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23 Attorneys for Plaintiff

24 UNITED STATES DISTRICT COURT

25 DISTRICT OF ARIZONA

26 Treace Medical Concepts, Inc.,

27 Plaintiff,

28 vs.

Fusion Orthopedics, LLC,

Defendant.

No.

**COMPLAINT FOR PATENT  
INFRINGEMENT, TRADEMARK  
INFRINGEMENT, UNFAIR  
COMPETITION AND COPYRIGHT  
INFRINGEMENT**

1 Plaintiff, Treace Medical Concepts, Inc. (“**Treace Medical**”), by its attorneys,  
2 brings this Complaint against defendants Fusion Orthopedics, LLC (“**Fusion**”). Treace  
3 Medical alleges as follows:

4 **NATURE OF THE ACTION**

5 1. This is a civil action arising out of Fusion’s: (a) patent infringement in  
6 violation of the Patent Laws of the United States, 35 U.S.C. §§ 271 and 281-285; (b)  
7 trademark infringement under 15 U.S.C. § 1114(a); (c) federal unfair competition; (d)  
8 common law trademark infringement and unfair competition, and (e) federal copyright  
9 infringement under 17 U.S.C. § 101, et seq.

10 **THE PARTIES**

11 2. Treace Medical is a Delaware corporation having its principal place of  
12 business at 203 Fort Wade Rd., Suite 150, Ponte Vedra, Florida, 32081.

13 3. On information and belief, Fusion is an Arizona limited liability company  
14 having its principal place of business at 4135 S. Power Rd., Ste. 118, Mesa, Arizona,  
15 85212.

16 **JURISDICTION AND VENUE**

17 4. This Court has subject matter jurisdiction over Treace Medical’s patent  
18 infringement claims under 28 U.S.C. § 1331 and 1338(a).

19 5. This Court has subject matter jurisdiction over Treace Medical’s federal  
20 trademark infringement claim under 15 U.S.C. § 1121(a), and under 28 U.S.C. §§ 1331  
21 and 1338.

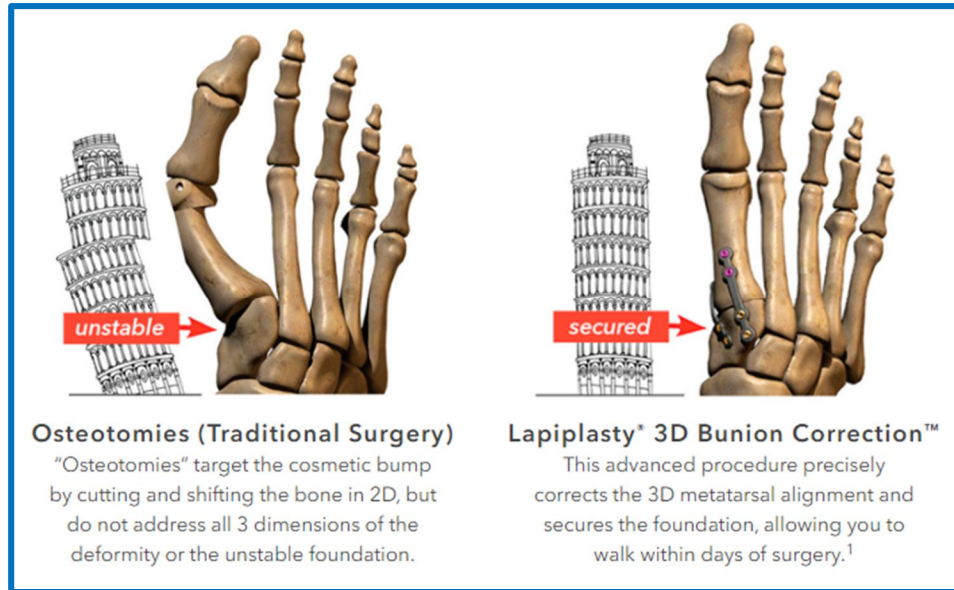
22 6. This Court has subject matter jurisdiction over Treace Medical’s common  
23 law trademark and unfair competition claims under 15 U.S.C. § 1121(a) and under 28  
24 U.S.C. §§ 1331 and 1338(b).

25 7. This Court has subject matter jurisdiction over Treace Medical's federal  
26 copyright infringement claim under 28 U.S.C. §§ 1331 and 1338(a).

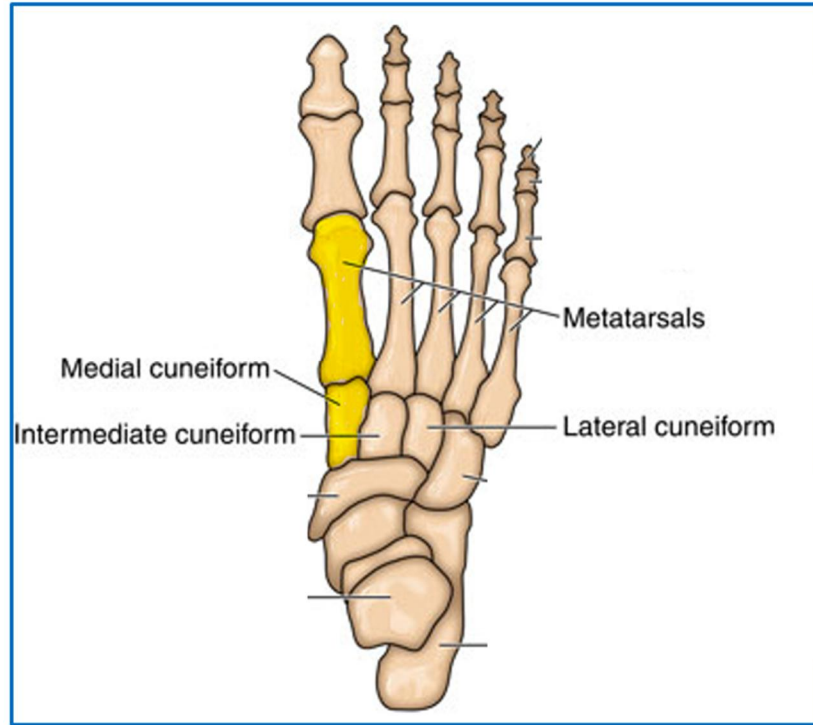


1 cuneiform-metatarsal joint. Treace Medical's procedure allows patients to walk in a  
2 surgical boot within days of the surgery.

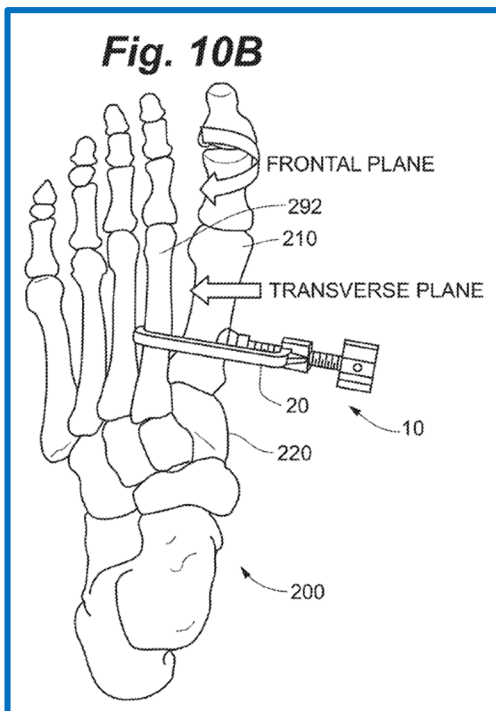
3 14. A simplified comparison of traditional bunion surgery with Treace Medical's  
4 LAPIPLASTY® 3D Bunion Correction™ surgical procedure is shown below:



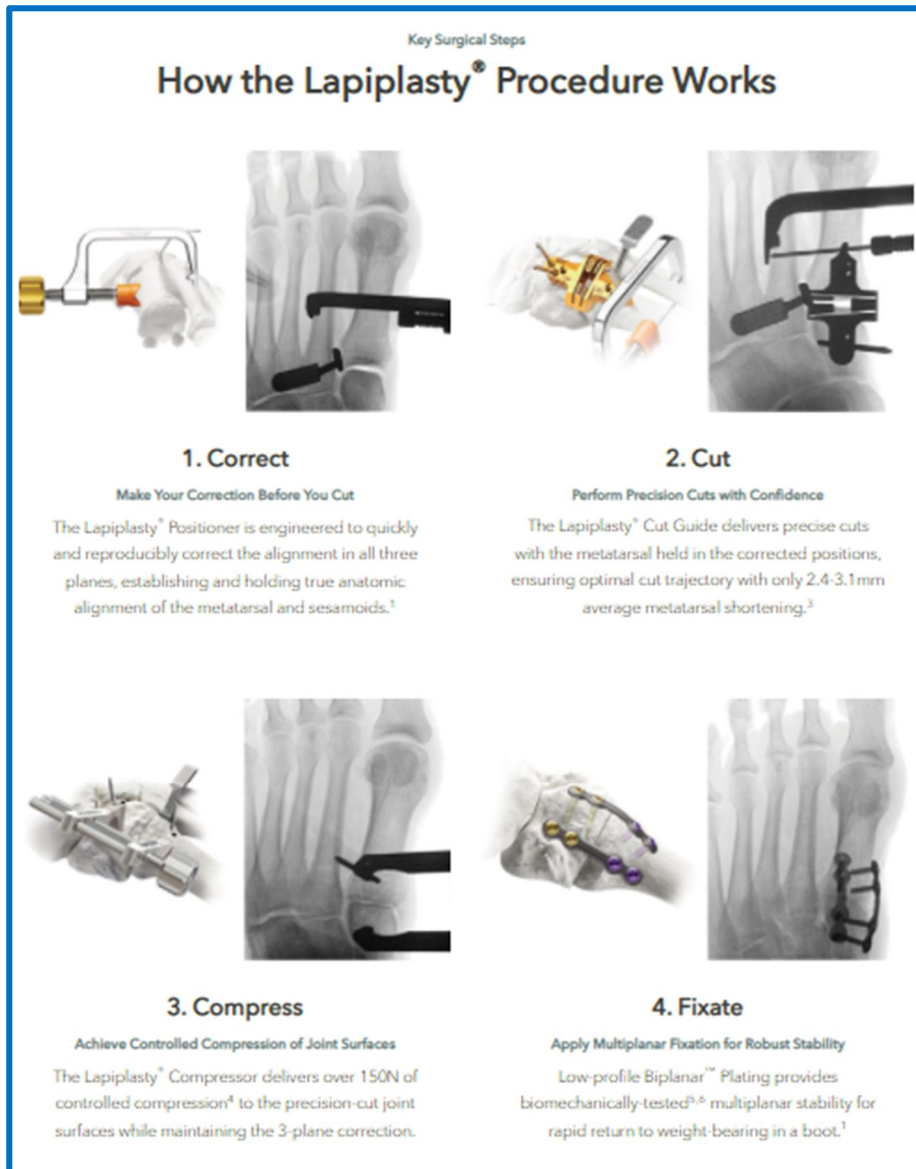
15 15. The bones of the foot most relevant to this case are the first metatarsal and  
16 the medial cuneiform. The first metatarsal and medial cuneiform bones (highlighted in  
17 yellow in the figure below) and the joint (cuneiform-metatarsal joint) between them are the  
18 general focus of bunion surgery using Treace Medical's patented methods.



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13 16. Treace Medical's LAPIPLASTY<sup>®</sup> 3D Bunion Correction<sup>™</sup> corrects the  
14 alignment of the first metatarsal in three planes: the transverse plane (right to left direction  
15 in the figure below), the sagittal plane (into and out of the page in the figure below) and  
16 the frontal plane (the big toe is rotated clockwise when viewed end on by the surgeon).



1 17. Treace Medical's LAPIPLASTY® 3D Bunion Correction™ allows the  
2 patient to quickly return to weight-bearing use (in a boot) of the treated foot (see below).



23 18. The surgical methods claimed by the Treace Medical patents asserted in this  
24 case include the steps, generally, of preparing or cutting the end of a bone, aligning the  
25 bones, compressing the ends of the bones together, inserting a fulcrum between bones, and  
26 fixing the bones in an aligned position.

1 19. Treace Medical’s surgical method has received extensive industry praise. As  
2 a result, surgeons have increasingly chosen to change the way they treat bunions, moving  
3 away from traditional surgical methods to Treace Medical’s LAPIPLASTY® 3D Bunion  
4 Correction™.

5 20. Unfortunately, along with praise and the commercial success of Treace  
6 Medical’s LAPIPLASTY® 3D Bunion Correction™, have come copyists like Fusion,  
7 seeking to capitalize on Treace Medical’s pioneering technology, Treace Medical’s  
8 impressive clinical data and Treace Medical’s commercial achievements for their own  
9 financial gain. Fusion has infringed Treace Medical’s patent, trademark and copyright  
10 rights.


11 **Fusion’s Infringing LapiLock 4D Bunion Correction System and Method**

12 21. Fusion has an internet website at [www.fusionorthopedics.com](http://www.fusionorthopedics.com). On that  
13 website, Fusion promotes its LapiLock 4D Bunion Correction System to both patients and  
14 surgeons. For example at, <https://lapilockbunionsurgery.com/?radius=25>, Fusion promotes  
15 its LapiLock 4D Bunion Correction and implant options to patients and provides a patient-  
16 directed video describing its LapiLock 4D Bunion Correction Surgery.

17  
18 **The LapiLock 4D**  
19 **Correction Surgery**

20 Break-through Bunion Surgery is finally here with  
the FDA cleared LapiLock 4D Correction System.

21 Bunion surgery requires the realignment of your  
22 toe and a surgical implant to fuse the unstable  
joint. The patent pending LapiLock 4D Correction  
23 System by Fusion Orthopedics provides the  
necessary realignment and 11 unique implant  
24 options for bunion surgery depending on patient  
preference and needs.

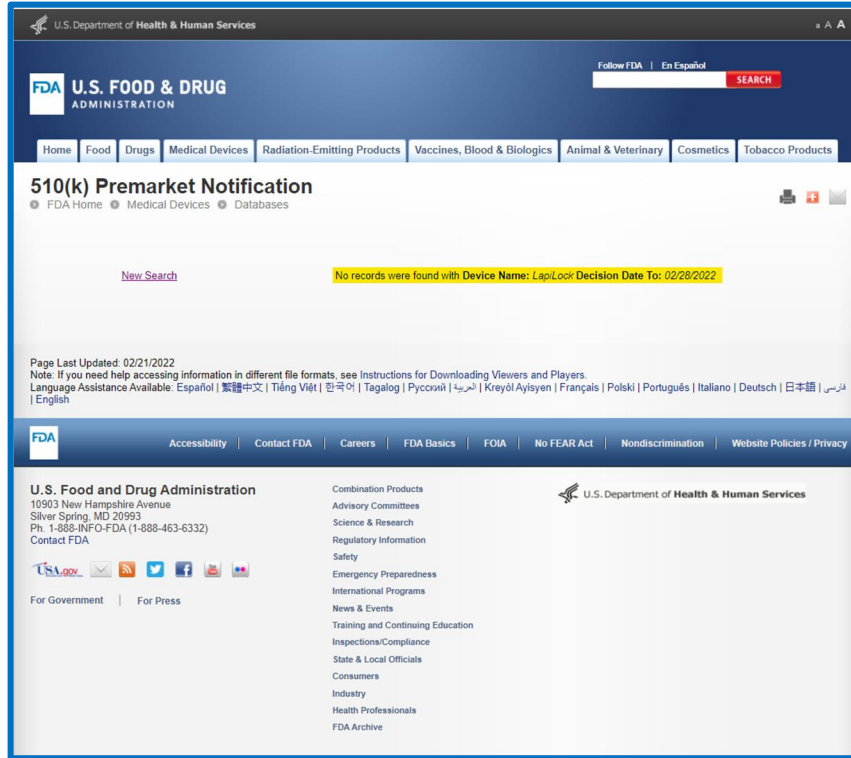


25 **FIND A DOCTOR**

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1           22.     While the above excerpt from Fusion’s website states that LapiLock 4D  
2 Correction System is FDA cleared, there is no record of a clearance of this system in the  
3 FDA’s 510(k) database (see below).

