryker and/or Wright representative present in the operating room for each LapiFuse™ Procedure monitors and directs the surgeon and will only provide the surgeon components of the LapiFuse™ System if the surgeon performs one or more steps of the '873 Claimed Method.

Induced Infringement of the '873 Patent

323. On information and belief, Stryker and Wright have induced and continue to induce infringement of the '873 Claimed Method in violation of 35 U.S.C. § 271(b).

324. Stryker and Wright have provided materials to hospitals and surgeons that demonstrate using the LapiFuse™ System to perform the '873 Claimed Method. For example, the LapiFuse Video and LapiFuse Brochure instruct, encourage, and assist surgeons to use the LapiFuse™ System in a manner that directly infringes the claims of the '873 Patent. On information and belief, Stryker and Wright sales staff, surgical site representatives, consulting

surgeons, and public and non-public instructional materials similarly instruct and encourage surgeons to use the LapiFuse™ System in a manner that directly infringes the claims of the '873 Patent as depicted and described above and in Exhibit 8. On information and belief, Stryker and Wright distributed these materials to hospitals and surgeons with the intent to cause surgeons to use the LapiFuse™ System and Procedure to perform the '873 Claimed Method. Stryker and/or Wright representatives present in the operating room for each LapiFuse™ Procedure monitor surgeons' performance of the LapiFuse™ Procedure and, on information and belief, direct them to use the LapiFuse™ System for the LapiFuse™ Procedure to infringe the claims of the '873 Patent.

325. On information and belief, Stryker and Wright have provided such instructions and encouragement despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the '873 Patent and the resulting infringement thereof by surgeons Stryker and Wright so instructed.

326. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The '873 Patent is listed on Treace Medical's patent marking webpage.

327. To the extent Stryker and Wright contend that they did not know of the '873 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '873 Patent and that the acts Stryker and Wright actively induced constituted infringement of the '873 Patent. On information and belief, Stryker and Wright at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® bunion System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known

status as the inventor of Instrumented TMT Bunion Systems; [redacted]

[redacted] Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; Treace Medical's substantial publicity regarding its patent portfolio; and Stryker's patent attorneys' citation to a patent in the same family as the '873 Patent as prior art to a Stryker patent application.

328. On information and belief, Stryker and Wright know that their surgeon customers and surgeon consultants are performing the '873 Claimed Method using the LapiFuse™ System and Procedure and are directly infringing the '873 Claimed Method.

329. Stryker's and Wright's inducing acts, such as distribution of the LapiFuse Video, LapiFuse Brochure, and other instructional materials, to promote and demonstrate the LapiFuse™ System and Procedure, and instructing and encouraging surgeons to use the LapiFuse™ System in a manner consistent with that Procedure described above and in Exhibit 8, caused and are causing surgeons to use the LapiFuse™ System and Procedure in a manner that infringes the '873 Claimed Method.

Contributory Infringement of the '873 Patent

330. On information and belief, Stryker and Wright have contributorily infringed the '873 Claimed Method in violation of 35 U.S.C. § 271(c).

331. Stryker and Wright have made, used, offered for sale, sold, and/or imported into the United States medical instruments and implants used in performing the infringing LapiFuse™ Procedure, including at least the LapiFuse Clamp, tissue removing instruments, and implants.

332. On information and belief, surgeons have performed and are performing the LapiFuse™ Procedure using the LapiFuse™ System as instructed, assisted, and encouraged by

Stryker and Wright in at least the LapiFuse Video and LapiFuse Brochure and by Stryker's and Wright's sales staff, surgical site representatives, and surgeon consultants, thereby directly infringing the '873 Claimed Method.

333. On information and belief, Stryker and Wright had actual knowledge of the '873 Patent and Treace Medical's infringement allegations at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint.

334. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because of Treace Medical's virtual marking through its internet website at https://www.treace.com/patents. The '873 Patent is listed on Treace Medical's patent marking webpage.

335. To the extent Stryker and Wright contend that they did not know of the '873 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '873 Patent and that the LapiFuse™ System is especially made or especially adapted for use in an infringement of the '873 Patent. On information and belief, Stryker and Wright at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; Treace Medical's substantial publicity regarding its patent portfolio; and Stryker's patent attorneys' citation to a patent in the same family as the '873 Patent as prior art to a Stryker patent application.

336. Components of the LapiFuse™ System including at least the LapiFuse Clamp, tissue removing instruments, and implants are material components for use in practicing the '873 Claimed Method. These components are especially made for use in a manner that infringes the '873 Claimed Method. The LapiFuse™ System components are not staple articles or commodities of commerce suitable for substantial non-infringing uses. For example, the only known use of the LapiFuse Clamp is for the infringing uses as described above and in Exhibit 8. Further, the implants (bone plates and screws) include "LapiFuse" or "Ortholoc 3Di" in their product name, and the tissue removing instruments are sold in a "LapiFuse" joint preparation kit.

337. On information and belief, Stryker and Wright have provided materials to hospitals and surgeons, including the LapiFuse Video and LapiFuse Brochure, demonstrating the use of the LapiFuse™ System to perform the '873 Claimed Method. The distribution of these materials further shows that Stryker and Wright especially made the LapiFuse™ System to perform the '873 Claimed Method. Stryker and/or Wright representatives present in the operating room for each LapiFuse™ Procedure monitor surgeons' performance of the LapiFuse™ Procedure and, on information and belief, direct them to use the LapiFuse™ System for the LapiFuse™ Procedure to infringe the claims of the '873 Patent.

338. On information and belief, at a date prior to the filing of this Complaint and at least as of the date of the filing and service of this Complaint, Stryker and Wright have known that the LapiFuse™ System (including the LapiFuse Clamp, tissue removing instruments, and implants) were especially made for use in a manner that infringes the '873 Claimed Method and were directly infringing the '873 Claimed Method.

339. On information and belief, surgeons have in fact used and continue to use the LapiFuse™ System and Procedure in a manner that infringes the '873 Claimed Method.

Willful Infringement of the '873 Patent

340. Stryker and Wright have willfully infringed the '873 Claimed Method.

341. On information and belief, Stryker and Wright have infringed and continue to infringe the '873 Claimed Method with knowledge of Treace Medical's rights in the '873 Patent.

342. On information and belief, Stryker's and Wright's acts of infringement of the '873 Claimed Method have been and continue to be willful, deliberate, and egregious.

343. On information and belief, Stryker and Wright acted despite an objectively high likelihood that their actions constituted infringement of a valid patent claim and knew or should have known of this objectively defined risk of infringement.

Requested Relief for Stryker's and Wright's Infringement of the '873 Patent

344. Stryker's and Wright's misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters a permanent injunction prohibiting Stryker, Wright, and those acting on their behalf from infringing the '873 Patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the LapiFuse™ System for performing the '873 Claimed Method. Stryker's and Wright's misconduct has caused Treace Medical to suffer irreparable injury that is not adequately compensated for by remedies available at law. The balance of hardships between the parties warrant a remedy in equity and the public interest would not be disserved by a permanent injunction.

345. Treace Medical is entitled to recover damages that would place Treace Medical as close as possible to the same financial position that it would have been in had Stryker's and Wright's infringement of the '873 Patent not occurred. Treace Medical is entitled to recover damages including all profits that it has lost as a result of Stryker's and Wright's sale of the LapiFuse™ System and the products used in the performance of instrumented TMT bunion

correction procedures using the LapiFuse™ System. At a minimum, Treace Medical is entitled to a reasonable royalty on Stryker's and Wright's sales of the LapiFuse™ System and products used in the performance and practicing of the patented instrumented TMT bunion correction procedures using the LapiFuse™ System.

346. Treace Medical requests pursuant to 35 U.S.C. § 284 that damages awarded to it in this matter for Stryker's and Wright's willful infringement of the '873 Patent be increased to three times the amount found or assessed by the fact finder.

COUNT IV
INFRINGEMENT OF U.S. PATENT NO. 11,116,558 BY LAPIFUSE™ SYSTEM
(Against Stryker Corp. and Wright Medical Tech., Inc.)

347. Treace Medical incorporates by reference Paragraphs 1-346 of this Complaint.

348. On September 14, 2021, the USPTO issued U.S. Patent Number 11,116,558 B2 ("**the '558 Patent**") to Treace Medical, listing inventors W. Bret Smith, Paul Dayton, Sean F. Scanlan, F. Barry Bays, Carlos Eduardo Gil, John T. Treace, Robert D. Santrock, Daniel J. Hatch, and Joe W. Ferguson. The '558 Patent is titled "Bone Positioning Guide" and is directed to "[a] method of correcting a bunion deformity on a foot …." A true and correct copy of the '558 Patent is attached to this Complaint as **Exhibit 9**. The '558 Patent remains in force and is assigned to Treace Medical. Treace Medical has owned the '558 Patent since it was issued and still owns the '558 Patent.

349. The '558 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

350. Stryker and Wright have made, used, offered for sale, sold, and/or imported into the United States medical instruments and implants used in performing bunion surgery. These medical instruments and implants are offered by Stryker and Wright for the use of the ORTHOLOC™ 2 LapiFuse™ Triplanar Correction System. The LapiFuse instruments and

implants are identified in Stryker's and Wright's LapiFuse Video and LapiFuse Brochure, as detailed above.

351. Attached to this Complaint as **Exhibit 10** is a claim chart explaining how Stryker and Wright describe through the LapiFuse Video and LapiFuse Brochure the performance of the steps of exemplary claim 1 of the '558 Patent using the LapiFuse™ System and thereby instruct and encourage surgeons to perform the method of claim 1 and other claims of the '558 Patent ("**the '558 Claimed Method**"). On information and belief, Stryker and Wright continue to instruct and encourage surgeons to perform the '558 Claimed Method. On information and belief, Stryker and Wright have not instructed surgeons to perform the LapiFuse™ Procedure using the LapiFuse™ System in a non-infringing manner. The LapiFuse™ System has no substantial non-infringing uses.

Direct Infringement of the '558 Patent

352. On information and belief, Stryker and Wright have directly infringed and continue to directly infringe, both literally and/or under the doctrine of equivalents, the '558 Patent by using (*e.g.*, by performing actual or simulated surgical procedures) the LapiFuse™ System to perform the patented surgical method of the '558 Patent in the United States in violation of 35 U.S.C. § 271(a), including within this judicial district, in a manner that infringes at least claim 1 of the '558 Patent without a license from Treace Medical.

353. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the LapiFuse Video and LapiFuse Brochure using the LapiFuse™ System directly infringe the '558 Patent.

354. On information and belief, surgeon consultants to Stryker and Wright, working at Stryker's or Wright's direction, tested and performed the '558 Claimed Method using the

LapiFuse™ System on Stryker's and Wright's behalf as part of developing the LapiFuse™ System and Procedure.

355. In addition, surgeon consultants to Stryker and Wright, working at Stryker's or Wright's direction, perform the '558 Claimed Method using the LapiFuse™ System as part of surgeon education.

356. Stryker and Wright have created at least the LapiFuse Video and LapiFuse Brochure showing the LapiFuse™ System being used to perform the LapiFuse™ Procedure and thereby performing the '558 Claimed Method. On information and belief, surgeons working on Stryker's or Wright's behalf and at Stryker's or Wright's direction, performed the '558 Claimed Method using the LapiFuse™ System in connection with creating the LapiFuse Brochure, which demonstrates performance of the '558 Claimed Method using the LapiFuse™ System.

357. Stryker and Wright also direct and/or control surgeons to perform the '558 Claimed Method using the LapiFuse™ System because, among other things, Stryker and Wright condition receipt of benefits to surgeons on their performance of one or more steps of the '558 Claimed Method, and establish that performance by, among other things, providing detailed instructions concerning the use of the LapiFuse™ System that, if not followed, will deprive the surgeons of the benefits they hope to obtain from the LapiFuse™ System and performing one or more steps of the '558 Claimed Method. For example, Stryker and Wright advertise surgeons on their websites who, on information and belief, use the LapiFuse™ System as Stryker and Wright instruct in the LapiFuse Video and LapiFuse Brochure to perform the '558 Claimed Method. On information and belief, the Stryker and/or Wright representative present in the operating room for each LapiFuse™ Procedure monitors and directs the surgeon and will only provide the surgeon

components of the LapiFuse™ System if the surgeon performs one or more steps of the '558 Claimed Method.

Induced Infringement of the '558 Patent

358. On information and belief, Stryker and Wright have induced and continue to induce infringement of the '558 Claimed Method in violation of 35 U.S.C. § 271(b).

359. Stryker and Wright have provided materials to hospitals and surgeons that demonstrate using the LapiFuse™ System to perform the '558 Claimed Method. For example, the LapiFuse Video and LapiFuse Brochure instruct, encourage, and assist surgeons to use the LapiFuse™ System in a manner that directly infringes the claims of the '558 Patent. On information and belief, Stryker and Wright sales staff, surgical site representatives, consulting surgeons, and public and non-public instructional materials similarly instruct and encourage surgeons to use the LapiFuse™ System in a manner that directly infringes the claims of the '558 Patent as depicted and described above and in Exhibit 10. On information and belief, Stryker and Wright distributed these materials to hospitals and surgeons with the intent to cause surgeons to use the LapiFuse™ System and Procedure to perform the '558 Claimed Method. Stryker and/or Wright representatives present in the operating room for each LapiFuse™ Procedure monitor surgeons' performance of the LapiFuse™ Procedure and, on information and belief, direct them to use the LapiFuse™ System for the LapiFuse™ Procedure to infringe the claims of the '558 Patent.

360. On information and belief, Stryker and Wright have provided such instructions and encouragement despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the '558 Patent and the resulting infringement thereof by surgeons Stryker and Wright so instructed.

361. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The '558 Patent is listed on Treace Medical's patent marking webpage.

362. To the extent Stryker and Wright contend that they did not know of the '558 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '558 Patent and that the acts Stryker and Wright actively induced constituted infringement of the '558 Patent. On information and belief, Stryker and Wright at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; Treace Medical's substantial publicity regarding its patent portfolio; and Stryker's patent attorneys' citation to a patent in the same family as the '558 Patent as prior art to a Stryker patent application.

363. On information and belief, Stryker and Wright know that their surgeon customers and surgeon consultants are performing the '558 Claimed Method using the LapiFuse™ System and Procedure and are directly infringing the '558 Claimed Method.

364. Stryker's and Wright's inducing acts, such as distribution of the LapiFuse Video, LapiFuse Brochure, and other instructional materials, to promote and demonstrate the LapiFuse™ System and Procedure, and instructing and encouraging surgeons to use the LapiFuse™ System

in a manner consistent with that Procedure described above and in Exhibit 10, caused and are causing surgeons to use the LapiFuse™ System and Procedure in a manner that infringes the '558 Claimed Method.

Contributory Infringement of the '558 Patent

365. On information and belief, Stryker and Wright have contributorily infringed the '558 Claimed Method in violation of 35 U.S.C. § 271(c).

