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(54) **BONE IMPLANT AND MEANS OF INSERTION**

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(2) Date: **Jan. 6, 2017**

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Publication Classification

(51) **Int. Cl.**

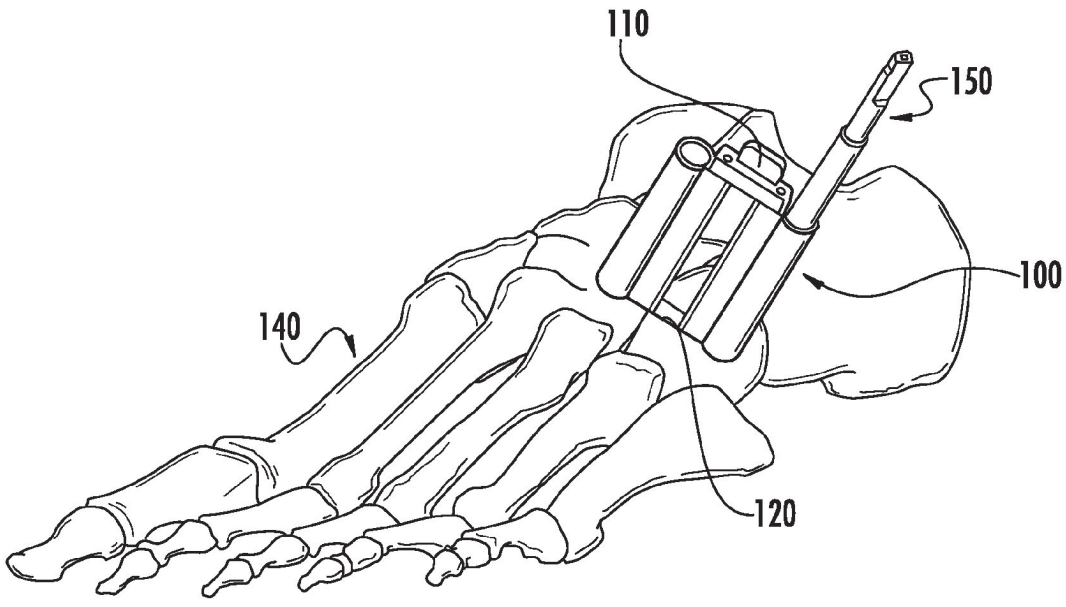
A61B 17/80	(2006.01)
A61B 17/068	(2006.01)
A61B 17/17	(2006.01)
A61B 17/064	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 17/808*** (2013.01); ***A61B 17/0642*** (2013.01); ***A61B 17/0682*** (2013.01); ***A61B 17/1775*** (2016.11); ***A61B 17/8061*** (2013.01); *A61B 2017/0645* (2013.01)

(57) **ABSTRACT**

An assembly used in osteosynthesis comprising a delivery instrument in combination with an implant wherein the delivery instrument releasably holds the implant in a first configuration prior to attachment of the implant to bone. The delivery instrument allows the implant to be affixed to bone before the implant is released from the instrument. And the instrument may comprise guide means for drills, depth gauges, screws, pins, pegs, blades and or drivers which are used or implanted when the implant is releasably attached to the instrument. After the implant is affixed to bone and released from the delivery instrument, the implant assumes at least a second configuration which provides compression and or distraction and or control of spacial orientation.



Treace Medical Concepts, Inc. v. Paragon 28, Inc.
IPR2027-00014
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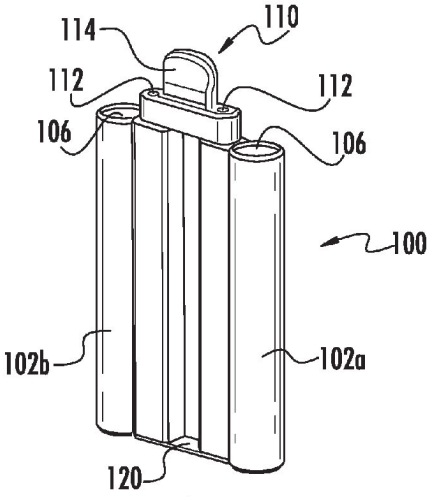