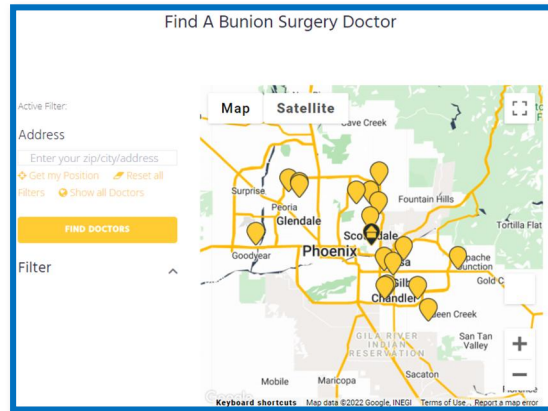


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17           23.     While the above except from Fusion’s website also states that the LapiLock  
18 4D Correction System is patent pending, there are no published patent applications  
19 available on the United States Patent and Trademark Office’s (“USPTO”) website  
20 assigned to Fusion that describe or claim Fusion’s LapiLock 4D Correction System or the  
21 method of its use.



1 24. Fusion’s internet website also invites prospective patients to “FIND A  
2 DOCTOR”. By pressing the “FIND A DOCTOR” button, the prospective patient is able  
3 to select from doctors in the greater Phoenix area at the link

4 <https://lapilockbunionsurgery.com/find-a-bunion-surgery-doctor/?radius=25>



12 25. Treace Medical has spent considerable amounts of money educating  
13 surgeons about the benefits of LAPIPLASTY® 3D Bunion Correction™ over traditional  
14 bunion surgery and on training surgeons in how to correctly perform LAPIPLASTY® 3D  
15 Bunion Correction™. Treace Medical sponsors cadaver labs and other educational  
16 seminars where surgeons can learn from and practice LAPIPLASTY® 3D Bunion  
17 Correction™ with experienced LAPIPLASTY® 3D Bunion Correction™ surgeons before  
18 they perform this surgery on their own.

19 26. On information and belief, Fusion targeted surgeons who are trained in  
20 performing LAPIPLASTY® 3D Bunion Correction™ as customers for its LapiLock 4D  
21 Correction System. By targeting trained LAPIPLASTY® 3D Bunion Correction™  
22 surgeons, Fusion avoids the substantial cost inherent in converting surgeons who perform  
23 traditional bunion surgery to a new technique and then ensuring that these surgeons  
24 perform the new technique correctly. Fusion’s efforts to target surgeons trained in  
25 performing LAPIPLASTY® 3D Bunion Correction™ have been most pronounced in  
26 Arizona and Utah. Fusion identifies fourteen (14) LAPIPLASTY® 3D Bunion  
27 Correction™ trained surgeons from these states at its “FIND A DOCTOR” link.  
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LAPILOCK SURGICAL TECHNIQUE

Learn More About LapiLock 4D Bunion Correction

Full Name

Zip Code

Phone #

Email

SUBMIT

8           27.     On information and belief, Fusion has also been hiring and attempting to hire  
9 sales representatives who represent Treace Medical and have been trained by Treace  
10 Medical to understand and sell Treace Medical’s LAPIPLASTY® 3D Bunion  
11 Correction™, to promote Fusion’s LapiLock 4D Bunion Correction, instead, to Treace  
12 Medical’s customers and potential customers.

13           28.     Fusion’s internet website also includes a “Surgeon Portal” at  
14 <https://lapilockbunionsurgery.com/surgeons/> where surgeons can download a current  
15 version of the “LAPILOCK SURGICAL TECHNIQUE” document (“**LapiLock**  
16 **Brochure**”) or watch a video demonstrating and explaining the LapiLock 4D Bunion  
17 Correction System and method of use titled DTP003 Rev 3 Surgical Technique Video  
18 (“**LapiLock Video**”) or “Learn More About LapiLock 4D Bunion Correction” by  
19 submitting their contact information.

20           29.     Fusion has used and is using and is offering to sell and selling technology  
21 that Treace developed over the past eight years at great expense. Treace Medical's  
22 LAPIPLASTY® 3D Bunion Correction™ has been refined and tested over that time to  
23 deliver optimum surgical results for patients. On information and belief, Fusion’s  
24 LapiLock 4D Bunion Correction has been subject to little or no clinical testing.

1           30. On information and belief, surgeons led to believe that Fusion’s LapiLock  
2 4D Bunion Correction will produce the consistently positive results that they achieve with  
3 Treace Medical’s LAPIPLASTY® 3D Bunion Correction™ have instead experienced  
4 inconsistent results with Fusion’s LapiLock 4D Bunion Correction, including failure of  
5 bones to fuse post-surgery.

6           31. On information and belief, patients experiencing poor outcomes with  
7 Fusion’s LapiLock 4D Bunion Correction are unlikely to distinguish between Fusion’s  
8 surgical method and system and Treace Medical’s surgical method and system. On  
9 information and belief, these patients are, however, likely to tell their friends and  
10 colleagues about their dissatisfaction with the “latest” surgical technique for treating  
11 bunions. On information and belief, this bad “word of mouth” taints Treace Medical’s  
12 LAPIPLASTY® 3D Bunion Correction™ in the minds of prospective patients. On  
13 information and belief, this bad “word of mouth” can also cause prospective patients who  
14 would otherwise be helped through surgery with Treace Medical’s LAPIPLASTY® 3D  
15 Bunion Correction™ to unnecessarily forego care and endure great pain and ongoing  
16 disfigurement.

17           **Treace Medical Requested Fusion Discontinue its Improper Activities**

18           32. On February 16, 2022, Mr. John Treace, the Chief Executive Officer and  
19 Founder of Treace Medical and a co-inventor of the ’590 Patent, sent a letter to Mr. Adam  
20 Cundiff, the Chief Executive Officer of Fusion. Mr. Treace’s letter attached a copy of the  
21 ’590 Patent and a detailed claim chart explaining, with citation to the LapiLock Brochure  
22 and LapiLock Video, how Fusion’s LapiLock 4D Bunion Correction infringed the claims  
23 of Treace Medical’s ’590 Patent. Mr. Treace’s letter also explained that Fusion’s use of  
24 the mark LapiLock 4D Bunion Correction infringed Treace Medical’s registered trademark  
25 LAPIPLASTY and 3D BUNION CORRECTION mark and was likely to cause  
26 confusion—confusion that could lead Treace Medical’s customers and potential customers  
27 to mistakenly believe that Fusion’s LapiLock 4D Bunion Correction is manufactured by  
28 Treace Medical, distributed by Treace Medical, associated or connected with Treace

1 Medical, or had the sponsorship, endorsement or approval of Treace Medical. Mr. Treace  
2 asked that Fusion confirm, no later than March 2, 2022, that it would:

- 3 1. Stop making, using, importing, offering for sale, and selling in the  
4 United States the devices used with [Fusion's] LapiLock;
- 5 2. Stop inducing infringement of [Treace Medical's] patents by removing  
6 all materials describing LapiLock from its own websites and all  
7 affiliated websites;
- 8 3. Stop distributing all printed and electronic literature related to  
9 LapiLock;
- 10 4. Stop all other activities that describe or encourage the performance of  
11 [Treace Medical's] patented methods using Fusion products;
- 12 5. Stop using the LAPILOCK mark, "4D Bunion Correction" language  
13 and all other confusingly similar themes, text and illustrations;
- 14 6. Produce to Treace [Medical, Fusion's relevant] sales information for the  
15 LapiLock system and components; and
- 16 7. Produce to Treace [Medical] all existing LapiLock inventory, training  
17 supplies, kits, loaners, demonstration products, related devices and  
18 promotional literature (or certify to Treace [Medical] in writing that the  
19 same have been destroyed).

20 33. On February 17, 2022, Mr. Sam Rocereta, representing himself as General  
21 Counsel for Fusion, acknowledged receipt of Mr. Treace's letter and responded, copying  
22 Adam Cundiff, Nathan Peterson (Fusion's President and Co-Founder) and Jason Graff  
23 (Fusion's Patent attorney) as follows:

24 John,

25 I am in receipt of your February 16th, 2022 correspondence addressed to Mr.  
26 Cundiff. I write as attorney for Fusion Orthopedics and if you are  
27 represented by an attorney, please put me in touch with them.

28 Fusion appreciates the positions outlined in the correspondence. To be clear,  
Fusion respects all intellectual property rights and would never infringe on  
anyone's intellectual property rights intentionally.

Generally, Fusion's position is contrary to the allegations in the  
correspondence. After cursory review, Fusion disagrees with your  
assessment that the LapiLock product infringes with the two '590 patent  
independent claims. Perhaps most concerning of the '590 patent claims is the  
probability that well known prior art existed before your earliest priority  
date. Intellectual property counsel is further assessing your allegations,  
claims, patent enforceability, and demands, as well as our pending patents.

1           Congratulations on your remarkable success with TMCI. As you envision  
2           productive conversations, or opportunities for our companies to work  
3           together, always feel free to reach out.

4           Kind regards,

5           34.     On February 18, 2022, Mr. Treace sent the following e-mail to Mr. Rocereta,  
6           copying Adam Cundiff, Nathan Peterson and Jason Graff:

7           Hi Sam,

8           Thank you for reaching out and for your kind words about the remarkable  
9           success that Treace continues to enjoy. As you can imagine, our success has  
10          been the result of years of hard work by the entire Treace team.

11          As a co-inventor of the '590 patent, I am curious about the views you  
12          express on infringement and validity. Could you please explain why Fusion  
13          believes that its LapiLock system and method does not infringe the two  
14          independent claims of the '590 patent? Similarly, could you please identify  
15          the "well known prior art" that you refer to in your letter. I would very much  
16          enjoy reviewing that art.

17          I appreciate your prompt response to my previous letter and hope that you  
18          will provide the requested information just as quickly.

19          Best regards,

20          35.     On February 18, 2022, Mr. Rocereta responded to Mr. Treace, copying  
21          Adam Cundiff, Nathan Peterson and Jason Graff, as follows:

22          John,

23          I've calendared your request for the week of the 28th. I'm unavailable some  
24          of the next week due to Presidents Day.  
25          We hope you have a great weekend.

26          Kind regards,

27          36.     On March 2, 2022, Mr. Rocereta sent an e-mail to Mr. Treace, copying  
28          Adam Cundiff, Nathan Peterson and Jason Graff stating:

1 John,

2 Fusion has made recent adjustments in their literature to better reflect the  
3 distinct differences in the two systems. Your intellectual property attorneys can  
4 analyze and advise you on why the LapiLock system does not infringe on the  
two '590 independent claims.

5 Regarding the independent literature, with which you have an interest, we will  
6 provide the literature at the appropriate time should it be necessary for us to go  
7 forward with an inter partes review proceeding on the '590 patent.

8 As always, should an opportunity arise for our companies to work together in a  
9 productive way, feel free to reach out.

10 Kind regards,

11 37. Fusion's website at <https://lapilockbunionsurgery.com/wp->  
12 [content/uploads/2022/02/STG015\\_LapiLock\\_2.pdf](https://lapilockbunionsurgery.com/wp-content/uploads/2022/02/STG015_LapiLock_2.pdf) did indeed direct the viewer to a new  
13 version of the LapiLock Brochure. The new brochure is entitled "STG015\_LapiLock\_2".  
14 The previous brochure at this location was entitled "STG015\_LapiLock\_4D Brochure-  
15 c.pdf". Fusion made minor changes, such as replacing the word "fulcrum" in the previous  
16 version of the brochure with the word "spacers" at three locations and removing the word  
17 "bunion" in the mark "LapiLock 4D Bunion Correction". However, elsewhere on Fusion's  
18 website, LapiLock 4D Bunion Correction remains in use. Fusion made minor changes to  
19 the described surgical procedure. Specifically, Fusion's literature now instructs surgeons  
20 to remove the fulcrum (now "spacer") prior to correction of the intermetatarsal angle  
21 ("IMA") and then replace the fulcrum after the IMA is corrected, whereas Fusion  
22 previously instructed LapiLock surgeons to leave the fulcrum in place while correcting the  
23 IMA. On information and belief, if this change were to be followed by surgeons, it would  
24 likely lead to reduced surgical efficacy and adverse outcomes for patients.

25 38. Whether and to what extent Fusion will ensure that this "new" surgical  
26 procedure will be taught or followed by either new or existing surgeon users of Fusion's  
27 products and surgical procedure is unknown, but unlikely.

1           39.     On March 15, 2022, Mr. Treace responded to Mr. Rocereta copying Adam  
2 Cundiff, Nathan Peterson and Jason Graff stating:

3           Sam,

4           I appreciate your response. Unfortunately, you did not sufficiently address  
5 any of the concerns raised in my letter. In fact, your response raises even  
6 more questions and concerns.

7           First, Fusion’s literature changes are tacit acknowledgement that it has  
8 infringed on Treace Medical’s intellectual property rights. My concern –  
9 which remains and is now further validated by your response – is that Fusion  
has infringed and may still be infringing Treace Medical’s ‘590 patent.

10          Second, the changes Fusion made to its literature do nothing to remediate the  
11 harm caused to Treace Medical nor do they stop surgeons trained and  
12 instructed under Fusion’s prior literature from continuing to perform the prior  
13 technique, as trained and instructed by Fusion. Consequently, the changes  
made by Fusion are insufficient to cure the past and continued harm to  
Treace Medical’s proprietary rights.

14          Third, I question the sincerity of the changes made to Fusion’s literature.  
15 Specifically, Fusion’s literature now instructs surgeons who use LapiLock to  
16 remove the fulcrum (which Fusion renamed “spacer” in its revised literature)  
17 prior to correction of the intermetatarsal angle (“IMA”) whereas Fusion  
previously instructed LapiLock surgeons to leave the fulcrum in place while  
correcting the IMA. I believe that Fusion made this change solely as an

18          attempt to evade clear culpability for infringement of Treace Medical’s ‘590  
19 patent because – if the change is actually followed by surgeons – it will  
20 obviously lead to poor surgical efficacy and adverse outcomes for patients.  
21 This also negatively affects Treace Medical’s solid reputation with patients  
22 who may not appreciate that their surgeon is using similarly named and  
described surgical equipment and techniques that are not affiliated with  
Treace Medical. We therefore believe that Fusion continues to instruct and/or  
23 train surgeons who use LapiLock to leave the fulcrum in place while  
24 correcting the IMA despite the changes made to its literature to now do the  
opposite.

25          Fourth, you did not address the other concern I raised in my letter, namely  
26 that Fusion’s use of LAPILOCK is causing consumer confusion with Treace  
27 Medical’s well-known LAPIPLASTY® mark. I mentioned in my letter that  
both marks are very similar and create a similar overall commercial

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1 impression. The similarities are particularly striking given Fusion’s use of the  
 2 language “4D Bunion Correction” in connection with LAPILOCK. Treace  
 3 Medical routinely uses the mark 3D Bunion Correction™ in connection with  
 4 its LAPIPLASTY® mark. This stylization and combination of terms  
 5 highlights the likelihood of confusion. In fact, many of the themes,  
 6 illustrations, videos and other materials on Fusion’s LapiLock website are  
 7 very similar to those appearing on Treace Medical’s websites, individually  
 8 and collectively giving the false and misleading impression that Fusion’s  
 9 LapiLock is made by, distributed by, associated with or endorsed by Treace  
 10 Medical. I remain concerned that Fusion’s selection of identifiers for its  
 11 products and procedure was intended to cause hospitals, surgeons, patients  
 12 and the public to confuse those products and procedures with those offered  
 13 by Treace Medical.

