

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TREACE MEDICAL CONCEPTS, INC.,
Petitioner,

v.

PARAGON 28, INC.,
Patent Owner.

IPR2027-00014
Patent 10,932,833

DECLARATION OF DANIEL C. FARBER, MD
IN SUPPORT OF PETITION FOR INTER PARTES REVIEW OF
U.S. PATENT NO. 10,932,833

I, Daniel C. Farber, do hereby declare:

1. I am making this declaration (the "Declaration") at the request of Treace Medical Concepts, Inc. ("Treace").

2. I am being compensated for my work in this matter, and I am being reimbursed at cost for any expenses. My compensation in no way depends upon the outcome of this proceeding.

3. In preparing this Declaration, I considered the following materials:

Exhibit No.	Description
1001	U.S. Patent No. 10,932,833 to Gephart ("the '833 Patent")
1005	US 2017/0196604 A1 ("Hartdegen").
1007	U.S. Provisional Application No. 62/022,811, filed July 10, 2014.
1008	US 2009/0281543 A1 ("Orbay")
1003	Curriculum Vitae of Daniel C. Farber, M.D.

I. BACKGROUND AND QUALIFICATIONS

4. I am an orthopaedic surgeon specializing in foot and ankle surgery. My current CV is being submitted as Exhibit 1003.

5. I received my Bachelor of Arts undergraduate degree in 1992 from Dartmouth College and my Doctor of Medicine degree in 1997 from the University of Maryland School of Medicine. In 2002, I completed my residency in Orthopaedic

Surgery at Penn State Milton S. Hershey Medical Center. In 2003, I held a fellowship in Orthopaedic Surgery, Foot and Ankle Surgery, at the Mayo Clinic in Jacksonville, Florida. I am board certified in Orthopaedic Surgery by the American Board of Orthopaedic Surgery.

6. My primary practice is with the Lehigh Valley Health Network where I am the Vice Chair, Academic Affairs, for the Lehigh Valley Orthopedic Institute.

7. For the past 22 years, I have performed between 250 and 350 surgeries per year, of which, roughly 50-80 per year involved bunion correction. Additionally, I have performed other podiatric and orthopaedic surgeries involving correcting and/or fusing joint deformities in the foot and ankle, including triple arthrodesis, 1st metatarsophalangeal joint fusion, midfoot (tarsal bone) fusions, osteotomies of the 1st metatarsal, cuneiforms, calcaneus, tibia, and fibula, and others.

8. My practice has included extensive experience with compression implants such as shape memory staples and implants first used around 2007, as well as multiple manufacturers' compression plates in 2007. I have used drill guide and inserter based instrumentation since the introduction of locking plates during my residency in 2001. Since then I have used multiple systems incorporating these types of devices including before March 2015.

II. NATURE OF MY ASSIGNMENT

9. I have been asked to provide my opinion as to whether the claims of the '833 Patent would have been anticipated and/or obvious to a person of ordinary skill in the art ("POSA") at the time of the alleged invention, in view of the prior art.

10. The opinions I am expressing in this Declaration are based on the application of my training and technical knowledge and experience to the evaluation of certain prior art to the '833 Patent.

11. I am not an expert in patent law. Attorneys from McCaulley Law Group and Van Hoven PC have provided me with guidance as to the applicable patent law in this matter. The paragraphs below express my understanding of how I must apply current principles related to patent validity to my analysis.

12. It is my understanding that in determining whether a patent claim is obvious in view of the prior art, the Patent Office construes the claim by giving the claim language its ordinary and customary meaning ascribed to it by a person of ordinary skill in the art ("POSA") at the time of the invention, consistent with the descriptive language contained in the other parts of the patent. I also understand that in reading the claim, I must not add into the claim other language that appears in the description portion of the patent; in other words, I must not restrict the scope of the claim terms by adding to the claim other parts of the patent's descriptive language that are not expressed literally in the claim.

13. With respect to anticipation of a patent claim, my understanding is that anticipation in patent law means a claimed invention lacks novelty because a single prior art reference describes every element of that claim, either expressly or inherently.

14. I understand that a claim is “obvious,” and therefore unpatentable, if the claimed subject matter as a whole would have been obvious to a POSA at the time of the invention. I also understand that an obviousness analysis takes into account the scope and content of the prior art, the differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art at the time of the invention.

15. In determining the scope and content of the relevant prior art, I understand that a reference is considered relevant prior art if it falls within the field of the inventor’s endeavor. The ‘833 Patent is directed to “a shape-retentive bone plate with an initial, unflexed configuration and . . . may be shifted to the flexed configuration and secured to bones using bone screws of the bone compression device.” Ex. 1001, Abstract. The ‘833 Patent explains that “[o]nce the bone plate has been secured to the bones, the bone plate returns toward its unflexed configuration which compresses the bones.” *Id.* In addition, a reference is relevant prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have commended itself to

an inventor's attention in considering their problem. If a reference relates to the same problem as the claimed invention, that supports use of the reference as prior art in an obviousness analysis.

16. To assess the differences between prior art and the subject matter claimed in the patent, I understand that the law requires the claimed invention to be considered as a whole. Thus it must be shown that a POSA at the time of the invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have been motivated to select the elements from the prior art and combine them in the claimed manner, and had a reasonable expectation of success in doing so.

17. I further understand that the obviousness analysis must be performed from the perspective of a POSA at the time of the invention. This is to avoid using impermissible hindsight in the analysis. The claims of the patent must not be used to provide a road map for obviousness.

18. The '833 Patent claims recite methods of preloading a bone compression device and applying a bone compression device to bones. See Ex. 1001, 11:43–16:30. The '833 Patent states that “a bone compression device 10 is provided having a bone plate 12 with a body 14 for being secured to bones with bone anchors, such as bone screws 16.” Id. at 3:45–60.

19. Annotated versions of Figures 11 and 12 from the '833 Patent are provided below.

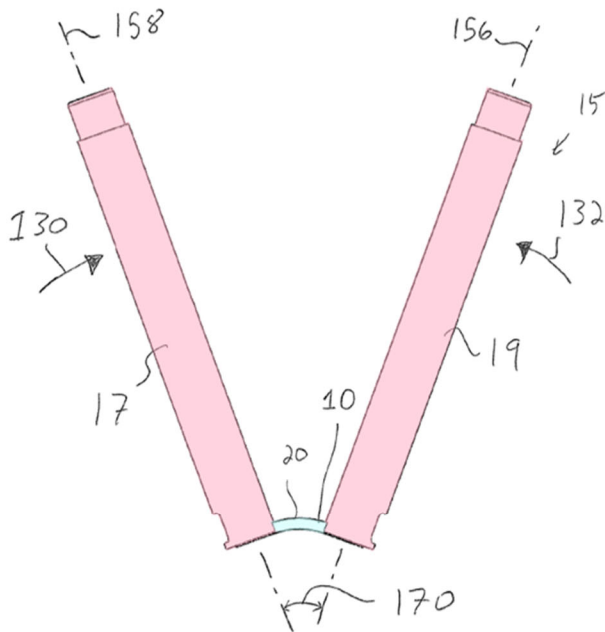


FIG. 11

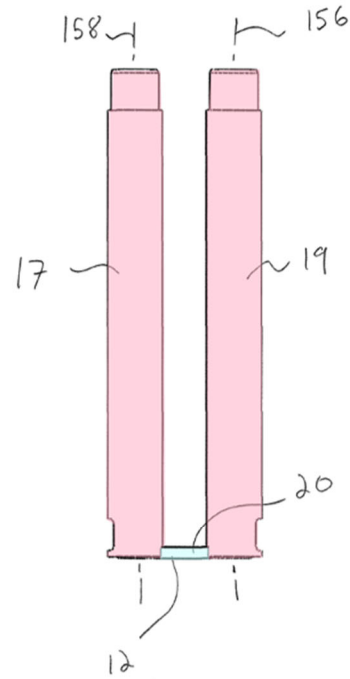


FIG. 12

Annotated Figures 11 and 12 above show bone plate 12 (teal) with its intermediate portion 20 deformed from its unflexed (unloaded) condition (Fig. 11) to its flexed (loaded) condition (Fig. 12) using manipulators 17, 19 (pink).

LEVEL OF ORDINARY SKILL IN THE ART

20. It is my opinion that a POSA would have included (i) a physician with a medical degree and at least 3 years of experience performing surgery using fixation devices including bone plates to compress bone or other biological elements, (ii) an engineer with a bachelor's degree in mechanical or biomedical engineering and at

least 3 years of experience designing surgical fixation devices and related installation mechanisms, or (iii) a collaborative team combining such clinical and engineering expertise. My opinions expressed in this Declaration would be the same under any of these alternative articulations of the level of ordinary skill in the art.

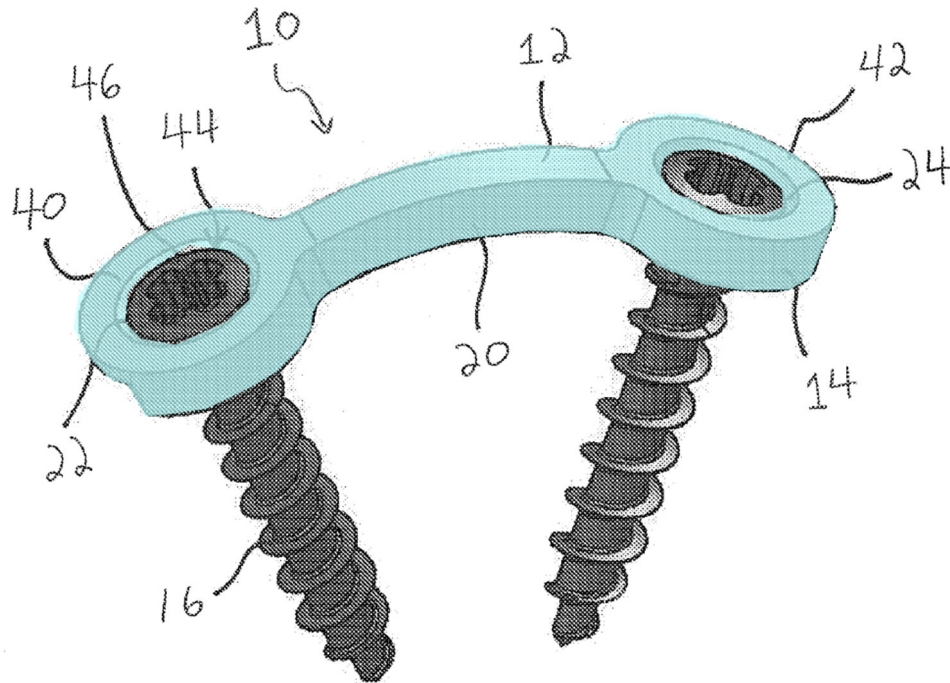
21. The level of skill I describe reflects the people who actually worked on the problems the '833 Patent addresses. Bone plates, compression implants, and their insertion instruments are typically designed by mechanical or biomedical engineers working closely with orthopaedic and podiatric surgeons. A surgeon with several years of experience using fixation devices to compress bone would understand how plates and their instruments are applied and why compression matters. Hartdegen and Orbay each describe implant structures and instruments in terms that a surgeon or device engineer with that experience would readily understand.

CLAIM CONSTRUCTION

A. “bone compression device including an elongated resilient member”

22. Each of the independent claims recites a “bone compression device including an elongated resilient member” having an unloaded configuration and a loaded configuration.

23. The '833 Patent describes “a bone compression device 10 . . . having a bone plate 12 with a body 14 for being secured to bones with bone anchors, such as bone screws 16,” shown in annotated Figure 1 below. Ex. 1001, 3:45–47.



The '833 Patent explains that the bone plate 12 (teal) “is made entirely or partially of a shape retentive material that permits elastic deformation of the bone plate 12 [which] resiliently biases the bone screws 16 and bones connected thereto together once the bone plate 12 has been implanted on the bones.” Id. at 3:47–52.

24. It is my opinion that, consistent with the '833 Patent specification, a bone plate having an elongate body which is made entirely or partially of a shape retentive material that permits elastic deformation of the bone plate is a bone compression device including an elongated resilient member.

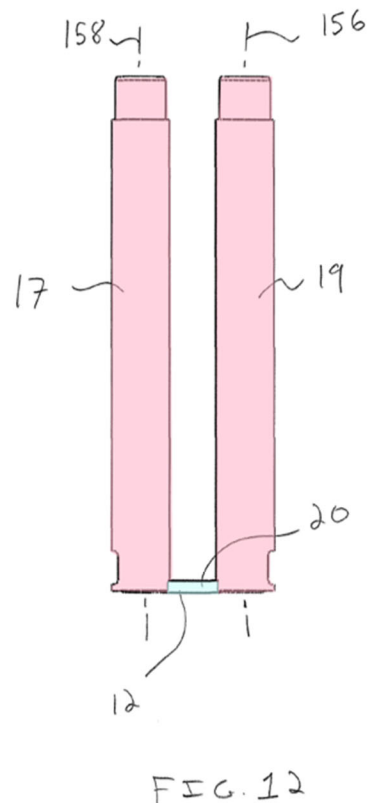
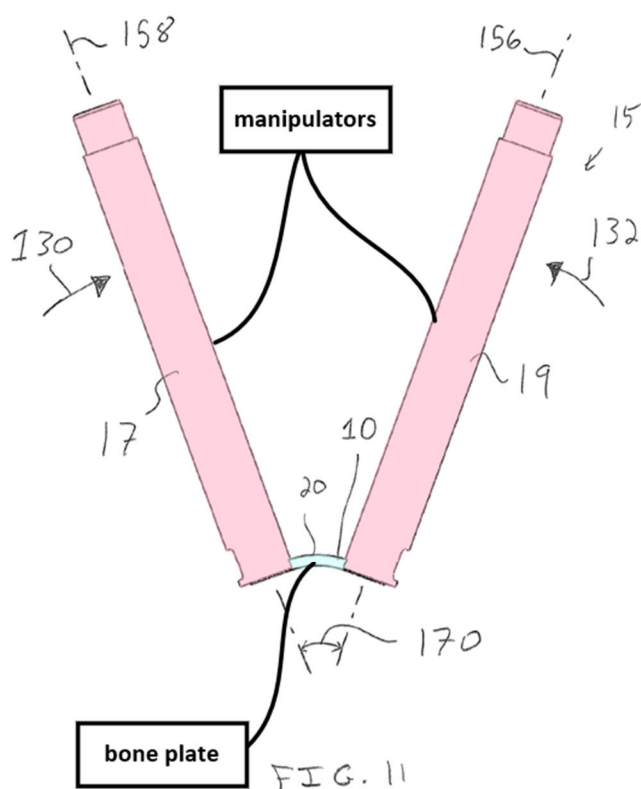
B. “body” and “tool”

25. Claim 1 recites “connecting at least one restraint to a body which is connected to one of the bone anchor receiving portions, the body being separate and distinct from the at least one restraint and the one bone anchor receiving portion.”

26. Claim 3 depends from claim 1 and recites “engaging a tool with one of the bone anchor receiving portions” and that “moving the bone anchor receiving portions relative to each other includes using the tool to move the one bone anchor receiving portion relative to the other bone anchor receiving portion.”

27. Claim 8 uses the term “body” in a similar manner as claim 1, reciting “disconnecting the at least one restraint from a body connected to one of the bone anchor receiving portions, the body being separate and distinct from the at least one restraint and the one bone anchor receiving portion.” Claims 4, 6, 7, and 14 use the term “tool” in a manner similar to claim 3.

28. The '833 Patent specification identifies tube-like members 17, 19, shown in Figures 11 and 12 below, as manipulators (pink).



The '833 Patent explains that “[t]he manipulators 17, 19 are connected to the bone plate 12 and squeezed together . . . which bends the bone plate 12 to the flexed configuration.” Ex. 1001, 4:9–15.

29. The '833 Patent does not use the term “body” to describe the structure connected with its restraint or bone plate. Nor does the Patent use the term “tool” to describe the structure used to move the bone anchor receiving portions of its bone plate (bone compression device) relative to one another. Rather, as noted above, the '833 Patent describes the manipulators 17, 19 (pink) as instruments by which a

surgeon flexes/deforms, positions, and fixes the bone plate during the surgical procedure.

30. It is my opinion that, consistent with the '833 Patent specification a tubular member (i.e., the manipulators) used to bend a bone plate is a tool.

31. The '833 Patent further explains that “[a] restraint 190 (see FIG. 14) may be connected to the manipulators 17, 19 to hold the manipulators 17, 19 in the installation orientation.” Ex. 1001, 4:16–18. Annotated versions of Figures 14 and 15 are reproduced below.

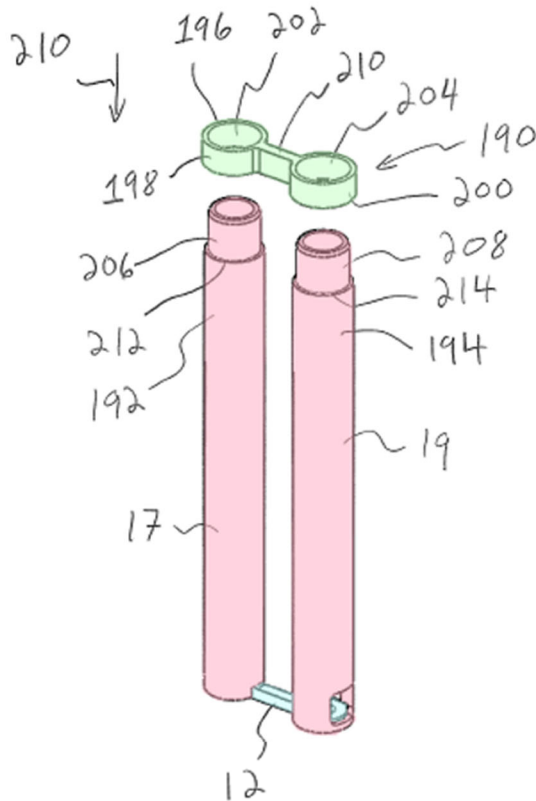


FIG. 14

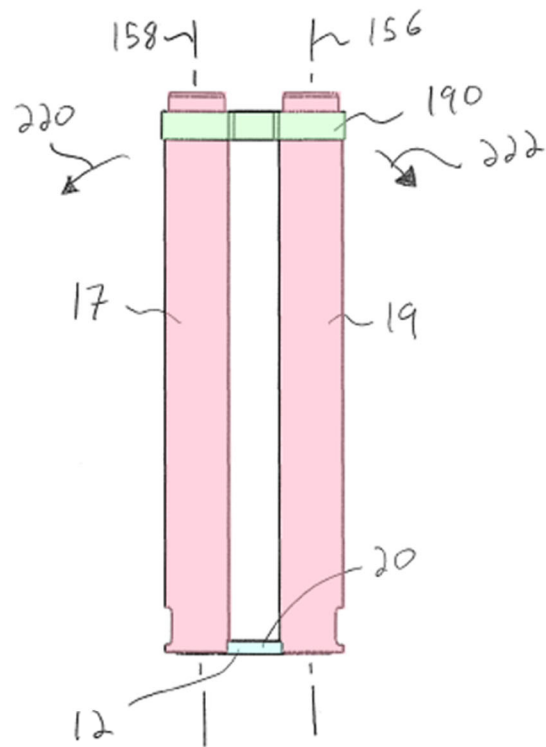


FIG. 15

As seen above, the restraint (restraint 190–green) is connected to one end of the tools (manipulators 17, 19–pink) and the opposite end of the tools (manipulators 17, 19–pink) are connected to the bone compression device (bone plate 12–teal) to move the bone anchor receiving portions of the bone plate relative to one another.

32. In my opinion, consistent with the embodiments described in the '833 Patent, the part of the recited “tool” (i.e., part of the manipulator) that connects with a restraint and bone plate would have been understood by a POSA as the recited body.

33. This reading also follows from how the claimed structures relate to one another physically. The claims require the “body” to be connected both to a bone anchor receiving portion and to the restraint, while being “separate and distinct” from each of them. In the embodiment of Figure 14, the only structure that satisfies all three conditions is the manipulator: one end is connected to the bone plate, the other end receives restraint 190, and it is a separate component from both. A POSA would therefore understand the “body” not as a structure of any particular shape, but as the portion of the instrument that bridges between the implant and the restraint and transmits the restraint’s holding force to the implant.

HARTDEGEN PRIOR ART REFERENCE

34. I have compared the disclosures of Hartdegen that I rely on in this Declaration with the Hartdegen provisional (Ex. 1007). In my opinion, the

disclosures relied upon in Hartdegen are described in the Hartdegen provisional. The relied-upon Hartdegen disclosures are supported nearly verbatim by the Hartdegen provisional. Compare, e.g., Ex. 1005 ¶111 (“the inserter 100 has two tube members 102a and 102b that allow the bone to be prepared through the internal diameters 106 . . . The two independent tubes are held in relative position to each other by clip 110”) with Ex. 1007, 9 (same disclosure in nearly identical language). The same is true of the disclosures relied upon at Ex. 1005 ¶¶7, 110, 112–117, and 125–126, each of which is supported by the corresponding pages of Ex. 1007 (pp. 3–4, 9–14).

35. In my opinion, a POSA reviewing the Hartdegen provisional would understand it to disclose each of the foregoing teachings relied upon in this Declaration.

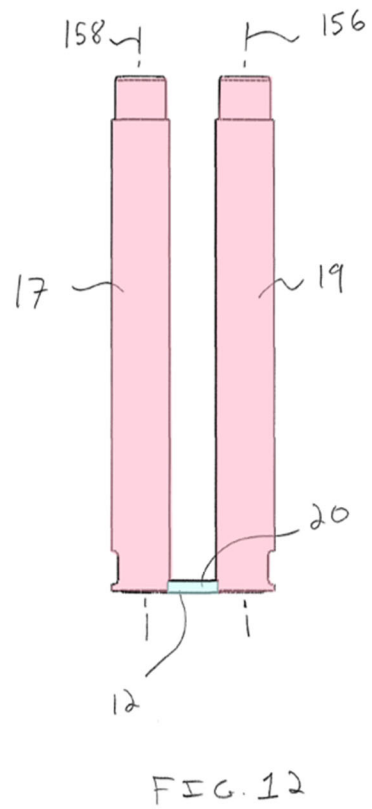
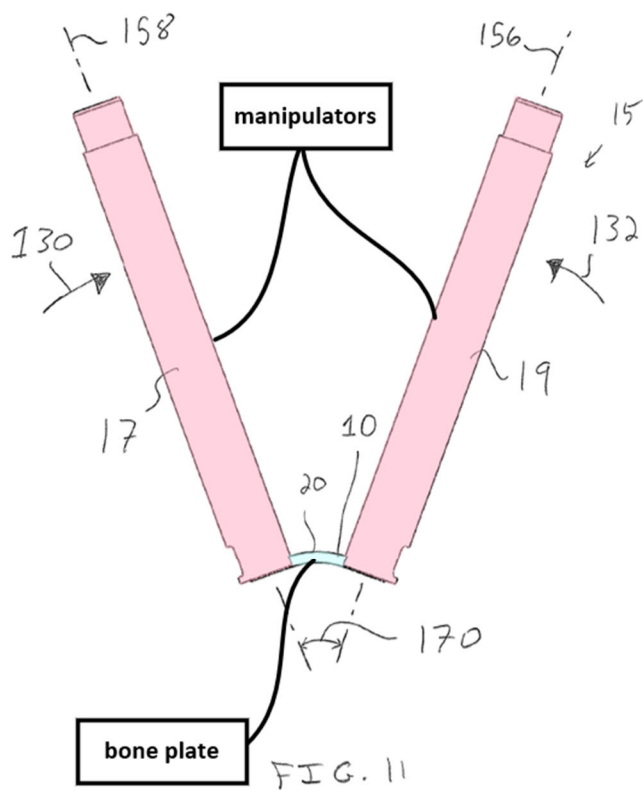
36. I understand that, for Hartdegen to be entitled to the July 10, 2014 filing date of its provisional application, the provisional must provide written description support under 35 U.S.C. § 112(a) for at least one claim of the Hartdegen publication, and must also describe the subject matter of Hartdegen relied on. I understand that written description is satisfied when the disclosure reasonably conveys to a POSA that the inventors possessed the claimed subject matter as of the filing date.

