**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF TEXAS**
**WACO DIVISION**

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| MEDSHAPE, INC., TRILLIANT SURGICAL LLC, and ENCORE MEDICAL, L.P. (d/b/a ENOVIS FOOT AND ANKLE)<br><br>Plaintiff,<br><br>v.<br><br>ARTHREX, INC. and ARTHREX MANUFACTURING, INC.<br><br>Defendants. | Civil Action No. 6:24-cv-151<br><br>**Jury Trial Demanded** |

# COMPLAINT

Plaintiffs Medshape, Inc., Trilliant Surgical LLC, and Encore Medical, L.P. (d/b/a Enovis Foot and Ankle) (collectively, "Enovis"), by and through undersigned counsel, make and file this Complaint against Defendants Arthrex, Inc. and Arthrex Manufacturing, Inc. (collectively, "Arthrex" or "Defendants"), and hereby allege and demand a jury trial as follows:

## NATURE OF THE ACTION

1. This action seeks damages and injunctive relief for Arthrex's acts of making, using, selling, offering for sale and/or importing its DualCompression System that infringes the Asserted Patents.

## THE PARTIES

2. Medshape, Inc. is a wholly owned subsidiary of Trilliant Surgical LLC, a privately held company organized under the laws of Texas. Trilliant Surgical LLC is wholly owned by Encore Medical, L.P., a privately held limited partnership organized under the laws of Delaware.

3. Medshape, Inc., Trilliant Surgical LLC, and Encore Medical, L.P. all do business under the name Enovis Foot and Ankle, which a place of business at 2900 Lake Vista Drive Suite 200, Lewisville, TX 75067.

4. Enovis, through Medshape, Inc., is the owner and assignee of U.S. Patent No. 7,985,222 and U.S. Patent No. 8,491,583 (the "Asserted Patents").

5. Upon information and belief, Arthrex is a Delaware corporation with its principal place of business at 1370 Creekside Boulevard, Naples, Florida 34108.

## JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. § 101 *et seq.*, including 35 U.S.C. § 271, *et seq*. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 and § 1338(a).

7. The Court has personal jurisdiction over Arthrex because Arthrex has committed acts within this District giving rise to this action and has established minimum contacts with this forum such that the exercise of personal jurisdiction over Arthrex would not offend traditional notions of fair play and substantial justice. Arthrex, directly and through subsidiaries or intermediaries, has committed and continues to commit acts of infringement in this District by, among other things, importing, offering to sell, and selling products that infringe the Asserted Patents, and by contributing to and inducing the infringement of the Asserted Patents by others.

8. Venue is proper pursuant to 28 U.S.C. §§ 1391 and 1400(b). Arthrex is registered to do business in Texas and has appointed an agent for service of process in Texas, CT Corporation System, located at 1999 Bryan St., Ste. 900 Dallas, TX 75201. Upon information and belief, Arthrex has transacted business in this District and has committed acts of direct and indirect infringement by, among other things, making, using, offering to sell, selling, and importing products that infringe the Asserted Patents. Arthrex has regular and established places

of business in this District through at least the following exclusive distributors of Arthrex's products who act as agents of Arthrex and who offer for sale and sell and support the infringing product in this District: Core Surgical Group, located at 6702 McNeil Drive, Austin, TX 78703, and Mission Medical Distribution, LLC, located at 814 Arion Pkwy Suite #405, San Antonio, TX 78216 (collectively, the "Exclusive Distributors").

9. Both Core Surgical Group and Mission Medical Distribution, LLC have physical places of business in this District which are attributable to Arthrex given the nature of the agency distributorship relationship between Arthrex and Core Surgical Group and Mission Medical Distribution, LLC.

10. On information and belief, Arthrex controls and directs day-to-day actions of the Exclusive Distributors' employees, who reside in this District and whose work in this District concerns the promotion, education, encouragement, provision, and sale of orthopedic implants, the sale and use of which infringe the Asserted Patents.

11. The offices of the Exclusive Distributors are regular and established places of business attributable to Arthrex because the Exclusive Distributors are agents of Arthrex, the Exclusive Distributors conduct Arthrex's business of offering for sale and selling orthopedic implants which infringe the Asserted Patents, and Arthrex has ratified the Exclusive Distributors as Arthrex's places of business. Specifically, Arthrex demonstrates interim, day-to-day control over the Exclusive Distributors and their employees in the following ways:

a. The Exclusive Distributors present themselves to the public as agents of Arthrex. *See, e.g.*, https://www.linkedin.com/company/core-surgical-group/ (Public LinkedIn page for Core Surgical Group titled "Core Surgical Group, Arthrex Agency").

b. Arthrex refers to its exclusive distributors as "Agents," touts its "Agency Business Model" as setting it apart from its competitors, and states, "the Agency Network is a critical part of the Arthrex family." *See, e.g.*, https://www.arthrex.com/job-seeker/sales/agency-overview.

c. Exclusive distributors "can only represent Arthrex, no other manufacturers" and Arthrex provides "unequaled financial, corporate, and marketing support" to the Exclusive Distributors. *See*, *e.g.*, https://www.arthrex.com/job-seeker/sales/agency-overview.

d. Arthrex approved the creation of the Exclusive Distributors and regulates the geographical territory in which the Exclusive Distributors can sell Arthrex products, to ensure that no distributor competes with any other distributor. *See, e.g.*, https://csg.atxclients.com/about/).

e. Arthrex's website hosts "Company Profiles" of the Exclusive Distributors, posts job openings for the Exclusive Distributors, and lists job requirements for prospective employees of the Exclusive Distributors. *See, e.g.*, https://www.arthrex.com/job-seeker/open-positions/4104/orthopedic-sales-associate-for-core-surgical.

f. Arthrex requires employees of the Exclusive Distributors to travel to Arthrex's headquarters to participate in rigorous, multi-day training on how to use and sell Arthrex's products before authorizing employees of the Exclusive Distributors to sell Arthrex products. These trainings are designed to teach the employees Arthrex's system for how to use and demonstrate the products to doctors, how the employees should prepare for surgeries, and how the employees should conduct

themselves in the operating room during surgeries. *See, e.g.*, https://csg.atxclients.com/careers/ (statement on Core Surgical Group's website stating "Arthrex believes that it is our responsibility to provide the most sophisticated medical device sales training programs in the industry. All our newly hired team members follow a detailed two-year development plan that enables them to master more than 100 different surgical procedures, while building trust with our surgeon customers.").

g. Upon information and belief, Arthrex exercises control over the selling price of products sold by the Exclusive Distributors, and the Exclusive Distributors cannot alter the price of any products during the sales process.

h. The sale and use of orthopedic implants, including those that are alleged to infringe the Asserted Patents, are regulated by the United States Food and Drug Administration ("FDA"). As part of seeking approval for the use of its products in patients, Arthrex submits information to the FDA, including the specific design of the product and the medical indications for which it can be used. Arthrex maintains controls over the design and acceptable indications for use of its orthopedic implants and does not permit its Exclusive Distributors to modify its orthopedic implants or offer its orthopedic implants for improper, off-label indications as part of the selling process.

i. Upon information and belief, Arthrex employees frequently travel to the Exclusive Distributors to host on-site trainings for employees of the Exclusive Distributors, as well as accompany employees of the Exclusive Distributors on sales calls to doctors and in the operating room to educate and direct the methods

in which the Exclusive Distributors sell Arthrex products, including orthopedic implants alleged to infringe the Asserted Patents.