14 Finally, as I mentioned in my letter of February 14, it appears that LapiLock  
 15 infringes on multiple Treace Medical patents. The ‘590 patent is merely one  
 16 example. Other Treace Medical patents practiced by Fusion, its LapiLock  
 17 products, and the techniques Fusion trains and instructs surgeons to perform  
 18 include, but are not limited to, United States Patent Nos. 10,561,426;  
 19 10,849,670; 10,888,335; and 10,945,764. I am providing claim charts  
 20 (Exhibits A-D) explaining how Fusion is infringing representative claims of  
 21 these patents. Of course, Fusion’s infringement is not limited to these  
 22 representative claims.

23 Accordingly, I ask that you provide to Treace Medical the following by noon  
 24 (Pacific Time) on March 22, 2022:

- 25 (1) Confirmation that Fusion now only instructs and/or trains surgeons –  
 26 through its literature, its training modules, labs, cases, procedures and  
 27 otherwise – to remove the fulcrum (which you now claim to call a  
 28 spacer) prior to correcting the IMA;
- (2) Confirmation that Fusion no longer instructs or trains surgeons –  
 through its literature, its training modules, labs, cases, procedures or  
 otherwise – to leave the fulcrum in place while correcting the IMA;
- (3) Confirmation that Fusion has provided remedial training and  
 instruction to its sales and marketing personnel, including any  
 distributors of LapiLock, educating them that the fulcrum cannot be in  
 place while correcting the IMA;
- (4) Confirmation that Fusion has provided written notice to all surgeons  
 who had previously been instructed and/or trained to leave the fulcrum  
 in place while correcting the IMA or who had previously performed  
 the LapiLock procedure leaving the fulcrum in place while correcting  
 the IMA, that they are required to remove the fulcrum before  
 proceeding to correct the IMA;

- 1 (5) A copy of the written notice and a complete list of all surgeons  
2 provided with the written notice referenced in (4) above;
- 3 (6) Confirmation that Fusion will immediately stop making, using,  
4 importing, offering for sale, and selling in the United States the  
5 devices specifically designed for use in performing any procedure that  
6 infringes any Treace Medical patent;
- 7 (7) Confirmation that Fusion will immediately stop inducing infringement  
8 of any and all Treace Medical patents, including the following U.S.  
9 patents: 10,561,426, 10,849,670, 10,888,335 and 10,945,764, by  
10 removing all materials from its literature, its own websites and all  
11 affiliated websites that would induce a surgeon to perform a surgical  
12 method covered by Treace Medical's patents;
- 13 (8) Confirmation that Fusion will immediately stop distributing all printed  
14 and electronic literature that would induce a surgeon to perform a  
15 surgical method covered by Treace Medical's patents;
- 16 (9) Confirmation that Fusion will immediately stop all other activities that  
17 describe or encourage the performance of Treace Medical's patented  
18 methods using Fusion products;
- 19 (10) To the extent Fusion refuses to confirm 6-9, a detailed explanation as  
20 to why Fusion is not practicing the claims of the 10,561,426,  
21 10,849,670, 10,888,335 and 10,945,764 patents;
- 22 (11) Confirmation that Fusion will immediately stop using the LAPILOCK  
23 mark and "4D Bunion Correction" language; and
- 24 (12) All existing LapiLock inventory, training supplies, kits, loaners,  
25 demonstration products, related devices and promotional literature for  
26 destruction, or written certification that you have destroyed these  
27 items.

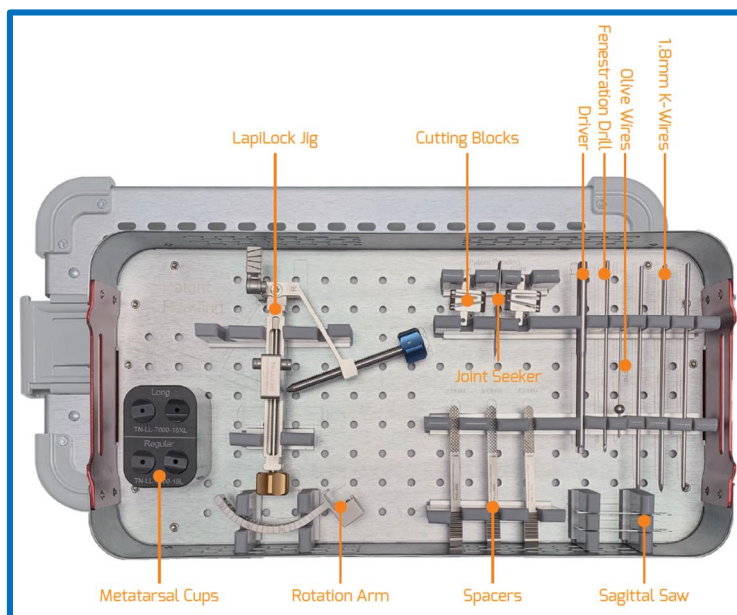
18 Unless you provide confirmation or performance, as applicable, of the items  
19 listed above by the date and time mentioned above, I am prepared to instruct  
20 our attorneys to take any and all necessary steps to vigorously protect Treace  
21 Medical's intellectual property rights. Fusion's infringement may subject it  
22 and its officers to a lawsuit seeking damages for past infringement, enhanced  
23 damages for willful infringement, attorneys' fees, costs and injunction to  
24 prohibit Fusion's future patent infringement, as well as all remedies available  
25 for Fusion's trademark infringement such as Fusion's profits and Treace  
26 Medical's attorneys' fees and costs.

27 I look forward to hearing from you promptly.

28 40. As of the filing of this complaint, Treace has not received a response to Mr.  
Treace's March 15, 2022 communication from Mr. Cundiff, Mr. Rocereta or any other  
person on Fusion's behalf.

### Allegations Common to Counts 1 through 5

41. Fusion has made, used, offered for sale, sold and/or imported into the United States medical instruments used in performing bunion surgery. These medical instruments are offered by Fusion for the performance of Fusion's LapiLock 4D Bunion Correction System. The LapiLock 4D Bunion Correction instruments (“**Accused Products**”) are shown in the image below which is found at Page 4 of the LapiLock Brochure.<sup>1</sup>



42. Treace virtually marks its products through its Internet website at <https://www.treace.com/patents> to alert competitors, like Fusion, to Treace Medical’s issued patents and pending patent applications. Treace Medical’s patent marking website 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:” United States Patent Nos. 10,561,426; 10,849,670; 10,888,335; 10,945,764 and 10,342,590 are listed on Treace Medical’s patent marking webpage.

43. Fusion had actual knowledge of United States Patent No. 10,342,590 by at least February 16, 2022, through its receipt of the letter from Mr. Treace of that date.

<sup>1</sup> Reference is made to the LapiLock Brochure entitled “STG015\_LapiLock\_2.pdf”.

1 44. Fusion had actual knowledge of United States Patent Nos. 10,561,426;  
2 10,849,670; 10,888,335; 10,945,764 by at least March 15, 2022, through its receipt of the  
3 letter from Mr. Treace of that date.

4 **COUNT 1 – INFRINGEMENT OF U.S. PATENT NO. 10,561,426 BY FUSION**

5 45. Treace Medical incorporates by reference Paragraphs 1-44 of this Complaint  
6 as if repeated verbatim in this Paragraph.

7 46. On February 18, 2020, the USPTO issued United States Patent Number  
8 10,561,426 B2 (the “**’426 Patent**”) to Paul Dayton, Robert D. Santrock, Daniel J. Hatch,  
9 W. Bret Smith, Carlos Eduardo Gil, Sean F. Scanlan, Joe William Ferguson, F. Barry Bays  
10 and John T. Treace. The ’426 Patent is entitled “Bone Cutting Guide Systems and  
11 Methods.” A true and correct copy of the ’426 Patent is attached to this Complaint as  
12 Exhibit A. The ’426 Patent remains in force and is assigned to Treace Medical. Treace  
13 Medical has owned the ’426 Patent since it issued and still owns the ’426 Patent.

14 47. Attached to this Complaint as Exhibit B is a detailed claim chart explaining  
15 how the Fusion document entitled STG015\_LapiLock\_2.pdf (“**LapiLock Brochure**”) and  
16 the LapiLock Video describe the performance of the steps of representative independent  
17 claim 1 of the ’426 Patent using the Accused Products and thereby instruct and encourage  
18 surgeons to perform the method of those claims. On information and belief, Fusion  
19 continues to instruct and encourage surgeons to perform the method of claim 1 and other  
20 claims of the ’426 Patent (the “**Claimed Method**”).

21 ***Fusion’s Direct Infringement of the ’426 Patent***

22 48. On information and belief, surgeons who have performed and are performing  
23 the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock  
24 Video using the Accused Products directly infringe the ’426 Patent.

25 49. On information and belief, Fusion has directly infringed and continues to  
26 directly infringe the Claimed Method by using the Accused Products in the performance of  
27 LapiLock 4D Bunion Correction in violation of 35 U.S.C. §271(a).

28

1           50.     On information and belief, surgeon consultants to Fusion, tested and  
2 performed the Claimed Method using the Accused Products on Fusion’s behalf as part of  
3 developing the Accused Products and LapiLock 4D Bunion Correction at least before the  
4 Accused Products were first offered for sale and sold in the United States.

5           51.     On information and belief, surgeon consultants to Fusion performed the  
6 Claimed Method using the Accused Products to perform LapiLock 4D Bunion Correction  
7 on Fusion’s behalf as part of surgeon education both before and after the Accused Products  
8 were offered for sale and sold in the United States.

9           52.     Fusion produced at least the LapiLock Brochure and LapiLock Video  
10 showing the Accused Products being used to perform LapiLock 4D Bunion Correction.  
11 On information and belief, surgeons working on Fusion’s behalf, performed the Claimed  
12 Method using the Accused Products on human patients in connection with creating the  
13 LapiLock Brochure and LapiLock Video, both of which demonstrate performance of the  
14 Claimed Method using the Accused Products.

15           ***Fusion’s Contributory Infringement of the ’426 Patent***

16           53.     On information and belief, Fusion has contributorily infringed the Claimed  
17 Method in violation of 35 U.S.C. §271(c).

18           54.     On information and belief, surgeons who have performed and are performing  
19 the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock  
20 Video using the Accused Products directly infringe the ’426 Patent.

21           55.     On information and belief, to the extent Fusion contends that it did not know  
22 of the ’426 Patent before it commercially released the Accused Products, that contention  
23 would be based on Fusion’s willful blindness to the ’426 Patent.

24           56.     On information and belief, Fusion had actual knowledge of the ’426 Patent  
25 before commercially releasing its LapiLock 4D Bunion Correction and the Accused  
26 Products.

27           57.     Devices including at least Fusion’s LapiLock Jig, Cutting Blocks and Joint  
28 Seeker are material components for use in practicing the Claimed Method.

1           58.     Fusion’s LapiLock Jig, Cutting Blocks and Joint Seeker are especially made  
2 for use in a manner that infringes the Claimed Method.

3           59.     Fusion’s LapiLock Jig, Cutting Blocks and Joint Seeker lack substantial non-  
4 infringing uses.

5           60.     Fusion has provided materials to hospitals and surgeons demonstrating the  
6 use of the Accused Products to perform the Claimed Method. These Fusion provided  
7 materials include the LapiLock Brochure and LapiLock Video. Distribution of these  
8 materials further shows that Fusion especially made the Accused Products to perform the  
9 Claimed Method.

10          61.     On information and belief, Fusion knew that surgeons were performing the  
11 Claimed Method using the Accused Products.

12          62.     On information and belief, surgeons have used the Accused Products in a  
13 manner that infringes the Claimed Method.

14           ***Fusion’s Induced Infringement of the ’426 Patent***

15          63.     On information and belief, Fusion has induced infringement of the Claimed  
16 Method in violation of 35 U.S.C. §271(b).

17          64.     On information and belief, surgeons who have performed and are performing  
18 the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock  
19 Video using the Accused Products directly infringe the ’426 Patent.

20          65.     On information and belief, to the extent Fusion contends that it did not know  
21 of the ’426 Patent before it commercially released the Accused Products, that contention  
22 would be based on willful blindness to the ’426 Patent.

23          66.     On information and belief, Fusion had actual knowledge of the ’426 Patent  
24 before commercially releasing its LapiLock 4D Bunion Correction and the Accused  
25 Products.

26          67.     On information and belief, Fusion has provided materials to hospitals and  
27 surgeons that demonstrate using the Accused Products to perform the Claimed Method.

28 On information and belief, These Fusion provided materials include the LapiLock



1 Brochure and LapiLock Video. On information and belief, Fusion distributed these  
2 materials to hospitals and surgeons with the intent to cause surgeons to use Accused  
3 Products to perform the Claimed Method.

4 68. On information and belief, Fusion knew that surgeons were performing the  
5 Claimed Method using the Accused Products and were directly infringing the Claimed  
6 Method.

7 69. On information and belief, Fusion's inducing acts caused surgeons to use the  
8 Accused Products in a manner that infringes the Claimed Method.

9 ***Fusion's Willful Infringement of the '426 Patent***

10 70. Fusion has willfully infringed the Claimed Method.

11 71. On information and belief, Fusion has infringed and continues to infringe the  
12 Claimed Method with knowledge of Treace Medical's rights in the '426 Patent.

13 72. On information and belief, Fusion's acts of infringement of the Claimed  
14 Method have been and continue to be willful, deliberate and egregious.

15 73. On information and belief, Fusion acted despite an objectively high  
16 likelihood that its actions constituted infringement of a valid patent claim and knew or  
17 should have known of this objectively-defined risk of infringement.

18 74. On information and belief, Fusion flaunted Treace Medical's notice of its  
19 rights in and to the '426 Patent by continuing to infringe the claims of the '426 patent, by  
20 failing to respond to Mr. Treace's letter at all, let alone by responding to Mr. Treace's  
21 letter with an explanation of a commercially reasonable non-infringement defense. In the  
22 words of the Supreme Court, Fusion's conduct is of the sort warranting enhanced  
23 damages—conduct which has been “variously described in our cases as willful, wanton,  
24 malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic  
25 of a pirate.”

26 ***Requested Relief for Fusion's Infringement of the '426 Patent***

27 75. Treace Medical is entitled to recover damages that would place Treace  
28 Medical in approximately the same financial position that it would have been in had



1 Fusion's infringement of the '426 Patent not occurred. Treace Medical is entitled to  
2 recover all profits that it has lost as a result of Fusion's sale of the Accused Products for the  
3 performance of the '426 Patent.

4 76. Treace Medical requests pursuant to 35 U.S.C. §284 that damages awarded  
5 to Treace in this matter for Fusion's infringement of the '426 Patent be increased by three  
6 times the amount found or assessed by the fact finder.

7 77. On information and belief, in furtherance of its infringement of the '426  
8 Patent, Fusion has targeted as prospective customers, surgeons trained by Treace Medical  
9 to perform Treace Medical's LAPIPLASTY® 3D Bunion Correction™.

10 78. On information and belief, Fusion has also targeted sales representatives who  
11 were educated by Treace Medical to promote and sell Treace Medical' LAPIPLASTY® 3D  
12 Bunion Correction™ to promote and sell Fusion's LapiLock 4D Bunion Correction and  
13 the Accused Products.

14 79. Fusion's misconduct has irreparably injured Treace Medical and will  
15 continue to injure Treace Medical unless and until the Court enters both a preliminary  
16 injunction and permanent injunction prohibiting Fusion and those acting on its behalf from  
17 infringing the '426 Patent, including by prohibiting the making, using, offering for sale,  
18 selling, and importing into the United States of the Accused Products for performing the  
19 '426 Patent.