37. I have compared claim 1 of the Hartdegen publication with the provisional. In my opinion, the provisional describes each element of that claim: (a)

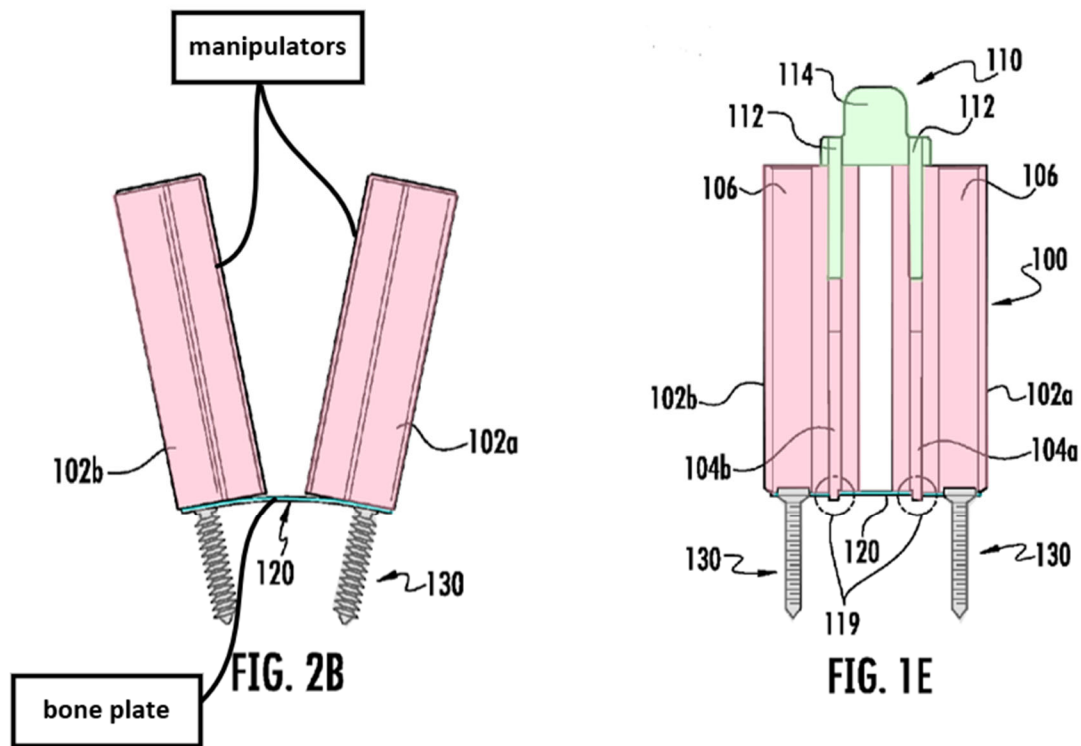
an assembly for delivering an implant to a surgical site for osteosynthesis (Ex. 1007, 3–5, 9–11); (b) an implant having a first configuration when releasably attached to a delivery instrument and a second configuration when not attached (id., 3–5, 9–11, Fig. 4 (first configuration), Figs. 8–9 (second configuration)); (c) the implant comprising a material that allows multiple configurations (id., 3–4, 10–11); (d) two or more means for fixation to bone (id., 10–11); (e) engagement means between implant and delivery instrument (id., 10–11); and (f) engagement means that do not impede placement of the implant onto bone (id., 9). The provisional also includes a claim (Ex. 1007, 17) that is nearly identical to claim 1 of the publication.

38. I have also compared each passage and figure of Hartdegen that I rely on in this Declaration with the provisional. In each case the provisional contains the same disclosure in materially identical language or the same figure.

39. The system disclosed in the '833 Patent, a multi-configuration bone implant held by instrumentation during fixation to bones and then released to apply compression to the bones, was already disclosed by Hartdegen. This concept is illustrated below in annotated Figs. 11–12 of the '833 Patent.



The same concept is illustrated below in Figures 1E and 2B of Hartdegen.



40. Hartdegen discloses an osteosynthesis system including a bone plate, bone screws, and an inserter having two tube members that releasably hold the implant in a first/deformed configuration (Figure 1E) while bone screws are advanced through the tube members and into the bone plate. Ex. 1005 ¶¶111–112; Ex. 1007, 9–10. After the bone plate is fastened to bone and released from the inserter, the bone plate assumes another configuration (Figure 2B) that applies compression. Ex. 1005 ¶¶111–112; Ex. 1007, 9–10. Hartdegen further discloses a clip that fixes the tube members relative to one another, as well as inserter/plate engagement features for manipulating and maintaining the plate in the first/deformed configuration. Ex. 1005 ¶¶111–112; Ex. 1007, 9–10.

41. From a clinical standpoint, a surgeon performing a fusion of small bones, such as a first tarsometatarsal or midfoot arthrodesis, wants two things from the fixation construct: stable alignment of the bones in the corrected position, and compression across the prepared joint surfaces. Compression closes the gap between the surfaces, increases contact area across the arthrodesis site, and promotes healing. An implant that is held in a loaded configuration during fixation and then released supplies that compression itself, and continues to urge the bones together as the fusion interface remodels during healing. Hartdegen expressly identifies this benefit: its implant “bridges a fracture generating compression” across the bone members. Ex. 1005 ¶2; Ex. 1007, 1. The ’833 Patent relies on the same principle. Ex. 1001, Abstract.

42. Hartdegen expressly teaches “[t]he embodiments described herein may be used in connection with any type of inserter or fixation device, including but not limited to various bone staples, bone plates, etc. that have more than one implant configuration where the insertion device does not interfere with the final placement of the implant.” Ex. 1005 ¶110, Ex. 1007, 9.

43. A POSA reviewing Hartdegen’s disclosure would understand that the individual features and embodiments described throughout Hartdegen are interchangeable and may be combined with one another, consistent with Hartdegen’s own statement that its embodiments are not mutually exclusive.

44. This is consistent with how inserter systems of this type are designed. In Hartdegen, the feature that attaches the inserter to the implant, the clip that holds the inserter members in position, and the guide passages through which bone is prepared and screws are placed each perform an independent function. Changing the form of one of those features, for example by using a different attachment feature to grip the plate, does not change how the others operate. A POSA would therefore have viewed the attachment means described in Hartdegen's various embodiments as interchangeable alternatives that could be used with the tube-and-clip inserter of Hartdegen's first embodiment.

ORBAY PRIOR ART REFERENCE

45. Orbay is directed to a formable bone-plate system for reconstructive bone surgery that includes a bone plate having screw-receiving nodes separated by deformable internodes, together with clamps configured to engage those nodes and bend or contour the plate before, during, or after fixation to bone. Ex. 1008 ¶7. Orbay further teaches sockets complementary to node engagement sections. Id. ¶¶66–67. Orbay also discloses drill guide holes through the clamp for guiding drilling into bone for later screw placement, reinforcing that its clamping structures are used in connection with the screw-receiving plate portions. Id. Orbay teaches devices and steps similar to those in the '833 Patent.

46. Although Orbay describes its system in the context of the small bones of the upper extremity, it states that the system may be used in “other parts of the human body.” Ex. 1008 ¶3. In my experience, the small bones of the foot and the small bones of the hand and wrist present similar fixation problems: comparable bone dimensions, limited soft-tissue coverage, and the need to hold small fragments or joint surfaces in a corrected position during fusion or osteotomy. Plates, screws, and instruments of similar size and design are used in both regions, and foot and ankle surgeons routinely consider hand and wrist fixation systems, and vice versa.

47. A foot and ankle surgeon seeking a way to hold and manipulate a small fixation plate would therefore have regarded Orbay as directly relevant.

ANALOGOUS ART

48. In my view, Hartdegen and Orbay are analogous art to the challenged claims of the '833 Patent. Both references are in the same field of endeavor as the '833 Patent (i.e., bone plates for orthopedic fixation). The '833 Patent discloses a bone-fixation device and method in which a bone-engaging implant is held in a first, temporary configuration for accurate placement adjacent bone and thereafter assumes or is placed into a second configuration, different from the first, to secure adjacent bone portions. Ex. 1001, Abstract, 1:14–16.

49. Hartdegen likewise discloses a bone fixation/osteosynthesis system including an implant maintained by an inserter in a first configuration for placement

on bone, bone screws, and guide structures for placing the implant on bone and securing it while the implant is maintained in a loaded configuration. Ex. 1005, Abstract; Ex. 1007, 2.

50. Orbay similarly discloses a formable bone plate system for reconstructive bone surgery, including screw-receiving nodes and clamping/manipulation instruments that engage those nodes to bend or contour the plate before, during, or after fixing the plate to the bones. Ex. 1008, Abstract, ¶7.

51. Hartdegen and Orbay are also reasonably pertinent to the problem addressed by the '833 Patent: how to place and hold a bone-fixation implant in a temporary configuration suitable for accurate positioning relative to bone, and how to cause or permit that implant to assume a different configuration relative to the bone. Ex. 1001, 1:14–16, 3:45–60.

52. In my opinion, Hartdegen and Orbay are analogous art because they are from the same orthopedic fixation field and are reasonably pertinent to the same implant-positioning, plate-manipulation, and screw-fixation problems addressed by the '833 Patent. Ex. 1005 ¶¶111–112; Ex. 1007, 9–10; Ex. 1008 ¶7.

III. ANTICIPATION OF CLAIMS 1–19 IN VIEW OF HARTDEGEN

CLAIM 1

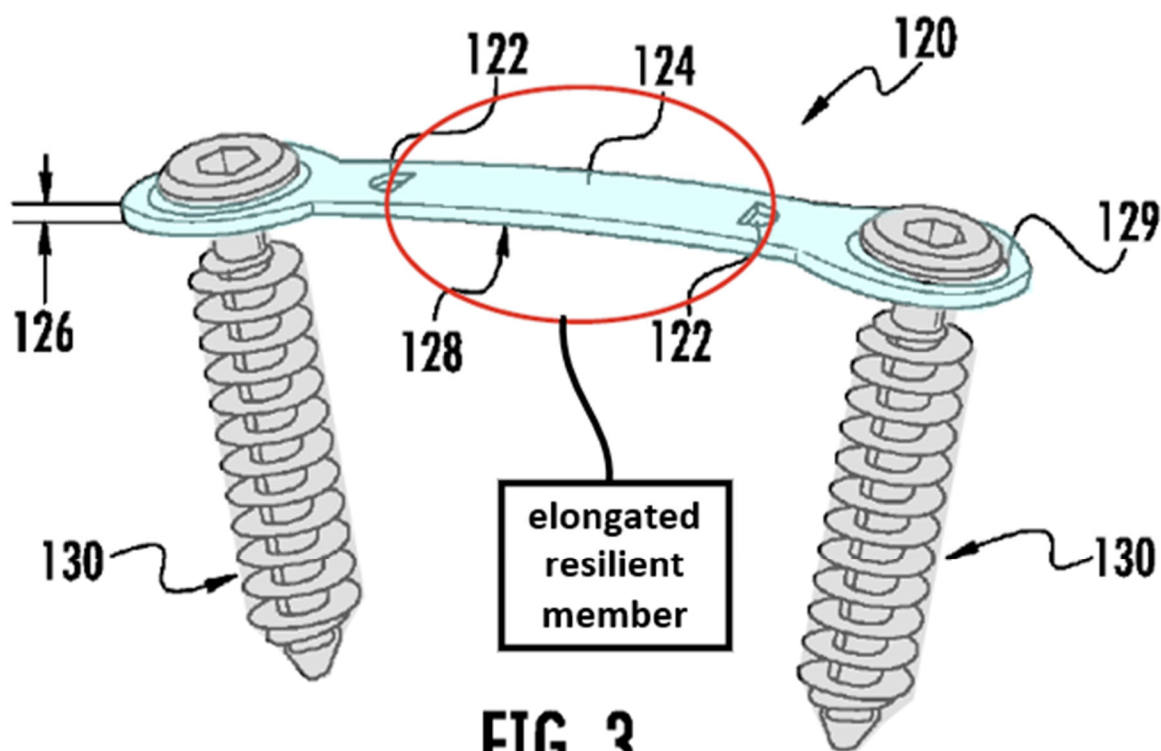
53. Hartdegen discloses “[a] method of preloading a bone compression device for subsequent application of the bone compression device to bones.”

Hartdegen discloses “a fixation system for bones of all types” comprising “an inserter and implant,” and that such systems are used in “osteosynthesis (bone fusion), wherein the implant bridges a fracture generating compression [] across the bone members.” Ex. 1005 ¶2; Ex. 1007, 1. Hartdegen further discloses that the inserter may be “preassembled to the implant or affixed to the implant at the time of use.” Ex. 1005 ¶6; Ex. 1007, 2.

Limitation 1[pre][i]

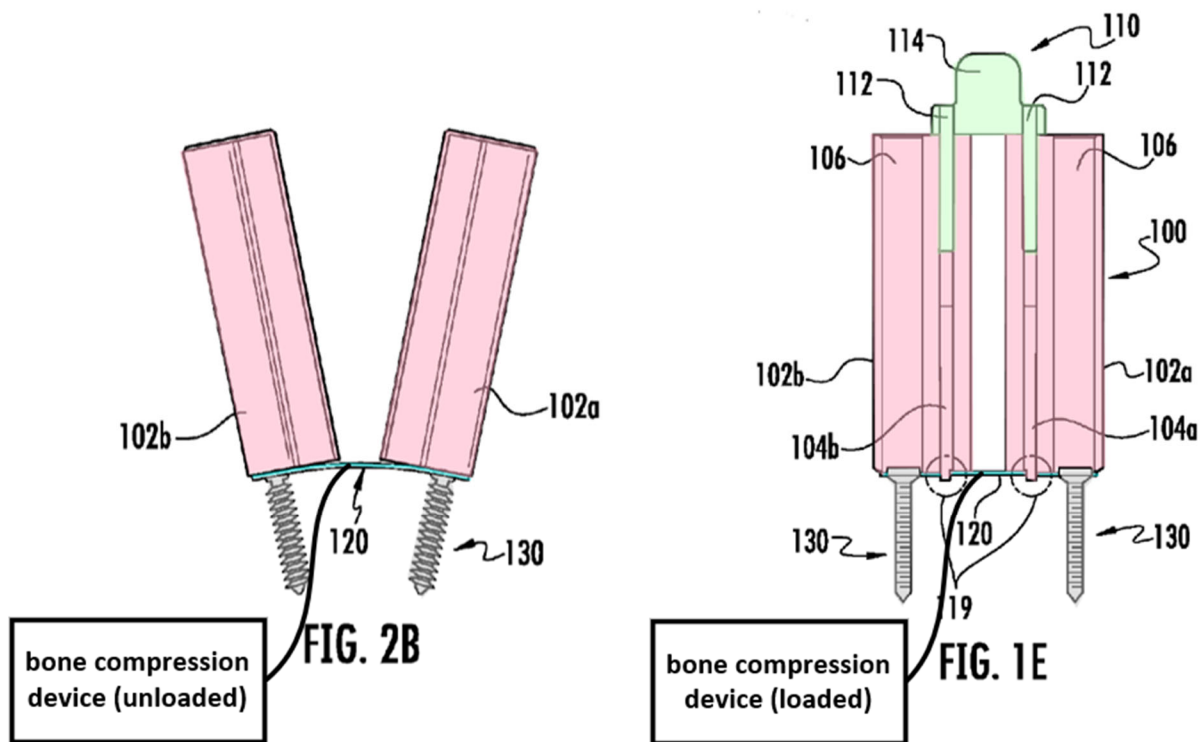
54. Hartdegen discloses “the bone compression device including an elongated resilient member having an unloaded configuration wherein the elongated resilient member has either a bent or a straight shape, the elongated resilient member further having a loaded configuration wherein the elongated resilient member has the other of the bent or the straight shape.”

An annotated version of Hartdegen Figure 3 is reproduced below.



55. Hartdegen discloses that the implant 120 may be a bone plate (bone compression device—teal) that receives bone screws 130 through corresponding attachment features 129 (bone anchor receiving portions), seen in the annotated Figure 3 above. Ex. 1005 ¶¶111–117, Fig. 3; Ex. 1007, 9–10. Hartdegen additionally explains that “FIG. 3 shows the implant 120 in a possible free-state or implanted-state of the device” and “shows the implant 120 having an arc or radius 128 while in its second configuration.” Ex. 1005 ¶117; Ex. 1007, 11. “FIG. 3 depicts the implant 120 in its second configuration” where it is not constrained. Ex. 1005 ¶113; Ex. 1007, 10.

56. Hartdegen discloses the bone plate having an unloaded configuration with a bent shape and a loaded configuration with a straight shape, as seen in annotated versions of Figures 2B and 1E from Hartdegen, reproduced below.



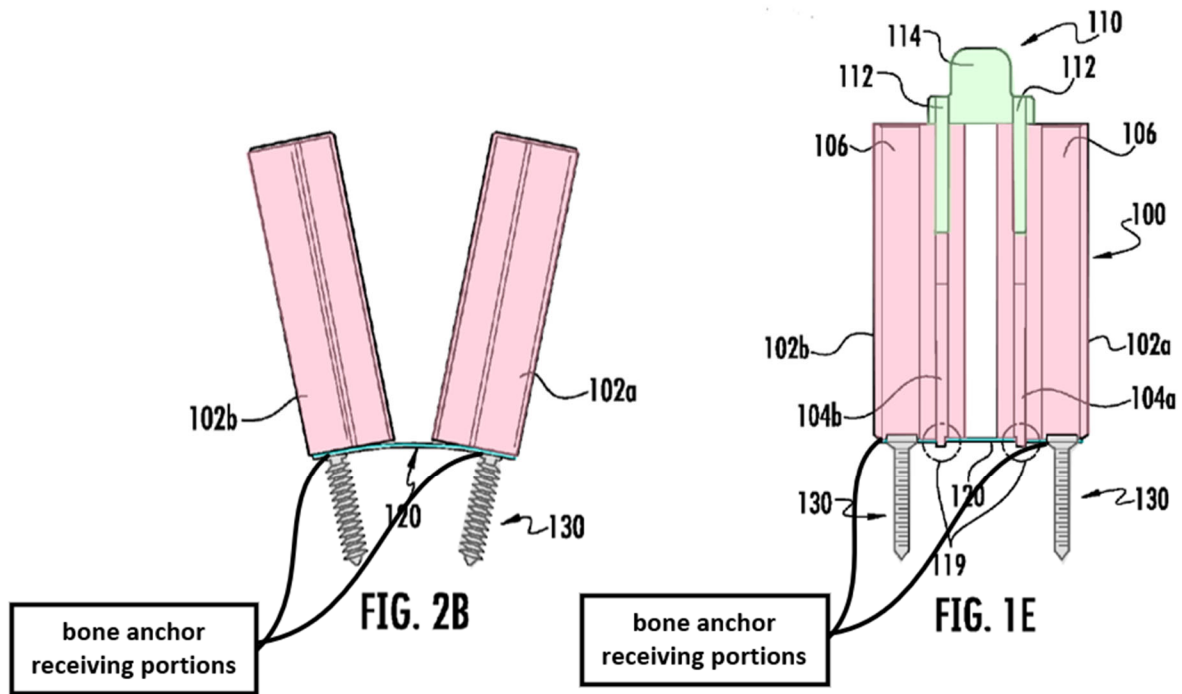
57. Hartdegen explains that “FIGS. 2a, 2b, 2c and 2d depict . . . [t]he implant 120 is shown in a second configuration . . . achieved either by the intrinsic mechanical properties of the material or secondary mechanical manipulation of one or more areas of the plate.” Ex. 1005 ¶111; Ex. 1007, 10. “As shown in FIGS. 1a, 1b, 1d and 1e, the inserter 100 is assembled to the implant 120” and “[t]he implant 120 is shown in a first configuration that . . . may be flat.” Ex. 1005 ¶111; Ex. 1007, 10.

58. The '833 Patent describes its bone plate as having a similar initial/unloaded configuration that is shifted into a loaded configuration for insertion and that returns toward the unloaded configuration after implantation. See Ex. 1001, 4:4–15 (discussing flexed and unflexed configurations, which correspond to the recited loaded and unloaded configurations). Accordingly, Hartdegen discloses limitation 1[pre][i].

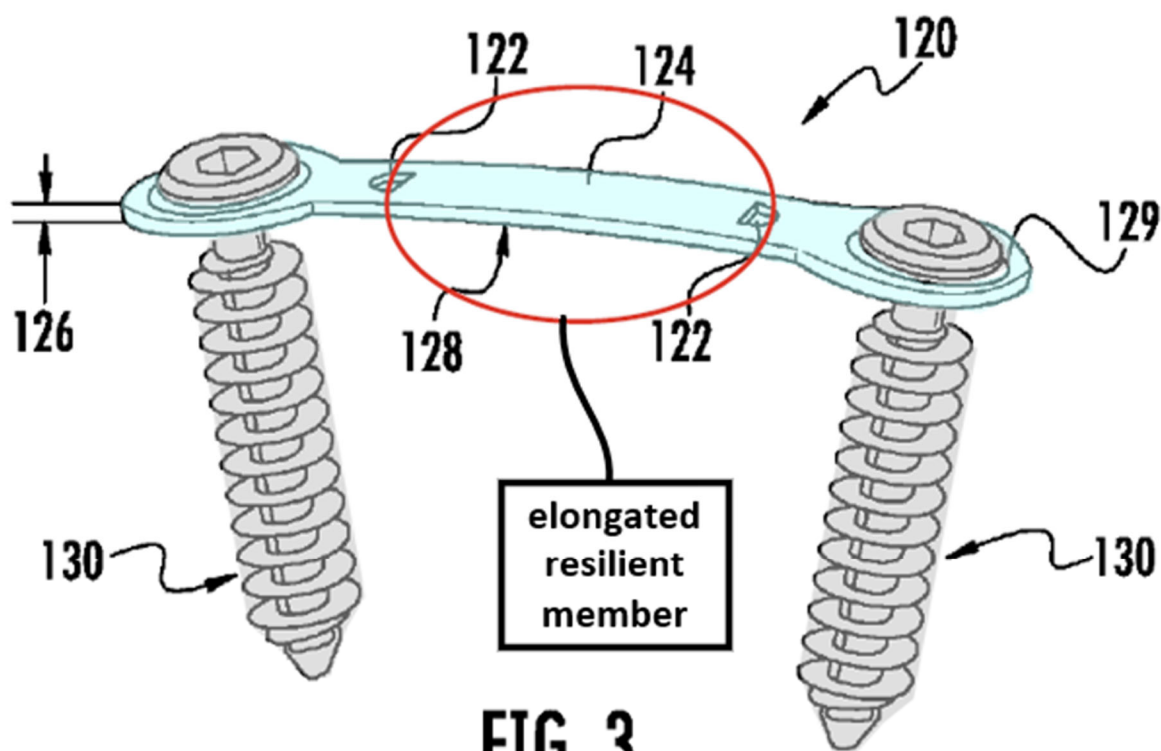
Limitation 1[a]

59. Hartdegen discloses “moving bone anchor receiving portions of the bone compression device relative to each other from a first configuration of the bone anchor receiving portions to a second configuration of the bone anchor receiving portions, the moving of the bone anchor receiving portions causing the elongated resilient member to shift from the unloaded configuration to the loaded configuration.”

60. As discussed above and illustrated below in annotated Figures 2B and 1E of Hartdegen, tube members 102a/102b are used to move the bone anchor receiving portions.



61. Hartdegen teaches using tube members 102a, 102b to move the bone anchor receiving portions relative to each other which shifts its elongated resilient member (bridge member 124—teal) from the unloaded bent configuration (seen in annotated Figure 3 below and Figure 2B above) to the loaded straight configuration (seen in Figure 1E above). Ex. 1005 ¶¶111–115; Ex. 1007, 9–11.



62. Moving bone anchor receiving portions relative to each other causes the elongated resilient member to shift from the unloaded configuration to the loaded configuration. Ex. 1005 ¶¶111–115; Ex. 1007, 9–11. Therefore, Hartdegen discloses limitation 1[a].

63. Hartdegen’s implant has a curved free state (Fig. 3, arc 128) and is flat when held by the assembled inserter (Fig. 1E; Ex. 1005 ¶111). Each tube is attached to the implant on its own side of the bridge, adjacent to the screw-receiving end portions. Because bridge member 124 physically joins those end portions, they cannot be rotated or spaced differently relative to one another without changing the

shape of the bridge between them. Pivoting the tubes from the diverging orientation of Figure 2B to the parallel orientation of Figure 1E therefore applies a bending moment to the bridge and straightens it. Because the implant is formed of a material that elastically resists that deformation (Ex. 1005 ¶117), the implant stores the resulting strain and is placed in its loaded configuration.

Limitation 1[b][i]

64. Hartdegen discloses “after moving the bone anchor receiving portions to the second configuration thereof, connecting at least one restraint to a body which is connected to one of the bone anchor receiving portions, the body being separate and distinct from the at least one restraint and the one bone anchor receiving portion.” Hartdegen’s restraint is shown in annotated Figure 1E below.