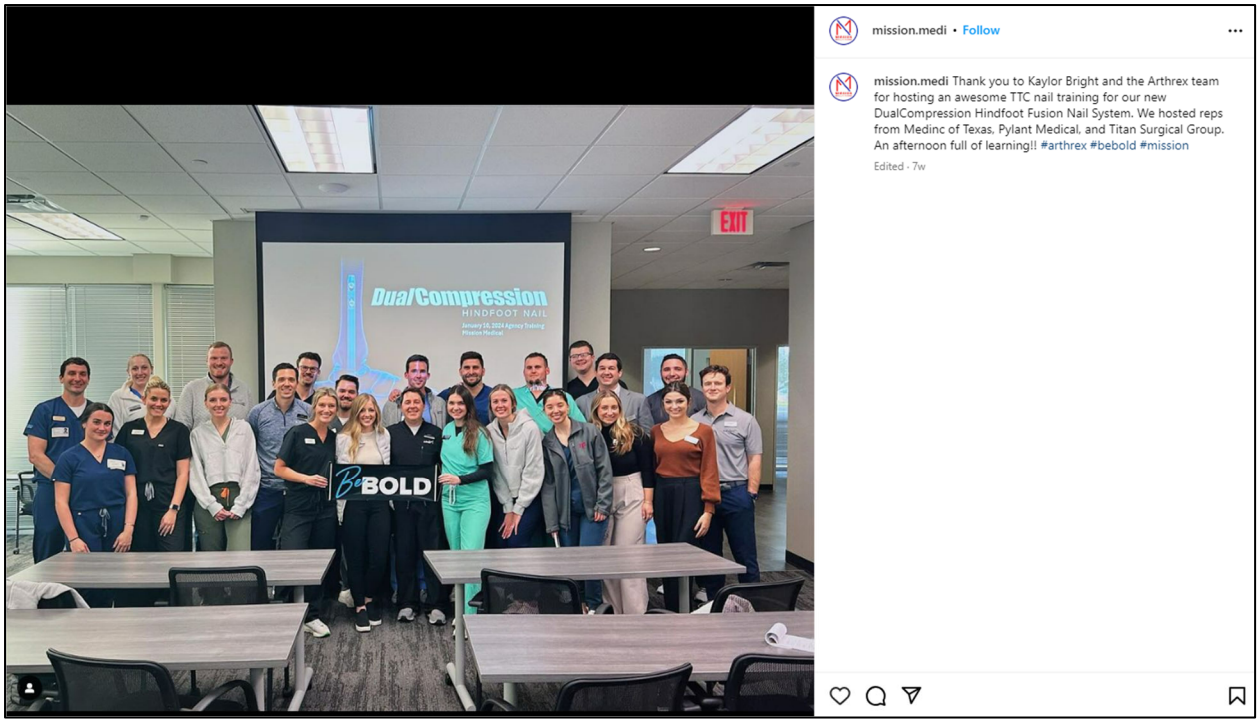
j. Upon information and belief, Arthrex retains ownership of surgical tools used to implant orthopedic implants such as those alleged to infringe the Asserted Patents, even after they are transferred to the Exclusive Distributors. Upon information and belief, Arthrex retains the authority and control to demand that its surgical tools be recalled from the Exclusive Distributors at any time and sent to Arthrex's headquarters or another exclusive distributor.

k. Upon the completion of a sale of orthopedic implants, including those alleged to infringe the Asserted Patents, the Exclusive Distributors are required to report to Arthrex the precise number of orthopedic implants sold in order to be compensated for the sale.

l. Arthrex encourages and promotes the Exclusive Distributors to use Arthrex's trademarked logo and imagery on its websites and on its physical offices. As a result, Arthrex holds itself out to customers that it has a physical place of business through which it conducts business in this District. *See, e.g.,* https://csg.atxclients.com/about/ (showing use of Arthrex's trademarks on its websites and on offices of Core Surgical Group in this District):


m. The websites of the Exclusive Distributors include listings for "Arthrex Products." *See* https://csg.atxclients.com/; *see also* https://missionmedi.com/products/. Clicking on any of the products redirects the user away from the Exclusive Distributor website and directly to the Arthrex website which contains specific information about the products.

n. The Exclusive Distributors publicly describe the Accused System as "our" product:




## FACTUAL BACKGROUND

### THE ’222 PATENT

12. U.S. Patent Number 7,985,222 (the “’222 Patent”) is entitled “Osteosynthetic Implants and Methods of Use and Manufacture.” The ’222 Patent was duly and legally issued on July 26, 2011, by the United States Patent and Trademark Office. A true and correct copy of the ’222 Patent is attached to this Complaint as Exhibit A.

13. Enovis, through Medshape, Inc., is the owner and assignee of the ’222 Patent. Enovis possesses all rights of recovery under the ’222 Patent, including the exclusive right to sue for infringement and recover past damages.

14. The ’222 patent has not expired and is in full force and effect.

15. Pursuant to 35 U.S.C. § 282, the ’222 Patent and each of its claims are valid and enforceable.

16. The ’222 Patent relates to “methods of stabilizing a fractured bone” using an “elongate element,” such as “a plate, a bone nail, a bone screw,” having “a responsive zone of a shape memory material” and “adapted to apply a desired pressure to the bone when coupled thereto.” The method involves “applying a force to the elongate element to lengthen the responsive zone a desired amount, maintaining the element in the lengthened position, coupling the element to the bone so that so that the lengthened responsive zone is positioned adjacent the fracture site, and releasing the elongate element” to “provide sustained compression (spontaneous dynamic compression) across a bone fracture over time” to facilitate fracture site stability and healing.

**THE ’583 PATENT**

17. U.S. Patent Number 8,491,583 (the “’583 Patent”) is entitled “Intramedullary Medical Device and Methods of Use and Manufacture.” The ’583 Patent was duly and legally issued July 23, 2013, by the United States Patent and Trademark Office. A true and correct copy of the ’583 Patent is attached to this Complaint as Exhibit B.

18. Enovis, through Medshape, Inc., is the owner and assignee of the ’583 Patent. Enovis possesses all rights of recovery under the ’583 Patent, including the exclusive right to sue for infringement and recover past damages.

19. The ’583 Patent has not expired and is in full force and effect.

20. Pursuant to 35 U.S.C. § 282, the ’583 Patent and each of its claims are valid and enforceable.

21. The ’583 Patent relates to “intramedullary medical devices (e.g., intramedullary nails)” that “may provide sustained compressive forces across a bone fusion site despite bone resorption processes.”