20 **COUNT 2—INFRINGEMENT OF U.S. PATENT NO. 10,849,670 BY FUSION**

21 80. Treace incorporates by reference paragraphs 1-79 as if set forth verbatim in  
22 this paragraph.

23 81. On December 1, 2020, the USPTO issued United States Patent Number  
24 10,849,670 B2 (the "**'670 Patent**") to Robert D. Santrock, Paul Dayton, Daniel J. Hatch,  
25 W. Bret Smith, F. Barry Bays, Carlos Eduardo Gil, Sean F. Scanlan, Joe William  
26 Ferguson, and John T. Treace. The '670 Patent is entitled "Bone Positioning and  
27 Preparing Guide Systems and Methods." A true and correct copy of the '670 Patent is  
28 attached to this Complaint as Exhibit C. The '670 Patent remains in force and is assigned

1 to Treace Medical. Treace Medical has owned the '670 Patent since it issued and still  
2 owns the '670 Patent.

3 82. Attached to this Complaint as Exhibit D is a detailed claim chart explaining  
4 how the LapiLock Brochure and the LapiLock Video describe the performance of the steps  
5 of representative independent claim 1 of the '670 Patent using the Accused Products and  
6 thereby instruct and encourage surgeons to perform the method of those claims. On  
7 information and belief, Fusion continues to instruct and encourage surgeons to perform the  
8 method of claim 1 and other claims of the '670 Patent (the "**Claimed Method**").

9 ***Fusion's Direct Infringement of the '670 Patent***

10 83. On information and belief, surgeons who have performed and are performing  
11 the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock  
12 Video using the Accused Products directly infringe the '670 Patent.

13 84. On information and belief, Fusion has directly infringed and continues to  
14 directly infringe the Claimed Method by using the Accused Products in the performance of  
15 LapiLock 4D Bunion Correction in violation of 35 U.S.C. §271(a).

16 85. On information and belief, surgeon consultants to Fusion, tested and  
17 performed the Claimed Method using the Accused Products on Fusion's behalf as part of  
18 developing the Accused Products and LapiLock 4D Bunion Correction at least before the  
19 Accused Products were first offered for sale and sold in the United States.

20 86. On information and belief, surgeon consultants to Fusion performed the  
21 Claimed Method using the Accused Products to perform LapiLock 4D Bunion Correction  
22 on Fusion's behalf as part of surgeon education both before and after the Accused Products  
23 were offered for sale and sold in the United States.

24 87. Fusion produced at least the LapiLock Brochure and LapiLock Video  
25 showing the Accused Products being used to perform LapiLock 4D Bunion Correction.  
26 On information and belief, surgeons working on Fusion's behalf, performed the Claimed  
27 Method using the Accused Products on human patients in connection with creating the  
28

1 LapiLock Brochure and LapiLock Video, both of which demonstrate performance of the  
2 Claimed Method using the Accused Products.

3 ***Fusion's Contributory Infringement of the '670 Patent***

4 88. On information and belief, Fusion has contributorily infringed the Claimed  
5 Method in violation of 35 U.S.C. §271(c).

6 89. On information and belief, surgeons who have performed and are performing  
7 the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock  
8 Video using the Accused Products directly infringe the '670 Patent.

9 90. On information and belief, to the extent Fusion contends that it did not know  
10 of the '670 Patent before it commercially released the Accused Products, that contention  
11 would be based on Fusion's willful blindness to the '670 Patent.

12 91. On information and belief, Fusion had actual knowledge of the '670 Patent  
13 before commercially releasing its LapiLock 4D Bunion Correction and the Accused  
14 Products.

15 92. Devices including at least Fusion's LapiLock Jig, Cutting Blocks and Joint  
16 Seeker are material components for use in practicing the Claimed Method.

17 93. Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker are especially made  
18 for use in a manner that infringes the Claimed Method.

19 94. Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker lack substantial non-  
20 infringing uses.

21 95. Fusion has provided materials to hospitals and surgeons demonstrating the  
22 use of the Accused Products to perform the Claimed Method. These Fusion provided  
23 materials include the LapiLock Brochure and LapiLock Video. Distribution of these  
24 materials further shows that Fusion especially made the Accused Products to perform the  
25 Claimed Method.

26 96. On information and belief, Fusion knew that surgeons were performing the  
27 Claimed Method using the Accused Products.

28

1           97.    On information and belief, surgeons have used the Accused Products in a  
2 manner that infringes the Claimed Method.

3           ***Fusion’s Induced Infringement of the ’670 Patent***

4           98.    On information and belief, Fusion has induced infringement of the Claimed  
5 Method in violation of 35 U.S.C. §271(b).

6           99.    On information and belief, surgeons who have performed and are performing  
7 the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock  
8 Video using the Accused Products directly infringe the ’670 Patent.

9           100. On information and belief, to the extent Fusion contends that it did not know  
10 of the ’670 Patent before it commercially released the Accused Products, that contention  
11 would be based on willful blindness to the ’670 Patent.

12           101. On information and belief, Fusion had actual knowledge of the ’670 Patent  
13 before commercially releasing its LapiLock 4D Bunion Correction and the Accused  
14 Products.

15           102. On information and belief, Fusion has provided materials to hospitals and  
16 surgeons that demonstrate using the Accused Products to perform the Claimed Method.

17 On information and belief, These Fusion provided materials include the LapiLock  
18 Brochure and LapiLock Video. On information and belief, Fusion distributed these  
19 materials to hospitals and surgeons with the intent to cause surgeons to use Accused  
20 Products to perform the Claimed Method.

21           103. On information and belief, Fusion knew that surgeons were performing the  
22 Claimed Method using the Accused Products and were directly infringing the Claimed  
23 Method.

24           104. On information and belief, Fusion’s inducing acts caused surgeons to use the  
25 Accused Products in a manner that infringes the Claimed Method.

26           ***Fusion’s Willful Infringement of the ’670 Patent***

27           105. Fusion has willfully infringed the Claimed Method.  
28

1           106. On information and belief, Fusion has infringed and continues to infringe the  
2 Claimed Method with knowledge of Treace Medical’s rights in the ’670 Patent.

3           107. On information and belief, Fusion’s acts of infringement of the Claimed  
4 Method have been and continue to be willful, deliberate and egregious.

5           108. On information and belief, Fusion acted despite an objectively high  
6 likelihood that its actions constituted infringement of a valid patent claim and knew or  
7 should have known of this objectively-defined risk of infringement.

8           109. On information and belief, Fusion flaunted Treace Medical’s notice of its  
9 rights in and to the ’670 Patent by continuing to infringe the claims of the ’670 patent, by  
10 failing to respond to Mr. Treace’s letter at all, let alone by responding to Mr. Treace’s  
11 letter with an explanation of a commercially reasonable non-infringement defense. In the  
12 words of the Supreme Court, Fusion’s conduct is of the sort warranting enhanced  
13 damages—conduct which has been “variously described in our cases as willful, wanton,  
14 malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic  
15 of a pirate.”

16           ***Requested Relief for Fusion’s Infringement of the ’670 Patent***

17           110. Treace Medical is entitled to recover damages that would place Treace  
18 Medical in approximately the same financial position that it would have been in had  
19 Fusion's infringement of the ’670 Patent not occurred. Treace Medical is entitled to  
20 recover all profits that it has lost as a result of Fusion's sale of the Accused Products for the  
21 performance of the ’670 Patent.

22           111. Treace Medical requests pursuant to 35 U.S.C. §284 that damages awarded  
23 to Treace in this matter for Fusion’s infringement of the ’670 Patent be increased by three  
24 times the amount found or assessed by the fact finder.

25           112. On information and belief, in furtherance of its infringement of the ’670  
26 Patent, Fusion has targeted as prospective customers, surgeons trained by Treace Medical  
27 to perform Treace Medical’s LAPIPLASTY® 3D Bunion Correction™.

28

1           113. On information and belief, Fusion has also targeted sales representatives who  
2 were educated by Treace Medical to promote and sell Treace Medical' LAPIPLASTY® 3D  
3 Bunion Correction™ to promote and sell Fusion's LapiLock 4D Bunion Correction and  
4 the Accused Products.

5           114. Fusion's misconduct has irreparably injured Treace Medical and will  
6 continue to injure Treace Medical unless and until the Court enters both a preliminary  
7 injunction and permanent injunction prohibiting Fusion and those acting on its behalf from  
8 infringing the '670 Patent, including by prohibiting the making, using, offering for sale,  
9 selling, and importing into the United States of the Accused Products for performing the  
10 '670 Patent.

11           **COUNT 3—INFRINGEMENT OF U.S. PATENT NO. 10,888,335 BY FUSION**

12           115. Treace Medical incorporates by reference Paragraphs 1-114 of this  
13 Complaint as if repeated verbatim in this Paragraph.

14           116. On January 12, 2021, the USPTO issued United States Patent Number  
15 10,888,335B2 (the **"'335 Patent"**) to Paul Dayton, Robert D. Santrock, Daniel J. Hatch,  
16 W. Bret Smith, Carlos Eduardo Gil, Sean F. Scanlan, Joe William Ferguson, F. Barry Bays  
17 and John T. Treace. The '335 Patent is entitled "Bone Cutting Guide Systems and  
18 Methods." A true and correct copy of the '335 Patent is attached to this Complaint as  
19 Exhibit E. The '335 Patent remains in force and is assigned to Treace Medical. Treace  
20 Medical has owned the '335 Patent since it issued and still owns the '590 Patent.

21           117. Attached to this Complaint as Exhibit F is a detailed claim chart explaining  
22 how the LapiLock Brochure and the LapiLock Video describe the performance of the steps  
23 of representative independent claim 1 of the '335 Patent using the Accused Products and  
24 thereby instruct and encourage surgeons to perform the method of those claims. On  
25 information and belief, Fusion continues to instruct and encourage surgeons to perform the  
26 method of claim 1 and other claims of the '335 Patent (the **"Claimed Method"**).  
27  
28

1           ***Fusion’s Direct Infringement of the ’335 Patent***

2           118. On information and belief, surgeons who have performed and are performing  
3 the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock  
4 Video using the Accused Products directly infringe the ’335 Patent.

5           119. On information and belief, Fusion has directly infringed and continues to  
6 directly infringe the Claimed Method by using the Accused Products in the performance of  
7 LapiLock 4D Bunion Correction in violation of 35 U.S.C. §271(a).

8           120. On information and belief, surgeon consultants to Fusion, tested and  
9 performed the Claimed Method using the Accused Products on Fusion’s behalf as part of  
10 developing the Accused Products and LapiLock 4D Bunion Correction at least before the  
11 Accused Products were first offered for sale and sold in the United States.

12           121. On information and belief, surgeon consultants to Fusion performed the  
13 Claimed Method using the Accused Products to perform LapiLock 4D Bunion Correction  
14 on Fusion’s behalf as part of surgeon education both before and after the Accused Products  
15 were offered for sale and sold in the United States.

16           122. Fusion produced at least the LapiLock Brochure and LapiLock Video  
17 showing the Accused Products being used to perform LapiLock 4D Bunion Correction. On  
18 information and belief, surgeons working on Fusion’s behalf, performed the Claimed  
19 Method using the Accused Products on human patients in connection with creating the  
20 LapiLock Brochure and LapiLock Video, both of which demonstrate performance of the  
21 Claimed Method using the Accused Products.

22           ***Fusion’s Contributory Infringement of the ’335 Patent***

23           123. On information and belief, Fusion has contributorily infringed the Claimed  
24 Method in violation of 35 U.S.C. §271(c).

25           124. On information and belief, surgeons who have performed and are performing  
26 the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock  
27 Video using the Accused Products directly infringe the ’335 Patent.

28



1           125. On information and belief, to the extent Fusion contends that it did not know  
2 of the '335 Patent before it commercially released the Accused Products, that contention  
3 would be based on Fusion's willful blindness to the '335 Patent.

4           126. On information and belief, Fusion had actual knowledge of the '335 Patent  
5 before commercially releasing its LapiLock 4D Bunion Correction and the Accused  
6 Products.

7           127. Devices including at least Fusion's LapiLock Jig, Cutting Blocks and Joint  
8 Seeker are material components for use in practicing the Claimed Method.

9           128. Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker are especially made  
10 for use in a manner that infringes the Claimed Method.

11           129. Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker lack substantial non-  
12 infringing uses.

13           130. Fusion has provided materials to hospitals and surgeons demonstrating the  
14 use of the Accused Products to perform the Claimed Method. These Fusion provided  
15 materials include the LapiLock Brochure and LapiLock Video. Distribution of these  
16 materials further shows that Fusion especially made the Accused Products to perform the  
17 Claimed Method.

18           131. On information and belief, Fusion knew that surgeons were performing the  
19 Claimed Method using the Accused Products.

20           132. On information and belief, surgeons have used the Accused Products in a  
21 manner that infringes the Claimed Method.

22           ***Fusion's Induced Infringement of the '335 Patent***

23           133. On information and belief, Fusion has induced infringement of the Claimed  
24 Method in violation of 35 U.S.C. §271(b).

25           134. On information and belief, surgeons who have performed and are performing  
26 the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock  
27 Video using the Accused Products directly infringe the '335 Patent.  
28

1           135. On information and belief, to the extent Fusion contends that it did not know  
2 of the '335 Patent before it commercially released the Accused Products, that contention  
3 would be based on willful blindness to the '335 Patent.

4           136. On information and belief, Fusion had actual knowledge of the '335 Patent  
5 before commercially releasing its LapiLock 4D Bunion Correction and the Accused  
6 Products.

7           137. On information and belief, Fusion has provided materials to hospitals and  
8 surgeons that demonstrate using the Accused Products to perform the Claimed Method.  
9 On information and belief, These Fusion provided materials include the LapiLock  
10 Brochure and LapiLock Video. On information and belief, Fusion distributed these  
11 materials to hospitals and surgeons with the intent to cause surgeons to use Accused  
12 Products to perform the Claimed Method.

13           138. On information and belief, Fusion knew that surgeons were performing the  
14 Claimed Method using the Accused Products and were directly infringing the Claimed  
15 Method.

16           139. On information and belief, Fusion's inducing acts caused surgeons to use the  
17 Accused Products in a manner that infringes the Claimed Method.

18           ***Fusion's Willful Infringement of the '335 Patent***

19           140. Fusion has willfully infringed the Claimed Method.

20           141. On information and belief, Fusion has infringed and continues to infringe the  
21 Claimed Method with knowledge of Treace Medical's rights in the '335 Patent.

22           142. On information and belief, Fusion's acts of infringement of the Claimed  
23 Method have been and continue to be willful, deliberate and egregious.

24           143. On information and belief, Fusion acted despite an objectively high  
25 likelihood that its actions constituted infringement of a valid patent claim and knew or  
26 should have known of this objectively-defined risk of infringement.

27           144. On information and belief, Fusion flaunted Treace Medical's notice of its  
28 rights in and to the '335 Patent by continuing to infringe the claims of the '335 patent, by

1 failing to respond to Mr. Treace’s letter at all, let alone by responding to Mr. Treace’s  
2 letter with an explanation of a commercially reasonable non-infringement defense. In the  
3 words of the Supreme Court, Fusion’s conduct is of the sort warranting enhanced  
4 damages—conduct which has been “variously described in our cases as willful, wanton,  
5 malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic  
6 of a pirate.”

7 ***Requested Relief for Fusion’s Infringement of the ’335 Patent***

8 145. Treace Medical is entitled to recover damages that would place Treace  
9 Medical in approximately the same financial position that it would have been in had  
10 Fusion's infringement of the ’335 Patent not occurred. Treace Medical is entitled to  
11 recover all profits that it has lost as a result of Fusion's sale of the Accused Products for the  
12 performance of the ’335 Patent.

