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11	Attorneys for Plaintiff Extremity Medical, LLC		
12	UNITED STATES DISTRICT COURT		
13	DISTRICT OF ARIZONA		
14	Extremity Medical, LLC, a New Jersey limited	Case No.:	
15	liability company,	COMPLAINT	
16	Plaintiff,	Jury Trial Demanded	
17	V.	oury Trial Demanded	
18	Fusion Orthopedics, LLC, a Delaware corporation,		
19	Defendant.		
20	Plaintiff Extremity Medical, LLC ("Extremity Medical" or "Plaintiff"), for its Complaint		
21	against Defendant Fusion Orthopedics, LLC ("Fusion" or "Defendant"), hereby alleges as		
22	follows:		
23	NATURE OF THE ACTION		
24	1. This is a civil action for patent infringement of U.S. Patent Nos. 11,298,16		
25	("the '166 Patent") in violation of the patent laws of the United States, 35 U.S.C. § 1, et seq.		
26	arising from Defendant's unauthorized manufacture, use, offer to sell, sale and/or importing into		
27	or in the United States its IntraLock System ("the Infringing System").		
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THE PARTIES

- 2. Extremity Medical is a limited liability company formed in the State of New Jersey and having its principal place of business at 300 Interpace Parkway, Suite 410, Parsippany, NJ 07054.
- 3. Upon information and belief, Fusion is a corporation organized under the laws of the State of Arizona and has its principal place of business at 4135 S. Power Road, Suite 118, Mesa, Arizona 85212.

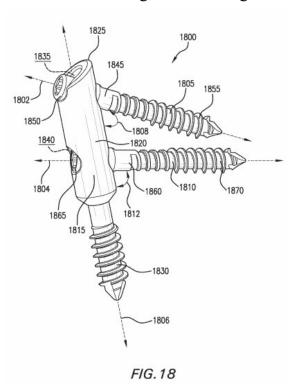
JURISDICTION AND VENUE

- 4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this is an action arising under the patent laws of the United States, 35 U.S.C. § 1, et seq.
- 5. This Court has personal jurisdiction over Defendant because, upon information and belief, Defendant: (a) was incorporated in the state of Arizona, (b) transacts business in Arizona through the sale of products from and/or into Arizona and therefore has substantial and continuous contacts within this judicial district; and (c) has committed, and continues to commit, tortious acts within the state of Arizona giving rise to this action. In short, Defendant has purposely availed itself of the privileges and benefits of the laws of the State of Arizona, Defendant derives benefits from its presence in this Judicial District, and Defendant should reasonably expect its actions to have consequences within this Judicial District.
 - 6. Venue is proper under 28 U.S.C. §§ 1391(b), 1391(c) and/or 1400(b).

THE PATENT-IN-SUIT

7. On April 12, 2022, U.S. Patent No. 11,298,166, entitled "Fixation System, an Intramedullary Fixation Assembly and Method Of Use", was duly and legally issued by the United States Patent and Trademark Office ("USPTO"). A true and correct copy of the '166 Patent is attached hereto as Exhibit A. The '166 Patent is valid, enforceable and currently in full force and effect.

- 8. Plaintiff is the owner and assignee of all rights, title, and interest in the '166 Patent, including the full and exclusive right to bring this action and enforce the '166 Patent against infringers, and the right to recover damages for all relevant time periods, including for past infringement.
- 9. The '166 Patent discloses, *inter alia*, bone fixation systems comprising intramedullary fixation assemblies for treating and fixating deteriorated, damaged and/or



fractured bones, such as bones in the human foot. For example, assemblies disclosed in the '166 Patent may be used to restore the arch in a human foot by coupling the assembly to the medullary canals of the first metatarsal, medial cuneiform, navicular and/or talus bones in the foot.

10. An exemplary figure, Figure 18, from the '166 Patent is provided below:

FACTUAL BACKGROUND

11. Extremity Medical was founded in 2008 by Matthew Lyons. Mr. Lyons has over 30 years of experience in the medical device industry and is named as inventor on numerous patents directed to orthopedics and medical devices. Mr. Lyons graduated from Syracuse

University in 1986 with a Bachelor of Science in Mechanical Engineering, specializing in biomechanics.

