IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TREACE MEDICAL CONCEPTS, INC., Plaintiff, v. ZIMMER BIOMET HOLDINGS, INC. and PARAGON 28, INC. Defendants.	C.A. No. _____ **JURY TRIAL DEMANDED**

TREACE MEDICAL CONCEPTS, INC.'S
COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Treace Medical Concepts, Inc. ("Treace Medical"), by its attorneys, brings this Complaint for patent infringement against defendants Zimmer Biomet Holdings, Inc. ("Zimmer Biomet") and Paragon 28, Inc. ("Paragon 28") (collectively, "Zimmer Defendants"). Treace Medical alleges as follows:

NATURE OF THE ACTION

1. This is a civil action arising out of the Zimmer Defendants' patent infringement in violation of the Patent Laws of the United States, 35 U.S.C. §§ 271 and 281-285.

2. Founded in 2014, Treace Medical is a medical technology company with the mission of advancing the standard of care for the surgical management of bunion and related midfoot deformities. Treace Medical pioneered and patented the novel Lapiplasty® 3D Bunion Correction System®—a combination of instruments, implants, and surgical methods designed to surgically correct all three planes of a bunion deformity and secure the unstable joint, addressing the bunion's root cause.

Paragon 28, Inc. v. Treace Medical Concepts, Inc.
PGR2026-00020
Treace Ex. 2001

3. The United States Patent and Trademark Office has awarded Treace Medical numerous patents covering its inventions relating to instrumented bunion correction, including U.S. Patent No. 12,102,368 ("the '368 patent"); U.S. Patent No. 12,268,397 ("the '397 patent"); U.S. Patent No. 12,268,428 ("the '428 patent"); and U.S. Patent No. 12,274,481 ("the '481 patent") (collectively, the "Asserted Patents").

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

THE PARTIES

5. Treace Medical is a Delaware corporation having its principal place of business at 100 Palmetto Park Place, Ponte Vedra, Florida 32081.

6. On information and belief, Zimmer Biomet is an entity incorporated under the laws of Delaware and having its principal place of business at 1800 West Center St., Warsaw, Indiana 46580.

7. On information and belief, Paragon 28 is an entity incorporated under the laws of Delaware and having its principal place of business at 14445 Grasslands Drive, Englewood, Colorado 80112.

JURISDICTION AND VENUE

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

9. This Court has personal jurisdiction over Zimmer Biomet because Zimmer Biomet is a Delaware Corporation and has a registered agent for service of process, the Corporation Service Company, in the state of Delaware.

10. On information and belief, Zimmer Biomet is doing business in this judicial district and has committed one or more of the acts complained of in this judicial district, providing additional bases for the Court's exercise of personal jurisdiction over Zimmer Biomet.

11. This Court has personal jurisdiction over Paragon 28 because Paragon 28 is a Delaware Corporation and has a registered agent for service of process, The Corporation Trust Company, in the state of Delaware.

12. On information and belief, Paragon 28 is doing business in this judicial district and has committed one or more of the acts complained of in this judicial district, providing additional bases for the Court's exercise of personal jurisdiction over Paragon 28.

13. Venue is proper in this district under 28 U.S.C. §§ 1391(b), (c), and 1400(b).

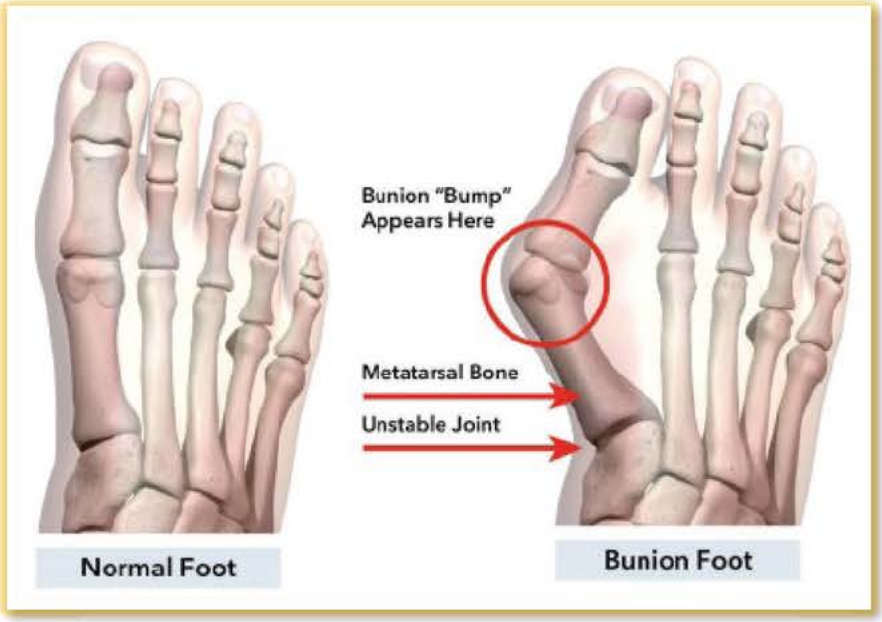
FACTUAL BACKGROUND

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

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

15. Bunions, the common name for hallux valgus deformities, are among the most commonly found midfoot problems and affect approximately 67 million Americans. Recognizable as a bump on the side of a big toe, bunions are not just a cosmetic problem. Bunions are a deformity of the bone structures within the foot that can result in painful disability that tends to worsen over time. Bunions can cause severe and debilitating pain, limited mobility, and greater risk of injury due to decreased stability. People with bunions also experience increased susceptibility to other pathologies, such as hammertoes and arthritis of the big toe joint, not to mention restrictions on footwear and the emotional burden related to the appearance of the bunion.

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



17. Bunions often progress to the point of requiring surgical intervention. Indeed, of the more than four million Americans who seek medical treatment for bunions each year, a quarter of those—over a million Americans—have a deformity or severity of condition that makes them a candidate for surgical bunion correction. Yet historically, these deformities regularly went

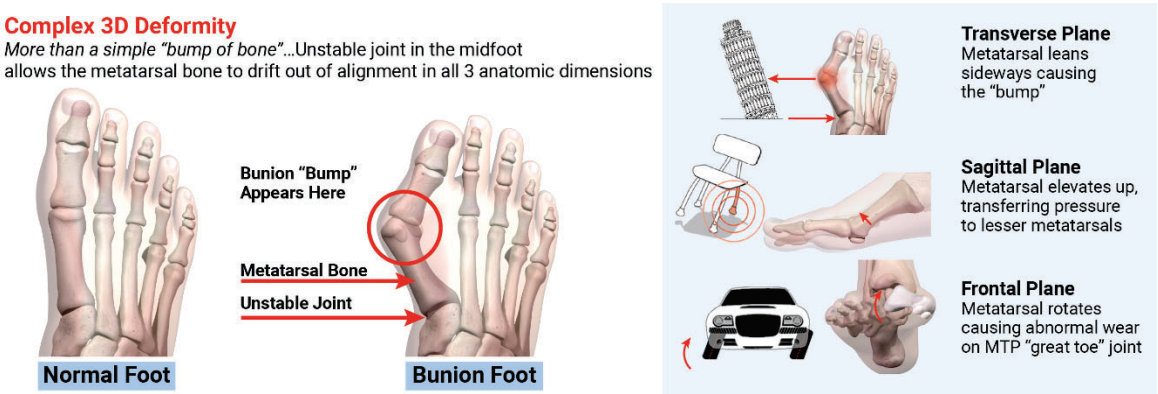
untreated. When treated, two primary surgical approaches existed. Both traditional approaches produced mixed results and neither consistently addressed the deformity, which can present in three anatomical planes.

18. Under one traditional approach, the bunion "bump" is merely shaved off and the metatarsal bone of the big toe is cut in half and shifted over to reduce the appearance of the bunion. This cut and shift "osteotomy" technique mainly addresses the cosmetic bump and does not correct the root cause of the deformity, creating an increased likelihood that the metatarsal bone will continue to drift out of position over time and the bunion will return. Recovery is also reported to require up to 6 weeks of non-weight bearing activity. This technique is illustrated below:

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

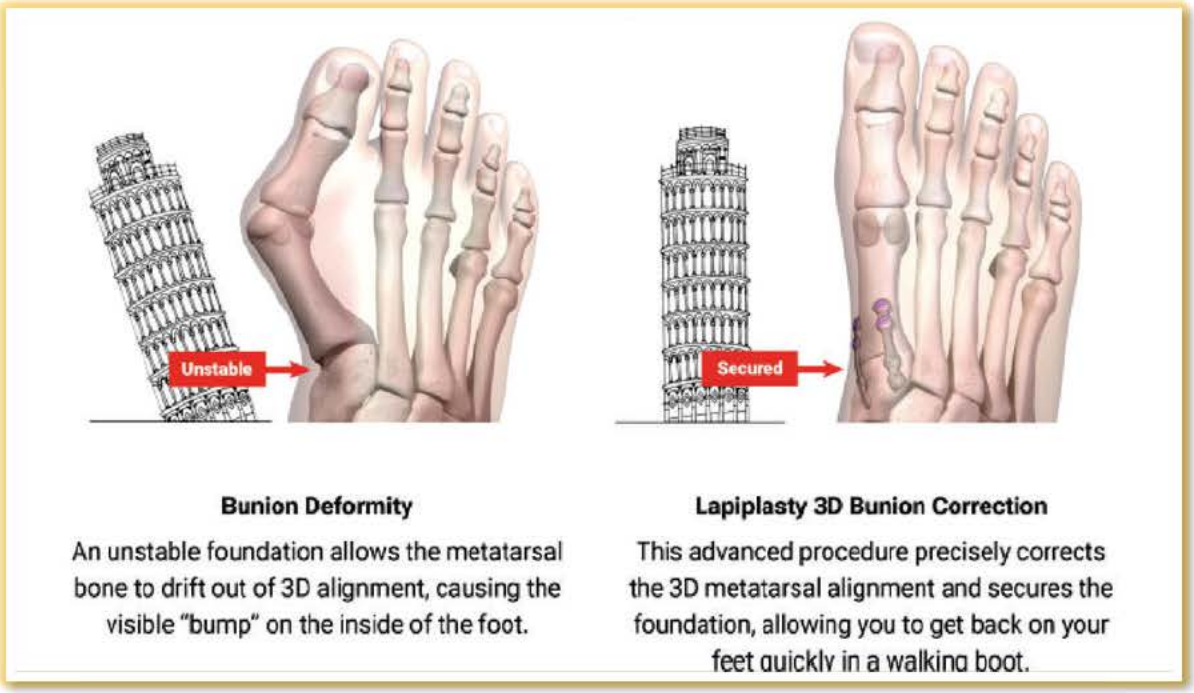
20. Treace Medical, founded by John Treace in 2014, set out to solve the problems associated with the traditional approaches.