13 146. Treace Medical requests pursuant to 35 U.S.C. §284 that damages awarded  
14 to Treace in this matter for Fusion’s infringement of the ’335 Patent be increased by three  
15 times the amount found or assessed by the fact finder.

16 147. On information and belief, in furtherance of its infringement of the ’335  
17 Patent, Fusion has targeted as prospective customers, surgeons trained by Treace Medical  
18 to perform Treace Medical’s LAPIPLASTY® 3D Bunion Correction™.

19 148. On information and belief, Fusion has also targeted sales representatives who  
20 were educated by Treace Medical to promote and sell Treace Medical’ LAPIPLASTY® 3D  
21 Bunion Correction™ to promote and sell Fusion’s LapiLock 4D Bunion Correction and  
22 the Accused Products.

23 149. Fusion’s misconduct has irreparably injured Treace Medical and will  
24 continue to injure Treace Medical unless and until the Court enters both a preliminary  
25 injunction and permanent injunction prohibiting Fusion and those acting on its behalf from  
26 infringing the ’335 Patent, including by prohibiting the making, using, offering for sale,  
27 selling, and importing into the United States of the Accused Products for performing the  
28 ’335 Patent.

1            **COUNT 4—INFRINGEMENT OF U.S. PATENT NO. 10,945,764 BY FUSION**

2            150. Treace incorporates by reference Paragraphs 1-149 of this Complaint as if  
3 repeated verbatim in this Paragraph.

4            151. On March 16, 2021, the USPTO issued United States Patent Number  
5 10,945,764 B2 (the “**’764 Patent**”) to Paul Dayton and F. Barry Bays. The ’764 Patent is  
6 entitled “Tarsal-Metatarsal Joint procedure Utilizing Fulcrum.” A true and correct copy of  
7 the ’764 Patent is attached to this Complaint as Exhibit G. The ’764 Patent remains in  
8 force and is assigned to Treace Medical. Treace Medical has owned the ’764 Patent since  
9 it issued and still owns the ’764 Patent.

10           152. Attached to this Complaint as Exhibit H is a detailed claim chart explaining  
11 how the LapiLock Brochure and the LapiLock Video describe the performance of the steps  
12 of representative independent claim 1 of the ’764 Patent using the Accused Products and  
13 thereby instruct and encourage surgeons to perform the method of those claims. On  
14 information and belief, Fusion continues to instruct and encourage surgeons to perform the  
15 method of claim 1 and other claims of the ’764 Patent (the “**Claimed Method**”).

16            ***Fusion’s Direct Infringement of the ’764 Patent***

17           153. On information and belief, surgeons who have performed and are performing  
18 the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock  
19 Video using the Accused Products directly infringe the ’764 Patent.

20           154. On information and belief, Fusion has directly infringed and continues to  
21 directly infringe the Claimed Method by using the Accused Products in the performance of  
22 LapiLock 4D Bunion Correction in violation of 35 U.S.C. §271(a).

23           155. On information and belief, surgeon consultants to Fusion, tested and  
24 performed the Claimed Method using the Accused Products on Fusion’s behalf as part of  
25 developing the Accused Products and LapiLock 4D Bunion Correction at least before the  
26 Accused Products were first offered for sale and sold in the United States.

27           156. On information and belief, surgeon consultants to Fusion performed the  
28 Claimed Method using the Accused Products to perform LapiLock 4D Bunion Correction

1 on Fusion's behalf as part of surgeon education both before and after the Accused Products  
2 were offered for sale and sold in the United States.

3 157. Fusion produced at least the LapiLock Brochure and LapiLock Video  
4 showing the Accused Products being used to perform LapiLock 4D Bunion Correction. On  
5 information and belief, surgeons working on Fusion's behalf, performed the Claimed  
6 Method using the Accused Products on human patients in connection with creating the  
7 LapiLock Brochure and LapiLock Video, both of which demonstrate performance of the  
8 Claimed Method using the Accused Products.

9 ***Fusion's Contributory Infringement of the '764 Patent***

10 158. On information and belief, Fusion has contributorily infringed the Claimed  
11 Method in violation of 35 U.S.C. §271(c).

12 159. On information and belief, surgeons who have performed and are performing  
13 the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock  
14 Video using the Accused Products directly infringe the '764 Patent.

15 160. On information and belief, to the extent Fusion contends that it did not know  
16 of the '764 Patent before it commercially released the Accused Products, that contention  
17 would be based on Fusion's willful blindness to the '764 Patent.

18 161. On information and belief, Fusion had actual knowledge of the '764 Patent  
19 before commercially releasing its LapiLock 4D Bunion Correction and the Accused  
20 Products.

21 162. Devices including at least Fusion's LapiLock Jig, Cutting Blocks and Joint  
22 Seeker are material components for use in practicing the Claimed Method.

23 163. Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker are especially made  
24 for use in a manner that infringes the Claimed Method.

25 164. Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker lack substantial non-  
26 infringing uses.

27 165. Fusion has provided materials to hospitals and surgeons demonstrating the  
28 use of the Accused Products to perform the Claimed Method. These Fusion provided

1 materials include the LapiLock Brochure and LapiLock Video. Distribution of these  
2 materials further shows that Fusion especially made the Accused Products to perform the  
3 Claimed Method.

4 166. On information and belief, Fusion knew that surgeons were performing the  
5 Claimed Method using the Accused Products.

6 167. On information and belief, surgeons have used the Accused Products in a  
7 manner that infringes the Claimed Method.

8 ***Fusion's Induced Infringement of the '764 Patent***

9 168. On information and belief, Fusion has induced infringement of the Claimed  
10 Method in violation of 35 U.S.C. §271(b).

11 169. On information and belief, surgeons who have performed and are performing  
12 the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock  
13 Video using the Accused Products directly infringe the '764 Patent.

14 170. On information and belief, to the extent Fusion contends that it did not know  
15 of the '764 Patent before it commercially released the Accused Products, that contention  
16 would be based on willful blindness to the '764 Patent.

17 171. On information and belief, Fusion had actual knowledge of the '764 Patent  
18 before commercially releasing its LapiLock 4D Bunion Correction and the Accused  
19 Products.

20 172. On information and belief, Fusion has provided materials to hospitals and  
21 surgeons that demonstrate using the Accused Products to perform the Claimed Method.  
22 On information and belief, These Fusion provided materials include the LapiLock  
23 Brochure and LapiLock Video. On information and belief, Fusion distributed these  
24 materials to hospitals and surgeons with the intent to cause surgeons to use Accused  
25 Products to perform the Claimed Method.

26 173. On information and belief, Fusion knew that surgeons were performing the  
27 Claimed Method using the Accused Products and were directly infringing the Claimed  
28 Method.

1 174. On information and belief, Fusion’s inducing acts caused surgeons to use the  
2 Accused Products in a manner that infringes the Claimed Method.

3 ***Fusion’s Willful Infringement of the ’764 Patent***

4 175. Fusion has willfully infringed the Claimed Method.

5 176. On information and belief, Fusion has infringed and continues to infringe the  
6 Claimed Method with knowledge of Treace Medical’s rights in the ’764 Patent.

7 177. On information and belief, Fusion’s acts of infringement of the Claimed  
8 Method have been and continue to be willful, deliberate and egregious.

9 178. On information and belief, Fusion acted despite an objectively high  
10 likelihood that its actions constituted infringement of a valid patent claim and knew or  
11 should have known of this objectively-defined risk of infringement.

12 179. On information and belief, Fusion flaunted Treace Medical’s notice of its  
13 rights in and to the ’764 Patent by continuing to infringe the claims of the ’764 patent, by  
14 failing to respond to Mr. Treace’s letter at all, let alone by responding to Mr. Treace’s  
15 letter with an explanation of a commercially reasonable non-infringement defense. In the  
16 words of the Supreme Court, Fusion’s conduct is of the sort warranting enhanced  
17 damages—conduct which has been “variously described in our cases as willful, wanton,  
18 malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic  
19 of a pirate.”

20 ***Requested Relief for Fusion’s Infringement of the ’764 Patent***

21 180. Treace Medical is entitled to recover damages that would place Treace  
22 Medical in approximately the same financial position that it would have been in had  
23 Fusion's infringement of the ’764 Patent not occurred. Treace Medical is entitled to  
24 recover all profits that it has lost as a result of Fusion's sale of the Accused Products for the  
25 performance of the ’764 Patent.

26 181. Treace Medical requests pursuant to 35 U.S.C. §284 that damages awarded  
27 to Treace in this matter for Fusion’s infringement of the ’764 Patent be increased by three  
28 times the amount found or assessed by the fact finder.



1 182. On information and belief, in furtherance of its infringement of the '764  
2 Patent, Fusion has targeted as prospective customers, surgeons trained by Treace Medical  
3 to perform Treace Medical's LAPIPLASTY® 3D Bunion Correction™.

4 183. On information and belief, Fusion has also targeted sales representatives who  
5 were educated by Treace Medical to promote and sell Treace Medical' LAPIPLASTY® 3D  
6 Bunion Correction™ to promote and sell Fusion's LapiLock 4D Bunion Correction and  
7 the Accused Products.

8 184. Fusion's misconduct has irreparably injured Treace Medical and will  
9 continue to injure Treace Medical unless and until the Court enters both a preliminary  
10 injunction and permanent injunction prohibiting Fusion and those acting on its behalf from  
11 infringing the '764 Patent, including by prohibiting the making, using, offering for sale,  
12 selling, and importing into the United States of the Accused Products for performing the  
13 '764 Patent.

14 **COUNT 5 – INFRINGEMENT OF U.S. PATENT NO. 10,342,590 BY FUSION**

15 185. Treace Medical incorporates by reference Paragraphs 1-184 of this  
16 Complaint as if repeated verbatim in this Paragraph.

17 186. On July 9, 2019, the USPTO issued United States Patent Number 10,342,590  
18 B2 (the **"'590 Patent"**) to F. Barry Bays, Robert D. Santrock, Paul Dayton, Daniel J.  
19 Hatch, W. Bret Smith, Carlos Eduardo Gil, Sean F. Scanlan, Joe William Ferguson, and  
20 John T. Treace. The '590 Patent is entitled "Tarsal-Metatarsal Joint procedure Utilizing  
21 Fulcrum." A true and correct copy of the '590 Patent is attached to this Complaint as  
22 Exhibit I. The '590 Patent remains in force and is assigned to Treace Medical. Treace  
23 Medical has owned the '590 Patent since it issued and still owns the '590 Patent.

24 187. Fusion's internet website includes a "Surgeon Portal" at  
25 <https://lapilockbunionssurgery.com/surgeons/> where surgeons could, before March 2, 2022,  
26 download a version of the "LAPILOCK SURGICAL TECHNIQUE" brochure entitled  
27 STG015\_LapiLock\_4D Brochure-c.pdf, (**"LapiLock Brochure 2"**) or watch an untitled  
28 video demonstrating and explaining the LapiLock 4D Bunion Correction System and

1 method (“**LapiLock Video 2**”) or “Learn More About LapiLock 4D Bunion Correction”  
2 by submitting their contact information.

3 188. Attached to this Complaint as Exhibit J is a detailed claim chart explaining  
4 how the LapiLock Brochure 2 and LapiLock Video 2 describe the performance of the steps  
5 of representative independent claim 1 of the ’590 Patent using the Accused Products and  
6 thereby instruct and encourage surgeons to perform the method of claim 1 and other claims  
7 of the ’590 Patent (the “**Claimed Method**”).

8 189. On information and belief, Fusion continues to instruct and encourage  
9 surgeons to perform the Claimed Method.

10 190. On information and belief, Fusion has not instructed surgeons to perform the  
11 Claimed Method in a non-infringing manner.

12 ***Fusion’s Direct Infringement of the ’590 Patent***

13 191. On information and belief, surgeons who have performed and are performing  
14 the surgical method as instructed and encouraged by the LapiLock Brochure 2 and  
15 LapiLock Video 2 using the Accused Products directly infringe the ’590 Patent.

16 192. On information and belief, Fusion has directly infringed and continues to  
17 directly infringe the Claimed Method by using the Accused Products in the performance of  
18 LapiLock 4D Bunion Correction in violation of 35 U.S.C. §271(a).

19 193. On information and belief, surgeon consultants to Fusion tested and  
20 performed the Claimed Method using the Accused Products on Fusion’s behalf as part of  
21 developing the Accused Products and LapiLock 4D Bunion Correction at least before the  
22 Accused Products were first offered for sale and sold in the United States.

23 194. On information and belief, surgeon consultants to Fusion performed the  
24 Claimed Method using the Accused Products to perform LapiLock 4D Bunion Correction  
25 on Fusion’s behalf as part of surgeon education both before and after the Accused Products  
26 were offered for sale and sold in the United States.

27 195. Fusion produced at least the LapiLock Brochure 2 and LapiLock Video 2  
28 showing the Accused Products being used to perform LapiLock 4D Bunion Correction.

1 On information and belief, surgeons working on Fusion's behalf performed the Claimed  
2 Method using the Accused Products on human patients in connection with creating the  
3 LapiLock Brochure 2 and LapiLock Video 2, both of which demonstrate performance of  
4 the Claimed Method using the Accused Products.

5 ***Fusion's Contributory Infringement of the '590 Patent***

6 196. On information and belief, Fusion has contributorily infringed the Claimed  
7 Method in violation of 35 U.S.C. §271(c).

8 197. On information and belief, surgeons who have performed and are performing  
9 the surgical method as instructed and encouraged by the LapiLock Brochure 2 and  
10 LapiLock Video 2 using the Accused Products directly infringe the '590 Patent.

11 198. On information and belief, to the extent Fusion contends that it did not know  
12 of the '590 Patent before it commercially released the Accused Products, that contention  
13 would be based on Fusion's willful blindness to the '590 Patent.

14 199. On information and belief, Fusion had actual knowledge of the '590 Patent  
15 before commercially releasing its LapiLock 4D Bunion Correction and the Accused  
16 Products.

17 200. Devices including at least Fusion's LapiLock Jig, Cutting Blocks and Joint  
18 Seeker are material components for use in practicing the Claimed Method.

19 201. Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker are especially made  
20 for use in a manner that infringes the Claimed Method.

21 202. Fusion's LapiLock Jig, Cutting Blocks and Joint Seeker lack substantial non-  
22 infringing uses.

23 203. Fusion has provided materials to hospitals and surgeons demonstrating the  
24 use of the Accused Products to perform the Claimed Method. These materials include the  
25 LapiLock Brochure 2 and LapiLock Video 2. Distribution of these materials further shows  
26 that Fusion especially made the Accused Products to perform the Claimed Method.

27 204. On information and belief, Fusion knew that surgeons were performing the  
28 Claimed Method using the Accused Products.

1           205. On information and belief, surgeons have used the Accused Products in a  
2 manner that infringes the Claimed Method.

3           ***Induced Infringement of the '590 Patent***

4           206. Fusion has induced infringement of the Claimed Method in violation of 35  
5 U.S.C. §271(b).

6           207. On information and belief, surgeons who have performed and are performing  
7 the surgical method as instructed and encouraged by the LapiLock Brochure and LapiLock  
8 Video using the Accused Products directly infringe the '590 Patent.

9           208. On information and belief, to the extent Fusion contends that it did not know  
10 of the '590 Patent before it commercially released the Accused Products, that contention  
11 would be based on willful blindness to the '590 Patent.

12           209. On information and belief, Fusion had actual knowledge of the '590 Patent  
13 before commercially releasing its LapiLock 4D Bunion Correction and the Accused  
14 Products.

15           210. On information and belief, Fusion has provided materials to hospitals and  
16 surgeons that demonstrate using the Accused Products to perform the Claimed Method.  
17 On information and belief, These Fusion provided materials include the LapiLock  
18 Brochure and LapiLock Video. On information and belief, Fusion distributed these  
19 materials to hospitals and surgeons with the intent to cause surgeons to use Accused  
20 Products to perform the Claimed Method.

