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(54) Title: SYSTEM AND METHOD FOR DISPLACEMENT OF BONY STRUCTURES

(57) Abstract: System and method for displacing bony structures relative to each other using a single device are disclosed. Displacement includes distraction and compression. Bony structures are engaged with displacement arms. The user selects one of a plurality of manners in which to manipulate a user interface, where a first manner results in compression and a second manner results in distraction. The user interface is manipulated in the selected manner until a desired amount of displacement has been reached. This displacement is performed in a manner that is minimally invasive to the patient



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1 **SYSTEM AND METHOD FOR DISPLACEMENT OF BONY STRUCTURES**

2 CROSS-REFERENCE TO RELATED APPLICATIONS

3 [0001] This application relates to co-pending and commonly assigned
4 United States patent application serial number 10/690,211, filed October 21, 2003,
5 entitled "SYSTEM AND METHOD FOR STABILIZING OF INTERNAL
6 STRUCTURES", the disclosure of which is hereby incorporated herein by reference.

1 BACKGROUND OF THE INVENTION

2 [0003] When a patient suffers from orthopedic injuries, deformities or
3 degenerative diseases, it is sometimes necessary to insert implants into the patient's body
4 to stabilize an internal structure, promote healing, or relieve pain. In the area of spinal
5 surgery, for example, a common procedure involves the use of screws or hooks joined by
6 a connecting brace in order to secure bones. Once the brace is placed in the patient's
7 body, the brace must be firmly secured to the screws or hooks in order to provide a stable
8 construct which effectively immobilizes a corresponding portion of the spine. Then, a
9 set screw or locking element presses against the brace to secure the brace to the hooks or
10 screws.

11 [0004] When surgery is performed, the surgeon often needs to distract bone
12 by pulling it away from the work site or compress bone to pull it together if broken, as an
13 example. In the area of spinal surgery, a surgeon may approach the spinal column of a
14 patient from a posterior position, and force is applied in order to move implants along a
15 rod in order to distract or compress bone or implants into the most favorable position.
16 Force also may be applied to distract or compress prior to insertion of a rod.

17 [0005] In the past, two separate devices have been used to perform
18 compression and distraction. As an example, U.S. Patent No. 6,716,218 issued to
19 Holmes et al., teaches a device that performs distraction. If the surgeon desires to
20 perform compression, another device would be required. Additionally, this type of
21 compression or distraction device is not minimally invasive. Rather, a large incision is
22 required to use this device. Thus, during a procedure, a surgeon has to switch devices
23 depending on whether compression or distraction is desired. This need for switching
24 devices may increase the amount of time required to perform the procedure, and thus
25 may result in a longer recovery time for the patient.

26 [0006] Alternatively, certain devices are available that allow for parts to be
27 substituted, or changed out, in order to perform distraction or compression. As shown in
28 U.S. Patent No. 6,551,316. ("the '316 patent"), for example, a device is provided having
29 two sets of handles that can be selectively interconnected on an assembly. One set of

1 handles would be affixed to a jaw section when compression is needed. This first set of
2 handles may be substituted with the second set of handles configured to be used for
3 distraction as desired. If the surgeon desires to perform compression, one set of handles
4 is attached to the assembly, and if distraction is desired, then the set of handles for
5 compression must be removed and replaced with the set of handles for use in distraction.
6 Accordingly, it takes time for the surgeon to replace the handles during the procedure.
7 Further, the surgeon must remove the jaw section of the device from the patient's body if
8 he/she decides to employ a different technique, causing the length of the surgical
9 procedure to increase. Additionally, the handles of the device described in the '316
10 patent that the surgeon manipulates are relatively large, causing the device to be top-
11 heavy due to the size of the handles. The surgeon's hand would likely cover
12 approximately half to two-thirds of the handle portion in order to steady the device
13 during the procedure. Thus, the device cannot be left unattended inside the patient.
14 Also, the device of the '316 patent is not minimally invasive, but instead requires a large
15 incision to insert the jaws of the device. Even if the surgical procedure itself is
16 minimally invasive, use of the non-minimally invasive '316 patent device would
17 effectively block the surgeon's ability to visualize the operative site and to conduct the
18 operation in a minimally invasive fashion.

1 BRIEF SUMMARY OF THE INVENTION

2 [0007] In view of the above, there exists a need in the industry for a system
3 and method for displacing, such as by compression or distraction, bony structures using a
4 single device. Further, a need exists for a system and method for performing at least one
5 of compression and distraction in a way that is minimally invasive (e.g., by making a
6 smaller incision to the patient).

7 [0008] The present invention is directed to a system and method which
8 allow for the displacement of bony structures, such as vertebrae of the spine relative to
9 each other. Displacement may include at least one of compression and distraction, and
10 embodiments of the present invention provide for a device that may perform
11 compression and distraction interchangeably without the need for having separate
12 compression and distraction devices. That is, embodiments of the present invention
13 provide for an integrated device that allows for compression and distraction to be
14 selectively performed with a single device. Further, embodiments are provided that
15 allow for distraction and/or compression to be performed in a manner that is minimally
16 invasive for the patient. That is, a displacement device is provided that minimizes the
17 incision made on a patient in order to perform displacement (compression and/or
18 distraction) of bony structures.

19 [0009] In certain embodiments, a medical instrument is provided that can
20 perform both compression and distraction of vertebral bodies through at least two
21 percutaneous incisions. This instrument allows for either distraction or compression to
22 be selectively performed without the removal or addition of parts to the instrument.
23 Further, no substitution of the instrument is needed to perform distraction or
24 compression.

25 [0010] The foregoing has outlined rather broadly the features and technical
26 advantages of the present invention in order that the detailed description of the invention
27 that follows may be better understood. Additional features and advantages of the
28 invention will be described hereinafter which form the subject of the claims of the
29 invention. It should be appreciated that the conception and specific embodiment

1 disclosed may be readily utilized as a basis for modifying or designing other structures
2 for carrying out the same purposes of the present invention. It should also be realized
3 that such equivalent constructions do not depart from the invention as set forth in the
4 appended claims. The novel features which are believed to be characteristic of the
5 invention, both as to its organization and method of operation, together with further
6 objects and advantages will be better understood from the following description when
7 considered in connection with the accompanying figures. It is to be expressly
8 understood, however, that each of the figures is provided for the purpose of illustration
9 and description only and is not intended as a definition of the limits of the present
10 invention.

1 BRIEF DESCRIPTION OF THE DRAWINGS

2 [0011] For a more complete understanding of the present invention,
3 reference is now made to the following descriptions taken in conjunction with the
4 accompanying drawings, in which:

5 [0012] FIGURE 1 shows an exploded view of an example embodiment of a
6 displacement device;

7 [0013] FIGURE 2 shows a front view of the example displacement device
8 of FIGURE 1 when assembled;

9 [0014] FIGURE 3 shows an isometric view from the back of the
10 assembled displacement device of FIGURE 2;

11 [0015] FIGURE 4 shows a front view of the example assembled
12 displacement device of FIGURE 2 where one of its guides is angled so as to not be
13 parallel with the other of its guides;

14 [0016] FIGURE 4A shows a front view of an alternative displacement
15 device where one of its guides is angled so as to not be parallel with the other of its
16 guides;

17 [0017] FIGURE 5 shows a cut-away view illustrating a stage of installation
18 of an example stabilization device with which embodiments of the displacement device
19 may be used in certain procedures;

20 [0018] FIGURE 6 shows an example of the assembled displacement device
21 of FIGURE 2 when in use with the example stabilization device of FIGURE 5;

22 [0019] FIGURE 7 shows a cut-away view illustrating a stage of
23 stabilizing/fixing the relative position of bony structures with the example stabilization
24 device;

1 **[0020]** FIGURE 8 shows the example stabilization device resulting from
2 the stabilization stage of FIGURE 7 in accordance with one embodiment;

3 **[0021]** FIGURE 9 shows an operational flow diagram displacing bony
4 structures relative to each other in accordance with certain embodiments;

5 **[0022]** FIGURE 10A shows another example embodiment of a
6 displacement device having a different user interface than the example device of
7 FIGURES 1-4, wherein the user interface is configured for compression;

8 **[0023]** FIGURE 10B shows the example displacement device of FIGURE
9 10A where the user interface is configured for distraction; and

10 **[0024]** FIGURE 11 shows an example displacement device configured for
11 multi-level surgery.

1 DETAILED DESCRIPTION OF THE INVENTION

2 [0025] Certain embodiments of the present invention provide a system and
3 method which allow for both the compression and distraction of bony structures, such as
4 a spine, during a surgical procedure. According to certain embodiments, a displacement
5 device comprises at least two guide members connected by cross members wherein the
6 guide members are displaced relative to each other responsive to manipulation of a user
7 interface. The guide members provide for the transmission of distraction or compression
8 force percutaneously to bony structures, thus allowing compression or distraction of
9 these bony structures. Although various embodiments are described with reference to a
10 displacement device that compresses or distracts, certain embodiments provide for a
11 displacement device that performs at least one of compression and distraction without
12 the need for a large incision, thereby performing compression or distraction in a
13 minimally invasive manner.

14 [0026] According to certain embodiments, it is unnecessary to disassemble
15 or change parts on the displacement device in order to compress or distract. Thus, no
16 assembly or disassembly of the displacement device is needed during the procedure, and
17 it is not necessary to remove the device from the patient's body if the surgeon desires to
18 switch between compression and distraction. The displacement device is light enough,
19 and small enough, to be left affixed to the extensions without holding. Thus, the device
20 is sufficiently stable so as to not be removed if the surgeon ceases using it momentarily.
21 Further, because of the size of the displacement device, the device will not interfere with
22 the surgeon's activities during an operation. As certain embodiments provide for a
23 displacement device that is minimally invasive, accordingly the region of the patient's
24 body in which the surgeon is operating does not need to be fully exposed in order to
25 perform compression or distraction. This results in minimal trauma to the patient and
26 perhaps a faster recovery time.