366. Stryker and Wright have made, used, offered for sale, sold, and/or imported into the United States medical instruments and implants used in performing the infringing LapiFuse™ Procedure, including at least the LapiFuse Clamp, tissue removing instruments, and implants.

367. On information and belief, surgeons have performed and are performing the LapiFuse™ Procedure using the LapiFuse™ System as instructed, assisted, and encouraged by Stryker and Wright in at least the LapiFuse Video and LapiFuse Brochure and by Stryker's and Wright's sales staff, surgical site representations, and surgeon consultants, thereby directly infringing the '558 Claimed Method.

368. On information and belief, Stryker and Wright had actual knowledge of the '558 Patent and Treace Medical's infringement allegations at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint.

369. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because of Treace Medical's virtual marking through its internet website at https://www.treace.com/patents. The '558 Patent is listed on Treace Medical's patent marking webpage.

370. To the extent Stryker and Wright contend that they did not know of the '558 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '558 Patent and that the LapiFuse™ System is especially made or especially adapted for use

in an infringement of the '558 Patent. On information and belief, Stryker and Wright at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted] Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; Treace Medical's substantial publicity regarding its patent portfolio; and Stryker's patent attorneys' citation to a patent in the same family as the '558 Patent as prior art to a Stryker patent application.

371. Components of the LapiFuse™ System including at least the LapiFuse Clamp, tissue removing instruments, and implants are material components for use in practicing the '558 Claimed Method. These components are especially made for use in a manner that infringes the '558 Claimed Method. The LapiFuse™ System components are not staple articles or commodities of commerce suitable for substantial non-infringing uses. For example, the only known use of the LapiFuse Clamp is for the infringing uses as described above and in Exhibit 10. Further, the implants (bone plates and screws) include "LapiFuse" or "Ortholoc 3Di" in their product name, and the tissue removing instruments are sold in a "LapiFuse" joint preparation kit.

372. On information and belief, Stryker and Wright have provided materials to hospitals and surgeons, including the LapiFuse Video and LapiFuse Brochure, demonstrating the use of the LapiFuse™ System to perform the '558 Claimed Method. The distribution of these materials further shows that Stryker and Wright especially made the LapiFuse™ System to perform the '558 Claimed Method. Stryker and/or Wright representatives present in the operating room for

each LapiFuse™ Procedure monitor surgeons' performance of the LapiFuse™ Procedure and, on information and belief, direct them to use the LapiFuse™ System for the LapiFuse™ Procedure to infringe the claims of the '558 Patent.

373. On information and belief, at least as of the date of the filing and service of this Complaint, Stryker and Wright have known that the LapiFuse™ System (including the LapiFuse Clamp, tissue removing instruments, and implants) were especially made for use in a manner that infringes the '558 Claimed Method and were directly infringing the '558 Claimed Method.

374. On information and belief, surgeons have in fact used and continue to use the LapiFuse™ System and Procedure in a manner that infringes the '558 Claimed Method.

Willful Infringement of the '558 Patent

375. Stryker and Wright have willfully infringed the '558 Claimed Method.

376. On information and belief, Stryker and Wright have infringed and continue to infringe the '558 Claimed Method with knowledge of Treace Medical's rights in the '558 Patent.

377. On information and belief, Stryker's and Wright's acts of infringement of the '558 Claimed Method have been and continue to be willful, deliberate, and egregious.

378. On information and belief, Stryker and Wright acted despite an objectively high likelihood that their actions constituted infringement of a valid patent claim and knew or should have known of this objectively defined risk of infringement.

Requested Relief for Stryker's and Wright's Infringement of the '558 Patent

379. Stryker's and Wright's misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters a permanent injunction prohibiting Stryker, Wright, and those acting on their behalf from infringing the '558 Patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the LapiFuse™ System for performing the '558 Claimed

Method. Stryker's and Wright's misconduct has caused Treace Medical to suffer irreparable injury that is not adequately compensated for by remedies available at law. The balance of hardships between the parties warrant a remedy in equity and the public interest would not be disserved by a permanent injunction.

380. Treace Medical is entitled to recover damages that would place Treace Medical as close as possible to the same financial position that it would have been in had Stryker's and Wright's infringement of the '558 Patent not occurred. Treace Medical is entitled to recover damages including all profits that it has lost as a result of Stryker's and Wright's sale of the LapiFuse™ System and the products used in the performance of instrumented TMT bunion correction procedures using the LapiFuse™ System. At a minimum, Treace Medical is entitled to a reasonable royalty on Stryker's and Wright's sales of the LapiFuse™ System and products used in the performance and practicing of the patented instrumented TMT bunion correction procedures using the LapiFuse™ System.

381. Treace Medical requests pursuant to 35 U.S.C. § 284 that damages awarded to it in this matter for Stryker's and Wright's willful infringement of the '558 Patent be increased to three times the amount found or assessed by the fact finder.

COUNT V
INFRINGEMENT OF U.S. PATENT NO. 11,602,386 BY LAPIFUSE™ SYSTEM
(Against Stryker Corp. and Wright Medical Tech., Inc.)

382. Treace Medical incorporates by reference Paragraphs 1-381 of this Complaint.

383. On March 14, 2023, the USPTO issued U.S. Patent Number 11,602,386 B2 ("**the '386 Patent**") to Treace Medical, listing inventors W. Bret Smith, Paul Dayton, Sean F. Scanlan, F. Barry Bays, Carlos Eduardo Gil, John T. Treace, Robert D. Santrock, Daniel J. Hatch, and Joe W. Ferguson. The '386 Patent is titled "Bone Positioning Guide" and is directed to "[a] bone positioning guide for a bunion correction procedure." A true and correct copy of the '386 Patent

is attached to this Complaint as **Exhibit 11**. The '386 Patent remains in force and is assigned to Treace Medical. Treace Medical has owned the '386 Patent since it was issued and still owns the '386 Patent.

384. The '386 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

385. Stryker and Wright have made, used, offered for sale, sold, and/or imported into the United States the ORTHOLOC™ 2 LapiFuse™ Triplanar Correction System. The LapiFuse™ System is exemplified in Stryker's and Wright's LapiFuse Video and LapiFuse Brochure, as detailed above.

386. Attached to this Complaint as **Exhibit 12** is a claim chart explaining how the LapiFuse™ System meets the elements of exemplary claim 1 of the '386 Patent. The LapiFuse™ System has no substantial non-infringing uses.

Direct Infringement of the '386 Patent

387. On information and belief, Stryker and Wright have directly infringed and continue to directly infringe, both literally and/or under the doctrine of equivalents, the '386 Patent by making, selling, offering for sale, and/or using (*e.g.*, by performing actual or simulated surgical procedures using) the LapiFuse™ System in the United States in violation of 35 U.S.C. § 271(a), including within this judicial district, in a manner that infringes at least claim 1 of the '386 Patent without a license from Treace Medical.

388. Stryker and Wright also direct and/or control surgeons to infringe the '386 Patent with the LapiFuse™ System because, among other things, Stryker and Wright condition receipt of benefits to surgeons on assembly and use of a device that infringes the '386 Patent, and establish that assembly and use by, among other things, providing detailed instructions concerning the assembly and use of the LapiFuse™ System that, if not followed, will deprive the surgeons of the

benefits they hope to obtain from the LapiFuse™ System and assembly and use of a device that infringes the '386 Patent. For example, Stryker and Wright advertise surgeons on their websites who, on information and belief, assemble and use the LapiFuse™ System as Stryker and Wright instruct in the LapiFuse Video and LapiFuse Brochure to infringe the '386 Patent. On information and belief, the Stryker and/or Wright representative present in the operating room for each LapiFuse™ Procedure monitors and directs the surgeon and will only provide the surgeon components of the LapiFuse™ System if the surgeon assembles and uses the LapiFuse™ System as provided by the '386 Patent.

Induced Infringement of the '386 Patent

389. On information and belief, Stryker and Wright have induced and continue to induce infringement of the '386 Patent in violation of 35 U.S.C. § 271(b).

390. The LapiFuse Video and LapiFuse Brochure instruct, encourage, and assist surgeons to use the LapiFuse™ System in a manner that directly infringes the claims of the '386 Patent. On information and belief, Stryker and Wright sales staff, surgical site representatives, consulting surgeons, and public and non-public instructional materials similarly instruct and encourage surgeons to use the LapiFuse™ System in a manner that directly infringes the claims of the '386 Patent as depicted and described above and in Exhibit 12. Stryker and/or Wright representatives present in the operating room for each LapiFuse™ Procedure monitor surgeons' use of the LapiFuse™ System and, on information and belief, direct them to assemble and use the LapiFuse™ System to infringe the claims of the '386 Patent.

391. On information and belief, Stryker and Wright have provided such instructions and encouragement despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the '386 Patent and the resulting infringement thereof by surgeons Stryker and Wright so instructed.

392. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The '386 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® Positioner heading.

393. To the extent Stryker and Wright contend that they did not know of the '386 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '386 Patent and that the acts Stryker and Wright actively induced constituted infringement of the '386 Patent. On information and belief, Stryker and Wright at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; Treace Medical's substantial publicity regarding its patent portfolio; and Stryker's patent attorneys' citation to a patent in the same family as the '386 Patent as prior art to a Stryker patent application.

394. On information and belief, Stryker and Wright have continued to distribute materials, including the LapiFuse Video and LapiFuse Brochure, to demonstrate the infringing use of the LapiFuse™ System. Continued distribution of these materials further shows that the LapiFuse™ System is especially made to infringe the '386 Patent.

395. On information and belief, Stryker and Wright know that their surgeon customers and surgeon consultants are performing bunion correction procedures using the LapiFuse™ System and are directly infringing the claims of the ’386 Patent.

396. Stryker’s and Wright’s inducing acts, such as distribution of the LapiFuse Video, LapiFuse Brochure, and other instructional materials, to promote and demonstrate the LapiFuse™ System, and instructing and encouraging surgeons to use the LapiFuse™ System in a manner consistent with that Procedure described above and in Exhibit 12, caused and are causing surgeons to use the LapiFuse™ System in a manner that infringes the claims of the ’386 Patent.

Contributory Infringement of the ’386 Patent

397. On information and belief, Stryker and Wright have contributorily infringed the ’386 Patent in violation of 35 U.S.C. § 271(c).

398. Stryker and Wright have made, used, offered for sale, sold, and/or imported into the United States medical instruments and implants used as part of the LapiFuse™ System, including at least components of the LapiFuse Clamp. These products are components of the apparatus covered by the ’386 Patent.

399. On information and belief, surgeons are assembling and using the LapiFuse™ System as instructed, assisted, and encouraged by Stryker and Wright in at least the LapiFuse Video and LapiFuse Brochure and by Stryker’s and Wright’s sales staff, surgical site representatives, and surgeon consultants, thereby directly infringing the claims of the ’386 Patent.

400. On information and belief, Stryker and Wright have provided components of a patented apparatus despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the ’386 Patent and the resulting infringement thereof by surgeons Stryker and Wright so instructed.

401. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The '386 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® Positioner heading.

402. To the extent Stryker and Wright contend that they did not know of the '386 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '386 Patent and that the LapiFuse™ System is especially made or especially adapted for use in an infringement of the '386 Patent. On information and belief, Stryker and Wright at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; Treace Medical's substantial publicity regarding its patent portfolio; and Stryker's patent attorneys' citation to a patent in the same family as the '386 Patent as prior art to a Stryker patent application.

403. Components of the LapiFuse™ System, including at least the components of the LapiFuse Clamp, are material components of a patented apparatus claimed the '386 Patent. These components are especially made for use in a manner that infringes the apparatus claimed in the '386 Patent. The LapiFuse™ System components are not staple articles or commodities of commerce suitable for substantial non-infringing uses. The only known use of the LapiFuse Clamp is for the infringing uses in a system as described above and in Exhibit 12. Further, the implants

(bone plates and screws) include "LapiFuse" or "Ortholoc 3Di" in their product name, and the tissue removing instruments are sold in a "LapiFuse" joint preparation kit.

404. On information and belief, Stryker and Wright have provided materials to hospitals and surgeons, including the LapiFuse Video and LapiFuse Brochure, demonstrating the infringing assembly of the LapiFuse™ System. The distribution of these materials further shows that Stryker and Wright especially made the LapiFuse™ System to infringe the '386 Patent. Stryker and/or Wright representatives present in the operating room for each LapiFuse™ Procedure monitor surgeons' use of the LapiFuse™ System and, on information and belief, direct them to assemble and use the LapiFuse™ System to infringe the claims of the '386 Patent with the awareness that the LapiFuse™ System (including components of the LapiFuse Clamp) have no substantial non-infringing uses.

405. On information and belief, at a date prior to the filing of this Complaint and at least as of the date of the filing and service of this Complaint, Stryker and Wright have known that the LapiFuse™ System (including components of the LapiFuse Clamp) were especially made for use in a manner that infringes the '386 Patent and were directly infringing the '386 Patent.

406. On information and belief, surgeons have in fact used and continue to use the LapiFuse™ System, thereby infringing the '386 Patent.

Willful Infringement of the '386 Patent

407. Stryker and Wright have willfully infringed the '386 Patent.

408. On information and belief, Stryker and Wright have infringed and continue to infringe the '386 Patent with knowledge of Treace Medical's rights in the '386 Patent.

409. On information and belief, Stryker's and Wright's acts of infringement of the '386 Patent have been and continue to be willful, deliberate, and egregious.

410. On information and belief, Stryker and Wright acted despite an objectively high likelihood that their actions constituted infringement of a valid patent claim and knew or should have known of this objectively defined risk of infringement.

Requested Relief for Stryker's and Wright's Infringement of the '386 Patent

411. Stryker's and Wright's misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters a permanent injunction prohibiting Stryker, Wright, and those acting on their behalf from infringing the '386 Patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the LapiFuse™ System. Stryker's and Wright's misconduct has caused Treace Medical to suffer irreparable injury that is not adequately compensated for by remedies available at law. The balance of hardships between the parties warrant a remedy in equity and the public interest would not be disserved by a permanent injunction.

412. Treace Medical is entitled to recover damages that would place Treace Medical as close as possible to the same financial position that it would have been in had Stryker's and Wright's infringement of the '386 Patent not occurred. Treace Medical is entitled to recover damages including all profits that it has lost as a result of Stryker's and Wright's promotion and sale of the LapiFuse™ System and component products. At a minimum, Treace Medical is entitled to a reasonable royalty on Stryker's and Wright's promotion and sales of the LapiFuse™ System and component products.

413. Treace Medical requests pursuant to 35 U.S.C. § 284 that damages awarded to it in this matter for Stryker's and Wright's willful infringement of the '386 Patent be increased to three times the amount found or assessed by the fact finder.

