

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXTREMITY MEDICAL, LLC, a New Jersey) limited liability company,)) Plaintiff,) v.) C.A. No.
NEXTREMITY SOLUTIONS, INC., a) Delaware corporation,) JURY TRIAL DEMANDED
ZIMMER BIOMET HOLDINGS, INC., a) Delaware corporation, and)
ZIMMER, INC., a Delaware corporation,)) Defendants.)

COMPLAINT

Plaintiff Extremity Medical, LLC (“Extremity Medical” or “Plaintiff”), for its Complaint against Defendants Nextremity Solutions, Inc. (“Nextremity”), Zimmer Biomet Holdings, Inc. (“Zimmer Biomet”), and Zimmer, Inc. (“Zimmer”), (collectively, “Defendants”), hereby alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent No. 8,303,589 (“the ‘589 Patent”) in violation of the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, arising from Defendants’ unauthorized manufacture, use, offer to sell, sale and/or importing into or in the United States its InCore Lapidus System (“the Infringing System”).

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, Nextremity is a corporation organized under the laws of the State of Delaware and has its principal place of business at 1195 Polk Drive, Warsaw, Indiana 46582.

4. Upon information and belief, Zimmer Biomet is a corporation organized under the laws of the State of Delaware and has its principal place of business at 345 East Main Street, Warsaw, Indiana 46580.

5. Upon information and belief, Zimmer is a corporation organized under the laws of the State of Delaware and has its principal place of business at 345 East Main Street, Warsaw, Indiana 46580.

JURISDICTION AND VENUE

6. 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.*

7. This Court has personal jurisdiction over Defendants because, upon information and belief, each Defendant: (a) was incorporated in the state of Delaware, (b) transacts business in Delaware through the sale of products from and/or into Delaware 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 Delaware giving rise to this action. In short, each Defendant has purposely availed itself of the privileges and benefits of the laws of the State of Delaware, each Defendant derives benefits from its presence in this Judicial District, and each Defendant should reasonably expect its actions to have consequences within this Judicial District.

8. Venue is proper under 28 U.S.C. §§ 1391(b), 1391(c) and/or 1400(b).

THE PATENT-IN-SUIT

9. On November 6, 2012, U.S. Patent No. 8,303,589, 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 ’589 Patent is attached hereto as Exhibit A. The ’589 Patent is valid, enforceable and currently in full force and effect.

10. Plaintiff is the owner and assignee of all rights, title, and interest in the ’589 Patent, including the full and exclusive right to bring this action and enforce the ’589 Patent against infringers, and the right to recover damages for all relevant time periods, including for past infringement.

11. The ’589 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 ’589 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.

12. An exemplary figure, Figure 18, from the ’589 Patent is provided below:

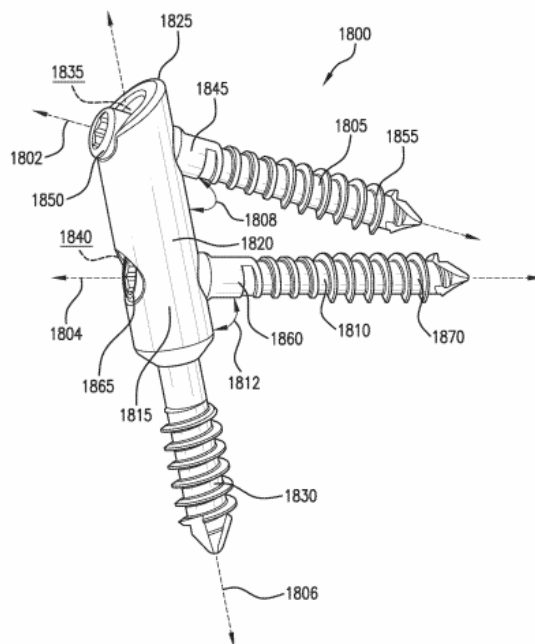


FIG. 18

FACTUAL BACKGROUND

13. Extremity Medical was founded in 2008 by Matthew Lyons. Mr. Lyons graduated from Syracuse University in 1986 with a Bachelor of Science in Mechanical Engineering, specializing in biomechanics. 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.