21. In 2015, Treace Medical introduced surgeons to a better way of surgically treating bunions—an instrumented bunion correction procedure later branded as the Lapiplasty® System and Procedure. Treace Medical and its team of surgeons and engineers invented an entire set of instrumentation, implants, and procedures that for the first time allowed surgeons to reproducibly correct the bunion in up to three planes and restore the natural biomechanical structure of the foot, addressing the root cause of the deformity. With help from Treace Medical's procedural instrumentation, the Lapiplasty® Procedure realigns the entire metatarsal bone into its normal anatomical position in three planes—the transverse plane, the sagittal plane, and the frontal plane, as illustrated below:

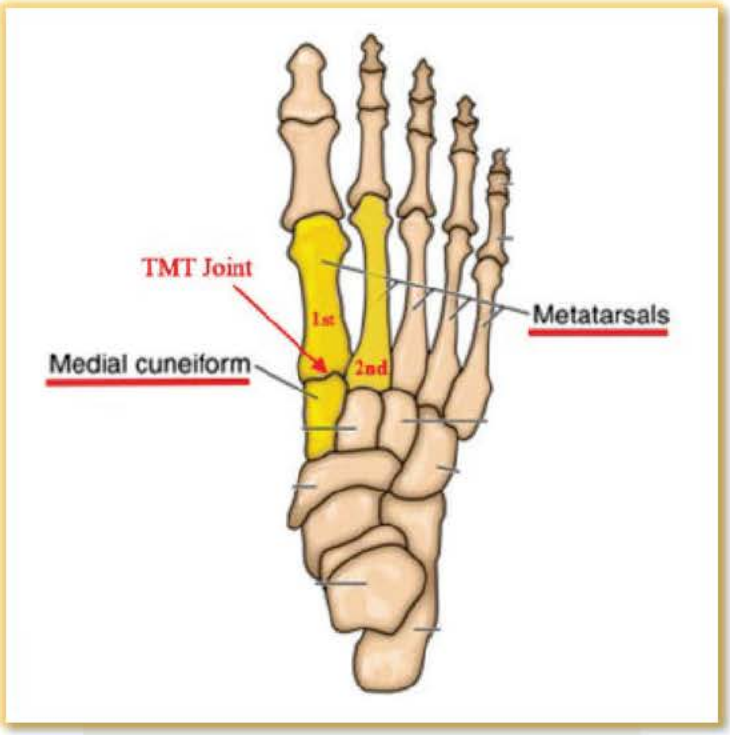


22. Treace Medical's novel system and methods have led to improved patient outcomes, as demonstrated in multiple clinical studies. Among other advantages, Treace Medical's instrumented procedure allows for quick return to weight-bearing in a walking boot with low risk of recurrence.

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

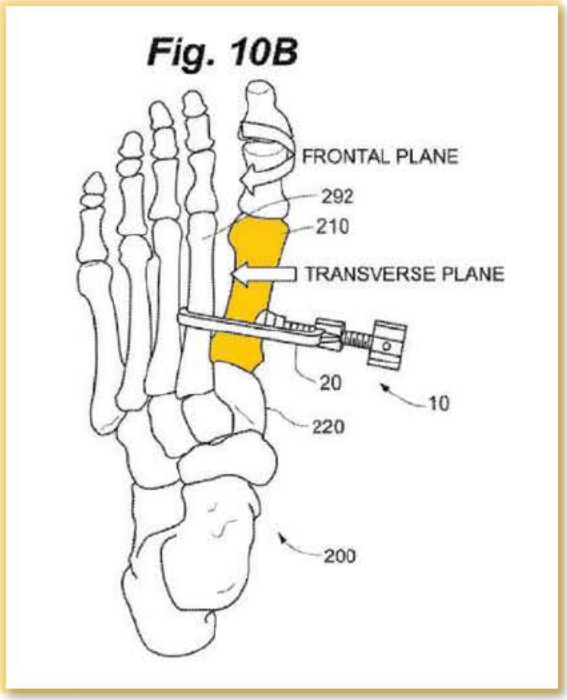


24. The bones of the foot most relevant to Treace Medical's novel Lapiplasty® System and Procedure are the metatarsal and cuneiform bones. The first metatarsal bone, second metatarsal bone, and medial cuneiform bone (each highlighted in yellow in the figure below) and the joint (tarsal-metatarsal joint, or "TMT" joint) between the first metatarsal and medial cuneiform bones are the general focus of bunion surgery using Treace Medical's patented methods, instruments, and implants:

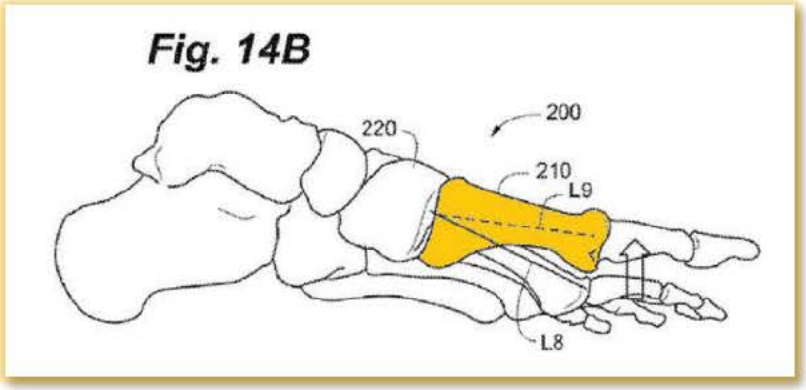


25. Treace Medical's surgical methods and instruments guide surgeons to restore the relative position and orientation of the first metatarsal bone with the medial cuneiform bone and the adjacent second metatarsal bone, and to permanently fix this restored position with implants that support the fusion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

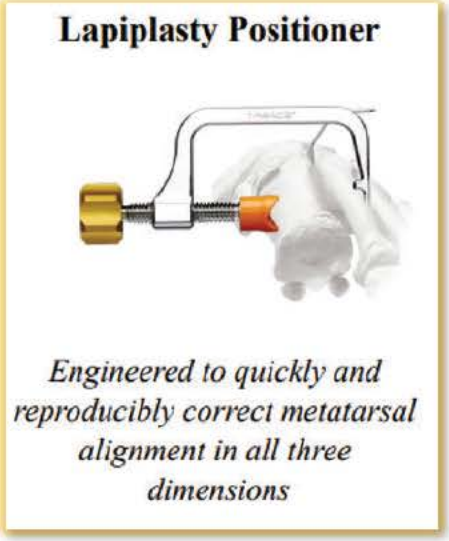
26. Treace Medical's patented Lapiplasty® System and Procedure is the first to provide the ability to accurately and reproducibly correct bunion deformity in all three planes. For example, as demonstrated in the below image from Treace Medical's asserted '368 patent, Treace Medical's Lapiplasty® System and Procedure uses instruments to correct the alignment of the first metatarsal in the transverse plane (from right to left direction in the figure below, to reduce an "intermetatarsal angle" between the first and second metatarsals). The Lapiplasty® System and Procedure also corrects the alignment of the first metatarsal in the frontal plane (the first metatarsal, highlighted in yellow, is rotated about its axis):



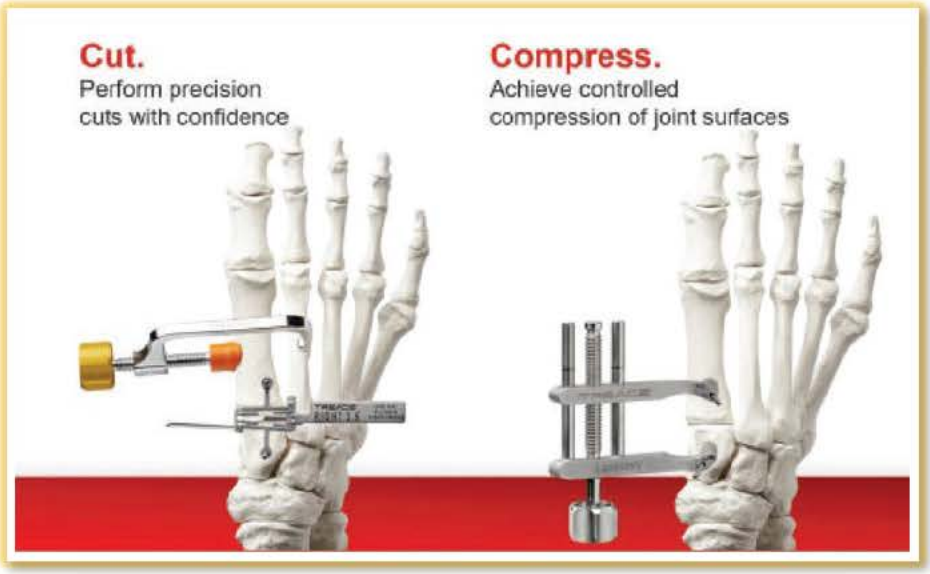
27. In addition, Treace Medical's Lapiplasty® System and Procedure can correct bone misalignment in the sagittal plane, including correcting the alignment of the first metatarsal upward or downward. In the image below, a misalignment of the first metatarsal in the sagittal plane is shown with an arrow,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



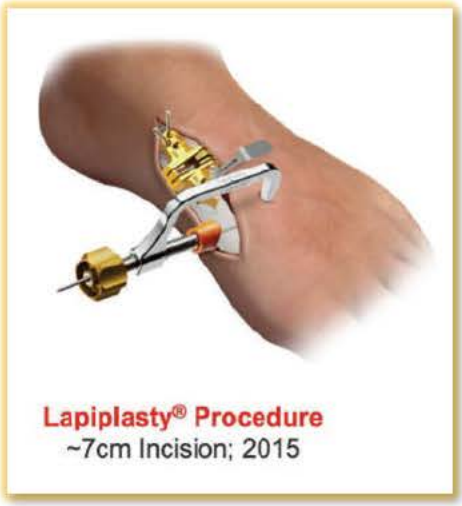
28. One key instrument used to accurately and reproducibly correct the position of the metatarsal bone for treatment of a bunion deformity in Treace Medical's Lapiplasty® System and Procedure is a bone positioning guide, commercially called the Positioner. Item 10 in Figure 10B above is one embodiment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



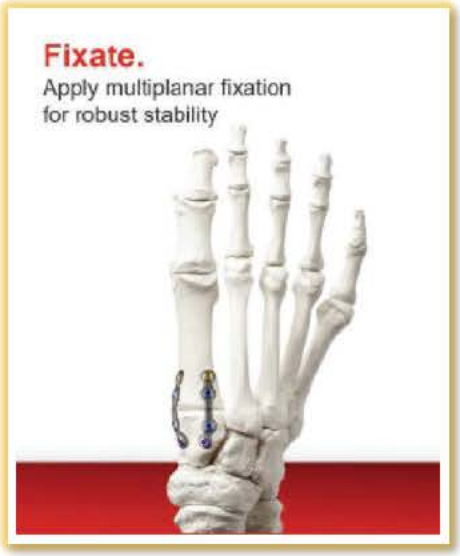
29. Treace Medical's Lapiplasty® System and Procedure also involves preparation of the ends of the medial cuneiform and first metatarsal for fusion, including cutting and then compressing the joint surfaces, as depicted in the image below. Preparing the bones is useful to facilitate flush contact between the bone surfaces and to present bleeding bone faces that can fuse together, stabilizing the TMT joint. Treace Medical's patents describe that preparation of the joint can be done by using a tissue removing instrument, for example, a saw, rotary bur, or osteotome.