- 12. Extremity Medical is a global medical engineering company, dedicated to creating innovative solutions for the challenges that extremity surgeons face. Extremity Medical develops next-generation products for fusion, fixation and motion-preserving systems for the upper and lower extremities of the human body, including the hands and feet. Plaintiff proudly manufactures its products in the United States, and sells and promotes them throughout the United States and worldwide.
- 13. Extremity Medical has invested substantial time and resources into the research, design and development of its products, and securing intellectual property rights to protect them. The company has obtained 49 patents and currently has seven additional patent applications pending.
- 14. Upon information and belief, Nathan Peterson founded Fusion in 2014 and is presently the President of Fusion.
- 15. From at least 2011 to 2019, Mr. Peterson was employed by Extremity Medical as a sales representative. This time period includes at least about five years when Mr. Peterson was building his own orthopedics medical device company (Fusion) while also actively selling Extremity Medical products in the same market space, at the same time. As a sales representative employed by Extremity Medical, Mr. Peterson received detailed information from Extremity Medical about Extremity Medical's products, including Extremity Medical's IOFiX line of products.
- 16. On or about August 30, 2019, Extremity Medical sent a letter to Mr. Peterson at Fusion, putting Fusion on notice of patents Extremity Medical had obtained as of that date directed to treating distal extremities. The '166 Patent claims priority to the applications that led to two of those patents, U.S. Patent Nos. 9,877,752 and 9,364,271. In the same letter, Extremity Medical advised Mr. Peterson that Extremity Medical had been informed that Fusion was using Extremity Medical products as models for its own products and might also be engaging with other

individuals (including individuals who had at that time, or previously had, a relationship with Extremity Medical) to copy Extremity Medical's products. The letter is attached as Exhibit B.

- 17. Fusion has used Extremity Medical's products as predicate devices to obtain 501(k) clearance from the U.S. Food and Drug Administration for Fusion products.
- 18. The IOFiX Plus and IOFiX 2.0 products are assemblies for bone fusion including a first member comprising a shaft and a head, and a thread extending outward from the external surface of the shaft; and a second member comprising an elongated body having a bore extending from an aperture at a terminal end of the elongated body to another aperture on an exterior surface of the second member, wherein the first member couples to the second member by inserting one end of the first member into the first aperture, through the bore, and out of the second aperture. As discussed further below, those elements are also included in Fusion's IntraLock product.
- 19. On November 23, 2021, Extremity Medical, by its counsel, sent another letter to Fusion. The letter explained that Extremity Medical has obtained over 20 patents on its inventions in the United States, and several others in foreign countries. The letter identified U.S. Patent No. 8,303,589 ("the '589 Patent"), noted the '589 Patent is owned by Extremity Medical, and explained that the Infringing System contains all of the elements recited in Claim 56 of the '589 Patent, and is therefore infringing at least this claim. This letter is attached as Exhibit C.
- 20. The Infringing System includes at least: (1) a Post Nail, (2) a Set Screw, and (3) a Below is an annotated image of the Infringing System. The image (without Lag Screw. annotations) is depicted on the cover of a surgical guide for the Infringing System, titled "First Tarsometatarsal Fusion Surgical Technique" (the "Surgical Guide"). A copy of the Surgical Guide is attached hereto as Exhibit D. Information about the Infringing System is also available on Defendant's website (See https://fusionorthopedics.com/products/).

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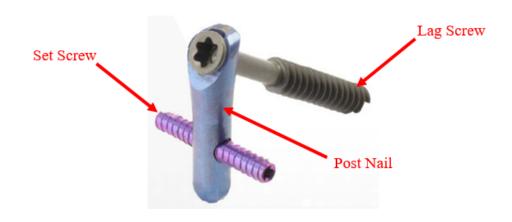


Exhibit D, cover.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF (INFRINGEMENT OF THE '166 PATENT)

- 21. Plaintiff hereby incorporates by reference paragraphs 1-20 as if fully set forth herein.
- 22. Defendant has infringed and continue to infringe, either literally or under the doctrine of equivalents, at least Claim 12 of the '166 Patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, selling and/or importing into or in the United States the Infringing System, without a license or permission from Plaintiff.
- 23. Upon information and belief, Defendant has also infringed and continues to infringe at least Claim 12 of the '166 Patent in violation of 35 U.S.C. § 271(b) by inducing vendors, customers and others to make, use, sell, or offer for sale within the United States, systems that practice inventions of the '166 Patent with knowledge of and intent that such vendors, customers and others infringe the '166 Patent. Defendant has intentionally caused, urged, encouraged, or aided in the actions—including the direct infringement of the '166 Patent—that induced infringement of the '166 Patent by vendors, customers and others. Upon information and belief, such intentional actions include, for example, inducing Defendant's customers to infringe the '166 Patent by making available on their website surgical guides that teach surgeons how to assemble and use the Infringing System. As a result of Defendant's conduct, Defendant has induced and is inducing such vendors, customers and others to make or use systems, such as the Infringing

System, to infringe at least Claim 12 of the '166 Patent. Additionally and in the alternative, Defendant has induced and is inducing its vendors, customers and others to implement and utilize parts of the Infringing System to infringe at least Claim 12 of the '166 Patent. Defendant has engaged and is engaging in this conduct while aware of the '166 Patent and with the intent to infringe, at least as of the filing of the Complaint.