21           211. On information and belief, Fusion knew that surgeons were performing the  
22 Claimed Method using the Accused Products and were directly infringing the Claimed  
23 Method.

24           212. On information and belief, Fusion's inducing acts caused surgeons to use the  
25 Accused Products in a manner that infringes the Claimed Method.

26           ***Willful Infringement of the '590 Patent***

27           213. Fusion has willfully infringed the Claimed Method.  
28

1           214. On information and belief, Fusion has infringed and continues to infringe the  
2 Claimed Method with knowledge of Treace Medical’s rights in the ’590 Patent.

3           215. On information and belief, Fusion’s acts of infringement of the Claimed  
4 Method have been and continue to be willful, deliberate and egregious.

5           216. On information and belief, Fusion acted despite an objectively high  
6 likelihood that its actions constituted infringement of a valid patent claim and knew or  
7 should have known of this objectively-defined risk of infringement.

8           217. Fusion flaunted Treace Medical’s notice of its rights in and to the ’590  
9 Patent. On information and belief, Fusion has taken no steps to ensure that surgeons  
10 performing Fusion’s LapiLock 4D Bunion Correction are being trained to perform  
11 Fusion’s LapiLock 4D Bunion Correction in a non-infringing manner. On information and  
12 belief, Fusion has not told the surgeons that it previously trained to perform Fusion’s  
13 LapiLock 4D Bunion Correction in an infringing manner that they must perform Fusion’s  
14 LapiLock 4D Bunion Correction in a different non-infringing manner. In the words of the  
15 Supreme Court, Fusion’s conduct is of the sort warranting enhanced damages—conduct  
16 which has been “variously described in our cases as willful, wanton, malicious, bad-faith,  
17 deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate.”

18           ***Requested Relief for Fusion’s Infringement of the ’590 Patent***

19           218. Treace Medical is entitled to recover damages that would place Treace  
20 Medical in approximately the same financial position that it would have been in had  
21 Fusion’s infringement of the ’590 Patent not occurred. Treace Medical is entitled to  
22 recover all profits that it has lost as a result of Fusion’s sale of the Accused Products for  
23 the performance of the ’590 Patent.

24           219. Treace Medical requests pursuant to 35 U.S.C. §284 that damages awarded  
25 to Treace in this matter for Fusion’s willful infringement of the ’590 Patent be increased  
26 by three times the amount found or assessed by the fact finder.

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1           220. On information and belief, in furtherance of its infringement of the '590  
2 Patent, Fusion has targeted as prospective customers, surgeons trained by Treace Medical  
3 to perform Treace Medical's LAPIPLASTY® 3D Bunion Correction™.

4           221. On information and belief, Fusion has also targeted sales representatives who  
5 were educated by Treace Medical to promote and sell Treace Medical' LAPIPLASTY® 3D  
6 Bunion Correction™ to promote and sell Fusion's LapiLock 4D Bunion Correction and  
7 the Accused Products.

8           222. Fusion's misconduct has irreparably injured Treace Medical and, on  
9 information and belief, will continue to injure Treace Medical unless and until the Court  
10 enters both a preliminary injunction and permanent injunction prohibiting Fusion and those  
11 acting on its behalf from infringing the '590 Patent, including by prohibiting the making,  
12 using, offering for sale, selling, and importing into the United States of the Accused  
13 Products for performing the '590 Patent.

14           **COUNT 6—FEDERAL TRADEMARK INFRINGEMENT BY FUSION**

15           223. Treace incorporates by reference Paragraphs 1-222 of this Complaint as if  
16 repeated verbatim in this Paragraph.

17           224. On October 28, 2015, Treace Medical filed an application for trademark  
18 protection of its LAPIPLASTY mark in International Class 10. Treace alleged a date of  
19 first use of January 1, 2016 and a date of first use in commerce of February 23, 2016.

20           225. Treace Medical's application for protection of its LAPIPLASTY mark  
21 published for opposition on August 23, 2016 as Serial No. 86802324.

22           226. Treace Medical's LAPIPLASTY® mark was registered on January 3, 2017  
23 on the USPTO's principal register as U.S. Registration No. 5,115,724.

24           227. Treace Medical is the registered owner of the LAPIPLASTY® mark.

25           228. Treace Medical's LAPIPLASTY® mark is valid and legally protectable.

26           229. Treace Medical's LAPIPLASTY® mark is currently in use and has been in  
27 use for more than five years since the date of its federal registration.  
28

1           230. On February 25, 2022, Treace Medical filed a Section 15 Declaration of  
2 Incontestability with the USPTO regarding the registered LAPIPLASTY® mark.

3           231. On April 5, 2021, Treace Medical filed for registration of its 3D BUNION  
4 CORRECTION™ mark in International Class 044 for “providing a website featuring  
5 information in the field of bunions and bunion surgery.” Treace Medical alleged that its  
6 first use and first commercial use of this mark occurred on July 6, 2018. Treace Medical’s  
7 U.S. Application No. 90/623,428 for the 3D BUNION CORRECTION mark is on the  
8 Principal Register of the USPTO.

9           232. Fusion’s infringing LAPILOCK mark is confusingly similar to Treace  
10 Medical’s federally registered LAPIPLASTY® mark in violation of 15 U.S.C. § 1114.

11           233. Fusion’s use of the confusingly similar mark LAPILOCK to identify the  
12 Accused Products and methods of their use is likely to create confusion, deception, and  
13 mistake by creating the false and misleading impression that Fusion’s LapiLock 4D  
14 Bunion Correction and the Accused Products are manufactured by Treace Medical,  
15 distributed by Treace Medical, are associated or connected with Treace Medical, or have  
16 the sponsorship, endorsement or approval of Treace Medical.

17           234. Fusion’s use of the LAPILOCK mark to identify the Accused Products and  
18 methods of their use in connection with the phrase “4D Bunion Correction”<sup>2</sup>, increases the  
19 likelihood of confusion with Treace Medical’s goods and services because Treace Medical  
20 uses its LAPIPLASTY® mark in connection with the mark 3D BUNION  
21 CORRECTION™.

22           235. Fusion’s use of the confusingly similar mark LAPILOCK and the  
23 confusingly similar phrase “4D Bunion Correction” to identify the Accused Products and  
24 methods of their use is causing and, unless enjoined by this Court, will continue to cause a  
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28           <sup>2</sup> While Fusion recently removed the word “bunion” from this phrase in its  
LapiLock Brochure, Fusion continues to use the phrase “4D Bunion Correction” in its  
other promotional materials and on its website.



1 likelihood of confusion and deception of medical personnel, hospitals, patients and the  
2 public.

3 236. Fusion’s use of the confusingly similar mark LAPILOCK and the  
4 confusingly similar phrase “4D Bunion Correction” to identify the Accused Products and  
5 methods of their use is causing and, unless enjoined by this Court, will continue to cause  
6 injury to Treace Medical’s goodwill and reputation, for which Treace Medical has no  
7 adequate remedy at law.

8 237. Fusion’s actions demonstrate an intentional, willful, and malicious intent to  
9 trade on the goodwill associated with Treace Medical’s LAPIPLASTY® mark and 3D  
10 BUNION CORRECTION™ mark and to cause Treace Medical great and irreparable  
11 harm.

12 238. Fusion’s actions have caused and are likely to continue causing substantial  
13 injury to the public and to Treace Medical, and Treace Medical is entitled to injunctive  
14 relief and to recover Fusion’s profits, actual damages, enhanced profits and damages,  
15 costs, and reasonable attorneys’ fees under 15 U.S.C. §§ 1114, 1116, and 1117.

16 **COUNT 7—FEDERAL UNFAIR COMPETITION BY FUSION**

17 239. Treace Medical incorporates by reference Paragraphs 1-238 of this  
18 Complaint as if repeated verbatim in this Paragraph.

19 240. On information and belief, Fusion’s use of a confusingly similar imitation of  
20 Treace Medical’s LAPIPLASTY® mark and 3D BUNION CORRECTION™ mark has  
21 caused and is likely to cause confusion, deception, and mistake by creating the false and  
22 misleading impression that Fusion’s goods are manufactured by Treace Medical,  
23 distributed by Treace Medical, are affiliated, connected, or associated with Treace  
24 Medical, or have the sponsorship, endorsement, or approval of Treace Medical.

25 241. On information and belief, Fusion has made false representations, false  
26 descriptions, and false designations of, on, or in connection with its goods in violation of  
27 15 U.S.C. § 1125(a). Fusion’s activities have caused and, unless enjoined by this Court,  
28 will continue to cause a likelihood of confusion and deception of members of the trade and

1 public, and, additionally, injury to Treace Medical’s goodwill and reputation as  
2 symbolized by Treace Medical’s LAPIPLASTY® mark and 3D BUNION  
3 CORRECTION™ mark, for which Treace Medical has no adequate remedy at law

4 242. Fusion’s actions demonstrate an intentional, willful, and malicious intent to  
5 trade on the goodwill associated with Treace Medical’s LAPIPLASTY® mark and 3D  
6 BUNION CORRECTION™ mark and to cause great and irreparable injury of Treace  
7 Medical.

8 243. Fusion’s conduct has caused, and is likely to continue causing, substantial  
9 injury to the public and to Treace Medical. Treace Medical is entitled to injunctive relief  
10 and to recover Fusion’s profits, actual damages, enhanced profits and damages, costs, and  
11 reasonable attorneys’ fees under 15 U.S.C. §§ 1125(a), 1116, and 1117.

12 **COUNT 8—COMMON LAW TRADEMARK INFRINGEMENT**  
13 **AND UNFAIR COMPETITION BY FUSION**

14 244. Treace incorporates by reference Paragraphs 1-243 of this Complaint as if  
15 repeated verbatim in this Paragraph.

16 245. On information and belief, Fusion’s use of a confusingly similar imitation of  
17 Treace Medical’s LAPIPLASTY® mark and 3D BUNION CORRECTION™ mark has  
18 caused and is likely to cause confusion, deception, and mistake by creating the false and  
19 misleading impression that Fusion’s goods are manufactured by Treace Medical,  
20 distributed by Treace Medical, are affiliated, connected, or associated with Treace  
21 Medical, or have the sponsorship, endorsement, or approval of Treace Medical.

22 246. Fusion’s acts constitute common law trademark infringement and unfair  
23 competition, and have created and will continue to create, unless restrained by this Court, a  
24 likelihood of confusion to the irreparable injury of Treace Medical. Treace Medical has no  
25 adequate remedy at law for this injury.

26 247. On information and belief, Fusion acted with full knowledge of Treace  
27 Medical’s use of, and statutory and common law rights to, Treace Medical’s  
28 LAPIPLASTY® mark and 3D BUNION CORRECTION™ mark. On information and

1 belief, Fusion acted without regard for the likelihood of confusion of the public created by  
2 its activities.

3 248. On information and belief, Fusion's deceptive and misleading  
4 representations about the FDA clearance status, patent pending status, and efficacy of its  
5 LapiLock 4D Correction System were made with the intention that others would rely upon  
6 these representations and thereby cause great and irreparable injury to Treace Medical.

7 249. Fusion's actions demonstrate an intentional, willful, and malicious intent to  
8 trade on the goodwill associated with Treace Medical's LAPIPLASTY® mark and 3D  
9 BUNION CORRECTION™ mark and to cause great and irreparable injury to Treace  
10 Medical.

11 250. As a result of Fusion's acts, Treace Medical has been damaged in an amount  
12 not yet determined or ascertainable. At a minimum, however, Treace Medical is entitled to  
13 injunctive relief, an accounting of Fusion's profits, damages, and costs. Further, in light of  
14 the deliberate and malicious use of a confusingly similar imitation of Treace Medical's  
15 LAPIPLASTY® mark and 3D BUNION CORRECTION mark, and the need to deter  
16 Fusion from engaging in similar conduct in the future, Treace Medical additionally is  
17 entitled to punitive damages.

18 **COUNT 9—COPYRIGHT INFRINGEMENT BY FUSION**

19 251. Treace Medical incorporates by reference Paragraphs 1-250 of this  
20 Complaint as if repeated verbatim in this Paragraph.

21 ***Treace Medical's Copyrighted Works***

22 252. In 2017, Treace Medical commissioned Hartman Brink, LLC to create an  
23 educational video to promote its LAPIPLASTY® 3D Bunion Correction™ procedure as a  
24 work made for hire under 17 U.S.C. § 101 ("2017 Work"). Hartman Brink created the  
25 2017 Work pursuant to this commission. Because Treace Medical specifically  
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1 commissioned the 2017 Work as a work made for hire, Treace Medical owns any and all  
2 copyrights in the 2017 Work.

3 253. In 2021, Treace Medical commissioned Hartman Brink, LLC to update the  
4 educational video as a work made for hire under 17 U.S.C. § 101 (“2021 Work”).  
5 Hartman Brink created the 2021 Work pursuant to this commission. Because Treace  
6 Medical specifically commissioned the 2021 Work as a work made for hire, Treace  
7 Medical owns any and all copyrights in the 2021 Work.

8 254. In this Complaint, the 2017 and 2021 Works are referred to as the  
9 “Copyrighted Works.” The Copyrighted Works are original motion pictures containing  
10 copyrightable subject matter for which copyright protection exists under the Copyright  
11 Act, 17 U.S.C. § 101, et seq. Treace Medical is the exclusive owner of all right, title and  
12 interest in the Copyrighted Works.

13 255. Treace Medical owns valid and subsisting United States Copyright  
14 Registration No. PA 2-339-616 for the 2017 Work, and United States Copyright  
15 Registration No. PA 2-340-075 for the 2021 Work. Proof of registration is attached as  
16 Exhibits K and L.

17 256. Treace Medical has published and distributed the Copyrighted Works on its  
18 website, [www.lapiplasty.com](http://www.lapiplasty.com). The 2021 Work is presently available to the public on  
19 Treace Medical’s website. Before the 2021 Work was available to the public on Treace  
20 Medical’s website, the 2017 Work was available to the public on the website. Treace  
21 Medical has also published the Copyrighted Works on social media websites, including  
22 YouTube and Facebook, where the Copyrighted Works have been viewed more than  
23 20,000 times.

24 257. The Copyrighted Works have been tremendously successful in promoting  
25 Treace Medical’s LAPIPLASTY® 3D Bunion Correction™ procedure. The Copyrighted  
26 Works have been viewed more than one million times on Treace Medical’s website.

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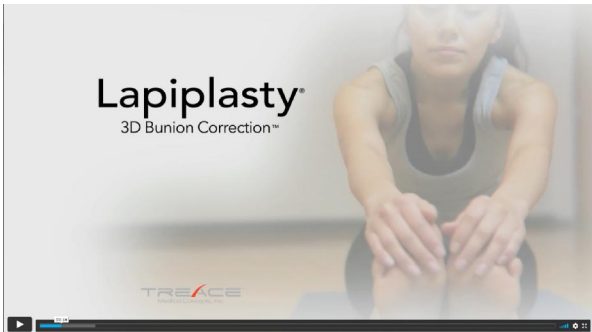

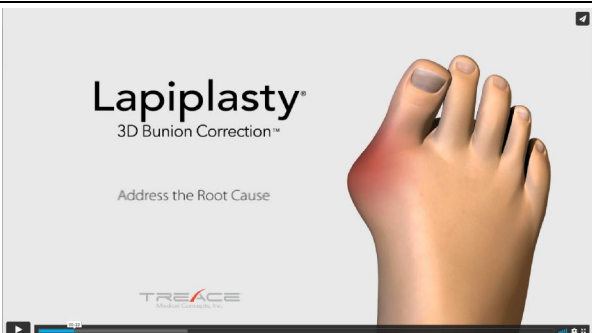

1 258. All public depictions of the Copyrighted Works are accompanied by an  
 2 appropriate copyright notice indicating that Treace Medical is the owner of all rights in the  
 3 Copyrighted Works.