COUNT VI
INFRINGEMENT OF U.S. PATENT NO. 11,602,386 BY PROSTEP® LAPIDUS SYSTEM
(Against Stryker Corp.)

414. Treace Medical incorporates by reference Paragraphs 1-413 of this Complaint.

415. As stated above in Count V, the USPTO issued the '386 Patent to Treace Medical on March 14, 2023, a copy of which is attached as Exhibit 11.

416. The '386 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

417. Stryker has made, used, offered for sale, sold, and/or imported into the United States the PROstep® MIS Lapidus System. The PROstep® Lapidus System is exemplified in Stryker's PROstep Operative Technique Brochure and PROstep Video, as detailed above.

418. Attached to this Complaint as **Exhibit 13** is a claim chart explaining how the PROstep® Lapidus System meets the elements of exemplary claim 1 of the '386 Patent. The PROstep® Lapidus System has no substantial non-infringing uses.

Direct Infringement of the '386 Patent

419. On information and belief, Stryker has directly infringed and continues to directly infringe, both literally and/or under the doctrine of equivalents, the '386 Patent by making, selling, offering for sale, and/or using (*e.g.*, by performing actual or simulated surgical procedures using) the PROstep® Lapidus System in the United States in violation of 35 U.S.C. § 271(a), including within this judicial district, in a manner that infringes at least claim 1 of the '386 Patent without a license from Treace Medical.

Induced Infringement of the '386 Patent

420. On information and belief, Stryker has induced and continues to induce infringement of the '386 Patent in violation of 35 U.S.C. § 271(b).

421. The PROstep Brochure and PROstep Video instruct, encourage, and assist surgeons to use the PROstep® Lapidus System in a manner that directly infringes the claims of the '386 Patent. On information and belief, Stryker sales staff, surgical site representatives, consulting surgeons, and public and non-public instructional materials similarly instruct and encourage surgeons to use the PROstep® Lapidus System in a manner that directly infringes the claims of the '386 Patent as depicted and described above and in Exhibit 13.

422. On information and belief, Stryker has provided such instructions and encouragement despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the '386 Patent and the resulting infringement thereof by surgeons Stryker so instructed.

423. Stryker at a minimum had constructive knowledge of Treace Medical's patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The '386 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® Positioner heading.

424. To the extent Stryker contends that it did not know of the '386 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '386 Patent and that the acts Stryker actively induced constituted infringement of the '386 Patent. On information and belief, Stryker at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker's attendance and participation at industry conferences (*e.g.*, AOFAS) where Treace Medical displayed and discussed the Lapiplasty®

System and where Stryker presented its infringing PROstep® Lapidus System; Treace Medical's substantial publicity regarding its patent portfolio; and Stryker's patent attorneys' citation to a patent in the same family as the '386 Patent as prior art to a Stryker patent application.

425. On information and belief, Stryker has continued to distribute materials, including the PROstep Brochure, to demonstrate the infringing use of the PROstep® Lapidus System. Continued distribution of these materials further shows that the PROstep® Lapidus System is especially made to infringe the '386 Patent.

426. On information and belief, Stryker knows that its surgeon customers and surgeon consultants are performing bunion correction procedures using the PROstep® Lapidus System and are directly infringing the claims of the '386 Patent.

427. Stryker's inducing acts, such as distribution of the PROstep Brochure, PROstep Video, and other instructional materials, to promote and demonstrate the PROstep® Lapidus System, and instructing and encouraging surgeons to use the PROstep® Lapidus System in a manner described above and in Exhibit 13, caused and are causing surgeons to use the PROstep® Lapidus System in a manner that infringes the claims of the '386 Patent.

Willful Infringement of the '386 Patent

428. Stryker has willfully infringed the '386 Patent.

429. On information and belief, Stryker has infringed and continues to infringe the '386 Patent with knowledge of Treace Medical's rights in the '386 Patent.

430. On information and belief, Stryker's acts of infringement of the '386 Patent have been and continue to be willful, deliberate, and egregious.

431. On information and belief, Stryker acted despite an objectively high likelihood that its actions constituted infringement of a valid patent claim and knew or should have known of this objectively defined risk of infringement.

Requested Relief for Stryker's Infringement of the '386 Patent

432. Stryker's misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters a permanent injunction prohibiting Stryker and those acting on its behalf from infringing the '386 Patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the PROstep® Lapidus System. Stryker's misconduct has caused Treace Medical to suffer irreparable injury that is not adequately compensated for by remedies available at law. The balance of hardships between the parties warrant a remedy in equity and the public interest would not be disserved by a permanent injunction.

433. Treace Medical is entitled to recover damages that would place Treace Medical as close as possible to the same financial position that it would have been in had Stryker's infringement of the '386 Patent not occurred. Treace Medical is entitled to recover damages including all profits that it has lost as a result of Stryker's promotion and sale of the PROstep® Lapidus System and component products. At a minimum, Treace Medical is entitled to a reasonable royalty on Stryker's promotion and sales of the PROstep® Lapidus System and component products.

434. Treace Medical requests pursuant to 35 U.S.C. § 284 that damages awarded to it in this matter for Stryker's willful infringement of the '386 Patent be increased to three times the amount found or assessed by the fact finder.

COUNT VII
INFRINGEMENT OF U.S. PATENT NO. 11,602,387 BY LAPIFUSE™ SYSTEM
(Against Stryker Corp. and Wright Medical Tech., Inc.)

435. Treace Medical incorporates by reference Paragraphs 1-434 of this Complaint.

436. On March 14, 2023, the USPTO issued U.S. Patent Number 11,602,387 B2 ("**the '387 Patent**") to Treace Medical, listing inventors Robert D. Santrock, Paul Dayton, Daniel J.

Hatch, W. Bret Smith, F. Barry Bays, Carlos Eduardo Gil, Sean F. Scanlan, Joe W. Ferguson, and John T. Treace. The '387 Patent is titled "Bone Positioning and Preparing Guide Systems and Methods" and is directed to "[a] metatarsal correction system." A true and correct copy of the '387 Patent is attached to this Complaint as **Exhibit 14**. The '387 Patent remains in force and is assigned to Treace Medical. Treace Medical has owned the '387 Patent since it was issued and still owns the '387 Patent.

437. The '387 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

438. Stryker and Wright have made, used, offered for sale, sold, and/or imported into the United States the ORTHOLOC™ 2 LapiFuse™ Triplanar Correction System. The LapiFuse™ System is exemplified in Stryker and Wright's LapiFuse Video, LapiFuse Brochure, and the LapiFuse Surgeon Presentation as detailed above.

439. Attached to this Complaint as **Exhibit 15** is a claim chart explaining how the LapiFuse™ System meets the elements of exemplary claim 1 of the '387 Patent. The LapiFuse™ System has no substantial non-infringing uses.

Direct Infringement of the '387 Patent

440. On information and belief, Stryker and Wright have directly infringed and continue to directly infringe, both literally and/or under the doctrine of equivalents, the '387 Patent by making, selling, offering for sale, and/or using (*e.g.*, by performing actual or simulated surgical procedures using) the LapiFuse™ System, including a cut guide, in the United States in violation of 35 U.S.C. § 271(a), including within this judicial district, in a manner that infringes at least claim 1 of the '387 Patent without a license from Treace Medical.

441. Stryker and Wright also direct and/or control surgeons to infringe the '387 Patent with the LapiFuse™ System because, among other things, Stryker and Wright condition receipt of

benefits to surgeons on assembly and use of a system that infringes the '387 Patent, and establish that assembly by, among other things, providing detailed instructions concerning the assembly and use of the LapiFuse™ System that, if not followed, will deprive the surgeons of the benefits they hope to obtain from the LapiFuse™ System and assembly and use of a device that infringes the '387 Patent. For example, Stryker and Wright advertise surgeons on their websites who, on information and belief, assemble and use the LapiFuse™ System as Stryker and Wright instruct in the LapiFuse Video, LapiFuse Brochure, and LapiFuse Surgeon Presentation to infringe the '387 Patent. On information and belief, the Stryker and/or Wright representative present in the operating room for each LapiFuse™ Procedure monitors and directs the surgeon and will only provide the surgeon components of the LapiFuse™ System if the surgeon assembles and uses components of the LapiFuse™ System as provided by the '387 Patent.

Induced Infringement of the '387 Patent

442. On information and belief, Stryker and Wright have induced and continue to induce infringement of the '387 Patent in violation of 35 U.S.C. § 271(b).

443. The LapiFuse Video, LapiFuse Brochure, and LapiFuse Surgeon Presentation instruct, encourage, and assist surgeons to use the LapiFuse™ System, including a cut guide, in a manner that directly infringes the claims of the '387 Patent. On information and belief, Stryker and Wright sales staff, surgical site representatives, consulting surgeons, and public and non-public instructional materials similarly instruct and encourage surgeons to use the LapiFuse™ System, including a cut guide, in a manner that directly infringes the claims of the '387 Patent as depicted and described above and in Exhibit 15. Stryker and/or Wright representatives present in the operating room for each LapiFuse™ Procedure monitor surgeons' use of the LapiFuse™ System and, on information and belief, direct them to assemble and use the LapiFuse™ System, including a cut guide, to infringe the claims of the '387 Patent.

444. On information and belief, Stryker and Wright have provided the LapiFuse™ System components and such instructions and encouragement despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the '387 Patent and the resulting infringement thereof by surgeons Stryker and Wright so instructed.

445. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The '387 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® System and Procedure heading.

446. To the extent Stryker and Wright contend that they did not know of the '387 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '387 Patent and that the acts Stryker and Wright actively induced constituted infringement of the '387 Patent. On information and belief, Stryker and Wright at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; Treace Medical's substantial publicity regarding its patent portfolio; and citations to patents in the same family as the '387 Patent as prior art in the patent prosecution of a Stryker patent application and a Wright patent application.

447. On information and belief, Stryker and Wright have continued to distribute materials, including the LapiFuse Video, LapiFuse Brochure, and instructions in the LapiFuse Surgeon Presentation, to demonstrate the infringing use of the LapiFuse™ System, including a cut guide. Continued distribution of these materials further shows that the LapiFuse™ System is especially made to infringe the '387 Patent.

448. On information and belief, Stryker and Wright know that their surgeon customers and surgeon consultants are performing bunion correction procedures using the LapiFuse™ System, including the cut guide, and are directly infringing the claims of the '387 Patent.

449. Stryker's and Wright's inducing acts, such as distribution of the LapiFuse Video, LapiFuse Brochure, LapiFuse Surgeon Presentation, and other instructional materials, to promote and demonstrate the LapiFuse™ System, and instructing and encouraging surgeons to use the LapiFuse™ System in a manner consistent with that Procedure described above and in Exhibit 15, caused and are causing surgeons to use the LapiFuse™ System in a manner that infringes the claims of the '387 Patent.

Contributory Infringement of the '387 Patent

450. On information and belief, Stryker and Wright have contributorily infringed the '387 Patent in violation of 35 U.S.C. § 271(c).

451. Stryker and Wright have offered for sale, sold, and/or imported into the United States medical instruments and implants used as part of the LapiFuse™ System, including at least the LapiFuse cut guide, LapiFuse Clamp, tissue removing instruments, and implants. These products constitute components of a system covered by the '387 Patent.

452. On information and belief, surgeons are assembling and using the LapiFuse™ System as instructed, assisted, and encouraged by Stryker and Wright in at least the LapiFuse Video, LapiFuse Brochure, and LapiFuse Surgeon Presentation and by Stryker's and Wright's

sales staff, surgical site representatives, and surgeon consultants, thereby directly infringing the claims of the '387 Patent.

453. On information and belief, Stryker and Wright have provided components of a patented system despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the '387 Patent and the resulting infringement thereof by surgeons Stryker and Wright so instructed.

454. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because of Treace Medical's virtual marking through its internet website at https://www.treace.com/patents. The '387 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® System and Procedure heading.

455. To the extent Stryker and Wright contend that they did not know of the '387 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '387 Patent and that the LapiFuse™ System components are especially made or especially adapted for use in an infringement of the '387 Patent. On information and belief, Stryker and Wright at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; Treace Medical's substantial publicity regarding its patent portfolio; and citations to patents in the

same family as the ’387 Patent as prior art in the patent prosecution of a Stryker patent application and a Wright patent application.

456. Components of the LapiFuse™ System including at least the LapiFuse cut guide, LapiFuse Clamp, tissue removing instruments, and implants are material components for use in the system claimed in the ’387 Patent. These components are especially made for use in a manner that infringes the system claimed of ’387 Patent. The LapiFuse™ System components are not staple articles or commodities of commerce suitable for substantial non-infringing uses. For example, the only known use of the LapiFuse cut guide and LapiFuse Clamp are for the infringing uses in a system as described above and in Exhibit 15. Further, the implants (bone plates and screws) include “LapiFuse” or “Ortholoc 3Di” in their product name, and the tissue removing instruments are sold in a “LapiFuse” joint preparation kit.

457. On information and belief, Stryker and Wright have provided materials to hospitals and surgeons, including the LapiFuse Video, LapiFuse Brochure, and LapiFuse Surgeon Presentation, demonstrating the infringing use of the LapiFuse™ System. The distribution of these materials further shows that Stryker and Wright especially made the LapiFuse™ System to infringe the ’387 Patent. Stryker and/or Wright representatives present in the operating room for each LapiFuse™ Procedure monitor surgeons’ use of the LapiFuse™ System and, on information and belief, direct them to assemble and use the LapiFuse™ System to infringe the claims of the ’387 Patent with the awareness that the LapiFuse™ System (including the LapiFuse cut guide and components of the LapiFuse Clamp) have no substantial non-infringing uses.

458. On information and belief, at a date prior to the filing of this Complaint and at least as of the date of the filing and service of this Complaint, Stryker and Wright have known that the LapiFuse™ System (including the LapiFuse cut guide, LapiFuse Clamp, tissue removing

instruments, and implants) were especially made for use in a manner that infringes the ’387 Patent and were directly infringing the ’387 Patent.

459. On information and belief, surgeons have in fact used and continue to use the LapiFuse™ System, thereby infringing the ’387 Patent.

Willful Infringement of the ’387 Patent

460. Stryker and Wright have willfully infringed the ’387 Patent.

461. On information and belief, Stryker and Wright have infringed and continue to infringe the ’387 Patent with knowledge of Treace Medical’s rights in the ’387 Patent.

462. On information and belief, Stryker’s and Wright’s acts of infringement of the ’387 Patent have been and continue to be willful, deliberate, and egregious.

463. On information and belief, Stryker and Wright acted despite an objectively high likelihood that their actions constituted infringement of a valid patent claim and knew or should have known of this objectively defined risk of infringement.