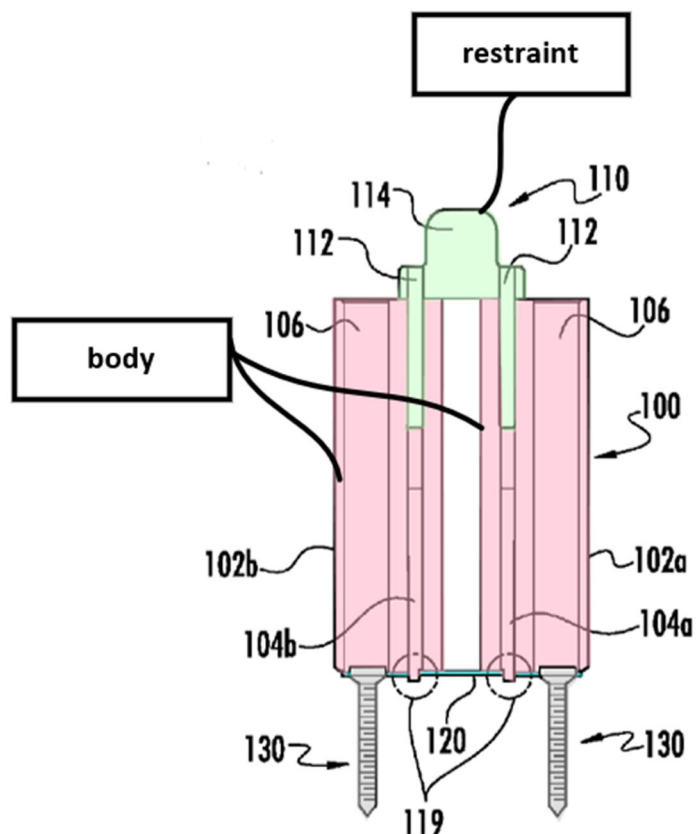


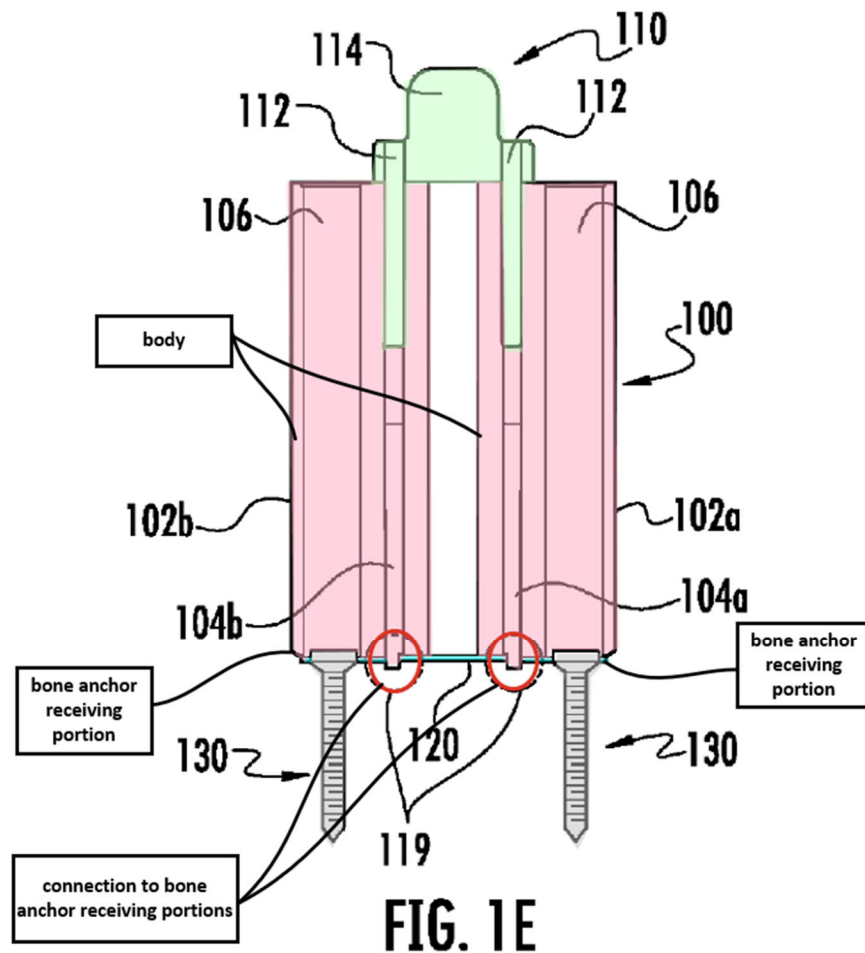
FIG. 1E

Hartdegen's clip 110 (green) is a restraint and is connected to tubes 102a, 102b (body—pink). Ex. 1005 ¶¶111–116; Ex. 1007, 9–11. Hartdegen explains that its “[c]lip has . . . two engagement pins 112” that “engage the tubes 102a and 102b to hold them in relative position to each other thereby maintaining the implant 120 in its first configuration.” Ex. 1005 ¶111; Ex. 1007, 9.

65. The engagement between Hartdegen's clip 110 and tubes 102a, 102b provides the claimed “connecting at least one restraint to a body which is connected to one of the bone anchor receiving portions.” Hartdegen discloses that inserter 100 includes two independent tube members 102a, 102b (pink) which are held in relative

position to each other by the clip 110 (green), and that the clip 110 includes engagement pins 112 that engage the tubes 102a, 102b to hold them in relative position, thereby maintaining bone anchor receiving portions in the loaded configuration. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11.

66. Hartdegen discloses its tube members 102a/102b (body–pink) are connected to the bone anchor receiving portions via engagement pins 104a and 104b (engagement features 119–circled in red below), as seen in annotated Figure 1E below.



Hartdegen discloses “a body which is connected to one of the bone anchor receiving portions” because its tubes 102a/102b (body–pink) are connected to the bone anchor receiving portions via engagement pins 104a/104b being connected to implant 120 (bone compression device–teal).

67. Hartdegen further discloses “the body being separate and distinct from the at least one restraint and the one bone anchor receiving portion.” As discussed above, Hartdegen discloses that inserter 100 includes “two tube members 102a and 102b” (pink). Ex. 1005 ¶¶111–117; Ex. 1007, 9–11. Each tube member 102a, 102b is a body “separate and distinct from the at least one restraint and the one bone anchor receiving portion” because Hartdegen describes the tubes as separate and distinct bodies that may be temporarily connected to both the implant and the clip. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11.

68. According to Hartdegen’s description of the surgical sequence, clip 110 is removed from the tubes first, and the inserter assembly is then removed from the surgical site while implant 120 remains in its final position on the bone. Ex. 1005 ¶115, Figs. 7–9. A structure that can be disconnected from the implant and withdrawn while the implant stays fixed to the bone is necessarily separate and distinct from the implant’s bone anchor receiving portions. Likewise, because clip 110 is removed from the tubes while the tubes remain in place, the tubes are separate and distinct from the restraint.

69. To the extent Patent Owner contends that the engagement features 119 are outside of the bone anchor receiving portions and/or that a direct connection is required at the bone anchor receiving portions of the implant 120, Hartdegen expressly states that “[t]he means of attaching the plate to the inserter . . . could occur anywhere on or around the periphery of the plate.” Ex. 1005 ¶111; Ex. 1007, 9. A POSA would have understood this as disclosing one option for the attachment location being at the bone anchor receiving portions of the bone plate (e.g., around the periphery of the bone anchor receiving portions). Accordingly, Hartdegen discloses limitation 1[b][i].

Limitation 1[b][ii]

70. Hartdegen discloses connecting its restraint “to inhibit the bone anchor receiving portions from moving from the second configuration back toward the first configuration thereof which keeps the elongated resilient member from shifting from the loaded configuration back toward the unloaded configuration.”

71. As discussed above, the claimed “body” is disclosed by at least one of Hartdegen’s inserter tube members 102a or 102b (pink) and Hartdegen further discloses the recited functional result: the restraint (green) inhibits the bone-anchor receiving portions and elongated resilient member from moving back toward the unloaded configuration, as seen in annotated Figure 1E below. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11.

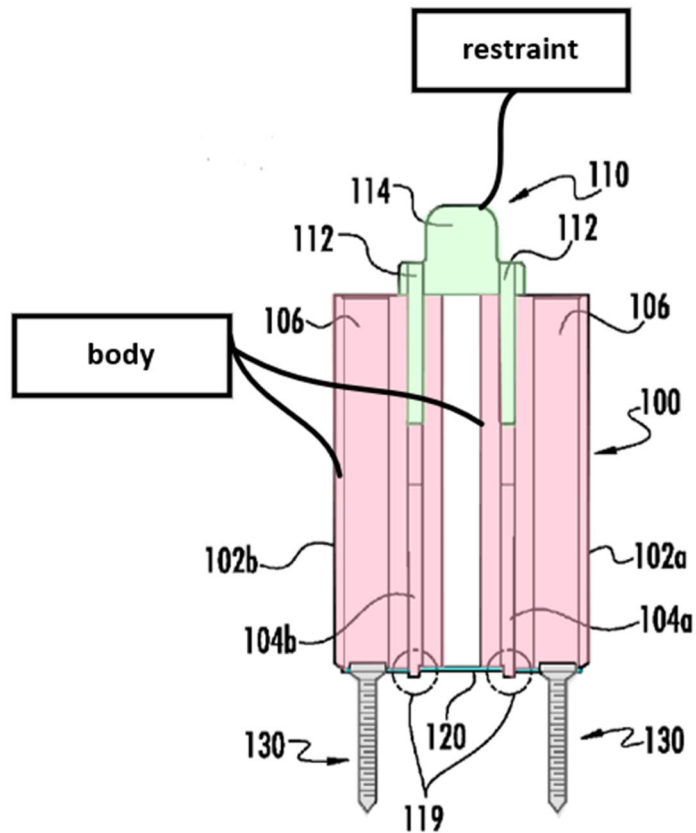


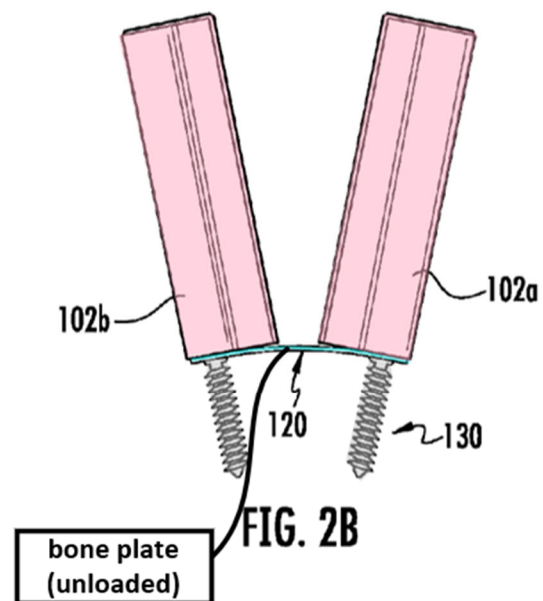
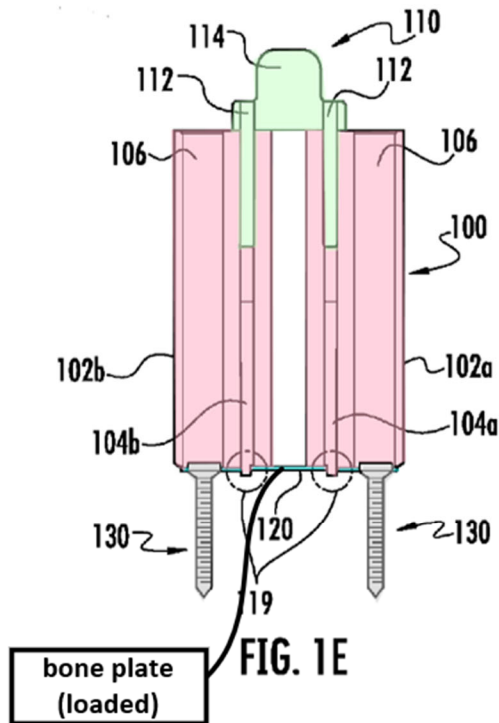
FIG. 1E

After the implant's bone-anchor receiving portions have been moved so the implant is in the loaded configuration, clip 110 restrains tube members 102a, 102b and inhibits the implant's bone-anchor receiving portions from moving back toward the unloaded/free-state configuration, and thereby keeps the elongate resilient member and bone anchor receiving portions of implant 120 from shifting from the loaded configuration back toward the unloaded configuration. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11.

72. Hartdegen confirms that the restraint inhibits the bone anchor receiving portions from returning toward the unloaded configuration because it discloses that

removal of restraint (clip 110—green) allows the bone compression device (implant 120—teal) to shift to its unloaded configuration. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11.

73. Stated differently, while clip 110 remains connected to the tube members 102a and 102b, the clip 110 prevents relative movement of the tube members 102a, 102b and corresponding bone anchor receiving portions of implant 120, thereby maintaining implant 120 in the loaded configuration. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11. Once the clip/restraint is removed, the implant is free to shift back toward its free-state/unloaded configuration, as seen in annotated Figures 1E and 2B below. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11.

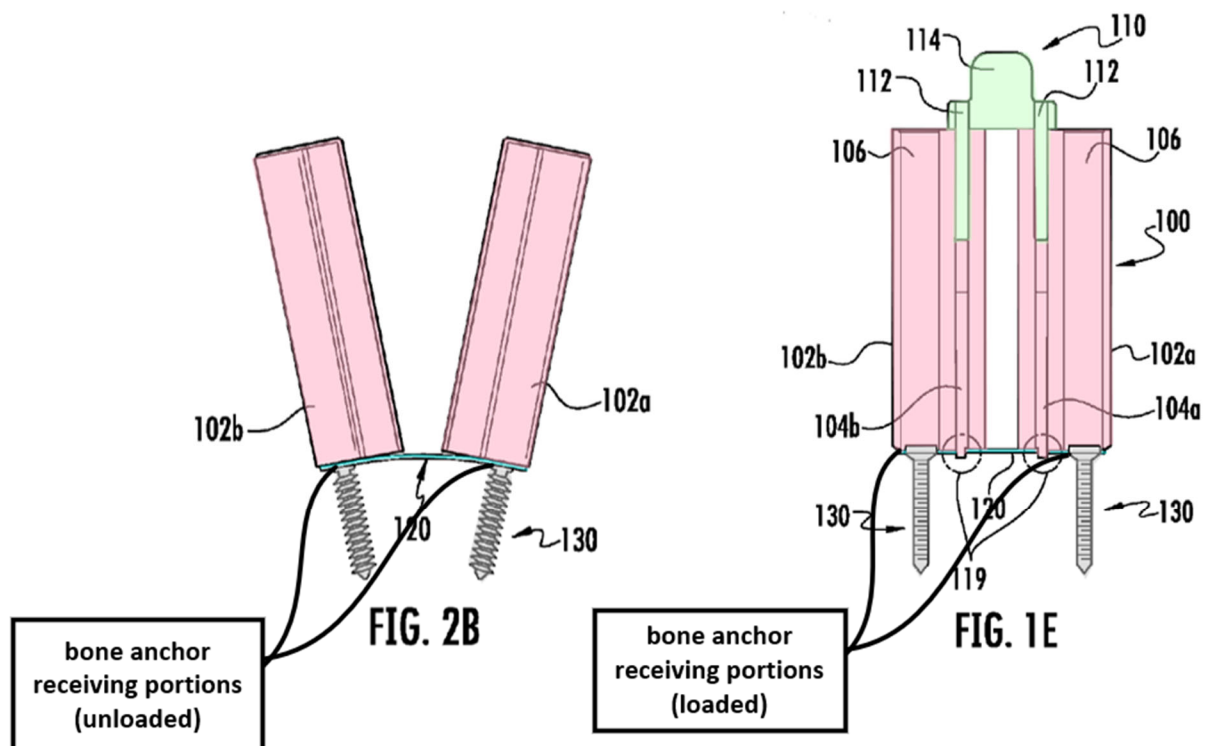


Hartdegen discloses limitation 1[b][ii].

CLAIM 2

74. Claim 2 depends from claim 1 and recites that “moving the bone anchor receiving portions relative to each other includes increasing a distance between the bone anchor receiving portions.”

75. Hartdegen discloses claim 2 because moving the bone anchor receiving portions relative to each other includes increasing a distance between the bone anchor receiving portions. Annotated Figs. 1E and 2B of Hartdegen are shown below illustrating the different loaded and unloaded configurations.



76. As seen above, moving the bone anchor receiving portions relative to each other from an unloaded configuration to a loaded configuration increases the

distance between the bone-anchor receiving portions. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11. Accordingly, Hartdegen discloses claim 2.

CLAIM 3

77. Claim 3 depends from claim 1 and further recites “engaging a tool with one of the bone anchor receiving portions; and moving the bone anchor receiving portions relative to each other includes using the tool to move the one bone anchor receiving portion relative to the other bone anchor receiving portion.”

Limitation 3[a]

78. Hartdegen discloses “engaging a tool with one of the bone anchor receiving portions,” as seen in annotated Figure 2D below.

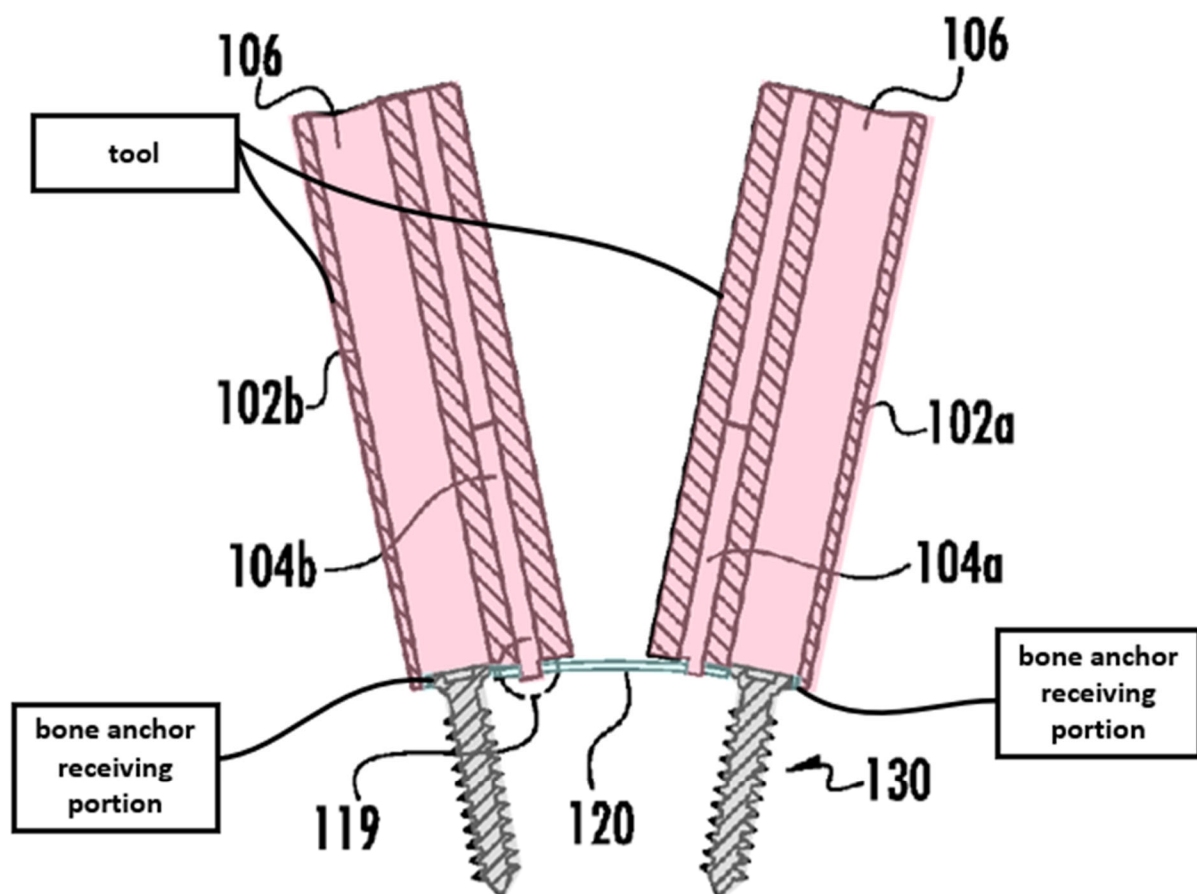


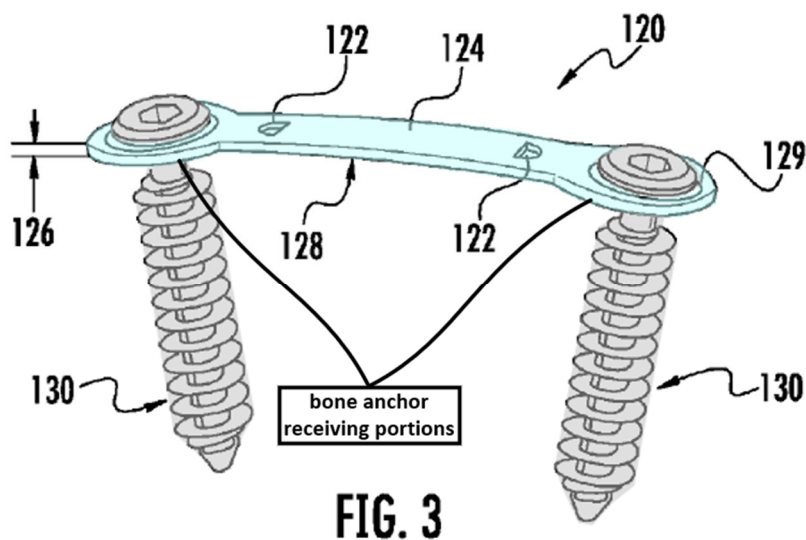
FIG. 2D

As explained in the construction of “tool” discussed above, Hartdegen’s inserter 100, including inserter tubes 102a and 102b and engagement pins 104a, 104b, is a “tool” because the tube members 102a, 102b are tubular members used to bend the implant 120 (bone compression device—teal) and are engaged with the implant 120.

79. Hartdegen discloses engaging a tool (tubes 102a, 102b; engagement pins 104a and 104b—pink) with a bone-anchor receiving portion of the bone compression device (implant 120—teal). Hartdegen explains that “[t]he inserter tubes

102a and 102b are . . . engaged in the implant 120 via the engagement pins 104a and 104b.” Ex. 1005 ¶112; Ex. 1007, 10. This engagement causes tubes 102a, 102b to engage with the bone-anchor receiving portions connected to the portion of the implant engaged by the tool.

80. Hartdegen explains that “FIG. 3 shows one embodiment of the engagement hole 122 that accepts the engagement pins 104a and 104b of the inserter tube[s] 102a and 102b.” Ex. 1005 ¶112; Ex. 1007, 10. An annotated version of Figure 3 is provided below.



81. As discussed above regarding limitation 1[b][i], to the extent Patent Owner contends that the engagement features 119 (engagement pins 104a and 104b; engagement holes 122) are outside of the bone anchor receiving portions and/or a direct connection is required at the bone anchor receiving portions of the implant 120, Hartdegen expressly states that “[t]he means of attaching the plate to the inserter

. . . could occur anywhere on or around the periphery of the plate.” Ex. 1005 ¶111; Ex. 1007, 9.

82. A POSA would have understood this as disclosing one option for the attachment location being at the bone anchor receiving portions of the bone plate (e.g., around the periphery of the bone anchor receiving portions).

Accordingly, Hartdegen discloses limitation 3[a].

Limitation 3[b]

83. Hartdegen discloses “moving the bone anchor receiving portions relative to each other includes using the tool to move the one bone anchor receiving portion relative to the other bone anchor receiving portion,” as seen in annotated Figure 1E below.