27 [0027] Embodiments of this displacement device may be used in certain
28 procedures in conjunction with an implantable stabilization device for maintaining the
29 relative displacement of the bony structures acquired using the displacement device. As
30 an example, a stabilization device may include a brace connected between anchors (e.g.,

pedicle screws) that anchor to the displaced bony structures. The displacement device is used in order to ensure correct positioning of the brace-screw assembly and the implant device overall preferably before an implant device is stabilized. In certain procedures, the displacement device may be used before the brace of the implanted stabilization device is locked down to stabilize displaced bony structures.

[0028] Embodiments of this displacement device may also be used in certain procedures in conjunction with an implantable dynamic stabilization device. Some dynamic stabilization devices have a need to distract elements of the spine to the insert the dynamic stabilization implant and then compress those elements to complete the assembly process. This device allows for the minimally invasive distraction of that dynamic stabilization device and aid in its insertion.

[0029] FIGURE 1 shows an exploded view of one example embodiment of a displacement device. Displacement device 10 is a device used to perform displacement of bony structures, such as vertebrae of the spine, relative to each other. The device 10 has two general elements: a user interface and a displacement mechanism. The displacement mechanism includes cross-action members and at least two guide tubes. Each of these elements are shown in FIGURE 1 and will be discussed in turn.

[0030] The user interface, as shown in the example embodiment of FIGURE 1, includes knob 112 and threaded rod 110. Threaded rod coupling 108 is a receiving part for receiving the distal end of threaded rod 110. Threaded block 111 provides a movable element threadably engaged to threaded rod 110 and movable along the longitudinal axis of the rod 110 relative to receiving part 108 in response to rotation of knob 112. Shoulder screw 113 fastens threaded rod coupling 108 to the displacement mechanism. Knob 112 is affixed to threaded rod 110 wherein knob 112 can be rotated in order to displace bony structures relative to each other, as described further below.

[0031] As will be discussed further below, alternative embodiments may include a handle-based user interface rather than a threaded rod-based user interface (as will be discussed in conjunction with FIGURES 10a and 10b).

1 **[0032]** Moving to the displacement mechanism of the displacement device
2 10, there is shown cross-action members for translating received input from the user
3 interface into relative displacement of guides 102, 104. Cross-action members 106 and
4 107 are coupled together via head shoulder screw 114b. Screw 114a connects member
5 106 to slider element 105a which is inserted in channel 118 of engaging element 101,
6 and similarly, screw 114c connects member 107 to slider element 105b which is inserted
7 into channel 115 of guide tube 104. As knob 112 is turned, cross-action members 106
8 and 107 then move relative to one another to ensure that guide tubes 102 and 104
9 perform compression and/or distraction as desired.

10 **[0033]** Also, below the user interface, there is shown pin 109 that mates the
11 hole in cross-action member 106 to guide 104. Pin 109 and the holes on the underside of
12 threaded block 111 function together as a macro adjustment for initial placement of the
13 device.

14 **[0034]** Moving to the guide tubes of device 10, two guide tubes 102 and
15 104 (also referred to as “displacement arms”) are shown in FIGURE 1. Guide tube 102
16 is mated with engaging element 101 to form an adjustable guide tube. Guide tube 102
17 and engaging element 101 are movable relative to each other thereby allowing guide 102
18 to be angled relative to guide tube 104 so as not to be parallel with guide tube 104.
19 Guide tube 104 may be referred to as “stationary” where guide tube 102 moves relative
20 to it during displacement. Of course, movement of either or both guides may be
21 performed to achieve the relative displacement desired.

22 **[0035]** As shown in FIGURE 1, displacement device 10 includes thumb
23 slide 103 positioned relative to guide tube 102. As will be discussed in more detail with
24 respect to FIGURE 4, thumb slide 103 is positioned on guide tube 102 and teeth 117A
25 engage teeth 117B of guide tube 102. When a user moves thumb slide 103 downward
26 (by engaging surface 116) to disengage teeth 117A and 117B, angulation of the guide
27 tube 102 may be changed. When the desired level of angulation is achieved, thumb slide
28 103 is released upward and the teeth engage locking guide tube 102 at the particular
29 angle. Spring 121 is arranged between wall 122 and thumb slide 103 to apply force to
30 cause teeth 117A of thumb slide 103 to engage teeth 117B of guide 102. When

1 sufficient force is applied to thumb slide 103, spring 121 compresses enabling teeth
2 117A to disengage teeth 117B.

3 [0036] Further, engaging element 101 and guide tube 104 of device 10
4 receive slider elements 105a, 105b through channels 118 and 115 respectively. As the
5 user interface is manipulated for compression or distraction, slider elements 105a, 105b
6 adjust up and down their respective channels to provide the desired amount of movement
7 in the cross-members 106 and 107. As shown, there is a gradual sloping 119, 120 on the
8 surface of guide tubes 102 and 104 respectively to allow for gentle insertion through an
9 incision and/or movement of the guide tubes within an incision, thus reducing harm to
10 the patient during the procedure. Displacement device 10 also provides for sloping of
11 the leading edges of guide tubes 102 and 104 to allow a surgeon to insert guides tubes
12 102, 104 along extensions into a patient's body in a minimally invasive manner.

13 [0037] FIGURE 2 is a front view of the embodiment of FIGURE 1 when
14 assembled. As shown, the two general elements (user interface and displacement
15 mechanism) of the displacement device are displayed. In this example embodiment, a
16 left-hand thread is used for threaded rod 110 of the user interface. Accordingly, when
17 knob 112 is turned to the right (clockwise), the knob will loosen and the distance
18 between knob 112 and threaded block 111 will increase. Responsive to this action, the
19 displacement device will compress or tighten the bony structures. Thus, guide tubes 102
20 and 104 will be moved closer together resulting in compression. On the other hand, if
21 knob 112 is rotated to the left (counter-clockwise), the device will distract or loosen the
22 bony structures relative to each other. That is, guides 102 and 104 will be pushed apart.
23 This implementation may be desirable in that one typically thinks of turning a screw to
24 the right (clockwise) to tighten (or compress) and turning the screw to the left (counter-
25 clockwise) to loosen (or distract). Of course, in other implementations, a right-hand
26 threaded screw may be used for rod 110 in which turning knob 112 clockwise results in
27 distraction and turning knob 112 counter-clockwise results in compression.

28 [0038] FIGURE 3 shows an isometric view of the example embodiment of
29 FIGURE 2 from the back. In FIGURE 3, thumb slide 103 can be seen. Further, the

1 sloped portions 119, 120 on the surface of guide tubes 102, 104, along with the channels
2 118, 115 for receiving slider elements 105a and 105b, respectively, can be seen.

3 **[0039]** FIGURE 4 illustrates a front view of the example embodiment of a
4 displacement device 10 of FIGURE 2, wherein guide tube 102 has been angularly
5 adjusted. Thumb slide 103 is used to alter the angular positioning of guide tube 102. As
6 shown in FIGURE 4, thumb slide 103 is positioned on guide tube 102 relative to guide
7 tube 104 so as to not be parallel with guide tube 104. Angular displacement of guide
8 tube 102 is achieved by moving thumb slide 103 to disengage the teeth 117. Teeth 117A
9 of thumb slide 103 engage teeth 117B. When the thumb slide shifts downward, for
10 example, the teeth are disengaged and the angulation of guide tube 102 may be changed.
11 While the teeth are disengaged, guide tube 102 can be adjusted until the desired
12 angulation is achieved. Responsive, slider elements 105a and 105b slide downward in
13 channels 118, 115 (in the direction away from rod 110), thus permitting the lower ends
14 106A, 107A of cross-members 106 and 107 to compress toward each other. This
15 compression is translated to guides 102 and 104, which in turn translate the compression
16 force to anchors (e.g., screws 602 and 603 of FIGURE 6) to which the guides engage.
17 Once guide tube 102 has been adjusted to its desired position relative to engaging
18 element 101 to which slide 105a is slidably engaged, thumb slide 103 is released, and the
19 teeth 117A, 117B will lock guide tube 102 into place. Similarly, when distraction is
20 desired, slider elements 105a and 105b slide upward in channels 118, 115 (in the
21 direction toward rod 110), thus permitting the lower ends (106A, 107A) of cross
22 members 106 and 107 to distract away from each other. This distraction is translated to
23 guides 102 and 104, which in turn translate distraction force to the anchors to which the
24 guides engage.

25 **[0040]** This angular adjustment may be desired, for example, when the
26 positioning of the anchors are not arranged perfectly parallel to each other. Further,
27 adjustment may be desired when a connecting brace positioned between the anchors is
28 not entirely straight (e.g., is curved to match the curvature of the patient's spine).

29 **[0041]** Turning now to FIGURE 4A, there is an alternative embodiment of
30 a displacement device 40, wherein guide tube 102 has been angularly adjusted so that

1 guide tube 102 is not parallel with channel 118. Consequently, guide tube 102 is also not
2 parallel with guide tube 104. In this alternative embodiment, there is a locking
3 mechanism 402 which locks the guide tube 102 relative to the channel 118. In certain
4 embodiments, the locking mechanism 402 may include a thumb screw 404 coupled to a
5 wedge 406 (which is partially shown in FIGURE 4A). The wedge 406 may be
6 positioned between a space created by a first shoulder (not shown) on a surface of the
7 guide tube 102 and a second shoulder on the opposing surface of the channel 118 (not
8 shown). The wedge is coupled to the thumb screw such that as the thumb screw is
9 rotated or tightened, the wedge translates in a lateral direction with respect to the
10 longitudinal axis of the guide tube 102. Thus, in some embodiments, as the thumb screw
11 402 is turned in a first rotation direction, the wedge 406 translates to a first position
12 where one of its edges engages the first shoulder and another edge engages the second
13 shoulder such that the guide tube 102 is locked or fixed relative to the channel.

14 [0042] On the other hand, when the thumb screw 402 is rotated in the
15 reverse direction, the wedge translates to a second position where one edge does not
16 engage the first shoulder such that the guide tube 102 is free to angularly move relative
17 to the first longitudinal guide means.

18 [0043] Thus, angular displacement of guide tube 102 is achieved by
19 moving the guide tube 102 relative to the channel 118 when the locking mechanism 402
20 is in the unlocked position. The guide tube 102, therefore, can be adjusted until the
21 desired angulation is achieved at which point, the thumb screw may be rotated to lock
22 the guide tube 102 relative to the channel 118.