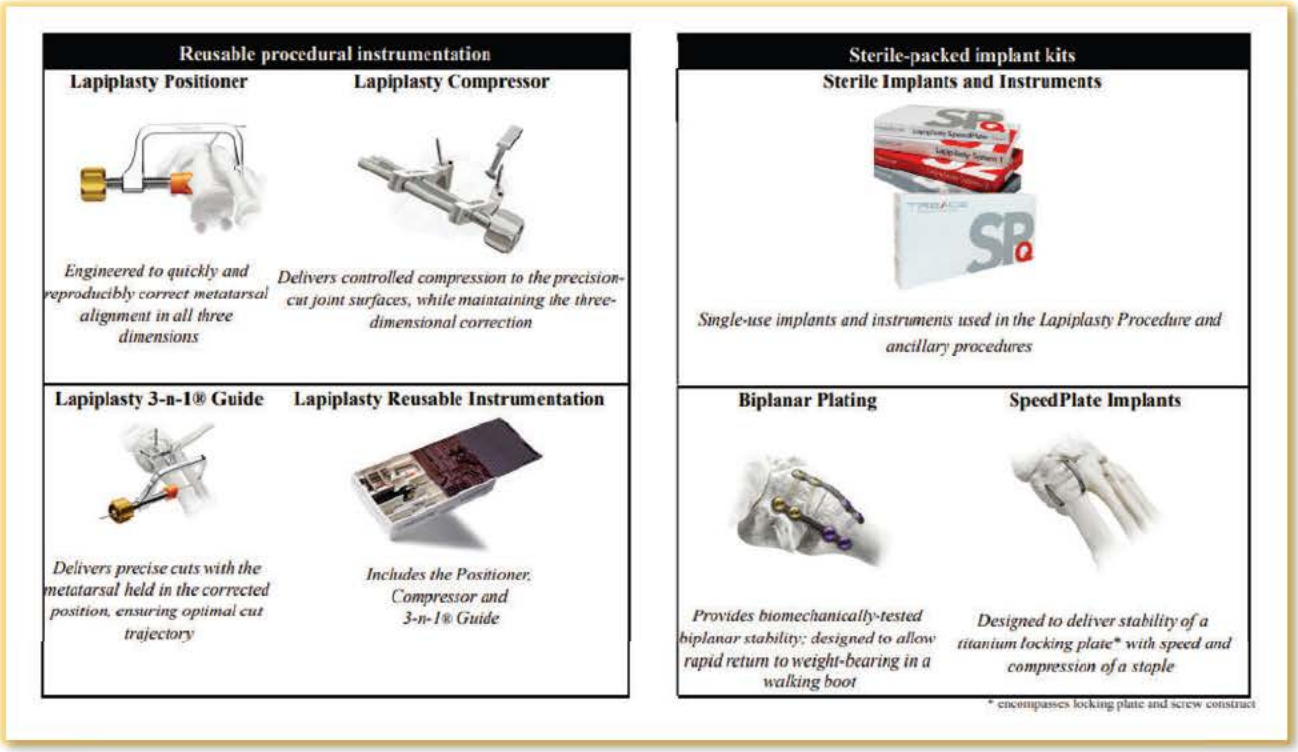
30. The Lapiplasty® System includes a cut guide that aids surgeons in making precise cuts at an optimal cut trajectory. Treace Medical's current commercial cut guide is shown in the image above as part of the "Cut" step. A prior version of the cut guide is depicted below:



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



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



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

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

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

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

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

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

38. In less than a decade, Treace Medical has created and launched a groundbreaking, innovative surgical technology. Treace Medical is the undisputed leader in the instrumented TMT bunion correction market that it created, having achieved a compound annual revenue growth rate of 40% from 2019 to 2024.

39. Unfortunately, following introduction of Treace Medical's novel Lapiplasty® System and Procedure and associated commercial success, the Zimmer Defendants sought to capitalize on Treace Medical's pioneering technology for their own financial gain. After Treace Medical's Lapiplasty® System and Procedure created the instrumented TMT bunion correction market, Paragon 28 came out with its own copycat TMT bunion correction offering seeking to address bunion deformities in the foot: the Bun-Yo-Matic™ Lapidus Clamp System (the "Bun-Yo-Matic™ System"). Zimmer Biomet and Paragon 28 continue to sell the Bun-Yo-Matic™ System today.

B. Treace Medical has protected its pioneering bunion-correction system and procedure with an extensive patent portfolio

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

41. Treace Medical filed its first patent applications related to the Lapiplasty® System and Procedure as U.S. Provisional Patent Application Nos. 62/024,546 and 62/192,319 on July 15, 2014. Treace Medical has over 75 granted U.S. patents, with an additional 26 granted foreign patents, and over 85 pending U.S. patent applications. Treace Medical's patents cover core Lapiplasty®-related instrumentation and surgical techniques as well as other associated innovations.

42. Zimmer Defendants' Bun-Yo-Matic™ System for bunion correction procedures infringes several of these issued utility patents.

43. Specifically, Bun-Yo-Matic™ System and surgical technique infringes at least the following four Asserted Patents: the '368 patent, the '397 patent, the '428 patent, and the '481 patent.

i. Treace Medical's Asserted Apparatus and System Patent

44. One of the Asserted Patents is directed to instrumented TMT bunion correction apparatus or systems: the '368 patent.

45. The '368 patent claims "[a] metatarsal bunion correction system." The 368 patent is directly infringed at least by the making, sale, and offer for sale of the Bun-Yo-Matic™ System, and by use of the Bun-Yo-Matic™ System in a bunion correction surgery or demonstration, as further alleged in Count I below. The '368 patent is titled "Bone Positioning Guide" and issued October 1, 2024. The '368 patent claims priority to two provisional patent applications, No. 62/192,319 filed on July 14, 2015, and No. 62/205,338 filed on August 14, 2015.

ii. Treace Medical's Asserted Method Patents

46. The other three Asserted Patents are directed to methods for performing instrumented TMT bunion correction surgery: the '397 patent, the '428 patent, and the '481 patent.

47. The '397 patent claims "[a] bunion correction method." The '397 patent is directly infringed when Zimmer Defendants' Bun-Yo-Matic™ System is used to perform or demonstrate a bunion correction surgery, as further alleged in Count II. The '397 patent is titled "Bone Cutting Guide Systems and Methods" and issued on April 8, 2025. The '397 patent claims priority to provisional application No. 62/100,641 filed on January 7, 2015.

48. The ’428 patent claims “[a]n instrumented surgical technique for treating a bunion deformity.” The ’428 patent is directly infringed when Zimmer Defendants’ Bun-Yo-Matic™ System is used to perform or demonstrate a bunion correction surgery, as further alleged in Count III. The ’428 patent is titled “Tarsal-Metatarsal Joint Procedure Utilizing Fulcrum” and issued April 8, 2025. The ’428 patent claims priority to two provisional patent applications, No. 62/293,189 filed on February 9, 2016, and No. 62/205,338 filed on August 14, 2015.

49. The ’481 patent claims “[a]n instrumented surgical technique for preparing a tarsal-metatarsal joint for fusion and for repositioning a first metatarsal to correct a bunion deformity.” The ’481 patent is directly infringed when Zimmer Defendants’ Bun-Yo-Matic™ System is used to perform or demonstrate a bunion correction surgery, as further alleged in Count IV. The ’481 patent is titled “Bone Positioning and Preparing Guide and Methods” and issued April 15, 2025. The ’481 patent claims priority to provisional application No. 62/205,338 filed on August 14, 2015.

C. The Zimmer Defendants’ infringing Bun-Yo-Matic System and surgical method

50. The Zimmer Defendants make, use, sell, and offer for sale in the United States an unauthorized copycat version of Treace Medical’s Lapiplasty® System and Procedure that they have branded as the “Bun-Yo-Matic™ Lapidus Clamp System”.

51. The Bun-Yo-Matic™ System was originally owned, manufactured, and sold by Paragon 28. Zimmer Biomet acquired Paragon 28 on April 21, 2025. *See* https://paragon28.com/zimmer-biomet-completes-acquisition-of-paragon-28. Paragon 28’s website now prominently displays and advertises that it is “a Zimmer Biomet company.” *See generally* https://paragon28.com. Upon information and belief, Paragon 28 and the Bun-Yo-Matic™ System are now part of Zimmer Biomet’s foot and ankle segment. *See* https://paragon28.com/zimmer-biomet-completes-acquisition-of-paragon-28.

52. Paragon 28 advertises its infringing Bun-Yo-Matic™ System to both patients and surgeons, including on its website, https://paragon28.com/products/bun-yo-matic-lapidus-clamp/. Paragon 28, for example, explains to patients and surgeons that "[t]he Bun-Yo-Matic™ Lapidus Clamp System is used to assist with the de-rotation, IM angle reduction, and joint closure in a Lapidus arthrodesis." https://paragon28.com/products/bun-yo-matic-lapidus-clamp. Paragon 28 promotes the Bun-Yo-Matic™ System as "an instrument to aid in correcting bunion deformities in a more reproducible and controlled manner, while allowing for options in surgeon fixation compatible with the device (Paragon 28 Phantom® Intramedullary Nail or Paragon 28 Gorilla® Lapidus Plate)." *Id.*

53. Paragon 28 also promotes the Bun-Yo-Matic™ System as being "equipped with cutting guides designed to remove minimal bone from the base of the first metatarsal and the medial cuneiform to prepare the joint for fusion" and that the "guides help establish parallel cut surfaces to improve apposition and arthrodesis following correction." *Id.*

54. Paragon 28's website includes several promotional and instructional videos (collectively, the "Bun-Yo-Matic Videos"). Two of the videos are animations that illustrate the features and functionality of the Bun-Yo-Matic™ System—one video is referred to as "Product Video" and the other video as "Product Features." There are also two instructional videos for surgeons that demonstrate the use of the Bun-Yo-Matic™ System and surgical technique for bunion correction surgery.

55. Paragon 28 also produces and distributes the Bun-Yo-Matic Surgical Technique Guide (the "Bun-Yo-Matic Guide"), which describes Bun-Yo-Matic™ System's instrumentation and surgical technique using the instrumentation. The Bun-Yo-Matic Guide is available at

https://20645419.fs1.hubspotusercontent-na1.net/hubfs/20645419/P30-STG-0006%20RevD_Gorilla_BunYoMatic_Lapidus_Clamp_STG%20(US).pdf.

56. Upon information and belief, Zimmer Biomet now sells and offers for sale the infringing Bun-Yo-Matic™ System. When announcing the proposed acquisition of Paragon 28, Zimmer Biomet stated that the transaction "complements Zimmer Biomet's global footprint and existing infrastructure with Paragon 28's expansive portfolio, which is expected to drive adoption and accelerate U.S. and international growth." https://investor.zimmerbiomet.com/news-and-events/news/2025/01-28-2025-225939148. Upon closing, Zimmer Biomet stated that the acquisition of Paragon 28 "strengthens and expands Zimmer Biomet's foot and ankle offerings" and "create[s] a dedicated foot and ankle sales channel within Zimmer Biomet." https://paragon28.com/zimmer-biomet-completes-acquisition-of-paragon-28. On Zimmer Biomet's Q1 2025 Earnings Call, Zimmer Biomet announced that Paragon 28's sales reps all "have transferred over to Zimmer Biomet." Exhibit 1 at 15.

57. Treace Medical has spent considerable amounts of money educating surgeons about the benefits of the Lapiplasty® Procedure over traditional bunion surgery and on training surgeons to correctly perform the Lapiplasty® Procedure. Treace Medical sponsors cadaver labs and other educational seminars where surgeons can learn from and practice the Lapiplasty® Procedure with experienced Lapiplasty® surgeons and/or Treace staff before they perform this surgery on their own.

58. Zimmer Biomet and Paragon 28 are freeriding off Treace Medical's substantial investments by using, offering to sell, and selling technology that Treace Medical developed over more than a decade at great expense. Treace Medical's Lapiplasty® Procedure has been refined

and tested over that time to deliver optimum surgical results for patients. On information and belief, Paragon 28's Bun-Yo-Matic™ System has been subject to little or no clinical testing.

D. The Zimmer Defendants had knowledge of Treace Medical's patent portfolio at the time of infringement

59. Paragon 28 launched the Bun-Yo-Matic™ System in or around January 2024. *See* https://paragon28.com/first-cases-and-limited-market-release-of-the-bun-yo-matic/.

60. Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents to alert the industry and potential infringers, like Zimmer Biomet and Paragon 28, to Treace Medical's issued patents and pending patent applications. Treace Medical's patent marking webpage states: "One or more implants, instruments, systems, and/or techniques associated with the product names below may be covered by claims in one or more of the United States Patents or Patent Applications as indicated[.]" The Asserted Patents are listed on Treace Medical's patent marking webpage along with the associated patented articles in compliance with 35 U.S.C. § 287(a).