FIG. 1A

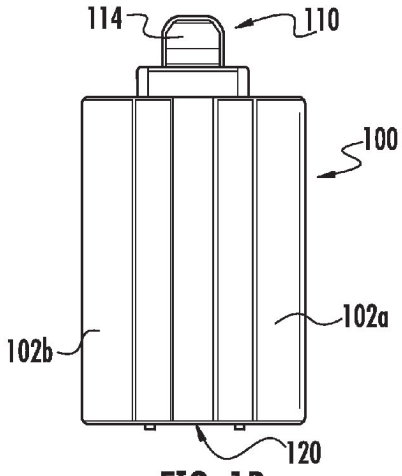


FIG. 1B

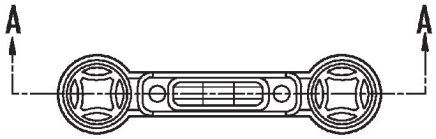


FIG. 1C

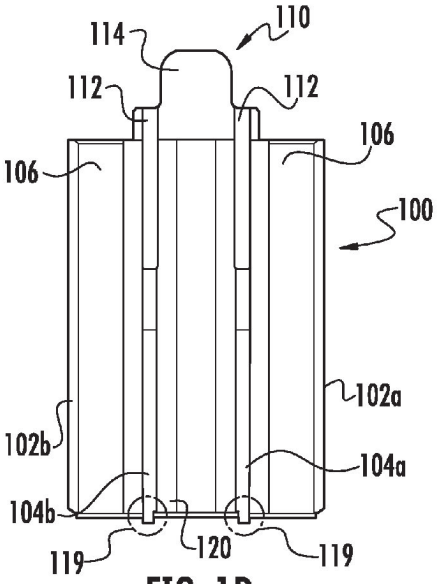


FIG. 1D

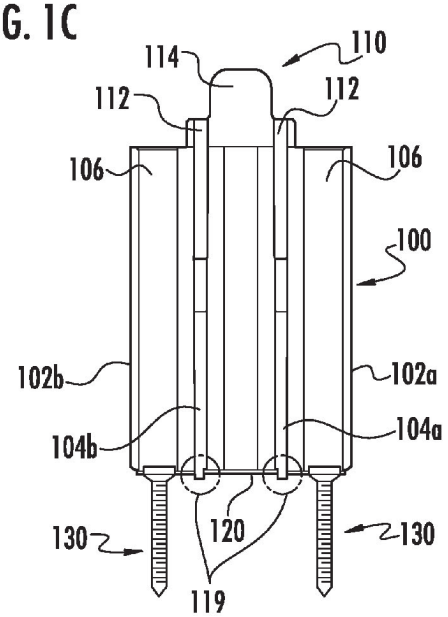


FIG. 1E

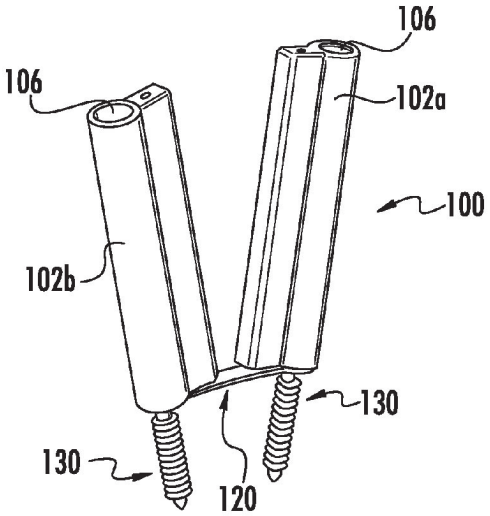


FIG. 2A

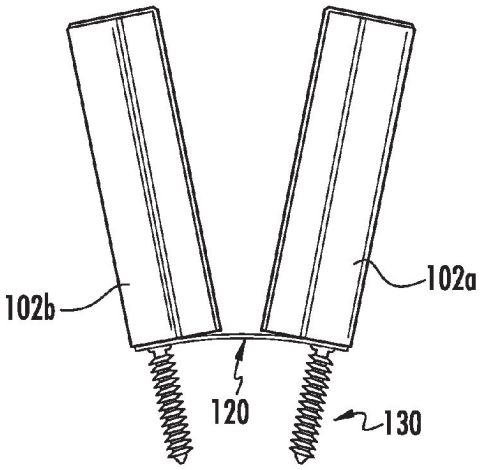


FIG. 2B

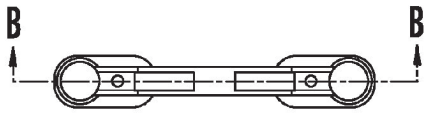


FIG. 2C

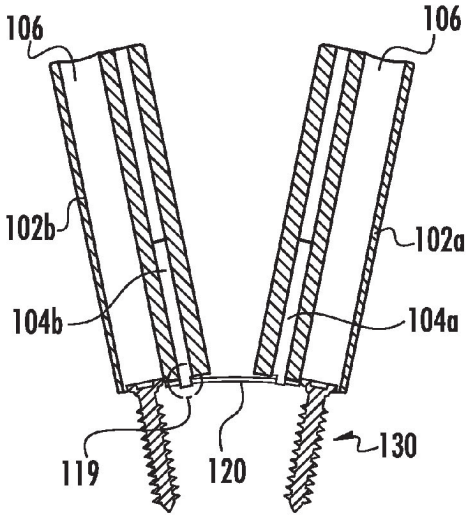


FIG. 2D

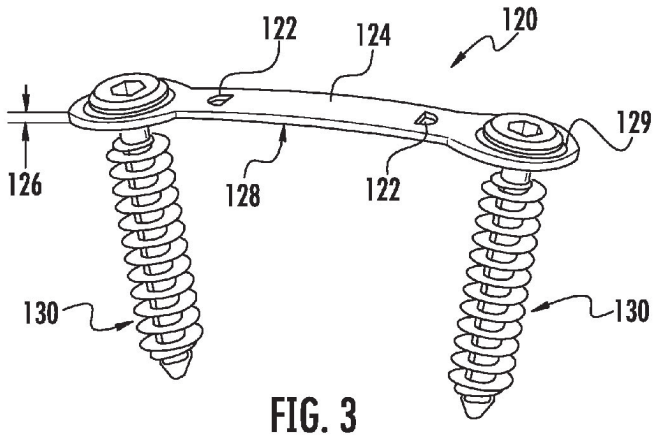


FIG. 3

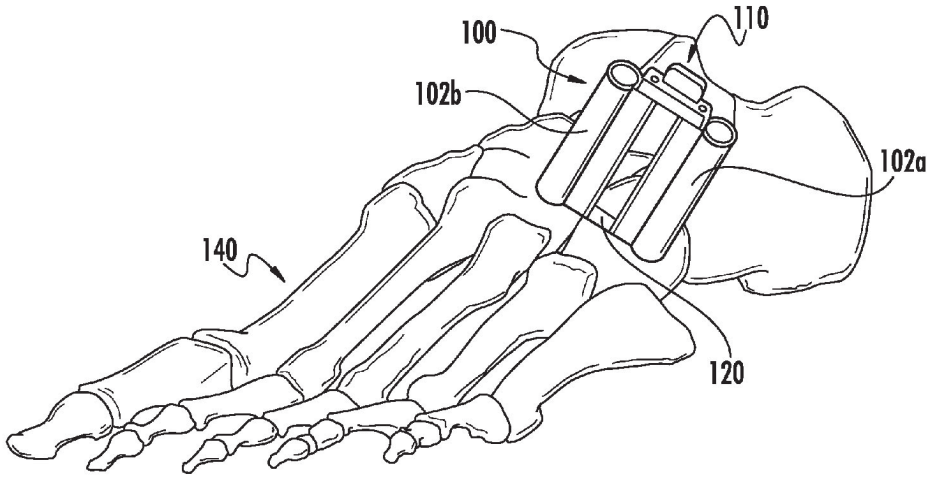


FIG. 4

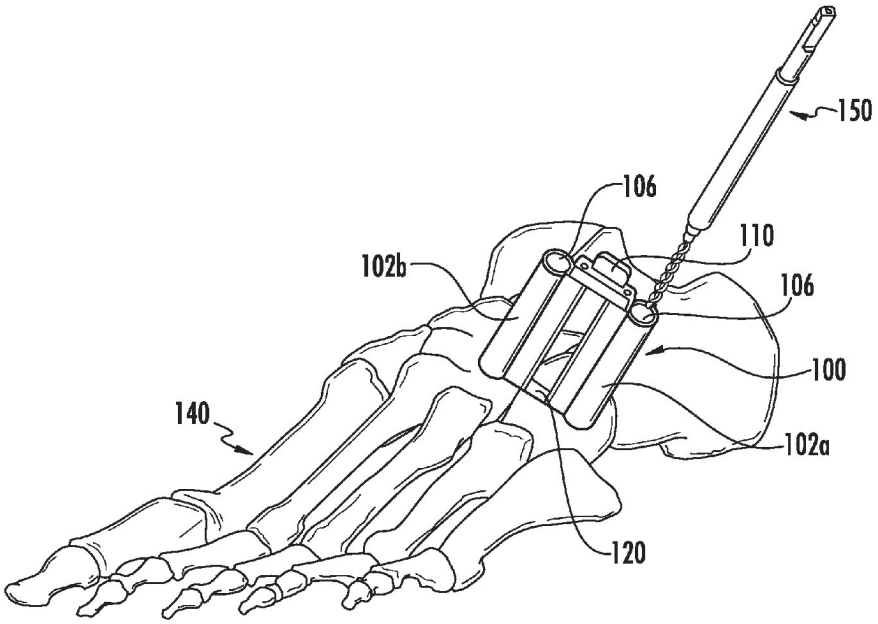


FIG. 5

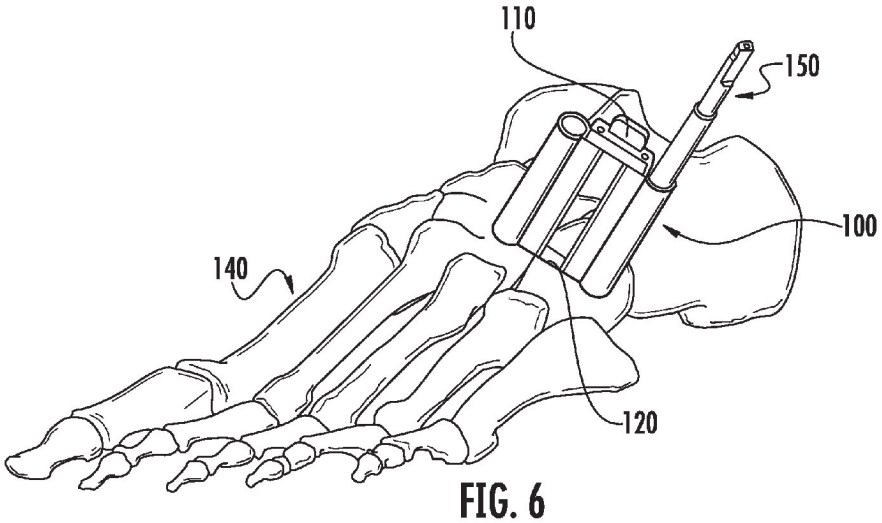


FIG. 6

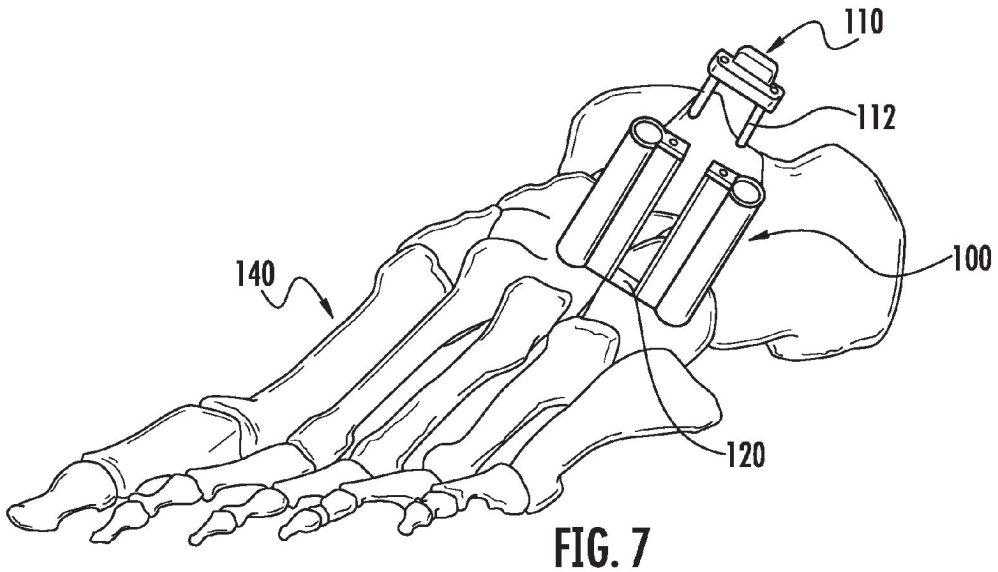


FIG. 7

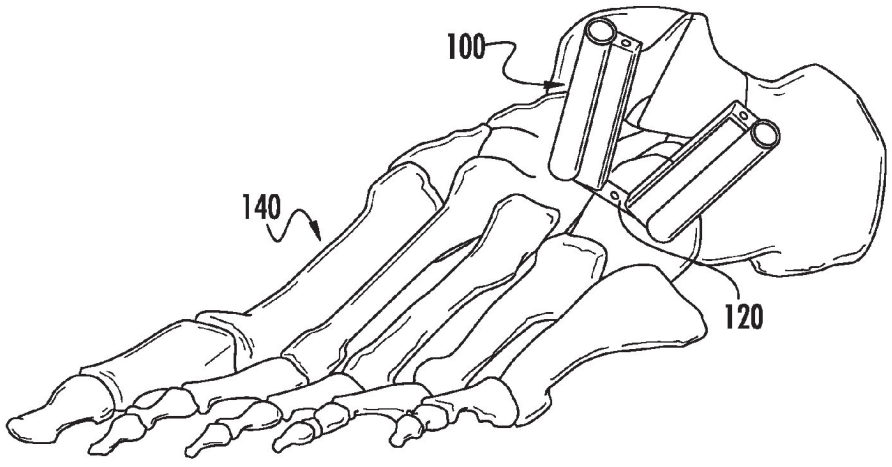


FIG. 8

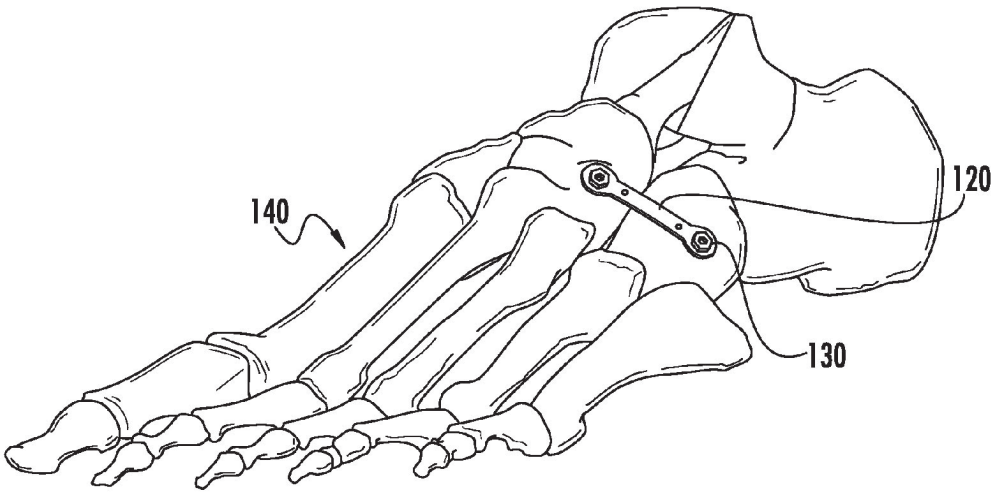


FIG. 9

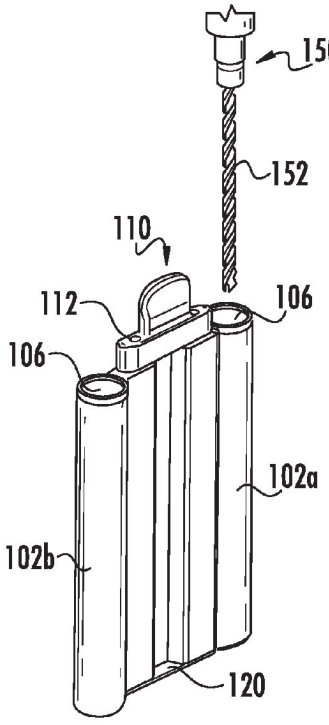


FIG. 10A

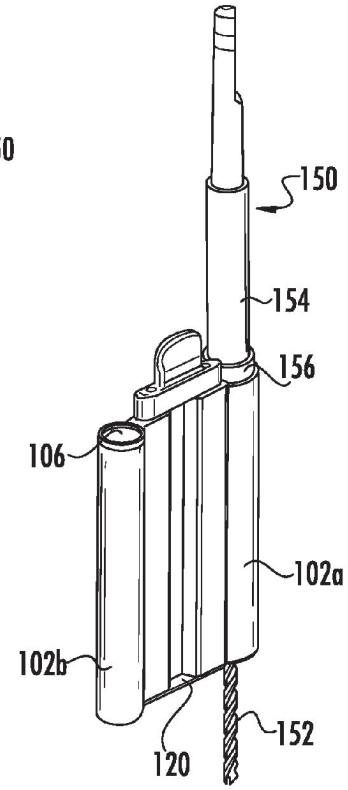


FIG. 10B

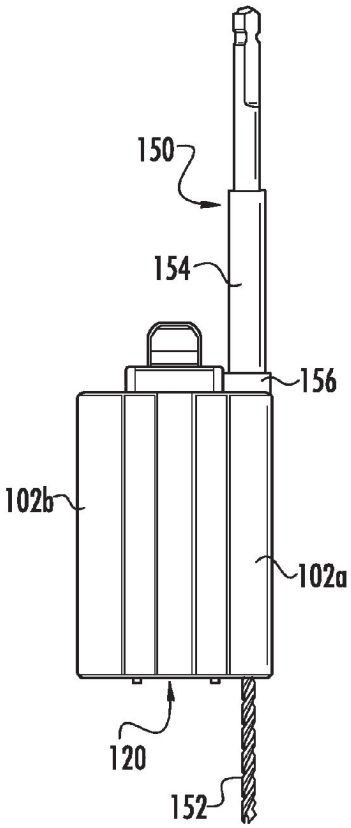


FIG. 10C

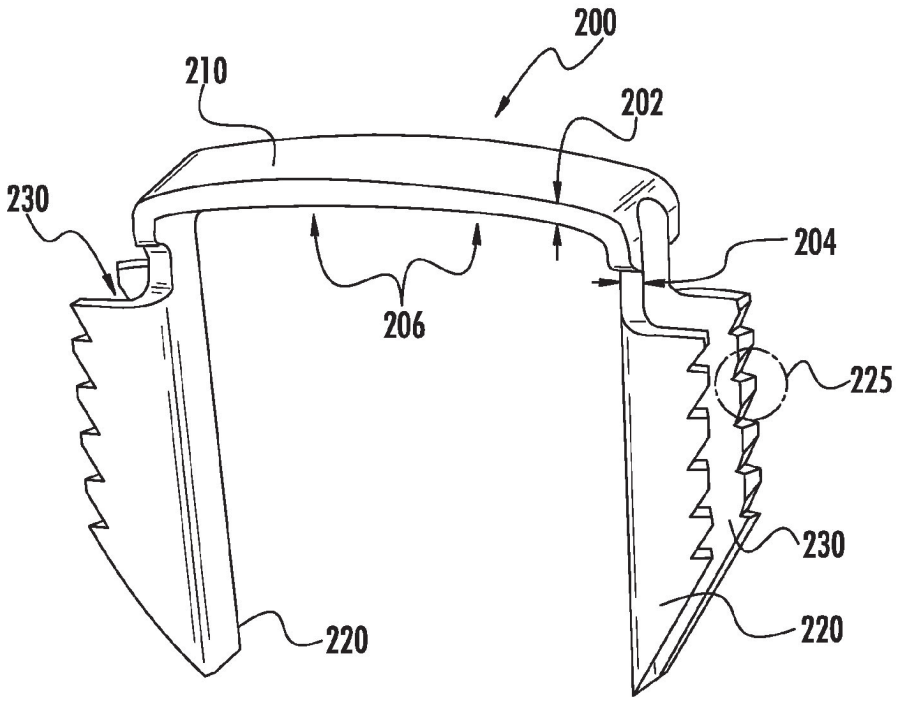

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FIG. 11

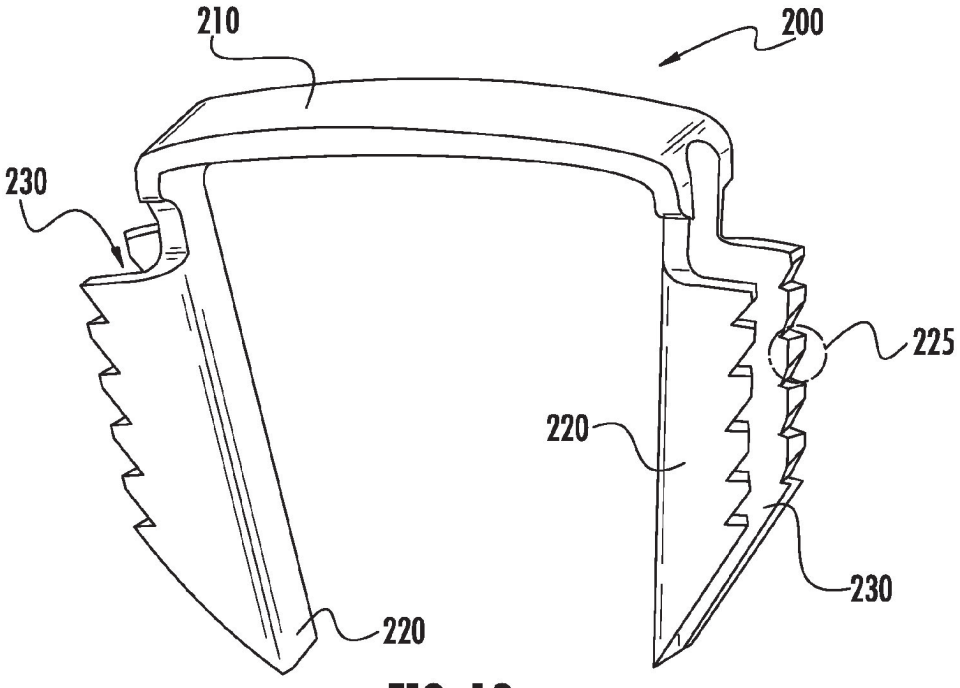

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FIG. 12

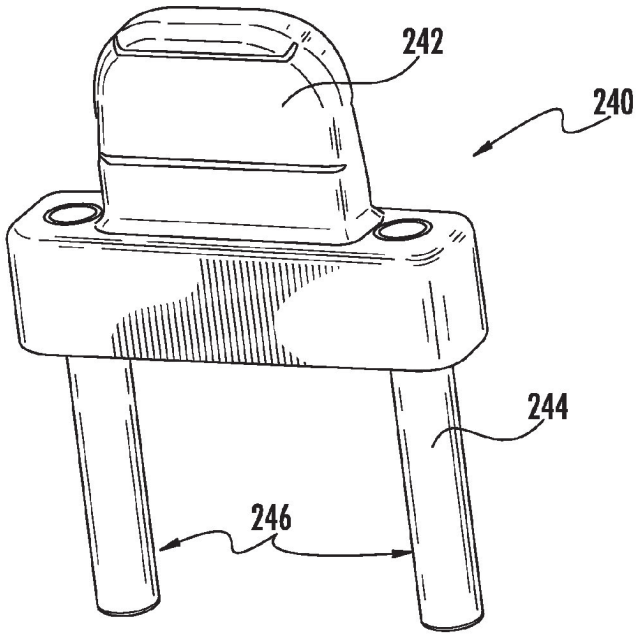


FIG. 13

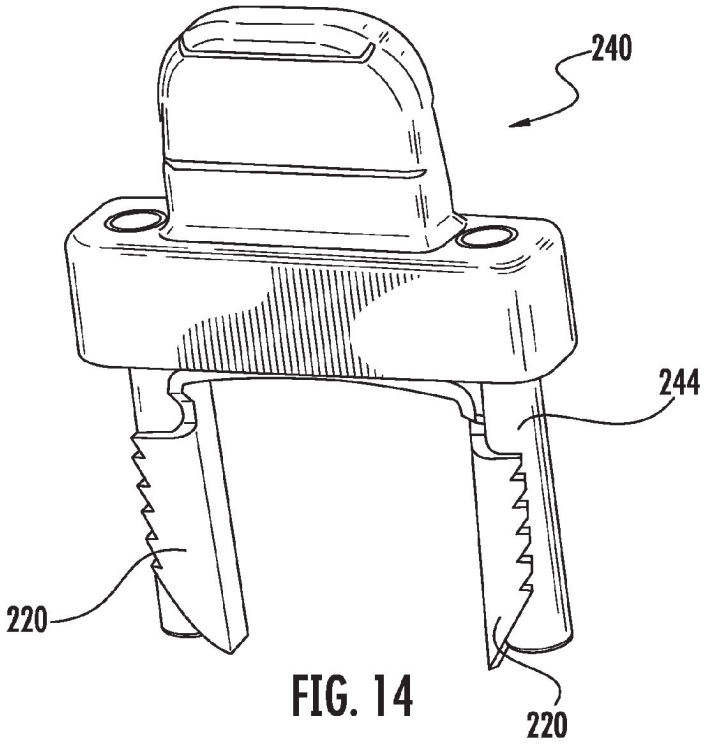


FIG. 14

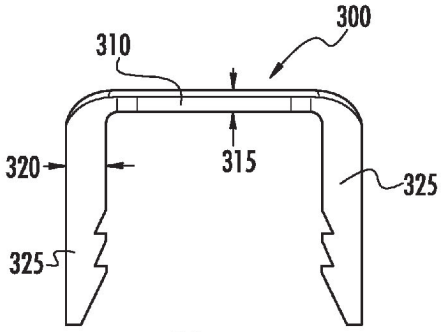


FIG. 15A

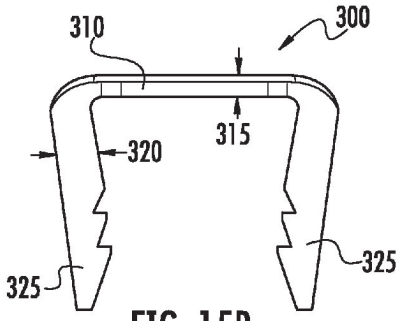


FIG. 15B

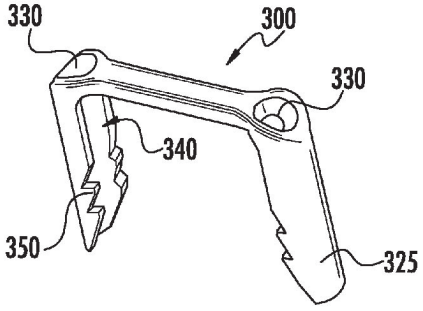


FIG. 16A

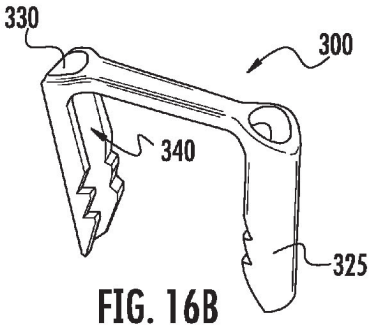


FIG. 16B

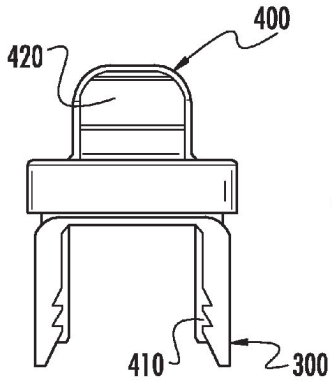


FIG. 17A

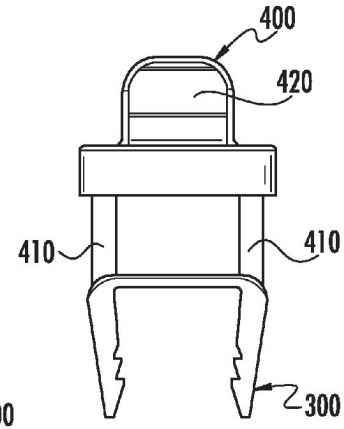


FIG. 17B

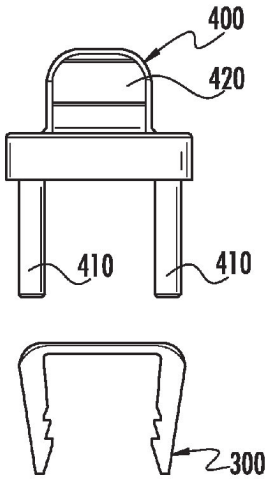


FIG. 17C

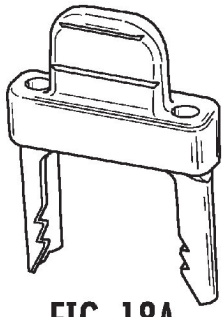


FIG. 18A

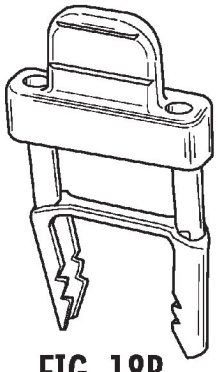


FIG. 18B

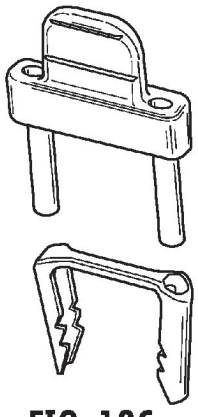


FIG. 18C