## ENOVIS'S DYNANAIL®

22. Since its inception in 1995 as the medical device company Colfax Corporation, Enovis has strived to develop high-quality orthopedic implants designed to maximize patient healing and recovery, including joint replacement implants, braces, and the technology covered by the Asserted Patents, bone fixation devices.

23. One bone fixation device Enovis provides is the DynaNail®. Enovis's DynaNail® System provides surgeons a system to use for surgeries involving ankle and foot fusion, such as tibiotalocalcaneal (TTC) fusion surgery.

24. TTC surgery involves fusing the tibia, talus, and calcaneal bones. It is performed to relieve pain and correct severe foot/ankle deformity, arthritis, instability, skeletal defects after tumor resection, or to salvage prior operations. Traditional titanium and stainless steel implants (screws and plates) used for TTC fusion surgeries lose compression post-operatively. This results in nonunion of the bones or development of a void between the bones.

25. While external fixation frames are available for use with titanium and stainless steel screws to allow for application of compression during treatment, they are surgically complex, have poor patient compliance, and have a relatively high rate of infection.

26. Continuing to drive innovation in medical technology, Enovis acquired Medshape, Inc. ("Medshape") in 2021. Medshape pioneered research into shape memory medical devices, earning eighteen patents in this field. Indeed, after developing the surgical method and technology and clearing 510(k) from the U.S. Food and Drug Administration, DynaNail® was successfully used in surgery performed by Dr. Doug Pacaccio, DPM, co-founder of Medshape, in 2012.

27. During initial development of DynaNail®, and the technology underlying those products, the inventors faced skepticism regarding the function, capability, and utility of the concepts of using shape memory alloys for compression of bony material.

28. DynaNail® was launched in 2013 and was the first fusion approach to harness the shape memory properties of NiTiNOL, a shape memory alloy that offers sustained, active compression to the bones, maintaining them in close apposition while also providing dynamization. Unlike other devices on the market that lose compression post-operatively, the DynaNail® maintains compression throughout the healing process to meet this need. Clinical results showed this sustained, dynamic compression allowed for faster fusion times and successful arthrodesis in a population at high risk for nonunion of the bones and also required less hardware.

29. DynaNail® was extremely successful commercially and differentiated Enovis in the marketplace as the only compression fusion nail for applications such as TTC of its kind. DynaNail® represents a significant portion of Enovis's total portfolio and has grown over 25% annually since 2021. DynaNail® is a differentiating product in the market and is a critical component of Enovis's innovative competitive standing in the market.

**ARTHREX'S KNOWLEDGE OF ENOVIS'S PATENTS AND PATENT RIGHTS**

30. Arthrex manufacturers medical devices and competes in the relevant area of orthopedic implants and fixation devices with various companies.

31. Given the competitive landscape in which Arthrex operates, on information and belief, Arthrex has monitored not only the products and techniques offered by its competitors, but also the intellectual property and licenses competitors have reached regarding third-party intellectual property rights.

32. The ’222 Patent, the earliest patent at issue in this Complaint, was published in 2005.

33. Upon information and belief, Arthrex has known of the ’222 Patent and ’583 Patent through its efforts to keep apprised of its industry and/or the intellectual property associated with its industry.

34. Arthrex has been aware of the technology described and claimed in the ’222 Patent and ’583 Patent since the early 2000s, when the owner of Arthrex met with Ken Gall of Medshape regarding the technology. Another such meeting occurred between Arthrex representatives and Ken Gall and Kurt Jacobus of Medshape at Arthrex’s headquarters in Naples, FL.

35. Arthrex has been aware of Enovis’s DynaNail® since that product was released on the market.

36. The ’222 Patent (and at least three other publications by inventor, Gall) are listed on the face of at least nine Arthrex U.S. Patents / Patent Applications. Specifically, on May 13, 2015, Arthrex included the ’222 Patent in an IDS during prosecution of Patent Application No. 14/541,017. By way of further example, Arthrex lists the ’222 Patent in an IDS filed on Arthrex Patent Application No. 15/288,108—the day the application was filed.

37. The ’583 Patent is listed on the face of at least two Arthrex U.S. Patents / Patent Applications. Specifically, on April 17, 2017, Arthrex included the ’583 Patent in an IDS during prosecution of Patent Application No. 15/489,067, filed on the same day the application was filed. By way of further example, on May 29, 2019, Arthrex listed the ’583 Patent in an IDS filed on Arthrex Patent Application No. 16/030,154

38. As further evidence of Arthrex's awareness of the Asserted Patents, Arthrex identifies the DynaNail® as a reference device for the DualCompression Hindfoot Fusion Nail in its December 19, 2022, 510(k) submission to the Food and Drug Administration. Ex. C (FDA 510(k)), pp. 2-4.

39. As such, Arthrex has affirmatively known of Enovis's intellectual property covering the implants and techniques associated with the Arthrex DualCompression Hindfoot Fusion Nail as described herein, or at the very least, been willfully blind to the existence of that intellectual property and its relation to the Arthrex DualCompression Hindfoot Fusion Nail as described herein.

**ARTHREX'S DUALCOMPRESSION SYSTEM**

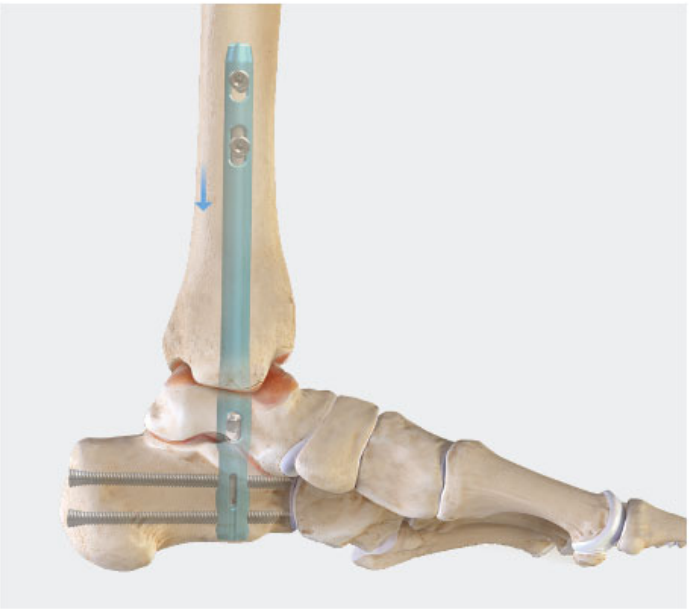
40. The term "Accused System" as used herein refers to the DualCompression Hindfoot Fusion Nail System. The term "Accused System" encompasses but is not limited to the DualCompression Hindfoot Fusion Nail System, and includes the combination of (a) the instruments of the DualCompression Hindfoot Fusion Nail System, together with (b) the DualCompression Hindfoot Nail, Interlocking Screws, Cable, and End Caps.

41. Upon information and belief, the Accused System was designed to compete in the market with products such as Enovis's DynaNail®.