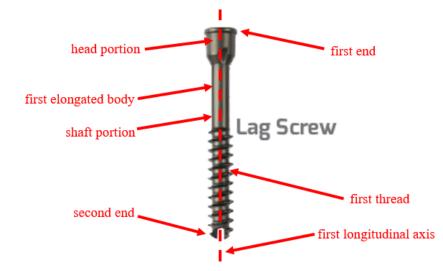
- 24. Upon information and belief, with knowledge of the '166 Patent, Defendant has also contributed to the infringement of the '166 Patent by offering for sale or selling within the United States or importing into the United States the Post Nail, which constitutes a material part of the Infringing System. Defendant knows the Post Nail is especially made or especially adapted for use in the Infringing System, and that the Post Nail is not a staple article or commodity of commerce suitable for substantial noninfringing use. By contributing to the use of the Infringing System by their vendors, customers and others, Defendant has been indirectly infringing under 35 U.S.C. § 271(c) one or more claims of the '166 Patent, either literally or under the doctrine of equivalents.
- 25. Claim 12 of the '166 Patent recites: [a]n assembly for bone fusion, comprising: a first member comprising" certain elements. The Infringing System is an assembly for bone fusion. Below is an annotated image of the Infringing System:



See Exhibit D at 13; see also id. at 3 ("IntraLock is indicated for reduction and internal fixation of arthrodeses, osteotomies, intra- and extra-articular fractures, and nonunions of the small bones and joints of the foot. The three-part construct is specifically intended for use in Talonavicular, Calcaneocuboid, and Metatarsocuneiform Arthrodesis.)."

26. Claim 12 further recites: "a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis, wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion" The Lag Screw of the Infringing System is a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis, wherein the Lag Screw comprises a shaft portion having an external surface and a head portion having an exterior surface, the Lag Screw further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion. An annotated image of the Lag Screw of the Infringing System is shown below:

See Exhibit D at 2.



27. Claim 12 further recites: "a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis, wherein the second member comprises a shaft having an external surface, said second member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft" The Set Screw of the Infringing System is a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis, wherein the Set Screw comprises a shaft having an external surface, the Set Screw further

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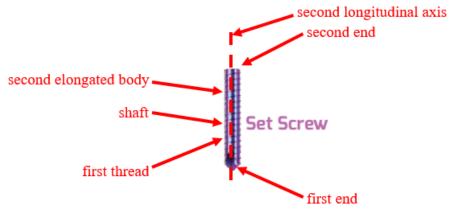
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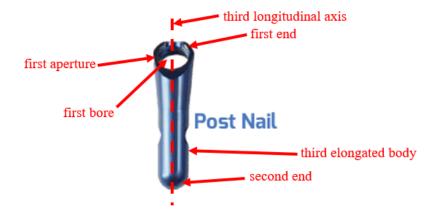
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comprising a first thread having a first thread height extending radially outward from the external surface of said shaft. An annotated image of the Set Screw of the Infringing System is shown below:

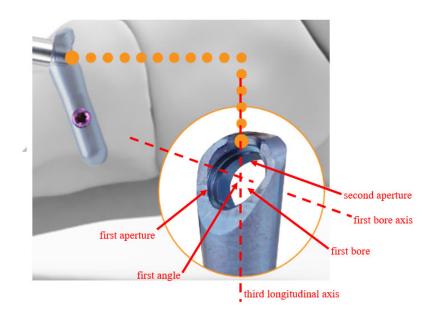


See Exhibit D at 2.