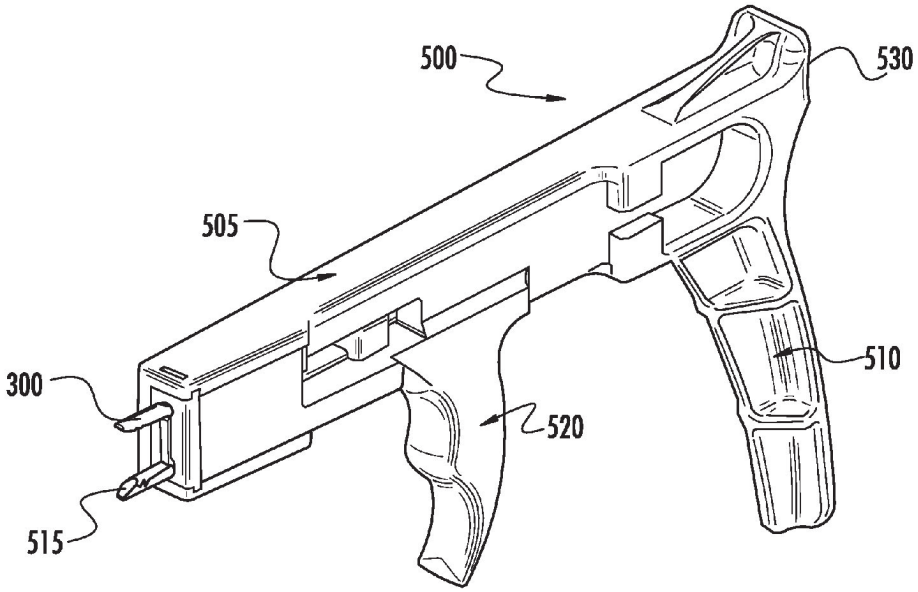


FIG. 19

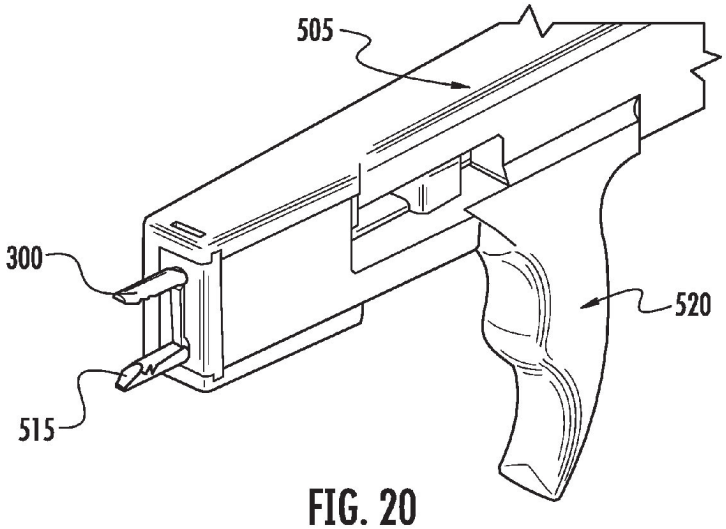


FIG. 20

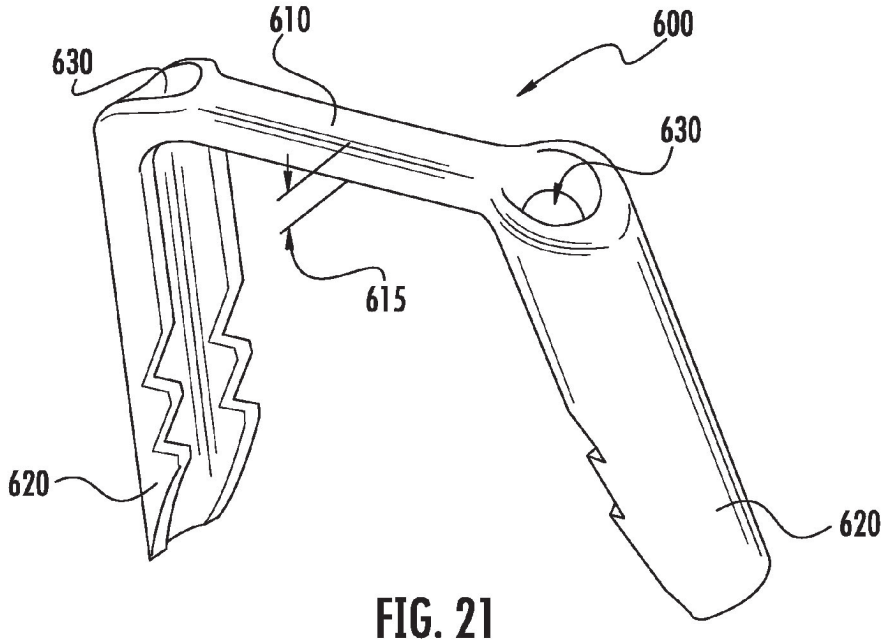


FIG. 21

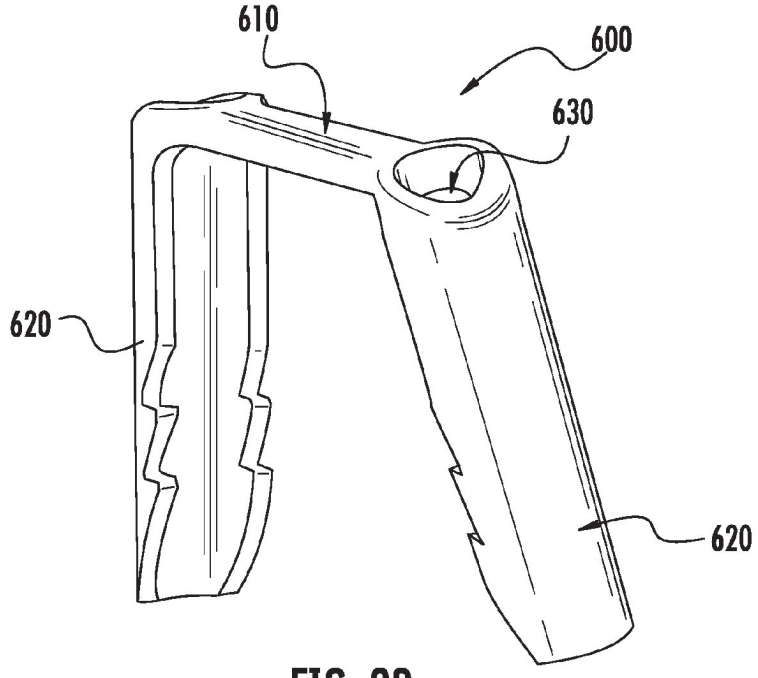


FIG. 22

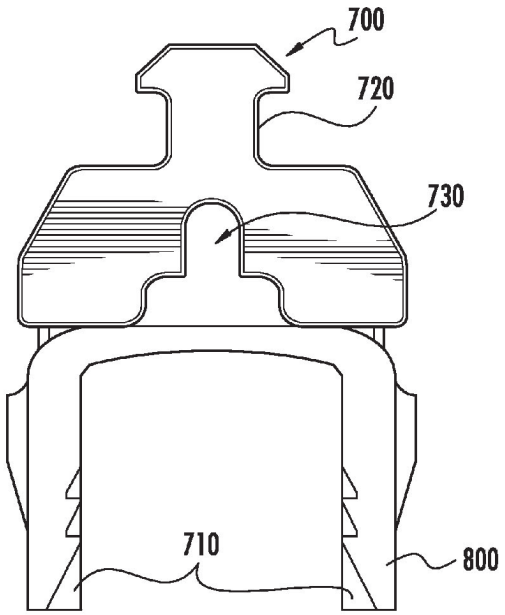


FIG. 23A

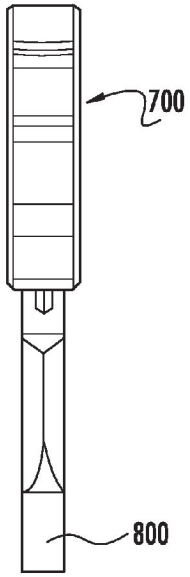


FIG. 23B

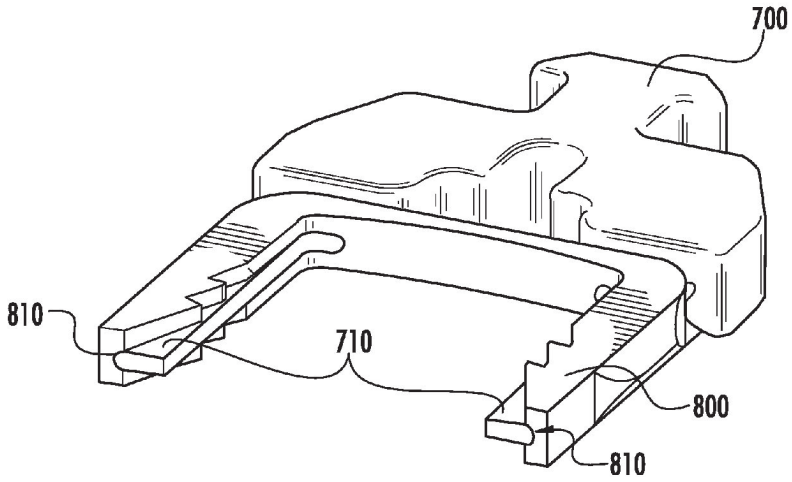


FIG. 24

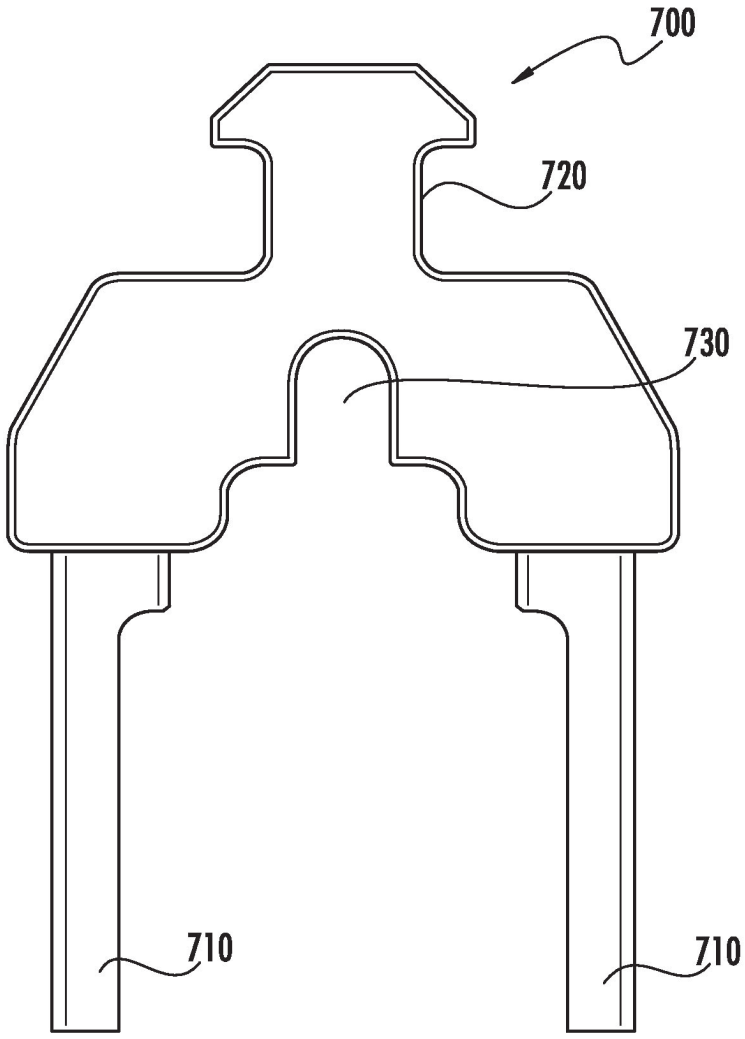


FIG. 25

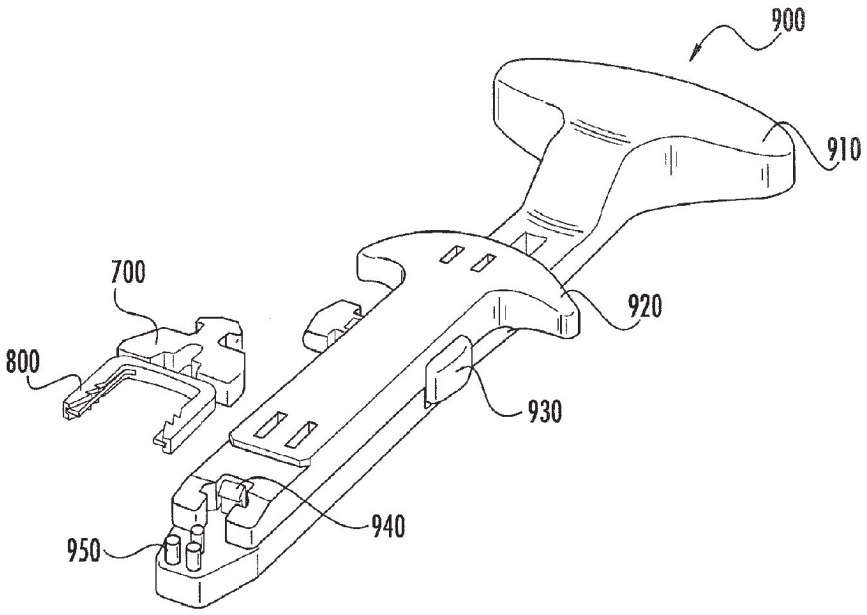


FIG. 26A

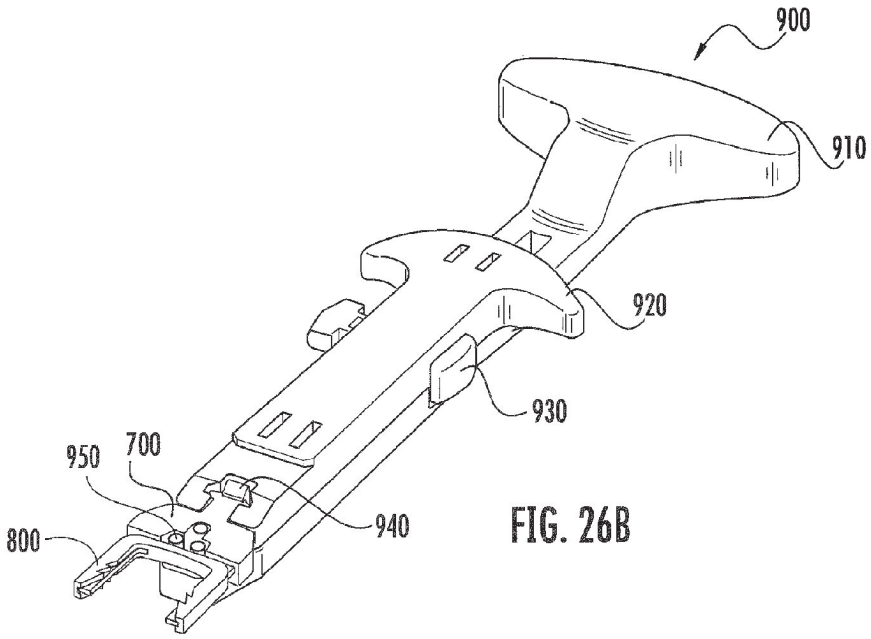


FIG. 26B

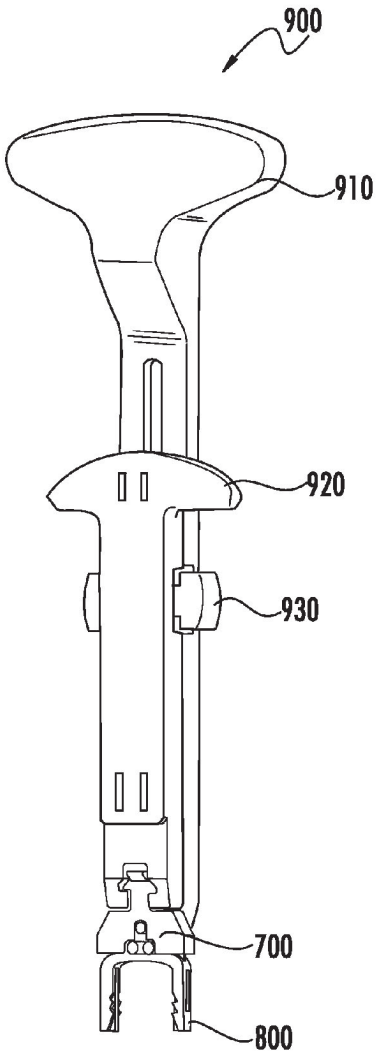


FIG. 27A

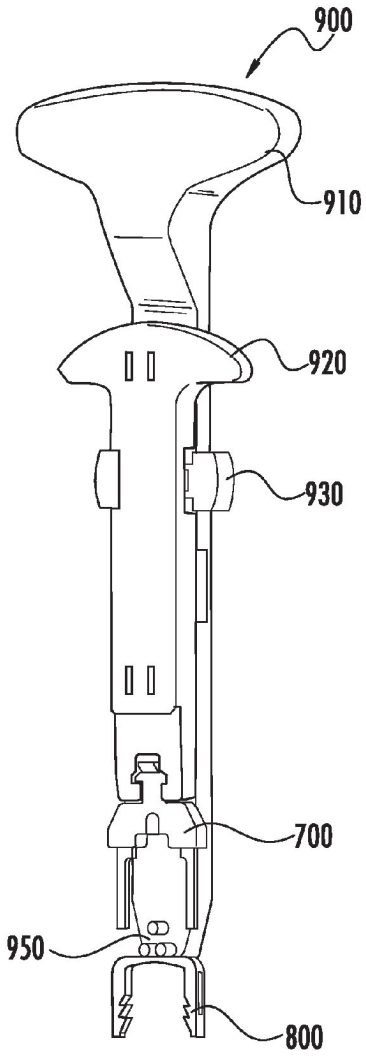


FIG. 27B

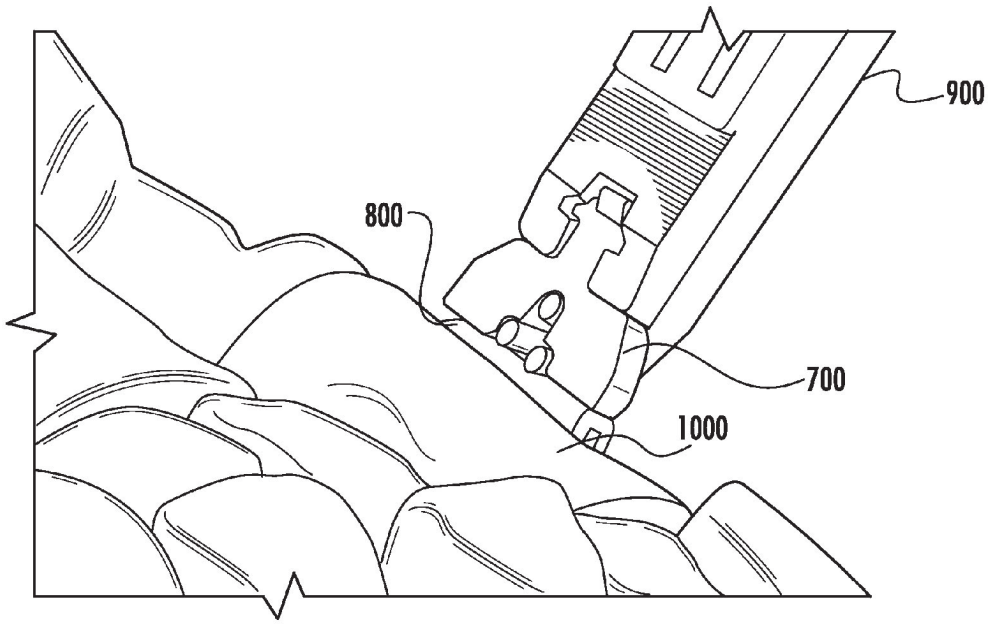


FIG. 28

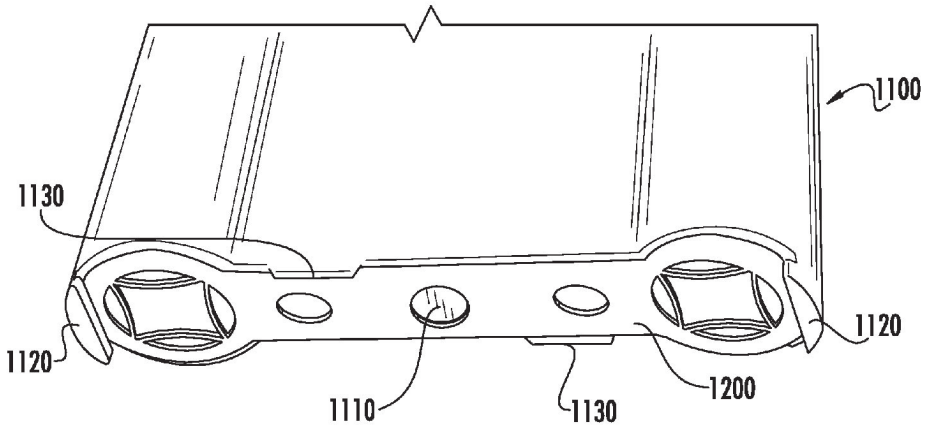

1100
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FIG. 29

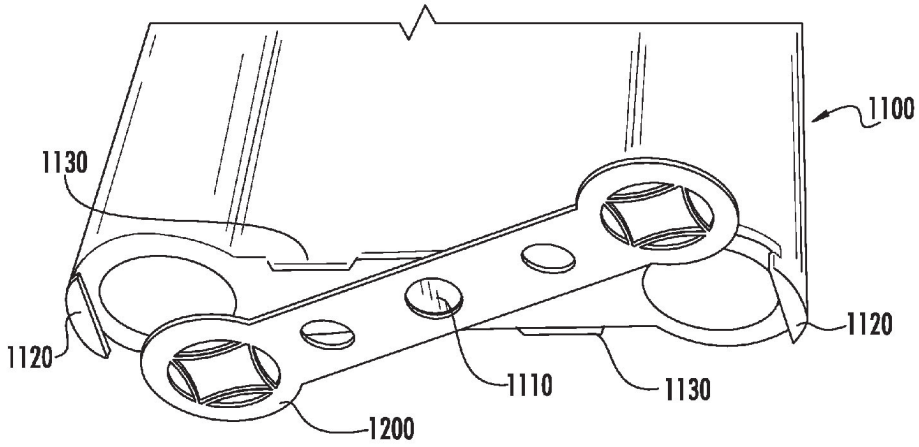

1100
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FIG. 30

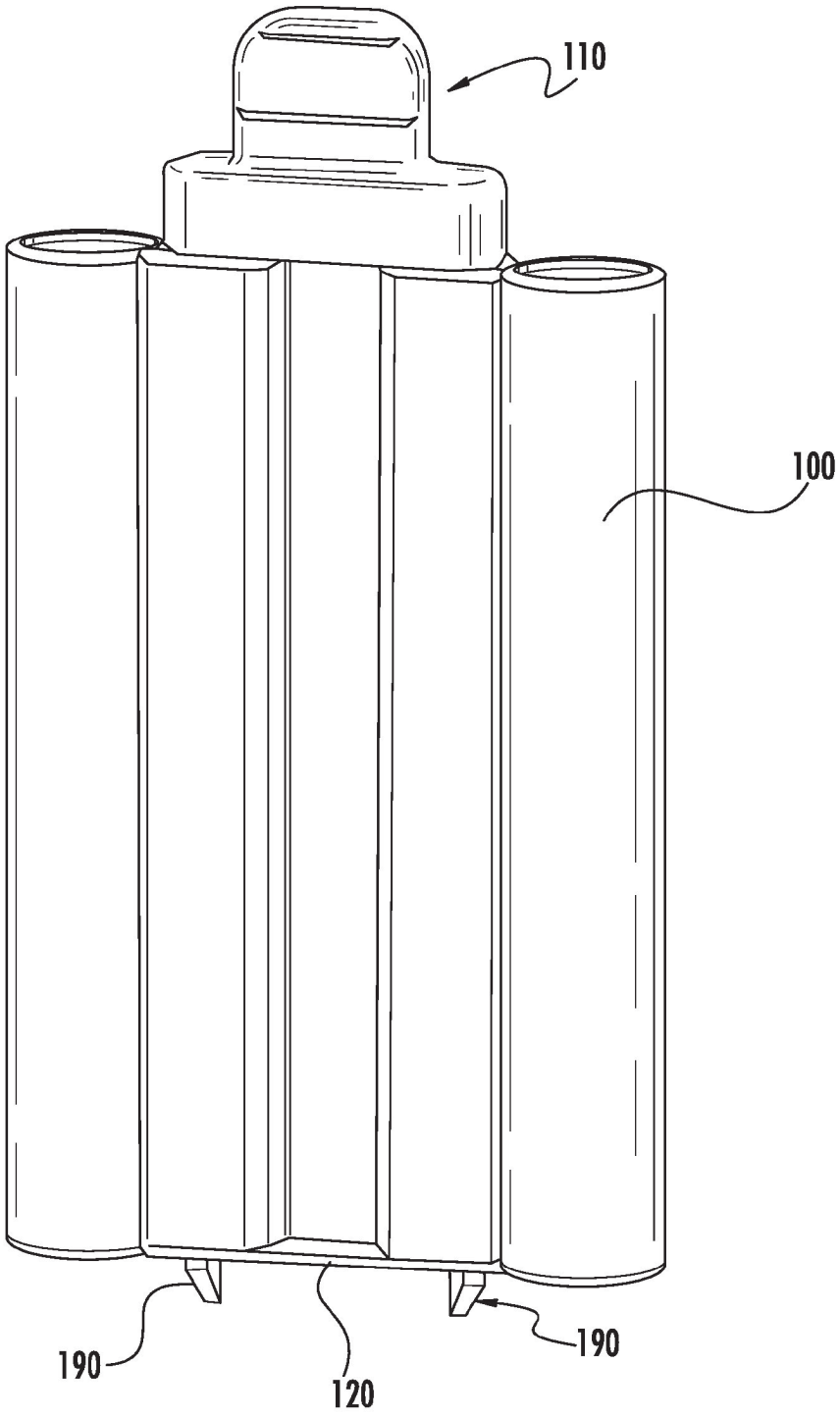


FIG. 31

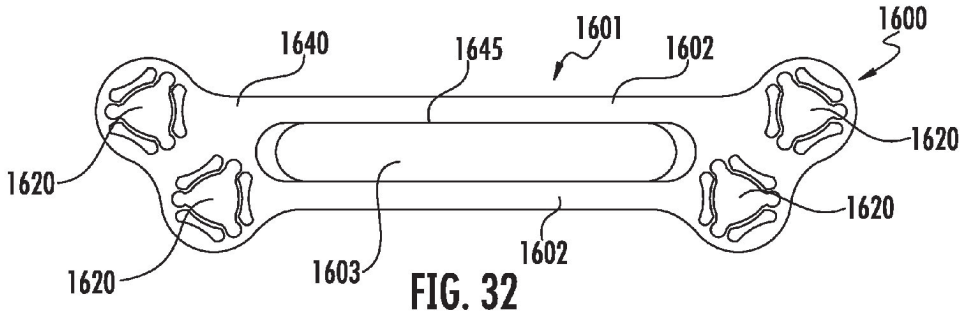


FIG. 32

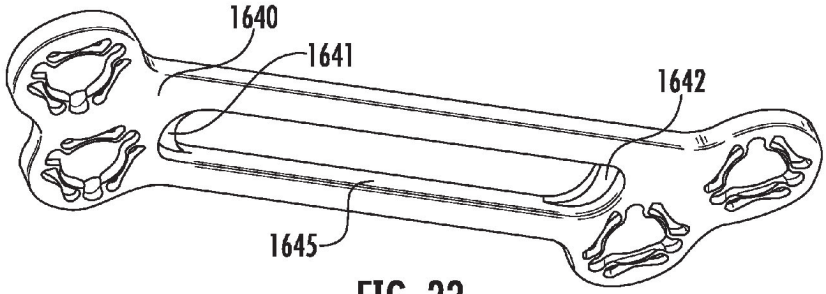


FIG. 33

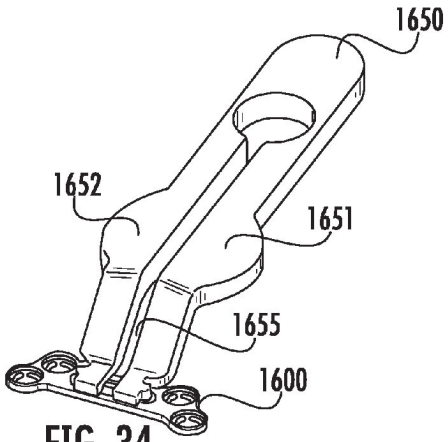


FIG. 34

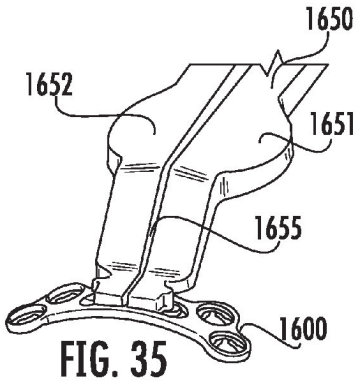


FIG. 35

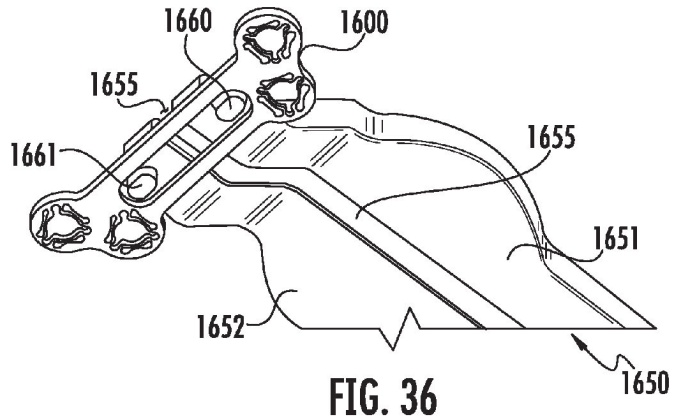


FIG. 36

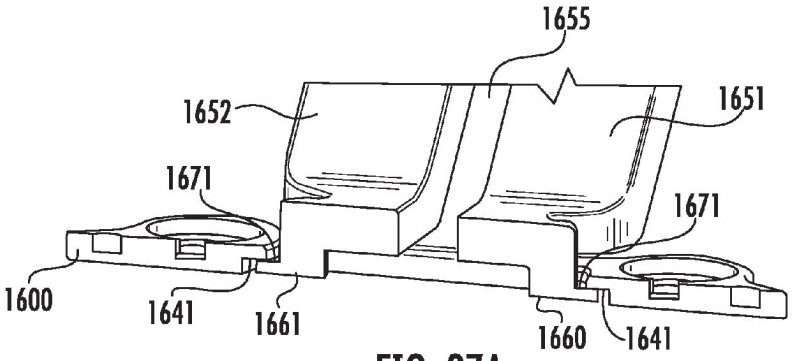


FIG. 37A

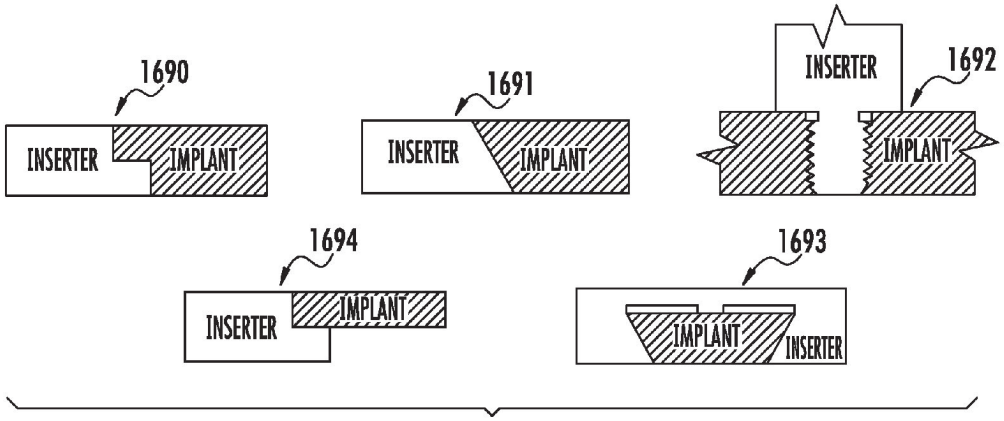


FIG. 37B

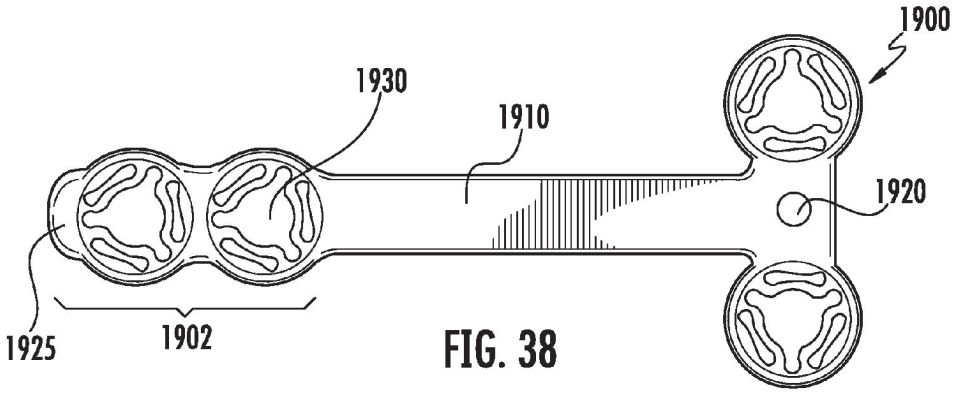

1900
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FIG. 38

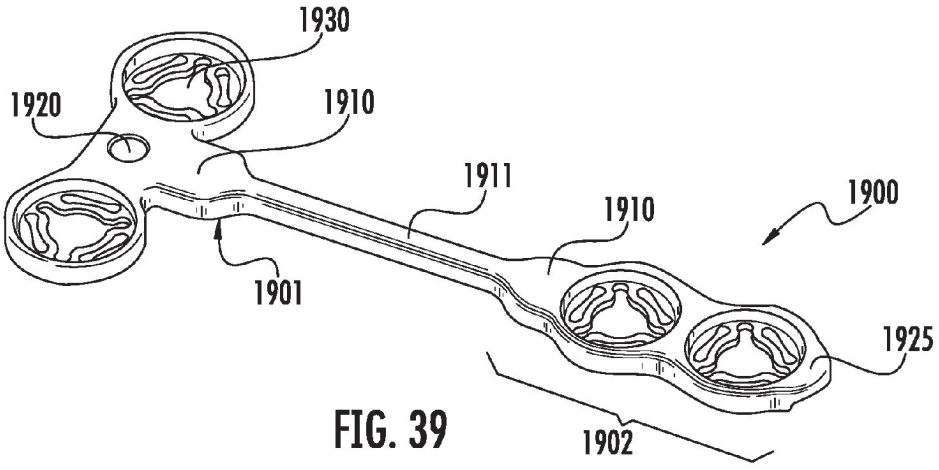

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FIG. 39

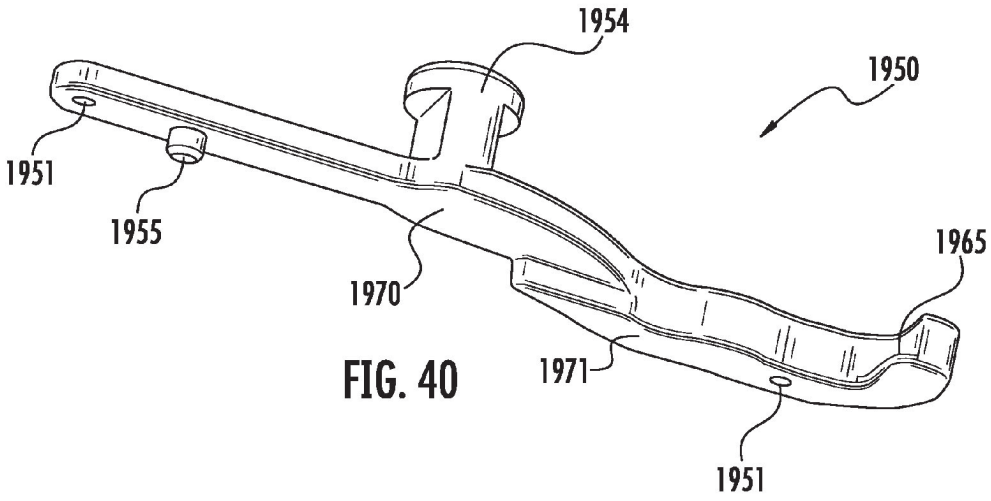

1954
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FIG. 40

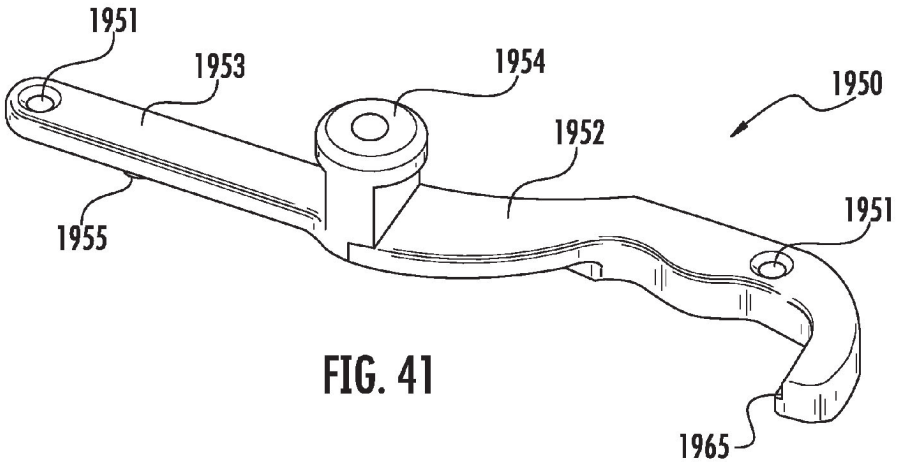

1951
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1954
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1952
1951
1955
1965