14. 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.

15. Extremity Medical has invested substantial time and resources into the research, design and development of its products, and secures intellectual property rights to protect them. The company has obtained 39 patents in the United States, Australia, Canada, the European Union, and Japan, and currently has seven additional patent applications pending.

16. On November 23, 2021, Extremity Medical, by its counsel, sent a letter to Defendants Nextremity and Zimmer Biomet. The letters explained that Extremity Medical has obtained over 20 patents on its inventions in the United States, and several others in foreign countries. The letters further explained that the '589 Patent is owned by Extremity Medical, and that the Infringing System contains all of the elements recited in Claim 59 of the '589 Patent, and is therefore infringing at least this claim.

17. On December 15, 2021 and January 14, 2022, Defendants Nextremity and Zimmer Biomet sent letters to Extremity Medical, confirming receipt of Extremity Medical's November 23, 2021 letter and acknowledging the notice provided by Extremity Medical regarding the '589 Patent.

18. The Infringing System includes at least: (1) an "InCore Post", (2) a "Targeting Guide," and (3) a screw. Below are annotated images of the Infringing System. The images (without annotations) are depicted on the cover and page 3 of product materials for the Infringing System, identified on Nextremity's website and Zimmer Biomet's website as the "InCore® Lapidus System Surgical Technique" Guide (the "Surgical Guide"). A copy of the Surgical Guide is attached hereto as Exhibit B. The Surgical Guide is available for download from Defendants' websites (See <https://www.nextremity.com/portfolio-items/incore-lapidus-system/> and <https://www.zimmerbiomet.com/en/products-and-solutions/specialties/foot-and-ankle/incore-lapidus-system.html#07-education>).

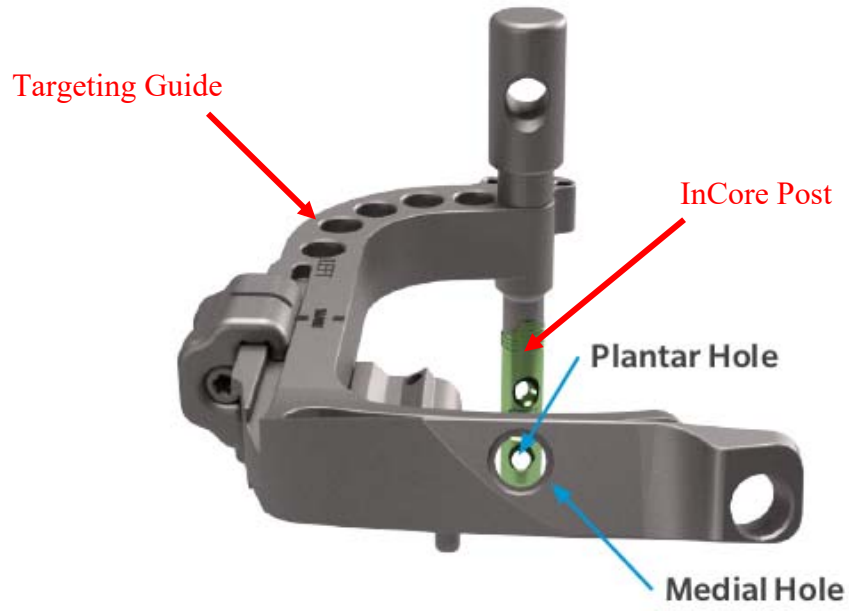


Exhibit B at 3;