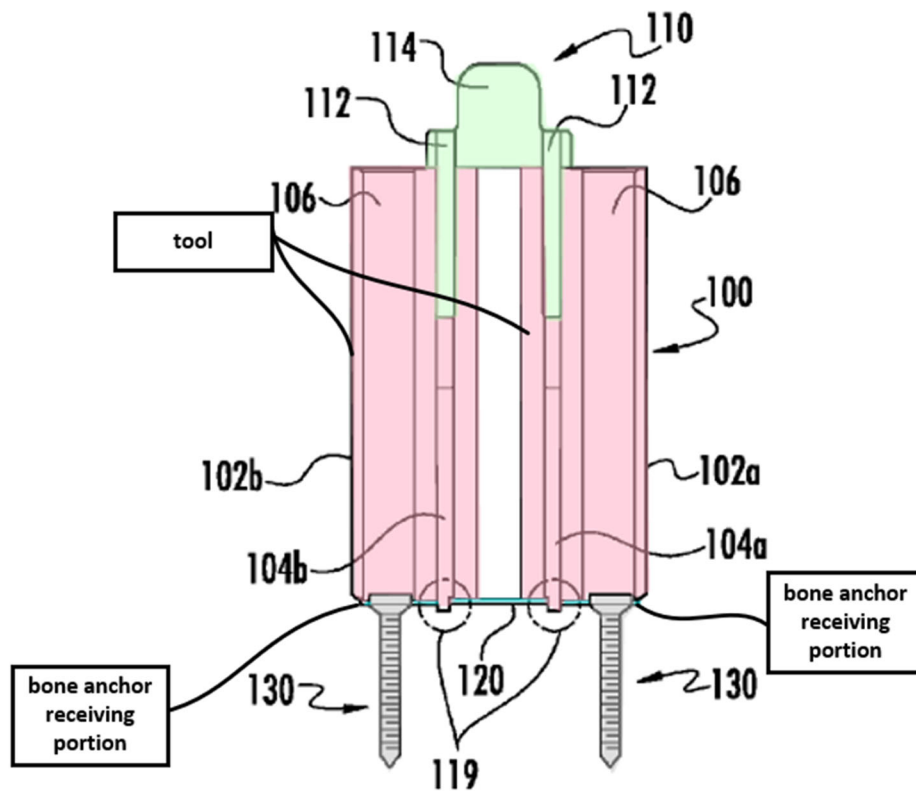
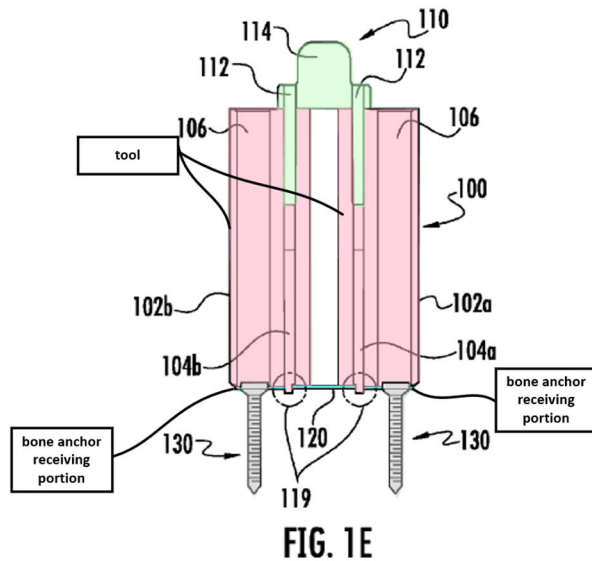
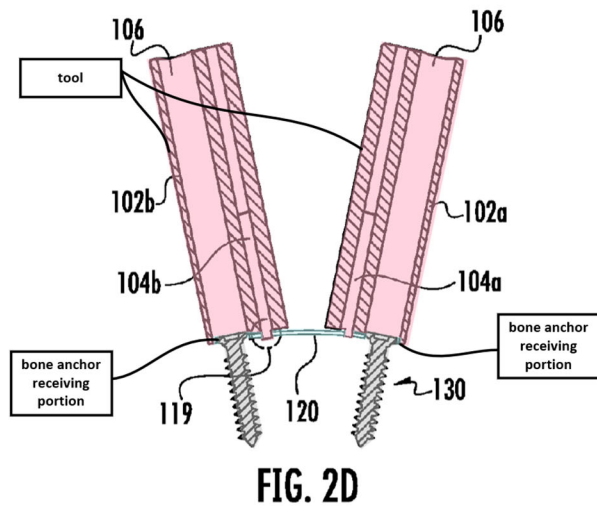


FIG. 1E

84. As discussed above and illustrated below by annotated Figs. 2D and 1E of Hartdegen, tube members 102a, 102b (tools—pink) are used to move the bone anchor receiving portions of implant 120 (bone compression device—teal) relative to each other.



85. Hartdegen explains that “[t]he present invention may have the inserter pre-assembled to the implant or affixed to the implant at the time of use.” Ex. 1005 ¶6; Ex. 1007, 3. A POSA would understand Hartdegen as disclosing pivoting its tubes 102a, 102b (tools/bodies) to flex the implant 120 (bone compression device) at least when the assembly happens at the time of use. The moving of bone anchor receiving portions relative to each other is accomplished through the tube members 102a, 102b (tools—pink), which causes the implant 120 (teal) to shift from the unloaded configuration (Figure 2D) to the loaded configuration (Figure 1E). Ex. 1005 ¶¶111–115; Ex. 1007, 9–11.

Accordingly, Hartdegen discloses limitation 3[b].

CLAIM 4

86. Claim 4 is substantially the same as claim 3 but recites “engaging tools with the bone anchor receiving portions” (limitation 4[a]) and “moving the bone anchor receiving portions relative to each other includes using the tools to move the bone anchor receiving portions relative to each other” (limitation 4[b]).

87. Claim 4 recites plural “tools” engaged with the bone-anchor receiving portions, whereas claim 3 recites engaging “a tool” with one of the bone-anchor receiving portions. As seen in the annotated Figures 1E and 2D provided above in connection with claim 3, Hartdegen includes multiple tools for the same reasons discussed above for claim 3. Hartdegen discloses a first tool (tube member 102a–pink) and a second tool (tube member 102b–pink).

Accordingly, Hartdegen discloses claim 4.

CLAIM 5

88. Claim 5 is an independent claim reciting “[a] method of preloading a bone compression device for subsequent application of the bone compression device to bones,” like claim 1. Hartdegen discloses such a method for the reasons discussed above regarding claim 1.

Limitation 5[pre][i]

89. Limitation 5[pre][i] is the same as limitation 1[pre][i].

Limitation 5[a]

90. Limitation 5[a] is the same as limitation 1[a].

Limitation 5[b]

91. Limitation 5[b] recites “after moving the bone anchor receiving portions to the second configuration thereof, applying at least one restraint to inhibit the bone anchor receiving portions from moving from the second configuration back toward the first configuration thereof which keeps the elongated resilient member from shifting from the loaded configuration back toward the unloaded configuration.”

92. Limitation 5[b] corresponds to limitations 1[b][i] and 1[b][ii], except that claim 5 uses the term “applying” the restraint, whereas claim 1 recites “connecting” the restraint. The terms “applying” and “connecting” have the same operative meaning in this context, namely, placing, attaching, engaging, or otherwise associating the restraint with the relevant structure so that the restraint performs the claimed function of preventing return movement. Nothing in the claims or specification suggests that “applying” requires a different act from “connecting” for purposes of these claims.

Accordingly, Hartdegen discloses limitation 5[b] for the same reasons discussed regarding limitation 1[b][i] and 1[b][ii].

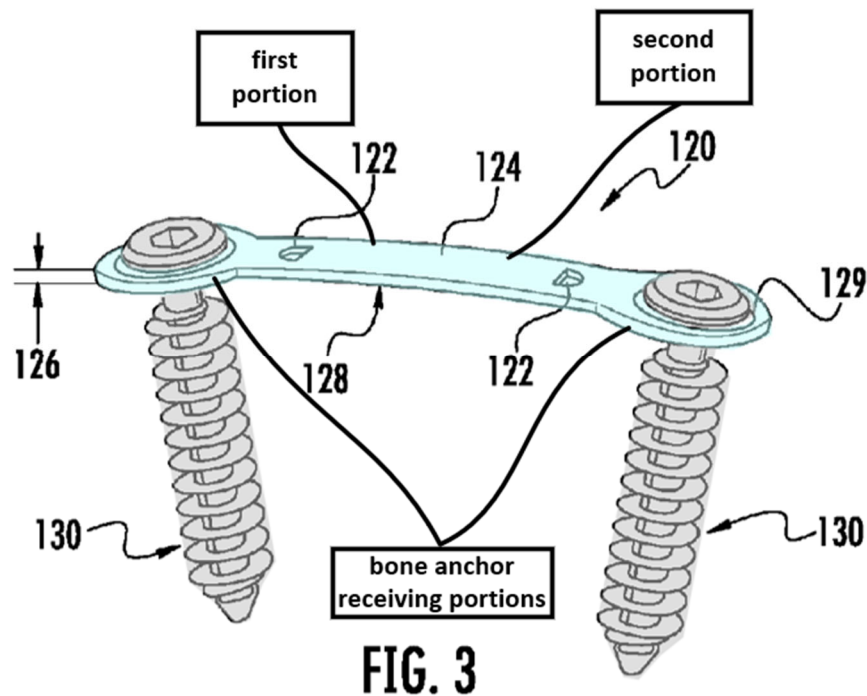
Limitation 5[c]

93. Limitation 5[c] recites “wherein moving the bone anchor receiving portions relative to each other includes reconfiguring first and second portions of the

elongated resilient member between a first configuration wherein the first and second portions extend transversely to each other and a second configuration wherein the first and second portions are coaxial with each other.”

94. Hartdegen discloses this limitation. Hartdegen describes first and second configurations for its implant 120 (elongated resilient member). The second configuration described in Hartdegen corresponds to the first configuration in the claim. The first configuration described in Hartdegen corresponds to the second configuration in the claim.

95. Annotated Figure 3 of Hartdegen below shows the first and second portions of the elongated resilient member (implant 120–teal).



96. Hartdegen explains that “FIG. 3 depicts the implant 120 in its second configuration” where it is not constrained (Ex. 1005 ¶113; Ex. 1007, 10) and “shows the implant 120 having an arc or radius 128 while in its second configuration” (Ex. 1005 ¶117; Ex. 1007, 11). The first and second portions are in “a first configuration wherein the first and second portions extend transversely to each other” as shown in annotated Figure 3 above and in annotated Figure 2B below (see blue lines indicating transverse orientation).

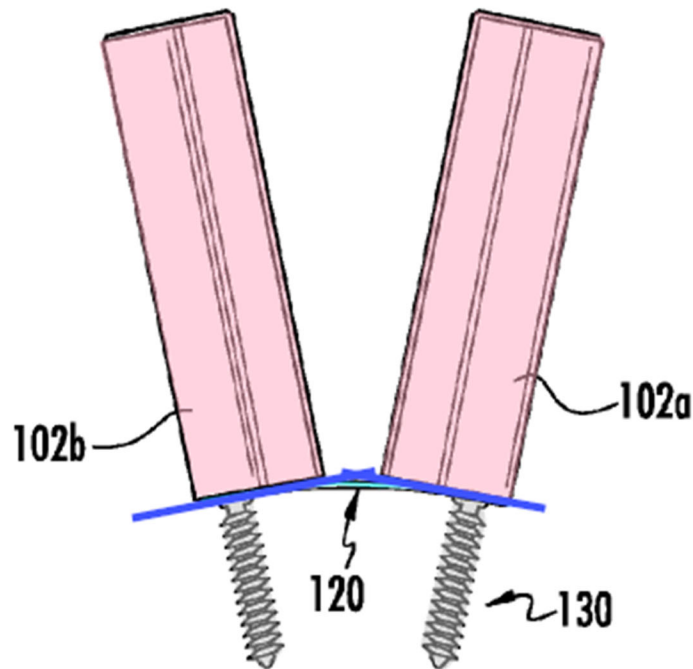


FIG. 2B

The first configuration corresponds to the bent shape in the unloaded configuration recited in limitation 5[pre][i].

97. Annotated Figure 1E from Hartdegen below shows “a second configuration wherein the first and second portions are coaxial with each other” (see blue line showing coaxial orientation).

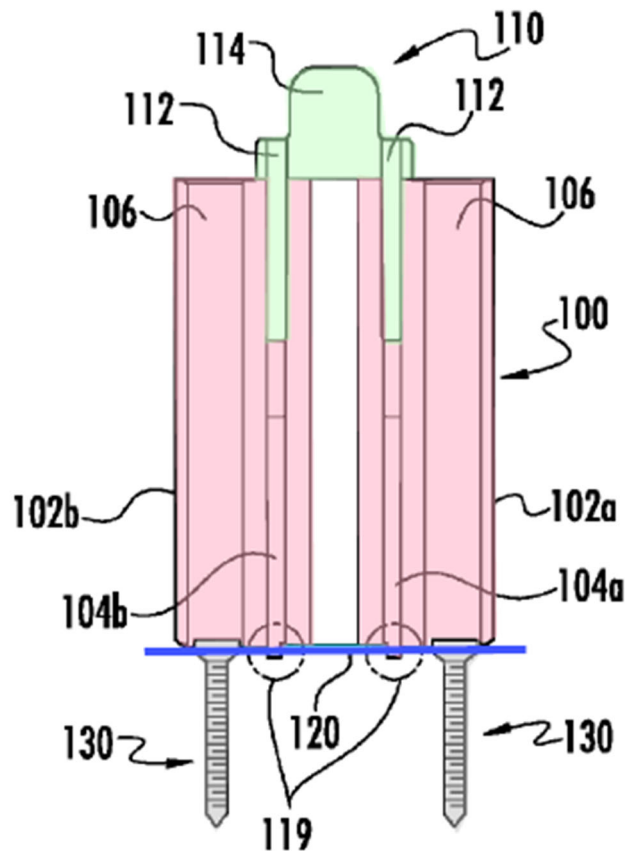


FIG. 1E

98. Hartdegen explains that “[a]s shown in FIGS. 1a, 1b, 1d and 1e, the inserter 100 is assembled to the implant 120” and “[t]he implant 120 is shown in a first configuration that . . . may be flat.” Ex. 1005 ¶111; Ex. 1007, 10. The second configuration where the implant 120 (elongated resilient member—teal) is flat

corresponds to the straight shape in the loaded configuration recited in limitation 5[pre][i]. This provides the same coaxial arrangement of the first and second portions of the implant 120 as recited in the claim.

Accordingly, claim 5 is disclosed by Hartdegen.

CLAIM 6

99. Claim 6 is an independent claim that includes limitations recited in claims 1, 4, and 5 as set forth in the table below.

Claim 6		
Claim 6 Limitation	Corresponding Limitation	Claim 6
6[pre]	1[pre]	A method of preloading a bone compression device for subsequent application of the bone compression device to bones,
6[pre][i]	1[pre][i]	the bone compression device including an elongated resilient member having an unloaded configuration wherein the elongated resilient member has either a bent or a straight shape, the elongated resilient member further having a loaded configuration wherein the elongated resilient member has the other of the bent or straight shape, the method comprising:
6[a]	1[a]	moving bone anchor receiving portions of the bone compression device relative to each other from a first configuration of the bone anchor receiving portions to a second configuration of the bone anchor receiving portions, the moving of the bone anchor receiving portions causing the elongated resilient member to shift from the unloaded configuration to the loaded configuration;

6[b]	1[b][i], 1[b][ii], 5[b] ¹	after moving the bone anchor receiving portions to the second configuration thereof, applying at least one restraint to inhibit the bone anchor receiving portions from moving from the second configuration back toward the first configuration thereof which keeps the elongated resilient member from shifting from the loaded configuration back toward the unloaded configuration;
6[c]	4[a]	engaging a first tool with one of the bone anchor receiving portions and engaging a second tool with the other of the bone anchor receiving portions; and
6[d]	4[b]	moving the bone anchor receiving portions relative to each other includes using the tools to move the bone anchor receiving portions relative to each other.

100. The reasons discussed above regarding the limitations in claims 1, 4, and 5 that correspond to those in claim 6 are incorporated herein by reference.

Accordingly, claim 6 is disclosed by Hartdegen.

CLAIM 7

101. Claim 7 is an independent claim reciting “[a] method of preloading a bone compression device for subsequent application of the bone compression device to bones,” like claim 1. Hartdegen discloses such a method of the reasons discussed above regarding claim 1.

Limitation 7[pre][i] and 7[a]

¹ As discussed above, claim 1 recites “connecting at least one restraint” and claim 5 recites “applying at least one restraint.” *See* the discussion of limitations 1[b][i] and 5[b] above.

102. Limitation 7[pre][i] is the same as limitation 1[pre][i]. Limitation 7[a] is the same as limitation 1[a].

Limitation 7[b]

103. Limitation 7[b] is the same as limitation 5[b] (see the discussion of limitation 5[b] above) and corresponds to limitations 1[b][i] and 1[b][ii], except that like claim 5, claim 7 uses the term “applying” the restraint, whereas claim 1 recites “connecting” the restraint. The terms “applying” and “connecting” have the same operative meaning in this context, namely, placing, attaching, engaging, or otherwise associating the restraint with the relevant structure so that the restraint performs the claimed function of preventing return movement. Nothing in the claims or specification suggests that “applying” requires a different act from “connecting” for purposes of these claims. Accordingly, Hartdegen discloses limitation 7[b] for the same reasons discussed regarding limitations 1[b][i], 1[b][ii], and 5[b].

Limitation 7[c]

104. Limitation 7[c] recites “providing a tool having a distal end portion configured to be connected to the bone compression device, the tool having a cannula sized to permit a bone screw to be advanced therethrough and into an opening of one of the bone anchor receiving portions.” Hartdegen’s tubes 102a and 102b are each a “tool” as explained above regarding claims 3 and 4.

105. An annotated version of Figure 1E from Hartdegen is reproduced below. Hartdegen's tubes 102a and 102b (tools–pink) each have internal diameters 106 (cannulas–outlined in red) sized to permit a bone screw to be advanced therethrough and into an opening of one of the bone anchor receiving portions.

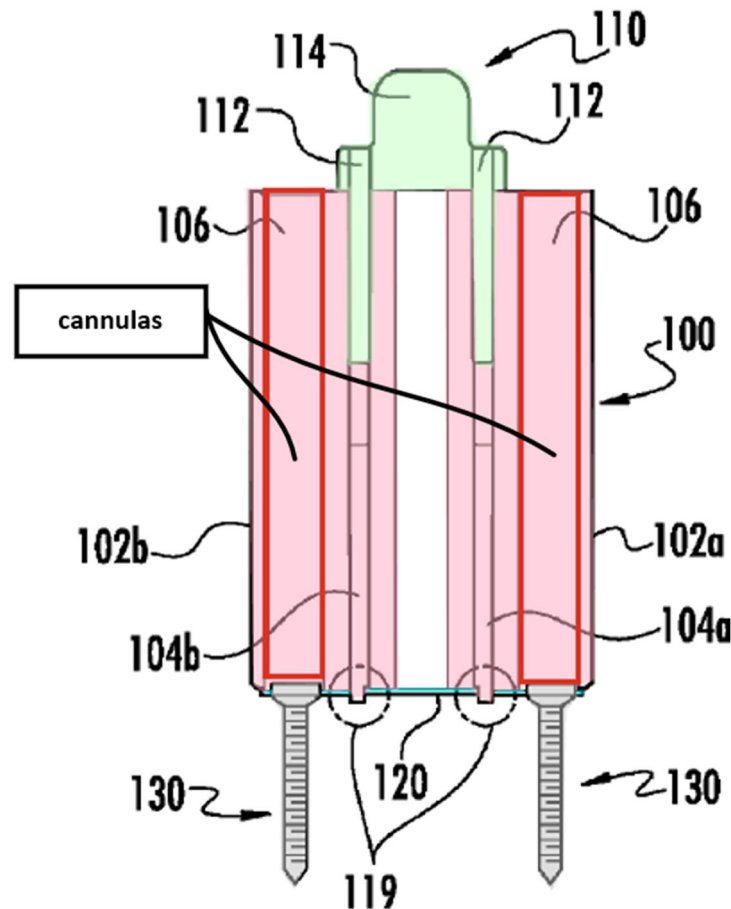


FIG. 1E

106. Hartdegen discloses that its “two tube members 102a and 102b . . . allow the bone to be prepared through the internal diameters 106,” and further explains that those tube members 102a, 102b “serve as drill guides,” confirming that internal diameters 106 are cannulas extending through the elongated tube members.

Ex. 1005 ¶111; Ex. 1007, 9. Hartdegen discloses, for example, that bone screws 130 (bone anchors–gray) may be inserted into the implant 120 (bone compression device–teal) while it is attached to the tube members 102a, 102b (tools–pink). Ex. 1005 ¶113; Ex. 1007, 10. Thus, the internal diameters 106 are aligned with the bone anchor receiving portions of implant 120 and sized to permit screws 130 therethrough.

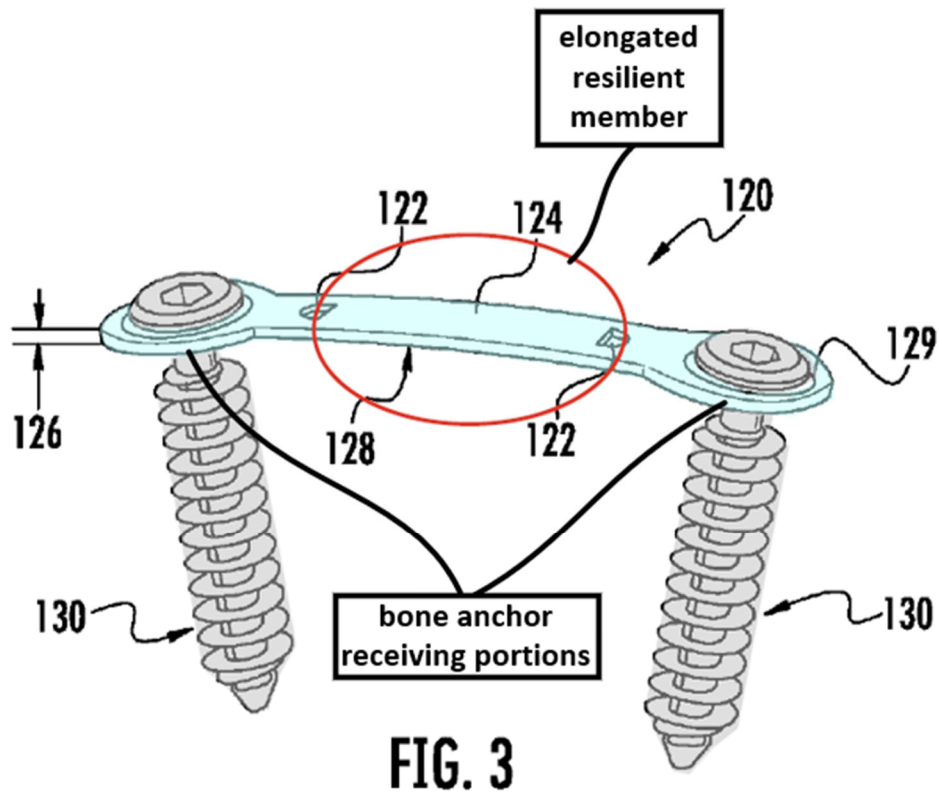
Accordingly, claim 7 is disclosed by Hartdegen.

CLAIM 8

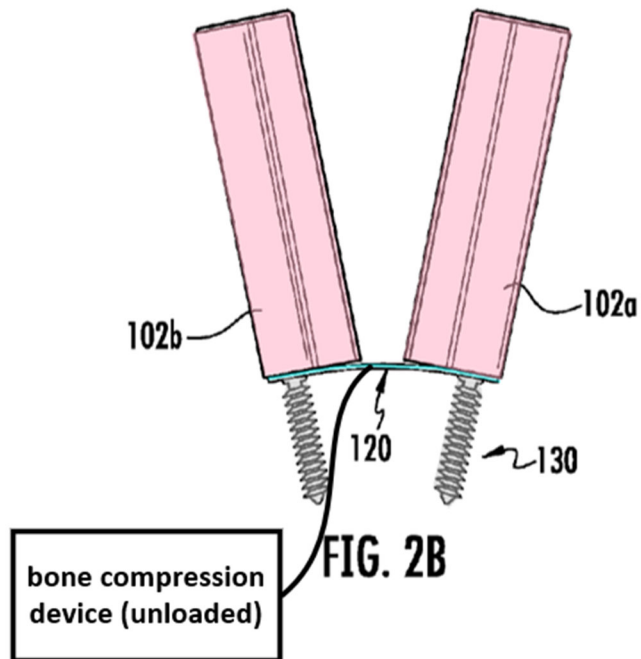
107. Hartdegen discloses “a method of applying a bone compression device to bones.” Hartdegen describes attachment of the implant to bone. Ex. 1005, Abstract; Ex. 1007, 9–11. Hartdegen states that the “delivery instrument releasably holds the implant in a first configuration prior to attachment of the implant to bone [and] allows the implant to be affixed to bone before the implant is released from the instrument.” Ex. 1005, Abstract; Ex. 1007, 2. After release, the implant 120 assumes at least a second configuration providing compression to the bones. Ex. 1005, Abstract; Ex. 1007, 2.