FIG. 41

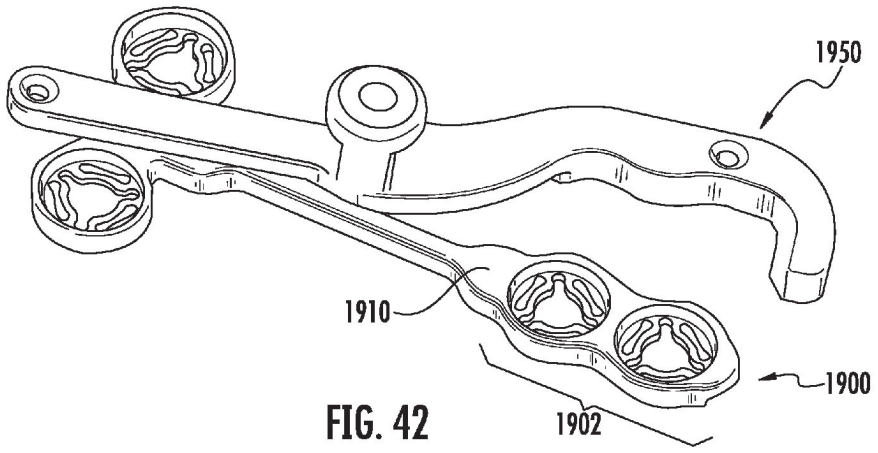


FIG. 42

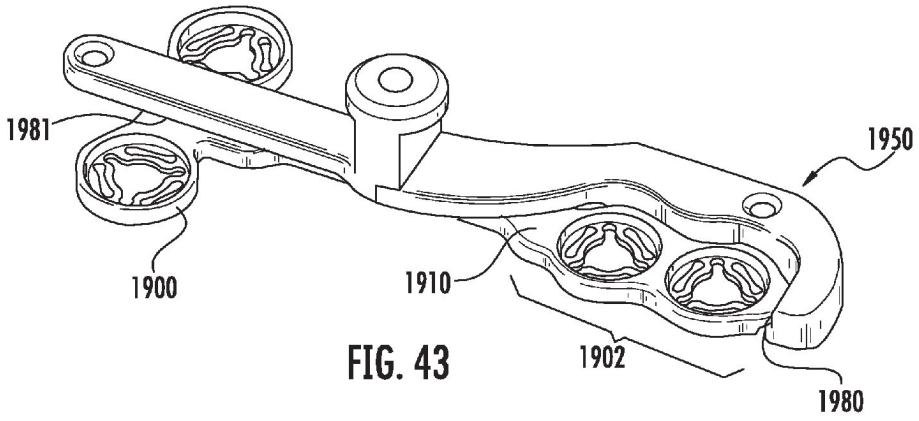


FIG. 43

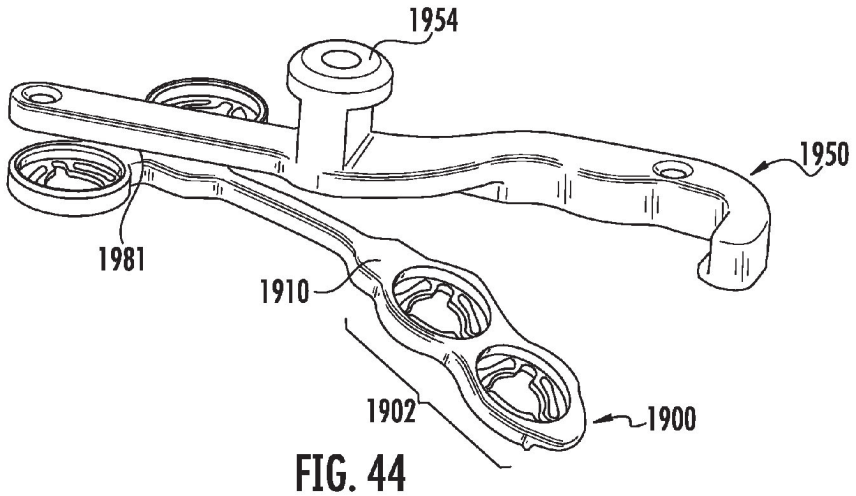


FIG. 44

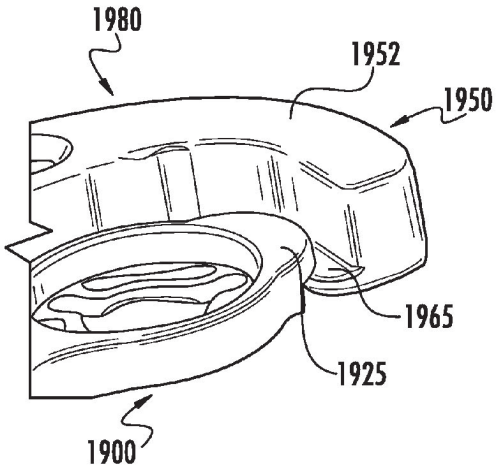


FIG. 45

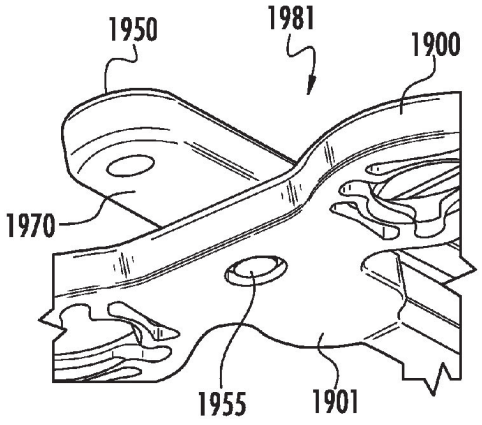


FIG. 46

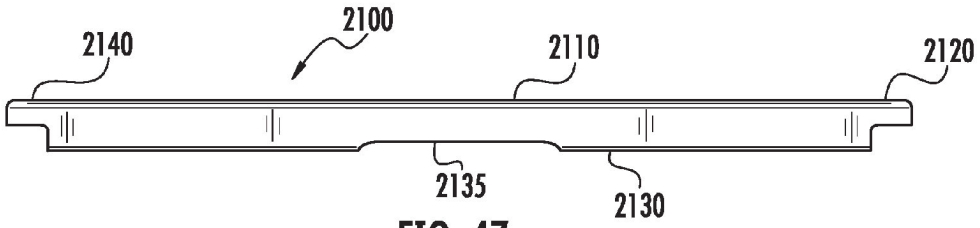


FIG. 47

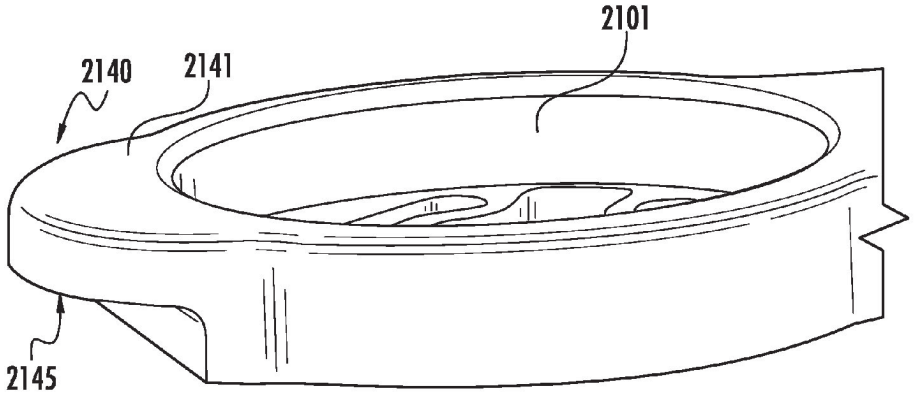


FIG. 48

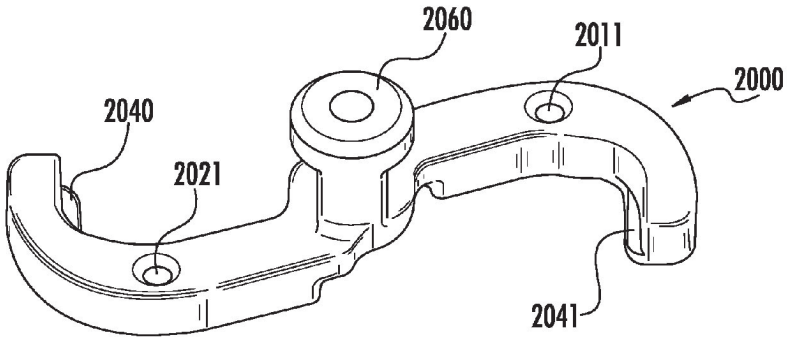


FIG. 49

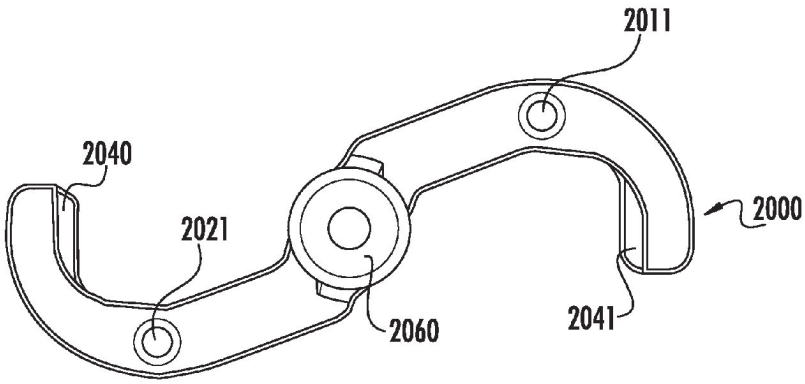


FIG. 50

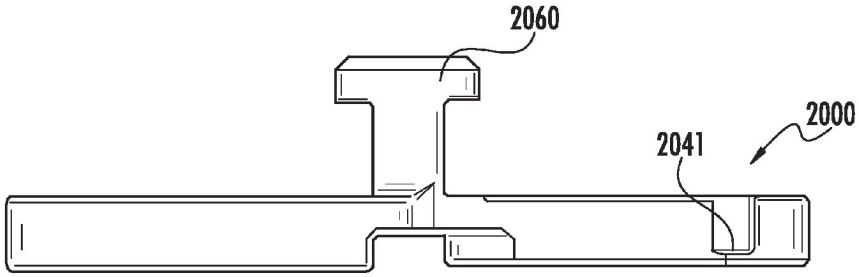


FIG. 51

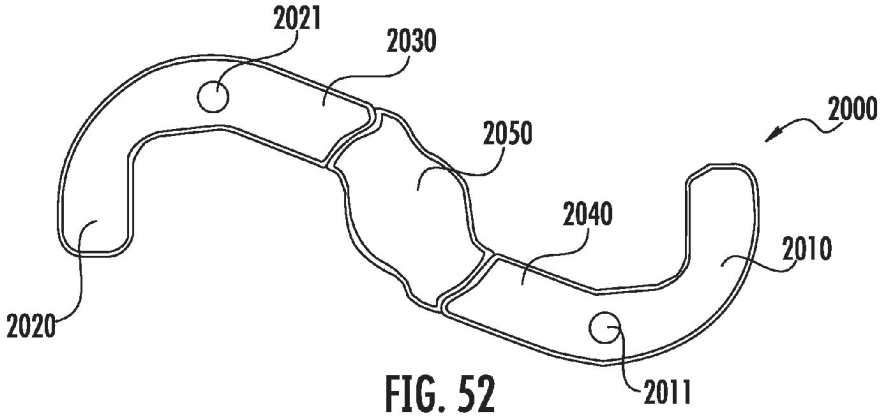

2021
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2011

FIG. 52

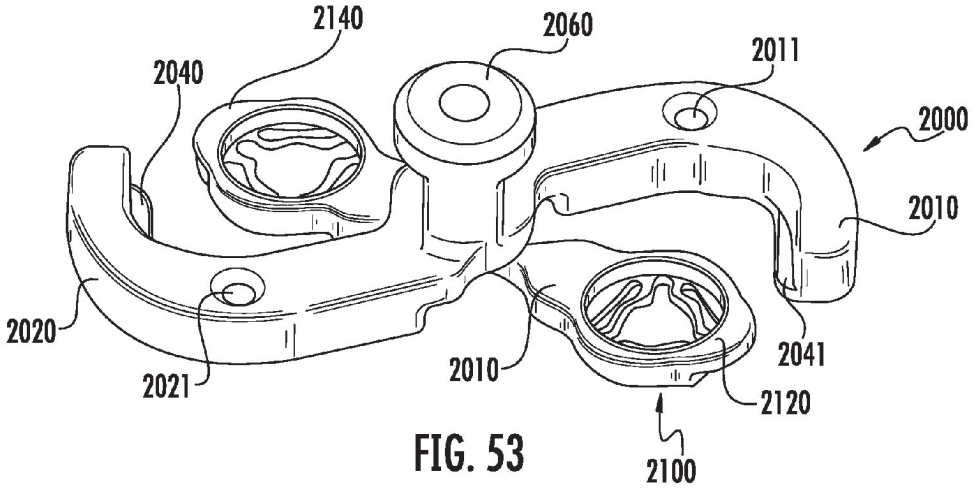

2140
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2011
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2041
2021
2010
2120
2100