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

62. Further, Treace Medical prioritizes educating competitors and customers of its substantial and ongoing efforts to utilize patents to protect its investments in the instrumented TMT bunion correction market that it created. Treace Medical regularly issues press releases announcing the issuance of its patents, including, for example:

- *Treace Announces Grant of Additional U.S. Patent on Instrumented Bunion Correction* (October 21, 2021): Announcing U.S. Patent No. 11,147,590, which is the parent to the asserted '849 Patent, and highlighting another patent in the same family as the '849 Patent, U.S. Patent No. 10,945,764. "The patent is an expansion

of a portfolio filed during Treace's pathbreaking development work in the field with early priority dating back to 2014…. The new patent is the Company's 30th granted US patent (Treace also holds 6 patents granted outside the U.S.)."

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

- *Treace Announces Grant of U.S. Patent on Instrumented Bunion Correction* (January 19, 2022): "'We are pleased that the Patent Office continues to recognize the novel advances made by Treace. The addition of this recent patent grant further strengthens our intellectual property position and highlights our commitment to innovation in advancing the surgical treatment of bunion patients,' said John T. Treace, CEO, Founder and Board Member of Treace."

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

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

63. Likewise, Treace Medical regularly attends industry meetings and conferences, such as the American College of Foot and Ankle Surgeons ("ACFAS") Annual Scientific Conference and the American Orthopaedic Foot & Ankle Society ("AOFAS") Annual Meeting. Treace Medical representatives are trained to discuss and do discuss that Treace Medical has revolutionized the field of TMT bunion correction surgery with an instrumented approach and promote the fact that Treace Medical has strong patent protection on both the systems and procedures.

64. Further, Zimmer Biomet was expressly aware of Treace Medical's extensive patent portfolio, including in relation to Paragon 28's products and surgical technique, at least as of September 2023.

COUNT I
(Infringement of U.S. Patent No. 12,102,368)

65. Treace Medical realleges and incorporates by reference paragraphs 1–64 of this Complaint.

66. On October 1, 2024, the USPTO issued U.S. Patent Number 12,102,368 B2 ("the '368 patent") to Treace Medical, listing inventors W. Bret Smith, Paul Dayton, Sean F. Scanlan, F. Barry Bays, Carlos Eduardo Gil, John T. Treace, Robert D. Santrock, Daniel J. Hatch, and Joe W. Ferguson. The '368 patent is titled "Bone Positioning Guide" and is directed to "[a] metatarsal bunion correction system." A true and correct copy of the '368 patent is attached to this Complaint as **Exhibit 2**. The '368 patent remains in force and is assigned to Treace Medical. Treace Medical has owned the '368 patent since it was issued and still owns the '368 patent.

67. The '368 patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

68. Zimmer Biomet and Paragon 28 have made, used, offered for sale, sold, and/or imported into the United States the Bun-Yo-Matic™ System.

69. Attached to this Complaint as **Exhibit 3** is a claim chart explaining how the Bun-Yo-Matic™ System meets the elements of an exemplary claim of the '368 patent. The Bun-Yo-Matic™ System has no substantial non-infringing uses.

Direct Infringement of the '368 Patent

70. On information and belief, Zimmer Biomet and Paragon 28 have directly infringed and continue to directly infringe, both literally and/or under the doctrine of equivalents, the '368

patent by making, selling, offering for sale, and/or using (*e.g.*, by performing actual or simulated surgical procedures) the Bun-Yo-Matic™ System in the United States in violation of 35 U.S.C. § 271(a), including within this judicial district, in a manner that infringes at least claim 1 of the ’368 patent without a license from Treace Medical.

71. Zimmer Biomet and Paragon 28 also direct and/or control surgeons to infringe the ’368 patent with the Bun-Yo-Matic™ System because, among other things, Zimmer Biomet and Paragon 28 condition receipt of benefits to surgeons on the assembly and use of a device that infringes the ’368 patent, and establish that assembly and use by, among other things, providing detailed instructions concerning the assembly and use of the Bun-Yo-Matic™ System that, if not followed, will deprive the surgeons of the benefits they hope to obtain from the Bun-Yo-Matic™ System and assembly and use of a device that infringes the ’368 patent. For example, Paragon 28 advertises to surgeons who, on information and belief, assemble the Bun-Yo-Matic™ System as Paragon 28 instructs in the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos to infringe the ’368 patent. On information and belief, the Zimmer Biomet or Paragon 28 representative present in the operating room for nearly every Bun-Yo-Matic™ System procedure monitors and directs the surgeon and will only provide the surgeon components of the Bun-Yo-Matic™ System if the surgeon assembles and uses the Bun-Yo-Matic™ System as provided by the ’368 patent.

Induced Infringement of the ’368 Patent

72. On information and belief, Zimmer Biomet and Paragon 28 have induced and continue to induce infringement of the ’368 patent in violation of 35 U.S.C. § 271(b).

73. The Bun-Yo-Matic Guide and Bun-Yo-Matic Videos instruct, encourage, and assist surgeons to use the Bun-Yo-Matic™ System in a manner that directly infringes the claims of the ’368 patent. On information and belief, Zimmer Biomet and Paragon 28 sales staff, surgical site

representatives, consulting surgeons, and public and non-public instructional materials similarly instruct and encourage surgeons to use the Bun-Yo-Matic™ System in a manner that directly infringes the claims of the ’368 patent as depicted and described above and in Exhibit 3. Zimmer Biomet or Paragon 28 representatives present in the operating room for each Bun-Yo-Matic™ Procedure monitor surgeons’ use of the Bun-Yo-Matic™ System and, on information and belief, direct them to assemble and use the Bun-Yo-Matic™ System to infringe the claims of the ’368 patent.

74. On information and belief, Zimmer Biomet and Paragon 28 have provided such instructions and encouragement despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the ’368 patent and the resulting infringement thereof by surgeons Zimmer Biomet and Paragon 28 so instructed.

75. Zimmer Biomet and Paragon 28 at a minimum had constructive knowledge of Treace Medical’s patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The ’368 patent is listed on Treace Medical’s patent marking webpage under the Lapiplasty® System and Procedure heading.

76. To the extent Zimmer Biomet or Paragon 28 contends that it did not know of the ’368 patent before the filing and service of this Complaint, that contention would be based on willful blindness to the ’368 patent and that the acts Zimmer Biomet and Paragon 28 actively induced constituted infringement of the ’368 patent. On information and belief, Zimmer Biomet and Paragon 28 at least subjectively believed that a high probability existed that Treace Medical’s Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical’s known status as the inventor of Instrumented TMT Bunion Systems; Zimmer Biomet’s and Paragon 28’s attendance and participation at industry conferences (*e.g.*,

AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System; and Treace Medical's substantial publicity regarding its patent portfolio.

77. On information and belief, Zimmer Biomet and Paragon 28 have continued to distribute materials, including the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos, to demonstrate the infringing use of the Bun-Yo-Matic™ System. Continued distribution of these materials further shows that the Bun-Yo-Matic™ System is especially made to infringe the '368 patent.

78. On information and belief, Zimmer Biomet and Paragon 28 know that its surgeon customers and surgeon consultants are performing bunion correction procedures using the Bun-Yo-Matic™ System and are directly infringing the claims of the '368 patent.

79. Zimmer Biomet's and Paragon 28's inducing acts, such as distribution of the Bun-Yo-Matic Guide, Bun-Yo-Matic Videos, and other instructional materials, to promote and demonstrate the Bun-Yo-Matic™ System, and instructing and encouraging surgeons to use the Bun-Yo-Matic™ System in a manner consistent with the Bun-Yo-Matic™ Procedure described above and in Exhibit 3, caused and are causing surgeons to use the Bun-Yo-Matic™ System in a manner that infringes the claims of the '368 patent.

Contributory Infringement of the '368 Patent

80. On information and belief, Zimmer Biomet and Paragon 28 have induced and continue to induce infringement of the '368 patent in violation of 35 U.S.C. § 271(c).

81. Zimmer Biomet and Paragon 28 have offered for sale, sold, and/or imported into the United States medical instruments and implants that are part of the Bun-Yo-Matic™ System, including at least components of the Bun-Yo-Matic clamp. These products are components of the apparatus covered by the '368 patent.

82. On information and belief, surgeons are assembling and using the Bun-Yo-Matic™ System as instructed, assisted, and encouraged by Zimmer Biomet and Paragon 28 in at least the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos and by Zimmer Biomet's and Paragon 28's sales staff, surgical site representatives, and surgeon consultants, thereby directly infringing the claims of the '368 patent.

83. On information and belief, Zimmer Biomet and Paragon 28 provided components of a patented apparatus despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the '368 patent and the resulting infringement thereof by surgeons Zimmer Biomet and Paragon 28 so instructed.

84. Zimmer Biomet and Paragon 28 at a minimum had constructive knowledge of Treace Medical's patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The '368 patent is listed on Treace Medical's patent marking webpage under the Lapiplasty® System and Procedure heading.

85. To the extent Zimmer Biomet or Paragon 28 contends that it did not know of the '368 patent before the filing and service of this Complaint, that contention would be based on willful blindness to the '368 patent and that the acts Zimmer Biomet and Paragon 28 actively induced constituted infringement of the '368 patent. On information and belief, Zimmer Biomet and Paragon 28 at least subjectively believed that a high probability existed that Treace Medical's Lapiplasty® System and Procedure were covered and protected by issued patents based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; Zimmer Biomet's and Paragon 28's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System; and Treace Medical's substantial publicity regarding its patent portfolio.

86. Components of the Bun-Yo-Matic™ System, including at least the components of the Bun-Yo-Matic clamp, are material components of a patented apparatus claimed in the ’368 patent. These components are especially made for use in a manner that infringes the apparatus claimed in the ’368 patent. The Bun-Yo-Matic™ System components are not staple articles or commodities of commerce suitable for substantial non-infringing uses. The only known use of the Bun-Yo-Matic clamp is for the infringing uses in the Bun-Yo-Matic™ System as described above and in Exhibit 3.

87. On information and belief, Zimmer Biomet and Paragon 28 have provided materials to hospitals and surgeons, including the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos, demonstrating the infringing assembly of the Bun-Yo-Matic™ System. The distribution of these materials further shows that Paragon 28 especially made the Bun-Yo-Matic™ System to infringe the ’368 patent. Zimmer Biomet and Paragon 28 representatives present in the operating room for each Bun-Yo-Matic™ Procedure monitor surgeons’ use of the Bun-Yo-Matic™ System and, on information and belief, direct them to assemble and use the Bun-Yo-Matic™ System to infringe the claims of the ’368 patent with the awareness that the Bun-Yo-Matic™ System (including components of the Bun-Yo-Matic clamp) have no substantial non-infringing uses.

88. On information and belief, at a date prior to the filing of this Complaint and at least as of the date of the filing and service of this Complaint, Zimmer Biomet and Paragon 28 have known that the Bun-Yo-Matic™ System (including components of the Bun-Yo-Matic clamp) were especially made for use in a manner that infringes the ’368 patent and were directly infringing the ’368 patent.

89. On information and belief, surgeons have in fact used and continue to use the Bun-Yo-Matic™ System, thereby infringing the ’368 patent.

Willful Infringement of the '368 Patent

90. Zimmer Biomet and Paragon 28 have willfully infringed the '368 patent.

91. On information and belief, Zimmer Biomet and Paragon 28 have infringed and continue to infringe the '368 patent with knowledge of Treace Medical's rights in the '368 patent, as described at least at paragraphs 59–64.

92. On information and belief, Zimmer Biomet's and Paragon 28's acts of infringement of the '368 patent have been and continue to be willful, deliberate, and egregious, as described at least at paragraphs 59–64.

93. On information and belief, Zimmer Biomet and Paragon 28 acted despite an objectively high likelihood that its actions constituted infringement of a valid patent claim and knew or should have known of this objectively defined risk of infringement, as described at least at paragraphs 59–64.