Requested Relief for Stryker’s and Wright’s Infringement of the ’387 Patent

464. Stryker’s and Wright’s misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters a permanent injunction prohibiting Stryker, Wright, and those acting on their behalf from infringing the ’387 Patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the LapiFuse™ System. Stryker’s and Wright’s misconduct has caused Treace Medical to suffer irreparable injury that is not adequately compensated for by remedies available at law. The balance of hardships between the parties warrant a remedy in equity and the public interest would not be disserved by a permanent injunction.

465. Treace Medical is entitled to recover damages that would place Treace Medical as close as possible to the same financial position that it would have been in had Stryker’s and

Wright's infringement of the '387 Patent not occurred. Treace Medical is entitled to recover damages including all profits that it has lost as a result of Stryker's and Wright's promotion and sale of the LapiFuse™ System and component products. At a minimum, Treace Medical is entitled to a reasonable royalty on Stryker's and Wright's promotion and sales of the LapiFuse™ System and component products.

466. Treace Medical requests pursuant to 35 U.S.C. § 284 that damages awarded to it in this matter for Stryker's and Wright's willful infringement of the '387 Patent be increased to three times the amount found or assessed by the fact finder.

COUNT VIII
INFRINGEMENT OF U.S. PATENT NO. 11,911,085 BY LAPIFUSE™ SYSTEM
(Against Stryker Corp. and Wright Medical Tech., Inc.)

467. Treace Medical incorporates by reference Paragraphs 1-466 of this Complaint.

468. On February 27, 2024, the USPTO issued U.S. Patent Number 11,911,085 B2 ("**the '085 Patent**") to Treace Medical, listing inventors Robert D. Santrock, Paul Dayton, Daniel J. Hatch, W. Bret Smith, F. Barry Bays, Carlos Eduardo Gil, Sean F. Scanlan, Joe W. Ferguson, and John T. Treace. The '085 Patent is titled "Bone Positioning and Preparing Guide Systems and Methods" and is directed to "[a] method of correcting a bunion deformity." A true and correct copy of the '085 Patent is attached to this Complaint as **Exhibit 16**. The '085 Patent remains in force and is assigned to Treace Medical. Treace Medical has owned the '085 Patent since it was issued and still owns the '085 Patent.

469. The '085 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

470. Stryker and Wright have made, used, offered for sale, sold, and/or imported into the United States medical instruments and implants used in performing bunion surgery. These medical instruments and implants are offered by Stryker and Wright for the performance of the

ORTHOLOC™ 2 LapiFuse™ Triplanar Correction System. The LapiFuse instruments and implants are identified in Stryker's and Wright's LapiFuse Video and LapiFuse Brochure, as detailed above.

471. Attached to this Complaint as **Exhibit 17** is a claim chart explaining how Stryker and Wright describe through the LapiFuse Video and LapiFuse Brochure the performance of the steps of exemplary claim 1 of the '085 Patent using the LapiFuse™ System and thereby instruct and encourage surgeons to perform the method of claim 1 and other claims of the '085 Patent ("**the '085 Claimed Method**"). On information and belief, Stryker and Wright continue to instruct and encourage surgeons to perform the '085 Claimed Method. On information and belief, Stryker and Wright have not instructed surgeons to perform the LapiFuse™ Procedure using the LapiFuse™ System in a non-infringing manner. The LapiFuse™ System has no substantial non-infringing uses.

Direct Infringement of the '085 Patent

472. On information and belief, Stryker and Wright have directly infringed and continue to directly infringe, both literally and/or under the doctrine of equivalents, the '085 Patent by using (*e.g.*, by performing actual or simulated surgical procedures) the LapiFuse™ System to perform the patented surgical method of the '085 Patent in the United States in violation of 35 U.S.C. § 271(a), including within this judicial district, in a manner that infringes at least claim 1 of the '085 Patent without a license from Treace Medical.

473. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the LapiFuse Video and LapiFuse Brochure using the LapiFuse™ System directly infringe the '085 Patent.

474. On information and belief, surgeon consultants to Stryker and Wright, working at Stryker's or Wright's direction, tested and performed the '085 Claimed Method using the

LapiFuse™ System on Stryker's and Wright's behalf as part of developing the LapiFuse™ System and Procedure.

475. In addition, surgeon consultants to Stryker and Wright, working at Stryker's or Wright's direction, perform the '085 Claimed Method using the LapiFuse™ System as part of surgeon education.

476. Stryker and Wright have created at least the LapiFuse Video and LapiFuse Brochure showing the LapiFuse™ System being used to perform the LapiFuse™ Procedure and thereby performing the '085 Claimed Method. On information and belief, surgeons working on Stryker's or Wright's behalf and at Stryker's or Wright's direction, performed the '085 Claimed Method using the LapiFuse™ System in connection with creating the LapiFuse Brochure, which demonstrates performance of the '085 Claimed Method using the LapiFuse™ System.

477. Stryker and Wright also direct and/or control surgeons to perform the '085 Claimed Method using the LapiFuse™ System because, among other things, Stryker and Wright condition receipt of benefits to surgeons on their performance of one or more steps of the '085 Claimed Method, and establish that performance by, among other things, providing detailed instructions concerning the use of the LapiFuse™ System that, if not followed, will deprive the surgeons of the benefits they hope to obtain from the LapiFuse™ System and performing one or more steps of the '085 Claimed Method. For example, Stryker and Wright advertise surgeons on their websites who, on information and belief, use the LapiFuse™ System as Stryker and Wright instruct in the LapiFuse Video and LapiFuse Brochure to perform the '085 Claimed Method. On information and belief, the Stryker and/or Wright representative present in the operating room for each LapiFuse™ Procedure monitors and directs the surgeon and will only provide the surgeon

components of the LapiFuse™ System if the surgeon performs one or more steps of the '085 Claimed Method.

Induced Infringement of the '085 Patent

478. On information and belief, Stryker and Wright have induced and continue to induce infringement of the '085 Claimed Method in violation of 35 U.S.C. § 271(b).

479. Stryker and Wright have provided materials to hospitals and surgeons that demonstrate using the LapiFuse™ System to perform the '085 Claimed Method. For example, the LapiFuse Video and LapiFuse Brochure instruct, encourage, and assist surgeons to use the LapiFuse™ System in a manner that directly infringes the claims of the '085 Patent. On information and belief, Stryker and Wright sales staff, surgical site representatives, consulting surgeons, and public and non-public instructional materials similarly instruct and encourage surgeons to use the LapiFuse™ System in a manner that directly infringes the claims of the '085 Patent as depicted and described above and in Exhibit 17. On information and belief, Stryker and Wright distributed these materials to hospitals and surgeons with the intent to cause surgeons to use the LapiFuse™ System and Procedure to perform the '085 Claimed Method. Stryker and/or Wright representatives present in the operating room for each LapiFuse™ Procedure monitor surgeons' performance of the LapiFuse™ Procedure and, on information and belief, direct them to use the LapiFuse™ System for the LapiFuse™ Procedure to infringe the claims of the '085 Patent.

480. On information and belief, Stryker and Wright have provided such instructions and encouragement despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the '085 Patent and the resulting infringement thereof by surgeons Stryker and Wright so instructed.

481. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The '085 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® System and Procedure heading.

482. To the extent Stryker and Wright contend that they did not know of the '085 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '085 Patent and that the acts Stryker and Wright actively induced constituted infringement of the '085 Patent. On information and belief, Stryker and Wright at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; Treace Medical's substantial publicity regarding its patent portfolio; and Stryker's patent attorneys' citation to a patent in the same family as the '085 Patent as prior art to a Stryker patent application.

483. On information and belief, Stryker and Wright know that their surgeon customers and surgeon consultants are performing the '085 Claimed Method using the LapiFuse™ System and Procedure and are directly infringing the '085 Claimed Method.

484. Stryker's and Wright's inducing acts, such as distribution of the LapiFuse Video, LapiFuse Brochure, and other instructional materials, to promote and demonstrate the LapiFuse™ System and Procedure, and instructing and encouraging surgeons to use the LapiFuse™ System

in a manner consistent with that Procedure described above and in Exhibit 17, caused and are causing surgeons to use the LapiFuse™ System and Procedure in a manner that infringes the '085 Claimed Method.

Contributory Infringement of the '085 Patent

485. On information and belief, Stryker and Wright have contributorily infringed the '085 Claimed Method in violation of 35 U.S.C. § 271(c).

486. Stryker and Wright have made, used, offered for sale, sold, and/or imported into the United States medical instruments and implants used in performing the infringing LapiFuse™ Procedure, including at least the LapiFuse Clamp, tissue removing instruments, and implants.

487. On information and belief, surgeons have performed and are performing the LapiFuse™ Procedure using the LapiFuse™ System as instructed, assisted, and encouraged by Stryker and Wright in at least the LapiFuse Video and LapiFuse Brochure and by Stryker's and Wright's sales staff, surgical representatives, and surgeon consultants, thereby directly infringing the '085 Claimed Method.

488. On information and belief, Stryker and Wright had actual knowledge of the '085 Patent and Treace Medical's infringement allegations at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint.

489. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because of Treace Medical's virtual marking through its internet website at https://www.treace.com/patents. The '085 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® System and Procedure heading.

490. To the extent Stryker and Wright contend that they did not know of the '085 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '085 Patent and that the LapiFuse™ System is especially made or especially adapted for use

in an infringement of the ’085 Patent. On information and belief, Stryker and Wright at least subjectively believed that a high probability existed that Treace Medical’s Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical’s known status as the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker’s and Wright’s attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; Treace Medical’s substantial publicity regarding its patent portfolio; and Stryker’s patent attorneys’ citation to a patent in the same family as the ’085 Patent as prior art to a Stryker patent application.

491. Components of the LapiFuse™ System including at least the LapiFuse Clamp, tissue removing instruments, and implants are material components for use in practicing the ’085 Claimed Method. These components are especially made for use in a manner that infringes the ’085 Claimed Method. The LapiFuse™ System components are not staple articles or commodities of commerce suitable for substantial non-infringing uses. For example, the only known use of the LapiFuse Clamp is for the infringing uses as described above and in Exhibit 17. Further, the implants (bone plates and screws) include “LapiFuse” or “Ortholoc 3Di” in their product name, and the tissue removing instruments are sold in a “LapiFuse” joint preparation kit.

492. On information and belief, Stryker and Wright have provided materials to hospitals and surgeons, including the LapiFuse Video and LapiFuse Brochure, demonstrating the use of the LapiFuse™ System to perform the ’085 Claimed Method. The distribution of these materials further shows that Stryker and Wright especially made the LapiFuse™ System to perform the ’085 Claimed Method. Stryker and/or Wright representatives present in the operating room for each

LapiFuse™ Procedure monitor surgeons' performance of the LapiFuse™ Procedure and, on information and belief, direct them to use the LapiFuse™ System for the LapiFuse™ Procedure to infringe the claims of the '085 Patent.

493. On information and belief, at least as of the date of the filing and service of this Complaint, Stryker and Wright have known that the LapiFuse™ System (including the LapiFuse Clamp, tissue removing instruments, and implants) were especially made for use in a manner that infringes the '085 Claimed Method and were directly infringing the '085 Claimed Method.

494. On information and belief, surgeons have in fact used and continue to use the LapiFuse™ System and Procedure in a manner that infringes the '085 Claimed Method.

Willful Infringement of the '085 Patent

495. Stryker and Wright have willfully infringed the '085 Claimed Method.

496. On information and belief, Stryker and Wright have infringed and continue to infringe the '085 Claimed Method with knowledge of Treace Medical's rights in the '085 Patent.

497. On information and belief, Stryker's and Wright's acts of infringement of the '085 Claimed Method have been and continue to be willful, deliberate, and egregious.

498. On information and belief, Stryker and Wright acted despite an objectively high likelihood that their actions constituted infringement of a valid patent claim and knew or should have known of this objectively defined risk of infringement.

Requested Relief for Stryker's and Wright's Infringement of the '085 Patent

499. Stryker's and Wright's misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters a permanent injunction prohibiting Stryker, Wright, and those acting on their behalf from infringing the '085 Patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the LapiFuse™ System for performing the '085 Claimed

Method. Stryker's and Wright's misconduct has caused Treace Medical to suffer irreparable injury that is not adequately compensated for by remedies available at law. The balance of hardships between the parties warrant a remedy in equity and the public interest would not be disserved by a permanent injunction.

500. Treace Medical is entitled to recover damages that would place Treace Medical as close as possible to the same financial position that it would have been in had Stryker's and Wright's infringement of the '085 Patent not occurred. Treace Medical is entitled to recover damages including all profits that it has lost as a result of Stryker's and Wright's sale of the LapiFuse™ System, and the products used in the performance of instrumented TMT bunion correction procedures using the LapiFuse™ System. At a minimum, Treace Medical is entitled to a reasonable royalty on Stryker's and Wright's sales of the LapiFuse™ System and products used in the performance and practicing of the patented instrumented TMT bunion correction procedures using the LapiFuse™ System.

501. Treace Medical requests pursuant to 35 U.S.C. § 284 that damages awarded to it in this matter for Stryker's and Wright's willful infringement of the '085 Patent be increased to three times the amount found or assessed by the fact finder.

COUNT IX
INFRINGEMENT OF U.S. PATENT NO. 11,911,085 BY PROSTEP® LAPIDUS SYSTEM
(Against Stryker Corp.)

502. Treace Medical incorporates by reference Paragraphs 1-501 of this Complaint.

503. As stated above in Count VIII, the USPTO issued the '085 Patent to Treace Medical on February 27, 2024, a copy of which is attached as Exhibit 16.

504. The '085 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

505. Stryker has made, used, offered for sale, sold, and/or imported into the United States medical instruments and implants used in performing bunion surgery. These medical instruments and implants are offered by Stryker for the performance of Stryker's PROstep® MIS Lapidus System. The PROstep instruments and implants are identified in Stryker's PROstep Operative Technique Brochure and PROstep Video, as detailed above.

506. Attached to this Complaint as **Exhibit 18** is a claim chart explaining how Stryker details through the PROstep Brochure and PROstep Video the performance of the steps of exemplary claim 1 of the '085 Patent using the PROstep® Lapidus System and thereby instructs and encourages surgeons to perform the method of claim 1 and other claims of the '085 Patent ("the '085 Claimed Method"). On information and belief, Stryker continues to instruct and encourage surgeons to perform the '085 Claimed Method. On information and belief, Stryker has not instructed surgeons to perform the PROstep® Lapidus Procedure in a non-infringing manner. The PROstep® Lapidus System has no substantial non-infringing uses.

Direct Infringement of the '085 Patent

507. On information and belief, Stryker has directly infringed and continues to directly infringe, both literally and/or under the doctrine of equivalents, the '085 Patent by using (*e.g.*, by performing actual or simulated surgical procedures) the PROstep® Lapidus System to perform the patented surgical method of the '085 Patent in the United States in violation of 35 U.S.C. § 271(a), including within this judicial district, in a manner that infringes at least claim 1 of the '085 Patent without a license from Treace Medical.

508. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by Stryker through, for example, the PROstep Brochure and PROstep Video and using the PROstep® Lapidus System directly infringe the '085 Patent.

509. In addition, surgeon consultants to Stryker, working at Stryker's direction, perform the '085 Claimed Method using the PROstep® Lapidus System as part of surgeon education related to Stryker's PROstep® Lapidus System.

510. Stryker has created at least the PROstep Brochure and PROstep Video showing the PROstep® Lapidus System being used to perform the PROstep® Lapidus Procedure and thereby performing the '085 Claimed Method. On information and belief, surgeons working on Stryker's behalf and at Stryker's direction, performed the '085 Claimed Method using the PROstep® Lapidus System in connection with creating the PROstep Brochure, which demonstrates performance of the '085 Claimed Method using the PROstep® Lapidus System.

511. Stryker also directs and/or controls surgeons to perform the '085 Claimed Method using the PROstep® Lapidus System because, among other things, Stryker conditions receipt of benefits to surgeons on their performance of one or more steps of the '085 Claimed Method, and establishes that performance by, among other things, providing detailed instructions concerning the use of the PROstep® Lapidus System that, if not followed, will deprive the surgeons of the benefits they hope to obtain from the PROstep® Lapidus System and performing one or more steps of the '085 Claimed Method. For example, Stryker advertises surgeons on their website who, on information and belief, use the PROstep® Lapidus System as Stryker instructs in the PROstep Brochure and PROstep Video to perform the '085 Claimed Method. On information and belief, the Stryker representative present in the operating room for each PROstep® Lapidus Procedure monitors and directs the surgeon and will only provide the surgeon components of the PROstep® Lapidus System if the surgeon performs one or more steps of the '085 Claimed Method.

Induced Infringement of the '085 Patent

512. On information and belief, Stryker has induced and continues to induce infringement of the '085 Claimed Method in violation of 35 U.S.C. § 271(b).

513. Stryker has provided materials to hospitals and surgeons that demonstrate using the PROstep® Lapidus System to perform the ’085 Claimed Method. For example, Stryker’s PROstep Brochure and PROstep Video instruct, encourage, and assist surgeons to use the PROstep® Lapidus System in a manner that directly infringes the claims of the ’085 Patent. On information and belief, Stryker sales staff, surgical site representatives, consulting surgeons, and public and non-public instructional materials similarly instruct and encourage surgeons to use the PROstep® Lapidus System in a manner that directly infringes the claims of the ’085 Patent as depicted and described above and in Exhibit 18. On information and belief, Stryker distributed these materials to hospitals and surgeons with the intent to cause surgeons to use the PROstep® Lapidus System and Procedure to perform the ’085 Claimed Method. Stryker representatives present in the operating room for each PROstep® Lapidus Procedure monitor surgeons’ performance of the PROstep® Lapidus Procedure and, on information and belief, direct them to use the PROstep® Lapidus System for the PROstep® Lapidus Procedure to infringe the claims of the ’085 Patent.

514. On information and belief, Stryker has provided such instructions and encouragement despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the ’085 Patent and the resulting infringement thereof by surgeons Stryker so instructed.

515. Stryker at a minimum had constructive knowledge of Treace Medical’s patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The ’085 Patent is listed on Treace Medical’s patent marking webpage under the Lapiplasty® System and Procedure heading.

516. To the extent Stryker contends that it did not know of the ’085 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the

'085 Patent and that the acts Stryker actively induced constituted infringement of the '085 Patent. On information and belief, Stryker at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker's attendance and participation at industry conferences (*e.g.*, AOFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker presented its infringing PROstep® Lapidus System; Treace Medical's substantial publicity regarding its patent portfolio; and Stryker's patent attorneys' citation to a patent in the same family as the '085 Patent as prior art to a Stryker patent application.

517. On information and belief, Stryker knows that its surgeon customers and surgeon consultants are performing the '085 Claimed Method using the PROstep® Lapidus System and Procedure and are directly infringing the '085 Claimed Method.

518. Stryker's inducing acts, such as distribution of the PROstep Brochure and PROstep Video and other instructional materials and instruction, encouragement, and direction and assistance of surgeons by its sales staff, surgical site representatives, and consulting surgeons, to promote and demonstrate the PROstep® Lapidus System and Procedure as described above in Exhibit 18, caused and are causing surgeons to use the PROstep® Lapidus System and Procedure in a manner that infringes the '085 Claimed Method.

Contributory Infringement of the '085 Patent

519. On information and belief, Stryker has contributorily infringed the '085 Claimed Method in violation of 35 U.S.C. § 271(c).

520. Stryker has made, used, offered for sale, sold, and/or imported into the United States medical instruments and implants used in performing the infringing PROstep® Lapidus

Procedure, including at least components of the PROstep MIS Lapidus Consumables Kit, the PROstep MIS Lapidus Instrument Kit (such as the Reduction Clamp), and implants.

521. On information and belief, surgeons have performed and are performing the PROstep® Lapidus Procedure using the PROstep® Lapidus System as instructed, assisted, and encouraged by Stryker in at least the PROstep Brochure and PROstep Video and by Stryker's sales staff, surgical site representatives, and surgeon consultants, thereby directly infringing the '085 Claimed Method.

522. On information and belief, Stryker had actual knowledge of the '085 Patent and Treace Medical's infringement allegations at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint.

523. Stryker at a minimum had constructive knowledge of Treace Medical's patent rights because of Treace Medical's virtual marking through its internet website at https://www.treace.com/patents. The '085 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® System and Procedure heading.

524. To the extent Stryker contends that it did not know of the '085 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '085 Patent and that the PROstep® System is especially made or especially adapted for use in an infringement of the '085 Patent. On information and belief, Stryker at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker's attendance and participation at industry conferences (*e.g.*, AOFAS) where Treace Medical displayed and

discussed the Lapiplasty® System and where Stryker presented its infringing PROstep® Lapidus System; Treace Medical's substantial publicity regarding its patent portfolio; and Stryker's patent attorneys' citation to a patent in the same family as the '085 Patent as prior art to a Stryker patent application.

525. Components of the PROstep® Lapidus System including at least components of the PROstep MIS Lapidus Consumables Kit, the PROstep MIS Lapidus Instrument Kit (such as the Reduction Clamp), and certain implants are material components for use in practicing the '085 Claimed Method. These components are especially made for use in a manner that infringes the '085 Claimed Method. Stryker's PROstep® Lapidus System components are not staple articles or commodities of commerce suitable for substantial non-infringing uses. For example, the only known use of the PROstep Reduction Clamp is for the infringing uses as described above and in Exhibit 18. Further, the tissue removing instruments are sold in a "PROstep MIS Lapidus Consumables Kit."

526. On information and belief, Stryker has provided materials to hospitals and surgeons, including the PROstep Brochure and PROstep Video, and provided other surgeon demonstration and instruction, demonstrating the use of the PROstep® Lapidus System to perform the '085 Claimed Method. The distribution of these materials further shows that Stryker especially made the PROstep® Lapidus System to perform the '085 Claimed Method. Stryker representatives present in the operating room for each PROstep® Lapidus Procedure monitor surgeons' performance of the PROstep® Lapidus Procedure and, on information and belief, direct them to use the PROstep® Lapidus System for the PROstep® Lapidus Procedure to infringe the claims of the '085 Patent.

527. On information and belief, at least as of the date of the filing and service of this Complaint, Stryker has known that the PROstep® Lapidus System (including the Reduction Clamp, tissue removing instruments, and implants) were especially made for use in a manner that infringes the ’085 Claimed Method and were directly infringing the ’085 Claimed Method.

528. On information and belief, surgeons have in fact used and continue to use the PROstep® Lapidus System and Procedure in a manner that infringes the ’085 Claimed Method.

Willful Infringement of the ’085 Patent

529. Stryker has willfully infringed the ’085 Claimed Method.

530. On information and belief, Stryker has infringed and continues to infringe the ’085 Claimed Method with knowledge of Treace Medical’s rights in the ’085 Patent.

531. On information and belief, Stryker’s acts of infringement of the ’085 Claimed Method have been and continue to be willful, deliberate, and egregious.

532. On information and belief, Stryker acted despite an objectively high likelihood that its actions constituted infringement of a valid patent claim and knew or should have known of this objectively defined risk of infringement.

Requested Relief for Stryker’s Infringement of the ’085 Patent

533. Stryker’s misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters a permanent injunction prohibiting Stryker and those acting on its behalf from infringing the ’085 Patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the PROstep® Lapidus System for performing the ’085 Claimed Method. Stryker’s misconduct has caused Treace Medical to suffer irreparable injury that is not adequately compensated for by remedies available at law. The balance of hardships between the parties

warrant a remedy in equity and the public interest would not be disserved by a permanent injunction.

534. Treace Medical is entitled to recover damages that would place Treace Medical as close as possible to the same financial position that it would have been in had Stryker's infringement of the '085 Patent not occurred. Treace Medical is entitled to recover damages including all profits that it has lost as a result of Stryker's sale of the PROstep® Lapidus System and the products used in the performance of instrumented TMT bunion correction procedures using the PROstep® Lapidus System. At a minimum, Treace Medical is entitled to a reasonable royalty on Stryker's sales of the PROstep® Lapidus System, and products used in the performance and practicing of the patented instrumented TMT bunion correction procedures using the PROstep® Lapidus System.

535. Treace Medical requests pursuant to 35 U.S.C. § 284 that damages awarded to it in this matter for Stryker's willful infringement of the '085 Patent be increased to three times the amount found or assessed by the fact finder.

COUNT X
INFRINGEMENT OF U.S. PATENT NO. 11,937,849 BY LAPIFUSE™ SYSTEM
(Against Stryker Corp. and Wright Medical Tech., Inc.)

536. Treace Medical incorporates by reference Paragraphs 1-535 of this Complaint.

537. On March 26, 2024, the USPTO issued U.S. Patent Number 11,937,849 B2 ("**the '849 Patent**") to Treace Medical, listing inventors Paul Dayton and F. Barry Bays. The '849 Patent is titled "Bone Positioning and Cutting System and Method" and is directed to "[a] method of performing a bunion surgery to correct an alignment between a first metatarsal and a first cuneiform." A true and correct copy of the '849 Patent is attached to this Complaint as **Exhibit 19**. The '849 Patent remains in force and is assigned to Treace Medical. Treace Medical has owned the '849 Patent since it was issued and still owns the '849 Patent.

538. The ’849 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

539. Stryker and Wright have made, used, offered for sale, sold, and/or imported into the United States medical instruments and implants used in performing bunion surgery. These medical instruments and implants are offered by Stryker and Wright for the performance of the ORTHOLOC™ 2 LapiFuse™ Triplanar Correction System. The LapiFuse instruments and implants are identified in Stryker and Wright’s LapiFuse Video, LapiFuse Brochure, and LapiFuse Surgeon Presentation, as detailed above.

540. Attached to this Complaint as **Exhibit 20** is a claim chart explaining how Stryker and Wright describe through the LapiFuse Video, LapiFuse Brochure, and LapiFuse Surgeon Presentation the performance of the steps of exemplary claim 1 of the ’849 Patent using the LapiFuse™ System and thereby instruct and encourage surgeons to perform the method of claim 1 and other claims of the ’849 Patent (“**the ’849 Claimed Method**”). On information and belief, Stryker and Wright continue to instruct and encourage surgeons to perform the ’849 Claimed Method. On information and belief, Stryker and Wright have not instructed surgeons to perform the LapiFuse™ Procedure using the LapiFuse™ System in a non-infringing manner. The LapiFuse™ System has no substantial non-infringing uses.

Direct Infringement of the ’849 Patent

541. On information and belief, Stryker and Wright have directly infringed and continue to directly infringe, both literally and/or under the doctrine of equivalents, the ’849 Patent by using (*e.g.*, by performing actual or simulated surgical procedures) the LapiFuse™ System, including a cut guide, to perform the patented surgical method of the ’849 Patent in the United States in violation of 35 U.S.C. § 271(a), including within this judicial district, in a manner that infringes at least claim 1 of the ’849 Patent without a license from Treace Medical.

542. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the LapiFuse Video, LapiFuse Brochure, and LapiFuse Surgeon Presentation using the LapiFuse™ System directly infringe the '849 Patent.

543. On information and belief, surgeon consultants to Stryker and Wright, working at Stryker's or Wright's direction, tested and performed the '849 Claimed Method using the LapiFuse™ System on Stryker's and Wright's behalf as part of developing the LapiFuse™ System and Procedure.

544. In addition, surgeon consultants to Stryker and Wright, working at Stryker's or Wright's direction, perform the '849 Claimed Method using the LapiFuse™ System as part of surgeon education.

545. Stryker and Wright have created at least the LapiFuse Video, LapiFuse Brochure, and LapiFuse Surgeon Presentation showing the LapiFuse™ System being used to perform the LapiFuse™ Procedure and thereby performing the '849 Claimed Method. On information and belief, surgeons working on Stryker's or Wright's behalf and at Stryker's or Wright's direction, performed the '849 Claimed Method using the LapiFuse™ System in connection with creating the LapiFuse Brochure and LapiFuse Surgeon Presentation, which demonstrate performance of the '849 Claimed Method using the LapiFuse™ System.

546. Stryker and Wright also direct and/or control surgeons to perform the '849 Claimed Method using the LapiFuse™ System because, among other things, Stryker and Wright condition receipt of benefits to surgeons on their performance of one or more steps of the '849 Claimed Method, and establish that performance by, among other things, providing detailed instructions concerning the use of the LapiFuse™ System that, if not followed, will deprive the surgeons of the benefits they hope to obtain from the LapiFuse™ System and performing one or more steps of

the ’849 Claimed Method. For example, Stryker and Wright advertise surgeons on their websites who, on information and belief, use the LapiFuse™ System as Stryker and Wright instruct in the LapiFuse Video, LapiFuse Brochure, and LapiFuse Surgeon Presentation to perform the ’849 Claimed Method. On information and belief, the Stryker and/or Wright representative present in the operating room for each LapiFuse™ Procedure monitors and directs the surgeon and will only provide the surgeon components of the LapiFuse™ System if the surgeon performs one or more steps of the ’849 Claimed Method.

Induced Infringement of the ’849 Patent

547. On information and belief, Stryker and Wright have induced and continue to induce infringement of the ’849 Claimed Method in violation of 35 U.S.C. § 271(b).