FIG. 53

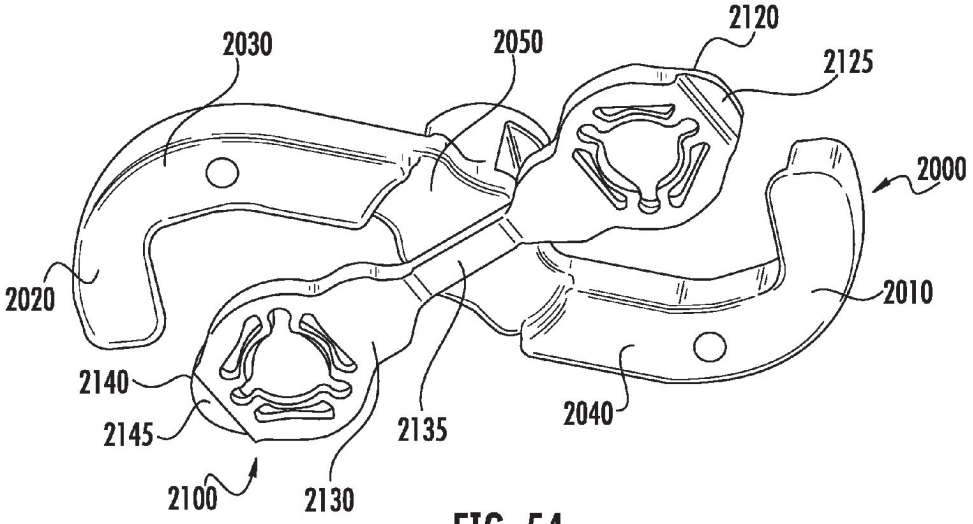

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FIG. 54

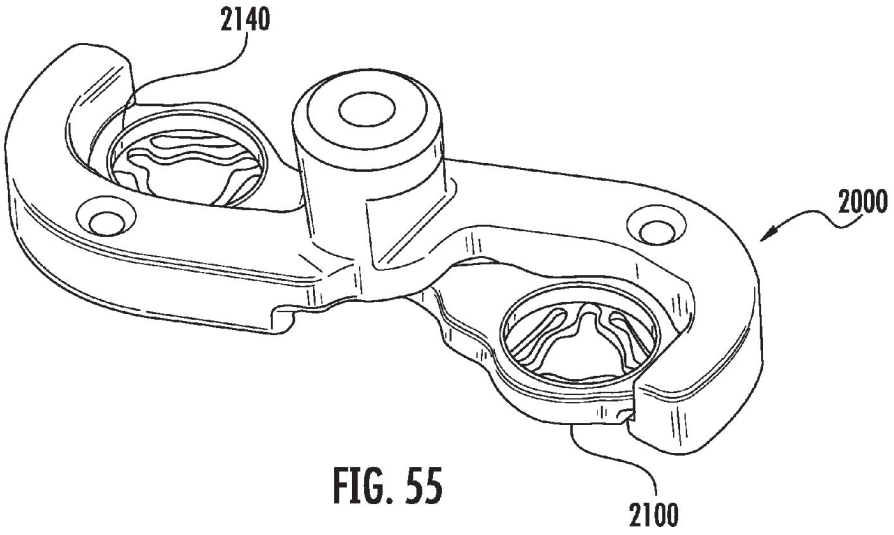

2140
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2100

FIG. 55

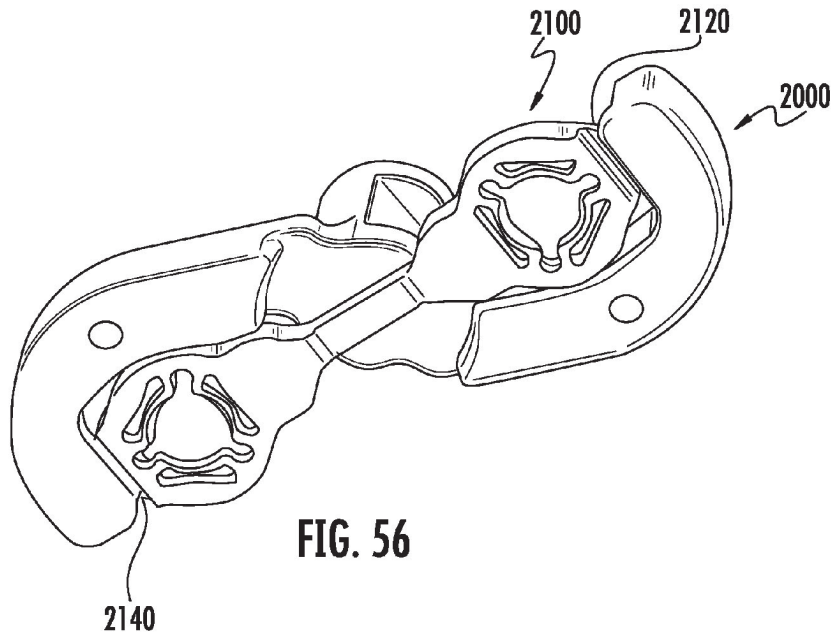


FIG. 56

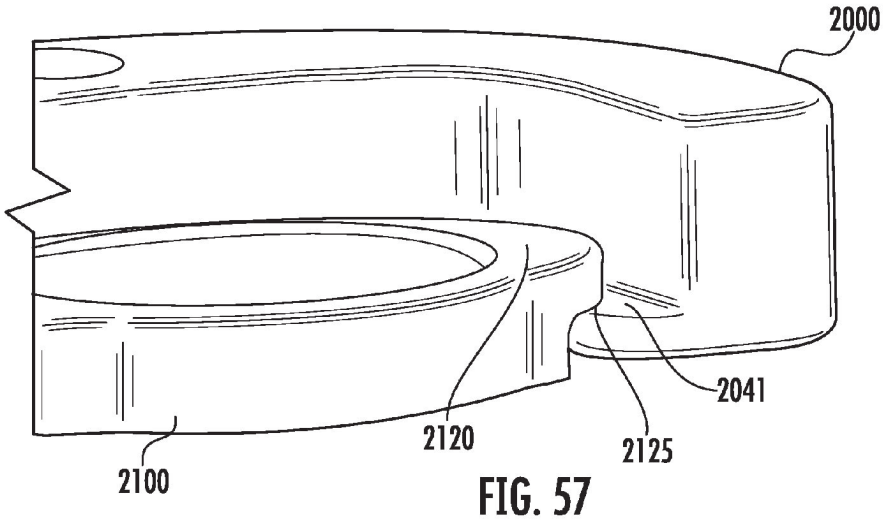


FIG. 57

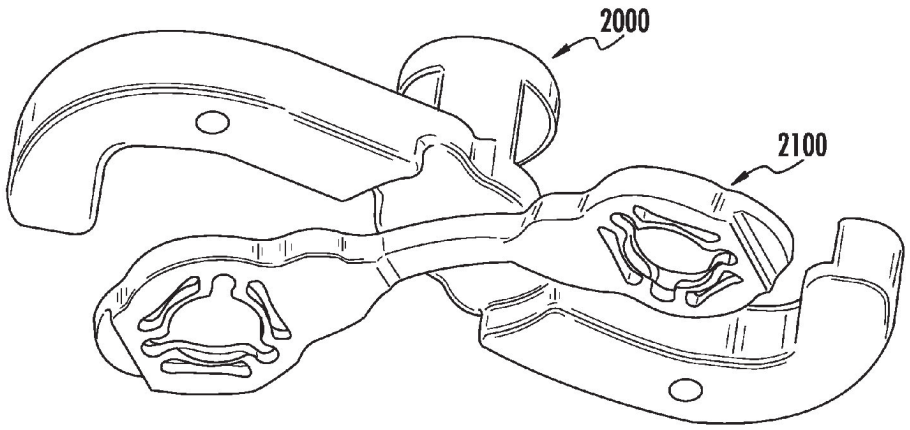


FIG. 58

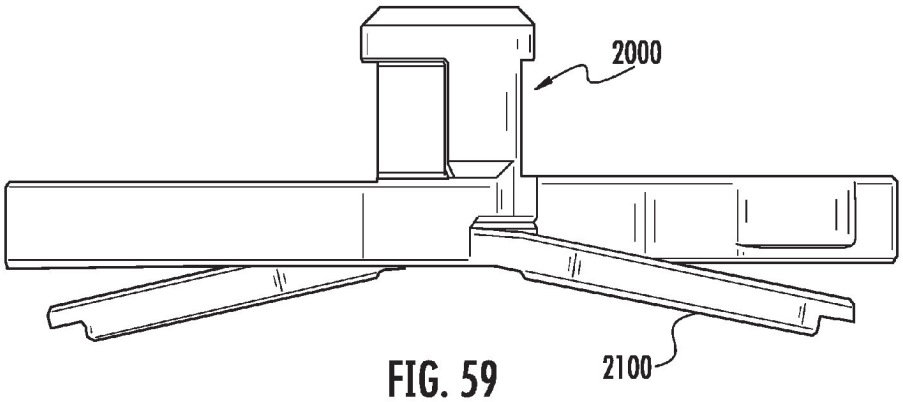


FIG. 59

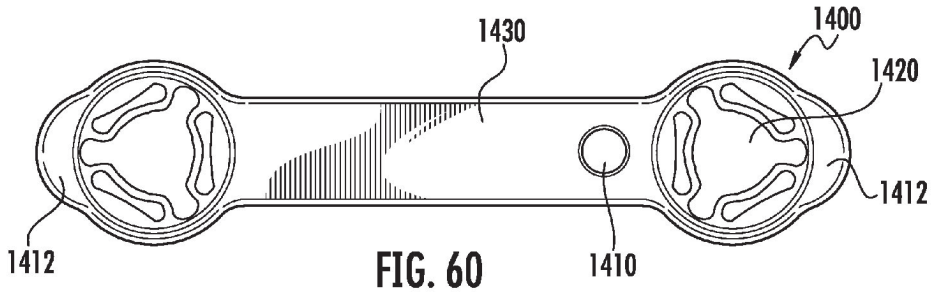

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FIG. 60

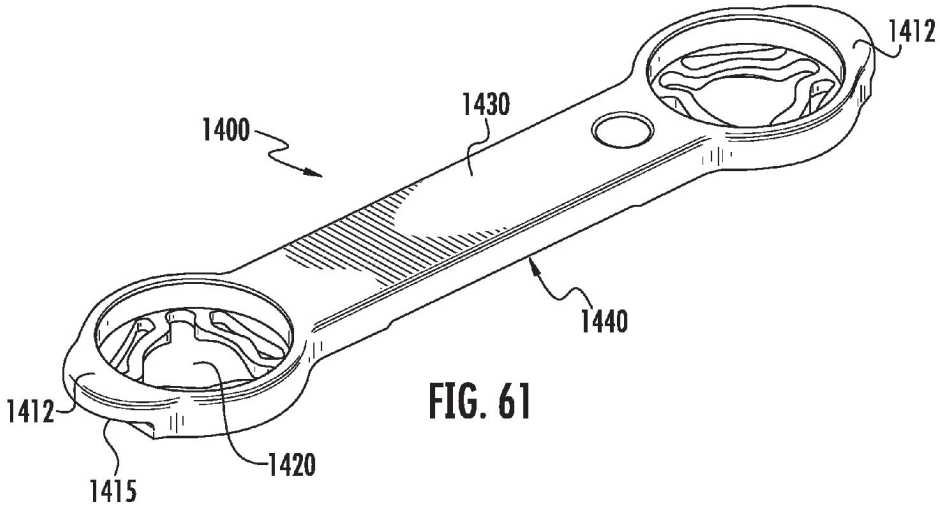

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FIG. 61

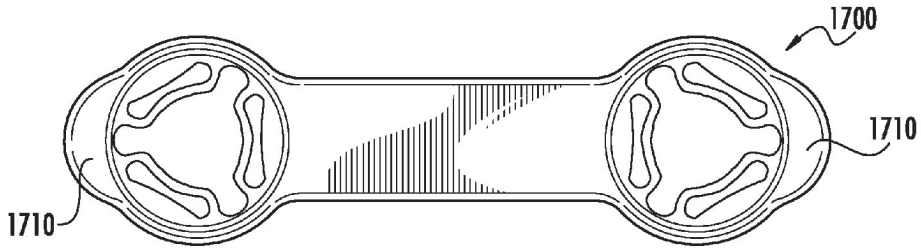


FIG. 62

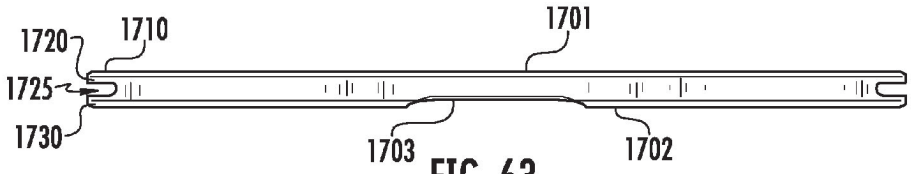


FIG. 63

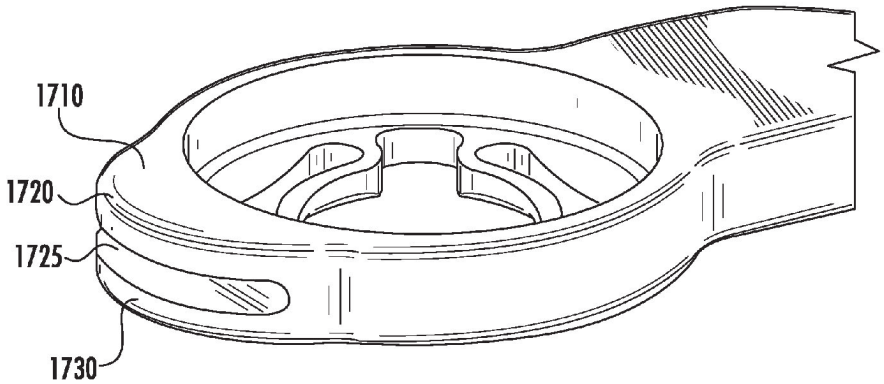


FIG. 64

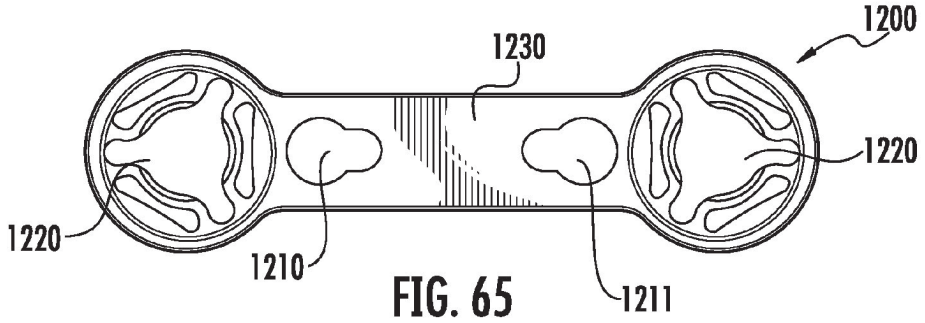


FIG. 65

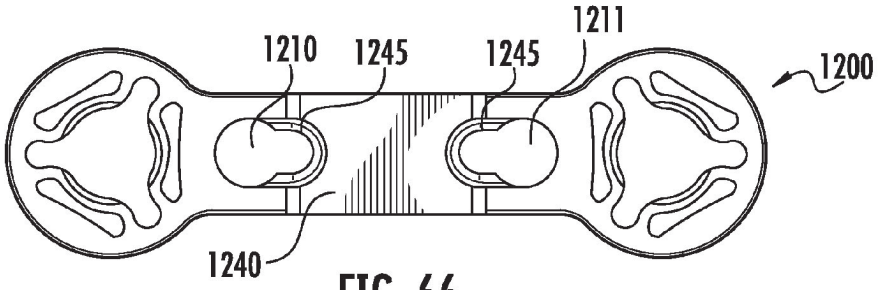


FIG. 66

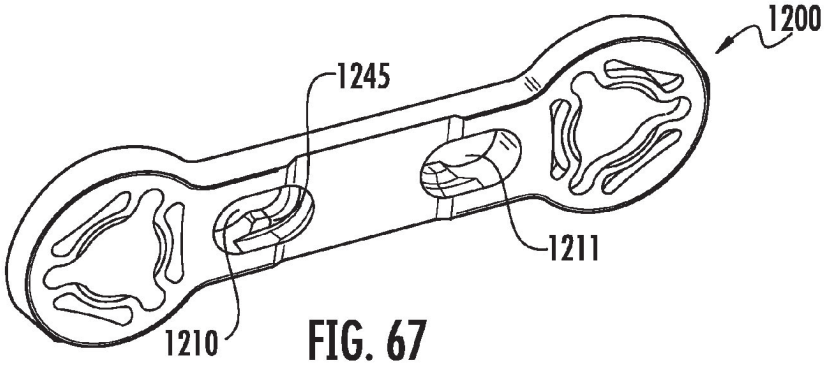


FIG. 67

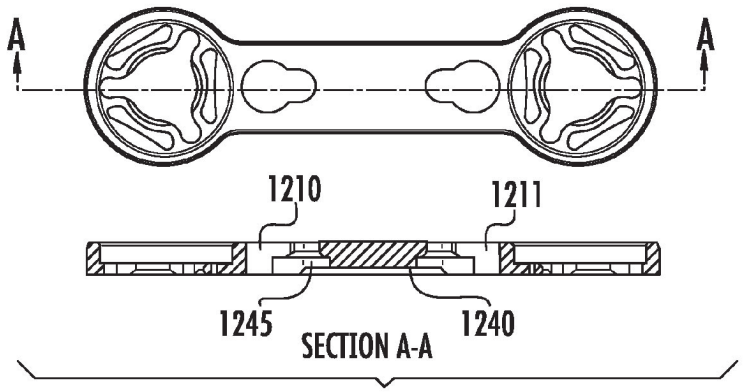


FIG. 68

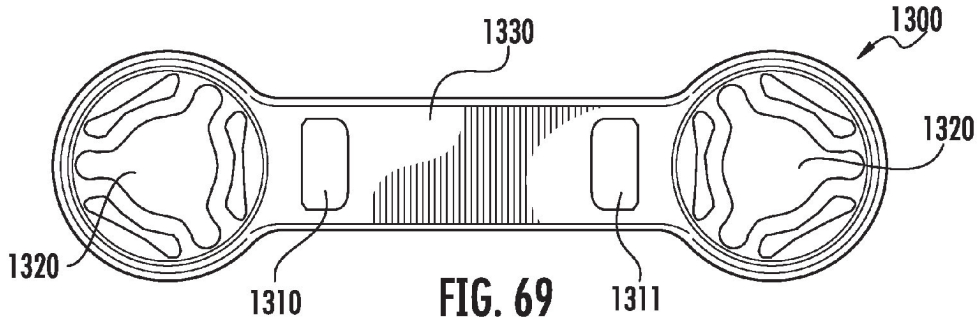


FIG. 69

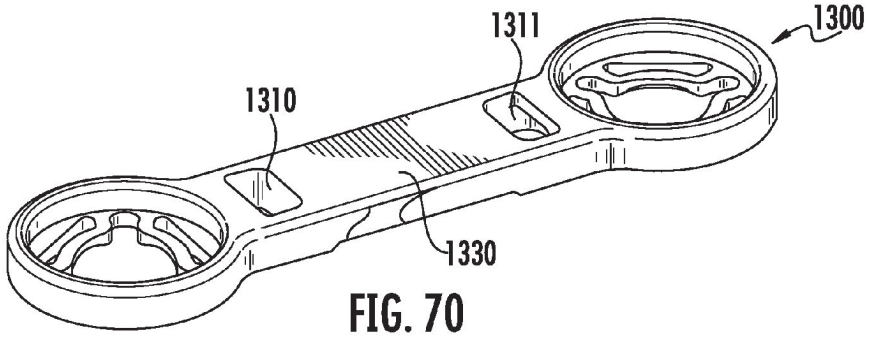


FIG. 70

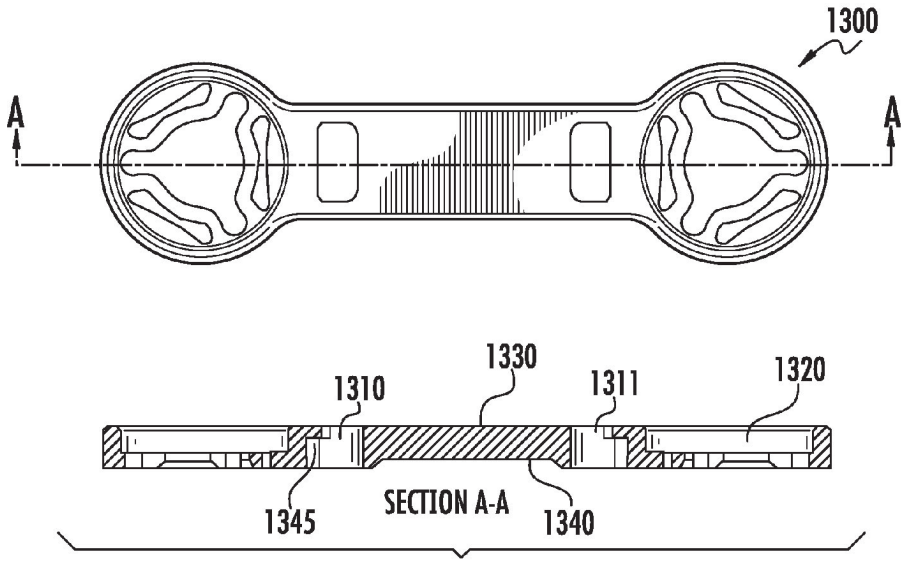


FIG. 71

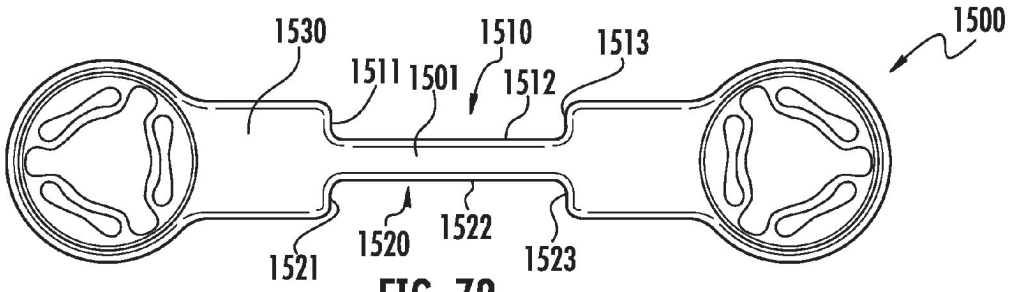


FIG. 72

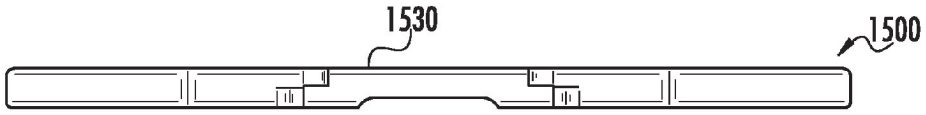


FIG. 73

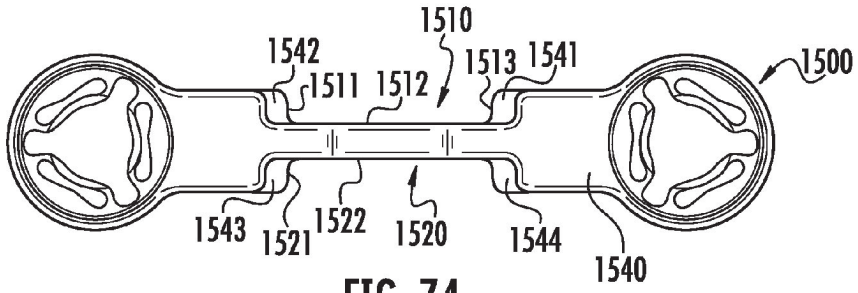


FIG. 74

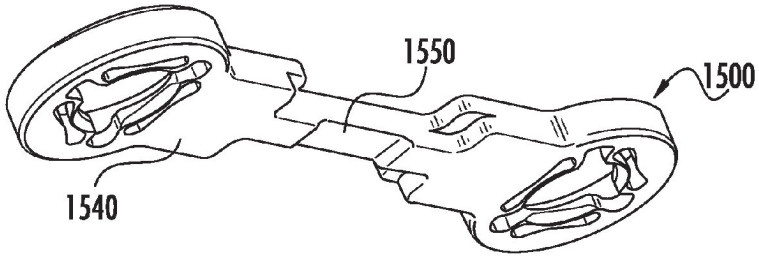


FIG. 75

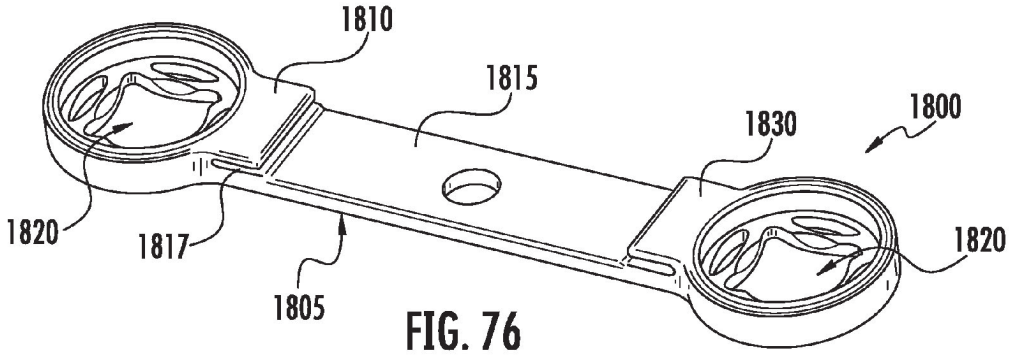

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FIG. 76

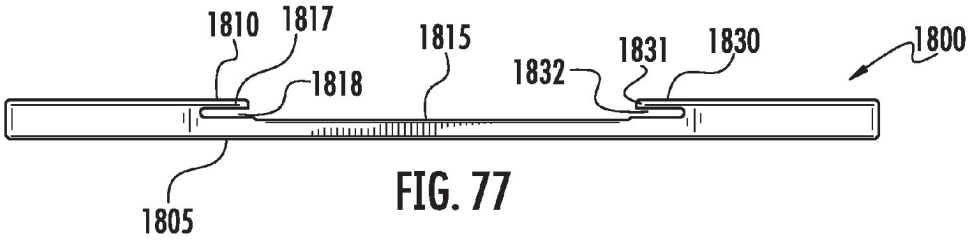

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FIG. 77

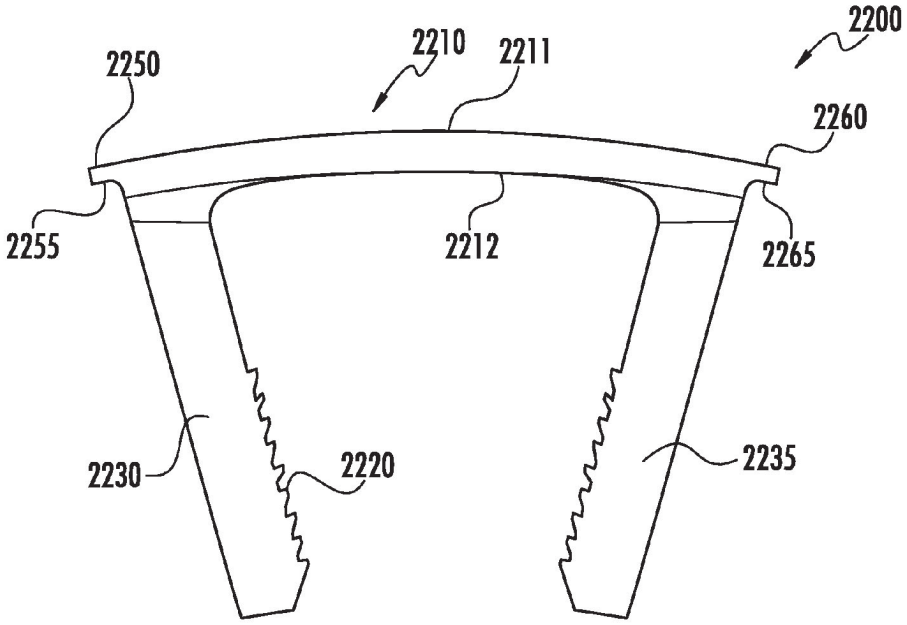

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FIG. 78

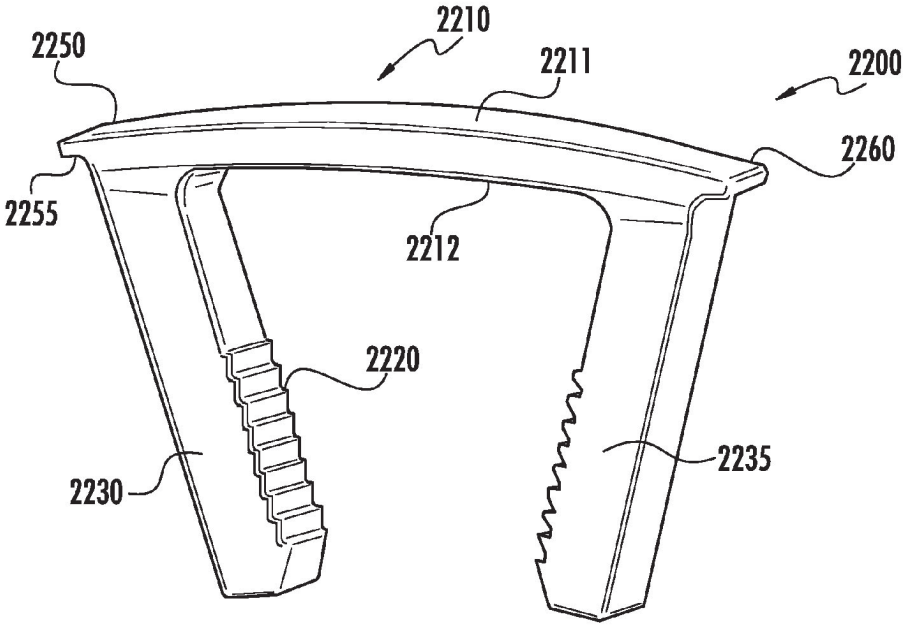

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FIG. 79

BONE IMPLANT AND MEANS OF INSERTION

BACKGROUND OF THE INVENTION

[0001] Field of the Invention

[0002] The present invention is in the technical field of medical devices. More particularly, the present invention is in the technical field of bone fixation or arthrodesis or deformity correction. The invention relates to a fixation system for bones of all types with an assembly comprised of an inserter and implant. Such systems are used in osteosynthesis (bone fusion), wherein the implant bridges the fracture generating compression (or distraction) across the bone members. The compression (or distraction) is generated by the properties of the implant and the different configurations of the implant. For example, the implant may have a first configuration when in free-state and a second configuration required for insertion. It is desirable for optimal implant placement and function to be able to pre-assemble or attach the implant to an inserter to facilitate placement of the implant on or in the bone. The implant may be indicated for the various bones of the entire skeleton. A "bone fixation device" or implant may include any of a variety of devices that secure an object to a bone, including but not limited to staples, bone plates, modular staples, bone screws, pins, blades, suture anchors, and the like.