4 259. The Copyrighted Works are of significant value to Treace Medical because  
 5 they increase interest in, and demand for, Treace Medical’s LAPIPLASTY® 3D Bunion  
 6 Correction™ procedure.

7 ***Fusion’s Infringing Conduct***

8 260. Fusion created a video that is a shot-for-shot remake of the Copyrighted  
 9 Works. The video is available on Fusion’s website at  
 10 <https://lapilockbunionsurgery.com/?radius=25>, where it is available to the public.  
 11 (Hereafter, “Infringing Work”).

12 261. The Infringing Work uses strikingly similar images arranged in a virtually  
 13 identical sequence as the Copyrighted Works, as illustrated in the screen shots below.

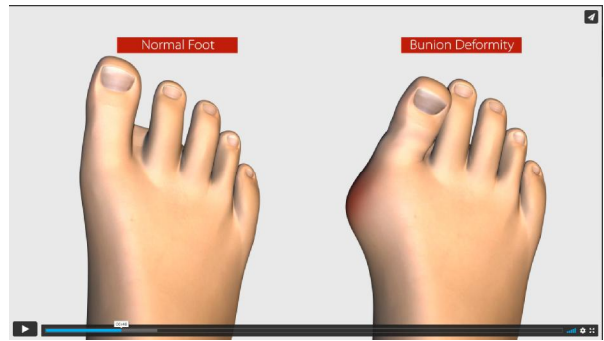
Copyrighted Works	Infringing Work
 <p data-bbox="500 1415 581 1457">00:14</p>	 <p data-bbox="1127 1415 1208 1457">00:12</p>
 <p data-bbox="500 1799 581 1839">00:23</p>	 <p data-bbox="1127 1799 1208 1839">00:24</p>

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### Copyrighted Works



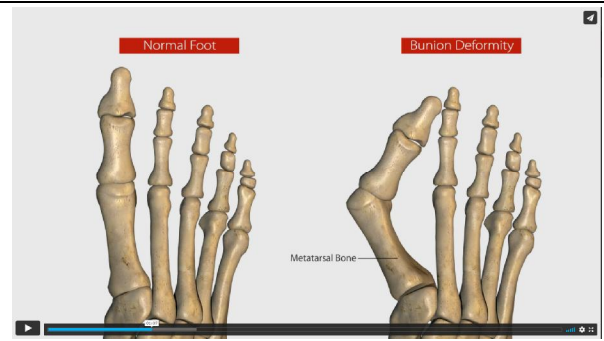
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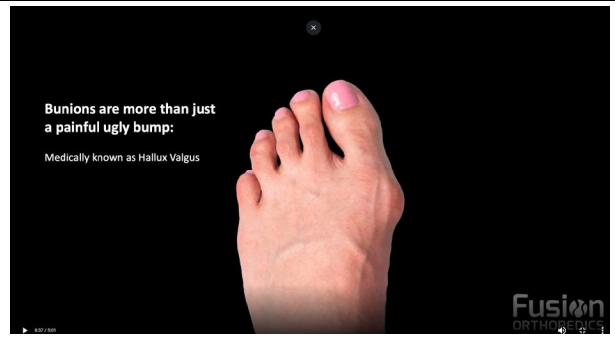


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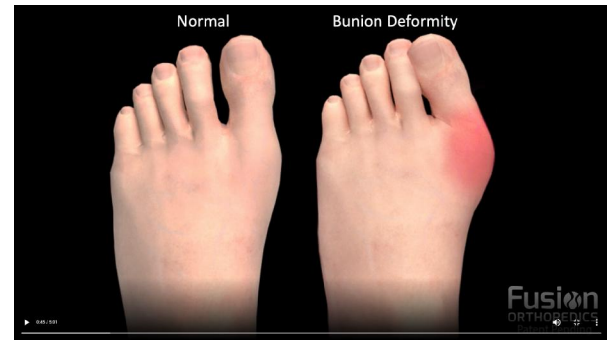


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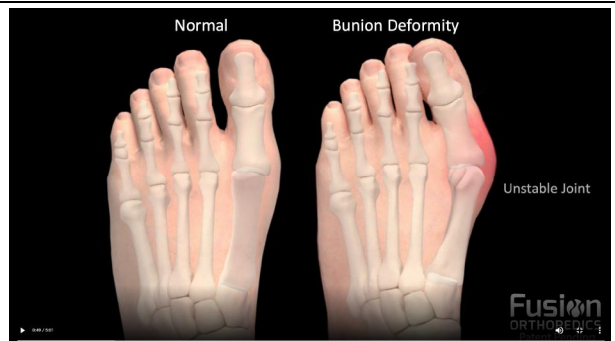
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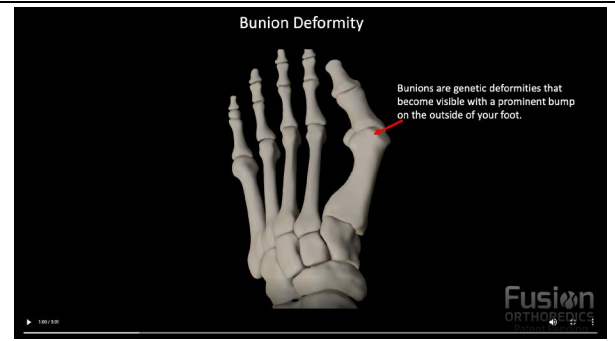
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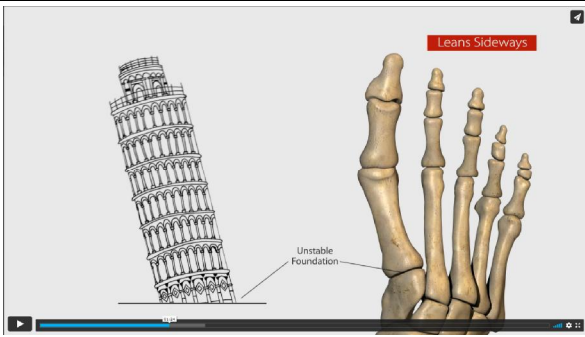


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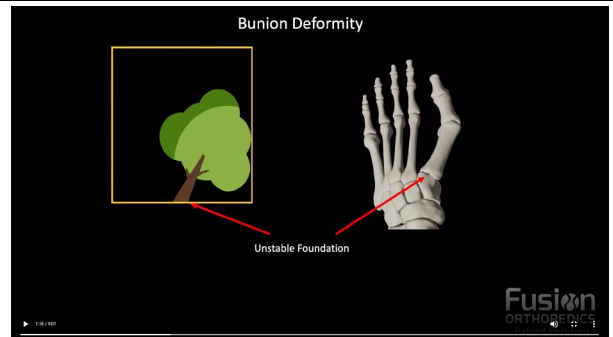
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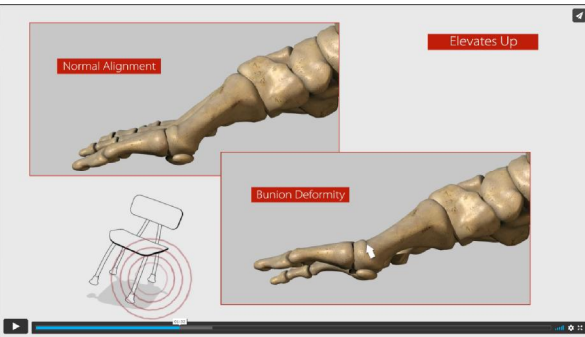


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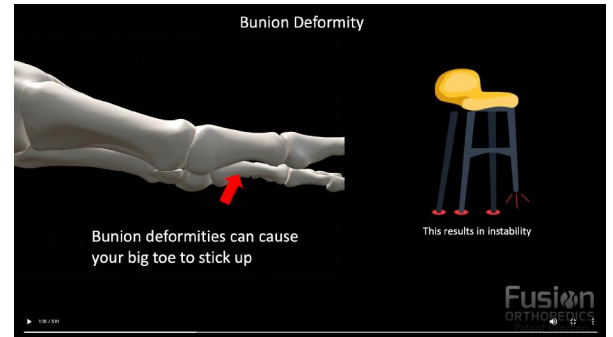
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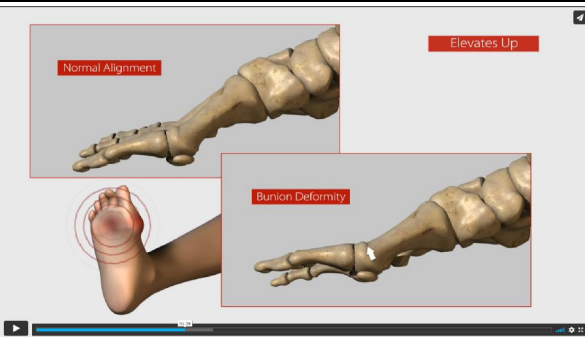
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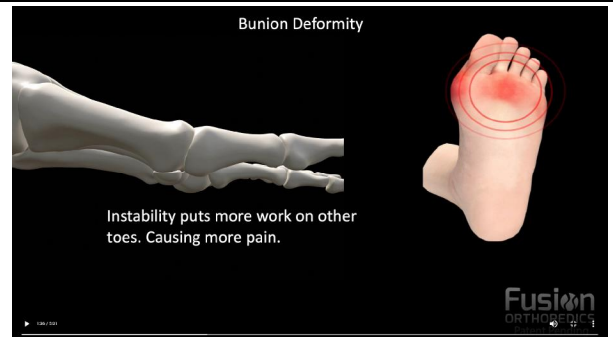
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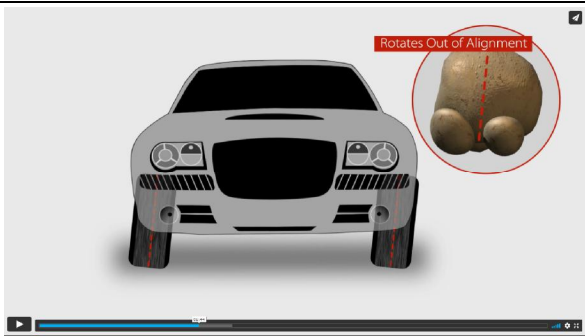
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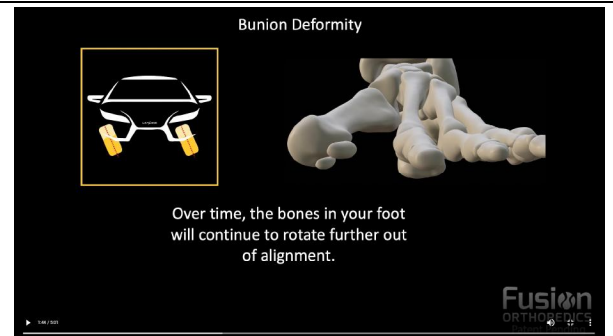
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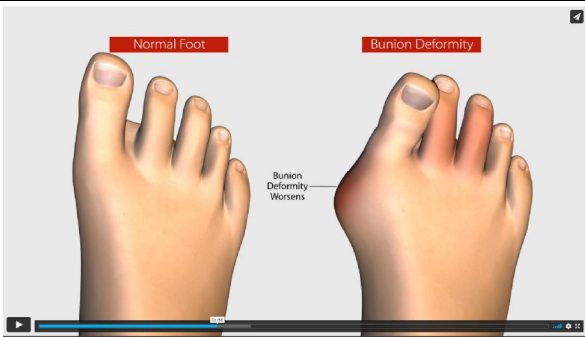


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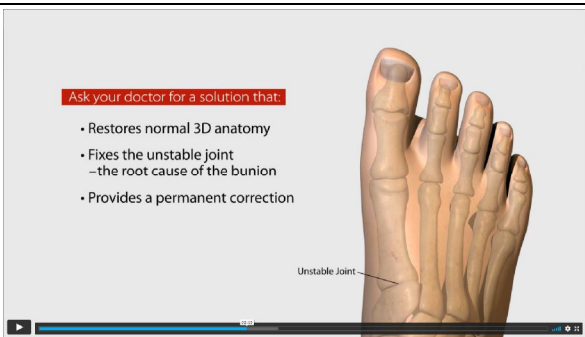
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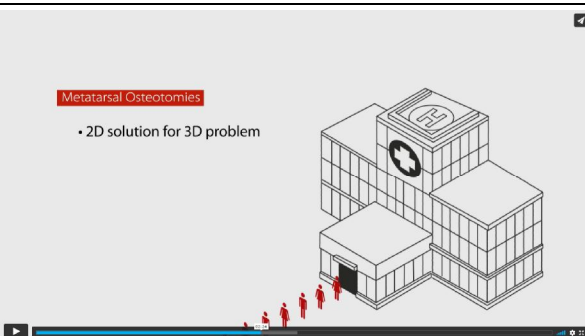
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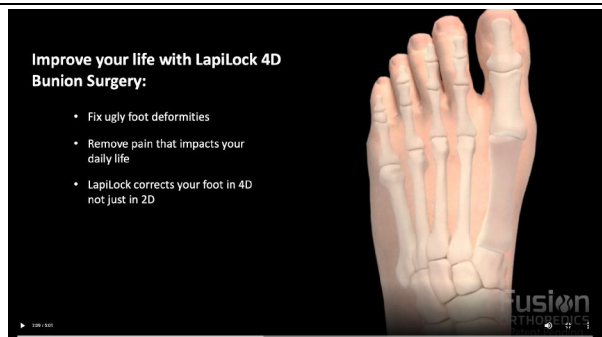
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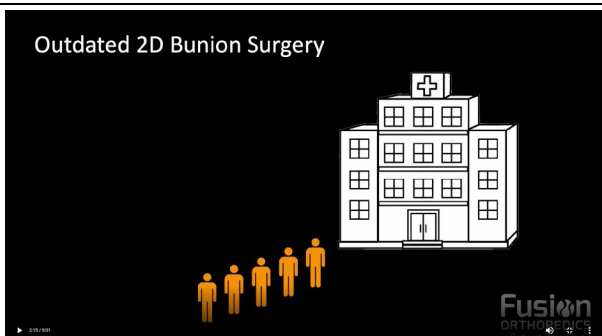
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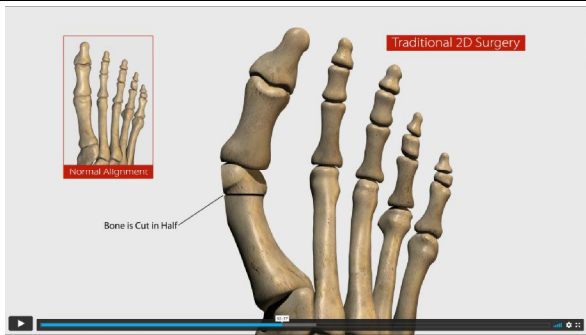
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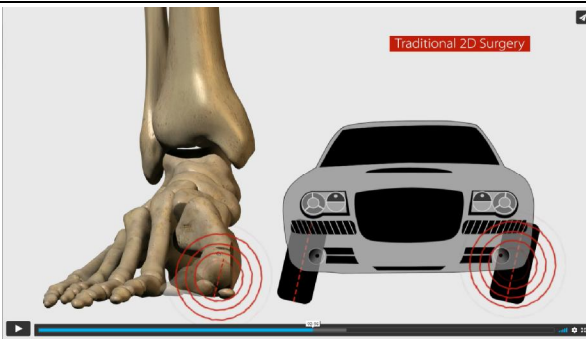
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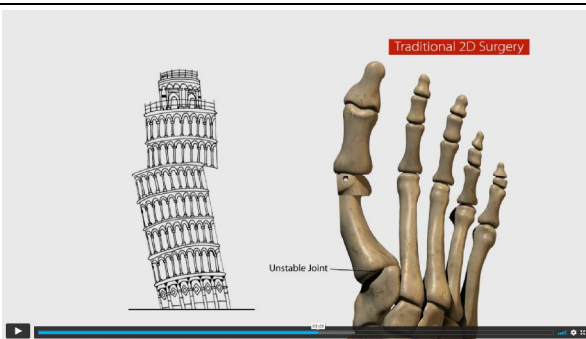
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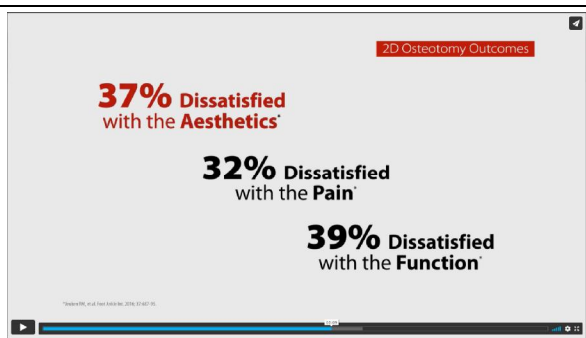
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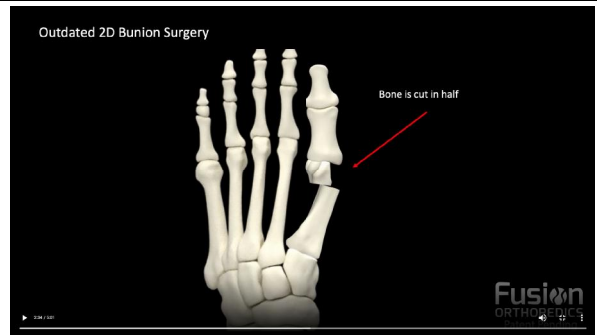