23 [0044] FIGURE 5 shows a cut-away view illustrating a stage of installation
24 of an example stabilization device 50 with which embodiments of the displacement
25 device of FIGURES 1-4 may be used in certain procedures. More specifically, FIGURE
26 5 shows a spine stabilization brace assembly that may be introduced into the vertebrae of
27 a patient's spine during a surgical procedure by coupling a brace to a pedicle screw as a
28 single assembly as described further in co-pending and commonly assigned United States
29 patent application serial number 10/690,211, filed October 21, 2003, entitled "SYSTEM
30 AND METHOD FOR STABILIZING OF INTERNAL STRUCTURES." FIGURE 5

1 shows the installation of example stabilization device 50 with respect to vertebrae L4 and
2 L5. Embodiments of a displacement device described herein may be used with other
3 stabilization devices such as that of U.S. Patent No. 6,530,929 issued to Justis et al., or in
4 procedures that do not involve implanted stabilization devices at all.

5 **[0045]** Although an example surgical procedure will be described in further
6 detail with respect to FIGURES 8 and 9, a brief overview of an example procedure may
7 be helpful to put the use of a displacement device into context. A small incision may be
8 made through the skin and a device is used to pinpoint where a pedicle screw, such as
9 pedicle screw 602, is to be placed. Dilators, such as dilators 503 and 504, are introduced
10 until a diameter suitable for passing the pedicle screw and its extensions is achieved.
11 After the appropriate diameter is achieved, brace (or "rod") 601 is attached to pedicle
12 screw ("anchor") 602 to form a brace-screw assembly. The assembly is placed at the
13 distal end of cannula 501, inserting pedicle screw 602 into a pre-tapped hole in vertebrae
14 L4. Then, pedicle screw ("anchor") 603 is inserted through cannula 502 into a pre-
15 tapped hole in vertebrae L5. Once these screws are in place, dilators 503, 504 are
16 removed, and a tool is used to part the muscle bundle below the skin between vertebrae
17 L4 and L5. The muscles and other tissue are only separated to a point where brace 601
18 may pass. Thus, the procedure may be performed with minimal invasion because no
19 incision is needed between the small incisions by which cannulas 501, 502 may pass.

20 **[0046]** After separating the muscles, brace 601 is positioned by pivoting
21 brace 601 into position as shown by the arrow pointing downward in FIGURE 5. Again,
22 this procedure will be discussed in further detail later with respect to FIGURES 8 and 9.
23 However, FIGURE 5 shows how brace 601 may be positioned between pedicle screws
24 602 and 603. Once brace 601 has been positioned in the area between pedicle screws
25 602, 603, the surgeon may assess what angular and lateral adjustments may be made in
26 the vertebrae L4 and L5, and accordingly, the surgeon may use the displacement device
27 as described with respect to FIGURES 1-4 in order to make these adjustments before
28 locking brace 601 into place. While brace 601 is used for stabilization in this example
29 device, in other devices other types of elements may be used such as a flexible material
30 or a wire. A cage, autograft or any other type of interbody fusion device may be placed

1 in between the vertebrae bodies. The device could be used with a dynamic stabilization
2 device.

3 [0047] FIGURE 6 illustrates the example displacement device 10 in use
4 with the example stabilization device 50 of FIGURE 5. The guide tubes 102 and 104 of
5 displacement device 10 are placed over anchor extensions 606 and 607. Anchor
6 extensions 606 and 607 are removably attached to rod cages 605 and 604 respectively.
7 Guides 102 and 104 may be displaced relative to each other responsive to manipulation
8 of the user interface (knob 112 in this example).

9 [0048] As shown in FIGURE 6, when knob 112 is turned, cross-action
10 members 106 and 107 move which displaces guide tubes 102 and 104 relative to one
11 another. Depending on whether compression or distraction of L4 and L5 is desired,
12 guides 102 and 104 will either be placed in closer relative position to each other (by
13 compression) or be pushed apart (by distraction).

14 [0049] In an embodiment of the present invention, guide tubes 102 and 104
15 may be used to perform adjustments to the relative displacement of L4 and L5 after brace
16 601 is inserted between pedicle screws 602, 603 but before it is locked down to such
17 pedicle screws using locking caps. The pedicle screws can be moved relative to each
18 other by displacement device 10, wherein rod cages 605, 604 are rotated and have
19 angular motion to the heads of the pedicle screws 602, 603. In an alternative
20 embodiment, the pedicle screws may be locked into position prior to insertion of locking
21 caps. In this scenario, displacement device 10 may force a particular angulation on the
22 pedicle screws 602, 603 even when the pedicle screws have been locked into position. In
23 either case, a displacement technique, such as compression or distraction, may be
24 performed. For example, while doing a fusion, the surgeon may first perform distraction
25 in order to insert an interbody device. Later the surgeon may compress the vertebrae to
26 embed the interbody device and secure the stabilization device (with set screws) before
27 stitching the incisions made for each of the cannulas.

28 [0050] When in use in the example procedure of FIGURE 6, the majority
29 of the displacement device 10 would not be positioned inside the patient's body. Rather,

1 the skin line typically would be just below the sloped portion 119, 120 of guide tubes
2 102, 104 respectively as shown in FIGURE 6. Because most of the displacement device
3 is located outside the patient's body, smaller incisions may be used because the incisions
4 would only need to be as wide as guide tubes 102 and 104. Thus, no incision would be
5 needed for insertion of cross-action members 106, 107 or threaded rod 110, for example,
6 because no additional incisions are needed over those required for inserting the anchors.
7 This is useful both for the patient and for the surgeon. The patient benefits because
8 smaller incisions are made due to the smaller size of the inserted position of the
9 displacement device, resulting in a potentially faster recovery time. The surgeon also
10 benefits because he/she may perform distraction and subsequently perform compression
11 without having to remove the device from its placement in the patient or without having
12 to switch devices to perform each type of displacement. Further, the portion of the
13 device that the surgeon operates is positioned far enough above the incision line that it is
14 easy for the surgeon to turn knob 112 making it user-friendly to perform the desired
15 displacement technique.

16 [0051] After the desired displacement of L4 and L5 relative to each other is
17 made, FIGURE 7 shows a cut-away view illustrating a stage of stabilizing/fixing the
18 displaced position of L4 and L5 bony structures with the example implanted stabilization
19 device 50. Set screws 701, or other locking devices, are introduced down cannulas 501
20 and 502 to lock each end of brace 601 to its respective pedicle screw 602, 603, while
21 displacement device 10 (not shown in FIGURE 7) maintains the desired displacement of
22 L4 and L5. Once the set screws are locked down, the displacement device 10 can be
23 removed. The resulting implanted stabilization device 50 is shown in FIGURE 9.

24 [0052] Turning to FIGURE 8, a flow diagram for operation of a
25 displacement device during a spinal procedure according to one embodiment of the
26 invention is shown. The flow diagram of FIGURE 8 will be discussed with reference to
27 the device 50 described above. The resulting implanted stabilization device 50 is shown
28 in FIGURE 9. Assemblies 500 and 700 (FIGURE 9) are coupled to pedicle screws 602
29 and 603, respectively in process 801. The pedicle screws are assembled with the
30 extensions and rod cages prior to insertion into the vertebrae bodies. In process 802,

1 pedicle screws 602 and 603 are inserted into vertebrae of a patient's spine, such as
2 vertebrae L4 and L5, respectively. Such assemblies 500 and 700 each form a receiving
3 member for receiving closure member (e.g., set screw) 701. Generally, such receiving
4 member formed by assemblies 500 and 700 is a noncontiguous (e.g., open-back member)
5 having at least two walls, such as walls 902 and 903, that are separated by slots. As
6 described further herein, closure member 701 and walls 902 and 903 are formed to have
7 complementary threads that are formed in an interlocking manner that preferably aids in
8 preventing splaying of the receiving members. In process 803, brace 601 is extended
9 from assembly 500 to assembly 700.

10 **[0053]** In implanting such stabilization device 50, in accordance with one
11 embodiment, a surgeon identifies the desired vertebral levels and pedicle positions via
12 standard techniques. Once the target vertebrae (vertebra levels L4 and L5 in this
13 example) are identified, a small incision is made through the patient's skin and a tracking
14 needle (or other device) is inserted to pinpoint exactly where each screw is to be placed.
15 A fluoroscope, or other x-ray technique, is used to properly position the tracking needle.
16 Once the proper position is located, a first guide wire (K wire) is positioned with its
17 distal end against the pedicle of vertebrae L4, and a second guide wire (K wire) is
18 positioned with its distal end against the pedicle of vertebrae L5. The surgeon then
19 slides a series of continuing larger sized dilators down each of these guide wires.

20 **[0054]** Approximately four or five dilators are used until a diameter
21 suitable for passing the pedicle screw and its extensions is achieved. A tap is sent down
22 over the K wire to tap a hole into the pedicle in preparation for receiving the anchor,
23 which in this case is a pedicle screw. This tap will usually be a size slightly smaller than
24 the pedicle screw thread size selected for that patient and that level.

25 **[0055]** After the hole is tapped and the K wire and the inner dilators are
26 removed, the surgeon is ready to introduce the anchor (e.g., pedicle screw) into the
27 vertebrae. Prior to inserting the screw, brace 601 is attached to screw 602 to form a
28 brace-screw assembly. This assembly then is positioned at the distal end of a first
29 cannula and a screwdriver or wrench is inserted into the first cannula and attached to the
30 proximal end of brace 601, and the entire assembly then is inserted into a remaining

1 dilator. The screwdriver engages with proximal end 904 of brace 601 so as to allow the
2 surgeon to screw pedicle screw 602 into the pre-tapped hole in vertebrae L5. Pressure on
3 the screwdriver forces the screw to be in-line with the brace, which, in turn, is in-line
4 with the screwdriver.

5 [0056] This same procedure may be repeated for each additional level, in
6 this case L4, except that screw 603 has assembly 700 affixed thereto. Assembly 700 is
7 adapted to receive the proximal end 904 of brace 601 as is more fully described below.