[0003] The Related Art

[0004] The present invention seeks to remedy the problems of the prior art. The invention produces a system that allows placement of an implant in its final required position with or without additional manipulation. In addition, the present invention will maintain an implant in a first configuration allowing the implant to assume at least a second configuration once placed in its final position. The current invention may not require additional implant positioning manipulation once the inserter is removed or it may be manipulated after insertion. Also, the current invention may incorporate other necessary features into the inserter and implant that are required for final placement. For example the inserter may allow preparation for drill holes, bone screws, etc. and or act to position to the implant in a particular location or position.

SUMMARY OF THE INVENTION

[0005] The present invention includes a fastening device or implant and a means of insertion and or manipulation. The fastening device may be a bone staple, bone plate, modular staple, or the like. The fastening device has elastic properties or other material properties that allow the device to have at least two configurations or configurable to various positions placed on the bone. The free-state or implanted-state of the device may provide compression and or distraction across two or more bone members. The inserter may hold the fastening device (or implant) in a configuration that is different than the free-state or implanted-state configuration. This first configuration may be useful in placement of the implant onto or into bone members. Fastening device and implant are used interchangeably in this application and are not intended to be limiting in nature. And the means of insertion or manipulation may be referred to herein as the inserter and or the delivery instrument.

[0006] The present invention may have the inserter pre-assembled to the implant or affixed to the implant at the time of use. The inserter may be temporarily attached to the implant to facilitate the final implantation of the implant device. The inserter may have features that engage the implant to facilitate the inserter maintaining the first implant configuration. Similarly, the implant may have features for engaging the inserter. The inserter is attached to or engaged with the implant in such a way that allows removal of the inserter once the implant is in its final position on or in the bone. Once the inserter is removed, additional manipulation may not be needed to position the implant in its final placement. Alternatively, the implant may be manipulated to achieve final orientation (e.g. compression). The inserter preferably engages the implant such that it does not interfere with final implant placement.

[0007] The present invention has an implant or portion of an implant that is made of an elastic material or a material that allows the implant to have multiple configurations. The ability of the implant to have multiple configurations may be a result of the material properties that have shape memory or super elastic properties or it may be a result of manipulation (mechanical, physical, chemical or otherwise) of the implant to create a second configuration. The implant may be held in one configuration during insertion or removal and returns to or is placed in another configuration in its free-state or implanted-state. The implant may have features for engaging the bone. These features may include bone screws, leg members, or other features for attaching the implant to bone. The implant may have features for engaging the inserter. The engagement between the implant and inserter may allow the implant to be placed in its final position without the inserter interfering with this final positioning. The implant may be placed in its final position while the inserter is still engaged to the implant eliminating the need for final/secondary seating. The inserter is preferably removed from the implant in a direction or manner that is conducive to the surgical procedure. For example, this removal may be from the top, side or any other direction or motion. Once the inserter is removed, the implant may take on the free-state or implanted-state configuration. The engaging features of the inserter and or implant may also be used to remove or revise the implant should such a need arise. While the implant is in its implanted position, the inserter may be re-engaged to the implant. The inserter device normally engages the implant in such a way that it maintains the implant in a first configuration. The implant may have at least a second configuration after the inserter is removed, which is different from the first configuration either via material properties or deformation to a final shape. The inserter may have a feature or features such as guide means that allow use of drills, screws, drivers, depth gages, etc. while the inserter is still attached to the implant. The inserter may have a feature or features that allow for preparation of the bone for the implant while the implant is attached to the inserter. The inserter may have features and/or mechanisms that allow manipulation of the implant to achieve at least a second configuration. The inserter may also have members or features that engage some aspect of the implant for maintaining a first configuration. The members may be stationary, non-stationary or movable (retractable, etc.). The inserter is preferably attached to the implant in such a way that it does not interfere with the final placement or seating of the implant. For example, the inserter may not be attached in such a way that it will inhibit the final positioning or placement of the implant on or into the bone. For example, the inserter may

be "top loading" or able to be removed in a direction away from the bone. The inserter may allow for a change in the relative position of for example the fastening member(s) or leg or legs to the bridge member to achieve a desired effect such as compression. This relative change or changes in position should not interfere with the final seating of the bridge member or legs on or into the bone.

[0008] The inserter may be a one piece construct, two piece construct, etc. or an assembly. The construct may separate into multiple pieces to facilitate attachment to or removal from the implant. The implant and inserter may be assembled to each other by the manufacturer or may be assembled at the time of use.

[0009] The implant may have multiple configurations, for example one for inserting into the bone and at least a second configuration for compressing, distracting, controlling spatial orientation or the like of one or more bone segments. The implant may have one or more bridge members. The implant may have leg members for engaging the bone. The implant may have modular members for engaging bone, such as bone screws, pins or pegs. To those skilled in the art, it will be evident that multiple options exist for connecting an implant to bone. The connecting members or features may not necessarily be of the same material as the bridge component. The deformability aspect of the current invention may be in the bridge member(s), the connecting member(s) or another member(s) of the implant or fixation device. The material properties of the current invention may be appropriate for allowing manipulation other than shape memory of the implant features to generate the desired outcome or final configuration of the implant. The leg member(s) may be configured to receive members from the inserter to hold the implant in its first configuration or to allow manipulation of the implant to another configuration. The first configuration may hold the implant in such a way to facilitate final seating of the implant in its final position against the bone. The inserter/implant assembly preferably is such that there is no interference of the inserter features between the implant and the bone. Removal of the inserter may allow the implant to take on a second or third or additional configuration. Alternatively, the inserter may be used to manipulate the implant into a second or third or additional configuration.

[0010] The foregoing summary of the current invention discusses the merits of the current invention in terms of an implantable device. The merits of the current invention may also apply to an embodiment of the invention in an external or non-implantable embodiment. The use of the current invention is not limited to just implantable embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. **1***a* is a perspective view of a first embodiment of the current invention depicting a multiple component inserter attached to a modular implant or fixation device.

[0012] FIG. **1***b* is a frontal view of the first embodiment shown in FIG. **1***a*.

[0013] FIG. **1***c* is a top view of the first embodiment showing a section line A-A.

[0014] FIG. **1***d* is the section view A-A shown is FIG. **1***c*

[0015] FIG. **1***e* is the section view A-A but with bone screws inserted as a means of fixating the implant to the bone.

[0016] FIG. **2***a* is a perspective view of the first embodiment of the current invention. depicting a multiple component inserter attached to a modular implant or fixation device.

[0017] FIG. **2***b* is a cross a front view of the first embodiment shown in FIG. **2***a*.

[0018] FIG. **2***c* is a top view of FIG. **2***b* showing a section line B-B.

[0019] FIG. **2***d* is the section view B-B shown in FIG. **2***c*.

[0020] FIG. **3** is a perspective view of the implant of the first embodiment in a second configuration with bone screws assembled.

[0021] FIG. **4** is a perspective view of the first embodiment of FIG. **1** on a bone.

[0022] FIG. **5** is a perspective view of the first embodiment of FIG. **1** on a bone and showing preparation of the bone with a drill bit.

[0023] FIG. **6** is a perspective view of the first embodiment of FIG. **1** on a bone and showing preparation of the bone with a drill bit.

[0024] FIG. **7** is a perspective view of the first embodiment of FIG. **1** on a bone after the final placement of the implant has been completed.

[0025] FIG. **8** is a perspective view of the first embodiment of FIG. **1** on a bone after the final placement of the implant has been completed.

[0026] FIG. **9** is a perspective view of the implant of the first embodiment of FIG. **1** on the bone after the final placement of the implant has been completed.

[0027] FIG. **10***a* is a perspective view of the first embodiment of FIG. **1** not shown on a bone showing the use of a drill.

[0028] FIG. **10***b* is a perspective view of the first embodiment showing the drill abutted against the drill guide.

[0029] FIG. **10***c* is a front view of the first embodiment of FIG. **1** not shown on a bone showing a drill abutted against the drill guide.

[0030] FIG. **11** is a perspective view of second embodiment of an implant or fixation device shown in a first configuration with parallel leg members.

[0031] FIG. **12** is a perspective view of the second implant embodiment of FIG. **11** shown in a second configuration with the legs converging.

[0032] FIG. **13** is a perspective view of a second embodiment of an inserter.

[0033] FIG. **14** is a perspective view of a second embodiment of an implant or fixation device shown in a first configuration with parallel leg members on the inserter of FIG. **13**.

[0034] FIG. **15***a* is a front view of a third embodiment of an implant or fixation device in a first configuration.

[0035] FIG. **15***b* is a front view of the third implant embodiment in FIG. **15***a* in a second configuration.

[0036] FIG. **16***a* is a perspective view of the third implant embodiment in FIG. **15***a*.

[0037] FIG. **16***b* is a perspective view of the third implant embodiment in FIG. **15***b*.

[0038] FIG. **17***a* is a front view of the third embodiment of an implant assembled to the third embodiment of the inserter.

[0039] FIG. **17***b* is a front view of the third embodiment of the implant at the end of engagement to the third embodiment of the inserter.

[0040] FIG. **17***c* is a front view of the third embodiment of the implant separated from the third embodiment of the inserter.

[0041] FIG. **18***a* is a perspective view of FIG. **17***a*.

[0042] FIG. **18***b* is a perspective view of FIG. **17***b*.

[0043] FIG. **18***c* is a perspective view of FIG. **17***c*.

[0044] FIG. **19** is a perspective view of a fourth embodiment of the current invention depicting an implant preassembled to an inserter with retractable engagement pins.

[0045] FIG. **20** is a close up view of the working tip of the fourth embodiment depicted in FIG. **19**.

[0046] FIG. **21** is a perspective view of a fifth embodiment of an implant in an alternate configuration with the legs or fixation members out of plane relative to each other.

[0047] FIG. **22** is another perspective view of the implant in FIG. **21** showing an alternate configuration with the legs or fixation members out of plane relative to each other.

[0048] FIG. **23***a* is a front view of an implant of a sixth embodiment assembled to an implant carrier.

[0049] FIG. **23***b* is a side view of the implant and implant carrier of FIG. **23***a*.

[0050] FIG. **24** is an isometric view of the sixth embodiment of the implant and implant carrier assembly shown in FIGS. **23***a* and **23***b*.

[0051] FIG. **25** is a front view of the implant carrier of the sixth embodiment shown in FIG. **24** without the implant assembled to it.

[0052] FIG. **26***a* is an isometric view showing the inserter and an implant/carrier assembly of the sixth embodiment prior to installing the carrier to the inserter.

[0053] FIG. **26***b* is an isometric view of the sixth embodiment shown in FIG. **26***a* further showing the implant/carrier assembled to the inserter.

[0054] FIG. **27***a* is an isometric view showing the sixth embodiment of FIG. **26** prior to releasing the implant from the inserter and carrier.

[0055] FIG. **27***b* is an isometric view showing the sixth embodiment of FIG. **26** after releasing the implant from the carrier, further showing the implant released from the carrier and the carrier still engaged with the inserter.

[0056] FIG. **28** shows the sixth embodiment further depicting the implant, assembled to the inserter via the carrier, being fully seated on the bone, further showing that the inserter and carrier do not interfere with the placement of the implant in its final position.

[0057] FIG. **29** is a close-up view of the implant/inserter interface of a seventh embodiment depicting an implant assembled to the inserter further showing the inserter engaging the periphery of the implant thereby not interfering with the final seating of the implant.

[0058] FIG. **30** shows the seventh embodiment of FIG. **29** depicting the inserter being released from the implant by rotating the inserter off the implant.

[0059] FIG. **31** shows an eighth embodiment of the current invention with engaging members extending through an implant for provisional fixation on the bone surface.

[0060] FIG. **32** is a bottom view of an implant of the ninth embodiment of the current invention depicting an implant with a means for connection to bone engaging features and a means for engaging an inserter.

[0061] FIG. **33** is a bottom perspective view of the embodiment shown in FIG. **32**.

[0062] FIG. **34** is a perspective view of the ninth embodiment depicting the implant depicted in FIG. **32** assembled to an inserter of the current invention. The implant is held in a first configuration.

[0063] FIG. **35** is a perspective view of the ninth embodiment depicting of the implant depicted in FIG. **32** assembled to an inserter of the current invention. The implant is shown in a second configuration.

[0064] FIG. **36** is a bottom perspective view of the implant-inserter assembly depicted in FIG. **34**

[0065] FIG. **37**A is a section view of the implant-inserter assembly depicted in FIG. **34**

[0066] FIG. **37**B depicts alternate geometries for various means of insertion.

[0067] FIG. **38** is a top view an of an implant of a tenth embodiment of the current invention depicting a "T" shaped implant with a means for connection to bone engaging features and various means for engaging an inserter.

[0068] FIG. **39** is a perspective view of the implant of the tenth embodiment of the current invention.

[0069] FIG. **40** is a bottom perspective view of an inserter of the tenth embodiment of the current invention depicting an inserter with means for engaging the implant depicted in FIG. **38**.

[0070] FIG. **41** is a top perspective view of an inserter of the tenth embodiment of the current invention depicting an inserter with means for engaging the implant depicted in FIG. **38**.

[0071] FIG. **42** is a top perspective view of a tenth embodiment of the current invention depicting a partial implant-inserter assembly of the implant depicted in FIG. **38** and the inserter depicted in FIG. **40**. The implant is shown in a first configuration.

[0072] FIG. **43** is a top perspective view of a tenth embodiment of the current invention depicting a completed implant-inserter assembly of the implant depicted in FIG. **38** and the inserter depicted in FIG. **40**. The implant is shown in a first configuration.

[0073] FIG. **44** is a top perspective view of the tenth embodiment depicting the implant-inserter combination depicted in FIG. **43** depicting a partial disassembly of the implant-inserter combination. The implant is shown in a second configuration.

[0074] FIG. **45** is a perspective view of one of the implant-inserter connection means of the assembly shown in FIG. **43**.

[0075] FIG. **46** is a perspective view of one of the implant-inserter connection means of the assembly shown in FIG. **43**.

[0076] FIG. **47** is a side view of an eleventh embodiment of the current invention depicting an implant with a means for engaging an inserter.

[0077] FIG. **48** is a perspective view of the embodiment depicted in FIG. **47** illustrating the means for engaging an inserter

[0078] FIG. **49** is a top perspective view of an eleventh embodiment of the current invention depicting an inserter with means for engaging an implant of the current invention.

[0079] FIG. **50** is a top view of the inserter depicted in FIG. **49**

[0080] FIG. **51** is a front view of the inserter depicted in FIG. **49**

[0081] FIG. **52** is a bottom view of the inserter depicted in FIG. **49**

[0082] FIG. **53** is a top perspective view of the eleventh embodiment of the current invention depicting a partial implant-inserter assembly of an implant and the inserter depicted in FIG. **49**. The implant is shown in a first configuration.

[0083] FIG. **54** is a bottom perspective view of the implant-inserter combination depicted in FIG. **53**

[0084] FIG. **55** is a top perspective view of an additional embodiment of the current invention depicting a completed implant-inserter assembly of an implant and the inserter depicted in FIG. **49**. The implant is shown in a first configuration.

[0085] FIG. **56** is a bottom a perspective view the implant-inserter combination depicted in FIG. **55**.

[0086] FIG. **57** is a perspective view of the eleventh embodiment depicting the implant-inserter connection means of the assembly shown in FIG. **55**. The implant is shown in a first configuration.

[0087] FIG. **58** is a top perspective view of the eleventh embodiment depicting the implant-inserter combination depicted in FIG. **55** depicting a partial disassembly of the implant-inserter assembly of an implant and the inserter depicted in FIG. **49**. The implant is shown in a second configuration.

[0088] FIG. **59** is a front view of partial disassembly of the implant-inserter assembly represented in FIG. **58**. The implant is shown in a second configuration.

[0089] FIG. **60** is a top view of a twelfth embodiment of the current invention depicting an implant with a means for connection to bone engaging features and various means for engaging an inserter.

[0090] FIG. **61** is a perspective view of the embodiment shown in FIG. **60**.

[0091] FIG. **62** is a top view of a thirteenth embodiment of the current invention depicting an implant with a means for connection to bone engaging features and a means for engaging an inserter.

[0092] FIG. **63** is a front view of the embodiment shown in FIG. **62**

[0093] FIG. **64** is a perspective view of the embodiment depicted in FIG. **62** illustrating the means for connection to bone engaging features and the means for engaging an inserter

[0094] FIG. **65** is a top view of a fourteenth embodiment of the current invention depicting an implant with a means for connection to bone engaging features and a means for engaging an inserter.

[0095] FIG. **66** is a bottom view of the embodiment shown in FIG. **65**.

[0096] FIG. **67** is a perspective view of the embodiment shown in FIG. **65**.

[0097] FIG. **68** is a section view of the embodiment shown in FIG. **65**.

[0098] FIG. **69** is a top view of a fifteenth embodiment of the current invention depicting an implant with a means for connection to bone engaging features and a means for engaging an inserter.

[0099] FIG. **70** is a perspective view of the embodiment shown in FIG. **69**.

[0100] FIG. **71** is a section view of the embodiment shown in FIG. **69**.

[0101] FIG. **72** is a top view of a sixteenth embodiment of the current invention depicting an implant with a means for connection to bone engaging features and a means for engaging an inserter.

[0102] FIG. **73** is a front view of the embodiment shown in FIG. **72**.

[0103] FIG. **74** is a bottom view of the embodiment shown in FIG. **72**.

[0104] FIG. **75** is a perspective view of the embodiment shown in FIG. **72**.

[0105] FIG. **76** is a perspective view of a seventeenth embodiment of the current invention depicting an implant with a means for connection to bone engaging features and a means for engaging an inserter.

[0106] FIG. **77** is a side view of the implant depicted in FIG. **76**.

[0107] FIG. **78** is a front view of an eighteenth of the current invention depicting an implant with bone engaging features and a means for engaging an inserter.

[0108] FIG. **79** is a perspective view of the embodiment depicted in FIG. **78**

DETAILED DESCRIPTION OF THE INVENTION

[0109] The present invention may include a fastening device and an inserter. Exemplary embodiments of the fastening device and inserter are shown in FIGS. **1**, **14** and **19**. The fastening device may be of a configuration similar to a modular staple or bone plate as shown in FIG. **3**. The fastening device may also have a configuration resembling a bone staple as shown in FIGS. **11**, **12**, **15** and **16**. The present invention may have the inserter pre-assembled or affixed to the implant as shown in FIGS. **1** and **14**. The implant or implants may not be pre-assembled to the inserter. The implant or implants could be held in a particular configuration in the packaging that facilitates engagement with the inserter. FIGS. **11** and **12** depict an embodiment of the fastening device or implant that shows one possible combination of implant configurations. FIGS. **11** and **14** show this embodiment maintained in a first configuration for insertion. FIG. **12** shows this embodiment in its free-state or implanted-state configuration.

[0110] The 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.

[0111] As shown in FIGS. **1***a*, **1***b*, **1***d* and **1** *e*, the inserter **100** is assembled to the implant **120**. The implant **120** is shown in a first configuration that may or may be flat. The inserter **100** may or may not have features that allow preparation of the bone for receiving other members of the implant. In this embodiment, the inserter **100** has two tube members **102***a* and **102***b* that allow the bone to be prepared through the internal diameters **106**. The tube members **102***a* and **102***b* also serve as drill guides. Implant **120** is temporarily connected to the tubes **102***a* and **102***b* by the engagement pins **104***a* and **104***b*. The two independent tubes **102***a* and **102***b* are individually connected to the implant **120** by the engagement pins **104***a* and **104***b*. The engagement pins may or may not extend completely through the implant. The engagement pins could also be temporarily or permanently attached to the implant as opposed to being part of the

inserter assembly. The engagement pins may extend through the implant with features that engage the bone for provisional fixation during the procedure. Also, this embodiment shows the use of circular pins, however, to those skilled in the art the use of other attachment means will be obvious and may or may not be separate pieces from the tube members. The 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. The two independent tubes are held in relative position to each other by clip **110**. Clip **110** has a means for holding during insertion or removal, tab member **114**, and two engagement pins **112**. The engagement pins **112** engage the tubes **102***a* and **102***b* to hold them in relative position to each other thereby maintaining the implant **120** in its first configuration. FIG. **1***e* depicts the inserter with the bone screws **130** inserted into the implant **120** while the implant is maintained in its first configuration. FIGS. **1***c* and **1***d* show an engagement **119** where the engagement pins **104***a* and **104***b* controllably interface with the engagement holes **122** shown in FIG. **3**. Implant **120** is shown in a first configuration in FIGS. **1***a*, **1***b*, **1***d* and **1** *e*. Alternatively, the inserter **100** may be used for implant manipulation or for holding the implant in a first configuration with or without a means for preparing for other implant members, e.g. bone screws. The bone preparation may or may not be distinct from the inserter. Bone preparation may be done in the implant first configuration and/or in a second configuration.

[0112] FIGS. **2***a*, **2***b*, **2***c* and **2***d* depict the inserter **100** without the clip **110**. The inserter assembly **100** is shown in a manner depicting an initial release step that may or may not allow the implant **120** to have a second configuration. In this embodiment, the bone screws **130** have been prepared and placed into the implant **120**. The inserter tubes **102***a* and **102***b* are still engaged in the implant **120** via the engagement pins **104***a* and **104***b*. The implant **120** is shown in a second configuration and is achieved either by the intrinsic mechanical properties of the material or secondary mechanical manipulation of one or more areas of the plate. FIGS. **2***a*, **2***b*, **2***c* and **2***d* show the inserter temporarily attached to the implant after preparation of the bone and placement of the bone screws **130**. The inserter **100** is shown just prior to removal of the inserter **100** from the implant **120**. The independent inserter tubes **102***a* and **102***b* accommodate the second configuration of the implant **120**.