548. Stryker and Wright have provided materials to hospitals and surgeons that demonstrate using the LapiFuse™ System to perform the ’849 Claimed Method. For example, the LapiFuse Video, LapiFuse Brochure, and LapiFuse Surgeon Presentation instruct, encourage, and assist surgeons to use the LapiFuse™ System, including a cut guide, in a manner that directly infringes the claims of the ’849 Patent. On information and belief, Stryker and Wright sales staff, surgical site representatives, consulting surgeons, and public and non-public instructional materials similarly instruct and encourage surgeons to use the LapiFuse™ System, including a cut guide, in a manner that directly infringes the claims of the ’849 Patent as depicted and described above and in Exhibit 20. On information and belief, Stryker and Wright distributed these materials to hospitals and surgeons with the intent to cause surgeons to use the LapiFuse™ System and Procedure to perform the ’849 Claimed Method. Stryker and/or Wright representatives present in the operating room for each LapiFuse™ Procedure monitor surgeons’ performance of the LapiFuse™ Procedure and, on information and belief, direct them to use the LapiFuse™ System, including a cut guide, for the LapiFuse™ Procedure to infringe the claims of the ’849 Patent.

549. On information and belief, Stryker and Wright have provided such instructions and encouragement despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the '849 Patent and the resulting infringement thereof by surgeons Stryker and Wright so instructed.

550. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The '849 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® System and Procedure heading.

551. To the extent Stryker and Wright contend that they did not know of the '849 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '849 Patent and that the acts Stryker and Wright actively induced constituted infringement of the '849 Patent. On information and belief, Stryker and Wright at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; and Treace Medical's substantial publicity regarding its patent portfolio.

552. On information and belief, Stryker and Wright know that their surgeon customers and surgeon consultants are performing the '849 Claimed Method using the LapiFuse™ System and Procedure, including a cut guide, and are directly infringing the '849 Claimed Method.

553. Stryker's and Wright's inducing acts, such as distribution of the LapiFuse Video, LapiFuse Brochure, LapiFuse Surgeon Presentation, and other instructional materials, to promote and demonstrate the LapiFuse™ System and Procedure, and instructing and encouraging surgeons to use the LapiFuse™ System in a manner consistent with that Procedure described above and in Exhibit 20, caused and are causing surgeons to use the LapiFuse™ System and Procedure in a manner that infringes the '849 Claimed Method.

Contributory Infringement of the '849 Patent

554. On information and belief, Stryker and Wright have contributorily infringed the '849 Claimed Method in violation of 35 U.S.C. § 271(c).

555. Stryker and Wright have made, used, offered for sale, sold, and/or imported into the United States medical instruments and implants used in performing the infringing LapiFuse™ Procedure, including at least the LapiFuse cut guide, LapiFuse Clamp, tissue removing instruments, and implants.

556. On information and belief, surgeons have performed and are performing the LapiFuse™ Procedure using the LapiFuse™ System as instructed, assisted, and encouraged by Stryker and Wright in at least the LapiFuse Video, LapiFuse Brochure, and LapiFuse Surgeon Presentation and by Stryker's and Wright's sales staff, surgical representatives, and surgeon consultants, thereby directly infringing the '849 Claimed Method.

557. On information and belief, Stryker and Wright had actual knowledge of the '849 Patent and Treace Medical's infringement allegations at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint.

558. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because of Treace Medical's virtual marking through its internet website at

https://www.treace.com/patents. The '849 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® System and Procedure heading.

559. To the extent Stryker and Wright contend that they did not know of the '849 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '849 Patent and that the LapiFuse™ System components are especially made or especially adapted for use in an infringement of the '849 Patent. On information and belief, Stryker and Wright at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; and Treace Medical's substantial publicity regarding its patent portfolio.

560. Components of the LapiFuse™ System including at least the LapiFuse cut guide, LapiFuse Clamp, tissue removing instruments, and implants are material components for use in practicing the '849 Claimed Method. These components are especially made for use in a manner that infringes the '849 Claimed Method. The LapiFuse™ System components are not staple articles or commodities of commerce suitable for substantial non-infringing uses. For example, the only known use of the LapiFuse cut guide and LapiFuse Clamp are for the infringing uses as described above and in Exhibit 20. Further, the implants (bone plates and screws) include "LapiFuse" or "Ortholoc 3Di" in their product name, and the tissue removing instruments are sold in a "LapiFuse" joint preparation kit.

561. On information and belief, Stryker and Wright have provided materials to hospitals and surgeons, including the LapiFuse Video, LapiFuse Brochure, and LapiFuse Surgeon Presentation, demonstrating the use of the LapiFuse™ System to perform the '849 Claimed Method. The distribution of these materials further shows that Stryker and Wright especially made the LapiFuse™ System to perform the '849 Claimed Method. Stryker and/or Wright representatives present in the operating room for each LapiFuse™ Procedure monitor surgeons' performance of the LapiFuse™ Procedure and, on information and belief, direct them to use the LapiFuse™ System for the LapiFuse™ Procedure, including the cut guide, to infringe the claims of the '849 Patent.

562. On information and belief, at least as of the date of the filing and service of this Complaint, Stryker and Wright have known that the LapiFuse™ System (including the LapiFuse cut guide, LapiFuse Clamp, tissue removing instruments, and implants) were especially made for use in a manner that infringes the '849 Claimed Method and were directly infringing the '849 Claimed Method.

563. On information and belief, surgeons have in fact used and continue to use the LapiFuse™ System and Procedure in a manner that infringes the '849 Claimed Method.

Willful Infringement of the '849 Patent

564. Stryker and Wright have willfully infringed the '849 Claimed Method.

565. On information and belief, Stryker and Wright have infringed and continue to infringe the '849 Claimed Method with knowledge of Treace Medical's rights in the '849 Patent.

566. On information and belief, Stryker's and Wright's acts of infringement of the '849 Claimed Method have been and continue to be willful, deliberate, and egregious.

567. On information and belief, Stryker and Wright acted despite an objectively high likelihood that their actions constituted infringement of a valid patent claim and knew or should have known of this objectively defined risk of infringement.

Requested Relief for Stryker's and Wright's Infringement of the '849 Patent

568. Stryker's and Wright's misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters a permanent injunction prohibiting Stryker, Wright, and those acting on their behalf from infringing the '849 Patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the LapiFuse™ System for performing the '849 Claimed Method. Stryker's and Wright's misconduct has caused Treace Medical to suffer irreparable injury that is not adequately compensated for by remedies available at law. The balance of hardships between the parties warrant a remedy in equity and the public interest would not be disserved by a permanent injunction.

569. Treace Medical is entitled to recover damages that would place Treace Medical as close as possible to the same financial position that it would have been in had Stryker's and Wright's infringement of the '849 Patent not occurred. Treace Medical is entitled to recover damages including all profits that it has lost as a result of Stryker's and Wright's sale of the LapiFuse™ System, and the products used in the performance of instrumented TMT bunion correction procedures using the LapiFuse™ System. At a minimum, Treace Medical is entitled to a reasonable royalty on Stryker's and Wright's sales of the LapiFuse™ System and products used in the performance and practicing of the patented instrumented TMT bunion correction procedures using the LapiFuse™ System.

570. Treace Medical requests pursuant to 35 U.S.C. § 284 that damages awarded to it in this matter for Stryker's and Wright's willful infringement of the '849 Patent be increased to three times the amount found or assessed by the fact finder.

COUNT XI
INFRINGEMENT OF U.S. PATENT NO. 11,950,819 BY LAPIFUSE™ SYSTEM
(Against Stryker Corp. and Wright Medical Tech., Inc.)

571. Treace Medical incorporates by reference Paragraphs 1-570 of this Complaint.

572. On April 9, 2024, the USPTO issued U.S. Patent Number 11,950,819 B2 ("**the '819 Patent**") to Treace Medical, listing inventors W. Bret Smith, Paul Dayton, Sean F. Scanlan, F. Barry Bays, Carlos Eduardo Gil, John T. Treace, Robert D. Santrock, Daniel J. Hatch, and Joe W. Ferguson. The '819 Patent is titled "Bone Positioning Guide" and is directed to "[a] bone positioning system." A true and correct copy of the '819 Patent is attached to this Complaint as **Exhibit 21**. The '819 Patent remains in force and is assigned to Treace Medical. Treace Medical has owned the '819 Patent since it was issued and still owns the '819 Patent.

573. The '819 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

574. Stryker and Wright have made, used, offered for sale, sold, and/or imported into the United States the ORTHOLOC™ 2 LapiFuse™ Triplanar Correction System. The LapiFuse™ System is exemplified in Stryker's and Wright's LapiFuse Video and LapiFuse Brochure, as detailed above.

575. Attached to this Complaint as **Exhibit 22** is a claim chart explaining how the LapiFuse™ System meets the elements of exemplary claim 13 of the '819 Patent. The LapiFuse™ System has no substantial non-infringing uses.

Direct Infringement of the '819 Patent

576. On information and belief, Stryker and Wright have directly infringed and continue to directly infringe, both literally and/or under the doctrine of equivalents, the '819 Patent by making, selling, offering for sale, and/or using (*e.g.*, by performing actual or simulated surgical procedures using) the LapiFuse™ System in the United States in violation of 35 U.S.C. § 271(a), including within this judicial district, in a manner that infringes at least claim 13 of the '819 Patent without a license from Treace Medical.

577. Stryker and Wright also direct and/or control surgeons to infringe the '819 Patent with the LapiFuse™ System because, among other things, Stryker and Wright condition receipt of benefits to surgeons on assembly and use of a system that infringes the '819 Patent, and establish that assembly and use by, among other things, providing detailed instructions concerning the assembly and use of the LapiFuse™ System that, if not followed, will deprive the surgeons of the benefits they hope to obtain from the LapiFuse™ System and assembly and use of a device that infringes the '819 Patent. For example, Stryker and Wright advertise surgeons on their websites who, on information and belief, assemble and use the LapiFuse™ System as Stryker and Wright instruct in the LapiFuse Video and LapiFuse Brochure to infringe the '819 Patent. On information and belief, the Stryker and/or Wright representative present in the operating room for each LapiFuse™ Procedure monitors and directs the surgeon and will only provide the surgeon components of the LapiFuse™ System if the surgeon assembles and uses components of the LapiFuse™ System as provided by the '819 Patent.

Induced Infringement of the '819 Patent

578. On information and belief, Stryker and Wright have induced and continue to induce infringement of the '819 Patent in violation of 35 U.S.C. § 271(b).

579. The LapiFuse Video and LapiFuse Brochure instruct, encourage, and assist surgeons to assemble and use the LapiFuse™ System in a manner that directly infringes the claims of the '819 Patent. On information and belief, Stryker and Wright sales staff, surgical site representatives, consulting surgeons, and public and non-public instructional materials similarly instruct and encourage surgeons to assemble and use the LapiFuse™ System in a manner that directly infringes the claims of the '819 Patent as depicted and described above and in Exhibit 22. Stryker and/or Wright representatives present in the operating room for each LapiFuse™ Procedure monitor surgeons' use of the LapiFuse™ System and, on information and belief, direct them to assemble and use the LapiFuse™ System to infringe the claims of the '819 Patent.

580. On information and belief, Stryker and Wright have provided such instructions and encouragement despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the '819 Patent and the resulting infringement thereof by surgeons Stryker and Wright so instructed.

581. Stryker and Wright at a minimum had constructive knowledge of Treace Medical's patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The '819 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® System and Procedure heading.

582. To the extent Stryker and Wright contend that they did not know of the '819 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '819 Patent and that the acts Stryker and Wright actively induced constituted infringement of the '819 Patent. On information and belief, Stryker and Wright at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as

the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; Treace Medical's substantial publicity regarding its patent portfolio; and Stryker's attorneys' citation to a patent in the same family as the '819 Patent as prior art to a Stryker patent application.

583. On information and belief, Stryker and Wright have continued to distribute materials, including the LapiFuse Video, to demonstrate the infringing assembly and use of the LapiFuse™ System. Continued distribution of these materials further shows that the LapiFuse™ System is especially made to infringe the '819 Patent.

584. On information and belief, Stryker and Wright know that their surgeon customers and surgeon consultants are performing bunion correction procedures using the LapiFuse™ System and are directly infringing the claims of the '819 Patent.

585. Stryker's and Wright's inducing acts, such as distribution of the LapiFuse Video, LapiFuse Brochure, and other instructional materials, to promote and demonstrate the LapiFuse™ System, and instructing and encouraging surgeons to assemble and use the LapiFuse™ System in a manner consistent with that Procedure described above and in Exhibit 22, caused and are causing surgeons to assemble and use the LapiFuse™ System in a manner that infringes the claims of the '819 Patent.

Contributory Infringement of the '819 Patent

586. On information and belief, Stryker and Wright have contributorily infringed the '819 Patent in violation of 35 U.S.C. § 271(c).

587. Stryker and Wright have offered for sale, sold, and/or imported into the United States medical instruments and implants used as part of the LapiFuse™ System, including at least the LapiFuse Clamp, tissue removing instruments, and implants. These products constitute components of a system covered by the ’819 Patent.

588. On information and belief, surgeons are assembling and using the LapiFuse™ System as instructed, assisted, and encouraged by Stryker and Wright in at least the LapiFuse Video and LapiFuse Brochure and by Stryker’s and Wright’s sales staff, surgical site representatives, and surgeon consultants, thereby directly infringing the claims of the ’819 Patent.

589. On information and belief, Stryker and Wright have provided components of a patented system despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the ’819 Patent and the resulting infringement thereof by surgeons Stryker and Wright so instructed.

590. Stryker and Wright at a minimum had constructive knowledge of Treace Medical’s patent rights because of Treace Medical’s virtual marking through its internet website at https://www.treace.com/patents. The ’819 Patent is listed on Treace Medical’s patent marking webpage under the Lapiplasty® System and Procedure heading.

591. To the extent Stryker and Wright contend that they did not know of the ’819 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the ’819 Patent and that the LapiFuse™ System components are especially made or especially adapted for use in an infringement of the ’819 Patent. On information and belief, Stryker and Wright at least subjectively believed that a high probability existed that Treace Medical’s Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical’s known status as the inventor of Instrumented TMT Bunion Systems;

[redacted]; Stryker's and Wright's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker and Wright presented their infringing LapiFuse™ System; Treace Medical's substantial publicity regarding its patent portfolio; and Stryker's attorneys' citation to a patent in the same family as the '819 Patent as prior art to a Stryker patent application.

592. Components of the LapiFuse™ System including at least the LapiFuse Clamp, tissue removing instruments, and implants are material components for use in the system claimed in the '819 Patent. These components are especially made for use in a manner that infringes the system claimed of '819 Patent. The LapiFuse™ System components are not staple articles or commodities of commerce suitable for substantial non-infringing uses. For example, the only known use of the LapiFuse Clamp is for the infringing uses in a system as described above and in Exhibit 22. Further, the implants (bone plates and screws) include "LapiFuse" or "Ortholoc 3Di" in their product name, and the tissue removing instruments are sold in a "LapiFuse" joint preparation kit.