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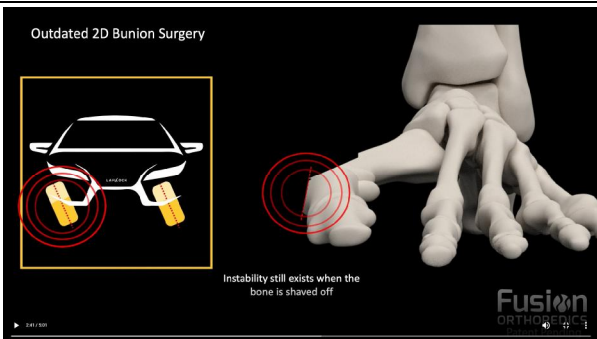


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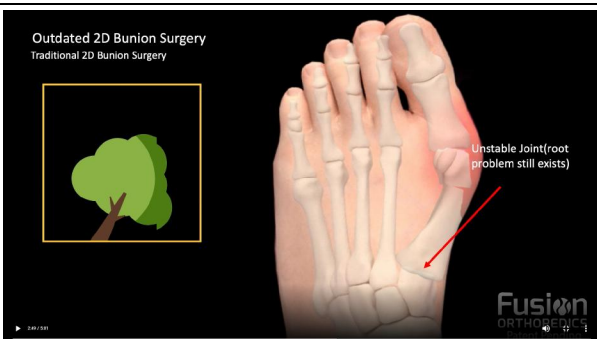
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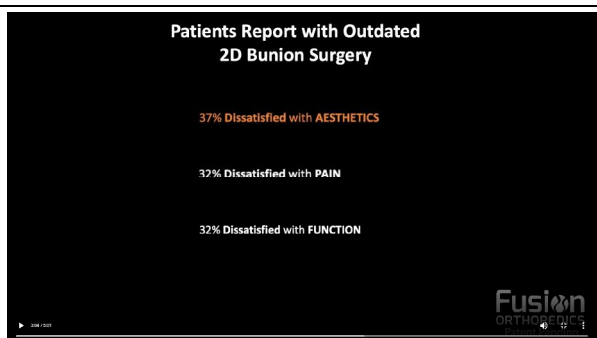
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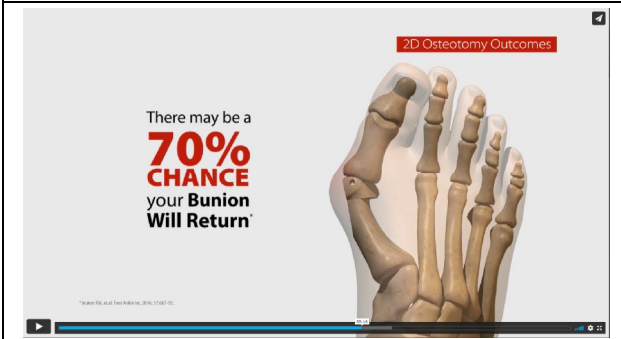


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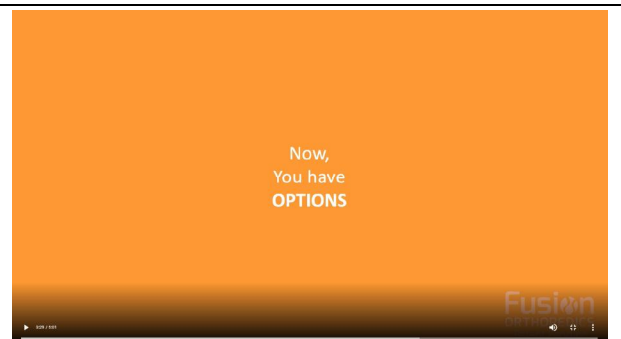
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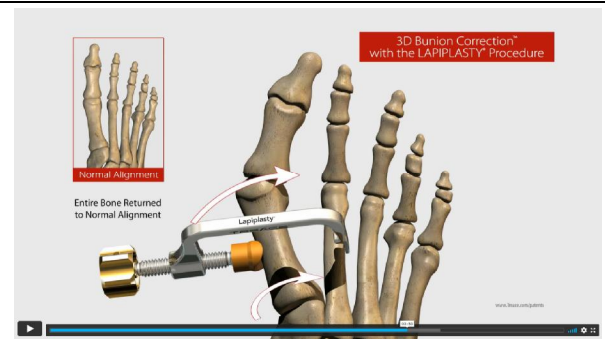


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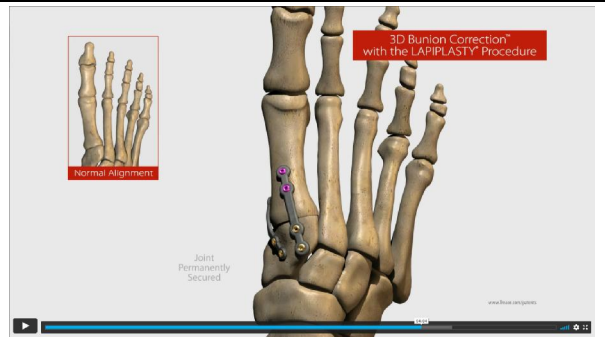
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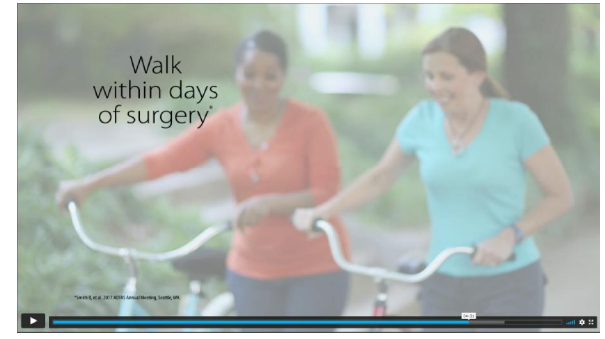
### Copyrighted Works



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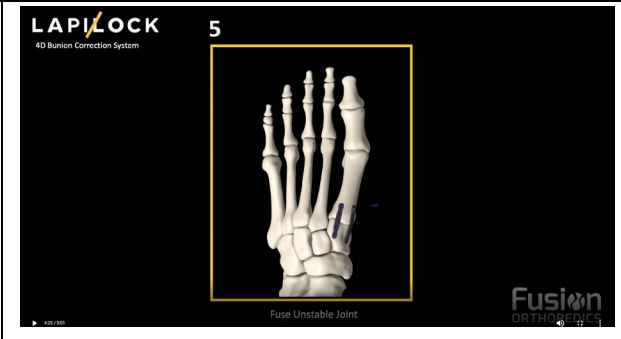


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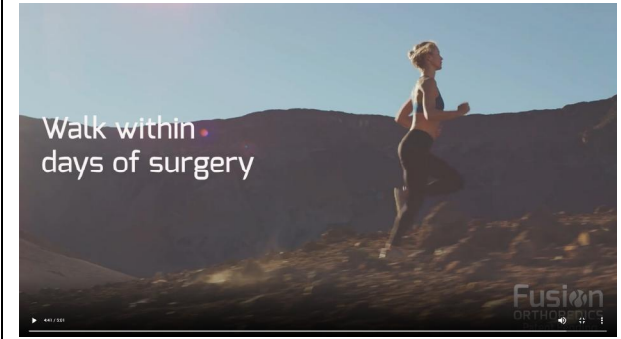
### Infringing Work



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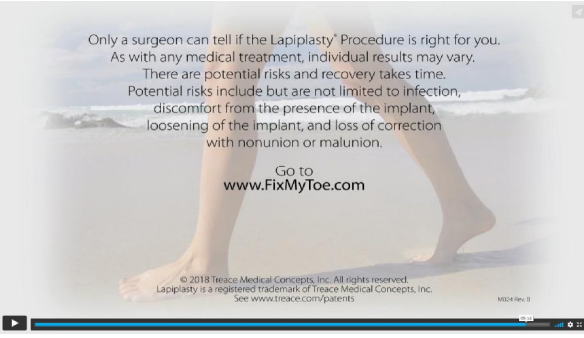

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Copyrighted Works	Infringing Work
 <p>Only a surgeon can tell if the Lapiplasty® Procedure is right for you. As with any medical treatment, individual results may vary. There are potential risks and recovery takes time. Potential risks include but are not limited to infection, discomfort from the presence of the implant, loosening of the implant, and loss of correction with nonunion or malunion.</p> <p>Go to <a href="http://www.FixMyToe.com">www.FixMyToe.com</a></p> <p>© 2018 Treace Medical Concepts, Inc. All rights reserved. Lapiplasty is a registered trademark of Treace Medical Concepts, Inc. See <a href="http://www.treace.com/parents">www.treace.com/parents</a></p> <p>05:16</p>	 <p>This video, and its contents are protected by US and International copyright laws. Reproduction and/or distribution of the video, and its contents, without the express written consent of Fusion Orthopedics, LLC is prohibited.</p> <p>© 2021 Fusion Orthopedics USA, LLC</p> <p>DTP002 Rev 1</p> <p>04:57</p>

262. As the above comparison demonstrates, the Copyrighted Works and the Infringing Work are substantially similar.

263. On information and belief, Fusion viewed Treace Medical's Copyrighted Works and intentionally copied the Copyrighted Works to create the Infringing Work. That Fusion copied the Copyrighted Work when it created the Infringing Work is evidenced by the striking similarities between the Copyrighted Work and the Infringing Work, which cannot possibly be explained other than as a result of copying.

264. Fusion reproduced and distributed the Copyrighted Works without Treace Medical's authorization, consent, or knowledge.

265. Through Fusion's conduct alleged herein, including Fusion's reproduction and distribution of portions of the Copyrighted Works, Fusion has directly infringed Treace Medical's exclusive rights in the Copyrighted Works in violation of Section 501 of the Copyright Act.

266. On information and belief, Fusion's infringing conduct alleged herein was and continues to be willful and with full knowledge of Treace Medical's rights in the Copyrighted Works, and has enabled Fusion to illegally obtain profit.

267. As a direct and proximate result of Fusion's infringing conduct, Treace Medical has been harmed and is entitled to damages in an amount to be proven at trial. Pursuant to 17 U.S.C. § 504(b), Treace Medical is also entitled to recover Fusion's profits



1 attributable to Fusion's infringing conduct. Treace Medical is further entitled to its  
2 attorney's fees and costs under 17 U.S.C. § 505.

3 268. As a direct and proximate result of Fusion's infringing conduct, Treace  
4 Medical has sustained and will continue to sustain substantial, immediate, and irreparable  
5 injury, for which there is no adequate remedy at law. On information and belief, unless  
6 Fusion's conduct is enjoined by this Court, Fusion will continue to infringe the  
7 Copyrighted Works. Treace Medical is therefore entitled to preliminary and permanent  
8 injunctive relief restraining and enjoining Fusion's ongoing infringement.

9 **PRAYER FOR RELIEF**

10 WHEREFORE, Plaintiff Treace Medical Concepts, Inc. prays for the following  
11 relief against Fusion:

12 1. For judgment in favor of Treace Medical that Fusion has infringed and is  
13 infringing the claims of the '590, '426, '670, '335 and '764 Patents, both directly and  
14 indirectly;

15 2. For a preliminary and permanent injunction prohibiting Fusion, including its  
16 officers, agents, employees, and all persons acting in concert or participation with them  
17 who receive actual notice of the Court's Order, from committing further acts of  
18 infringement of the '590, '426, '670, '335 and '764 Patents;

19 3. For an award of damages for Fusion's infringement of the '590, '426, '670,  
20 '335 and '764 Patents in the amount of at least a reasonable royalty, together with interest  
21 (both pre-and post-judgment), costs and disbursements as fixed by this Court under 35  
22 U.S.C. § 284;

23 4. For an award of damages for Fusion's infringement of the '590, '426, '670,  
24 '335 and '764 Patents in the amount of Treace Medical's lost profits associated with  
25 Fusion's sale of the Accused Products, together with interest (both pre-and post-judgment),  
26 costs and disbursements as fixed by this Court under 35 U.S.C. § 284;

27 5. For a determination that Fusion's infringement of the '590, '426, '670, '335  
28 and '764 Patents has been and is willful;

1           6. For an award of enhanced damages under 35 U.S.C. § 284;

2           7. For a determination that this is an exceptional case within the meaning of  
3 35 U.S.C. § 285;

4           8. For an award to Treace Medical of its reasonable attorneys' fees;

5           9. For an accounting for damages;

6           10. For a preliminary and permanent injunction prohibiting Fusion, including its  
7 officers, agents, employees, and all persons acting in concert or participation with them  
8 who receive actual notice of the Court's Order, from committing further acts of trademark  
9 infringement and unfair competition associated with Fusion's illegal use of the  
10 LAPILOCK mark and 4D BUNION CORRECTION phrase;

11           11. For an award of Fusion's profits, actual damages, enhanced profits and  
12 damages, costs, and reasonable attorneys' fees under 15 U.S.C. §§ 1114, 1116, and 1117  
13 for Fusion's illegal use of the LAPILOCK mark and 4D BUNION CORRECTION phrase;

14           12. For a preliminary and permanent injunction prohibiting Fusion, including its  
15 officers, agents, employees, and all persons acting in concert or participation with them  
16 who receive actual notice of the Court's Order, from committing further acts of unfair  
17 competition, including deceptive and misleading representations about the FDA clearance  
18 status, patent pending status, and efficacy of its LapiLock 4D Bunion Correction;

19           13. For judgment in favor of Treace Medical that Fusion has infringed and is  
20 infringing the Copyrighted Works;

21           14. For a preliminary and permanent injunction prohibiting Fusion, including its  
22 officers, agents, employees, and all persons acting in concert or participation with them  
23 who receive actual notice of the Court's Order, from committing further acts of  
24 infringement of the Copyrighted Works;

25           15. For an award of damages for Fusion's infringement of the Copyrighted Works;

26           16. For an award of the profits Fusion obtained as a result of its infringement of  
27 the Copyrighted Works;

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