[0113] FIG. **3** depicts the implant **120** in its second configuration after removal of the inserter **100** or possibly after secondary mechanical manipulation/deformation. The bone screws **130** may be prepared and positioned through the internal diameter **106** while the inserter **100** was still attached to the implant **120**. FIG. **3** shows one embodiment of the engagement hole **122** that accepts the engagement pins **104***a* and **104***b* of the inserter tube **102***a* and **102***b*.

[0114] FIG. **4** depicts one embodiment of the inserter **100** assembled to implant **120** on a foot **140**. 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 or other fixation features of the implant **120**. In FIGS. **4**, **5** and **6**, clip **110** maintains the tubes **102***a* and **102***b* in a relative position to each other. Clip **110** may or may not be a separate assembly; the functionality could be achieved via an integral feature, molded-in for example, to the tube(s). Clip **110** is shown to provide a rigid, static connection between the tubes **102***a* and **102***b*. The connection mechanism between the tubes **102***a* and **102***b* may also have a dynamic, moveable connection (e.g. application of springs) so that the tubes will allow the plate to conform in some way to the bone prior to complete removable of clip **110**. The tubes **102***a* and **102***b* are controllably engaged in implant **120** via engagement pins **104***a* and **104***b* and engagement features **122**. In this embodiment, the clip **110**, the tubes **102***a* and **102***b*, engagement pins **104***a* and **104***b* and engagement holes **122** act together to maintain the implant **120** in a first configuration. In alternate embodiments more components or fewer may be needed to maintain the implant in a first configuration.

[0115] FIG. **7** depicts one embodiment of the inserter **100** assembled to implant **120** on a foot **140**. This figure depicts the first removal step for this particular embodiment of the inserter **100**. In FIG. **7** the bone has been prepared accordingly and the implant **120** is in its final position on the bone and its first configuration. FIG. **7** shows removal of clip **110** from inserter **100**. As further shown in FIG. **8**, removal of the clip **110** from the inserter **100** after completing the appropriate bone preparation allows the implant **120** to adapt to a second configuration while the implant **120** is in its final implant position. Bone screws **130** (not shown in FIG. **7** or **8**) may or may not have been prepared and positioned while the inserter assembly **100** was engaged to the implant **120**. FIG. **9** shows implant **120** on bone **140** after removal of the inserter assembly **100** after the implant **120** is in its final position either before or after the implant achieves its second configuration.

[0116] FIG. **10***a* depicts an exemplary embodiment of the inserter assembly **100** and implant **120** while also showing preparation steps with drill **150** lined up with the internal diameter **106** of the tubes **102***a* and/or **102***b*. FIGS. **10***a*, **10***b* and **10***c* further show implant **120** controllably engaged to the tubes **102***a* and **102***b* with engagement pins **104***a* and **104***b* (pins not shown in image) engaged in engagement holes **122**. Clip **110** is controllably maintaining the tubes relative to each other with the engagement pins **112** engaged in the tubes **102***a* and **102***b*. Drill **150** has a fluted region **152**, a shaft **154** and a stop **156**. FIG. **10***b* and FIG. **10***c* show the drill stop **156** abutted against the top surface of the drill tube **102***a* or **102***b*. The stop **156** may be used to prevent the drill from extending too far into the bone during preparation. The stop **156** may be used to control the drill depth so the fluted region **152** only protrudes through the drill guide/tubes **102***a* and/or **102***b* to a predetermined depth.

[0117] In this exemplary embodiment the implant **120** may be made of a material that may have elastic or spring properties that allow the implant to have more than one configuration. FIG. **3** shows the implant **120** in a possible free-state or implanted-state of the device. The free-state or implanted-state may provide compression (or distraction) across bone members. FIG. **3** shows the implant **120** having a thickness **126** and a bridge member **124**. It further shows the implant **120** having an arc or radius **128** while in its second configuration. FIG. **3** also shows an example of a bone attachment device **130**, which in this case resembles a bone screw. The attachment device **130** is rigidly attached to the implant **120** through the attachment feature **129**. The attachment feature **129** is such that it allows the bone attachment device to be locked to the material that may have elastic properties. The bridge member **124** depicted in FIG. **3** also has an engagement feature **122** for controllably

engaging the inserter for maintaining the first configuration. The embodiment depicted thus far allows the implant **120** to be fully seated to the bone in its final position without the inserter interfering with this final position. When the implant is placed in its final position, it may or may not be in its second configuration. The implant may remain in a first configuration until the inserter is removed or further manipulation is performed.

[0118] FIG. **11** shows an exemplary embodiment of an implant **200** that resembles a bone staple. The implant is shown in a first configuration where the legs **220** are relatively parallel to each other. This first configuration may be useful in facilitating implantation of the implant **200** into bone. The first configuration may be the configuration that is maintained by an inserter. FIG. **11** depicts implant **200** having a bridge member **210** with a thickness **202**. Thickness **202** may or may not be more or less than thickness **204**. This particular embodiment shows the bridge member **210** have a radius **206**. Radius **206** may or may not be present. FIG. **11** further shows legs **220** having a feature **230** for engaging an inserter. The engaging feature **230** may be an internal feature, external feature, may be positioned on the interior or exterior of the legs **230**. It is also reasonable to have an engagement feature similar to engaging holes **122** in this type of device. Implant **200** has bone engagement means in the form of barbs **225** which engage the bone in order to maintain the implant in the bone. FIG. **12** shows the implant **200** of FIG. **11** in a second configuration. In this particular configuration of FIG. **12**, the legs **220** converge towards each other. Either one or multiple legs may move to create this convergence or distraction. The second configuration may be the free-state or implanted-state.

[0119] FIG. **13** shows another embodiment of an inserter **240**. Inserter **240** has a holding piece **242** and at least one engaging pin **244**. The engaging pins **244** are spaced and oriented appropriately to interact with an implant to maintain a first configuration. FIG. **14** shows the inserter **240** assembled to an implant **200**. The engaging pins **244** of inserter **240** engage the internal diameter **230** of implant **200** to maintain the implant **200** in a first configuration. When the inserter **240** is removed the implant assumes a second configuration as shown in FIG. **12**.

[0120] FIG. **15***a* shows yet another embodiment of an implant or fixation device **300**. The implant **300** has a bridge member **310** and leg members **325**. The bridge member **310** has a thickness **315** that may or may not be the same as the leg thickness **320**. FIG. **15***a* shows the implant in a first configuration. FIG. **15***b* shows the implant **300** in a second configuration. The implant of FIGS. **15***a* and **15***b* is also shown in FIGS. **16***a* and **16***b* depicting an internal diameter **330**. Opening **340** is generated by the internal diameter **330** breaking out into the inside of the leg. The opening **340** may or may not be needed for this current invention. The internal diameter **330** may be used to engage the inserter and maintain the implant in a particular configuration. The internal diameter **330** may also be used to manipulate the implant into another configuration whereas the relationship between the implant legs **325** is changed by creating convergence, divergence or some other out of plane relationship.

[0121] Alternate embodiments may include an inserter and implant that work in conjunction to create a first and second configuration.

[0122] FIG. **17***a* shows an embodiment of an implant **300** on an inserter **400** with the implant being in a first configuration. FIG. **17***b* shows the same embodiment with the implant **300** at the end of the engagement pins **410** of the inserter **400**. The implant in FIG. **17***b* is transitioning to a second configuration. FIG. **17***c* shows the implant **300** fully disengaged from the inserter **400**. The implant **300** is in a second configuration. FIGS. **18***a*, **18***b* and **18***c* depict the embodiments in FIGS. **17***a*, **17***b* and **17***c* in a perspective view.

[0123] The embodiments shown herein depict the engagement between the implant and inserter as using pins. Those skilled in the art will appreciate that various means may be used to attach the implant to the inserter.

[0124] FIGS. **19** and **20** depict an embodiment of an inserter **500** that is preassembled to an implant **300**. The inserter **500** has a holding means **510** and an impact or seating means **530**. Handle **520** is slide-ably engaged in the body **505**. The assembly **500** has means for engaging an implant, **515**. In this embodiment the engaging means are pins **515**. Pins **515** are connected to handle **520** such that the pins will retract from implant **300** thereby ejecting or releasing the implant from the inserter assembly **500**. In this embodiment the pins or engagement means are retractable. Those skilled in the art will appreciate that the same effect can be achieved without retractable engagement means where the implant may be pushed off the engagement means with a plunger type mechanism that may push the implant off or from the inserter assembly.

[0125] FIGS. **21** and **22** show an embodiment of an implant in an alternate configuration. This embodiment resembles a bone staple, but those skilled in the art will appreciated that this embodiment could also be achieved with modular fixation means such as bone screws. The implant **600** has a bridge member **610** with thickness **615**. The bridge member **610** is connected to fixation members or legs **620**. Legs **620** are out of plane relative to each other. Legs **620** may or may not be out of plane relative to the bridge member **610**. The implant **600** may have engaging features **630** to control and/or manipulate the implant into alternate configurations. The engaging features **630** may or may not extend through the entire implant. The engaging features **630** may be positive or negative features in the implant or inserter. This alternate configuration may or may not be achieved through the inherent material properties of the implant material. The implant may achieve this alternate configuration by transitioning from, for example, configuration **1** to configuration **2** to configuration **3**. Where configuration **1** may be that as attached to the inserter or delivery instrument and configuration **2** may be a configuration where the leg members **620** are in a compressed state and where configuration **3** may be a configuration where the compressed legs of configuration **2** are made to be out of plane to each other. Alternately, the implant may achieve this alternate configuration by transitioning from, for example, configuration **1** to configuration **2**. Where configuration **1** may be that as attached to the inserter or delivery instrument and configuration **2** may be a configuration where the leg members **620** are in a compressed state and are made to be out of plane to each other. This embodiment is not intended to be limiting. The transition from one configuration to another configuration may be one distinct transition or more than one distinct transition. The transition may be due to the

inherent material properties or achieved by a manipulation of the material or a combination thereof.

[0126] The embodiments described herein can be manufactured from a number of different materials or combinations of materials. Nitinol, for example, possess material properties, such as shape memory and/or super elasticity that may provide the inherent properties to allow an embodiment to have multiple configurations with or without an external mechanical manipulation. Stainless steel and/or titanium also have desirable material properties for the embodiments described herein. Stainless steel and/or titanium may not possess shape memory or super elasticity, but may possess the mechanical properties for embodiments that may benefit from mechanical manipulation to achieve multiple configurations. Still other materials such as PEEK or other polymers may also possess material properties beneficial for the embodiment described herein. A combination of materials may also be preferred. For example, a nitinol plate with titanium screws may be the materials of choice for some embodiments. Those skilled in the art are aware of the typical materials and combinations of materials applicable to the current invention.

[0127] Yet another embodiment of this invention may have the implant assembled onto a holding means such as an apparatus or carrier that may be assembled to an inserter at the time of surgery, as shown in FIGS. **23***a*, **23***b*, **24**, and **25-28**.

[0128] FIGS. **23***a* and **23***b* show an exemplary embodiment of an implant carrier, **700**, assembled to an implant embodiment, **800**. FIG. **23***a* is a front view of the assembly and FIG. **23***b* is a side view of the assembly. FIG. **24** shows the carrier, **700**, slidably engaged to the implant, **800**. Implant **800** has features **810** for receiving the engaging features **710** of the carrier. The carrier **700** may have features and/or geometries **720** for engaging the inserter. The carrier **700** may have features and/or geometries **730** for additionally engaging the inserter. The engaging features and or geometries **720** and **730** may be used separately or in combination to provide a poka-yoke feature that prevents incorrect assembly of the carrier to the inserter. Features **720** and or **730** may also be used to assist the inserter in removing the carrier from the implant, i.e. releasing the implant from the carrier, at the time of implantation. The carrier **700** may be configured to fit multiple sized implants. The engaging features **710** of the carrier **700** may change from size to size in order to optimize the fit between the implant **800** and carrier **700**. The engaging features (e.g. **720** and **730**) of the carrier may or may not change by implant size. Keeping such features consistent among varying implant sizes may allow the use of multiple implant carriers with the same inserter.

[0129] FIG. **25** more clearly shows the carrier **700** without an implant assembled. As previously described the carrier **700** has features **710** for slidably or by other means attaching and securing the implant in position on the carrier. The inserter engaging feature **720** may have multiple configurations or geometries. The engaging feature **720** may provide an engagement with the inserter that allows the inserter to retract the carrier from the implant **800**. Engaging feature **730** may also be used to attach to the inserter and may provide a poka-yoke feature to prevent improper assembly of the carrier **700** to an inserter. To those skilled in the art, it will be apparent that the function of features **720** and **730** may be combined or alternated to achieve the same purpose and function described in this embodiment.

[0130] FIG. **26***a* and FIG. **26***b* show an exemplary embodiment of an inserter **900** and the implant **800** assembled to the carrier **700**. FIG. **26***a* shows the inserter **900** with the implant carrier **700** prior to assembling the carrier **700** to the inserter **900**. FIG. **26***b* shows the carrier **700** with the attached implant **800** assembled to the inserter **900**. In this exemplary embodiment the inserter **900** has a base component **910**, a handle component **920** and a locking means **930**. The inserter also may have a retaining member **940** that may be used for assisting in maintaining the carrier **700** in a specified position. Retaining member **940** may or may not be integrated into the handle component **920**. This inserter embodiment has features **950** for engaging with the carrier **700** in a poka-yoke means. The locking means **930** may be used to secure the handle component **920** to the base component **910**.

[0131] FIG. **27***a* and FIG. **27***b* show the exemplary embodiments of FIG. **26***a* and FIG. **26***b* in an upright isometric view. FIG. **27***a* shows the carrier **700** and implant **800** attached to the inserter **900** prior to releasing the implant **800** from its carrier **700**. FIG. **27***b* demonstrates one embodiment for releasing the implant **800** from the carrier **700**. FIG. **27***b* shows the handle **920** in a retracted position that removes the carrier **700** from the implant **800**. In the state shown in FIG. **27***b* the implant is now free from the carrier **700**. The carrier **700** may be removed from the inserter **900** and replaced with another implant/carrier assembly.

[0132] FIG. **28** demonstrates the exemplary embodiments of the inserter **900** the carrier **700** and the implant **800** allowing the implant **800** to be seated flush against a bone surface **1000**. One will notice that the inserter **900** does not interfere with the final placement of the implant **800**. For an implant **800** having a second configuration where the parallel legs are allowed to converge after releasing from the inserter **900** and carrier **700**, not having to perform a secondary final seating of the implant after release from an inserting device is beneficial.

[0133] FIG. **29** shows a close-up view of the implant/inserter interface of another exemplary embodiment of an inserter **1100** and an implant **1200**. The inserter **1100** has means **1120**, **1130** and **1110** for attaching to the implant. These attachment means engage the implant **1200** in such a way to not prohibit final seating of the implant **1200** in its final desired position. FIG. **30** shows one possible means for releasing the implant **1200** from the inserter **1100**. This embodiment demonstrates a rotation of the inserter **1100** relative to the implant **1200**. This rotation releasing the engaging means **1120** and **1130** while rotating about the pin **1110**. Once fully rotated and released the inserter **1100** can be removed from implant **1200**.

[0134] FIG. **31** shows the previously described inserter embodiment **100** and **110** assembled to implant **120**. It further shows an embodiment of the engaging means **190** that may purposely extend beyond the implant **120**. The engaging means **190** shown may have tips that are configured to penetrate into a bone surface to provide provisional fixation.

[0135] FIG. **32** depicts an embodiment of the implant **1600** which includes multiple connection means (means for fixation to a bone) **1620** for receiving bone engaging members. The bone engaging members may be bone screws, pegs, blades or other means suitable for engaging bone or

soft tissue. The connection means **1620** may be of the same or varying styles or geometries for a particular implant. For example, some of the connection means **1620** in implant **1600** may be threaded and or locking while others may be non-threaded or non-locking. Implant **1600** has a bridge area **1601** spanning between the connection means **1620**. The bridge area **1601** may or may not have multiple rails or members **1602**. This particular embodiment depicts two rail members **1602** defining a space **1603** with a perimeter **1645**. As further shown in FIG. **33** the space **1603** has a lower surface **1641** and **1642** that is recessed from the bottom surface **1640**. Lower surfaces **1641** and **1642** may be of similar or different configurations and or geometries suitable for engaging a means of insertion. FIG. **34** depicts an inserter **1650** that is engaged with the implant **1600**. Inserter **1650** has two members **1652** and **1651** with a space **1655** therein. FIG. **34** shows the implant **1600** held in a first configuration which may or may not be flat. This first configuration may facilitate the surgical implantation. This first configuration may act to store a compressive force or other force. FIG. **35** shows the inserter **1650** partially disengaged from implant **1600**. The members **1651** and **1652** may come together thereby reducing the space **1655** that may enable or facilitate assembly and or disassembly of the inserter **1650** and implant **1600**. As depicted in FIG. **35** as the inserter **1650** is disengaged from the implant **1600** the implant is allowed to take on a second configuration. This second configuration may be achieved by the design of the implant **1600** and or in combination with the intrinsic material properties of the implant and or in combination with the processing of the implant **1600**. This second configuration may act to create a compressive force or other force across one or two bone or tissue segments.

[0136] FIG. **36** depicts the implant **1600** releasably attached to the inserter **1650**. The implant engaging means **1660** and **1661** of the inserter **1650** may engage the implant **1600** by interfacing the implant surface **1641** and **1642**. The arms of the inserter **1651** and **1652** may pass through space **1603** to engage the implant **1600**.

[0137] FIG. **37**A depicts a possible cross section of the implant-inserter combination. The implant is shown in a first configuration. The arms **1651** and **1652** of the inserter **1650** may pass through space **1603** of the implant thereby allowing the upper surfaces **1671** of the engaging members **1660** and **1661** to interface with the lower surfaces **1641** of implant **1600**. Once engaged the inserter arms **1651** and **1652** may provide a force that maintains the implant in a first configuration. In this exemplary embodiment the inserter **1650** is depicted passing through an internal space **1603** of implant **1600**. In other embodiments the inserter may engage on an external feature as will be demonstrated herein. In the current embodiment, the general shape of the engagement is depicted as an "L" shape interface. However to those skilled in the art it is apparent that numerous geometries and configuration or combination of geometries and configurations that are possible and may be encompassed by the current invention. FIG. **37**B depicts several possible alternative geometries for connection to a means of insertion that may be used to maintain a particular implant configuration. FIG. **37**B depicts geometry **1690** which may be generally "L" shaped. FIG. **37**B depicts geometry **1691** which may be generally angled faces or tapered faces or chamfered edges. FIG. **37**B depicts geometry **1692** which may be generally a threaded or other fastening geometry. FIG. **37**B depicts geometry **1693** which may generally represent a bending modality that may utilize specific geometries in combination with locations on an implant surface to maintain a particular implant configuration. FIG. **37**B depicts geometry **1694** which generally may be a combination of a square geometry and a "L" shaped geometry. The means of insertion may or may not be flush with the implant. A combination of features may be used to maintain an implant in a particular configuration or combination of configurations. Certain combinations may be used to hold certain implant features in a configuration that may or may not be the same as the entire implant. For example, certain features or combinations of features may be used to hold one arm or projection of an implant in an upward direction while another feature or combination of features may be used to hold a different arm or projection or portion of an implant in a downward direction. This may allow certain aspects of an implant to achieve various configurations. The connection between an implant and inserter and the means of insertion my hold the implant in a first configuration and or an alternate configuration. As the inserter and implant are disassembled, the disassembly may allow the implant to achieve a second or alternative configuration. This disassembly may allow the implant to achieve multiple alternative configurations. For example, step **1** of the disassembly may allow the implant to achieve a second configuration and step **2** may allow the implant to achieve a third configuration and step **4** of the disassembly may allow the implant to achieve a third configuration. This disassembly may allow the implant or portions of the implant to achieve multiple alternative configurations. For example, step **1** of the disassembly may allow the portion A of the implant to achieve a second configuration and step **2** may allow portion B of the implant to achieve an alternate configuration and step **4** of the disassembly may allow portion C of the implant to achieve an alternate configuration. Those skilled in the art will understand that combinations of alternate configurations of an implant or portions of an implant may be possible with the current invention. Certain alternate configurations may be intermediate configurations that will revert to a previous configuration or may proceed to a final configuration once fully disassembled from the inserter. The embodiments described herein do not limit the scope of the current invention. Further embodiments and combinations of embodiment may be possible and will become evident to those skilled in the art. The current invention may include an inserter and inserter-implant combination that may be used with an implant that has one or more configurations.

[0138] An implant of the current invention may be assembled to an inserter or other delivery instrument by several means that will be evident to those skilled in the art. The implant may be pre-assembled in the packaging or assembled at the time of use. The implant may be predisposed to a first configuration then assembled to an inserter. The implant may be predisposed by various means to achieve a first configuration for assembly with an inserter. Alternatively, an implant may be predisposed by various means to achieve a pre-assembly configuration for assembly with an inserter whereas the pre-assembly configuration may or may not be equivalent to the first configuration or second configuration. The implant may be predisposed by various means to achieve this alternate configuration for assembly with an inserter or other delivery instrument which may include physical deformation of the implant such as bending

or mechanical manipulation, for example applying a force to the implant on flat surface or other surface to temporarily hold the implant in a shape for assembly to the inserter. The implant may be predisposed by various means to achieve this alternate configuration for assembly with an inserter which may include application of an external temperature change, either by heating, cooling and or freezing the implant that may create a change in the physical properties of the material such as to facilitate an alternate configuration for assembly. The implant may be predisposed by various means to achieve this alternate configuration for assembly or re-assembly with an inserter which may include assembly or re-assembly at the time of use. If an implant is already positioned or implanted, either partially or fully, the implant may be in a sufficient configuration that would allow re-assembly of the inserter or other instruments. This may have advantages over existing technologies and may be beneficial in allowing an implant to be removed, repositioned or otherwise adjusted. In addition, the advantages of the current invention may include the ability for the end user to assemble a multi configuration implant to an instrument at the time of use. As shown in the embodiments described herein, the inserter may be designed to provide a means for assembly; a means for maintaining a first implant configuration; and or a means for delivering an implant and achieving an alternate configuration. The instrument may include features such as chamfers, ramps, steps, shoulders, mechanical levers, mechanical interfaces, complementary geometries, etc. for manipulating an implant from an alternate configuration to a first configuration for means of assembly and maintaining a first configuration. The means of assembly may be achieved by a single feature or multiple features on a single inserter or delivery instrument. The means of assembly may be achieved by a single feature or multiple features on a single inserter or delivery instrument or by the use of multiple delivery instruments used sequentially or simultaneously in combination.