593. On information and belief, Stryker and Wright have provided materials to hospitals and surgeons, including the LapiFuse Video and LapiFuse Brochure, demonstrating the infringing use of the LapiFuse™ System. The distribution of these materials further shows that Stryker and Wright especially made the LapiFuse™ System to infringe the '819 Patent. Stryker and/or Wright representatives present in the operating room for each LapiFuse™ Procedure monitor surgeons' use of the LapiFuse™ System and, on information and belief, direct them to assemble and use the LapiFuse™ System to infringe the claims of the '819 Patent.

594. On information and belief, at a date prior to the filing of this Complaint and at least as of the date of the filing and service of this Complaint, Stryker and Wright have known that the LapiFuse™ System (including the LapiFuse Clamp, tissue removing instruments, and implants) were especially made for use in a manner that infringes the ’819 Patent and were directly infringing the ’819 Patent.

595. On information and belief, surgeons have in fact used and continue to use the LapiFuse™ System, thereby infringing the ’819 Patent.

Willful Infringement of the ’819 Patent

596. Stryker and Wright have willfully infringed the ’819 Patent.

597. On information and belief, Stryker and Wright have infringed and continue to infringe the ’819 Patent with knowledge of Treace Medical’s rights in the ’819 Patent.

598. On information and belief, Stryker’s and Wright’s acts of infringement of the ’819 Patent have been and continue to be willful, deliberate, and egregious.

599. On information and belief, Stryker and Wright acted despite an objectively high likelihood that their actions constituted infringement of a valid patent claim and knew or should have known of this objectively defined risk of infringement.

Requested Relief for Stryker’s and Wright’s Infringement of the ’819 Patent

600. Stryker’s and Wright’s misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters a permanent injunction prohibiting Stryker, Wright, and those acting on their behalf from infringing the ’819 Patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the LapiFuse™ System. Stryker’s and Wright’s misconduct has caused Treace Medical to suffer irreparable injury that is not adequately compensated for by

remedies available at law. The balance of hardships between the parties warrant a remedy in equity and the public interest would not be disserved by a permanent injunction.

601. Treace Medical is entitled to recover damages that would place Treace Medical as close as possible to the same financial position that it would have been in had Stryker's and Wright's infringement of the '819 Patent not occurred. Treace Medical is entitled to recover damages including all profits that it has lost as a result of Stryker's and Wright's promotion and sale of the LapiFuse™ System and component products. At a minimum, Treace Medical is entitled to a reasonable royalty on Stryker's and Wright's promotion and sales of the LapiFuse™ System and component products.

602. Treace Medical requests pursuant to 35 U.S.C. § 284 that damages awarded to it in this matter for Stryker's and Wright's willful infringement of the '819 Patent be increased to three times the amount found or assessed by the fact finder.

COUNT XII
INFRINGEMENT OF U.S. PATENT NO. 11,950,819 BY PROSTEP® LAPIDUS SYSTEM
(Against Stryker Corp.)

603. Treace Medical incorporates by reference Paragraphs 1-602 of this Complaint.

604. As stated above in Count XI, the USPTO issued the '819 Patent to Treace Medical on April 9, 2024, a copy of which is attached as Exhibit 21.

605. The '819 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

606. Stryker has made, used, offered for sale, sold, and/or imported into the United States the PROstep® MIS Lapidus System. The PROstep® Lapidus System is exemplified in Stryker's PROstep Operative Technique Brochure and PROstep Video, as detailed above.

607. Attached to this Complaint as **Exhibit 23** is a claim chart explaining how the PROstep® Lapidus System meets the elements of exemplary claim 13 of the ’819 Patent. The PROstep® Lapidus System has no substantial non-infringing uses.

Direct Infringement of the ’819 Patent

608. On information and belief, Stryker has directly infringed and continues to directly infringe, both literally and/or under the doctrine of equivalents, the ’819 Patent by making, selling, offering for sale, and/or using (*e.g.*, by performing actual or simulated surgical procedures using) the PROstep® Lapidus System in the United States in violation of 35 U.S.C. § 271(a), including within this judicial district, in a manner that infringes at least claim 13 of the ’819 Patent without a license from Treace Medical.

Induced Infringement of the ’819 Patent

609. On information and belief, Stryker has induced and continue to induce infringement of the ’819 Patent in violation of 35 U.S.C. § 271(b).

610. The PROstep Brochure and PROstep Video instruct, encourage, and assist surgeons to use the PROstep® Lapidus System in a manner that directly infringes the claims of the ’819 Patent. On information and belief, Stryker sales staff, surgical site representatives, consulting surgeons, and public and non-public instructional materials similarly instruct and encourage surgeons to use the PROstep® Lapidus System in a manner that directly infringes the claims of the ’819 Patent as depicted and described above and in Exhibit 23.

611. On information and belief, Stryker has provided such instructions and encouragement despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the ’819 Patent and the resulting infringement thereof by surgeons Stryker so instructed.

612. Stryker at a minimum had constructive knowledge of Treace Medical's patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The '819 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® System and Procedure heading.

613. To the extent Stryker contends that they did not know of the '819 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '819 Patent and that the acts Stryker actively induced constituted infringement of the '819 Patent. On information and belief, Stryker at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted]; Stryker's attendance and participation at industry conferences (*e.g.*, AOFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker presented its infringing PROstep® Lapidus System; Treace Medical's substantial publicity regarding its patent portfolio; and Stryker's attorneys' citation to a patent in the same family as the '819 Patent as prior art to a Stryker patent application.

614. On information and belief, Stryker has continued to distribute materials, including the PROstep Brochure, to demonstrate the infringing use of the PROstep® Lapidus System. Continued distribution of these materials further shows that the PROstep® Lapidus System is especially made to infringe the '819 Patent.

615. On information and belief, Stryker knows that its surgeon customers and surgeon consultants are performing bunion correction procedures using the PROstep® Lapidus System and are directly infringing the claims of the '819 Patent.

616. Stryker's inducing acts, such as distribution of the PROstep Brochure, PROstep Video, and other instructional materials, to promote and demonstrate the PROstep® Lapidus System, and instructing and encouraging surgeons to use the LapiFuse™ System in a manner described above and in Exhibit 23, caused and are causing surgeons to use the PROstep® Lapidus System in a manner that infringes the claims of the '819 Patent.

Contributory Infringement of the '819 Patent

617. On information and belief, Stryker has contributorily infringed the '819 Patent in violation of 35 U.S.C. § 271(c).

618. Stryker has offered for sale, sold, and/or imported into the United States medical instruments and implants used as part of the PROstep® Lapidus System, including at least the Reduction Clamp, tissue removing instruments, and implants. These products constitute components of a system covered by the '819 Patent.

619. On information and belief, surgeons are using the PROstep® Lapidus System as instructed, assisted, and encouraged by Stryker in at least the PROstep Brochure and PROstep Video and by Stryker's sales staff, surgical representatives, and surgeon consultants, thereby directly infringing the claims of the '819 Patent.

620. On information and belief, Stryker has provided components of a patented system despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the '819 Patent and the resulting infringement thereof by surgeons Stryker so instructed.

621. Stryker at a minimum had constructive knowledge of Treace Medical's patent rights because of Treace Medical's virtual marking through its internet website at https://www.treace.com/patents. The '819 Patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® System and Procedure heading.

622. To the extent Stryker contends that they did not know of the '819 Patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '819 Patent and that the PROstep® System components are especially made or especially adapted for use in an infringement of the '819 Patent. On information and belief, Stryker at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; [redacted] Stryker's attendance and participation at industry conferences (*e.g.*, AOFAS) where Treace Medical displayed and discussed the Lapiplasty® System and where Stryker presented its infringing PROstep® Lapidus System; Treace Medical's substantial publicity regarding its patent portfolio; and Stryker's attorneys' citation to a patent in the same family as the '819 Patent as prior art to a Stryker patent application.

623. Components of the PROstep® Lapidus System including at least the Reduction Clamp, tissue removing instruments, and implants are material components for use in the system claimed in the '819 Patent. These components are especially made for use in a manner that infringes the system claimed of '819 Patent. The PROstep® Lapidus System components are not staple articles or commodities of commerce suitable for substantial non-infringing uses. For example, the only known use of the Reduction Clamp is for the infringing uses in a system as described above and in Exhibit 23. Further, the tissue removing instruments are sold in a "PROstep MIS Lapidus Consumables Kit."

624. On information and belief, Stryker has provided materials to hospitals and surgeons, including the PROstep Brochure and PROstep Video, demonstrating the infringing use

of the PROstep® Lapidus System. The distribution of these materials further shows that Stryker especially made the PROstep® Lapidus System to infringe the '819 Patent.

625. On information and belief, at least as of the date of the filing and service of this Complaint, Stryker has known that the PROstep® Lapidus System (including the Reduction Clamp, tissue removing instruments, and implants) were especially made for use in a manner that infringes the '819 Patent and were directly infringing the '819 Patent.

626. On information and belief, surgeons have in fact used and continue to use the PROstep® Lapidus System, thereby infringing the '819 Patent.

Willful Infringement of the '819 Patent

627. Stryker has willfully infringed the '819 Patent.

628. On information and belief, Stryker has infringed and continues to infringe the '819 Patent with knowledge of Treace Medical's rights in the '819 Patent.

629. On information and belief, Stryker's acts of infringement of the '819 Patent have been and continue to be willful, deliberate, and egregious.

630. On information and belief, Stryker acted despite an objectively high likelihood that its actions constituted infringement of a valid patent claim and knew or should have known of this objectively defined risk of infringement.

Requested Relief for Stryker's Infringement of the '819 Patent

631. Stryker's misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters a permanent injunction prohibiting Stryker and those acting on its behalf from infringing the '819 Patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the PROstep® Lapidus System. Stryker's misconduct has caused Treace Medical to suffer irreparable injury that is not adequately compensated for by remedies available at law. The

balance of hardships between the parties warrant a remedy in equity and the public interest would not be disserved by a permanent injunction.

632. Treace Medical is entitled to recover damages that would place Treace Medical as close as possible to the same financial position that it would have been in had Stryker's infringement of the '819 Patent not occurred. Treace Medical is entitled to recover damages including all profits that it has lost as a result of Stryker's promotion and sale of the PROstep® Lapidus System and component products. At a minimum, Treace Medical is entitled to a reasonable royalty on Stryker's promotion and sales of the PROstep® Lapidus System and component products.

633. Treace Medical requests pursuant to 35 U.S.C. § 284 that damages awarded to it in this matter for Stryker's willful infringement of the '819 Patent be increased to three times the amount found or assessed by the fact finder.

COUNT XIII
VIOLATIONS OF SECTION 1 OF THE SHERMAN ACT
(Against Stryker Corp.)

634. Treace Medical incorporates by reference Paragraphs 1-633 of this Complaint.

635. For purposes of antitrust review, there exist relevant markets in the United States for the sale of medical devices for (1) the trauma service line; and (2) TMT Bunion Systems.

636. Stryker has a dominant position in the trauma service line market, as one of the two primary suppliers in a highly concentrated market, and as one of only two *de facto* suppliers for the entire service line. Its position in this market is protected by high barriers to entry and expansion.

637. As detailed and pleaded in this Complaint, Stryker has engaged in exclusive dealing and entered into anticompetitive agreements with IDNs through bundled service line agreements for its trauma service line, including unlawful bundling of products within the trauma service line

with TMT Bunion Systems, which are not trauma products and which have not traditionally been subject to bundled service line agreements and bundled rebates by virtue of being new products and being in the foot and ankle space. Requirements of these trauma service line bundling agreements, such as the required percentage of purchases to achieve substantial rebates, effectively require hospitals to purchase all or nearly all their TMT Bunion System needs from Stryker for extended periods of time.

638. As detailed and pleaded in this Complaint, Stryker has engaged in anticompetitive bundling whereby it conditions discounts and rebates in its trauma service line on the purchase of TMT Bunion Systems, which are not trauma systems, and which have not traditionally been subject to bundled service line agreements and bundled rebates by virtue of being new products and being in the foot and ankle space. The quantities and revenue of TMT Bunion Systems are much smaller than the quantities and revenue of the overall trauma bundle, and in most cases likely less than the trauma rebate. Competitors cannot profitably offer TMT Bunion Systems when competing with the trauma bundle because the exclusionary rebate on the trauma bundle far exceeds any reduction in price that could be available from an equally efficient competitor. Stryker is thus selling its TMT Bunion Systems below its average variable costs, after allocating the exclusionary rebate given by Stryker on the entire trauma bundle to the TMT Bunion Systems.

639. Stryker has a dominant position in the trauma service line. Stryker has used this dominance to coerce its customers into buying TMT Bunion Systems as part of the trauma bundle, rather than allowing customers the option of purchasing TMT Bunion Systems in a competitive process based on factors such as price, features, quality, clinical data, service, and training. Stryker has conditioned the sale and servicing of its trauma service line on customers buying TMT Bunion Systems with that service line, based on coercive rebates that effectively prohibit purchasing of

TMT Bunion Systems from competitors, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. This tying arrangement has anticompetitive effects in the market for TMT Bunion Systems.

640. Stryker's anticompetitive acts involve a substantial amount of interstate commerce, and unlawfully restrain trade by excluding equally and more efficient competitors from the TMT Bunion Market. Stryker's bundling substantially forecloses competition both with respect to cost and the choice of, and access to, better surgical devices. This is to the detriment of health insurers, and ultimately consumers, in the form of higher effective prices paid for lower quality surgical devices, which ultimately contributes to higher insurance costs.

641. Through its agreements and arrangements, Stryker has succeeded in restraining trade by foreclosing a substantial portion of the TMT Bunion Market, causing demonstrable harm to competition in the TMT Bunion Market, as pleaded in detail above. Stryker has foreclosed competition in a substantial portion of the above-pleaded market and as more trauma contracts come up for renewal or bid, has the potential to foreclose 50% or more of the TMT Bunion Market.

642. Stryker's anticompetitive practices, as pleaded above, have distorted and undermined the competitive process and do not further any legitimate or pro-competitive purpose. Any purported legitimate or pro-competitive purpose could have been achieved without Stryker's anticompetitive practices and by less restrictive means that would not have the same anticompetitive effects. Stryker's anticompetitive practices cause harm to hospitals and surgical centers that are coerced into purchasing inferior products at effectively higher prices, surgeons who are deprived of choice to provide the best results to patients, patients who are denied access to the latest innovations in TMT bunion care, and the health care ecosystem generally where public and insurance dollars are spent inefficiently while IDNs chase substantial trauma rebates.

643. Stryker's anticompetitive conduct has caused harm to Treace Medical's business, property, reputation, and ability to compete on price and product, which harm will continue unless Stryker's anticompetitive conduct is enjoined. Indeed, if Stryker's conduct is not enjoined, it will expand its anticompetitive conduct significantly as more contracts come up for renewal and its bundling of non-trauma products with trauma products is normalized. Treace Medical has lost and will lose tens to hundreds of millions of dollars in sales and profits for Instrumented TMT Bunion Systems that it would have received but for Stryker's anticompetitive conduct. Treace Medical's injuries are of the type that antitrust laws are intended to prohibit, and flow directly from Stryker's anticompetitive conduct in violation of Section 1 of the Sherman Act.