Requested Relief for the Zimmer Defendants' Infringement of the '368 Patent

94. Zimmer Biomet's and Paragon 28's misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters a permanent injunction prohibiting Zimmer Biomet and Paragon 28 and those acting on its behalf from infringing the '368 patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the Bun-Yo-Matic™ System. Zimmer Biomet's and Paragon 28's misconduct has caused Treace Medical to suffer irreparable injury that is not adequately compensated for by remedies available at law. The balance of hardships between the parties warrants a remedy in equity and the public interest would not be disserved by a permanent injunction.

95. Treace Medical is entitled to recover damages that would place Treace Medical as close as possible to the same financial position that it would have been in had Zimmer Biomet's and Paragon 28's infringement of the '368 patent not occurred. Treace Medical is entitled to recover damages including all profits that it has lost as a result of Zimmer Biomet's and Paragon 28's sale of the Bun-Yo-Matic™ System and the products used in the performance of instrumented TMT bunion correction procedures using the Bun-Yo-Matic™ System. At a minimum, Treace Medical is entitled to a reasonable royalty on Zimmer Biomet's and Paragon 28's sales of the Bun-Yo-Matic™ System and products used in the performance and practicing of the patented instrumented TMT bunion correction procedures using the Bun-Yo-Matic™ System.

96. Treace Medical requests pursuant to 35 U.S.C. § 284 that damages awarded to it in this matter for Zimmer Biomet's and Paragon 28's willful infringement of the '368 patent be increased to three times the amount found or assessed by the factfinder.

COUNT II
(Infringement of U.S. Patent No. 12,268,397)

97. Treace Medical realleges and incorporates by reference paragraphs 1–96 of this Complaint.

98. On April 8, 2025, the USPTO issued U.S. Patent Number 12,268,397 B2 ("the '397 patent") to Treace Medical, listing inventors Paul Dayton, Robert D. Santrock, Daniel J. Hatch, W. Bret Smith, Carlos Eduard Gil, Sean F. Scanlan, Joe William Ferguson, F. Barry Bays, and John T. Treace. The '397 patent is titled "Bone Cutting Guide Systems and Methods" and is directed to "[a] bunion correction method." A true and correct copy of the '397 patent is attached to this Complaint as **Exhibit 4**. The '397 patent remains in force and is assigned to Treace Medical. Treace Medical has owned the '397 patent since it was issued and still owns the '397 patent.

99. The ’397 patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

100. Zimmer Biomet and Paragon 28 have made, used, offered for sale, sold, and/or imported into the United States the Bun-Yo-Matic™ Lapidus Clamp System

101. Attached to this Complaint as **Exhibit 5** is a claim chart explaining how Zimmer Biomet and Paragon 28 describe through the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos the performance of the steps of an exemplary claim of the ’397 patent using the Bun-Yo-Matic™ System and thereby instruct and encourage surgeons to perform the method of the claims of the ’397 patent (“the ’397 Claimed Method”). On information and belief, Zimmer Biomet and Paragon 28 continue to instruct and encourage surgeons to perform the ’397 Claimed Method. On information and belief, Zimmer Biomet and Paragon 28 have not instructed surgeons to perform the Bun-Yo-Matic™ Procedure using the Bun-Yo-Matic™ System in a non-infringing manner. The Bun-Yo-Matic™ System has no substantial non-infringing uses.

Direct Infringement of the ’397 Patent

102. On information and belief, Zimmer Biomet and Paragon 28 have directly infringed and continue to directly infringe, both literally and/or under the doctrine of equivalents, the ’397 patent by using (*e.g.*, by performing actual or simulated surgical procedures) the Bun-Yo-Matic™ System to perform the patented surgical method of the ’397 patent in the United States in violation of 35 U.S.C. § 271(a), including within this judicial district, in a manner that infringes at least claim 1 of the ’397 patent without a license from Treace Medical.

103. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos using the Bun-Yo-Matic™ System directly infringe the ’397 patent.

104. On information and belief, surgeon consultants to Paragon 28, working Paragon 28's direction, tested and performed the '397 Claimed Method using the Bun-Yo-Matic™ System on Paragon 28's behalf as part of developing the Bun-Yo-Matic™ System and Procedure at least before the Bun-Yo-Matic™ System was first offered for sale and sold in the United States.

105. In addition, surgeon consultants to Zimmer Biomet and Paragon 28, working at Zimmer Biomet's or Paragon 28's direction, perform the '397 Claimed Method using the Bun-Yo-Matic™ System as part of surgeon education both before and after the Bun-Yo-Matic™ System was offered for sale and sold in the United States.

106. Paragon 28 has created at least the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos showing the Bun-Yo-Matic™ System being used to perform the Bun-Yo-Matic™ Procedure and thereby performing the '397 Claimed Method. On information and belief, surgeons working on Zimmer Biomet's and Paragon 28's behalf and at Zimmer Biomet's and Paragon 28's direction, performed the '397 Claimed Method using the Bun-Yo-Matic™ System in connection with creating the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos, which demonstrates performance of the '397 Claimed Method using the Bun-Yo-Matic™ System.

107. Zimmer Biomet and Paragon 28 also direct and/or control surgeons to perform the '397 Claimed Method using the Bun-Yo-Matic™ System because, among other things, Zimmer Biomet and Paragon 28 condition receipt of benefits to surgeons on their performance of one or more steps of the '397 Claimed Method, and establish that performance by, among other things, providing detailed instructions concerning the assembly of the Bun-Yo-Matic™ System that, if not followed, will deprive the surgeons of the benefits they hope to obtain from the Bun-Yo-Matic™ System and performing one or more steps of the '397 Claimed Method. For example, Paragon 28 advertises to surgeons who, on information and belief, use the Bun-Yo-Matic™

System as Paragon 28 instructs in the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos to perform the ’397 Claimed Method. On information and belief, the Zimmer Biomet or Paragon 28 representative present in the operating room for nearly every Bun-Yo-Matic™ Procedure monitors and directs the surgeon and will only provide the surgeon components of the Bun-Yo-Matic™ System if the surgeon performs one or more steps of the ’397 Claimed Method.

Induced Infringement of the ’397 Patent

108. On information and belief, Zimmer Biomet and Paragon 28 have induced and continue to induce infringement of the ’397 Claimed Method in violation of 35 U.S.C. § 271(b).

109. Zimmer Biomet and Paragon 28 have provided materials to hospitals and surgeons that demonstrate using the Bun-Yo-Matic™ System to perform the ’397 Claimed Method. For example, the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos instruct, encourage, and assist surgeons to use the Bun-Yo-Matic™ System in a manner that directly infringes the claims of the ’397 patent. On information and belief, Zimmer Biomet and Paragon 28 sales staff, surgical site representatives, consulting surgeons, and public and non-public instructional materials similarly instruct and encourage surgeons to use the Bun-Yo-Matic™ System in a manner that directly infringes the claims of the ’397 patent as depicted and described above and in Exhibit 5. On information and belief, Zimmer Biomet and Paragon 28 distributed these materials to hospitals and surgeons with the intent to cause surgeons to use the Bun-Yo-Matic™ System and Procedure to perform the ’397 Claimed Method. Zimmer Biomet and Paragon 28 representatives present in the operating room for each Bun-Yo-Matic™ Procedure monitor surgeons’ performance of the Bun-Yo-Matic™ Procedure and, on information and belief, direct them to use the Bun-Yo-Matic™ System for the Bun-Yo-Matic™ Procedure to infringe the claims of the ’397 patent.

110. On information and belief, Zimmer Biomet and Paragon 28 have provided such instructions and encouragement despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the ’397 patent and the resulting infringement thereof by surgeons Zimmer Biomet and Paragon 28 so instructed.

111. Zimmer Biomet and Paragon 28 at a minimum had constructive knowledge of Treace Medical’s patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The ’397 patent is listed on Treace Medical’s patent marking webpage.

112. Any contention that Zimmer Biomet or Paragon 28 did not know that the acts Zimmer Biomet and Paragon 28 actively induced constituted infringement of the ’397 patent would be based on willful blindness to the ’397 patent and that the acts Zimmer Biomet and Paragon 28 actively induced constituted infringement of the ’397 patent. On information and belief, Zimmer Biomet and Paragon 28 were on notice of Treace Medical’s patent rights based on, for example, Treace Medical’s known status as the inventor of Instrumented TMT Bunion Systems; Zimmer Biomet’s and Paragon 28’s attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System; and Treace Medical’s substantial publicity regarding its patent portfolio. At a minimum, Zimmer Biomet and Paragon 28 were on notice that they would need to conduct a right-to-use study that included reviewing Treace Medical’s patents before releasing and promoting its Bun-Yo-Matic™ System and Procedure.

113. On information and belief, Zimmer Biomet and Paragon 28 know that their surgeon customers and surgeon consultants are performing the ’397 Claimed Method using the Bun-Yo-Matic™ System and Procedure and are directly infringing the ’397 Claimed Method.

114. Zimmer Biomet's and Paragon 28's inducing acts, such as distribution of the Bun-Yo-Matic Guide, Bun-Yo-Matic Videos, and other instructional materials, to promote and demonstrate the Bun-Yo-Matic™ System and Procedure, and instructing and encouraging surgeons to use the Bun-Yo-Matic™ System in a manner consistent with the Bun-Yo-Matic™ Procedure described above and in Exhibit 5, caused and are causing surgeons to use the Bun-Yo-Matic™ System and Procedure in a manner that infringes the '397 Claimed Method.

Contributory Infringement of the '397 patent

115. On information and belief, Zimmer Biomet and Paragon 28 have contributorily infringed the '397 Claimed Method in violation of 35 U.S.C. § 271(c).

116. Zimmer Biomet and Paragon 28 have made, used, offered for sale, sold, and/or imported into the United States medical instruments and implants used in performing the infringing Bun-Yo-Matic™ Procedure, including at least the Bun-Yo-Matic clamp, cut guides, tissue removing instruments, and implants.

117. On information and belief, surgeons have performed and are performing the Bun-Yo-Matic™ Procedure using the Bun-Yo-Matic™ System as instructed, assisted, and encouraged by Zimmer Biomet and Paragon 28 in at least the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos and by Zimmer Biomet and Paragon 28 sales staff, surgical site representatives, and surgeon consultants, thereby directly infringing the '397 Claimed Method.

118. On information and belief, Zimmer Biomet and Paragon 28 had actual knowledge of the '397 patent and Treace Medical's infringement allegations at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint.

119. Zimmer Biomet and Paragon 28 at a minimum had constructive knowledge of Treace Medical's patent rights because of Treace Medical's virtual marking through its internet

website at https://www.treace.com/patents. The ’397 patent is listed on Treace Medical’s patent marking webpage.

120. Any contention that Zimmer Biomet or Paragon 28 did not know that the Bun-Yo-Matic™ System is especially made or especially adapted for use in an infringement of the ’397 patent would be based on willful blindness to the ’397 patent and that the acts Zimmer Biomet and Paragon 28 actively induced constituted infringement of the ’397 patent. On information and belief, Zimmer Biomet and Paragon 28 were further on notice of Treace Medical’s patent rights based on, for example, Treace Medical’s known status as the inventor of Instrumented TMT Bunion Systems; Zimmer Biomet’s and Paragon 28’s attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System; and Treace Medical’s substantial publicity regarding its patent portfolio. At a minimum, Paragon 28 was on notice that it would need to conduct a right-to-use study that included reviewing Treace Medical’s patents before releasing and promoting its Bun-Yo-Matic™ System and Procedure.

121. Components of the Bun-Yo-Matic™ System including at least the Bun-Yo-Matic clamp, cut guides, tissue removing instruments, and implants are material components for use in practicing the ’397 Claimed Method. These components are especially made for use in a manner that infringes the ’397 Claimed Method. The Bun-Yo-Matic™ System components are not staple articles or commodities of commerce suitable for substantial non-infringing uses. For example, the only known use of the Bun-Yo-Matic clamp is for the infringing uses as described above and in Exhibit 5.