Limitation 8[pre][i]

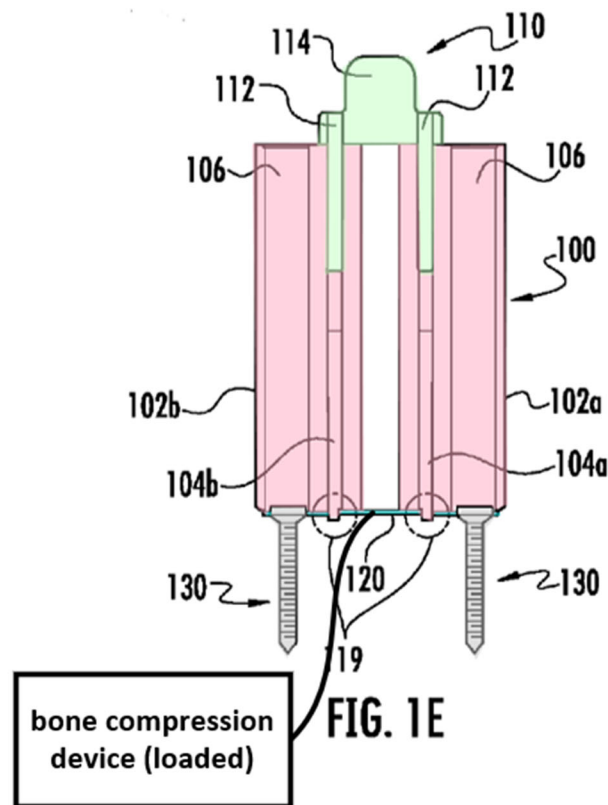
108. Hartdegen discloses a “bone compression device including bone anchor receiving portions and an elongated resilient member,” as seen in annotated Figure 3 below.



109. Hartdegen discloses its “bone anchor receiving portions having a first configuration which places the elongated resilient member in an unloaded configuration wherein the elongated resilient member has . . . a bent . . . shape,” as seen in annotated Figure 2B below and explained above regarding limitation 1[pre][i].



110. Hartdegen discloses its “bone anchor receiving portions having a second configuration which places the elongated resilient member in a loaded configuration wherein the elongated resilient member has the . . . straight shape,” as seen in annotated Figure 1E below and explained above regarding limitation 1[pre][i].



Accordingly, Hartdegen discloses limitation 8

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[pre][i]
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Limitation 8[a]

111. Hartdegen discloses “positioning the bone compression device against the bones with the bone anchor receiving portions in the second configuration and the elongated resilient member in the loaded configuration.”

112. As discussed above for limitation 8

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[pre][i]
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, Hartdegen’s loaded configuration corresponds to the claimed second configuration of the bone-anchor receiving portions. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11.

113. Hartdegen’s implant 120 (bone compression device—teal) is maintained in a loaded configuration by inserter 100 (pink), with tube members 102a and 102b

secured by clip 110 (green). Ex. 1005 ¶¶111–114; Ex. 1007, 9–11. As shown below in annotated Figure 4, the inserter 100 is used to position the loaded implant 120 (bone compression device–teal) adjacent to bones while the inserter (pink) remains engaged. Ex. 1005 ¶¶111–114; Ex. 1007, 9–11.

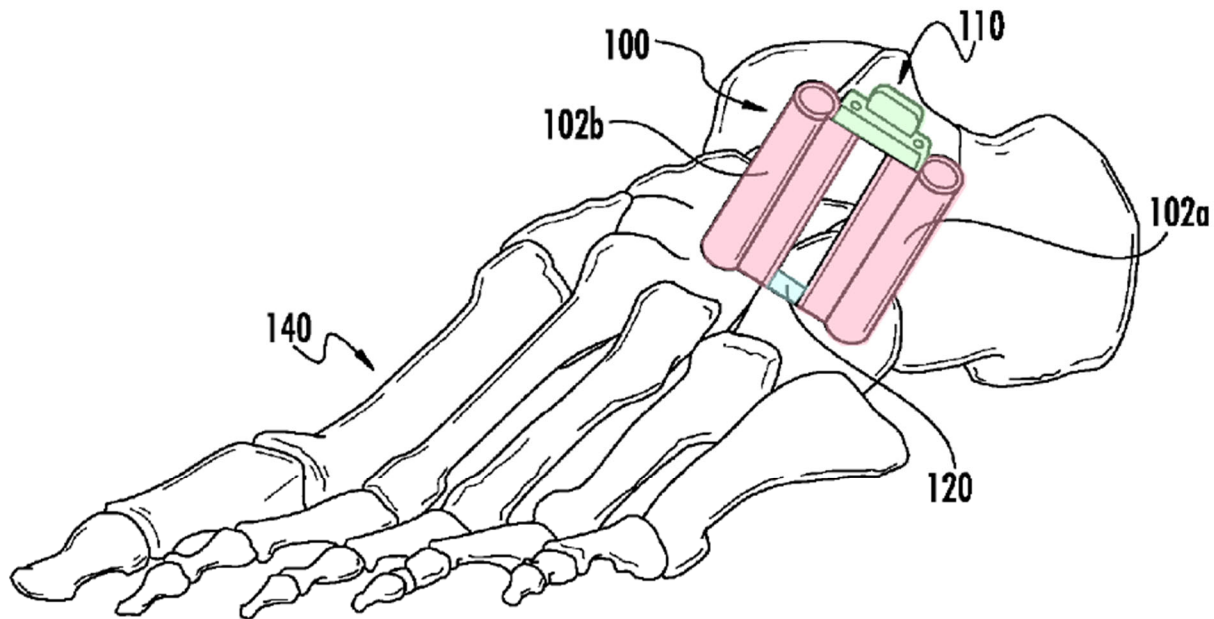


FIG. 4

114. Hartdegen explains, for example, that “FIG. 4 depicts one embodiment of the inserter 100 assembled to implant 120 on a foot 140” and shows the implant adjacent bones of the foot. Ex. 1005 ¶114; Ex. 1007, 10.

Accordingly, Hartdegen discloses limitation 8[a].

Limitation 8[b]

115. Hartdegen discloses “permitting at least one restraint to hold the bone anchor receiving portions in the second configuration, the holding of the bone anchor

receiving portions in the second configuration maintaining the elongated resilient member in the loaded configuration.”

116. Hartdegen’s restraint is shown in Figure 4 above and annotated Figure 1E below.

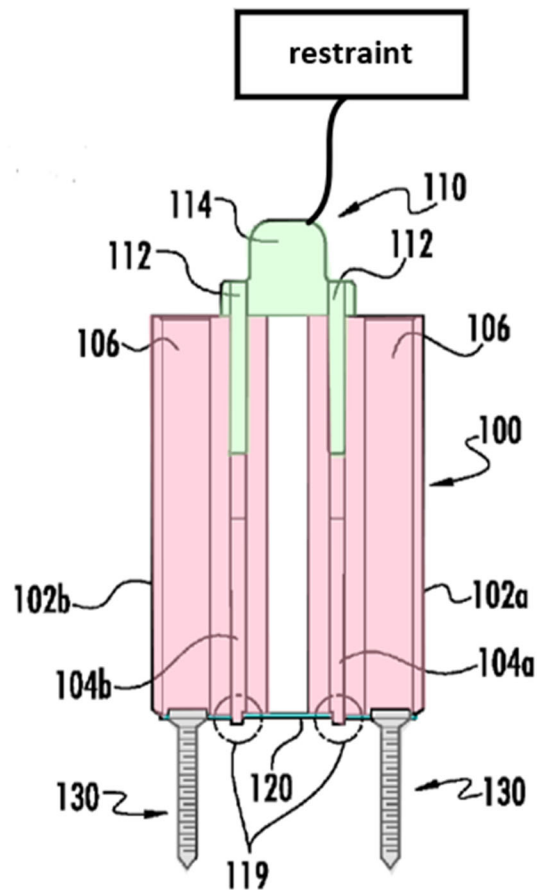


FIG. 1E

117. Hartdegen’s clip 110 (green) is a restraint. Ex. 1005 ¶¶111–116; Ex. 1007, 9–11. Hartdegen explains that its “[c]lip has . . . two engagement pins 112” that “engage the tubes 102a and 102b to hold them in relative position to each other thereby maintaining the implant 120 in its first configuration.” Ex. 1005 ¶111; Ex.

1007, 9. As discussed above, Hartdegen's first configuration corresponds to the loaded configuration recited in the claim.

Accordingly, Hartdegen discloses limitation 8[b].

Limitation 8[c]

118. Hartdegen discloses "driving shanks of bone screws through openings of the bone anchor receiving portions of the bone compression device and into engagement with the bones."

119. As explained above regarding limitation 7[c], and seen in annotated Figure 1E below, Hartdegen's tube members 102a and 102b (pink) include internal diameters 106 (cannulas—pink) that act as passages for drilling and guiding bone screws 130 (gray) into the openings of the implant 120 (bone compression device—teal). Ex. 1005 ¶111; Ex. 1007, 9.

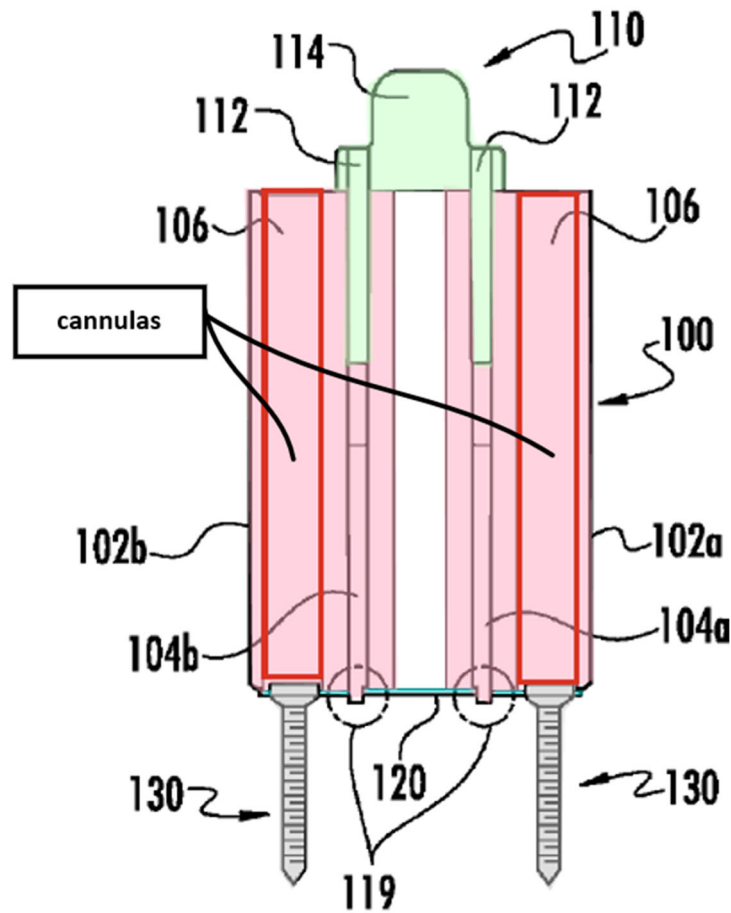


FIG. 1E

Hartdegen explains that bone screws 130 (gray) may be inserted into the implant 120 (bone compression device—teal) while it is attached to the tube members 102a, 102b (pink). Ex. 1005 ¶113; Ex. 1007, 10.

120. As seen above in annotated Figure 4 and discussed in connection with limitation 8[a], the inserter 100 (pink) is used to position the loaded implant 120 (bone plate—teal) adjacent to bones while the inserter remains engaged. Ex. 1005 ¶¶111–114; Ex. 1007, 9–11. Annotated versions of Figures 5 and 6 from Hartdegen are provided below.

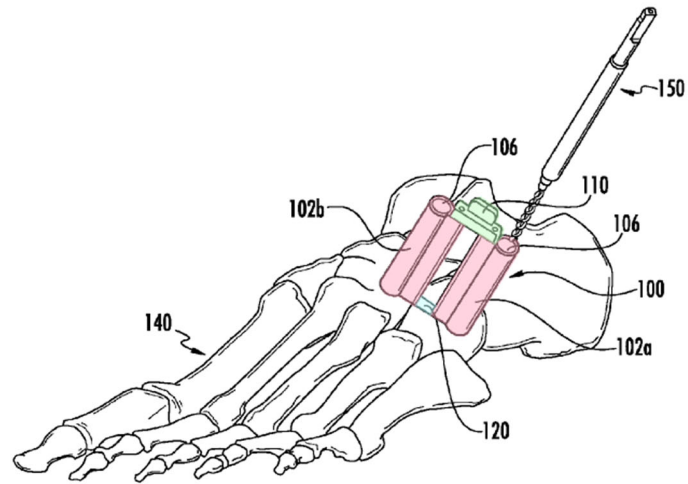


FIG. 5

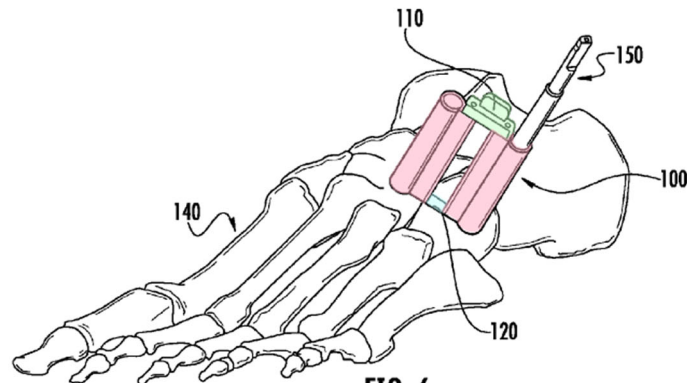


FIG. 6

121. Hartdegen explains that “FIGS. 5 and 6 depict one embodiment of the inserter 100 assembled to implant 120 on a foot 140 further showing preparation of the bone 140 with drill 150 through the internal diameter 106 to accept bone screws.” Ex. 1005 ¶114; Ex. 1007, 10. Figures 5–6 of Hartdegen depict tube members 102a and 102b (pink) connected to the implant 120 (bone compression device–teal) and clip 110 (restraint–green) maintaining the relative position of the tube members 102a, 102b and the bone compression device in the loaded configuration while the

bone is being prepared. Ex. 1005 ¶¶111–115; Ex. 1007, 9–11. Hartdegen explains that “[b]one screws 130 may [be] prepared and positioned while the inserter assembly 100 was engaged to the implant 120.” Ex. 1005 ¶115; Ex. 1007, 11.

122. A POSA would have understood the disclosure discussed above as the bone first being prepared by advancing a drill 150 through internal diameters 106 to create pilot holes at locations aligned with the screw-receiving openings of implant 120 followed by bone screws 130 being inserted into implant 120 while the implant is maintained in its loaded configuration (i.e., the same internal diameters 106 used to guide drilling of the pilot holes are subsequently used to drive shanks of bone screws through openings of the bone anchor receiving portions into engagement with the bones). Ex. 1005 ¶¶111–115; Ex. 1007, 9–11.

123. Hartdegen’s description of the sequence confirms that the screws are driven while the implant is held in its loaded configuration. During bone preparation and screw placement, clip 110 holds tubes 102a, 102b in position, “thereby maintaining the implant 120 in its first configuration,” which is flat. Ex. 1005 ¶¶111, 114–115; Ex. 1007, 9–11. Hartdegen explains that the clip is removed “after completing the appropriate bone preparation,” and only then does the implant “adapt to a second configuration while the implant 120 is in its final implant position.” Ex. 1005 ¶115. For the implant to be in its final implant position when the clip is removed, it must already be fixed to the bone. An implant that was not yet secured

would have no final position and would spring away from the bone when released. When the screws are placed through the tubes while the inserter is attached, as Hartdegen describes (id. ¶113), they are therefore necessarily placed while the clip holds the implant in its loaded configuration.

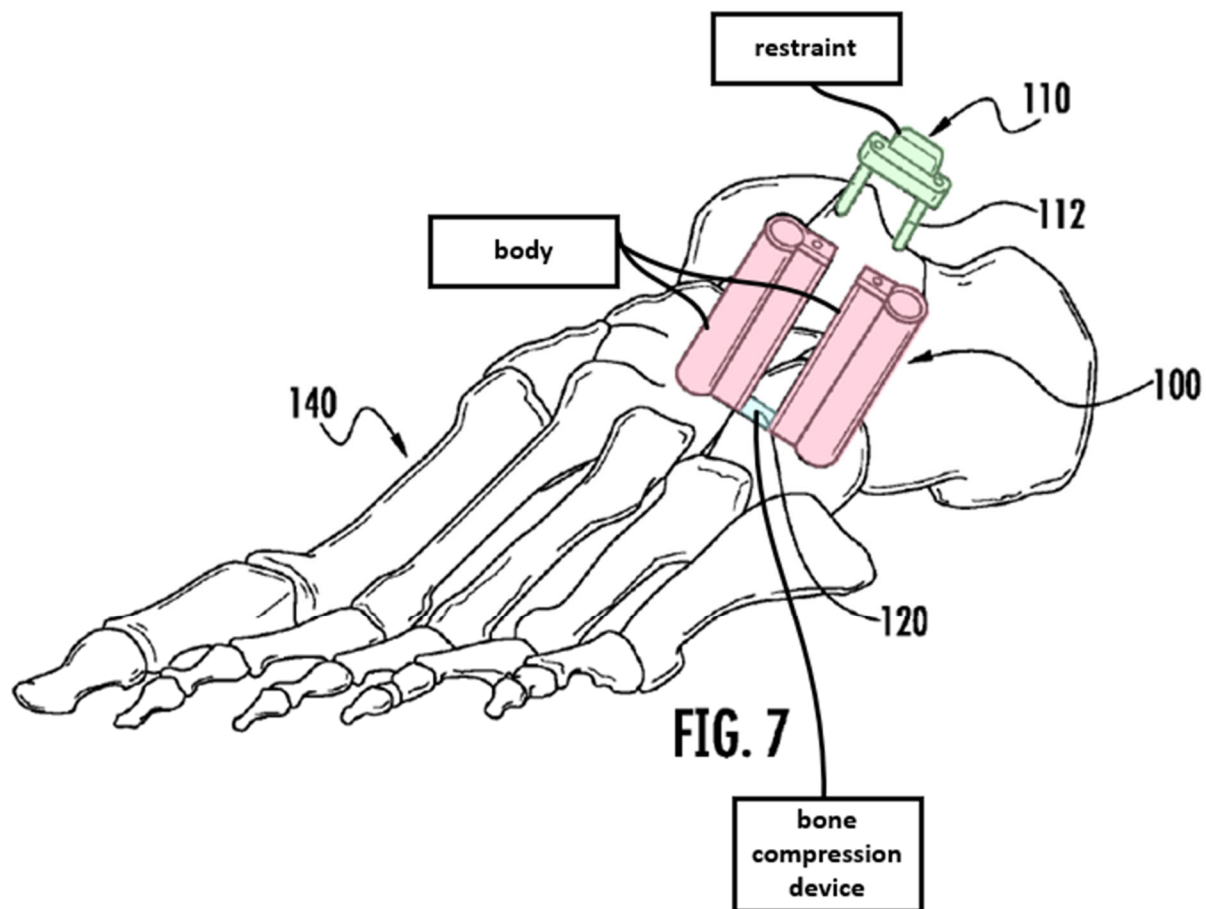
124. In my experience, the interval between drilling and screw insertion is when alignment is most easily lost. Once a guide is removed, the drilled pilot hole must be re-located through soft tissue, and any shift of the plate relative to the bone misaligns the plate hole with the pilot hole. The screw may then be inserted off-axis, strip the pilot hole, or seat incompletely in the plate. Placing the screw through the same internal diameter 106 used to guide the drill eliminates that step: the screw follows the same trajectory as the drill, through the same guide that is still holding the implant. A POSA would have recognized that this reduces operative time and instrument exchanges and improves the accuracy of screw placement.

Accordingly, Hartdegen discloses limitation 8[c].

Limitation 8[d][i]

125. Hartdegen discloses “disconnecting the at least one restraint from a body connected to one of the bone anchor receiving portions, the body being separate and distinct from the at least one restraint and the one bone anchor receiving portion.”

126. As discussed above regarding limitation 1[b][ii], the claimed “body” is disclosed by at least one of Hartdegen’s inserter tube members 102a or 102b (pink). As seen in annotated Figure 7, Hartdegen discloses disconnecting its clip 110 (restraint–green) from tube members 102a or 102b (body–pink) after implantation. Ex. 1005 ¶¶114–115, Figs. 4–8; Ex. 1007, 9–10, Figs. 4–8.



127. To the extent Patent Owner contends that the engagement features 119 are outside of the bone anchor receiving portions and/or a direct connection is required at the bone anchor receiving portions of the implant 120, as discussed above regarding limitation 1[b][i], Hartdegen expressly states that “[t]he means of

attaching the plate to the inserter . . . could occur anywhere on or around the periphery of the plate.” Ex. 1005 ¶111; Ex. 1007, 9.

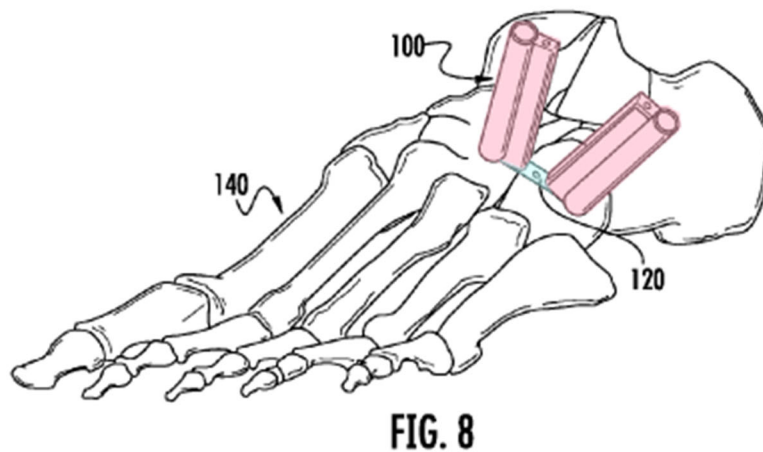
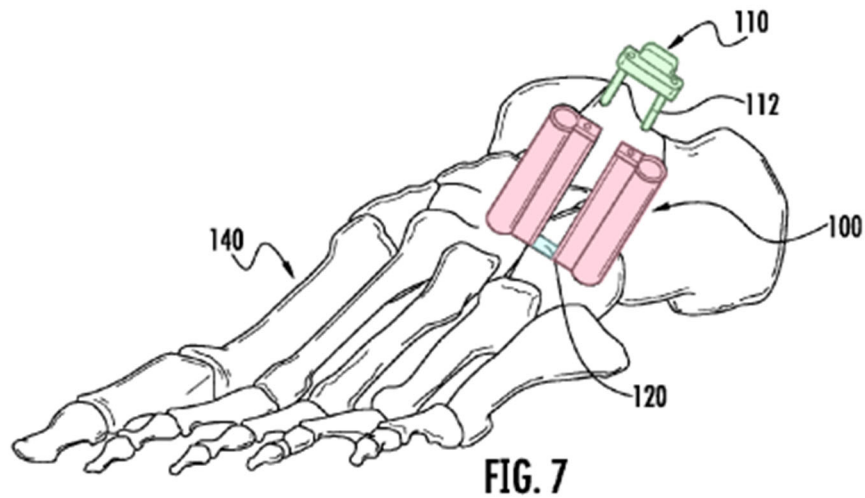
128. In my opinion, a POSA would have understood this as disclosing one option for the attachment location being at the bone anchor receiving portions of the bone plate (e.g., around the periphery of the bone anchor receiving portions).

Accordingly, Hartdegen discloses limitation 8[d][i].

Limitation 8[d][iii]

129. Hartdegen discloses “permit[ting] the elongated resilient member to shift from the loaded configuration toward the unloaded configuration and urge the bone anchor receiving portions of the bone compression device from the second configuration back toward the first configuration.”

130. As discussed above regarding limitation 8[d][i], and seen in annotated Figures 7 and 8 below, removal of clip 110 (restraint–green) after implantation (Figure 7) permits implant 120 (elongated resilient member–teal) to adapt to a second configuration (Figure 8). Ex. 1005 ¶¶114–115, Figs. 4–8; Ex. 1007, 9–10, Figs. 4–8.