8 [0057] Once both screws 602 and 603 are in place in vertebrae L4 and L5,
9 respectively, the remaining dilator is removed, and the surgeon slides a blunt dissection
10 tool into the skin incision and gently parts the muscle bundle below the skin between
11 vertebrae L4 and L5. Alternatively, the blunt dissection tool could go down the second
12 cannula (through which screw 603 was inserted) and, starting at the bottom of the second
13 cannula, work open the muscle bundle between the cannula working upward as far as is
14 necessary. Using this procedure, the muscles (and other tissue) only need to be separated
15 to a point where the brace 601 must pass. Thus, the separation need not go to the skin
16 level. This reduces patient trauma even further.

17 [0058] Once an opening in the muscles has been developed between the
18 first and second cannulas, brace 601 then is positioned, by pivoting (as described above
19 with respect to FIGURE 5) and sliding a tool down the first cannula in which it resides to
20 engage the proximal end 904 of brace 601.

21 [0059] Then, angular and lateral adjustments may be made using a
22 displacement device. As discussed above, displacement may include compression,
23 distraction, or a combination of distraction and compression. In order to perform
24 displacement, guide tubes of a displacement device are inserted over anchor extensions
25 in process 804. Although the displacement device is inserted over the anchor extensions
26 in the example embodiment, further embodiments provide for additional devices to be
27 inserted over the bone anchor for direct compression and/or distraction. Another
28 embodiment has the displacement device placed over extensions or bone anchors, such
29 as a device for applying force in a direction that is perpendicular to the direction in which

1 distraction or compression occurs, as in a spondylolisthesis reduction. Force is then
2 transmitted to the anchor extensions in order to begin compression or distraction in
3 process 805. Alternatively, force is transmitted directly to the rod cages in order to begin
4 compression or distraction. The surgeon may engage the displacement mechanism by
5 turning knob 112, as discussed above with respect to FIGURE 1.

6 [0060] Assuming that distraction is desired, then the surgeon may choose
7 to place an interbody device into the patient and distract while the device is being
8 inserted. Alternatively, the surgeon may choose to perform distraction before the
9 interbody device is introduced into the patient's body. Following introduction of the
10 interbody device, then compression may be performed in order to ensure that the device
11 is properly positioned relative to the bony structures.

12 [0061] In a further embodiment, in order to determine when the desired
13 amount of compression or distraction has been achieved, the surgeon may use as force
14 measurement mechanism or displacement scale device as described with respect to
15 FIGURE 8.

16 [0062] A device then may be used in process 806 to determine if enough
17 compression or distraction has been performed such as a device that will measure how
18 much threaded block 111 has moved relative to threaded rod coupling 108. This device
19 301 (shown in FIGURE 3) will employ a basic scaling technique where the display of the
20 device may be set at zero, and the device will count incrementally based on the number
21 of turns that knob 112 completes. This typically would be based on a scale where one
22 turn of knob 112 translates into 1 millimeter of advancement, although another scale may
23 be used as desired. The surgeon may view the display of device 301 and determine
24 whether further displacement is desired.

25 [0063] In another embodiment, the level of compression or distraction may
26 be measured using a force measurement device 302 (as shown in FIGURE 2). This
27 device preferably is located inside threaded block 111, and the device may include a
28 stationary member and a member that may be deflected depending on the amount of
29 force that is created by compression or distraction. Again, the device 302 may have a

1 display located on the outside of threaded block 111 for the surgeon to view to determine
2 how much force has been exerted.

3 [0064] Although the FIGURES have been described with respect to a
4 device that performs both compression and distraction with minimal invasion, alternative
5 embodiments may provide a device that performs compression alone or distraction alone
6 while resulting in minimal invasion of the patient. As an example, assume there is a
7 device to perform compression alone. Although the device may be constructed to
8 perform both compression and distraction, the device may be configured so that when
9 the device is loosened following compression, the cross-members disengage and no force
10 is exerted in the opposite direction. Alternatively, the device may be configured to
11 perform distraction.

12 [0065] After all angular and lateral adjustments are made, set screws 901
13 are introduced down the first and second cannulas to lock each end of brace 601 to its
14 respective anchor to maintain the desired displacement in process 807. Once the
15 proximal end 904 of brace 601 is snapped in place to screw 602 and set screws 901 are
16 tightened, the displacement device and anchor extensions may be removed and the
17 incision closed in process 808. The process of using such a stabilization device 50 in
18 which a brace-screw assembly (of brace 601 attached to pedicle screw 602) are first
19 inserted via a first cannula and attached to a vertebrae (e.g., vertebrae L5) and then brace
20 601 is pivoted such that one end 904 remains positioned over pedicle screw 602 and its
21 opposite end is positioned over pedicle screw 603 is described further in the '211 patent
22 application.

23 [0066] FIGURES 10a and 10b show alternative embodiments of the
24 present invention where the user interface described with respect to FIGURE 1 has been
25 replaced with a set of handles that may be configured to perform compression or
26 distraction. Although the user interface has been altered, the cross-action mechanism
27 and guide tubes as described in FIGURE 1 remain the same and are numbered in
28 FIGURES 10a and 10b according to their placement in FIGURE 1.

1 **[0067]** Turning to FIGURE 10a, this figure illustrates an example
2 embodiment of a user interface employing handles that are manipulated to result in
3 compression. The handle assembly includes upper handle 1001 and lower handle 1004,
4 which are interconnected at a center attachment 1003. Upper handle 1001 is joined to
5 lever 1002 which is positioned in a first position 1007 or a second position 1008
6 depending on whether compression or distraction is desired. The first position 1007 is
7 used to produce the distraction of the guides. The second position 1008 is used to
8 produce compression of the guides. When the user squeezes the handle assembly when
9 the lever 1002 is in second position 1008 (as shown by the arrow pointing downward on
10 upper handle 1001), weight is applied to member 1005 to cause a downward shift and
11 causing pivot 1006 to rotate clockwise as shown by the arrow on pivot 1006, causing
12 guide tubes 102, 104 to move closer together (as shown by the arrow pointing downward
13 to the right of guide tube 104).

14 **[0068]** Similarly, FIGURE 10b shows an example embodiment of a user
15 interface employing handles that are manipulated to result in distraction. Again, upper
16 handle 1001 is joined to lever 1002, but in this case, lever 1002 is positioned in first
17 position 1007 in the slot provided in member 1005. When the user squeezes the handle
18 assembly, depressing upper handle 1001 (as shown by the arrow pointing downward on
19 upper handle 1001), force is applied to pivot 1006, wherein pivot 1006 rotates counter-
20 clockwise (as shown by the arrow on pivot 1006), causing guide tubes 102, 104 to be
21 move apart (as shown by the arrow pointing upward below guide tube 104).

22 **[0069]** Although user interfaces employing a threaded rod mechanism or a
23 set of handles for manipulating a displacement mechanism have been described, other
24 means for displacement include, but are not limited to, CAM, rack and pinion as well as
25 a circular linear motion device.

26 **[0070]** FIGURE 11 illustrates an example displacement device having
27 more than two guide tubes. Guide tubes 102B and 104 are depicted as described above
28 with respect to FIGURE 6. Guide tubes 102B and 104 may be displaced relative to each
29 other responsive to manipulation of the user interface (knob 112B in this example).
30 When knob 112B is turned, cross-action members 106B and 107B move which displaces

1 guide tubes 102B and 104 relative to one another, depending on whether compression or
2 distraction is desired. Guide tube 104 is stationary and guide tube 102B moves relative
3 to guide tube 104. Similarly, guide tubes 102A and 104 may be displaced relative to
4 each other responsive to manipulation of the user interface (knob 112A in this example).
5 When knob 112A is turned, cross-action members 106A and 107A move which displaces
6 guide tubes 102A and 104 relative to each other. Again, guide tube 104 is stationary and
7 guide tube 102A moves relative to guide tube 104. Accordingly, the displacement
8 device shown makes it possible to displace more than two vertebrae (such as L3, L4, and
9 L5) relative to each other. Although FIGURE 11 depicts a displacement device having
10 three guide tubes affixed to three anchors, further embodiments provide for additional
11 guide tubes to be included in the displacement device.

12 [0071] Although the present invention and its advantages have been
13 described in detail, it should be understood that various changes, substitutions and
14 alterations can be made herein without departing from the invention as defined by the
15 appended claims. Moreover, the scope of the present application is not intended to be
16 limited to the particular embodiments of the process, machine, manufacture, composition
17 of matter, means, methods and steps described in the specification. As one will readily
18 appreciate from the disclosure, processes, machines, manufacture, compositions of
19 matter, means, methods, or steps, presently existing or later to be developed that perform
20 substantially the same function or achieve substantially the same result as the
21 corresponding embodiments described herein may be utilized. Accordingly, the
22 appended claims are intended to include within their scope such processes, machines,
23 manufacture, compositions of matter, means, methods, or steps.

24 [0072] The foregoing description of the embodiments of the invention has been
25 presented for the purposes of illustration and description. It is not intended to be
26 exhaustive or to limit the invention to the precise form disclosed. Many modifications
27 and variations are possible in light of the above teaching. It is intended that the scope of
28 the invention be limited not by this detailed description, but rather by the claims
29 appended hereto.

1 **[0073]** For instance, in some embodiments, there may be a displacement device
2 for displacing bony structures, said device comprising a user interface mechanism; and a
3 displacement mechanism operable to compress two displacement arms responsive to a
4 first manipulation of said user interface, and distract said two displacement arms
5 responsive to a second manipulation of said user interface.

6 **[0074]** The above device could also comprise two displacement arms; and cross
7 members pivotally attached to said two displacement arms, wherein said cross members
8 translate input received from said user interface into relative displacement of said two
9 displacement arms.

10 **[0075]** Furthermore, one of said two displacement arms is mated with an
11 engaging element to form an adjustable displacement arm.

12 **[0076]** Furthermore, each of said two displacement arms include channels for
13 slidably receiving slider elements, wherein said slider elements adjust up and down said
14 channels to allow for movement of said cross members.