122. On information and belief, Zimmer Biomet and Paragon 28 have provided materials to hospitals and surgeons, including the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos,

demonstrating the use of the Bun-Yo-Matic™ System to perform the ’397 Claimed Method. The distribution of these materials further shows that Paragon 28 especially made the Bun-Yo-Matic™ System to perform the ’397 Claimed Method. Zimmer Biomet and Paragon 28 representatives present in the operating room for each Bun-Yo-Matic™ Procedure monitor surgeons’ performance of the Bun-Yo-Matic™ Procedure and, on information and belief, direct them to use the Bun-Yo-Matic™ System for the Bun-Yo-Matic™ Procedure to infringe the claims of the ’397 patent.

123. On information and belief, at a date prior to the filing of this Complaint and at least as of the date of the filing and service of this Complaint, Zimmer Biomet and Paragon 28 have known that the Bun-Yo-Matic™ System (including the Bun-Yo-Matic clamp, cut guides, tissue removing instruments, and implants) were especially made for use in a manner that infringes the ’397 Claimed Method and were directly infringing the ’397 Claimed Method.

124. On information and belief, surgeons have in fact used and continue to use the Bun-Yo-Matic™ System and Procedure in a manner that infringes the ’397 Claimed Method.

Willful Infringement of the ’397 patent

125. Zimmer Biomet and Paragon 28 have willfully infringed the ’397 Claimed Method.

126. On information and belief, Zimmer Biomet and Paragon 28 have infringed and continue to infringe the ’397 Claimed Method with knowledge of Treace Medical’s rights in the ’397 patent, as described at least at paragraphs 59–64.

127. On information and belief, Zimmer Biomet’s and Paragon 28’s acts of infringement of the ’397 Claimed Method have been and continue to be willful, deliberate, and egregious, as described at least at paragraphs 59–64.

128. On information and belief, Zimmer Biomet and Paragon 28 acted despite an objectively high likelihood that its actions constituted infringement of a valid patent claim and

knew or should have known of this objectively defined risk of infringement, as described at least at paragraphs 59–64.

Requested Relief for the Zimmer Defendants' Infringement of the '397 patent

129. Zimmer Biomet's and Paragon 28's misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters a permanent injunction prohibiting Zimmer Biomet and Paragon 28 and those acting on its behalf from infringing the '397 patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the Bun-Yo-Matic™ System for performing the '397 Claimed Method. Zimmer Biomet's and Paragon 28's misconduct has caused Treace Medical to suffer irreparable injury that is not adequately compensated for by remedies available at law. The balance of hardships between the parties warrants a remedy in equity and the public interest would not be disserved by a permanent injunction.

130. Treace Medical is entitled to recover damages that would place Treace Medical as close as possible to the same financial position that it would have been in had Zimmer Biomet's and Paragon 28's infringement of the '397 patent not occurred. Treace Medical is entitled to recover damages including all profits that it has lost as a result of Zimmer Biomet's and Paragon 28's sale of the Bun-Yo-Matic™ System and the products used in the performance of instrumented TMT bunion correction procedures using the Bun-Yo-Matic™ System. At a minimum, Treace Medical is entitled to a reasonable royalty on Zimmer Biomet's and Paragon 28's sales of the Bun-Yo-Matic™ System and products used in the performance and practicing of the patented instrumented TMT bunion correction procedures using the Bun-Yo-Matic™ System.

131. Treace Medical requests pursuant to 35 U.S.C. § 284 that damages awarded to it in this matter for Zimmer Biomet's and Paragon 28's willful infringement of the '397 patent be increased to three times the amount found or assessed by the fact finder.

COUNT III
(Infringement of U.S. Patent No. 12,268,428)

132. Treace Medical realleges and incorporates by reference paragraphs 1–131 of this Complaint.

133. On April 8, 2025, the USPTO issued U.S. Patent Number 12,268,428 B2 ("the '428 patent") to Treace Medical, listing inventors F. Barry Bays, Robert D. Santrock, Paul Dayton, Daniel J. Hatch, Bret Smith, Carlos Eduardo Gil, Sean F. Scanlan, Joe William Ferguson, and John T. Treace. The '428 patent is titled "Tarsal-Metatarsal Joint Procedure Utilizing Fulcrum" and is directed to "[a]n instrumented surgical technique for treating a bunion deformity." A true and correct copy of the '428 patent is attached to this Complaint as **Exhibit 6**. The '428 patent remains in force and is assigned to Treace Medical. Treace Medical has owned the '428 patent since it was issued and still owns the '428 patent.

134. The '428 patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

135. Zimmer Biomet and Paragon 28 have made, used, offered for sale, sold, and/or imported into the United States the Bun-Yo-Matic™ Lapidus Clamp System

136. Attached to this Complaint as **Exhibit 7** is a claim chart explaining how Zimmer Biomet and Paragon 28 describe through the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos the performance of the steps of an exemplary claim of the '428 patent using the Bun-Yo-Matic™ System and thereby instruct and encourage surgeons to perform the method of the claims of the '428 patent ("the '428 Claimed Method"). On information and belief, Zimmer Biomet and

Paragon 28 continue to instruct and encourage surgeons to perform the ’428 Claimed Method. On information and belief, Zimmer Biomet and Paragon 28 have not instructed surgeons to perform the Bun-Yo-Matic™ Procedure using the Bun-Yo-Matic™ System in a non-infringing manner. The Bun-Yo-Matic™ System has no substantial non-infringing uses.

Direct Infringement of the ’428 Patent

137. On information and belief, Zimmer Biomet and Paragon 28 have directly infringed and continue to directly infringe, both literally and/or under the doctrine of equivalents, the ’428 patent by using (*e.g.*, by performing actual or simulated surgical procedures) the Bun-Yo-Matic™ System to perform the patented surgical method of the ’428 patent in the United States in violation of 35 U.S.C. § 271(a), including within this judicial district, in a manner that infringes at least claim 1 of the ’428 patent without a license from Treace Medical.

138. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos using the Bun-Yo-Matic™ System directly infringe the ’428 patent.

139. On information and belief, surgeon consultants to Paragon 28, working at Paragon 28’s direction, tested and performed the ’428 Claimed Method using the Bun-Yo-Matic™ System on Paragon 28’s behalf as part of developing the Bun-Yo-Matic™ System and Procedure at least before the Bun-Yo-Matic™ System was first offered for sale and sold in the United States.

140. In addition, surgeon consultants to Zimmer Biomet and Paragon 28, working at Zimmer Biomet’s or Paragon 28’s direction, perform the ’428 Claimed Method using the Bun-Yo-Matic™ System as part of surgeon education both before and after the Bun-Yo-Matic™ System was offered for sale and sold in the United States.

141. Paragon 28 has created at least the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos showing the Bun-Yo-Matic™ System being used to perform the Bun-Yo-Matic™ Procedure and thereby performing the '428 Claimed Method. On information and belief, surgeons working on Zimmer Biomet's and Paragon 28's behalf and at Zimmer Biomet's and Paragon 28's direction, performed the '428 Claimed Method using the Bun-Yo-Matic™ System in connection with creating the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos, which demonstrates performance of the '428 Claimed Method using the Bun-Yo-Matic™ System.

142. Zimmer Biomet and Paragon 28 also direct and/or control surgeons to perform the '428 Claimed Method using the Bun-Yo-Matic™ System because, among other things, Zimmer Biomet and Paragon 28 condition receipt of benefits to surgeons on their performance of one or more steps of the '428 Claimed Method, and establish that performance by, among other things, providing detailed instructions concerning the assembly of the Bun-Yo-Matic™ System that, if not followed, will deprive the surgeons of the benefits they hope to obtain from the Bun-Yo-Matic™ System and performing one or more steps of the '428 Claimed Method. For example, Paragon 28 advertises to surgeons who, on information and belief, use the Bun-Yo-Matic™ System as Paragon 28 instructs in the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos to perform the '428 Claimed Method. On information and belief, the Zimmer Biomet or Paragon 28 representative present in the operating room for nearly every Bun-Yo-Matic™ Procedure monitors and directs the surgeon and will only provide the surgeon components of the Bun-Yo-Matic™ System if the surgeon performs one or more steps of the '428 Claimed Method.

Induced Infringement of the '428 Patent

143. On information and belief, Zimmer Biomet and Paragon 28 have induced and continue to induce infringement of the '428 Claimed Method in violation of 35 U.S.C. § 271(b).

144. Zimmer Biomet and Paragon 28 have provided materials to hospitals and surgeons that demonstrate using the Bun-Yo-Matic™ System to perform the '428 Claimed Method. For example, the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos instruct, encourage, and assist surgeons to use the Bun-Yo-Matic™ System in a manner that directly infringes the claims of the '428 patent. On information and belief, Zimmer Biomet and Paragon 28 sales staff, surgical site representatives, consulting surgeons, and public and non-public instructional materials similarly instruct and encourage surgeons to use the Bun-Yo-Matic™ System in a manner that directly infringes the claims of the '428 patent as depicted and described above and in Exhibit 7. On information and belief, Zimmer Biomet and Paragon 28 distributed these materials to hospitals and surgeons with the intent to cause surgeons to use the Bun-Yo-Matic™ System and Procedure to perform the '428 Claimed Method. Zimmer Biomet and Paragon 28 representatives present in the operating room for each Bun-Yo-Matic™ Procedure monitor surgeons' performance of the Bun-Yo-Matic™ Procedure and, on information and belief, direct them to use the Bun-Yo-Matic™ System for the Bun-Yo-Matic™ Procedure to infringe the claims of the '428 patent.

145. On information and belief, Zimmer Biomet and Paragon 28 have provided such instructions and encouragement despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the '428 patent and the resulting infringement thereof by surgeons Zimmer Biomet and Paragon 28 so instructed.

146. Zimmer Biomet and Paragon 28 at a minimum had constructive knowledge of Treace Medical's patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The '428 patent is listed on Treace Medical's patent marking webpage.

147. Any contention that Zimmer Biomet or Paragon 28 did not know that the acts Zimmer Biomet and Paragon 28 actively induced constituted infringement of the ’428 patent would be based on willful blindness to the ’428 patent and that the acts Zimmer Biomet and Paragon 28 actively induced constituted infringement of the ’428 patent. On information and belief, Zimmer Biomet and Paragon 28 were on notice of Treace Medical’s patent rights based on, for example, Treace Medical’s known status as the inventor of Instrumented TMT Bunion Systems; Zimmer Biomet’s and Paragon 28’s attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System; and Treace Medical’s substantial publicity regarding its patent portfolio. At a minimum, Zimmer Biomet and Paragon 28 were on notice that they would need to conduct a right-to-use study that included reviewing Treace Medical’s patents before releasing and promoting its Bun-Yo-Matic™ System and Procedure.

148. On information and belief, Zimmer Biomet and Paragon 28 know that their surgeon customers and surgeon consultants are performing the ’428 Claimed Method using the Bun-Yo-Matic™ System and Procedure and are directly infringing the ’428 Claimed Method.

149. Zimmer Biomet’s and Paragon 28’s inducing acts, such as distribution of the Bun-Yo-Matic Guide, Bun-Yo-Matic Videos, and other instructional materials, to promote and demonstrate the Bun-Yo-Matic™ System and Procedure, and instructing and encouraging surgeons to use the Bun-Yo-Matic™ System in a manner consistent with the Bun-Yo-Matic™ Procedure described above and in Exhibit 7 caused and are causing surgeons to use the Bun-Yo-Matic™ System and Procedure in a manner that infringes the ’428 Claimed Method.

Contributory Infringement of the ’428 patent

150. On information and belief, Zimmer Biomet and Paragon 28 have contributorily infringed the ’428 Claimed Method in violation of 35 U.S.C. § 271(c).