42. Arthrex has manufactured, sold, distributed, loaned, consigned, or otherwise made available the surgical instruments and implants for TTC fusion procedures under the name DualCompression Hindfoot Fusion Nail System.

43. For example, the Accused System is indicated for TTC fusion procedures. Ex. D (Arthrex, "DualCompression Hindfoot Nail: Surgical Technique." (LT1-000194-en-US C (Oct. 15, 2023)) ("ST Guide")), p. 4 ("The DualCompression hindfoot fusion nail implant system is

intended to facilitate tibiotalocalcaneal arthrodesis to treat severe foot/ankle deformity, arthritis, instability, and skeletal defects after tumor resection."); Ex. C (FDA 510(k)), p. 1. Provided below is an image of a DualCompression Hindfoot Nail that has been implanted and fixed to the tibial and calcaneal bones.



Ex. D (ST Guide), p. 4. With reference to this image, Arthrex states the "nitinol core dynamically tensions the construct between the tibial and calcaneal interlocking screws, creating compression across the tibiotalar and subtalar joints postoperatively." *Id.*

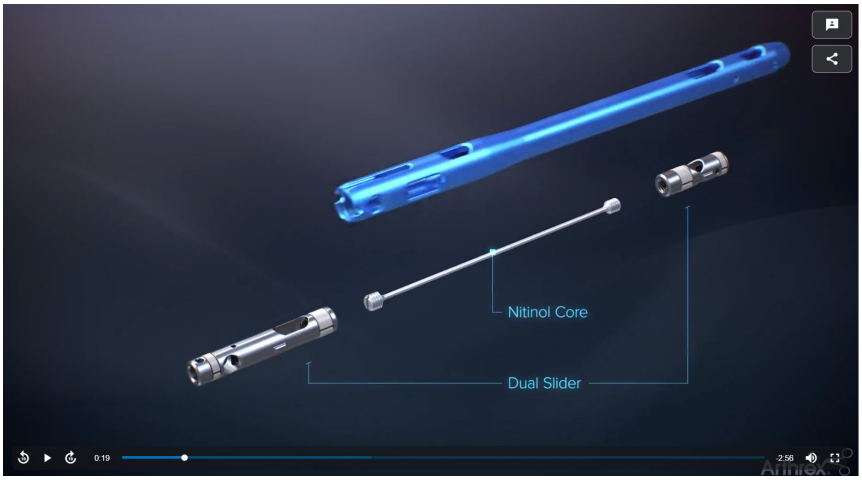
44. Arthrex provides demonstrations and materials teaching the use of its Accused System in TTC fusion procedures. For example, Arthrex provides a Surgical Technique Guide that is describes as "an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products." Ex. D (ST Guide), p. 32.

45. On its website, Arthrex provides a product demonstration video (*available at* https://www.arthrex.com/resources/AN1-000272-en-US/dualcompression-hindfoot-fusion-nail-system?referringteam=foot_and_ankle), a surgical technique animation (*available at*

https://www.arthrex.com/resources/AN1-000544-en-US/dualcompression-hindfoot-nail?referringteam=foot_and_ankle), and a surgical technique video (*available at* https://www.arthrex.com/resources/VID1-002194-en-US/dualcompression-hindfoot-nail-surgical-technique?referringteam=foot_and_ankle). These materials describe, *inter alia*, steps for inserting the DualCompression Hindfoot Nail into the tibia and calcaneus bones, securing the Nail to the calcaneus using calcaneal screws, securing the Nail to the tibia using tibial screws, and tensioning the nitinol core of the Nail.

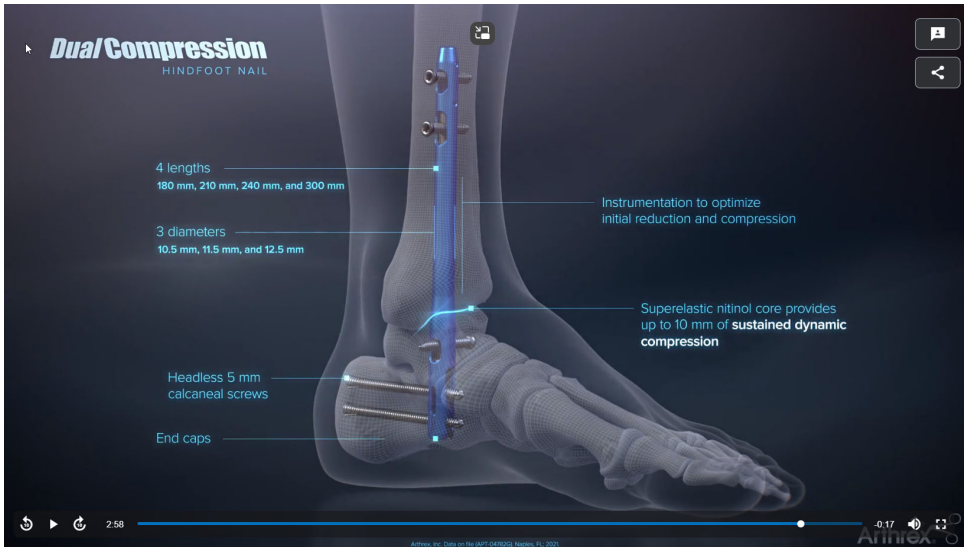
46. Arthrex advertises the Accused System "is designed to streamline application of intraoperative and sustained dynamic compression." Ex. E (Arthrex, "Scope This Out" Vol 24, No. 2).

47. Arthrex states the DualCompression Hindfoot Nail "contains a nitinol core and dual slider mechanism that allows for sustained dynamic compression post operatively" in its product demonstration video, "DualCompression Hindfoot Fusion Nail System: Product Demonstration" (July 21, 2023) AN1-000272-en-US. An excerpt from the video at 0:19 is produced below.




*Available at* https://www.arthrex.com/resources/AN1-000272-en-US/dualcompression-hindfoot-fusion-nail-system?referringteam=foot_and_ankle.

48. Arthrex further teaches that "the stretched nitinol core maintains compression across the joint and enables sustained dynamic compression across the joint post-operatively," in its Surgical Technique Animation (*available at* https://www.arthrex.com/resources/AN1-000544-en-US/dualcompression-hindfoot-nail?referringteam=foot_and_ankle). An excerpt from the video at 2:58 is shown below:




49. Arthrex asserted to the FDA that the Accused System is substantially equivalent to two NiTiNOL DynaNail® solutions. The "reference devices cleared under … K171376 [Medshape Solutions DynaNail® TTC Fusion System] and K113828 [Medshape Solutions DynaNail® Ankle Arthrodesis Nail], with minor dimensional modifications with no change to intended use or function. Any differences between the Accused System and the predicate devices are considered minor and do not raise different questions of safety or effectiveness." Ex. C (FDA 510(k)), p. 4.