131. Hartdegen discloses that clip 110 (restraint–green) holds tubes 102a and 102b (body–pink) in relative position and that removal of the clip 110 allows the implant 120 (elongated resilient member–teal) to shift toward the unloaded configuration. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11. Thus, removing clip 110 disconnects the restraint from the tube members 102a and 102b and the elongated

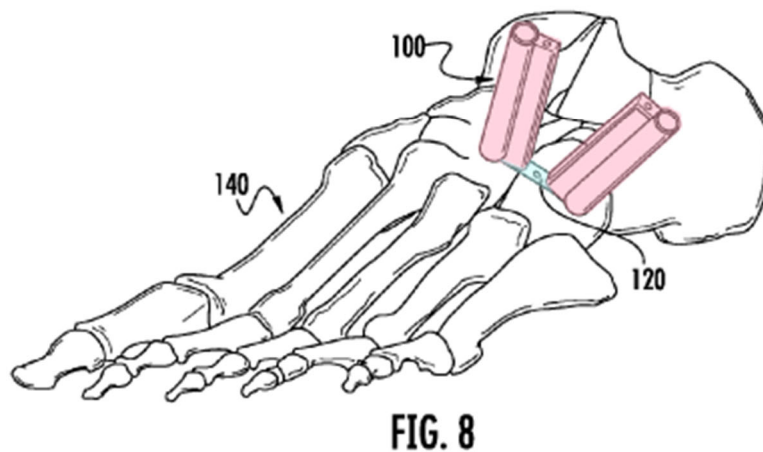
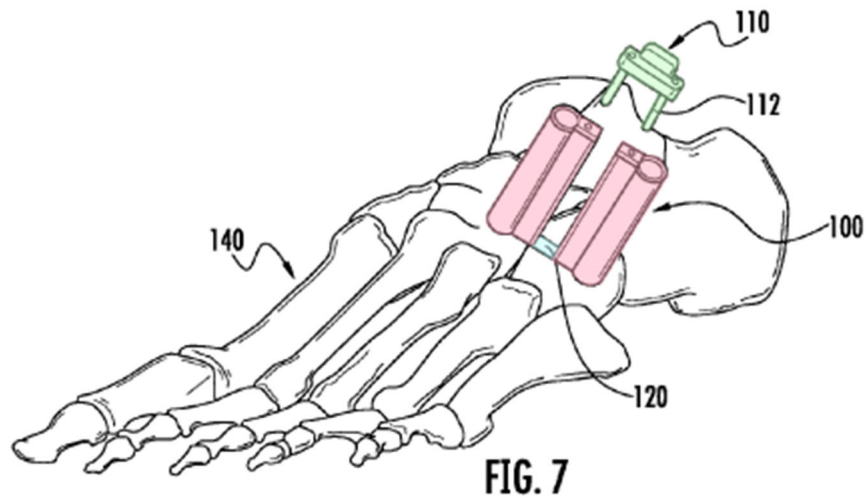
resilient member urges the bone anchor receiving portions back toward the first (unloaded) configuration.

Accordingly, Hartdegen discloses limitation 8[d][ii].

CLAIM 9

132. Claim 9 depends from claim 8 and recites that “removing the at least one restraint to permit the elongated resilient member to shift from the loaded configuration toward the unloaded configuration includes decreasing a distance between the bone anchor receiving portions.”

133. This limitation is disclosed for the reasons discussed above regarding claim 2. As discussed above regarding limitation 8[d][ii], and seen in annotated Figures 7 and 8 below, removal of clip 110 (restraint–green) after implantation (Figure 7) permits implant 120 to adapt to a second configuration (Figure 8). Ex. 1005 ¶¶114–115, Figs. 4–8; Ex. 1007, 9–10, Figs. 4–8.



134. As discussed above regarding claim 2, the distance between the bone anchor receiving portions is greater in the loaded configuration than the unloaded configuration. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11.

135. When the screws are driven, implant 120 is held flat, and each end portion is fixed by a screw to a different bone or bone fragment. Once the clip is removed and the inserter released, the bridge tends to return to its arched free shape

(Fig. 3, arc 128). An arched plate spans a shorter distance between its ends than the same plate held flat. Because the ends are now anchored in bone, the bridge's tendency to return to its arched shape pulls the screw-receiving ends, and the bones in which they are anchored, toward each other. That is the compression Hartdegen describes: an implant that “bridges a fracture generating compression” across the bone members. Ex. 1005 ¶2; Ex. 1007, 1.

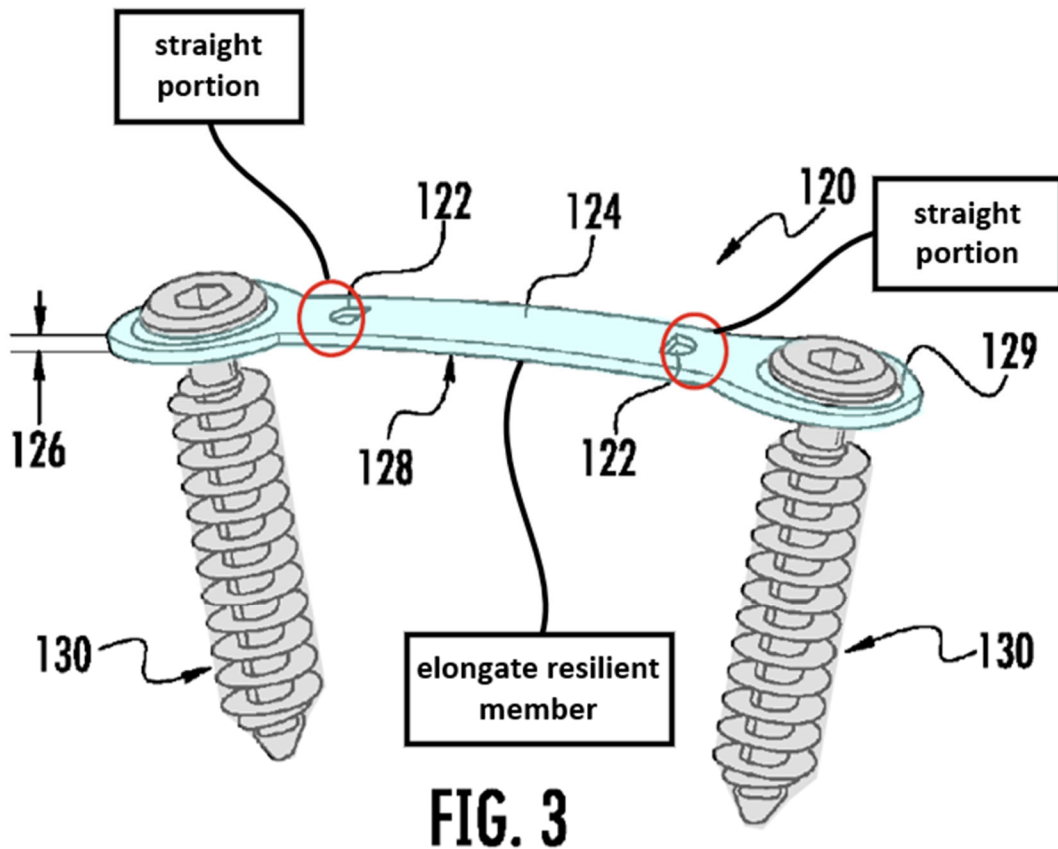
Accordingly, Hartdegen discloses claim 9.

CLAIM 10

136. Claim 10 depends from claim 8 and recites that “removing the at least one restraint to permit the elongated resilient member to shift from the loaded configuration toward the unloaded configuration includes changing an angle between two straight portions of the elongated resilient member.”

137. As explained above regarding limitation 8[pre][i], Hartdegen discloses a loaded configuration where its implant 120 has a straight shape and an unloaded configuration where its implant 120 has a bent shape. The angle between the bone anchor receiving portions of the implant 120 and adjacent straight portions of the elongate resilient member changes when the implant shifts from the straight (loaded) configuration to the bent (unloaded) configuration.

138. Hartdegen discloses the recited “two straight portions” of the elongated resilient member, as seen in annotated Figure 3 below.



139. “FIG. 3 shows the implant 120 in a possible free-state or implanted-state of the device” and “shows the implant 120 having an arc or radius 128 while in its second configuration” at bridge member 124. Ex. 1005 ¶117; Ex. 1007, 11. As seen in annotated Figure 2B of Hartdegen below, portions of bridge member 124 (elongate resilient member—teal) remain straight in the loaded and unloaded conditions, as the tubes 102a, 102b act on those portions, keeping them generally straight, when bending bridge member 124.

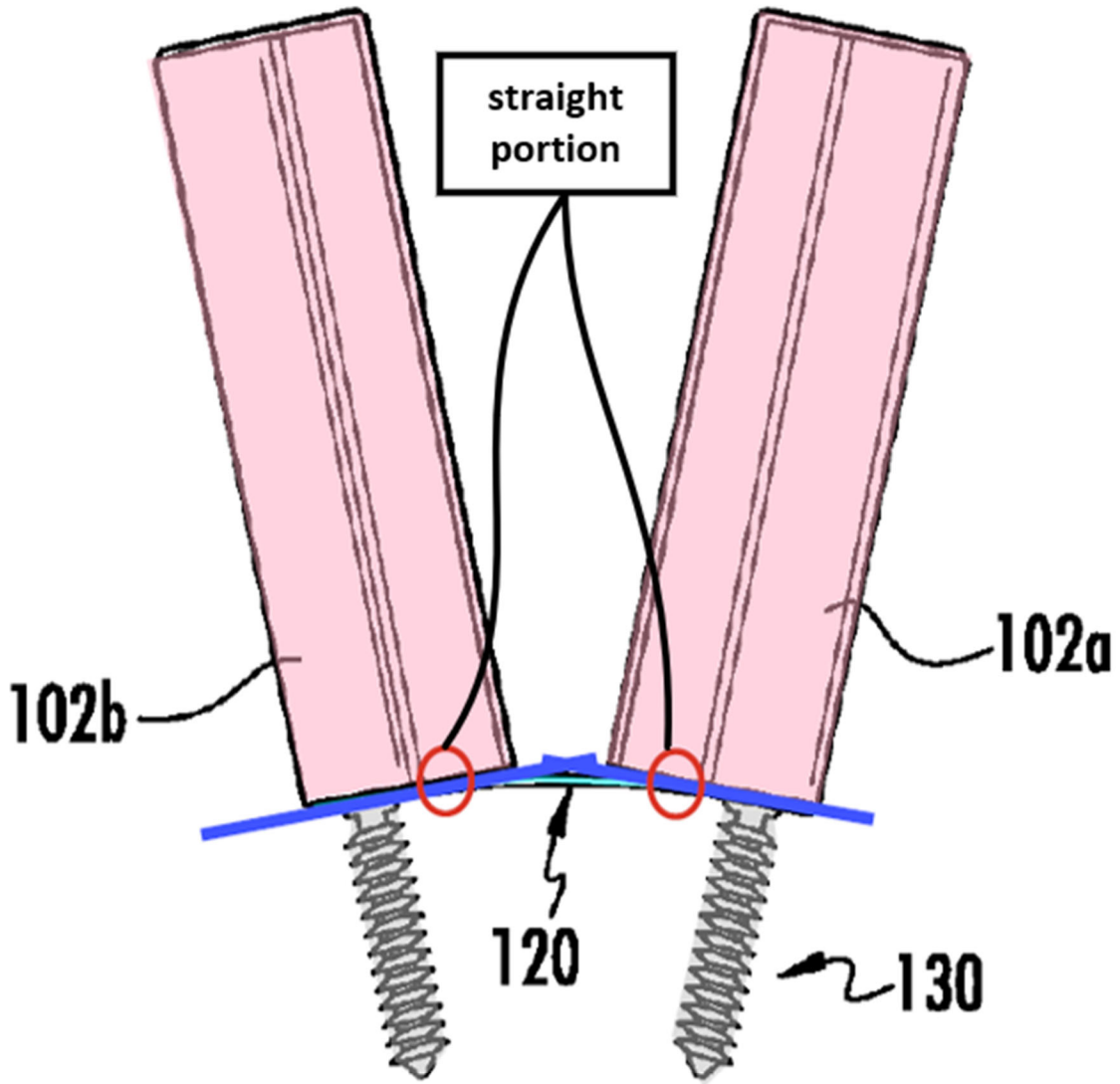


FIG. 2B

As seen in the annotated Figure 2B above, the blue lines circled in red indicate the straight portions of Hartdegen's elongate resilient member when it is in the unloaded (bent) configuration.

140. These portions remain straight because of how the tubes engage the implant. As depicted in Figures 1E and 2B, the distal end of each tube 102a, 102b is flat and bears against the upper surface of the implant over the tube's footprint. The segment of the implant beneath each tube is supported by that flat face and moves with the tube as a unit, so bending is concentrated in the unsupported span of bridge member 124 between the two tubes. A POSA would therefore understand that, as the implant moves between its flat and bent configurations, the two tube-supported segments remain generally straight while the angle between them changes as the intervening span bends.

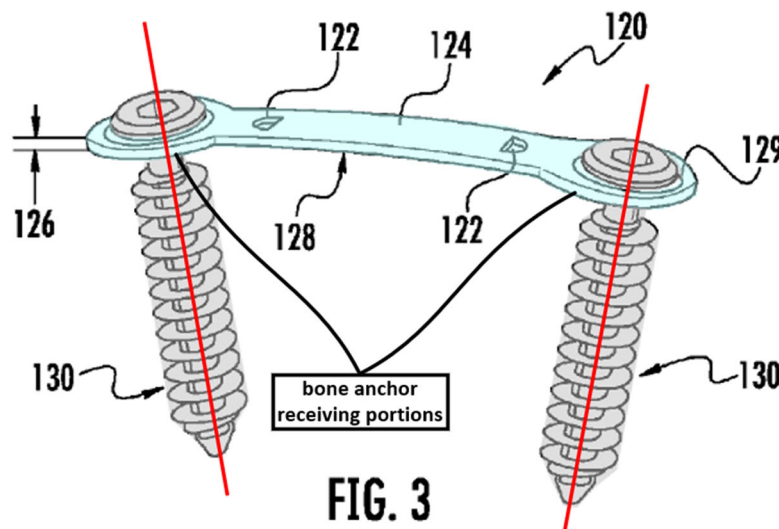
141. For the same reasons discussed above for limitations 8[d][i] and 8[d][ii], removing the at least one restraint causes the elongated resilient member to shift from the loaded configuration toward the unloaded configuration, thereby changing an angle between the two straight portions of the implant 120. Hartdegen discloses claim 10.

CLAIM 11

142. Claim 11 depends from claim 8 and recites that “the bone anchor receiving portions each have a through opening for receiving a bone screw and a central axis of the through opening, the bone compression device including a longitudinal axis intersecting the central axes of the through openings when the bone

anchor receiving portions are in the first configuration and the second configuration.”

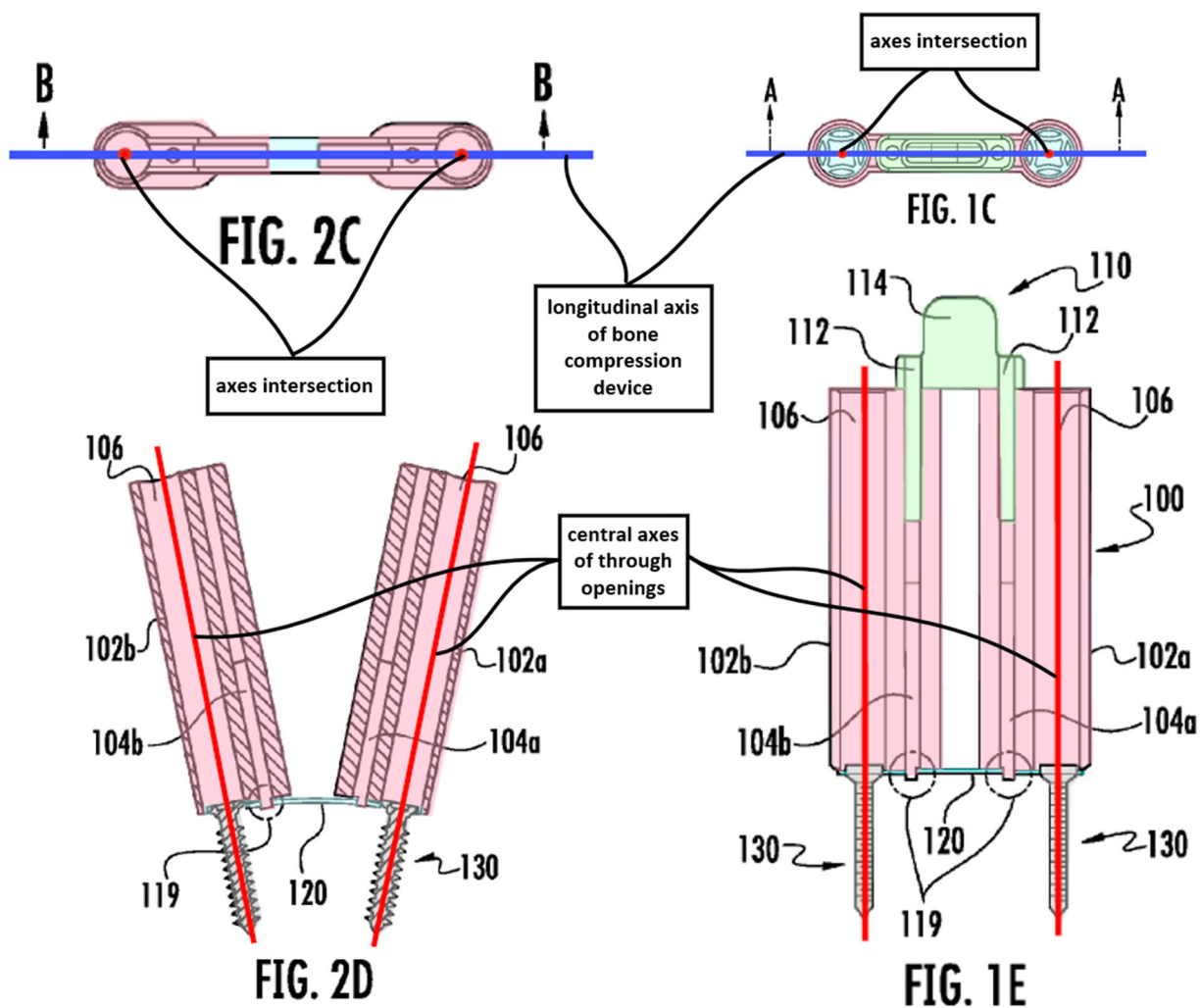
143. Annotated Figure 3 of Hartdegen below shows the bone anchor receiving portions of its implant 120 (bone compression device—teal).



144. The bone screws 130 (bone anchors—gray) are located in the through openings of the bone anchor receiving portions. The central axes (red lines) of the through openings are intersected by the longitudinal axis (blue line) of the implant 120 (bone compression device—teal) in both the first and second configurations recited in the claim, as illustrated below.

145. Hartdegen’s tube members 102a and 102b are aligned with the bone anchor receiving openings so that drills and bone screws can pass through the internal diameters 106 and into the corresponding openings. Ex. 1005 ¶¶111–117, Ex. 1007, 9–11. Annotated versions of Hartdegen’s Figures 2C and 2D, provided

below, illustrate the intersecting axes in the first configuration recited in the claim and annotated versions of Hartdegen's Figures 1C and 1E, provided below, illustrate the intersecting axes in the second configuration recited in the claim.



146. As seen above, in both the first and second configurations, Hartdegen's implant 120 through hole central axes (red lines) intersect its longitudinal axis (blue line). Hartdegen discloses claim 11.

CLAIM 12

147. Claim 12 depends from claim 8 and recites that “permitting the at least one restraint to hold the bone anchor receiving portions in the second configuration includes permitting the at least one restraint to extend intermediate the bone anchor receiving portions and removing the at least one restraint includes removing the at least one restraint from being intermediate the bone anchor receiving portions.”

148. Hartdegen discloses claim 12 as seen in annotated Figure 1E of Hartdegen below.

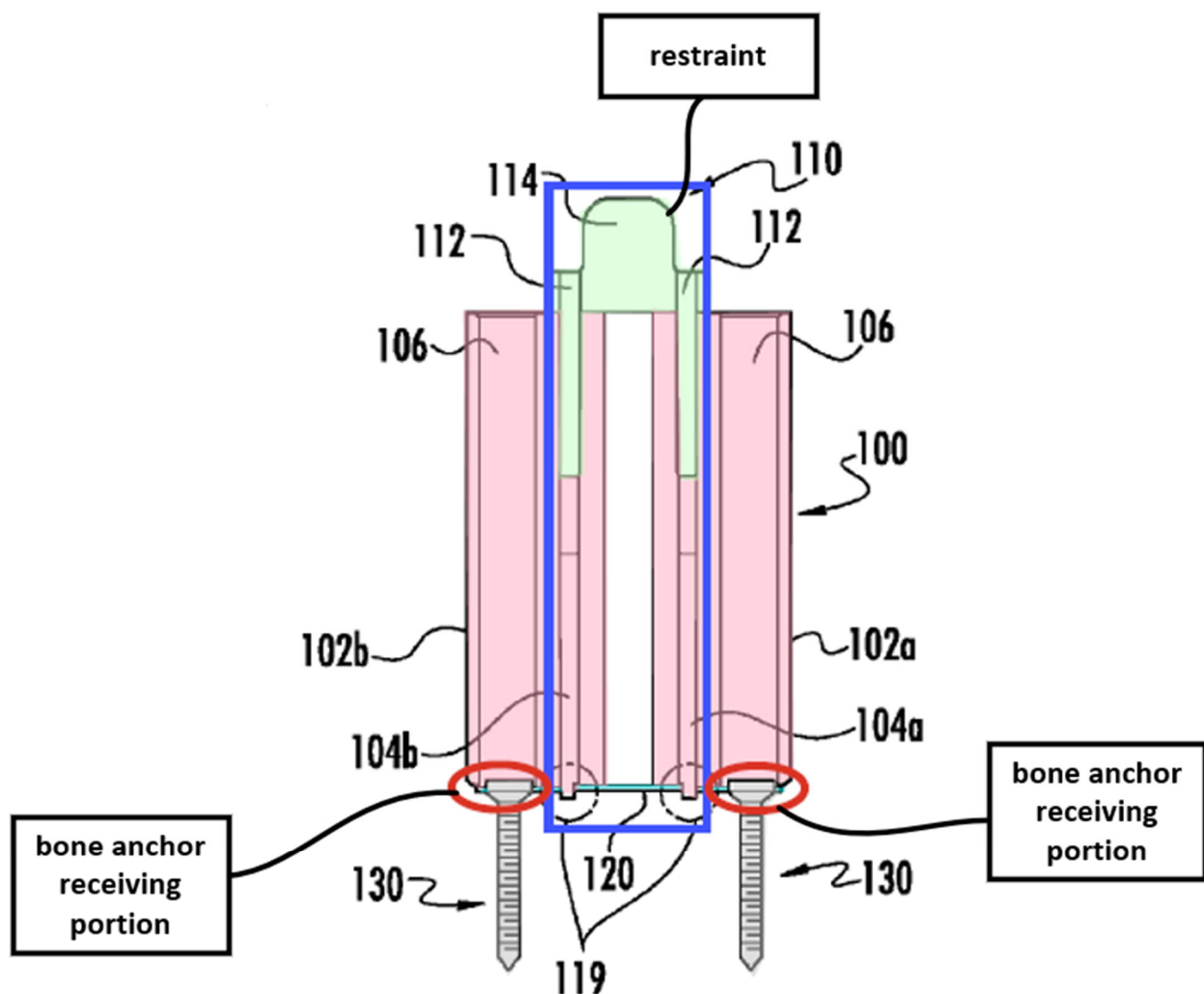


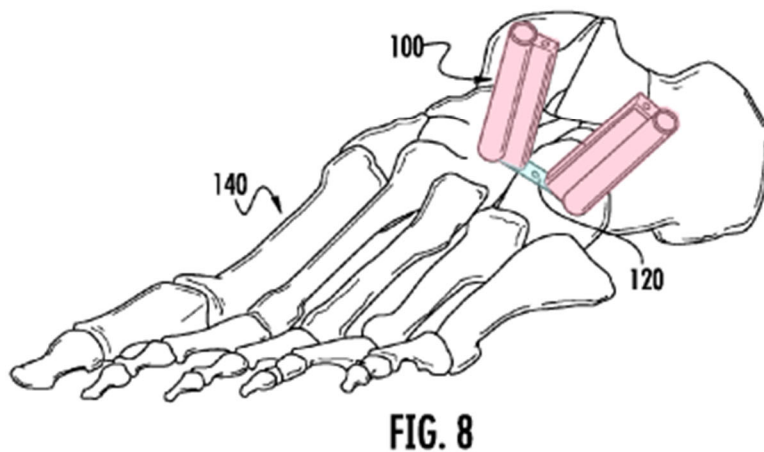
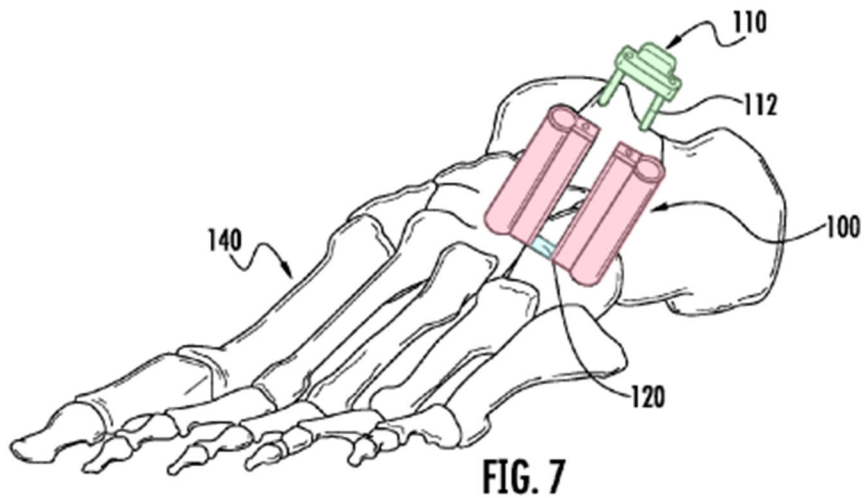
FIG. 1E

149. As discussed for claim 8, Hartdegen’s clip 110 (green) corresponds to the claimed “at least one restraint.” Ex. 1005 ¶¶111–117; Ex. 1007, 9–11. Hartdegen discloses that implant 120 is temporarily connected to two independent inserter tube members 102a, 102b (pink). Ex. 1005 ¶¶111–117; Ex. 1007, 9–11. Hartdegen further discloses that clip 110 holds tubes 102a and 102b in relative position to each other,

thereby maintaining implant 120 in its loaded configuration. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11.