644. By so acting, Stryker has employed trade practices that constitute unlawful restraints of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

645. Without injunctive relief, Stryker will continue to restrain trade in the market for TMT Bunion Systems, harming health care facilities, surgeons, and patients, and excluding rivals from a substantial portion of the TMT Bunion Market.

COUNT XIV
VIOLATIONS OF SECTION 3 OF THE CLAYTON ACT
(Against Stryker Corp.)

646. Treace Medical incorporates by reference Paragraphs 1-645 of this Complaint.

647. For purposes of antitrust review, there exist relevant markets in the United States for the sale of medical devices for (1) the trauma service line; and (2) TMT Bunion Systems.

648. Stryker has a dominant position in the trauma service line market, as one of the two primary suppliers in a highly concentrated market, and as one of only two *de facto* suppliers for the entire service line. Its position in this market is protected by high barriers to entry and expansion.

649. As detailed and pleaded in this Complaint, Stryker has engaged in exclusive dealing and entered into anticompetitive agreements with IDNs through bundled service line agreements for its trauma service line, including bundling of products within the trauma service line and additionally bundling trauma products with TMT Bunion Systems, which are not trauma systems and which have not traditionally been subject to bundled service line agreements and bundled rebates by virtue of being new products and being in the foot and ankle space. Requirements of these trauma service line bundling agreements, such as the required percentage of purchases to achieve substantial rebates, effectively require hospitals to purchase all or nearly all their TMT Bunion Systems from Stryker for extended periods of time.

650. As detailed and pleaded in this Complaint, Stryker has engaged in predatory pricing through anticompetitive bundling whereby it conditions discounts and rebates in its trauma service line on the purchase of TMT Bunion Systems, which are not trauma systems, and which have not traditionally been subject to bundled service line agreements and bundled rebates by virtue of being new products and being in the foot and ankle space. The quantities and revenue of TMT Bunion Systems are much smaller than the quantities and revenue of the overall trauma bundle, and in most cases likely less than the trauma rebate. Competitors cannot profitably offer TMT Bunion Systems when competing with the trauma bundle because the exclusionary discount on the trauma bundle far exceeds any reduction in price that could be available from an equally efficient competitor. Stryker is thus selling its TMT Bunion Systems below its average variable costs, after allocating the exclusionary rebate given by Stryker on the entire trauma bundle to the TMT Bunion Systems.

651. Stryker has a dominant position within the trauma service line. Stryker has engaged in tying by using this dominance to coerce its customers into buying TMT Bunion Systems as part

of the trauma bundle, rather than allowing customers the option of purchasing TMT Bunion Systems in a competitive process based on factors such as price, features, quality, and training. Stryker has conditioned the sale and servicing of its trauma service line on customers buying TMT Bunion Systems with the trauma service line, based on coercive rebates that effectively prohibit purchasing of TMT Bunion Systems from a competitor, in violation of Section 3 of the Clayton Act, 15 U.S.C. § 14. This tying arrangement has anticompetitive effects in the market for TMT Bunion Systems.

652. Stryker's anticompetitive acts involve a substantial amount of interstate commerce, and unlawfully restrain trade by excluding equally and more efficient competitors from the TMT Bunion Market. Stryker's bundling substantially forecloses competition both with respect to cost and the choice of, and access to, better surgical devices. This is to the detriment of health insurers, and ultimately consumers, in the form of higher effective prices paid for lower quality surgical devices, which contributes to higher insurance costs that result in some patients being uninsured and unable to afford life-changing procedures.

653. Through its agreements and arrangements, Stryker has succeeded in restraining trade by foreclosing a substantial portion of the TMT Bunion Market, causing demonstrable harm to competition in the TMT Bunion Market, as pleaded in detail above. Stryker has foreclosed competition in a substantial portion of the above-pleaded market, and as more trauma contracts come up for renewal or bid, has the potential to foreclose 50% or more of the TMT Bunion Market.

654. Stryker's anticompetitive practices, as pleaded above, have distorted and undermined the competitive process and do not further any legitimate or pro-competitive purpose. Any purported legitimate or pro-competitive purpose could have been achieved without Stryker's anticompetitive practices and by less restrictive means that would not have the same

anticompetitive effects. Stryker's anticompetitive practices cause harm to hospitals that are coerced into purchasing inferior products at effectively higher prices, surgeons who are deprived of choice to provide the best results to patients, patients who are denied access to the latest innovations in TMT bunion care, and the health care ecosystem generally where public and insurance dollars are spent inefficiently while IDNs chase substantial trauma rebates.

655. Stryker's anticompetitive conduct has caused harm to Treace Medical's business, property, reputation, and ability to compete on price and product, which harm will continue unless Stryker's anticompetitive conduct is enjoined. Indeed, if Stryker's conduct is not enjoined it will expand its anticompetitive conduct significantly as more contracts come up for renewal and its bundling of non-trauma products with trauma products is normalized. Treace Medical has lost and will lose tens to hundreds of millions of dollars in sales and profits for TMT Bunion Systems that it would have received but for Stryker's anticompetitive conduct. Treace Medical's injuries are of the type that antitrust laws are intended to prohibit, and flow directly from Stryker's anticompetitive conduct.

656. By so acting, Stryker has employed trade practices that violated Section 3 of the Clayton Act, 15 U.S.C. § 14.

657. Without injunctive relief, Stryker will continue to restrain trade in the market for TMT Bunion Systems, harming health care facilities, surgeons, and patients, and excluding rivals from a substantial portion of the TMT Bunion Market.

COUNT XV
UNLAWFUL RESTRAINT OF TRADE UNDER THE NEW JERSEY ANTITRUST ACT
(Against Stryker Corp.)

658. Treace Medical incorporates by reference Paragraphs 1-657 of this Complaint.

659. For purposes of antitrust review, there exist relevant markets in the United States for the sale of medical devices for (1) the trauma service line; and (2) TMT Bunion Systems.

660. Stryker has a dominant position within the trauma service line, as one of the two primary suppliers in a highly concentrated market, and as one of only two *de facto* suppliers for the entire service line. Its position in this market is protected by high barriers to entry and expansion.

661. As discussed above, Stryker has engaged in exclusive dealing and entered into anticompetitive agreements with IDNs through bundled service line agreements for its trauma service line, including unlawful bundling of products within the trauma service line with TMT Bunion Systems, which are not trauma products and which have not traditionally been subject to bundled service line agreements and bundled rebates by virtue of being new products and being in the foot and ankle space. Requirements of these trauma service line bundling agreements, such as the required percentage of purchases to achieve substantial rebates, effectively require hospitals to purchase all or nearly all their TMT Bunion needs from Stryker for extended periods of time.

662. Through its agreements and arrangements, Stryker has succeeded in restraining trade by foreclosing a substantial portion of the TMT Bunion Market, causing demonstrable harm to competition in the TMT Bunion Market, as pleaded in detail above. Stryker has foreclosed competition in a substantial portion of the above-pleaded market and as more trauma contracts come up for renewal or bid, has the potential to foreclose 50% or more of the TMT Bunion Market.

663. Stryker's anticompetitive practices, as pleaded above, have distorted and undermined the competitive process and do not further any legitimate or pro-competitive purpose. Any purported legitimate or pro-competitive purpose could have been achieved without Stryker's anticompetitive practices and by less restrictive means that would not have the same anticompetitive effects. Stryker's anticompetitive practices cause harm to hospitals and surgical centers that are coerced into purchasing inferior products at effectively higher prices, surgeons

who are deprived of choice to provide the best results to patients, patients who are denied access to the latest innovations in TMT bunion care, and the health care ecosystem generally where public and insurance dollars are spent inefficiently while IDNs chase substantial trauma rebates.

664. Stryker's anticompetitive conduct has caused harm to Treace Medical's business, property, reputation, and ability to compete on price and product, which harm will continue unless Stryker's anticompetitive conduct is enjoined. Indeed, if Stryker's conduct is not enjoined it will expand its anticompetitive conduct significantly as more contracts come up for renewal and its bundling of non-trauma products with trauma products is normalized. Treace Medical has lost and will lose tens to hundreds of millions of dollars in sales and profits for TMT Bunion Systems that it would have received but for Stryker's anticompetitive conduct. Treace Medical's injuries are of the type that antitrust laws are intended to prohibit, and flow directly from Stryker's anticompetitive conduct in violation of the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9–3.

665. Without injunctive relief, Stryker will continue to restrain trade in the market for TMT Bunion Systems, harming health care facilities, surgeons, and patients, and excluding rivals from a substantial portion of the TMT Bunion Market.

666. By so acting, Stryker has employed trade practices that constitute unlawful restraints of trade in violation of the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9–3.

COUNT XVI
UNLAWFUL INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE
(Against Stryker Corp.)

667. Treace Medical incorporates by reference Paragraphs 1-666 of this Complaint.

668. Treace Medical had a reasonable expectation of economic advantage and benefit from marketing and selling Lapiplasty® Systems in the TMT Bunion Market and from entering into agreements with hospitals and surgical centers within IDNs. In addition, Treace Medical had a reasonable expectation of economic advantage and benefit from capturing a material share of the

TMT Bunion Market, since the Lapiplasty® System is the most complete and innovative product in the TMT Bunion Market as proven in 24 studies and papers. The Lapiplasty® System performs better and is of higher quality than the Stryker TMT Bunion Systems. Treace Medical invested in training the relevant surgeon population and has over 3,000 surgeons actively using the Lapiplasty® System. Treace Medical has also driven patient demand for TMT Bunion Procedures through patient education and visibility campaigns.

669. Among others, Stryker has interfered with at least the following prospective customers of Treace Medical: Ascension Health, Cleveland Clinic, Intermountain Health Care, and Lovelace Health System.

670. Stryker knew that Treace Medical had a reasonable expectation of economic advantage and benefit through business relations with health care systems. Without justification, Stryker intentionally and wrongfully interfered with Treace Medical's expected economic advantage and benefit by, among other things, engaging in the anticompetitive conduct discussed above; targeting specific IDNs where surgeons were using the Lapiplasty® System under agreements with IDNs or where Treace Medical had contracts or was bidding on contracts; monitoring Treace Medical procedures to enlist IDN staff to push the bundled Stryker products; and deceptively promising illusory discounts to induce hospitals to exclude the Lapiplasty® System. Stryker intentionally took such measures to restrain hospitals from purchasing the Lapiplasty® System, thus, effectively excluding Treace Medical from larger portions of the TMT Bunion Market.

671. As a direct result of Stryker's intentional and wrongful interference, IDNs have decreased their usage of the Lapiplasty® System or have been dissuaded from using the

Lapiplasty® System, thereby damaging Treace Medical's expected economic advantage and benefit.

672. But for Stryker's interference, there was a reasonable probability that Treace Medical would receive the economic advantage and benefits resulting from its sale of the Lapiplasty® System in the TMT Bunion Market and would thereafter capture a substantial share of the TMT Bunion Market within IDNs.

673. Stryker had no adequate justification to interfere with Treace Medical's economic advantage and benefit. Stryker's conduct is outrageous and against the public interest because Stryker acted with malice and/or reckless indifference to the rights of others.

674. Stryker's interference with Treace Medical's economic advantage and benefit has caused and will continue to cause Treace Medical to suffer damages, including lost profits and other damages.

675. Stryker's acts of unlawful interference will continue unless restrained by this Court.

676. Treace Medical is entitled to injunctive relief and such other relief as this cause of action allows.

JURY DEMAND

677. Pursuant to Federal Rule of Civil Procedure 38(b), Treace Medical hereby requests a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Treace Medical Concepts, Inc. prays for the following relief against Stryker Corporation and Wright Medical Technology, Inc.:

1. For judgment in favor of Treace Medical that Stryker Corporation and Wright Medical Technology, Inc. have infringed and are infringing United States Patent Nos. 9,622,805;

10,874,446; 11,039,873; 11,116,558; 11,602,386; 11,602,387; 11,911,085; 11,937,849; and 11,950,819, both directly and indirectly;

2. For a permanent injunction prohibiting Stryker Corporation and Wright Medical Technology, Inc., including their officers, agents, employees, and all persons acting in concert or participation with them, from committing further acts of infringement of United States Patent Nos. 9,622,805; 10,874,446; 11,039,873; 11,116,558; 11,602,386; 11,602,387; 11,911,085; 11,937,849; and 11,950,819;

3. For an award of damages for Stryker Corporation's and Wright Medical Technology, Inc.'s infringement of United States Patent Nos. 9,622,805; 10,874,446; 11,039,873; 11,116,558; 11,602,386; 11,602,387; 11,911,085; 11,937,849; and 11,950,819 in the amount of Treace Medical's lost profits associated with Stryker Corporation's and Wright Medical Technology, Inc.'s sale of the accused systems, together with interest (both pre- and post-judgment), costs and disbursements as fixed by this Court under 35 U.S.C. § 284;

4. For an award of damages for Stryker Corporation's and Wright Medical Technology, Inc.'s infringement of United States Patent Nos. 9,622,805; 10,874,446; 11,039,873; 11,116,558; 11,602,386; 11,602,387; 11,911,085; 11,937,849; and 11,950,819 in the amount of at least a reasonable royalty, together with interest (both pre- and post-judgment), costs and disbursements as fixed by this Court under 35 U.S.C. § 284;

5. For a determination that Stryker Corporation's and Wright Medical Technology, Inc.'s infringement of United States Patent Nos. 9,622,805; 10,874,446; 11,039,873; 11,116,558; 11,602,386; 11,602,387; 11,911,085; 11,937,849; and 11,950,819 has been and is willful;

6. For an award of enhanced damages under 35 U.S.C. § 284;

7. For a determination that this is an exceptional case within the meaning of 35 U.S.C. § 285;

8. For a declaration that Stryker Corporation has violated § 1 of the Sherman Act, § 3 of the Clayton Act, engaged in unlawful restraint of trade under New Jersey's Antitrust Act, and engaged in tortious interference;

9. For damages in an amount to be determined at trial and trebled pursuant to 15 U.S.C. § 15(a) and the New Jersey Antitrust Act;

10. For injunctive relief pursuant to 15 U.S.C. § 26 and the New Jersey Antitrust Act;

11. For an award to Treace Medical of its costs and reasonable attorneys' fees;

12. For an accounting for damages;

13. For an award of pre-judgment and post-judgment interest; and

14. For such other and further relief in law or in equity to which Treace Medical may be justly entitled.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, Treace Medical, by its undersigned counsel, hereby certifies that the matter in controversy is not subject to any other action pending in any court, or any pending arbitration or administrative proceeding.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Treace Medical, by its undersigned counsel, hereby certifies that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: October 14, 2024

s/ Rebekah R. Conroy

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