15 **[0077]** Furthermore, said cross members are coupled to each other to pivot
16 relative to each other.

17 **[0078]** Furthermore, said two displacement arms have gradual sloping to allow
18 for gentle movement of said two displacement arms.

19 **[0079]** The above device could also comprise a knob affixed to a threaded rod,
20 wherein said knob is rotated so as to displace said bony structures relative to each other.

21 **[0080]** In some embodiments, the user interface mechanism could further
22 comprise: a receiving element for receiving distal end of said threaded rod; and a
23 movable element threadably engaged to said threaded rod and movable along the
24 longitudinal axis of said threaded rod relative to said receiving element.

25 **[0081]** Furthermore, said movable element moves relative to said receiving
26 element in response to rotation of said knob.

1 [0082] Furthermore, said threaded rod is a left-hand thread.

2 [0083] Furthermore, when said knob is turned clockwise, said knob loosens and
3 the distance between said knob and said receiving element increases.

4 [0084] Furthermore, in response to the action of said knob, said displacement
5 mechanism compresses said bony structures.

6 [0085] Furthermore, when said knob is rotated counter-clockwise, said
7 displacement mechanism distracts said bony structures relative to each other.
8 Furthermore, said threaded rod is a right-hand thread.

9 [0086] Furthermore, when said knob is turned clockwise, said displacement
10 mechanism distracts said bony structures relative to each other and when said knob is
11 turned counter-clockwise, said displacement mechanism compresses said bony
12 structures.

13 [0087] In some embodiments, the user interface mechanism comprises: a set of
14 handles having a lever that may be selectively engaged in a slot having a first position
15 and a second position to perform either compression or distraction when said handles are
16 manipulated by a user. Furthermore, the compression occurs when force is applied to
17 shift said lever to said second position of said slot that is closer to said displacement
18 mechanism. Furthermore, distraction occurs when force is applied to shift said lever to
19 said first position of said slot that is further from said displacement mechanism.

20 [0088] In other embodiments, the displacement device operable to perform at
21 least one of distraction and compression of bony structures, wherein said displacement
22 device operates in a minimally invasive manner.

23 [0089] The above device could also comprise a user interface mechanism; and a
24 displacement mechanism including at least two guides and cross members pivotally
25 attached to said at least two guides.

26 [0090] Furthermore, said user interface mechanism is a threaded rod
27 mechanism.

1 **[0091]** The threaded rod mechanism could comprise a knob attached to a
2 threaded rod, wherein a user manipulates said knob to control how said bony structures
3 are displaced relative to each other.

4 **[0092]** Furthermore, the user interface mechanism may comprise a movable
5 element threadably engaged to said threaded rod, wherein said movable element houses a
6 force measurement device.

7 **[0093]** The force measurement device may include a stationary member and a
8 member that is deflected depending on the amount of force, wherein deflection
9 determines the degree to which said at least of compression or distraction has occurred.

10 **[0094]** The user interface mechanism may also include a receiving element for
11 receiving the distal end of said threaded rod; a movable element threadably engaged to
12 said threaded rod and movable along the longitudinal axis of said threaded rod relative to
13 said receiving element; and a displacement measurement device, wherein said
14 displacement measurement device measures how much said movable element has moved
15 relative to said receiving element during said at least one of distraction and compression
16 of bony structures.

17 **[0095]** Furthermore, said user interface mechanism is a set of handles having a
18 lever that may be selectively engaged to perform compression or distraction.

19 **[0096]** The minimally invasive manner could comprise selectively performing
20 distraction and compression without removal of said displacement device from a
21 patient's body during a surgical procedure.

22 **[0097]** Furthermore, said at least two guide tubes having gradual sloping on the
23 surface of said guide tubes for gentle insertion of said guide tubes in a minimally
24 invasive manner.

25 **[0098]** Furthermore, the use of said displacement device is minimally invasive
26 in that no additional incisions are needed over those required to insert anchors into said
27 bony structures.

1 **[0099]** In other embodiments, there is a method comprising: engaging a first
2 bony structure with a first displacement arm and a second bony structure with a second
3 displacement arm of a displacement device; selecting one of a plurality of manners to
4 manipulate a user interface, where a first manner results in compression and the second
5 manner results in distraction; and manipulating said user interface of said displacement
6 device in the selected manner.

7 **[0100]** Furthermore, said user interface is a knob attached to a threaded rod.

8 **[0101]** Furthermore, said manipulating could comprise rotating said knob in
9 said first manner to result in compression of bony structures relative to each other.

10 **[0102]** Furthermore, said manipulating could comprise rotating said knob in
11 said second manner to result in distraction of bony structures relative to each other.

12 **[0103]** Furthermore, said user interface may be a set of handles having a lever
13 that is selectively engaged depending on which one of said plurality of manners is
14 chosen.

15 **[0104]** Furthermore, the method may further include measuring the degree to
16 which said first displacement arm and said second displacement arm have been displaced
17 in said selected manner.

18 **[0105]** In other embodiments, there may be a displacement device for
19 displacing bony structures, said device comprising: at least two user interface
20 mechanisms; and a displacement mechanism operable to compress and distract
21 responsive to manipulation of one of said at least two user interface mechanism, having
22 three displacement arms, said first displacement arm and said second displacement arm
23 displaced relative to each other and said second displacement arm and said third
24 displacement arm displaced relative to each other, wherein said second displacement is
25 stationary relative to said first displacement arm and said third displacement arm.

1 **[0106]** Furthermore said device could further comprises a first set of cross
2 members pivotally attached to said first displacement arm and said second displacement
3 arm; and a second set of cross members pivotally attached to said second displacement
4 arm and said third displacement arm, wherein said first set and said second set of cross
5 members translate input received from said at least two user interface mechanisms into
6 relative displacement of said three displacement arms.

1 CLAIMS

2 1. A surgical instrument for adjusting distances between bony structures, the
3 surgical instrument comprising:

4 a first guide tube and a second guide tube;

5 a first and second longitudinal guide means, wherein the first longitudinal guide
6 means is coupled to the first guide tube and the second longitudinal guide means is
7 coupled to the second guide tube;

8 a lateral adjustment means for adjusting a lateral distance between the first and
9 second longitudinal guide means;

10 an angular adjustment means for adjusting an angular position between the first
11 guide tube and the first longitudinal guide means; and

12 an angular fixation means for angularly locking the first guide tube relative to the
13 first longitudinal guide means.

14 2. The surgical instrument of claim 1 further comprising:

15 a third guide tube;

16 a third longitudinal guide means, wherein the third longitudinal guide means is
17 coupled to the third guide tube;

18 a second lateral adjustment means for adjusting the relative lateral distance
19 between the third and second longitudinal guide means;

20 a second angular adjustment means for adjusting an angular position between the
21 third guide tube and the third longitudinal guide means; and

22 an angular fixation means for angularly locking the third guide tube relative to
23 the third longitudinal guide means.

24 3. The surgical instrument of claims 1 or 2 wherein the lateral adjustment
25 means comprises:

26 a threaded rod coupled to the first and second longitudinal guide means;

1 a human interface means coupled to the threaded rod such that when the human
2 interface means is rotated, the lateral distance changes between the first and second
3 longitudinal guide means.

4 4. The surgical instrument of claims 1, 2 or 3 wherein the lateral adjustment
5 means further includes:

6 slider elements adapted to slidingly engage the first and second longitudinal
7 guide means; and

8 two cross members which are coupled to each other to pivot relative to each
9 other, each cross member having a distal end, wherein the distal end is pivotally attached
10 to a slider element such that as the cross members pivot relative to each other, the slider
11 element moves longitudinally within the longitudinal guide means.

12 5. The surgical instrument of claims 1 or 2 wherein the angular adjustment
13 means is a pin means coupled to the first guide tube and the first longitudinal guide
14 means for allowing the first guide tube to rotate with relative to the first longitudinal
15 guide means.

16 6. The surgical instrument of claims 1 or 2 wherein the angular fixation
17 means comprises:

18 a screw means;

19 a first shoulder on a surface of the first guide tube means;

20 a second shoulder on an opposing surface of the first longitudinal guide means;

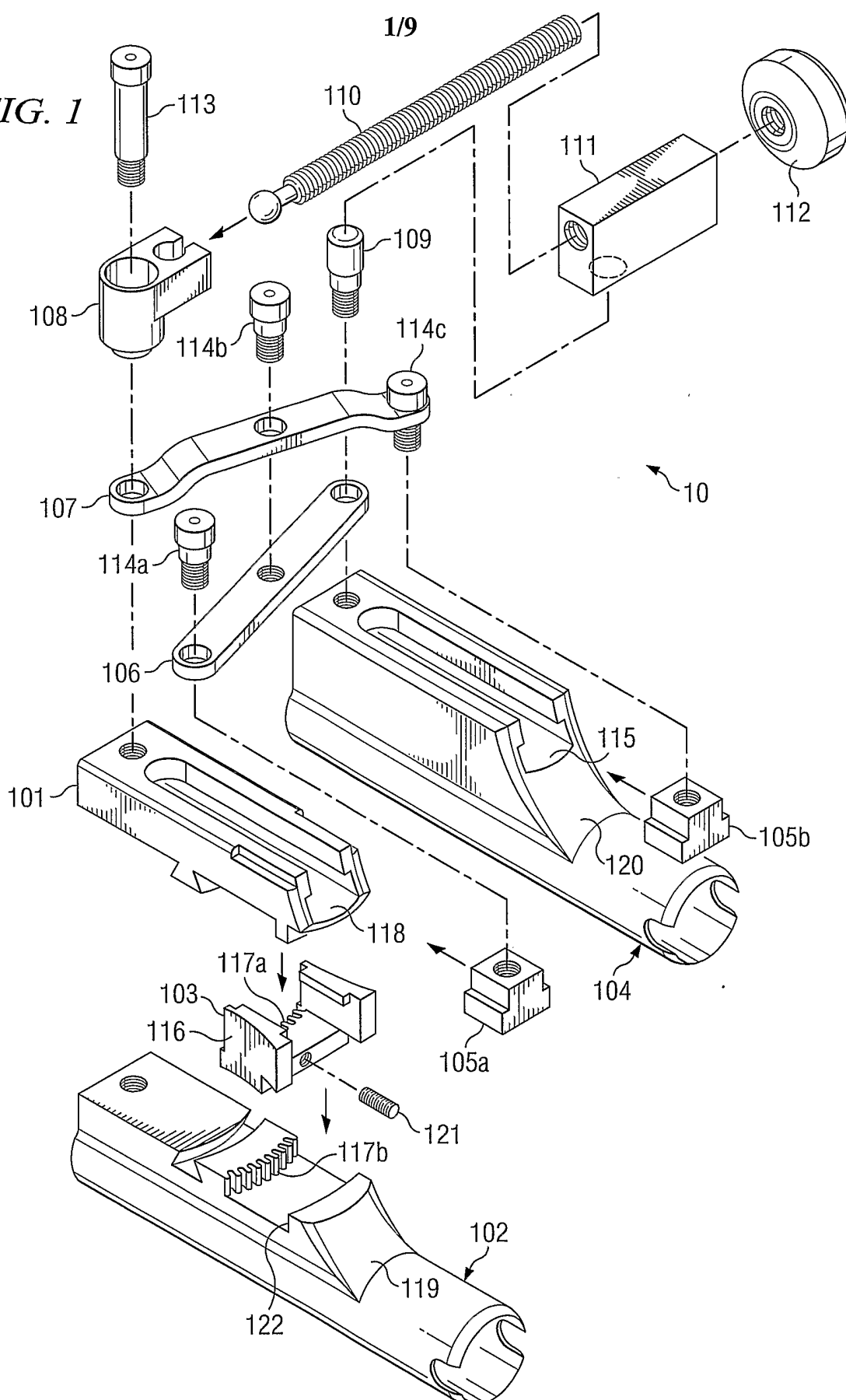
21 a wedge coupled to the screw means having a first edge for selectively engaging
22 the first shoulder and a second edge for selectively engaging the second shoulder,