151. Zimmer Biomet and Paragon 28 have made, used, offered for sale, sold, and/or imported into the United States medical instruments and implants used in performing the infringing Bun-Yo-Matic™ Procedure, including at least the Bun-Yo-Matic clamp, cut guides, tissue removing instruments, and implants.

152. On information and belief, surgeons have performed and are performing the Bun-Yo-Matic™ Procedure using the Bun-Yo-Matic™ System as instructed, assisted, and encouraged by Zimmer Biomet and Paragon 28 in at least the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos and by Zimmer Biomet and Paragon 28 sales staff, surgical site representatives, and surgeon consultants, thereby directly infringing the ’428 Claimed Method.

153. On information and belief, Zimmer Biomet and Paragon 28 had actual knowledge of the ’428 patent and Treace Medical’s infringement allegations at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint.

154. Zimmer Biomet and Paragon 28 at a minimum had constructive knowledge of Treace Medical’s patent rights because of Treace Medical’s virtual marking through its internet website at https://www.treace.com/patents. The ’428 patent is listed on Treace Medical’s patent marking webpage.

155. Any contention that Zimmer Biomet or Paragon 28 did not know that the Bun-Yo-Matic™ System is especially made or especially adapted for use in an infringement of the ’428 patent would be based on willful blindness to the ’428 patent and that the acts Zimmer Biomet and Paragon 28 actively induced constituted infringement of the ’428 patent. On information and belief, Zimmer Biomet and Paragon 28 were further on notice of Treace Medical’s patent rights

based on, for example, Treace Medical's known status as the inventor of Instrumented TMT Bunion Systems; Zimmer Biomet's and Paragon 28's attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System; and Treace Medical's substantial publicity regarding its patent portfolio. At a minimum, Paragon 28 was on notice that it would need to conduct a right-to-use study that included reviewing Treace Medical's patents before releasing and promoting its Bun-Yo-Matic™ System and Procedure.

156. Components of the Bun-Yo-Matic™ System including at least the Bun-Yo-Matic clamp, cut guides, tissue removing instruments, and implants are material components for use in practicing the '428 Claimed Method. These components are especially made for use in a manner that infringes the '428 Claimed Method. The Bun-Yo-Matic™ System components are not staple articles or commodities of commerce suitable for substantial non-infringing uses. For example, the only known use of the Bun-Yo-Matic clamp is for the infringing uses as described above and in Exhibit 7.

157. On information and belief, Zimmer Biomet and Paragon 28 have provided materials to hospitals and surgeons, including the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos, demonstrating the use of the Bun-Yo-Matic™ System to perform the '428 Claimed Method. The distribution of these materials further shows that Paragon 28 especially made the Bun-Yo-Matic™ System to perform the '428 Claimed Method. Zimmer Biomet and Paragon 28 representatives present in the operating room for each Bun-Yo-Matic™ Procedure monitor surgeons' performance of the Bun-Yo-Matic™ Procedure and, on information and belief, direct them to use the Bun-Yo-Matic™ System for the Bun-Yo-Matic™ Procedure to infringe the claims of the '428 patent.

158. On information and belief, at a date prior to the filing of this Complaint and at least as of the date of the filing and service of this Complaint, Zimmer Biomet and Paragon 28 have known that the Bun-Yo-Matic™ System (including the Bun-Yo-Matic clamp, cut guides, tissue removing instruments, and implants) were especially made for use in a manner that infringes the ’428 Claimed Method and were directly infringing the ’428 Claimed Method.

159. On information and belief, surgeons have in fact used and continue to use the Bun-Yo-Matic™ System and Procedure in a manner that infringes the ’428 Claimed Method.

Willful Infringement of the ’428 patent

160. Zimmer Biomet and Paragon 28 have willfully infringed the ’428 Claimed Method.

161. On information and belief, Zimmer Biomet and Paragon 28 have infringed and continue to infringe the ’428 Claimed Method with knowledge of Treace Medical’s rights in the ’428 patent, as described at least at paragraphs 59–64.

162. On information and belief, Zimmer Biomet’s and Paragon 28’s acts of infringement of the ’428 Claimed Method have been and continue to be willful, deliberate, and egregious, as described at least at paragraphs 59–64.

163. On information and belief, Zimmer Biomet and Paragon 28 acted despite an objectively high likelihood that their actions constituted infringement of a valid patent claim and knew or should have known of this objectively defined risk of infringement, as described at least at paragraphs 59–64.

Requested Relief for the Zimmer Defendants’ Infringement of the ’428 patent

164. Zimmer Biomet’s and Paragon 28’s misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters a permanent injunction prohibiting Zimmer Biomet and Paragon 28 and those

acting on their behalf from infringing the ’428 patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the Bun-Yo-Matic™ System for performing the ’428 Claimed Method. Zimmer Biomet’s and Paragon 28’s misconduct has caused Treace Medical to suffer irreparable injury that is not adequately compensated for by remedies available at law. The balance of hardships between the parties warrants a remedy in equity and the public interest would not be disserved by a permanent injunction.

165. Treace Medical is entitled to recover damages that would place Treace Medical as close as possible to the same financial position that it would have been in had Zimmer Biomet’s and Paragon 28’s infringement of the ’428 patent not occurred. Treace Medical is entitled to recover damages including all profits that it has lost as a result of Zimmer Biomet’s and Paragon 28’s sale of the Bun-Yo-Matic™ System and the products used in the performance of instrumented TMT bunion correction procedures using the Bun-Yo-Matic™ System. At a minimum, Treace Medical is entitled to a reasonable royalty on Zimmer Biomet’s and Paragon 28’s sales of the Bun-Yo-Matic™ System and products used in the performance and practicing of the patented instrumented TMT bunion correction procedures using the Bun-Yo-Matic™ System.

166. Treace Medical requests pursuant to 35 U.S.C. § 284 that damages awarded to it in this matter for Zimmer Biomet’s and Paragon 28’s willful infringement of the ’428 patent be increased to three times the amount found or assessed by the fact finder.

COUNT IV
(Infringement of U.S. Patent No. 12,274,481)

167. Treace Medical realleges and incorporates by reference paragraphs 1–166 of this Complaint.

168. On April 15, 2025, the USPTO issued U.S. Patent Number 12,274,481 B2 (“the ’481 patent”) to Treace Medical, listing inventors Robert D. Santrock, Paul Dayton, Daniel J.

Hatch, W. Bret Smith, F. Barry Bays, Carlos Eduardo Gil, Sean F. Scanlan, Joe W. Ferguson, F. Barry Bays, and John T. Treace. The ’481 patent is titled “Bone Positioning and Preparing Guide Systems and Methods” and is directed to “[a]n instrumented surgical technique for preparing a tarsal-metatarsal joint for fusion and for repositioning a first metatarsal to correct a bunion deformity.” A true and correct copy of the ’481 patent is attached to this Complaint as **Exhibit 8**. The ’481 patent remains in force and is assigned to Treace Medical. Treace Medical has owned the ’481 patent since it was issued and still owns the ’481 patent.

169. The ’481 patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

170. Zimmer Biomet and Paragon 28 have made, used, offered for sale, sold, and/or imported into the United States the Bun-Yo-Matic™ Lapidus Clamp System

171. Attached to this Complaint as **Exhibit 9** is a claim chart explaining how Zimmer Biomet and Paragon 28 describe through the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos the performance of the steps of an exemplary claim of the ’481 patent using the Bun-Yo-Matic™ System and thereby instruct and encourage surgeons to perform the method of the claims of the ’481 patent (“the ’481 Claimed Method”). On information and belief, Zimmer Biomet and Paragon 28 continue to instruct and encourage surgeons to perform the ’481 Claimed Method. On information and belief, Zimmer Biomet and Paragon 28 have not instructed surgeons to perform the Bun-Yo-Matic™ Procedure using the Bun-Yo-Matic™ System in a non-infringing manner. The Bun-Yo-Matic™ System has no substantial non-infringing uses.

Direct Infringement of the ’481 Patent

172. On information and belief, Zimmer Biomet and Paragon 28 have directly infringed and continue to directly infringe, both literally and/or under the doctrine of equivalents, the ’481

patent by using (*e.g.*, by performing actual or simulated surgical procedures) the Bun-Yo-Matic™ System to perform the patented surgical method of the ’481 patent in the United States in violation of 35 U.S.C. § 271(a), including within this judicial district, in a manner that infringes at least claim 1 of the ’481 patent without a license from Treace Medical.

173. On information and belief, surgeons who have performed and are performing the surgical method as instructed and encouraged by the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos using the Bun-Yo-Matic™ System directly infringe the ’481 patent.

174. On information and belief, surgeon consultants to Paragon 28, working at Paragon 28’s direction, tested and performed the ’481 Claimed Method using the Bun-Yo-Matic™ System on Paragon 28’s behalf as part of developing the Bun-Yo-Matic™ System and Procedure at least before the Bun-Yo-Matic™ System was first offered for sale and sold in the United States.

175. In addition, surgeon consultants to Zimmer Biomet and Paragon 28, working at Zimmer Biomet’s or Paragon 28’s direction, perform the ’481 Claimed Method using the Bun-Yo-Matic™ System as part of surgeon education both before and after the Bun-Yo-Matic™ System was offered for sale and sold in the United States.

176. Paragon 28 has created at least the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos showing the Bun-Yo-Matic™ System being used to perform the Bun-Yo-Matic™ Procedure and thereby performing the ’481 Claimed Method. On information and belief, surgeons working on Zimmer Biomet’s and Paragon 28’s behalf and at Zimmer Biomet’s and Paragon 28’s direction, performed the ’481 Claimed Method using the Bun-Yo-Matic™ System in connection with creating the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos, which demonstrates performance of the ’481 Claimed Method using the Bun-Yo-Matic™ System.

177. Zimmer Biomet and Paragon 28 also direct and/or control surgeons to perform the ’481 Claimed Method using the Bun-Yo-Matic™ System because, among other things, Zimmer Biomet and Paragon 28 condition receipt of benefits to surgeons on their performance of one or more steps of the ’481 Claimed Method, and establish that performance by, among other things, providing detailed instructions concerning the assembly of the Bun-Yo-Matic™ System that, if not followed, will deprive the surgeons of the benefits they hope to obtain from the Bun-Yo-Matic™ System and performing one or more steps of the ’481 Claimed Method. For example, Paragon 28 advertises to surgeons who, on information and belief, use the Bun-Yo-Matic™ System as Paragon 28 instructs in the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos to perform the ’481 Claimed Method. On information and belief, the Zimmer Biomet or Paragon 28 representative present in the operating room for nearly every Bun-Yo-Matic™ Procedure monitors and directs the surgeon and will only provide the surgeon components of the Bun-Yo-Matic™ System if the surgeon performs one or more steps of the ’481 Claimed Method.

Induced Infringement of the ’481 Patent

178. On information and belief, Zimmer Biomet and Paragon 28 have induced and continue to induce infringement of the ’481 Claimed Method in violation of 35 U.S.C. § 271(b).

179. Zimmer Biomet and Paragon 28 have provided materials to hospitals and surgeons that demonstrate using the Bun-Yo-Matic™ System to perform the ’481 Claimed Method. For example, the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos instruct, encourage, and assist surgeons to use the Bun-Yo-Matic™ System in a manner that directly infringes the claims of the ’481 patent. On information and belief, Zimmer Biomet and Paragon 28 sales staff, surgical site representatives, consulting surgeons, and public and non-public instructional materials similarly instruct and encourage surgeons to use the Bun-Yo-Matic™ System in a manner that directly

infringes the claims of the ’481 patent as depicted and described above and in Exhibit 9. On information and belief, Zimmer Biomet and Paragon 28 distributed these materials to hospitals and surgeons with the intent to cause surgeons to use the Bun-Yo-Matic™ System and Procedure to perform the ’481 Claimed Method. Zimmer Biomet and Paragon 28 representatives present in the operating room for each Bun-Yo-Matic™ Procedure monitor surgeons’ performance of the Bun-Yo-Matic™ Procedure and, on information and belief, direct them to use the Bun-Yo-Matic™ System for the Bun-Yo-Matic™ Procedure to infringe the claims of the ’481 patent.