28. Claim 12 further recites: "a third member comprising a third elongated body extending along a straight line from a first end to a second end along a third longitudinal axis, wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body, and a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member, wherein the first bore comprises an interior surface at the first aperture, wherein there are no threads adjacent to the second aperture on the exterior surface of the third member, and wherein the third longitudinal axis and the first bore axis define a first angle" The Post Nail of the Infringing System is a third member comprising a third elongated body extending along a straight line from a first end to a second end along a third longitudinal axis, wherein the Post Nail comprises a first aperture at a terminal end of the first end of the third elongated body, and a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the Post Nail, wherein the first bore comprises an interior surface at the first aperture, wherein there are no threads adjacent to the second aperture on the exterior surface of the Post Nail, and wherein the third longitudinal axis and the first bore axis define a first angle. Annotated images of the Post Nail of the Infringing System are shown below:



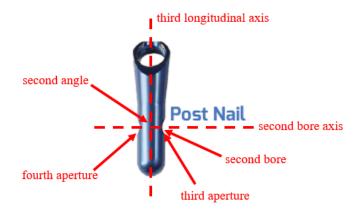
See Exhibit D at 2;



See Exhibit D at 11.

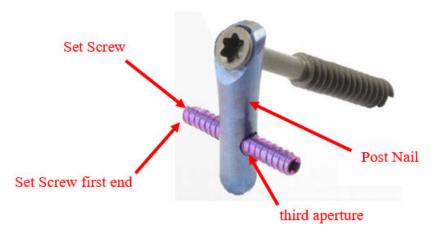
29. Claim 12 further recites: "wherein the third member further comprises a third aperture on the exterior surface of the third member, and a second bore extending along a second bore axis from the third aperture to a fourth aperture on an exterior surface of the third member, wherein the third longitudinal axis and the second bore axis define a second angle" The Post Nail of the Infringing System further comprises a third aperture on the exterior surface of the Post Nail, and a second bore extending along a second bore axis from the third aperture to a fourth

aperture on an exterior surface of the Post Nail, wherein the third longitudinal axis and the second bore axis define a second angle. An annotated image of the Post Nail of the Infringng System is shown below:



See Exhibit D at 2.

30. Claim 12 further recites: "wherein the second member couples to the third member by inserting the first end of the second member into the third aperture, through the second bore, and out of the fourth aperture" As shown in the following annotated image, the Set Screw couples to the Post Nail by inserting the first end of the Set Screw into the third aperture, through the second bore, and out of the fourth aperture:



See Exhibit D, cover.

31. Claim 12 further recites: "wherein the second angle is in the range of about 0 degrees to about 90 degrees; and wherein the second bore axis is substantially perpendicular to the third longitudinal axis." As shown in the following annotated image, the second angle is in the range

second angle

Post Nail
second bore axis

of about 0 degrees to about 90 degrees, and the second bore axis is substantially perpendicular to

See Exhibit D at 2.

the third longitudinal axis:

- 32. Plaintiff has already been damaged by Defendant's infringement of the '166 Patent, has been irreparably harmed by that infringement, and will suffer additional damages and irreparable harm for which there is no adequate remedy at law unless and until such infringing conduct is enjoined pursuant to 35 U.S.C. § 283 and/or the equitable powers of this Court.
- 33. Plaintiff is entitled to an award of Plaintiff's costs and attorneys' fees in this action pursuant to 35 U.S.C. § 285 and/or other applicable laws.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

- A. Entry of a judgment in favor of Plaintiff on all Counts of the Complaint;
- B. Entry of a judgment that each Defendant has directly and/or indirectly infringed the '166 Patent and that such infringement has been willful;
- C. Entry of a preliminary and permanent injunction against Defendant, pursuant to 35 U.S.C. § 283 and/or the equitable powers of this Court, to prevent further direct and/or indirect infringement of the '166 Patent;

1	D. An award of damages, in an amount to be determined, adequate to compens	
2	Plaintiff for the infringement that has occurred, pursuant to 35 U.S.C. § 284;	
3	E. An Order requiring Defendant to pay Plaintiff its costs and attorneys' fees in t	
4	action pursuant to 35 U.S.C. § 285 and/or other applicable laws;	
5	F. Such other and further relief as the Court may deem just and proper.	
6	6 JURY DEMAND	
7	Plaintiff hereby demands a trial by jury of all issues so triable.	
8	DATED this 28 th day of April, 2022.	
9	KELLEY DRYE & WARREN LLP	
10		
11	By: /s/ Michael J. Zinna Michael J. Zinna (admission pending)	
12	David Lindenbaum (admission pending)	
13	LANG & KLAIN, P.C.	
14		
15	By: /s/ William G. Klain William G. Klain	
16	George H. King Attorneys for Plaintiff Extremity Medical, LLC	
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