## COUNT ONE
## INFRINGEMENT OF U.S. PATENT NO. 7,985,222

50. Enovis incorporates by reference the preceding paragraphs of this Complaint.

51. Arthrex, without license or authorization to do so, induces the infringement of and contributes to infringement of the ’222 Patent in violation of 35 U.S.C. §§ 271(b)-(c), by manufacturing, selling, distributing, loaning, consigning, or otherwise making available the Accused System to orthopedic surgeons who implant the DualCompression Hindfoot Nail using the Accused System, resulting in the infringement of at least claim 1 of the ’222 Patent, in violation of 35 U.S.C. § 271(a).

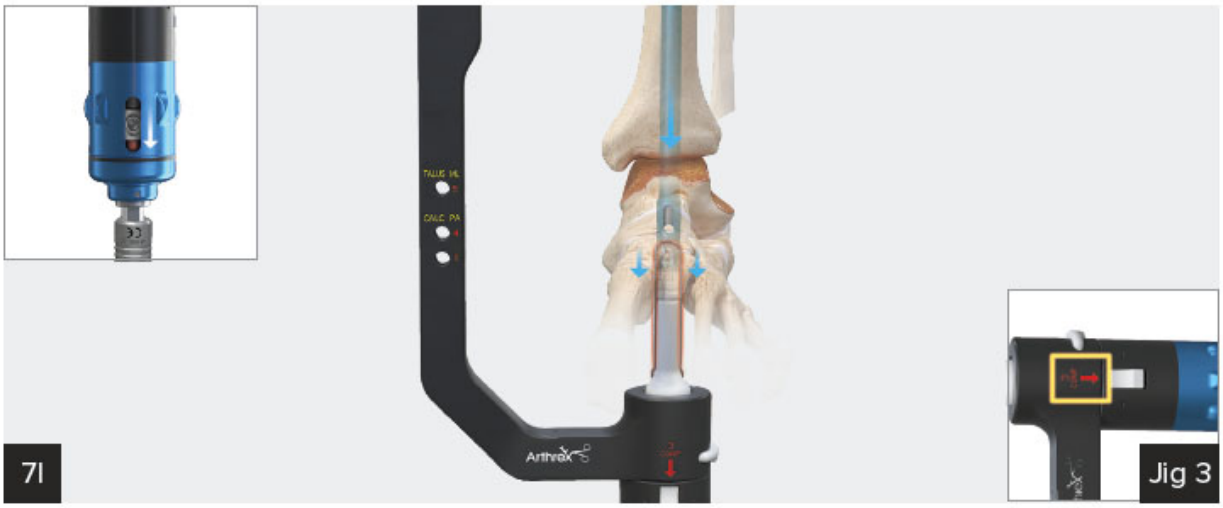
52. Arthrex induces the infringement of at least claim 1 of the ’222 Patent by providing, either along with or in conjunction with the Accused System, instruction, education, and/or encouragement to surgeons to use the Accused System to perform the methods of at least claim 1 of the ’222 Patent.

53. Arthrex provides instruction, education, and/or encouragement to surgeons on how to implant the DualCompression Hindfoot Fusion Nail using the Accused Systemin a manner that infringes at least claim 1 of the ’222 Patent.

54. For example, Arthrex instructs surgeons to insert a bone device having a longitudinal axis into a first bone fragment and a second bone fragment, wherein the inserting causes a first portion of the bone device to contact the first bone fragment and causes a second portion of the bone device to contact the second bone fragment, the second portion different from the first portion, through its Surgical Technique Guide for the Accused System, as depicted below:

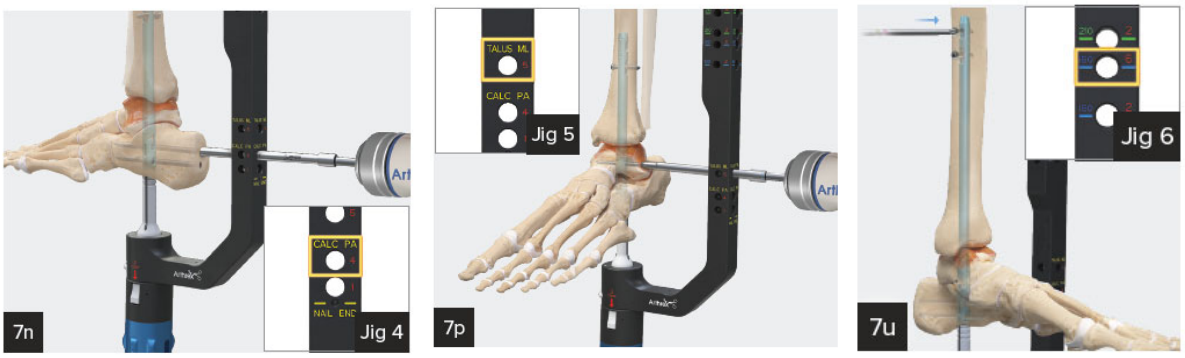

Ex. D (ST Guide), p. 17.

55. Arthrex's Surgical Technique Guide further teaches the bone device comprises a shape memory alloy having an austenite finish temperature and creating in a responsive portion of the bone device at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis. For example, as shown below, Arthrex instructs surgeons to "[t]urn the T-handle on the cable-tensioning device until the hard stop of the device is reached. This ensures that the nitinol core is fully stretched and the distal slider is seated in the correct position," with reference to the figure below:




Ex. D (ST Guide), p. 21.

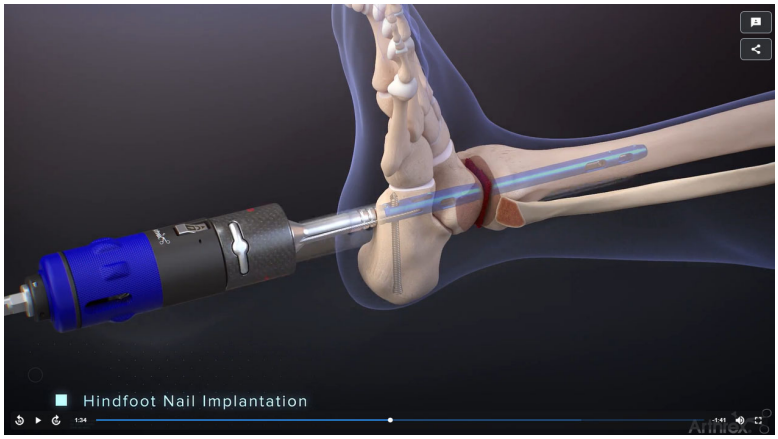
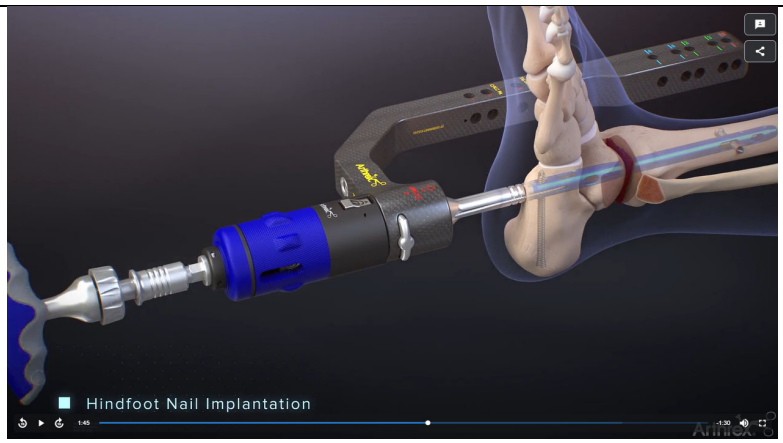
56. Arthrex's Surgical Technique Guide instructs surgeons to fix the second portion of the bone device to the second bone fragment after performing the stretching. For example, the Surgical Technique Guide instructs surgeons to, after stretching the nitinol element, insert a calcaneal screw, and optionally a talar screw and/or a tibial screw:




Ex. D (ST Guide), pp. 20, 23, 24.