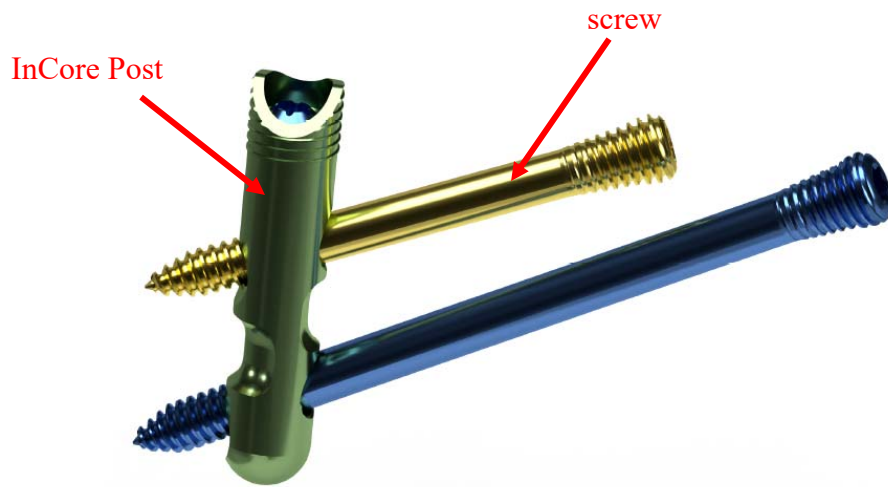


Exhibit B, cover.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
(INFRINGEMENT OF THE '589 PATENT)

19. Plaintiff hereby incorporates by reference paragraphs 1-18 as if fully set forth herein.

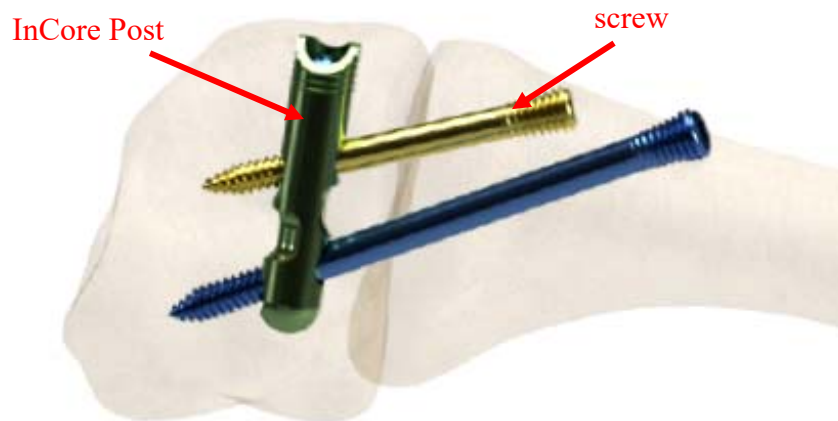
20. Defendants have infringed and continue to infringe, either literally or under the doctrine of equivalents, at least Claim 59 of the '589 Patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, selling and/or importing into or in the United States the Infringing System, without a license or permission from Plaintiff.

21. Upon information and belief, Defendants have also infringed and continue to infringe at least Claim 59 of the '589 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 '589 Patent with knowledge of and intent that such vendors, customers and others infringe the '589 Patent. Defendants have intentionally caused, urged, encouraged, or aided in the actions—including the direct infringement of the '589 Patent—that induced infringement of the '589 Patent by vendors, customers and others. Upon information and belief, such intentional actions include, for example, inducing Defendants' customers to infringe the '589 Patent by making available on their website surgical guides that teach surgeons how to assemble and use the Infringing System. As a result of Defendants' conduct, Defendants have induced and are inducing such vendors, customers and others to make or use systems, such as the Infringing System, to infringe at least Claim 59 of the '589 Patent. Additionally and in the alternative, Defendants have induced and are inducing their vendors, customers and others to implement and utilize parts of the Infringing System to infringe at least Claim 59 of the '589 Patent. Defendants