180. On information and belief, Zimmer Biomet and Paragon 28 have provided such instructions and encouragement despite having actual knowledge, at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint, of both the ’481 patent and the resulting infringement thereof by surgeons Zimmer Biomet and Paragon 28 so instructed.

181. Zimmer Biomet and Paragon 28 at a minimum had constructive knowledge of Treace Medical’s patent rights because Treace Medical virtually marks its products through its internet website at https://www.treace.com/patents. The ’481 patent is listed on Treace Medical’s patent marking webpage.

182. Any contention that Zimmer Biomet or Paragon 28 did not know that the acts Zimmer Biomet and Paragon 28 actively induced constituted infringement of the ’481 patent would be based on willful blindness to the ’481 patent and that the acts Zimmer Biomet and Paragon 28 actively induced constituted infringement of the ’481 patent. On information and belief, Zimmer Biomet and Paragon 28 were on notice of Treace Medical’s patent rights based on, for example, Treace Medical’s known status as the inventor of Instrumented TMT Bunion Systems; Zimmer Biomet’s and Paragon 28’s attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty®

System; and Treace Medical's substantial publicity regarding its patent portfolio. At a minimum, Zimmer Biomet and Paragon 28 were on notice that they would need to conduct a right-to-use study that included reviewing Treace Medical's patents before releasing and promoting its Bun-Yo-Matic™ System and Procedure.

183. On information and belief, Zimmer Biomet and Paragon 28 knows that its surgeon customers and surgeon consultants are performing the '481 Claimed Method using the Bun-Yo-Matic™ System and Procedure and are directly infringing the '481 Claimed Method.

184. Zimmer Biomet's and Paragon 28's inducing acts, such as distribution of the Bun-Yo-Matic Guide, Bun-Yo-Matic Videos, and other instructional materials, to promote and demonstrate the Bun-Yo-Matic™ System and Procedure, and instructing and encouraging surgeons to use the Bun-Yo-Matic™ System in a manner consistent with the Bun-Yo-Matic™ Procedure described above and in Exhibit 9 caused and are causing surgeons to use the Bun-Yo-Matic™ System and Procedure in a manner that infringes the '481 Claimed Method.

Contributory Infringement of the '481 patent

185. On information and belief, Zimmer Biomet and Paragon 28 have contributorily infringed the '481 Claimed Method in violation of 35 U.S.C. § 271(c).

186. Zimmer Biomet and Paragon 28 have made, used, offered for sale, sold, and/or imported into the United States medical instruments and implants used in performing the infringing Bun-Yo-Matic™ Procedure, including at least the Bun-Yo-Matic clamp, cut guides, tissue removing instruments, and implants.

187. On information and belief, surgeons have performed and are performing the Bun-Yo-Matic™ Procedure using the Bun-Yo-Matic™ System as instructed, assisted, and encouraged by Zimmer Biomet and Paragon 28 in at least the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos

and by Zimmer Biomet and Paragon 28 sales staff, surgical site representatives, and surgeon consultants, thereby directly infringing the ’481 Claimed Method.

188. On information and belief, Zimmer Biomet and Paragon 28 had actual knowledge of the ’481 patent and Treace Medical’s infringement allegations at a date prior to the filing of this Complaint and at least as of the filing and service of this Complaint.

189. Zimmer Biomet and Paragon 28 at a minimum had constructive knowledge of Treace Medical’s patent rights because of Treace Medical’s virtual marking through its internet website at https://www.treace.com/patents. The ’481 patent is listed on Treace Medical’s patent marking webpage.

190. Any contention that Zimmer Biomet or Paragon 28 did not know that the Bun-Yo-Matic™ System is especially made or especially adapted for use in an infringement of the ’481 patent would be based on willful blindness to the ’481 patent and that the acts Zimmer Biomet and Paragon 28 actively induced constituted infringement of the ’481 patent. On information and belief, Zimmer Biomet and Paragon 28 were further on notice of Treace Medical’s patent rights based on, for example, Treace Medical’s known status as the inventor of Instrumented TMT Bunion Systems; Zimmer Biomet’s and Paragon 28’s attendance and participation at industry conferences (*e.g.*, AOFAS and ACFAS) where Treace Medical displayed and discussed the Lapiplasty® System; and Treace Medical’s substantial publicity regarding its patent portfolio. At a minimum, Paragon 28 was on notice that it would need to conduct a right-to-use study that included reviewing Treace Medical’s patents before releasing and promoting its Bun-Yo-Matic™ System and Procedure.

191. Components of the Bun-Yo-Matic™ System including at least the Bun-Yo-Matic clamp, cut guides, tissue removing instruments, and implants are material components for use in

practicing the ’481 Claimed Method. These components are especially made for use in a manner that infringes the ’481 Claimed Method. The Bun-Yo-Matic™ System components are not staple articles or commodities of commerce suitable for substantial non-infringing uses. For example, the only known use of the Bun-Yo-Matic clamp is for the infringing uses as described above and in Exhibit 9.

192. On information and belief, Zimmer Biomet and Paragon 28 have provided materials to hospitals and surgeons, including the Bun-Yo-Matic Guide and Bun-Yo-Matic Videos, demonstrating the use of the Bun-Yo-Matic™ System to perform the ’481 Claimed Method. The distribution of these materials further shows that Paragon 28 especially made the Bun-Yo-Matic™ System to perform the ’481 Claimed Method. Zimmer Biomet and Paragon 28 representatives present in the operating room for each Bun-Yo-Matic™ Procedure monitor surgeons’ performance of the Bun-Yo-Matic™ Procedure and, on information and belief, direct them to use the Bun-Yo-Matic™ System for the Bun-Yo-Matic™ Procedure to infringe the claims of the ’481 patent.

193. On information and belief, at a date prior to the filing of this Complaint and at least as of the date of the filing and service of this Complaint, Zimmer Biomet and Paragon 28 have known that the Bun-Yo-Matic™ System (including the Bun-Yo-Matic clamp, cut guides, tissue removing instruments, and implants) were especially made for use in a manner that infringes the ’481 Claimed Method and were directly infringing the ’481 Claimed Method.

194. On information and belief, surgeons have in fact used and continue to use the Bun-Yo-Matic™ System and Procedure in a manner that infringes the ’481 Claimed Method.

Willful Infringement of the ’481 patent

195. Zimmer Biomet and Paragon 28 have willfully infringed the ’481 Claimed Method.

196. On information and belief, Zimmer Biomet and Paragon 28 have infringed and continue to infringe the ’481 Claimed Method with knowledge of Treace Medical’s rights in the ’481 patent, as described at least at paragraphs 59–64.

197. On information and belief, Zimmer Biomet’s and Paragon 28’s acts of infringement of the ’481 Claimed Method have been and continue to be willful, deliberate, and egregious, as described at least at paragraphs 59–64.

198. On information and belief, Zimmer Biomet and Paragon 28 acted despite an objectively high likelihood that their actions constituted infringement of a valid patent claim and knew or should have known of this objectively defined risk of infringement, as described at least at paragraphs 59–64.

Requested Relief for the Zimmer Defendants’ Infringement of the ’481 patent

199. Zimmer Biomet’s and Paragon 28’s misconduct has irreparably injured Treace Medical and, on information and belief, will continue to injure Treace Medical unless and until the Court enters a permanent injunction prohibiting Zimmer Biomet and Paragon 28 and those acting on their behalf from infringing the ’481 patent, including by prohibiting the making, using, offering for sale, selling, and importing into the United States of the Bun-Yo-Matic™ System for performing the ’481 Claimed Method. Zimmer Biomet’s and Paragon 28’s misconduct has caused Treace Medical to suffer irreparable injury that is not adequately compensated for by remedies available at law. The balance of hardships between the parties warrants a remedy in equity and the public interest would not be disserved by a permanent injunction.

200. Treace Medical is entitled to recover damages that would place Treace Medical as close as possible to the same financial position that it would have been in had Zimmer Biomet’s and Paragon 28’s infringement of the ’481 patent not occurred. Treace Medical is entitled to

recover damages including all profits that it has lost as a result of Zimmer Biomet's and Paragon 28's sale of the Bun-Yo-Matic™ System and the products used in the performance of instrumented TMT bunion correction procedures using the Bun-Yo-Matic™ System. At a minimum, Treace Medical is entitled to a reasonable royalty on Zimmer Biomet's and Paragon 28's sales of the Bun-Yo-Matic™ System and products used in the performance and practicing of the patented instrumented TMT bunion correction procedures using the Bun-Yo-Matic™ System.

201. Treace Medical requests pursuant to 35 U.S.C. § 284 that damages awarded to it in this matter for Zimmer Biomet's and Paragon 28's willful infringement of the '481 patent be increased to three times the amount found or assessed by the fact finder.

JURY DEMAND

202. Pursuant to Federal Rule of Civil Procedure 38(b), Treace Medical hereby requests a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Treace Medical Concepts, Inc. prays for the following relief against Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.:

1. For judgment in favor of Treace Medical that Zimmer Biomet and Paragon 28 have infringed and are infringing United States Patent Nos. 12,102,368; 12,268,397; 12,268,428; and 12,274,481, both directly and indirectly;

2. For a permanent injunction prohibiting Zimmer Biomet and Paragon 28, including their officers, agents, employees, and all persons acting in concert or participation with them, from committing further acts of infringement of United States Patent Nos. 12,102,368; 12,268,397; 12,268,428; and 12,274,481;

3. For an award of damages for Zimmer Biomet's and Paragon 28's infringement of United States Patent Nos. 12,102,368; 12,268,397; 12,268,428; and 12,274,481 in the amount of Treace Medical's lost profits associated with Zimmer Biomet's and Paragon 28's sale of the accused systems, together with interest (both pre- and post-judgment), costs and disbursements as fixed by this Court under 35 U.S.C. § 284;

4. For an award of damages for Zimmer Biomet's and Paragon 28's infringement of United States Patent Nos. 12,102,368; 12,268,397; 12,268,428; and 12,274,481 in the amount of at least a reasonable royalty, together with interest (both pre- and post-judgment), costs and disbursements as fixed by this Court under 35 U.S.C. § 284;

5. For a determination that Zimmer Biomet's and Paragon 28's infringement of United States Patent Nos. 12,102,368; 12,268,397; 12,268,428; and 12,274,481 has been and is willful;

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

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

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

9. For such other and further relief in law or in equity to which Treace Medical may be justly entitled.

HEYMAN ENERIO
GATTUSO & HIRZEL LLP

/s/ Dominick T. Gattuso
Dominick T. Gattuso (#3630)
300 Delaware Avenue, Ste. 200
Wilmington, DE 19801
302-472-7300
dgattuso@hegh.law

Attorneys for Plaintiff Treace Medical Concepts, Inc.

OF COUNSEL:

WINSTON & STRAWN LLP
Nimalka Wickramasekera
333 South Grand Avenue, 38th Floor
Los Angeles, CA 90071-1543
213-615-1819
nwickramasekera@winston.com

Robert T. Vlasis III
1901 L Street NW
Washington, DC 20036
202-282-5000
rvlasis@winston.com

Michael A. Meneghini
35 W. Wacker Drive
Chicago, IL 60601-9703
312-558-3749
mmeneghini@winston.com

Olivia A. Wogon
800 Capitol Street, Suite 2400
Houston, TX 77002
713-651-2743
owogon@winston.com

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