57. Further, the creating of the transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis is performed at a temperature greater than the austenite finish temperature of the nitinol.

58. In addition to the Surgical Technique Guide, Arthrex provides videos inducing surgeons to infringe the '222 Patent. The video shows such inducement in step-by-step instructions that, when practiced by surgeons, depicts infringement of at least claim 1 of the '222 Patent:

| | |
|---|---|
| 1:22-1:44 |  <br>  |
| 1:44-2:05 |  |

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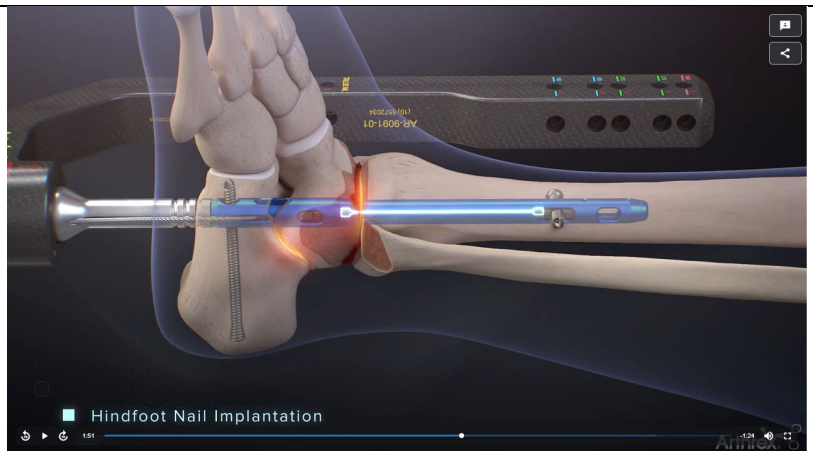
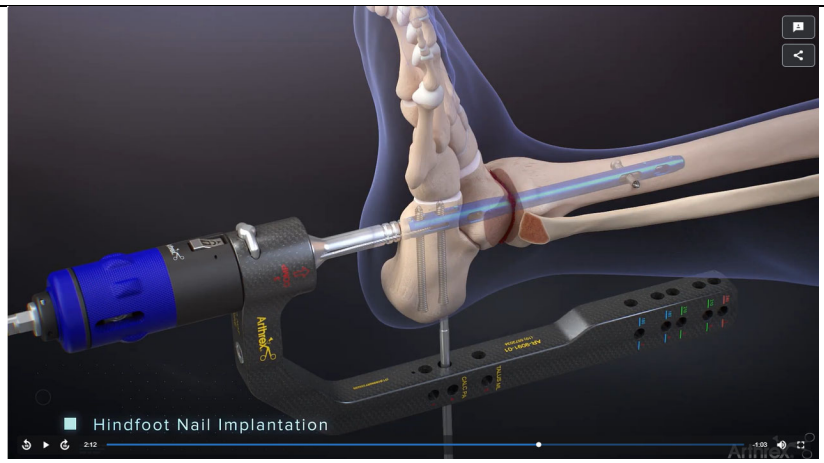
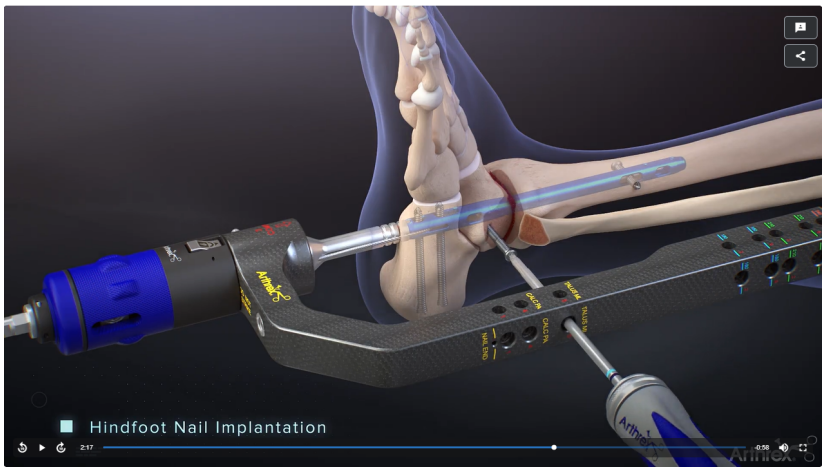
|---|---|
| |  Hindfoot Nail Implantation |
| 2:08-2:27 |  Hindfoot Nail Implantation<br>  Hindfoot Nail Implantation |

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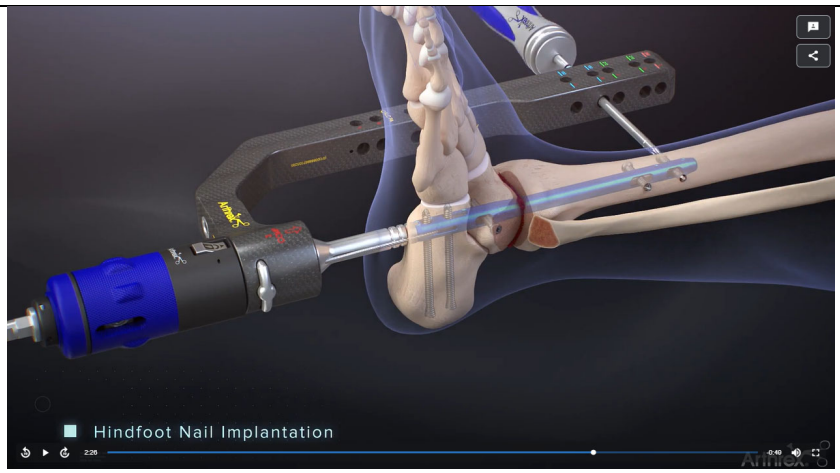
|---|---|
| |  |

*Available at:* https://www.arthrex.com/resources/AN1-000272-en-US/dualcompression-hindfoot-fusion-nail-system (last visited March 21, 2024).

59. In this manner, Arthrex induces surgeons to infringe at least claim 1 of the ’222 Patent when they use the Accused System.

60. Arthrex also indirectly infringes by contributing to the direct infringement of surgeons under 35 U.S.C. § 271(c) by providing its Accused System, which is specially made for use in a manner infringing one or more claims of the ’222 Patent and has no non-infringing uses.