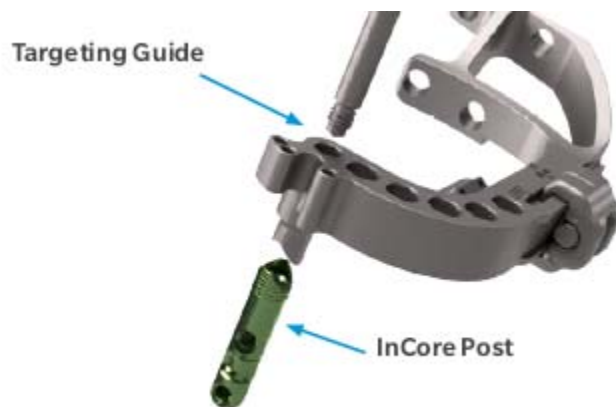
have engaged and are engaging in this conduct while aware of the '589 Patent and with the intent to infringe, at least as of the filing of the Complaint.

22. Upon information and belief, with knowledge of the '589 Patent, Defendants have also contributed to the infringement of the '589 Patent by offering for sale or selling within the United States or importing into the United States the InCore Post, which constitutes a material part of the Infringing System. Defendants know the InCore Post is especially made or especially adapted for use in the Infringing System, and that the InCore Post 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, Defendants have been indirectly infringing under 35 U.S.C. § 271(c) one or more claims of the '589 Patent, either literally or under the doctrine of equivalents.

23. Claim 59 of the '589 Patent recites: “[a] fixation system for compressing bone, comprising” certain elements. The Infringing System is a fixation system for compressing bone. Below is an annotated image of the InCore Post and screw of the Infringing System:

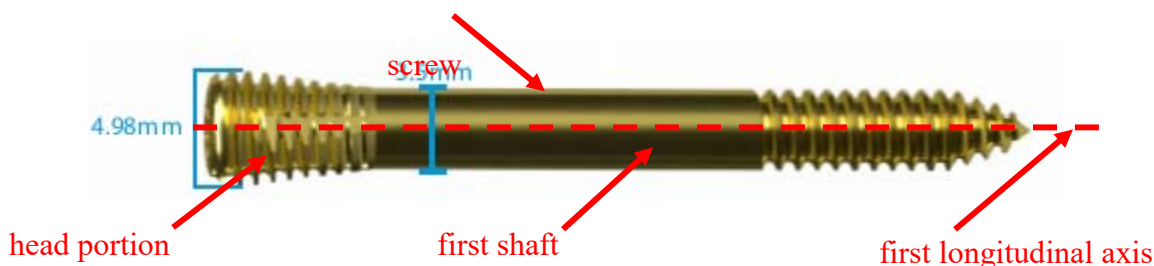


See Exhibit B, cover. Below is an image of the Targeting Guide and InCore Post of the Infringing System:



See Exhibit B at 2; *see also id.* at 1 (“Targeting Guide includes built-in Compression-Distraction Fixture providing compression parallel to the long axis of the first metatarsal”).