23 wherein as the screw means is rotated in a first direction, the wedge translates to
24 a first position where the first edge engages the first shoulder and the second edge
25 engages the second shoulder such that the first guide tube means is fixed relative to the
26 first longitudinal guide means, and

27 wherein as the screw means is rotated in a second direction, the wedge translates
28 to a second position where the first edge does not engage the first shoulder such that the
29 first guide tube means is free to angularly move relative to the first longitudinal guide
30 means.

- 1 7. The surgical instrument of claims 1 or 2 wherein the angular fixation
2 means comprises:
3 a plurality of teeth coupled to the first guide means;
4 a slider means for engaging the plurality of teeth, wherein the slider means is
5 slideably coupled to the first longitudinal guide means;
6 a biasing means for positioning the slider means such that the slider means
7 engages the plurality of teeth to prevent angular movement between the first guide
8 member and the first longitudinal guide means; and
9 wherein the sliding means is adapted to be slid in a first direction such that the
10 sliding means does not engage the plurality of teeth thereby allowing angular movement
11 between the first guide member and the first longitudinal guide means.
- 12 8. The surgical instrument of claims 1 or 2, wherein the guide tubes are
13 adapted to engage bone anchors.
- 14 9. The surgical instrument of claims 1 or 2, wherein the longitudinal guide
15 means is a channel means or a slot means.
- 16 10. A spine stabilization system incorporating the surgical instrument of
17 claims 1 through 9.
- 18 11. A minimally invasive spine stabilization system incorporating the surgical
19 instrument of claims 1 through 9.
- 20 12. The surgical instrument of claim 1, further comprising a set of handles
21 having a lever that may be selectively engaged in a slot having a first position and a
22 second position to perform either compression or distraction when said handles are
23 manipulated by a user.
- 24 13. The surgical instrument of claim 12 wherein compression occurs when
25 force is applied to shift said lever to said second position of said slot that is closer to said
26 displacement mechanism.
- 27 14. The surgical instrument of claim 13 wherein distraction occurs when
28 force is applied to shift said lever to said first position of said slot that is further from
29 said displacement mechanism.

FIG. 1



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FIG. 2

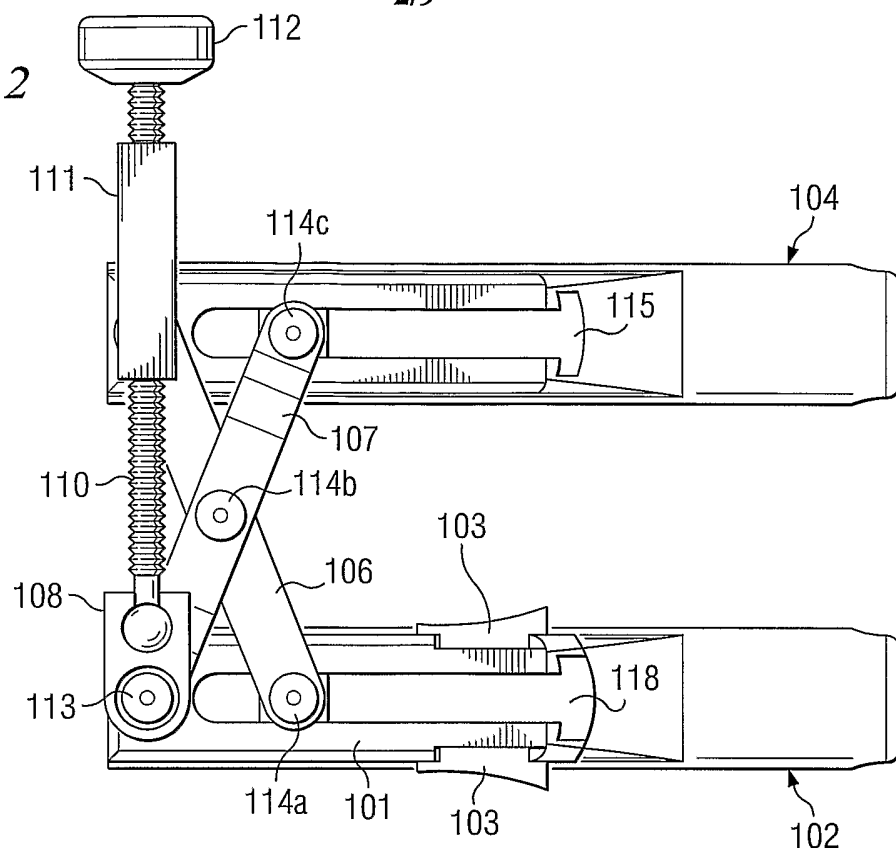
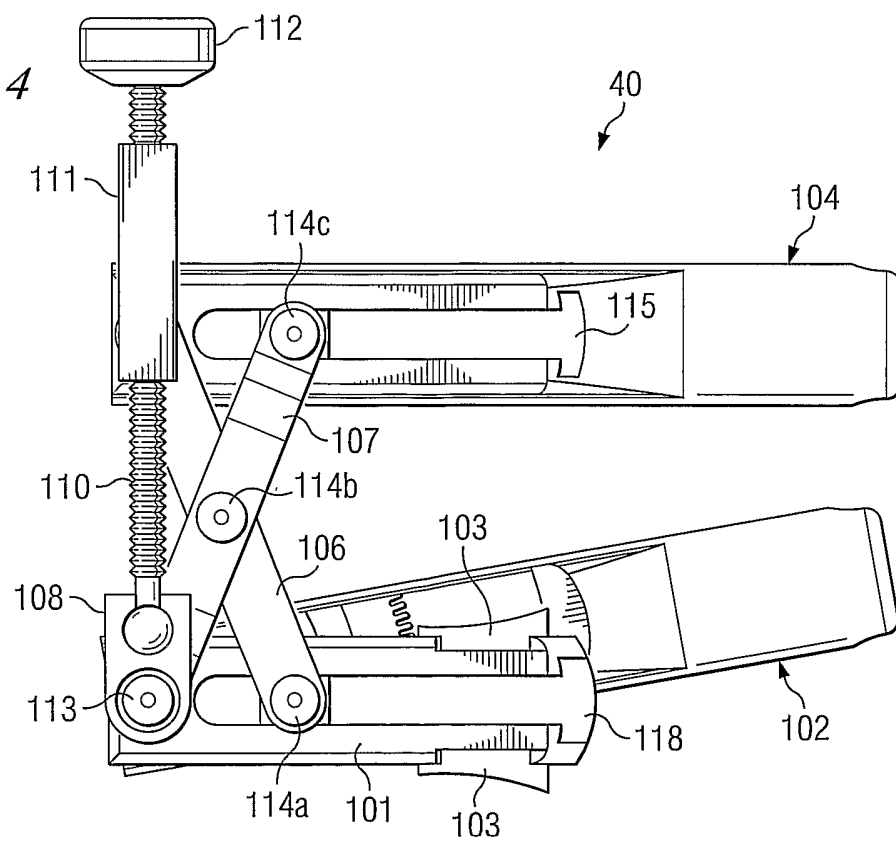