61. Arthrex provides the DualCompression Hindfoot Nail specifically for use with the Accused System in a method that infringes at least claim 1 of the ’222 Patent. The DualCompression Hindfoot Nail does not appear to be available for use with other Arthrex systems. The Accused System is specifically designed so that the nitinol core is stretched and then provides compressive loading, bringing a first and second bone fragment together, and thus is not a staple article of commerce capable of substantial non-infringing uses.

62. Because Arthrex knows and at all relevant times has known of its infringement of the ’222 Patent, or at the very least has been willfully blind to its infringement of the ’222 Patent, its infringement is deliberate and willful.

63. Enovis has been and continues to be damaged and irreparably harmed by Arthrex's infringement of the '222 Patent.

64. Upon information and belief, such infringement has been, and will continue to be willful, and upon further belief, Arthrex lacks any reasonable invalidity or non-infringement defense making this case exceptional and entitling Enovis to increased damages and reasonable attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285.

**COUNT TWO**
**INFRINGEMENT OF U.S. PATENT NO. 8,491,583**

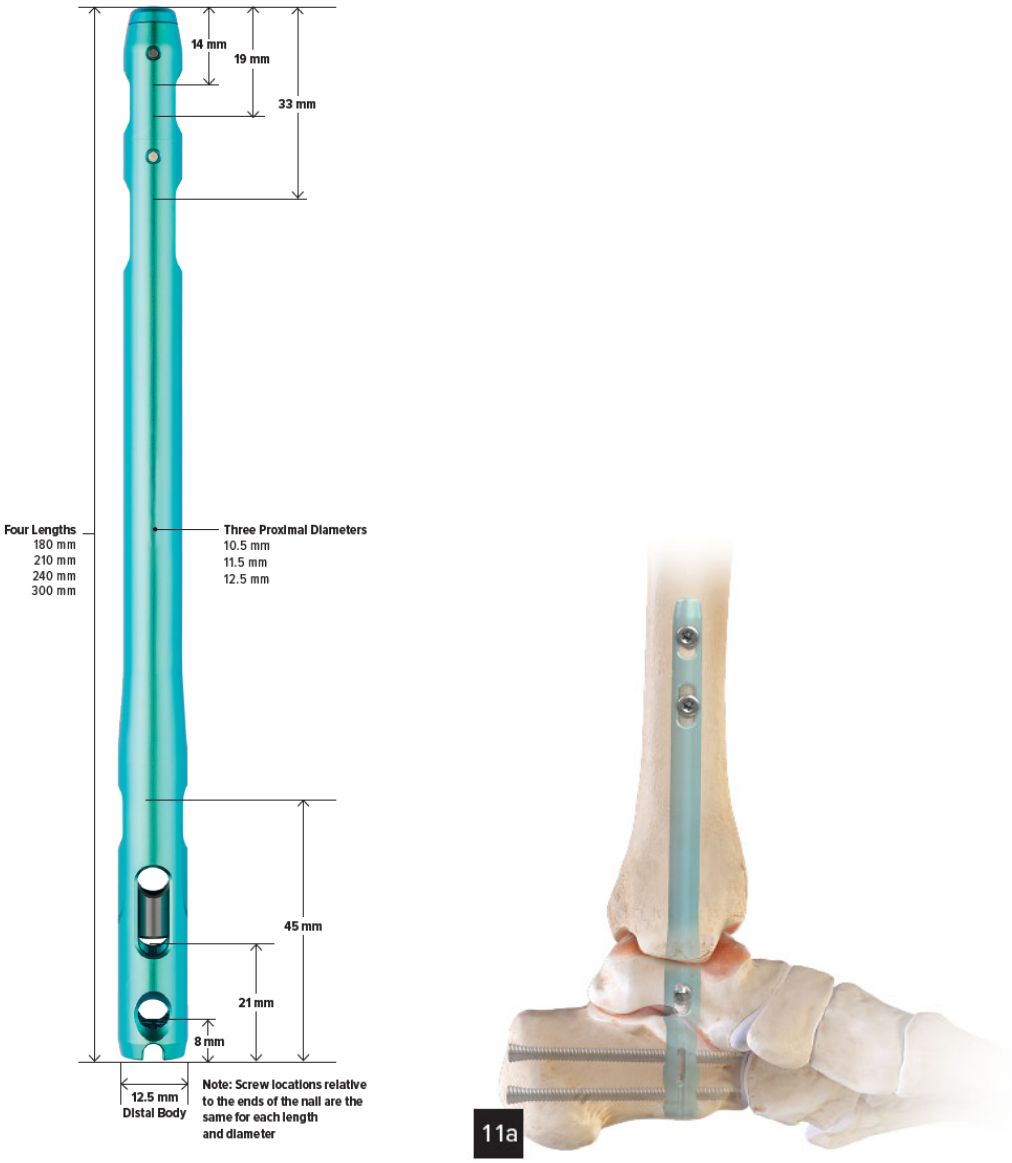
65. Enovis incorporates by reference the preceding paragraphs of this Complaint.

66. Arthrex, without license or authorization to do so, has directly infringed and is directly infringing one or more claims of the '583 Patent, literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing its Accused System within the United States, in violation of 35 U.S.C. § 271(a).

67. The Accused System includes an intramedullary medical device adapted to provide contracting forces between a patient's bones. Ex. D (ST Guide), p. 4 ("[The] nitinol core dynamically tensions the construct between the tibial and calcaneal interlocking screws, creating compression across the tibiotalar and subtalar joints postoperatively."). For example, the Accused System includes the Arthrex DualCompression Hindfoot Nail, which is an intramedullary device adapted to provide contracting forces between a patient's bones, including a patient's tibia, talus, and a calcaneus:


Ex. D, (ST Guide), p. 26.

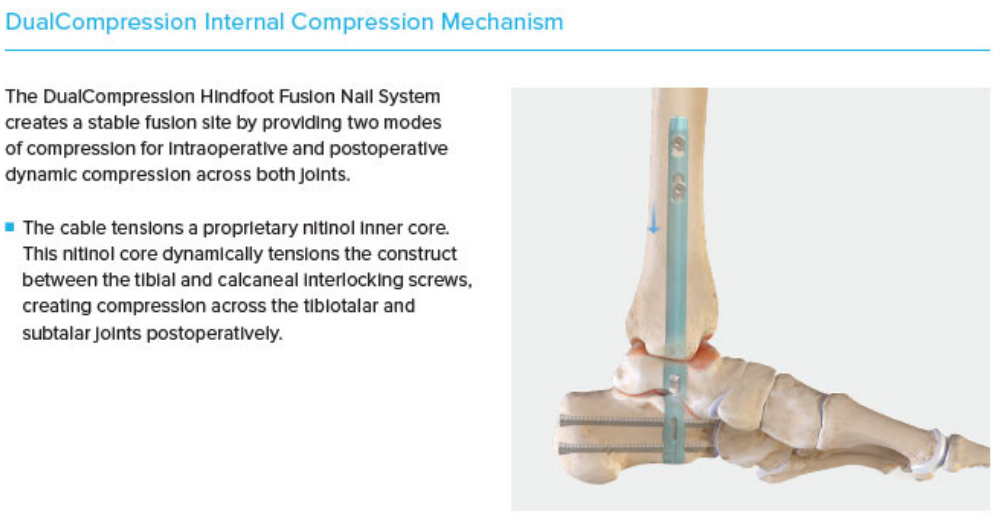
68. The Arthrex DualCompression Hindfoot Nail further contains: (1) an encasement adapted to connect under pressure separate bones of an ankle joint, containing a proximal end designed to be fixed within a medullary canal in a patient's tibia, a distal end designed to be fixed to a patient's calcaneus, and an intermediate portion designed to be installed within a patient's talus; (2) a distal anchor element adapted to be fixed to a patient's calcaneus; and (3) a non-linear contracting element comprising a shape memory alloy adapted to hold the separate bones of the patient's ankle in direct contact and under compression:



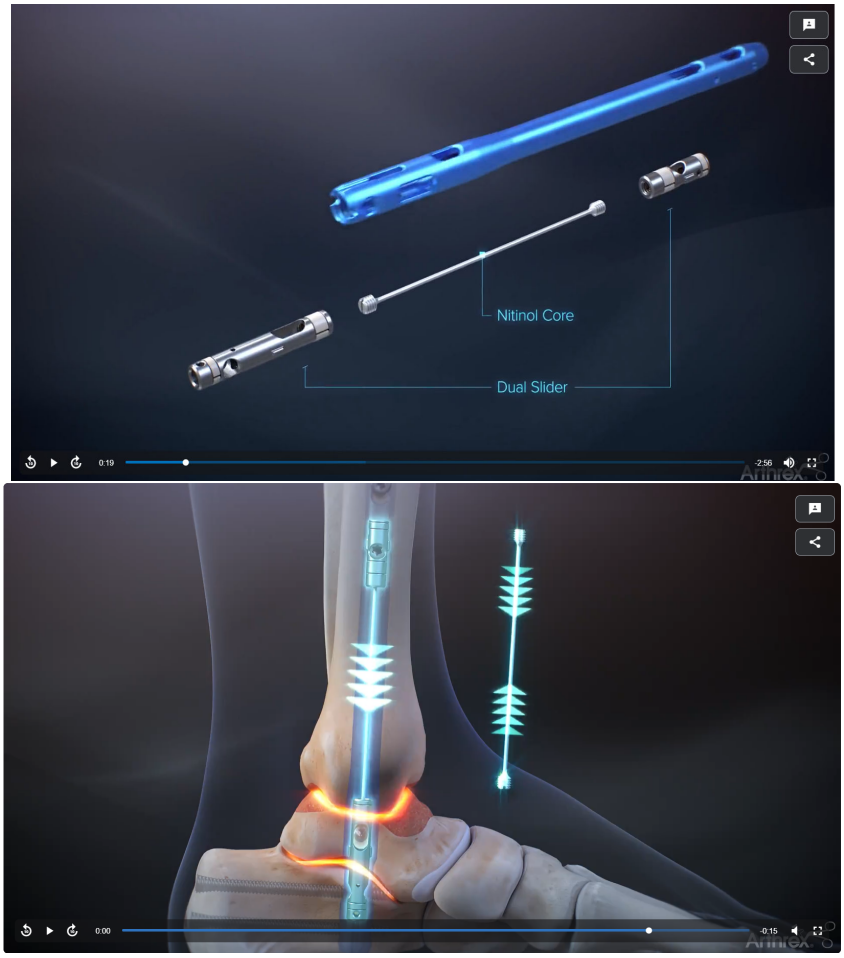

Ex. D, (ST Guide) pp. 5, 26.

69. The above images depict non-limiting examples of the encasement of the Arthrex DualCompression Hindfoot Nail, having a proximal end adapted to be fixed to a patient's tibia, a distal end adapted to be fixed to a patient's calcaneus, and an intermediate portion adapted to be fixed to a patient's talus. Ex. D (Arthrex DualCompression Hindfoot Nail Surgical Technique Guide), pp. 5, 26.

70. The following excerpts from the Surgical Technique Guide for the Accused System and product demonstration video show the non-linear contracting element that is connected between an internal surface of the encasement and an internal surface of the distal anchor element, which contains a shape-memory alloy adapted to provide compression between the separate bones of the ankle joint through moving the distal anchor element within the encasement toward the proximal end of the encasement, to exhibit pseudo-elastic stress-strain response over a pseudo-elastic range of expansive strain imparted to the non-linear contracting element based on the distal anchor element being moved distally with respect to the proximal anchor element, and to hold the separate bones of the patient's ankle in direct contact and under compression as a result of the contracting elements pseudo-elastic stress strain response:




Ex. D, (ST Guide), p. 4.




*Available at* https://www.arthrex.com/resources/AN1-000272-en-US/dualcompression-hindfoot-fusion-nail-system?referringteam=foot_and_ankle (last visited March 21, 2024).

71. In this manner, the Accused System infringes at least claim 1 of the ’583 Patent.

72. Because Arthrex knows and at all relevant times has known of its infringement of the ’583 Patent, or at the very least has been willfully blind to its infringement of the ’583 Patent, its infringement is deliberate and willful.

73. Enovis has been and continues to be damaged and irreparably harmed by Arthrex’s infringement of the ’583 Patent.

74. Upon information and belief, such infringement has been, and will continue to be willful, and upon further belief, Arthrex lacks any reasonable invalidity or non-infringement

defense making this case exceptional and entitling Enovis to increased damages and reasonable attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285.

## JURY DEMAND

75. Enovis hereby requests a trial by jury on all issues properly heard by a jury pursuant to the Seventh Amendment of the United States Constitution.

## PRAYER FOR RELIEF

76. Enovis respectfully requests that the Court find in its favor and against Arthrex, and that the Court grant Enovis the following relief:

A. Judgment under 35 U.S.C. § 271 that Arthrex willfully infringes Enovis's patents referenced and detailed above;

B. Entry of a **permanent injunction** enjoining Arthrex from directly or indirectly infringing any valid claim of Enovis' patents referenced and detailed above;

C. Damages under 35 U.S.C. § 284 adequate to compensate Enovis for Arthrex's willful infringement and continued infringement of Enovis' patents referenced and detailed above;

D. Trebling or other enhancement of the damages pursuant to 35 U.S.C. § 284 as a result of Arthrex's willful and deliberate acts of infringement;

E. Award pursuant to 35 U.S.C. § 284 of costs and pre- and post-judgment interest on Enovis' compensatory damages;

F. Award pursuant to 35 U.S.C. § 285 of Enovis's attorneys' fees incurred in this action; and

G. All other relief the Court deems warranted and appropriate.

DATED: March 22, 2024

Respectfully submitted,

By: /s/ *Steve R. Borgman*
Steve R. Borgman

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