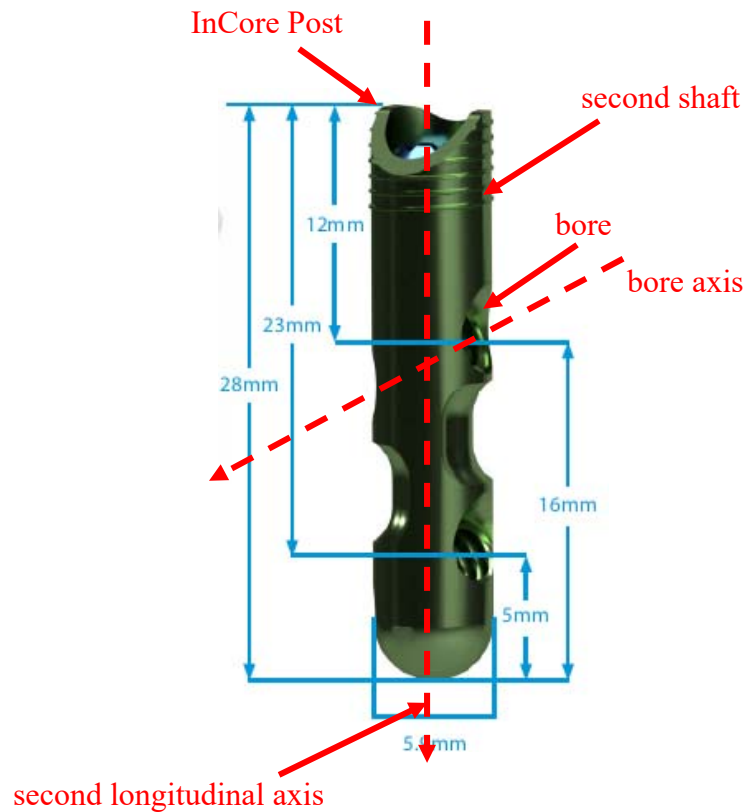
24. Claim 59 further recites: “a first screw member comprising a head portion and a first shaft extending along a first longitudinal axis” The screw of the Infringing System is a first screw member comprising a head portion and a first shaft extending along a first longitudinal axis. An annotated image of a screw of the Infringing System is shown below.



See Exhibit B at 1.

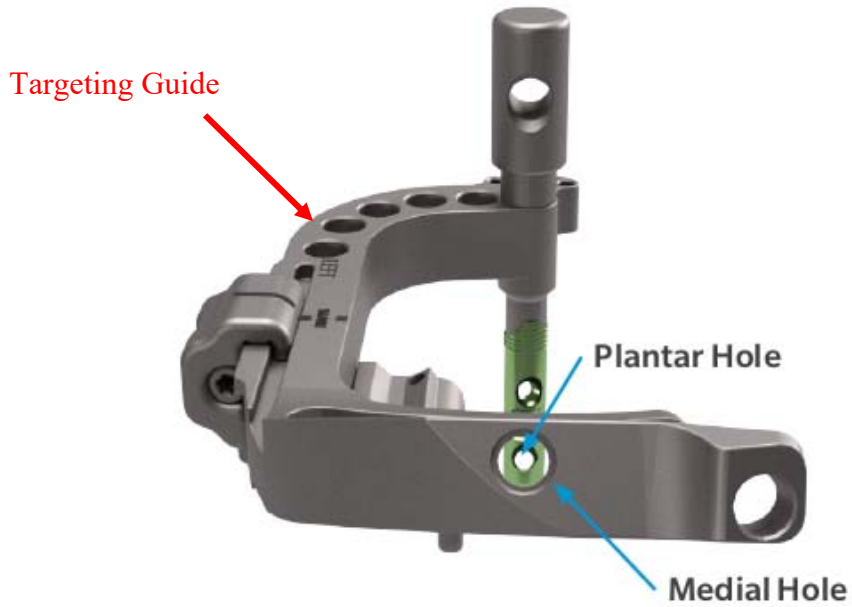
25. Claim 59 further recites: “a second member comprising a second shaft extending along a second longitudinal axis and a bore extending through said second shaft along a bore axis” The InCore Post of the Infringing System is a second member comprising a second shaft

extending along a second longitudinal axis and a bore extending through said second shaft along a bore axis. An annotated image of the InCore Post of the Infringing System is shown below:

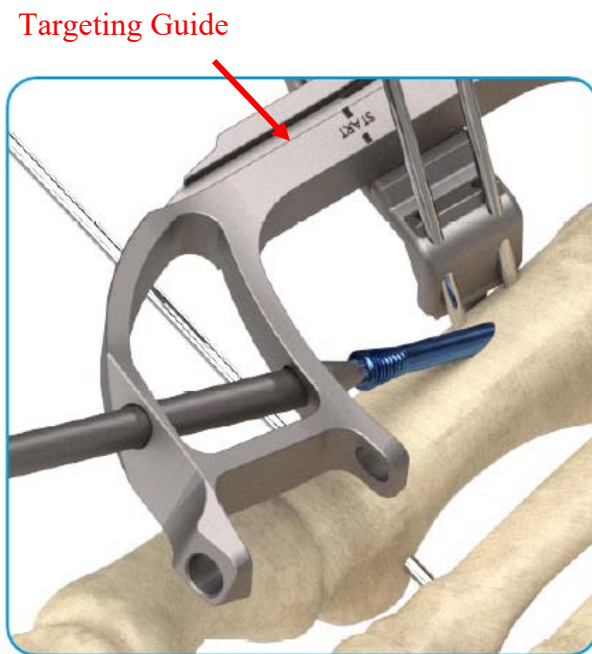


See Exhibit B at 1.

26. Claim 59 further recites: “an instrument adapted for coupling said first screw member to said second member” The Targeting Guide of the Infringing System is an instrument adapted for coupling the screw of the Infringing System to the InCore Post. Annotated images of the Targeting Guide as part of the Infringing System are shown below:

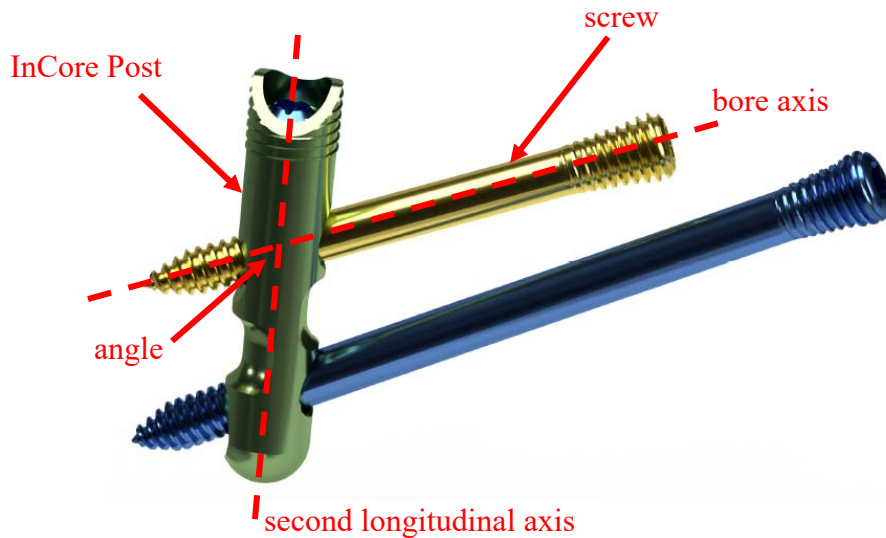


See Exhibit B at 3;



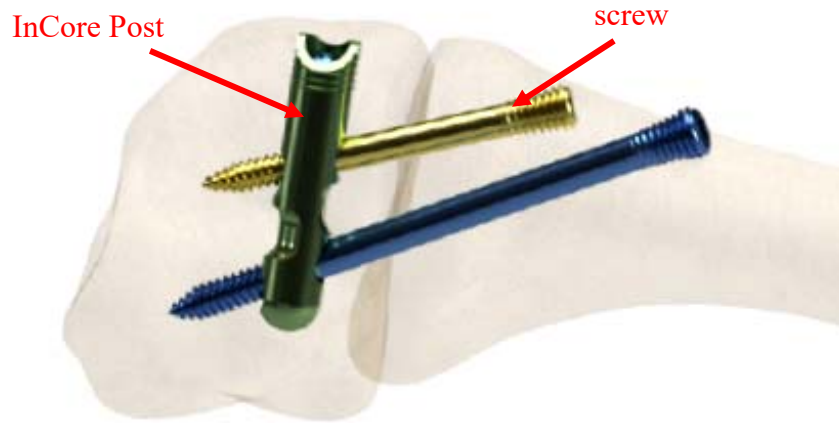
See Exhibit B at 9. According to the Surgical Guide, “[s]ighting the holes in the Targeting Guide, alignment can be visualized to ensure proper assembly and left/right foot selection.” Exhibit B at 3.