FIG. 4



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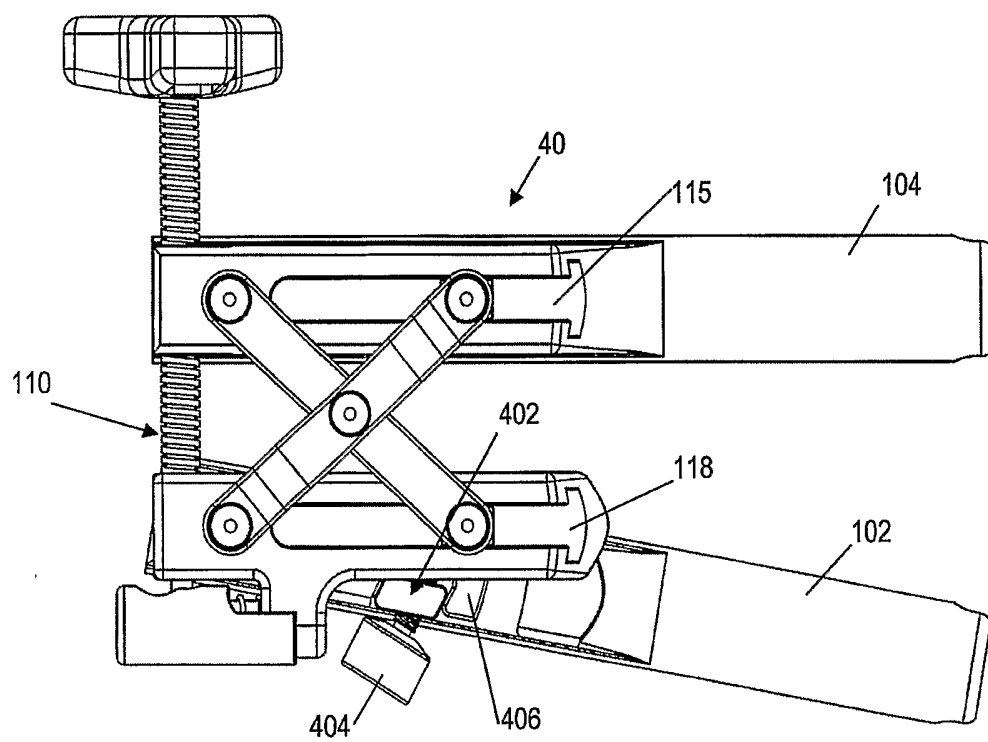
*FIG. 4a*

FIG. 5

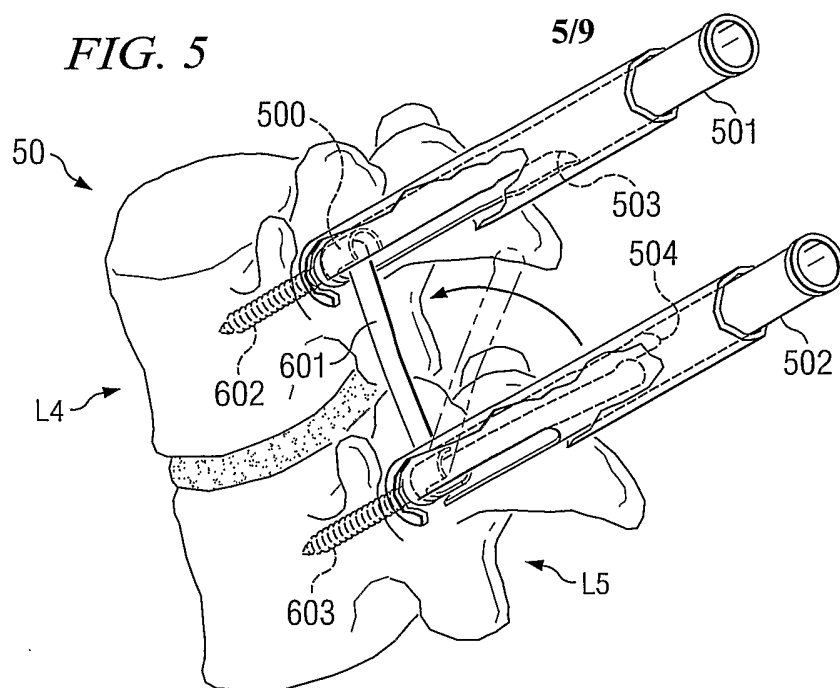
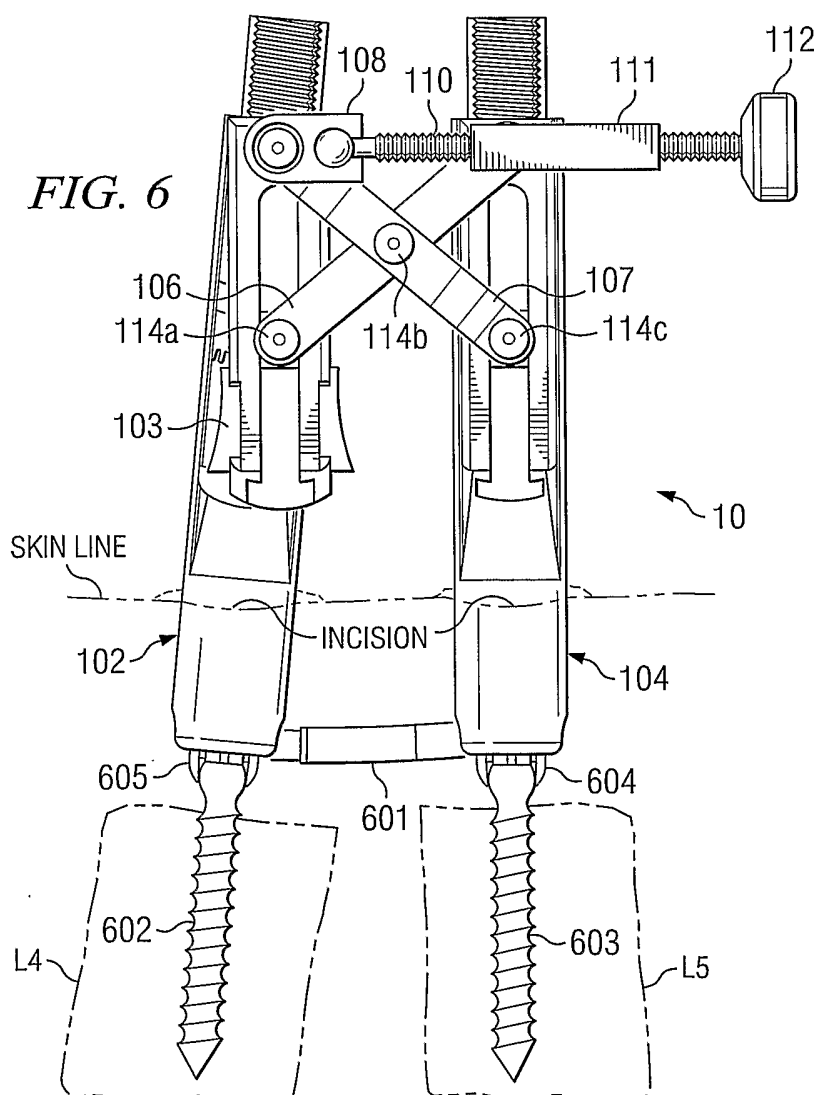
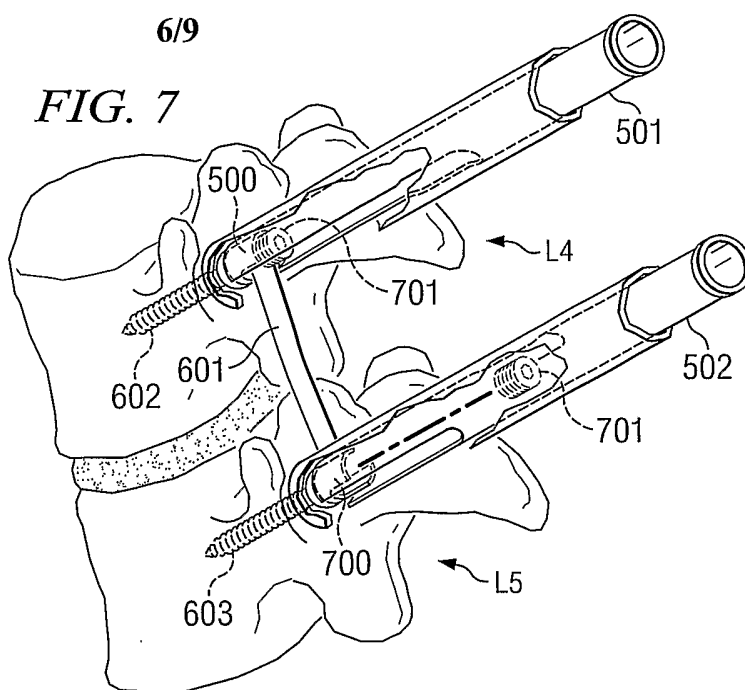
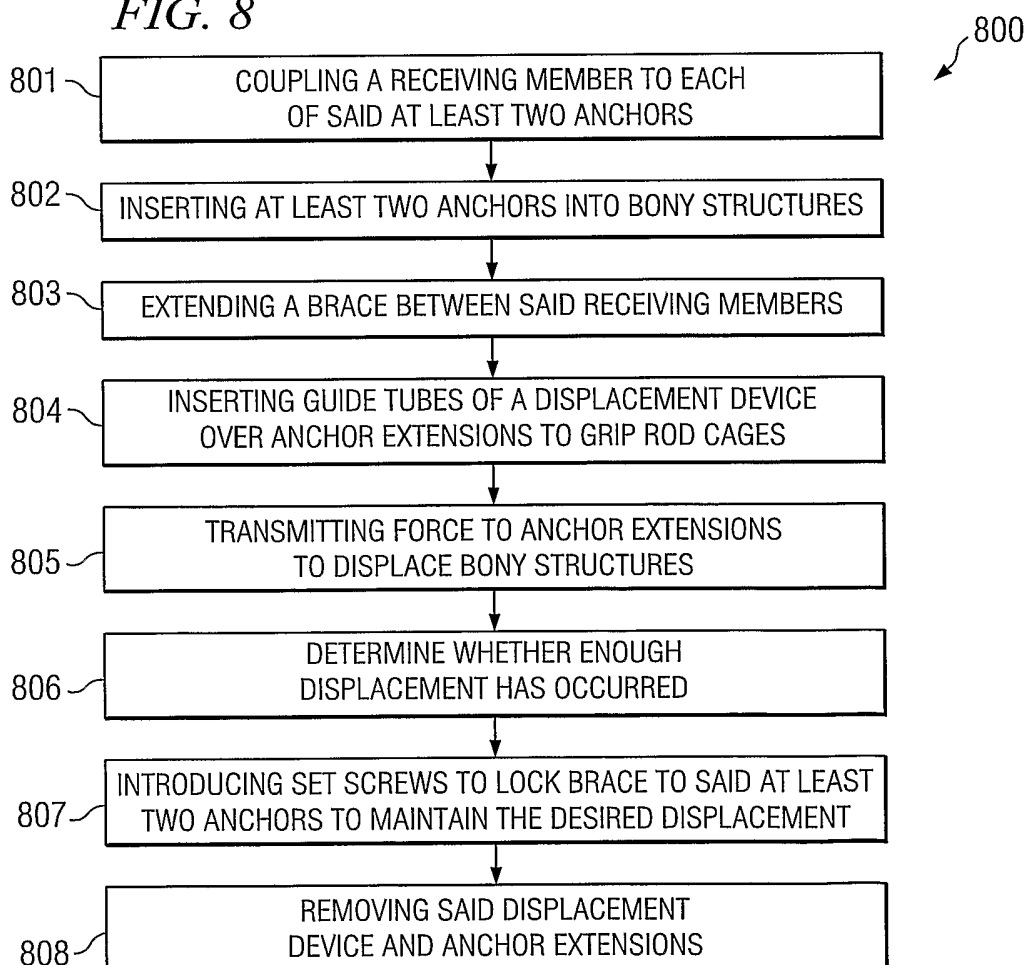
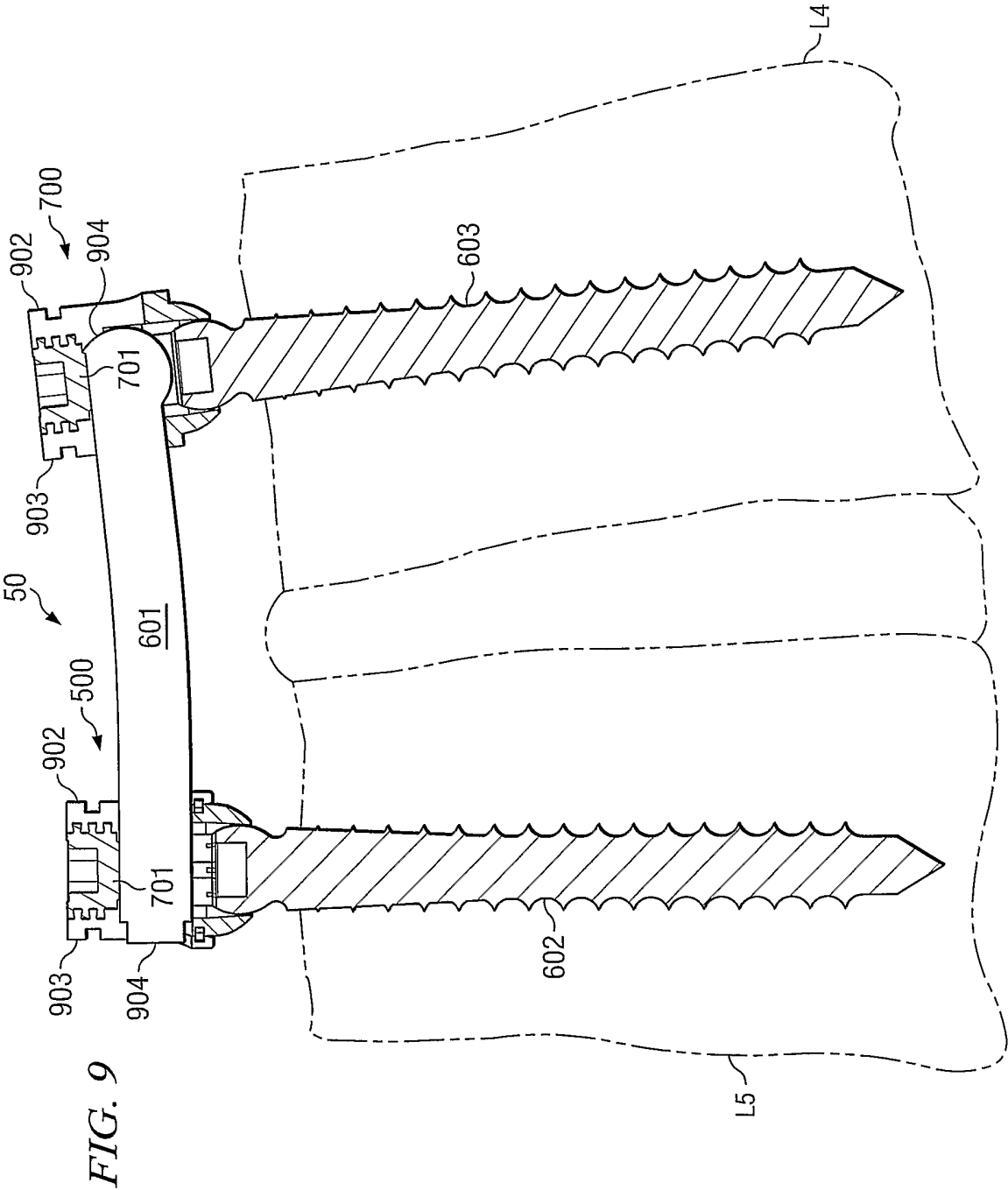