150. As seen above, Hartdegen’s clip 110 (restraint–green) is positioned intermediate (location outlined in blue) the bone-anchor receiving portions (the regions outlined in red). Clip 110 (restraint–green) spans between and connects the two tube members 102a and 102b, which are respectively connected to opposite bone anchor receiving portions of implant 120. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11. Thus, when clip 110 holds the tube members in relative position, it extends intermediate the bone anchor receiving portions and maintains those portions in the loaded configuration.

151. Hartdegen also discloses that removal of the restraint includes removing the restraint from being intermediate the bone-anchor receiving portions. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11. Hartdegen explains that Figure 7 depicts the first removal step for the embodiment and specifically shows removal of clip 110 from inserter 100 while implant 120 is in its final position on bone and in its first configuration. Ex. 1005 ¶115; Ex. 1007, 11. Hartdegen then explains that removal of clip 110 (restraint–green) allows implant 120 (bone compression device–teal) to adapt to a second configuration while the implant 120 remains in its final implant position. Ex. 1005 ¶115; Ex. 1007, 11.

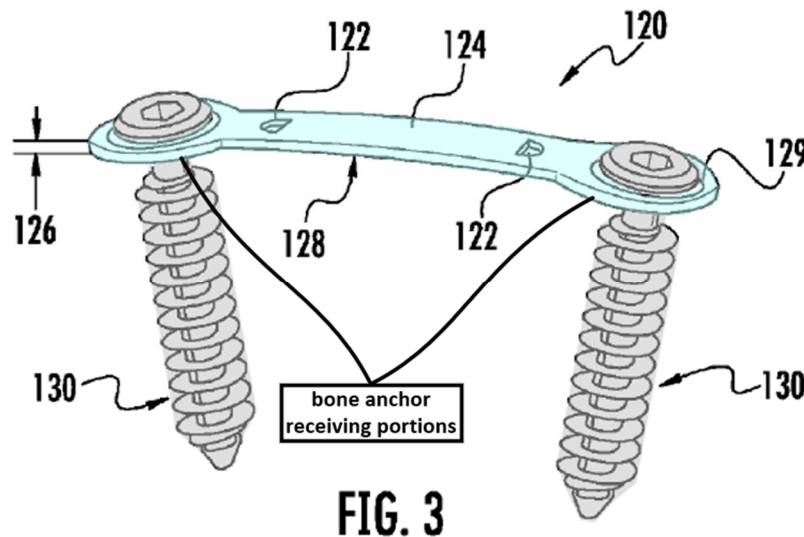


152. Because clip 110 (restraint-green) is the structure extending between the two tube-connected bone anchor receiving portions, removing clip 110 from inserter 100 (pink) removes the restraint from the intermediate position between those bone-anchor receiving portions. Ex. 1005 ¶115; Ex. 1007, 11. Once clip 110 is removed, the restraint no longer holds tubes 102a and 102b in their fixed relative

position, and implant 120 is permitted to shift toward its unloaded configuration. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11. Therefore, Hartdegen discloses claim 12.

CLAIM 13

153. Claim 13 depends from claim 8 and recites “seating heads of the bone screws against unthreaded surfaces of the bone anchor receiving portions.” Hartdegen discloses seating the heads of the bone screws against surfaces of the implant’s screw-receiving portions. For example, annotated Figure 3 (below) depicts bone screws 130 (gray) inserted into implant 120 through the openings of the bone anchor receiving portions. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11.



154. As seen below in the annotated top view from Figure 1C without the bone screws inserted, the bone anchor receiving portions where the bone screw heads seat are unthreaded as recited in the claim.

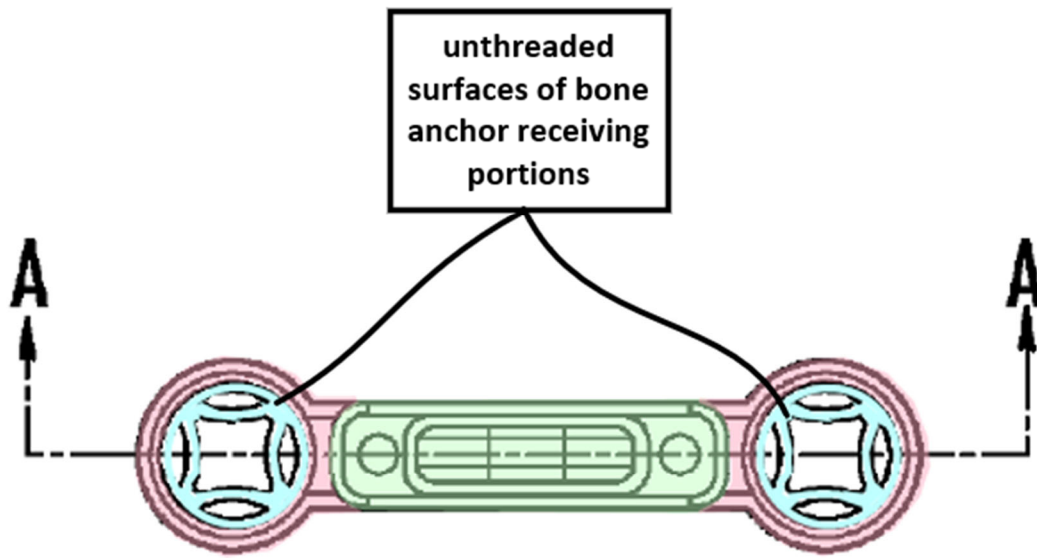


FIG. 1C

Hartdegen explains that “[t]he attachment feature 129 is such that it allows the bone attachment device [130] to be locked to the material that may have elastic properties.” Ex. 1005 ¶117; Ex. 1007, 11.

155. Annotated Figure 9 of Hartdegen below shows implant 120 on bone 140 after removal of the inserter assembly 100 with the implant 120 is in its final position. Ex. 1005 ¶115; Ex. 1007, 11.

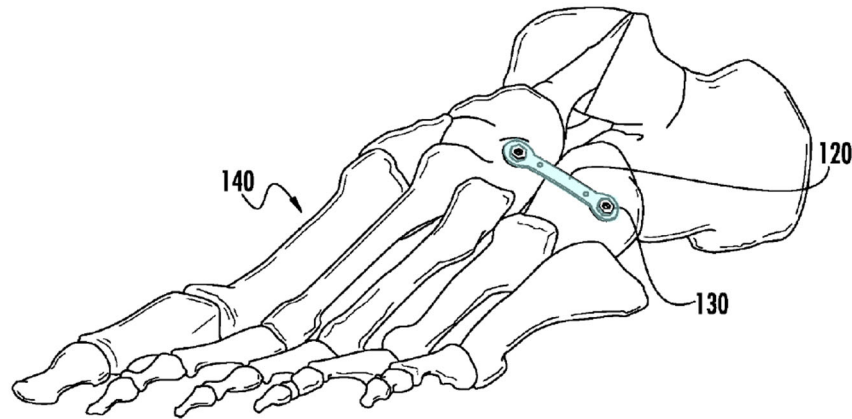


FIG. 9

156. When the implant 120 (bone compression device—teal) is in its final position shown above, the heads of bone screws 130 seat against corresponding upper surfaces of the implant 120's bone-anchor receiving portions to secure the implant 120 to bone. Ex. 1005 ¶¶111–117; Ex. 1007, 9–11. Hartdegen, therefore, discloses claim 13.

CLAIM 14

157. Claim 14 is an independent claim that includes limitations recited in claims 7 and 8 as set forth in the table below.

Claim 14		
Claim 14 Limitation	Corresponding Limitation	Claim 14
14[pre]	8[pre]	A method of applying a bone compression device to bones,
14[pre][i]	8[pre][i]	the bone compression device including bone anchor receiving portions and an elongated resilient member, the bone anchor receiving portions having a first configuration which places the elongated resilient member in an unloaded configuration wherein the elongated resilient member has either a bent or a straight

		shape, the bone anchor receiving portions having a second configuration which places the elongated resilient member in a loaded configuration wherein the elongated resilient member has the other of the bent or straight shape, the method comprising:
14[a]	8[a]	positioning the bone compression device against the bones with the bone anchor receiving portions in the second configuration and the elongated resilient member in the loaded configuration;
14[b]	8[b]	permitting at least one restraint to hold the bone anchor receiving portions in the second configuration, the holding of the bone anchor receiving portions in the second configuration maintaining the elongated resilient member in the loaded configuration;
14[c]	8[c]	driving shanks of bone screws through opening of the bone anchor receiving portions of the bone compression device and into engagement with the bones; and
14[d]	8[d][i], 8[d][ii]	removing the at least one restraint to permit the elongated resilient member to shift from the loaded configuration toward the unloaded configuration and urge the bone anchor receiving portions of the bone compression device from the second configuration back toward the first configuration;
14[e]	7[c]	wherein driving shanks of bone screws through openings of the bone anchor receiving portions includes advancing one of the bone screws through a cannula of a tool connected to the bone compression device.

The reasons discussed above regarding the limitations in claims 7 and 8 that correspond to those in claim 14 are incorporated herein by reference.

158. It is noted that limitation 14[d] corresponds to limitation 8[d][i] and 8[d][ii], except that limitation 14[d] uses the term “removing” the restraint, whereas claim 8 recites “disconnecting” the restraint. In this context, “removing” and “disconnecting” should be understood to have the same operative meaning: separating the restraint from the structure it restrains so that the restraint no longer holds the bone-anchor receiving portions in the loaded configuration. Nothing in the claim language or specification suggests that “removing” requires a materially different act than “disconnecting” for purposes of releasing the restraint. Accordingly, claim 14 is disclosed by Hartdegen.

CLAIM 15

159. Claim 15 is an independent claim that includes limitations recited in claims 5, 8, and 14 as set forth in the table below.

Claim 15		
Claim 15 Limitation	Corresponding Limitation	Claim 15
15[pre]	14[pre]	A method of applying a bone compression device to bones,
15[pre][i]	14[pre][i]	the bone compression device including bone anchor receiving portions and an elongated resilient member, the bone anchor receiving portions having a first configuration which places the elongated resilient member in an unloaded configuration wherein the elongated resilient member has either a bent or a straight shape, the bone anchor receiving portions having a second configuration which places the elongated resilient member in a loaded configuration wherein the elongated resilient

		member has the other of the bent or straight shape,
15[pre][ii]	14[b]	wherein at least one restraint holds the bone anchor receiving portions in the second configuration which maintains the elongated resilient member in the loaded configuration, the method comprising:
15[a]	14[a]/8[a]	positioning the bone compression device against the bones with the bone anchor receiving portions in the second configuration and the elongated resilient member in the loaded configuration;
15[b]	14[c]/8[c]	driving shanks of bone screws through opening of the bone anchor receiving portions of the bone compression device and into engagement with the bones; and
15[c]	14[d]	removing the at least one restraint to permit the elongated resilient member to shift from the loaded configuration toward the unloaded configuration and urge the bone anchor receiving portions of the bone compressions device from the second configuration back toward the first configuration;
15[d]	5[c]	wherein the elongated resilient member has first and second portions extending transversely to each other with the elongated resilient member in one of the loaded configuration and the unloaded configuration; and
15[e]	5[c]	wherein the first and second portions of the elongated resilient member are coaxial with each other with the elongated resilient member in the other of the loaded configuration and the unloaded configuration.

The reasons discussed above regarding the limitations in claims 5, 8, and 14 that correspond to those in claim 15 are incorporated herein by reference. Accordingly, claim 15 is disclosed by Hartdegen.

CLAIM 16

160. Claim 16 depends from claim 15 and adds the same limitations recited in claim 9. Thus, claim 16 is disclosed by Hartdegen for the reasons stated for claim 9.

CLAIM 17

161. Claim 17 depends from claim 15 and adds limitations similar to those recited in claim 10, but does not require that the first and second portions are straight portions as required by claim 10. Thus, claim 17 is disclosed by Hartdegen for the reasons stated for claim 10.

162. Further, as explained for limitations 15[d] and 15[e], Hartdegen discloses first and second portions of implant 120 that are coaxial with each other when implant 120 is in the flat, loaded configuration shown in Figure 1E and that extend transversely to each other when implant 120 assumes the bent, unloaded configuration shown in Figures 2B and 3. See Ex. 1005 ¶¶111–117; Ex. 1007, 9–11.

163. Hartdegen further discloses that removal of clip 110 permits implant 120 to shift from the flat configuration toward the bent configuration. In shifting between those configurations, the angle between the identified first and second portions changes from the coaxial relationship shown in Figure 1E to the transverse relationship shown in Figures 2B and 3. Therefore, Hartdegen discloses claim 17 for this reason as well.

CLAIM 18

164. Claim 18 depends from claim 15 and adds the same limitations recited in claim 11. Thus, claim 18 is disclosed by Hartdegen for the reasons stated for claim 11.

CLAIM 19

165. Claim 19 depends from claim 15 and adds the same limitations recited in claim 12. Thus, claim 19 is disclosed by Hartdegen for the reasons stated for claim 12.

166. For at least the reasons discussed above, claims 1–19 are anticipated by Hartdegen.

IV. OBVIOUSNESS OF CLAIMS 1–19 OVER HARTDEGEN IN VIEW OF ORBAY

CLAIM 1

167. Hartdegen teaches the limitations of claim 1 for the reasons discussed above in Section III. As discussed above regarding limitation 1[b][i], however, to the extent Patent Owner contends that Hartdegen’s engagement features 119 are outside of the bone anchor receiving portions and/or that a direct connection is required at the bone anchor receiving portions of the implant 120, Hartdegen expressly states that “[t]he means of attaching the plate to the inserter . . . could occur anywhere on or around the periphery of the plate.” Ex. 1005 ¶111; Ex. 1007, 9.

168. A POSA would have understood this as disclosing one option for the attachment location being at the bone anchor receiving portions of the bone plate (e.g., around the periphery of the bone anchor receiving portions).

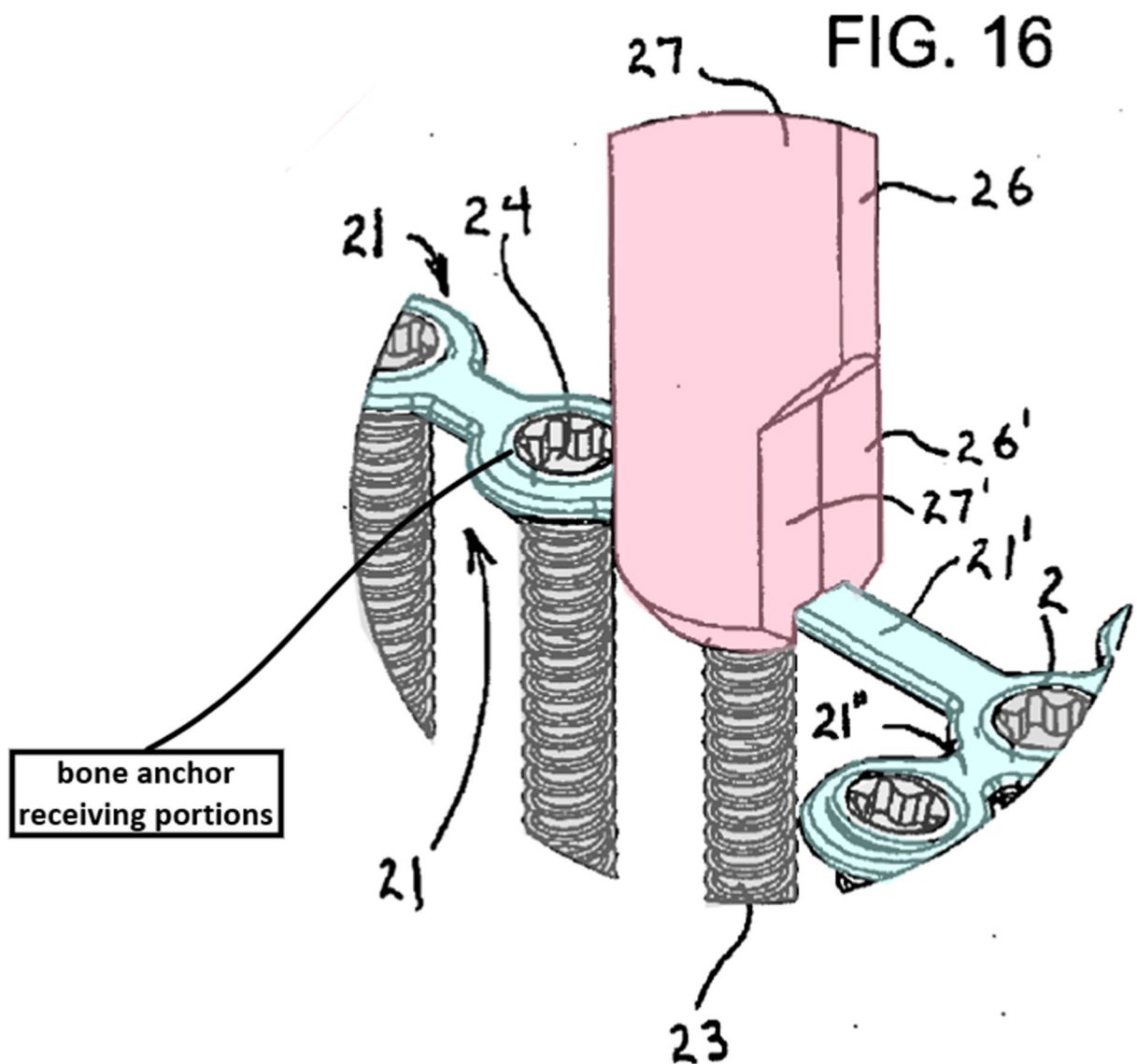
169. To the extent the disclosure of Hartdegen noted above does not expressly disclose a connection at bone anchor receiving portions, such an arrangement would have been obvious, as Hartdegen discloses that the attachment location is a design choice that can be made anywhere on or around the plate's periphery.

170. A POSA would have recognized the bone anchor receiving portions as one of a finite number of identified, predictable locations for this attachment, with a reasonable expectation that doing so would successfully enable the inserter to flex and manipulate the plate as intended. The modification would have been the application of a known technique (attaching the inserter at a peripheral location) to a known device (the bone plate) in an obvious manner to achieve a predictable result. This also would have been obvious because selecting the bone anchor receiving portions as the attachment point, rather than another peripheral location, amounts to no more than a predictable design choice among a limited set of known options expressly contemplated by Hartdegen, yielding no unexpected results.

171. The locations for attaching Hartdegen's tubes to the plate are the bridge (as illustrated), the sides of the plate, and the screw-receiving end portions. Of these,

a POSA would have regarded the end portions as an obvious choice. First, gripping the ends applies the bending moment across the full length of the bridge, which is the portion Hartdegen intends to flex (Ex. 1005 ¶¶111, 117). Second, each tube already must sit over a screw hole to serve as a drill and screw guide (id. ¶111), so gripping at that location co-locates the grip with the guide and makes alignment of tube and screw hole automatic. Third, the end portions are the most robust portions of the plate, and gripping them leaves the bridge free of engagement features.

172. Such an arrangement also would have been obvious in view of Orbay, which teaches tools for deforming a bone plate. An annotated version of Figure 16 from Orbay is reproduced below.



173. Orbay teaches a bone plate (teal) with bone anchor receiving portions that have openings that receive bone screws (gray). Ex. 1008 ¶62 (“a bone plate 1 . . . having a plate body with . . . nodes . . . and may be linear, T-shaped, L-shaped, Y-shaped, arched, curved or any combination of shapes.”). Orbay explains that “[t]he nodes 2 each have an inner surface 4, which can be . . . shape[d] as required for

seating or engaging the complementarily shaped head of a screw, surrounding a hole 5 for permitting passage of the shaft of a screw 23.” Id.

174. Orbay teaches deforming its bone plate with its clamps (pink). Ex. 1008 ¶73 (“Rotating or torqueing (sic) the second clamp generates bending forces which cause bending or formation of the plate in the direction of any of the X, Y, and/or Z axes.”), ¶74 (“The plates . . . have the advantage of being able to be formed by the surgeon to match the patient’s anatomical circumstances before application, during application or after being partially or fully affixed ‘in-situ’ and fit common reconstructive clinical needs and present dedicated deformable sections for correction adjustment.”).

175. Orbay explains that “first clamp 20, 40, 50 is opened, then placed circumferentially around a node” and “[t]hen, a second clamp 20, 40, 50 is opened and secured in a similar way to a second node.” Ex.1008 ¶73. The clamps form the body recited in claim 1. Annotated Figures 15 and 16 below provide one example of the body (clamp–pink).

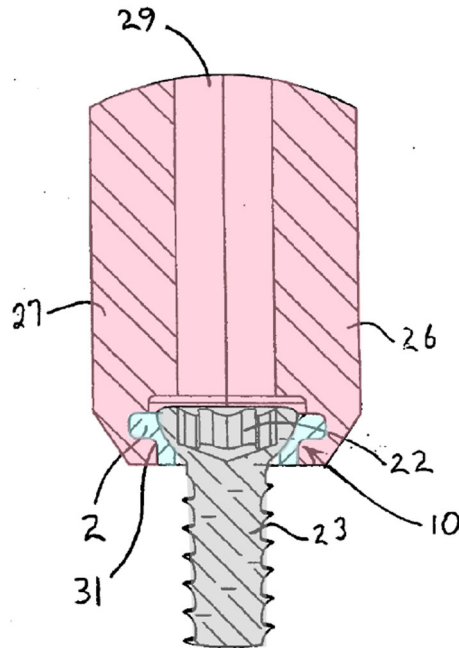


FIG. 20

Orbay explains that “clamp 20 . . . is placed over, and engages with, a node 2, thus receiving a head 22 of a screw 23 passing through a hole 5 in one of the nodes 2.” Ex. 1008 ¶65. As seen above, Orbay’s “clamping jaws 26, 27 engage a node 2 nested therein by gripping the annular or circumferential step 10.” Id. ¶67.

177. As discussed above, Hartdegen teaches that the specific attachment mechanism shown in its first embodiment is not limiting: although engagement pins are illustrated, “the use of other attachment means will be obvious,” and the means of attaching the plate to the inserter “could occur anywhere on or around the periphery of the plate.” Ex. 1005 ¶111; Ex. 1007, 9. Orbay supplies the known alternative attachment at the periphery of the bone anchor receiving portions as noted above.

178. In my opinion, combining Hartdegen and Orbay would have been no more than the predictable use of a known bone plate/instrument engagement structure to improve a similar bone-plate insertion system. Orbay expressly teaches that its clamp bodies are constructed to “mate with the plate geometry and selectively and securely hold the nodes of a plate.” Ex. 1008 ¶¶10, 74.

179. A POSA would have recognized that protrusions from a bone plate received by complementary mating geometries in clamps (bodies—pink), as taught by Orbay, provide a secure, repeatable connection between the body and the bone plate, improve stability during plate manipulation, and maintain alignment between internal diameters of the clamps and the screw-receiving openings of the bone plate.

180. In Hartdegen’s illustrated embodiment, pins 104a, 104b engage features 119 in the bridge. Ex. 1005 ¶111. Gripping the plate at its ends leaves the bridge uninterrupted. It also co-locates the screw hole with the cannula. Each tube already must sit directly over a screw hole to work as a drill and screw guide (id.). Gripping the plate at that same location makes alignment self-registering: the tube cannot be seated on the screw-receiving portion unless its cannula is aligned with the screw hole.