[0139] FIG. **38** depicts an embodiment of an implant **1900** of the current invention in a "T" shape. Implants may take on many various configurations. The merits of the current invention are not limited by the shape or style of the implant. In FIG. **38** implant **1900** is shown in a first configuration. The implant **1900** may include multiple connection means for bone engaging members. The bone engaging members may be bone screws, pegs, blades or other means suitable for engaging bone or soft tissue. The connection means **1930** may be of the same or varying styles or geometries for a particular implant. For example, some of the connection means **1930** in implant **1900** may be threaded and or locking while others may be non-threaded or non-locking. Implant **1900** may include a connection for a means for insertion **1925** that is an external feature and may also include a connection for a means for insertion **1920** that is internal. Implant **1900** may include multiple connections **1920** and or **1925** for a means of insertion that may vary in size, geometry, orientation and or configuration. Implant **1900** as depicted in FIG. **38** has a top surface **1910** that may be of uniform shape, size, geometry and or configuration. The perspective view of implant **1900** is shown in FIG. **39**. Implant **1900** may include a top surface **1910** and a bottom surface **1901**. In FIG. **39** implant **1900** may have a rail or bridge member **1911** that may be of varying size, geometry and or configuration. Bridge member **1911** may or may not be similar in size, shape, geometry and or orientation as top surface **1910** or bottom surface **1901**. Implant **1900** may have one or more arms or projections **1902** that may extend from the implant. In FIGS. **38** and **39** implant **1900** is shown in a flat configuration or first configuration. The first configuration may or may not be flat. The first configuration may be flat, angled, arched, bent or some combination thereof. This first configuration may facilitate the surgical implantation. This first configuration may act to store a compressive force or other force.

[0140] FIGS. **40** and **41** depict one embodiment of an inserter of the current invention. Inserter **1950** is configured to interact and or engage implant **1900** shown in FIG. **39**. The inserter **1950** may hold an implant in a first configuration. Inserter **1950** has a connection means **1954** that may be used for engaging a separate handle or other holding means. This exemplary embodiment may also have feature **1951** in various locations, orientations or configurations. One or more features **1951** may be present in a particular implant. Feature **1951** may be used to provisionally or temporarily attach the inserter and implant combination to a surface such as bone or tissue. A pin or other means may be used to pass through features **1951** for maintaining a relative position of the inserter or inserter-implant combination on the bone or tissue. The current invention may include an inserter and inserter-implant combination that may be used with an implant that has one or more configurations. The inserter **1950** may have an implant connection means **1955** for releasably and or rotatably engaging an implant. Inserter **1950** may include at least a second implant connection means **1965** for releasably engaging an implant. Connection means **1965** and **1955** may or may not be of the same size, shape, geometry, orientation or configuration. FIG. **41** depicts a top side perspective view showing how a temporary fixation means **1951** may extend from the upper surfaces **1952** and **1953** through the bottom surfaces **1971** and **1970**. Surfaces **1970** and **1971** may or may not be in the same plane or of the some configuration.

[0141] FIG. **42** depicts inserter **1950** partially engaged with implant **1900**. Implant **1900** may be held in a first configuration by the engagement features **1965** and **1955** of inserter **1950**. FIG. **43** shows the implant **1900** fully engaged with inserter **1950**. Implant **1900** is maintained in a first configuration by the interactions **1980** and **1981** between the implant **1900** and the inserter **1950**. The means of insertion may utilize features similar to **1925** as described herein in combination with other surfaces such as top surface **1910**. This combination of means of insertion **1925** and surface **1910** may be used to maintain one or more features or arms or projection **1902**. A combination of means of insertion such as **1925**, **1910** and or **1920** may be used to create a bending modality, such as a three point or four point bend, to maintain a specific implant configuration or combination of configurations. A combination of surfaces and means of insertion, such as **1925**, **1910** and or **1920**, may be used on the entire implant or portions of an implant to create or maintain a particular configuration of an implant or portions of an implant. For example, a tab such as **1925** and surface, such as **1910**, may be used to maintain one arm or projection such as **1902** of an implant in a particular configuration. When disassembled, that arm may have a configuration that is different from or the same as the configuration of the rest of the implant.

[0142] FIG. **44** depicts the inserter **1950** partially disassembled from implant **1900**. As the implant **1900** disengages

from the inserter **1950** it may achieve a second configuration. This second configuration may be achieved by the design of the implant **1900** and or in combination with the intrinsic material properties of the implant and or in combination with the processing of the implant **1900**. This second configuration may act to create a compressive force or other force across one or two bone or tissue segments.

[0143] FIG. **45** depicts the interaction **1980** between the implant **1900** and the inserter **1950**. The surface **1965** may releasably engage or interact with the connection means **1925** of implant **1900**. Interaction or interface **1980** may work in combination with the interaction or interface **1981** to maintain an implant in a first configuration. Feature **1955** of inserter **1950** may releasably engage feature **1920** of implant **1900**. This interaction or interface may allow rotation, pivoting, latching or other motion to facilitate the assembly or interaction between the implant and inserter.

[0144] The embodiment of the current invention depicted in FIG. **47** is an implant **2100** having a top surface **2110** and one or more connection means **2101** for bone engaging members. The bone engaging members may be bone screws, pegs, blades or other means suitable for engaging bone or soft tissue. The connection means **2101** may be of the same or varying styles or geometries for a particular implant. For example, some of the connection means **2101** in implant **2100** may be threaded and or locking while others may be non-threaded or non-locking. Implant **2100** may have one or more means **2140** and **2120** for connecting to an inserter or other means of insertion. One embodiment of means **2140** may include a top surface **2141** and a bottom surface **2145** as depicted in FIG. **48**. Means **2140** may or may not be in close proximity to connection means **2101**. The embodiment of implant **2100** in FIG. **47** is shown is a first configuration.

[0145] The advantages of the current invention and embodiment shown in FIGS. **42-46** are numerous and may include the ability of the means of insertion to maintain an implant in a first configuration. These embodiments may also allow the implant-inserter combination to be provisionally fixed or temporarily fixed to bone segment or tissue segments while maintaining the implant in a first configuration during the method of implantation. The inserter may be releasably engaged to the implant to facilitate assembly and disassembly of the implant and inserter. The assembly and disassembly is in a direction or movement that is conducive to the surgical procedure. Once the implant and inserter are fully disassembled the implant may achieve a second configuration. This second configuration may be achieved by the design of the implant and or in combination with the intrinsic material properties of the implant and or in combination with the processing of the implant **1600**. This second configuration may act to create a compressive force or other force across one or two bone or tissue segments. The implant may or may not be pre-assembled to the inserter in the final packaging.

[0146] FIGS. **49**, **50**, **51** and **52** depict an inserter **2000** of the current invention. Inserter **2000** may or may not have a connection means **2060** for attaching to a handle or other holding means. The inserter **2000** may have one or more features **2011** and **2012** for temporarily attaching the inserter to one or more bone or tissue segments. The inserter may have means **2040** and **2041** for releasably engaging an implant to maintain an implant in a first configuration or a configuration that is different than the implant configuration of the implant. Inserter **2000** may have one or more projections or arms **2020** and **2010** for facilitating connection to an implant. Inserter **2000** may have bottom surfaces **2030**, **2040** and **2050** for engaging and or facilitating connection to an implant.

[0147] FIGS. **53** and **54** depict inserter **2000** partially assembled to an implant **2100**. The implant may be held or maintained in a first configuration. Top surface **2110** of implant **2100** may slidably interface with bottom surfaces **2030** and **2040** of inserter **2000**. These surfaces may be coplanar and may or may not physically engage one another. Surface **2040** of inserter **2000** may releasably engage bottom surface **2145** of means **2140** on implant **2100**. Surface **2041** of inserter **2000** may releasably engage bottom surface **2125** of means **2120** on implant **2100**. The engagement of surface **2041** with surface **2125** may occur simultaneously with engagement of surface **2040** and surface **2145**. This interaction may maintain implant **2100** in a first configuration. The engagement of surface **2041** with surface **2125** and the engagement of surface **2040** with surface **2145** may occur from opposite directions which may require inserter **2000** to pivot relative to implant **2100**. This engagement may occur from the same direction as a sliding motion or top load motion. The merits of the current invention are maintained regardless of the direction of assembly.

[0148] FIGS. **55** and **56** depict inserter **2000** fully or completely assembled to an implant **2100**. The implant may be held or maintained in this first configuration. FIG. **55** depicts the implant **2100** held in a first configuration which may or may not be flat. The first configuration may be flat, angled, arched, bent or some combination thereof. This first configuration may facilitate the surgical implantation. This first configuration may act to store a compressive force or other force. Top surface **2110** of implant **2100** may slidably interface with bottom surfaces **2030** and **2040** of inserter **2000**. These surfaces may be coplanar and may or may not physically engage one another. Surface **2040** of inserter **2000** may releasably engage bottom surface **2145** of means **2140** on implant **2100**. Surface **2041** of inserter **2000** may releasably engage bottom surface **2125** of means **2120** on implant **2100**. The engagement of surface **2041** with surface **2125** may occur simultaneously with engagement of surface **2040** and surface **2145**. This interaction may maintain implant **2100** in a first configuration. The engagement of surface **2041** with surface **2125** and the engagement of surface **2040** with surface **2145** may occur from opposite directions which may require inserter **2000** to pivot relative to implant **2100**. This engagement may occur from the same direction as a sliding motion or top load motion. The merits of the current invention are maintained regardless of the direction of assembly.

[0149] FIG. **57** depicts the interaction of the holding means between inserter **2000** and implant **2100**. Top surface **2041** slidably engages with bottom surface **2125** of implant **2100**. This may provide the necessary support to maintain an implant in a first configuration or a configuration may be different than the implanted configuration. In this embodiment, the general shape of the engagement is depicted as an "L" shape interface. As previously described herein, alternate geometries and or configurations may be used. However to those skilled in the art it is apparent that numerous geometries and configuration or combination of geometries and configurations are possible and may be encompassed by the current invention. Other possible alternative embodiment of geometries for connection to a means of insertion

have been described herein. The means of insertion may or may not be flush with the implant. The connection between an implant and inserter and the means of insertion my hold the implant in a first configuration and or an alternate configuration. As the inserter and implant are disassembled, the disassembly may allow the implant to achieve a second or alternative configuration. This disassembly may allow the implant to achieve multiple alternative configurations. For example, step **1** of the disassembly may allow the implant to achieve a second configuration and step **2** may allow the implant to achieve a third configuration and step **4** of the disassembly may allow the implant to achieve a third configuration. This disassembly may allow the implant or portions of the implant to achieve multiple alternative configurations. For example, step **1** of the disassembly may allow the portion A of the implant to achieve a second configuration and step **2** may allow portion B of the implant to achieve an alternate configuration and step **4** of the disassembly may allow portion C of the implant to achieve an alternate configuration. Those skilled in the art will understand that combinations of alternate configurations of an implant or portions of an implant may be possible with the current invention. Certain alternate configurations may be intermediate configurations that will revert to a previous configuration or may proceed to a final configuration once fully disassembled from the inserter. The embodiments described herein do not limit the scope of the current invention.

[0150] FIGS. **58** and **59** depict the implant **2100** disengaged or released from the inserter **2000**. The implant **2100** is allowed to achieve a second configuration or a configuration different than the one maintained by the inserter. This second configuration may be achieved by the design of the implant **2100** and or in combination with the intrinsic material properties of the implant and or in combination with the processing of the implant **1600**. This second configuration may act to create a compressive force or other force across one or two bone or tissue segments. The connection between an implant and inserter and the means of insertion my hold the implant in a first configuration and or an alternate configuration. As the inserter and implant are disassembled, the disassembly may allow the implant to achieve a second or alternative configuration. This disassembly may allow the implant to achieve multiple alternative configurations. For example, step **1** of the disassembly may allow the implant to achieve a second configuration and step **2** may allow the implant to achieve a third configuration and step **4** of the disassembly may allow the implant to achieve a third configuration. This disassembly may allow the implant or portions of the implant to achieve multiple alternative configurations. For example, step **1** of the disassembly may allow the portion A of the implant to achieve a second configuration and step **2** may allow portion B of the implant to achieve an alternate configuration and step **4** of the disassembly may allow portion C of the implant to achieve an alternate configuration. Those skilled in the art will understand that combinations of alternate configurations of an implant or portions of an implant may be possible with the current invention. Certain alternate configurations may be intermediate configurations that will revert to a previous configuration or may proceed to a final configuration once fully disassembled from the inserter. The embodiments described herein do not limit the scope of the current invention. Further embodiments and combinations of embodiment may be possible and will become evident to those skilled in the art. The current invention may include an inserter and inserter-implant combination that may be used with an implant that has one or more configurations.

[0151] Based on the description herein, those skilled in the art will know that various mechanisms may be created as a means of insertion that may maintain an implant in one configuration that may vary from a second or implant configuration. The merits of the current invention are particularly beneficial in application where an implant may have means for connecting with bone engaging members such as bone screws or pegs. Controlling the ability of an implant to have multiple configurations is beneficial to ensure proper implant sizing, orientation, placement, and or fixation to one or more bone or tissue segments.

[0152] FIGS. **60** and **61** depict yet another embodiment of an implant **1400** with multiple means of connecting to an inserter. This embodiment of the implant **1400** may combine an internal means of connection **1410** with one or more external means of connection **1412**. The means of connecting to an inserter may or may not be in close proximity to the means of connecting to bone engaging features **1420**. Various means of connecting to an inserter may be used in combination with various implant configurations. FIGS. **62**, **63** and **64** depict a means of connection **1710** to an inserter that may include a tab consisting of a top element **1720** and a bottom element **1730** that may create a space **1725**. The implant **1700** has a top surface **1701** and a bottom surface **1702** that may include at least one or more thinner sections **1703**. The combination of surfaces **1701**, **1702** and **1703** may constitute a bridge or rail member that may be designed to achieve a second configuration or predict or determine the geometry of the second configuration. The means of insertion may utilize features similar to **1710** as described herein in combination with other surfaces such as top surface **1701**. This combination of means of insertion may be used to maintain one or more features or arms or projections. This combination of means of insertion may create a bending modality, such as a three point or four point bend, to maintain a specific implant configuration or combination of configurations. A combination of surfaces and means of insertion, such as **1710**, may be used on the entire implant or portions of an implant to create or maintain a particular configuration of an implant or portions of an implant. For example, a tab such as **1710** and top surface, such as **1701** may be used to maintain one side, one arm, one projection and or one portion of an implant in a particular configuration. When disassembled, that arm may have a configuration that is different from or the same as the configuration of the rest of the implant.

[0153] FIG. **65** depicts the implant **1200** in a first configuration. Implant **1200** has one or more connection means **1220** for fastening bone engaging members to the implant. Connection means **1220** may be a multitude of geometries for connecting bone engaging members to the implant. For example these connection means **1220** may be one of the following or a combination of the following: threads, locking geometries, or mating geometries conducive to interfacing with a bone engaging member. Those skilled in the art will understand the various options available for connecting an implant to a bone engaging member, such as a bone screw or peg. Implant **1200** has a means **1210** and **1211** for attaching to an inserter. FIG. **65** shows inserter attaching means **1210** and **1211** as mirror images. These means could

be any number of geometries or orientations. Exemplary embodiments are described herein. The implant **1200** may have one or more inserter connection means. These connection means may be similar in geometry or vastly different in geometry. In this embodiment, the inserter connection means **1210** and **1211** have an upper surface **1230** and pass from the upper surface **1230** to a lower surface **1240**. As shown in FIGS. **65**, **66**, and **67** the insert connection means may have different geometries at the upper surface **1230** and the lower surface **1240**. In this embodiment the inserter connection means **1210** and **1211** have geometry that provides a lower surface **1245**. The passage ways for **1210** and **1211** may work with the lower surface **1245** to engage a mating geometry of an inserter for holding the implant in a first configuration that may be flat or may have some non linear geometry. The features of this embodiment are further depicted in FIG. **68** by the section view. The lower surface **1245** of the inserter connection means **1210** and **1211** may not be at the same level or orientation as the lower surface **1240** of the implant **1200**.

[0154] FIG. **69** depicts the implant **1300** in a first configuration. Implant **1300** has one or more connection means **1320** for fastening bone engaging members to the implant. Connection means **1320** may be a multitude of geometries for connecting bone engaging members to the implant. For example these connection means **1320** may be one of the following or a combination of the following: threads, locking geometries, or mating geometries conducive to interfacing with a bone engaging member. Those skilled in the art will understand the various options available for connecting an implant to a bone engaging member, such as a bone screw or peg. Implant **1300** has a means **1310** and **1311** for attaching to an inserter. FIG. **70** shows inserter attaching means **1310** and **1311** as mirror images. These means may be any number of geometries or orientations. Exemplary embodiments are described herein. The implant **1300** may have one or more inserter connection means. These connection means may be similar in geometry or vastly different in geometry. In this embodiment, the inserter connection means **1310** and **1311** have an upper surface **1330** and pass from the upper surface **1330** to a lower surface **1340**. As shown in FIGS. **69**, **70** and **71** the inserter connection means may have different geometries at the upper surface **1330** and the lower surface **1340**. In this embodiment the inserter connection means **1310** and **1311** have geometry that provides a lower surface **1345**. The passage ways for **1310** and **1311** may work with the lower surface **1345** to engage a mating geometry of an inserter for holding the implant in a first configuration that may be flat or may have some non linear geometry. The features of this embodiment are further depicted in FIG. **71** by the section view. The lower surface **1345** of the inserter connection means **1310** and **1311** may not be at the same level or orientation as the lower surface **1340** of the implant **1300**.

[0155] FIGS. **72**, **73**, **74** and **75** depict an implant embodiment **1500** of the current invention. The implant **1500** may utilize the geometry of the rail or bridge member **1501** as the means for connecting to an inserter. The rail or bridge member may be used to determine or predict the second configuration and may also be used as the connection means for an inserter. The bridge member **1501** has a top surface **1530** that may not have a uniform perimeter. The bridge member **1501** has a perimeter that may include edges **1511**, **1512**, **1513**, **1521**, **1522** and **1523**. The perimeter of the bridge member may or may not be consistent or uniform with the top surface **1530**. As depicted in FIG. **74** the bridge member has a bottom surface **1541**, **1542**, **1543**, and **1544** that may be used to releasably engage an inserter. Engagement between the bridge member geometry and the inserter may maintain the implant **1500** in a first configuration.

[0156] FIGS. **76** and **77** depict an implant embodiment **1800** of the current invention that may have a top loading means of engagement **1810** and **1830** for interaction with a means of insertion. Connection means **1810** and **1830** have upper elements **1817** and **1831**, respectively. Connection means **1810** and **1820** may share a bottom element **1815** which may thereby create independent spaces **1818** and **1832** for releasably engaging a means of insertion. In an alternate embodiment, connection means **1810** and **1820** may share a bottom element **1815** and a top element which may thereby create at least one space for releasably engaging a means of insertion.

[0157] FIGS. **78** and **79** depict an implant embodiment **2200** that may have bone engaging members **2230** and **2235** integral to the implant bridge **2210**. Implant bridge **2210** has an upper surface **2211** and a lower surface **2212**. The bone engaging members **2230** and **2235** may have features **2220** that may improve bone purchase or improve pull out strength of the implant **2200** from bone or soft tissue. The implant **2200** may have projections or other connecting means **2250** and **2260** for connection with a means of insertion. The connecting means **2250** and **2260** may have a lower surface **2255** and **2265** respectively that may releasably engage with a means of insertion that may allow the inserter or other means of insertion to be side loading, top loading or pivotably loaded. The means of insertion may maintain a one piece implant in a first configuration thereby allowing a second implant configuration once the implant is disassembled from the implant. The means of insertion may utilize features similar to **2250** and **2260** as described herein in combination with other surfaces such as top surface **2211**. This combination of means of insertion may be used to maintain one or more features or arms or projections. This combination of means of insertion may create a bending modality, such as a three point or four point bend, to maintain a specific implant configuration or combination of configurations. A combination of surfaces and means of insertion, such as **2250**, may be used on the entire implant or portions of an implant to create or maintain a particular configuration of an implant. For example, a tab such as **2250** and top surface, such as **2211** may be used to maintain one side of an implant or one arm of an implant in a particular configuration. When disassembled, that arm may have a configuration that is different from or the same as the configuration of the rest of the implant.

[0158] The exemplary embodiments described herein are not intended to be limiting. To those skilled in the art the benefits of the invention are apparent. Furthermore those skilled in the art will appreciate that the intent of this invention may be realized in other embodiments not necessarily described herein.

What is claimed is:

1. An assembly for delivering an implant to a surgical site for osteosynthesis comprising:

an implant having a first configuration when it is releasably attached to a delivery instrument and a second configuration when it is not attached to the delivery

instrument, the implant or a portion thereof being comprised of a material that allows the implant to have multiple configurations,

the implant having two or more than two means for fixation to a bone and having means for engaging the delivery instrument, or the delivery instrument having means for engaging the implant, or both the implant and delivery instrument having means for engaging one another, wherein the means for engaging do not impede the placement of the implant onto the bone.

2. The assembly device of claim **1** wherein the implant provides compression and or distraction and or control of spacial orientation when it is affixed to two or more than two bone members.

3. The assembly of claim **1** wherein the implant is comprised of a material having shape memory or super elastic properties or a material that can be shaped by manipulation before or after implantation.

4. The assembly of claim **1** wherein the implant has means for fixation to a bone comprising leg members or means for receiving bone engaging members.

5. The assembly of claim **4** wherein the implant is a bone plate or a staple.

6. The assembly of claim **1** wherein the delivery instrument with the implant attached thereto comprises guide means for drills, depth gauges, screws, pins, pegs, blades and or drivers.

7. The assembly of claim **1** wherein the delivery instrument further comprises means for manipulating the shape of the implant to at least a second configuration after the implant is affixed to bone.

8. The assembly of claim **1** wherein the delivery instrument is comprised of a one piece construct, a two piece construct or a multiple piece construct.

9. The assembly of claim **5** wherein the bone plate has means for locking in place a screw, pin, peg or blade in an implanted bone plate.

10. The assembly of claim **5** wherein the staple has bone engagement means for maintaining the implanted implant in engagement with bone.

11. The assembly of claim **1** wherein the implant is releasably attached to the delivery instrument during manufacture.

12. The assembly of claim **1** wherein the implant is releasably attached to the delivery instrument at the time of surgery.

13. The assembly of claim **1** further comprising a holding means to which the implant is releasably attached prior to affixing the implant to the delivery instrument.

14. The assembly of claim **13** wherein the holding means has means for engaging the delivery instrument and means for engaging the implant wherein the implant is released from the holding means at the time of implantation.

15. The assembly of claim **1** wherein the two or more than two mean for fixation to a bone are adapted to receive bone engaging members and said means for fixation may be threaded or non-threaded and locking or non-locking.

16. A delivery instrument for delivering an implant to a surgical site for osteosynthesis comprising:

a means for engaging the implant and maintaining the implant in a first configuration and

a means for releasing the implant following fixation of the implant to bone segments,

wherein the means for engaging do not impede the placement of the implant onto the bone.

17. The delivery instrument of claim **16** further comprising guide means for drills, depth gauges, screws, pins, pegs, blades and or drivers.

18. The delivery instrument of claim **16** further comprising means for manipulating the shape of the implant to at least a second configuration after the implant is affixed to a bone.

19. The delivery instrument of claim **16** comprised of a one piece construct, a two piece construct or a multiple piece construct.

20. A surgical method of using the assembly of claim **1** comprising the sequential steps of arranging the implant on the surgical site, affixing the implant to bone and then releasing the implant from the delivery instrument.

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