FIG. 6



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FIG. 7*FIG. 8*



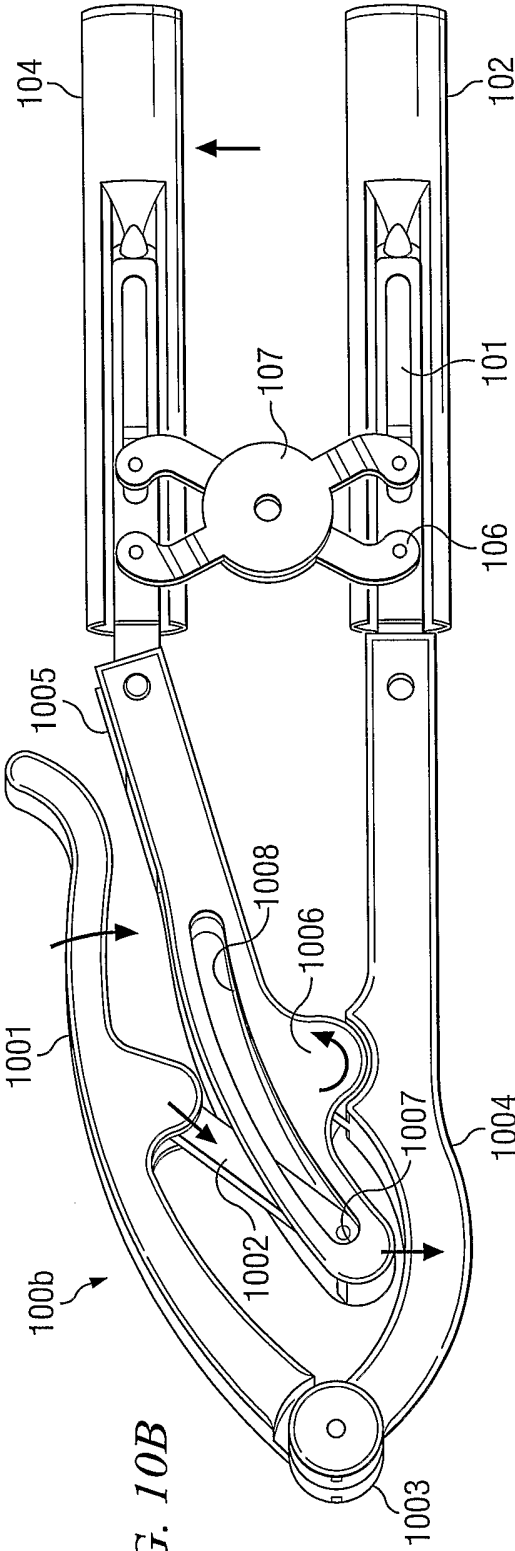
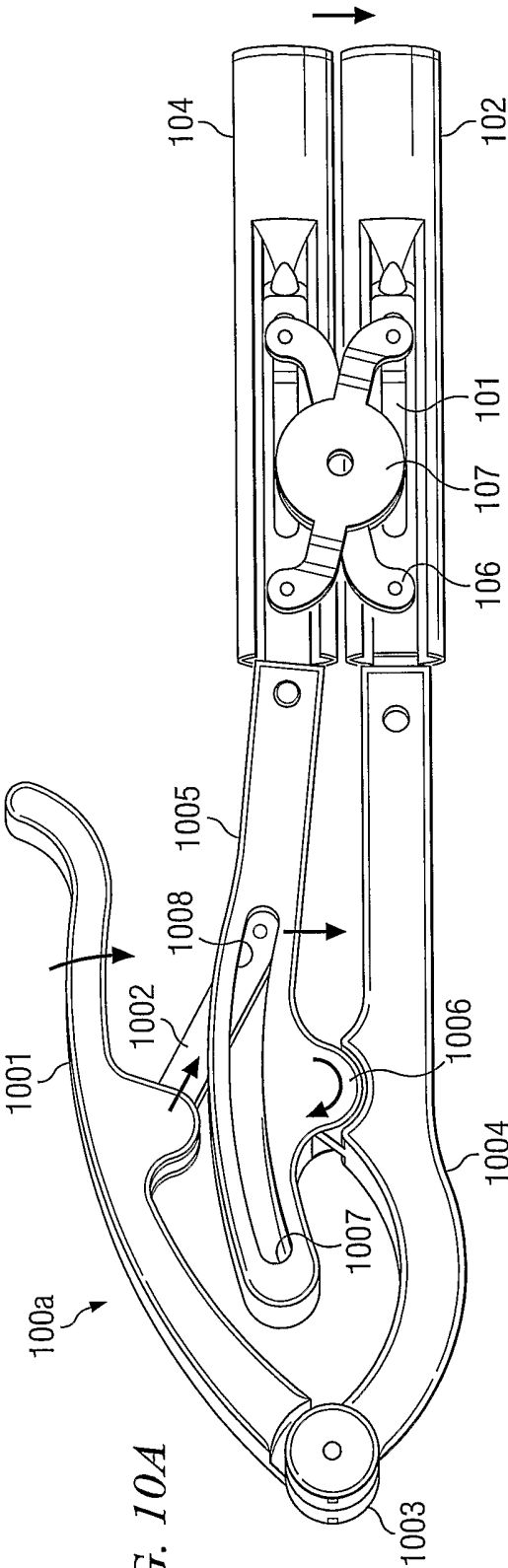


FIG. 11