181. Gripping each end of the plate and pivoting the tubes applies a bending moment across the entire intermediate portion. That is the portion Hartdegen intends to flex. Ex. 1005 ¶¶111, 117. Orbay teaches a known way to grip a screw-receiving

node so that rotating the instrument bends the plate. Ex. 1008 ¶¶67, 73. Its jaws engage both the top of the node and the underside of the circumferential step, so that when the instrument is torqued one surface bears down while the other pulls up, and its drill guide hole passes through the center of the jaws, aligned with the node's screw hole. Id. ¶¶65, 67, Fig. 20. A POSA designing or modifying an inserter for Hartdegen's plate would therefore have looked to Orbay's node-gripping geometry as a proven way to transmit that moment at the plate ends while keeping the guide aligned with the screw hole.

182. A POSA also would have recognized the clamping arrangement from Orbay discussed above as one of the alternative attachment arrangements contemplated by Hartdegen. In addition to Hartdegen expressly contemplating that “[t]he means of attaching the plate to the inserter is shown on the bridge area of the plate, but could occur anywhere on or around the periphery of the plate” (Ex. 1005 ¶111; Ex. 1007, 9), Hartdegen also contemplates a sidewall receiving structure in another embodiment, seen in Figure 30 below, that would be compatible with Orbay's stepped bone plate structure.

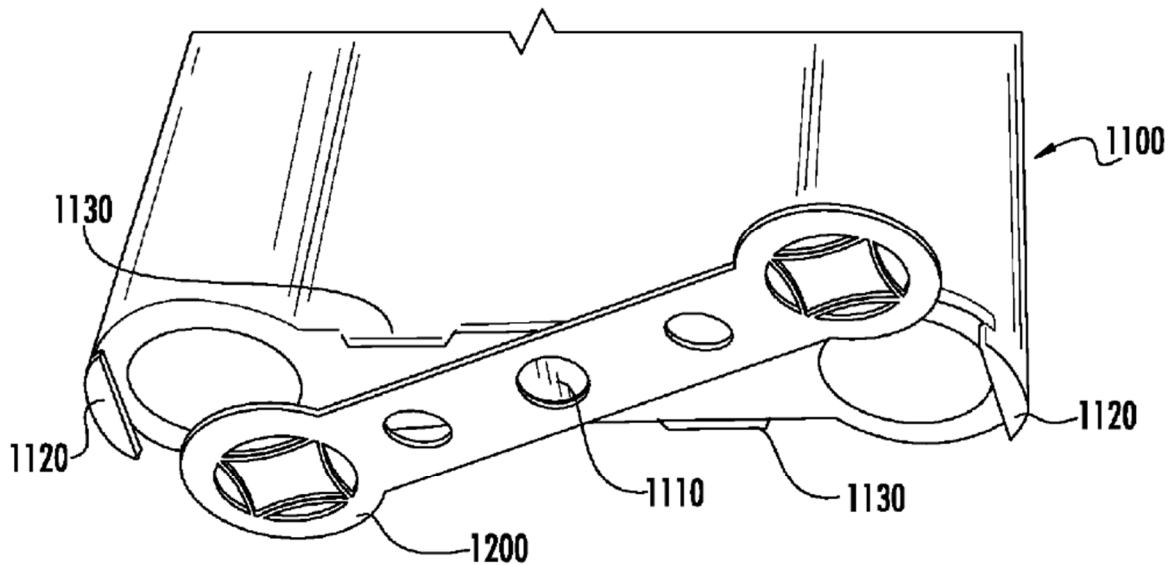


FIG. 30

183. The “means 1120 . . . for attaching to the implant” (Ex. 1005 ¶133; Ex. 1007, 16) has a similar stepped structure as Orbay’s clamp as seen in annotated Figure 20 above. It would have been obvious to include features like Hartdegen’s “means 1120” on each of its inserter tubes 102a, 102b as a known alternate attachment means that would facilitate use of the stepped profile bone plate to incorporate its benefits of minimizing tissue damage while also taking advantage of the engagement structure enabling bone plate forming as taught by Orbay. In my opinion, claim 1 would have been obvious in view of the combined teachings of Hartdegen and Orbay.

CLAIM 2

184. Claim 2 is disclosed at least for the reasons stated above. Thus, claim 2 would have been obvious over the combined teachings of Hartdegen and Orbay.

CLAIM 3

185. The additional limitations recited in claim 3 are taught by Hartdegen for the reasons discussed above. To the extent Patent Owner contends that Hartdegen does not expressly disclose “engaging a tool with one of the bone anchor receiving portions,” claim 3 would have been obvious for the reasons discussed above regarding claim 1. Accordingly, claim 3 would have been obvious over the combined teachings of Hartdegen and Orbay.

CLAIM 4

186. The additional limitations recited in claim 4 are taught by Hartdegen for the reasons discussed above. To the extent Patent Owner contends that Hartdegen does not expressly disclose “engaging tools with one of the bone anchor receiving portions,” claim 4 would have been obvious for the reasons discussed above regarding claim 1. Accordingly, claim 4 would have been obvious over the combined teachings of Hartdegen and Orbay.

CLAIM 5

187. Hartdegen teaches claim 5’s preloading method, including application of the restraint and reconfiguration of the first and second portions between

transverse and coaxial relationships, for the reasons I discuss above regarding claim 5 in Section III.

188. To the extent the bone anchor receiving portions are construed to require the tool-to-plate engagement discussed above regarding claim 1 in this Section, that engagement would have been obvious in view of Hartdegen and Orbay for the reasons I explain there. The modification retains Hartdegen's resilient implant 120, tubes 102a/102b, and clip 110, and does not change the transverse-to-coaxial reconfiguration discussed above regarding limitation 5[c]. Accordingly, in my opinion, claim 5 would have been obvious over the combined teachings of Hartdegen and Orbay.

CLAIM 6

189. Claim 6 is independent and would have been obvious for the reasons I discuss above. Hartdegen teaches the features recited in claim 6, but to the extent there is a dispute as to whether Hartdegen teaches "engaging a first tool with one of the bone anchor receiving portions and engaging a second tool with the other of the bone anchor receiving portions," such an engagement would have been obvious as I have previously explained. Therefore, in my opinion, claim 6 would have been obvious over the combined teachings of Hartdegen and Orbay.

CLAIM 7

190. Hartdegen teaches claim 7's preloading and restraint steps, and its tubes 102a/102b have cannulas sized to pass bone screws into the implant openings, for the reasons I discuss above regarding claim 7 in Section III. To the extent claim 7 requires the distal end portion of the cannulated tool to connect at a bone anchor receiving portion, the peripheral engagement taught by Orbay would have been an obvious attachment for Hartdegen's tubes for the reasons discussed above regarding claim 1 in this Section.

191. The proposed modification retains Hartdegen's tube and its internal diameter 106, with that cannula aligned with the corresponding screw-receiving opening. Accordingly, in my opinion, claim 7 would have been obvious over the combined teachings of Hartdegen and Orbay.

CLAIM 8

192. Claim 8 is independent and would have been obvious for the reasons I have previously discussed. Hartdegen teaches the features recited in claim 8, but to the extent there is a dispute as to whether Hartdegen teaches "a body connected to one of the bone anchor receiving portions," such a connection would have been obvious as I have explained above. In my view, therefore, claim 8 would have been obvious over the combined teachings of Hartdegen and Orbay.

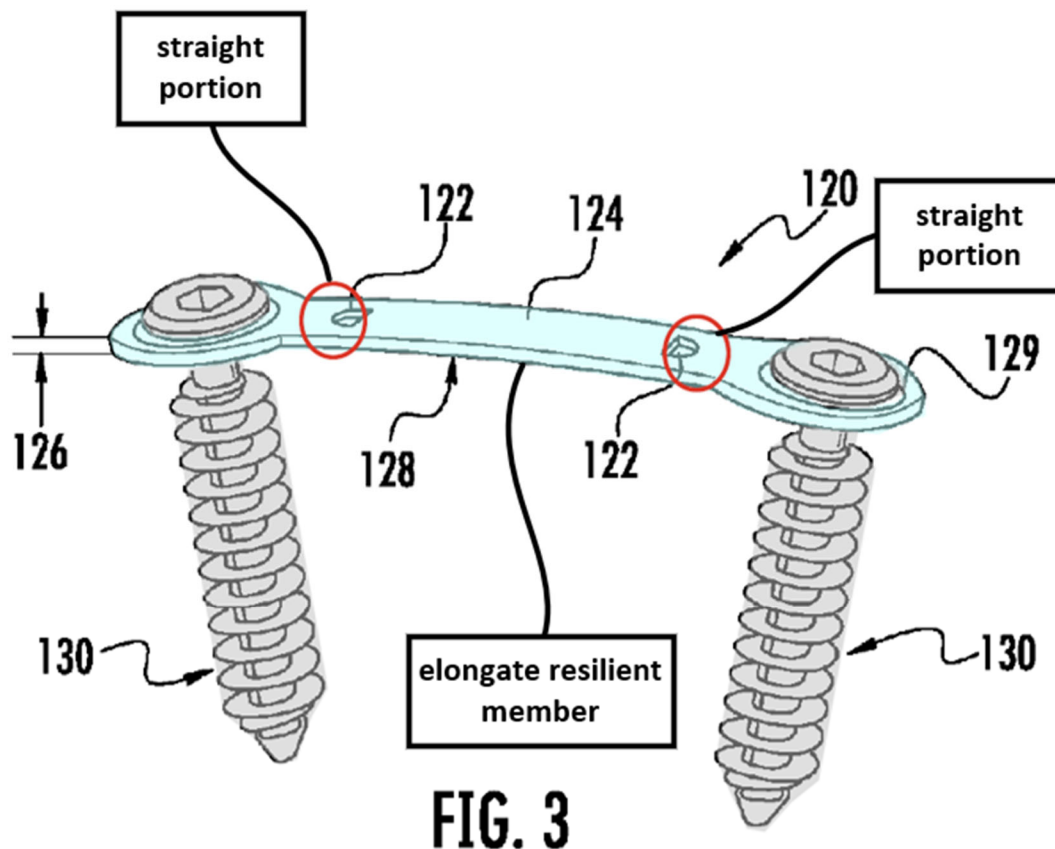
CLAIMS 9, 11, AND 12

193. Claims 9, 11, and 12 depend from claim 8. The additional limitations recited in claims 9, 11, and 12 are taught by Hartdegen at least for the reasons stated above. Accordingly, claims 9, 11, and 12 would have been obvious over the combined teachings of Hartdegen and Orbay.

CLAIM 10

194. Claim 10 depends from claim 8 and recites that “removing the at least one restraint to permit the elongated resilient member to shift from the loaded configuration toward the unloaded configuration includes changing an angle between two straight portions of the elongated resilient member.” As discussed above, Hartdegen teaches the features recited in claim 10, but to the extent there is a dispute as to whether Hartdegen teaches “changing an angle between two straight portions of the elongated resilient member,” such a configuration and resulting angular change would have been obvious.

195. As discussed above regarding claim 10 in Section III, Hartdegen discloses the recited “two straight portions” of the elongated resilient member, as seen in annotated Figure 3 below.



196. “FIG. 3 shows the implant 120 in a possible free-state or implanted-state of the device” and “shows the implant 120 having an arc or radius 128 while in its second configuration” at bridge member 124. Ex. 1005 ¶117; Ex. 1007, 11. As seen in annotated Figs. 1E and 2B of Hartdegen below, portions of bridge member 124 (elongate resilient member—teal) remain straight in the loaded and unloaded conditions, as the tubes 102a, 102b act on those portions, keeping them generally straight, when bending bridge member 124, as seen in annotated Figure 2D below.

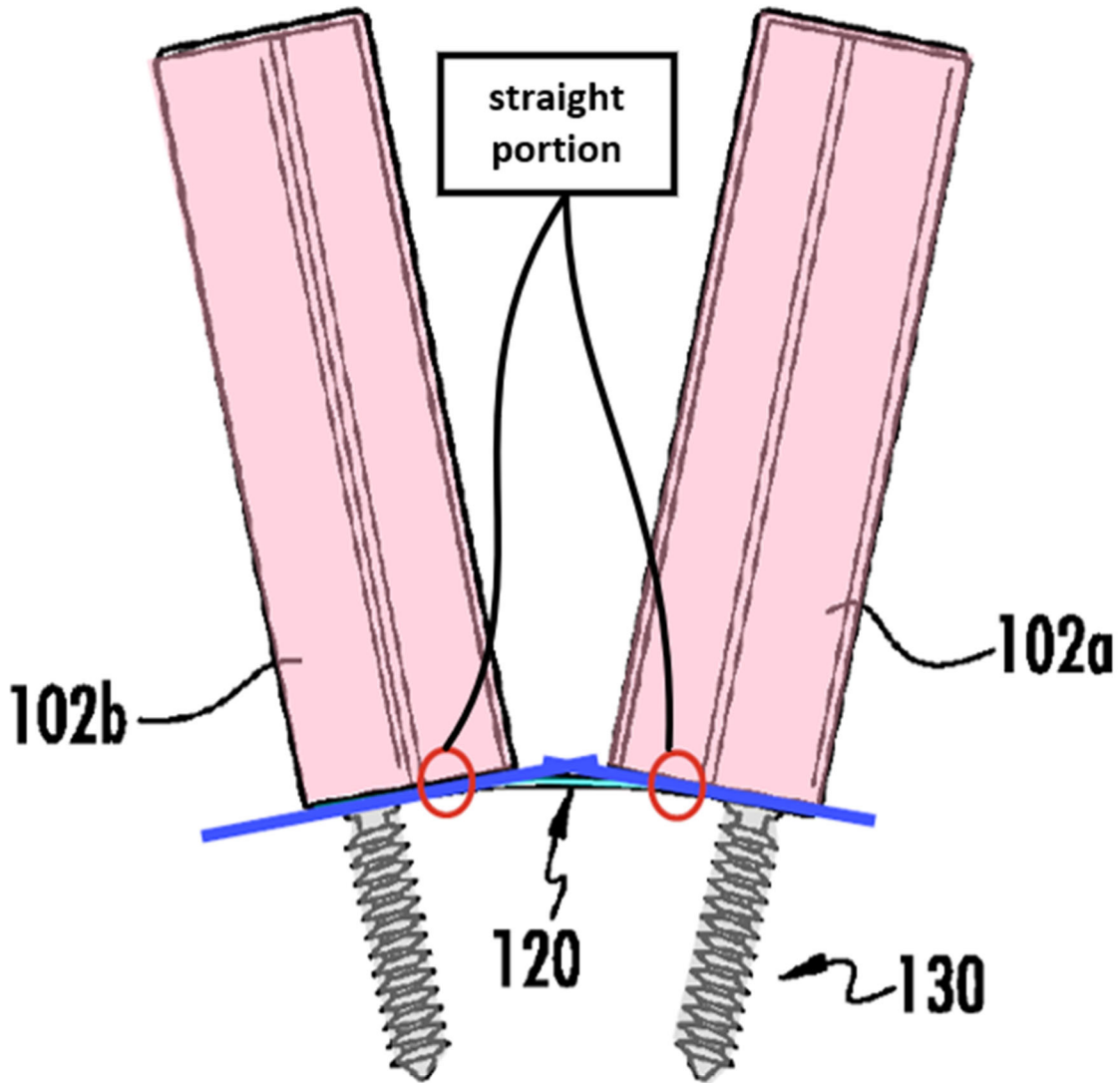


FIG. 2B

197. As discussed above in connection with claim 1, it would have been obvious to use an engagement with bone anchor receiving portions like that taught by Orbay. As noted above, Hartdegen discloses that the attachment location is a

design choice that can be made anywhere on or around the plate's periphery, and a POSA would have recognized the bone anchor receiving portions as one of a finite number of identified, predictable locations for this attachment, with a reasonable expectation that doing so would successfully enable the inserter to flex and manipulate the plate as intended.

198. Locating the tube-to-implant interfaces at the periphery of the implant (e.g., from the area surrounding engagement holes 122 to the bone anchor receiving portions) would constrain and manipulate those end portions while deformation is concentrated in the intervening bridge region, consistent with Orbay's teaching of bending at an internode between tool-engaged nodes.

199. Moreover, Orbay teaches bone plates having relatively rigid plate portions connected by dedicated bendable internode or neck portions. Orbay explains that its bendable internode and neck permit adjustment of the "angle of correction" and that its plates include "dedicated deformable sections for correction adjustment." Ex. 1008 ¶¶11–13.

200. As shown in Orbay's Figure 16, the legs (e.g., 21') connecting Orbay's screw-receiving nodes 2 are narrower than the nodes themselves, and Orbay describes these internodes as providing "an area more easily deformed." Ex. 1008 ¶5. A POSA would understand that narrowing the portion between the nodes is what makes it easier to deform. The reduced cross-section concentrates bending in that

portion, while the screw-receiving nodes, which must hold the screws, remain stiffer. Applied to Hartdegen's bridge member 124, the same principle yields first and second straight end portions joined by a localized bending portion.

201. In view of Orbay, a POSA would have had reason to configure Hartdegen's bridge member 124 with first and second straight end portions joined by a localized resilient bending portion. This would apply Orbay's known geometry for controlled angular correction to Hartdegen's known resilient compression plate while retaining Hartdegen's elastic material, tube members 102a and 102b, clip 110, and restraint-release operation.

202. In the loaded configuration, clip 110 would maintain the identified straight portions in a first angular relationship. Upon removal of clip 110, Hartdegen's resilient central portion would return toward its unloaded configuration, changing the angle between the first and second straight portions.

203. In my opinion, a POSA would have reasonably expected this geometry to function in that manner because Orbay expressly teaches concentrating deformation in an internode or neck to adjust the angle between adjoining plate portions, while Hartdegen expressly teaches that its implant returns toward another configuration after release. Claim 10, therefore, would have been obvious over the combined teachings of Hartdegen and Orbay.

CLAIM 13

the seating surface of the bone anchor receiving portion. This is consistent with Hartdegen's disclosure, which does not show or describe any threaded seating surface. Moreover, this would provide improved engagement compared to a threaded engagement at the bone anchor receiving portion, as the unthreaded engagement with the bone plate allows the bone plate to be drawn down to the bone rather than being fixed along the axial extent of the bone screw. Accordingly, claim 13 would have been obvious over the combined teachings of Hartdegen and Orbay.

CLAIM 14

207. Hartdegen teaches claim 14's application method and restraint removal for the reasons I discuss above regarding claim 14 in Section III, including the corresponding analysis of claims 7 and 8. For limitation 14[e], Hartdegen's cannulated tube 102a or 102b remains connected to implant 120 while a screw is advanced through internal diameter 106 into a screw-receiving opening.

208. To the extent connection of that tool at a bone anchor receiving portion is required, the modification I describe above regarding claims 1 and 7 in this Section supplies that connection while retaining the cannula and its alignment with the opening. Hartdegen's clip 110 remains the restraint removed after screw fixation. Accordingly, in my opinion, claim 14 would have been obvious over the combined teachings of Hartdegen and Orbay.

CLAIM 15

209. Hartdegen teaches claim 15's application method, restraint removal, and transverse and coaxial relationships of the first and second portions for the reasons I discuss above regarding claim 15 in Section III, including the analysis of claims 5, 8, and 14 incorporated there.

210. To the extent the claimed bone anchor receiving portions require the engagement addressed above regarding claim 1 in this Section, Orbay supplies that known engagement. That change retains Hartdegen's bent, unloaded implant and straight, loaded implant, so the identified portions retain the transverse and coaxial relationships discussed above regarding limitation 5[c] and claim 15 in Section III.

211. Alternatively, to the extent Hartdegen's bridge member 124 is disputed as providing identifiable portions in the claimed relationships, the first and second portions joined by a localized resilient bending portion discussed above regarding claim 10 in this Section would provide those relationships as the implant moves between its bent and straight configurations. Accordingly, in my opinion, claim 15 would have been obvious over the combined teachings of Hartdegen and Orbay.

CLAIM 16

212. Claim 16 depends from claim 15 and adds the distance-decreasing limitation addressed for claim 9. Hartdegen teaches that limitation for the reasons I discuss above regarding claims 9 and 16 in Section III. Neither the attachment modification discussed above regarding claim 1 in this Section nor the alternative

resilient bending geometry discussed above regarding claim 10 in this Section changes the operation in which removing clip 110 permits the bone anchor receiving portions to move toward one another. Accordingly, in my opinion, claim 16 would have been obvious over the combined teachings of Hartdegen and Orbay.

CLAIM 17

213. Claim 17 depends from claim 15 and requires an angular change between the first and second portions, without claim 10's additional requirement that both portions be straight. Hartdegen teaches that change as the identified portions move from the coaxial, loaded relationship toward the transverse, unloaded relationship upon removal of clip 110, as I discuss above regarding claims 10, 15, and 17 in Section III. To the extent that angular change is disputed, Orbay's localized bending geometry provides the alternative I explain above regarding claim 10 in this Section, applied to claim 15 as I explain above regarding claim 15 in this Section. Accordingly, in my opinion, claim 17 would have been obvious over the combined teachings of Hartdegen and Orbay.

CLAIM 18

214. Claim 18 depends from claim 15 and adds the through-opening and intersecting-axis limitations addressed for claim 11. Hartdegen teaches those limitations for the reasons I discuss above regarding claims 11 and 18 in Section III. The attachment modification discussed above regarding claim 1 in this Section

engages the periphery of the screw-receiving portions while preserving the through openings and their alignment with the implant's longitudinal axis, as required for Hartdegen's guided screw placement. Accordingly, in my opinion, claim 18 would have been obvious over the combined teachings of Hartdegen and Orbay.

CLAIM 19

215. Claim 19 depends from claim 15 and adds the intermediate-restraint limitation addressed for claim 12. Hartdegen's clip 110 occupies and is removed from that intermediate position for the reasons I discuss above regarding claims 12 and 19 in Section III. The attachment modification discussed above regarding claim 1 in this Section changes the tube-to-implant interface, while retaining the clip between the tubes and its removal during the claimed method. Accordingly, in my opinion, claim 19 would have been obvious over the combined teachings of Hartdegen and Orbay.

REASONABLE EXPECTATION OF SUCCESS

216. In my opinion, a POSA would have had a reasonable expectation of success in combining the teachings of Hartdegen and Orbay. The combination includes modifications of bone plates and mating geometries in devices having similar operating characteristics and involves no more than routine skill in the art.

217. As explained above, Hartdegen already discloses a plate-and-tool/body system that positions and secures a bone plate through cannulated tube members,

and Orbay discloses a lip-and-socket/stepped-profile engagement geometry performing the identical function of retaining and aligning a bone plate within a tool/body. Ex. 1005 ¶111; Ex. 1007, 9–10; Ex. 1008 ¶¶65, 67. Because both structures are similar components that interface at the same bone-anchor-receiving portion of a bone plate, incorporating Orbay's lip-and-socket/stepped-profile engagement geometry onto Hartdegen's tube members would have amounted to no more than the use of a known engagement geometry to improve a similar device in the same way, yielding the predictable result of a secure, visualizable connection.

218. I understand that Orbay's plate is designed to be contoured permanently, while Hartdegen's implant returns elastically toward its free state. This does not affect the expectation of success. In the combination, Orbay supplies only the node-gripping engagement geometry; Hartdegen's implant material, its loaded and free-state configurations, its clip, and its release sequence are unchanged. Orbay's grip would hold and bend the plate exactly as Orbay describes (Ex. 1008 ¶¶67, 73). The only difference is that, on release, the plate returns toward its free state and compresses the bones, which is the result Hartdegen teaches. Holding a resilient plate in a flexed configuration with instruments attached to it was well within the skill of a POSA. Hartdegen shows it being done.

219. Moving the engagement to the screw-receiving portions also shortens the load path between each tube and the portion being moved and eliminates

engagement features from the bending region, both of which make the implant's behavior more predictable rather than less. Designing a gripping interface that seats on a stepped node or a comparable feature at the end of a plate is routine instrument-design work of the type a POSA performed regularly.

220. For at least the reasons I discuss above, claims 1–19 would have been obvious in view of Hartdegen and Orbay.

V. CONCLUSION

221. For the foregoing reasons, it is my opinion that claims 1-19 are anticipated by the teachings of the Hartdegen prior art reference.

222. Additionally, for the foregoing reasons, it is my opinion that claims 1–19 would have been obvious in view of Hartdegen and Orbay.

223. I reserve the right to supplement my opinions in the future to respond to any arguments or positions that Patent Owner Paragon may raise, taking account of new information as it becomes available to me.

224. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on: October 12, 2026

By: /s/ Daniel C. Farber
Dr. Daniel C. Farber