27. Claim 59 further recites: “wherein said second longitudinal axis and said bore axis define an angle, wherein said first screw member is adapted for coupling to said second member at said angle” As shown in the following annotated image of the Infringing System, the second longitudinal axis and bore axis of the InCore Post define an angle, and the screw of the Infringing System is adapted for coupling to the InCore Post at that angle:



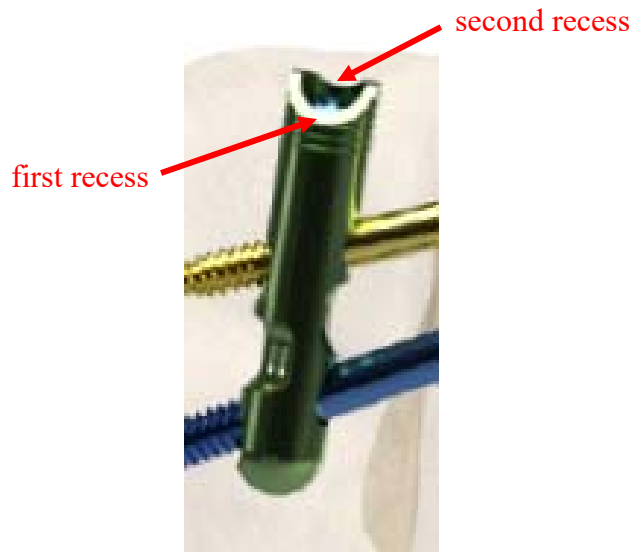
See Exhibit B, cover.

28. Claim 59 further recites: “wherein each of said first screw member and said second member is adapted for residing substantially within at least one bone” As shown in the following annotated image, the InCore Post and screw are adapted for residing substantially within at least one bone:



See Exhibit B at 1.

Claim 59 further recites: “wherein said second member comprises first and second circumferentially spaced recesses adapted for coupling to said instrument.” As shown in the following annotated image, the InCore Post includes first and second circumferentially spaced recesses adapted for coupling to the Targeting Guide:



See Exhibit B at 1;

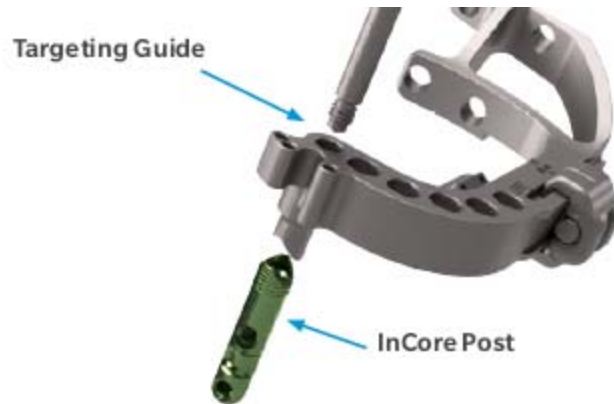


Exhibit B at 2.



Exhibit B at 2.

29. Plaintiff has already been damaged by Defendants' infringement of the '589 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.

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 '589 Patent and that such infringement has been willful;
- C. Entry of a preliminary and permanent injunction against each 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 '589 Patent;
- D. An award of damages, in an amount to be determined, adequate to compensate Plaintiff for the infringement that has occurred, pursuant to 35 U.S.C. § 284;
- E. An Order requiring each Defendant to pay Plaintiff its costs and attorneys' fees in this action pursuant to 35 U.S.C. § 285 and/or other applicable laws;
- F. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury of all issues so triable.

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Dated: February 25, 2022