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(54) **SPINAL DISC SPACE DISTRACTOR**

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(60) Provisional application No. 60/102,669, filed on Oct. 2, 1998.

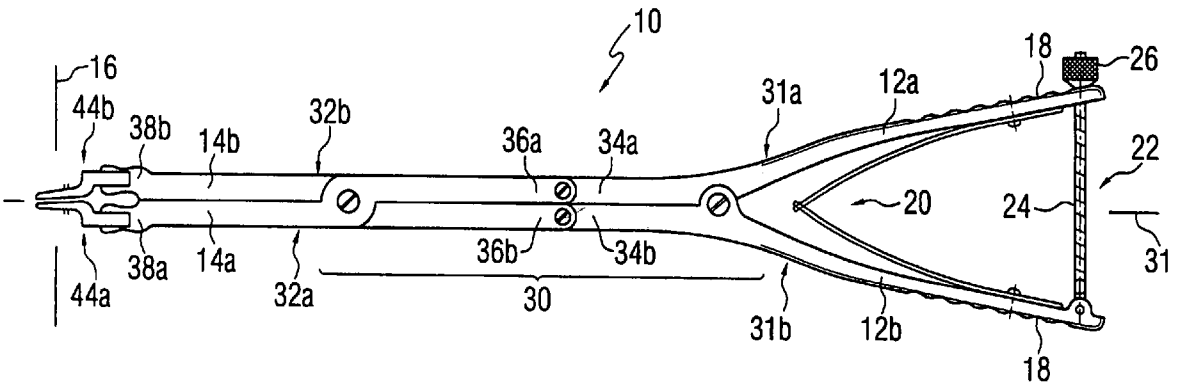
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(51) **Int. Cl.**[7] **A61F 2/44**

(52) **U.S. Cl.** **606/105**; 606/86

(57) **ABSTRACT**

A distractor for separating adjacent elements, such as vertebrae. The distractor preferably has a scissors-type distracting mechanism, either in a simple scissors or double-acting scissors configuration. A set of blades is provided on each jaw such that an implant may be inserted between the spaced apart blades. The set of blades includes at least two blades.



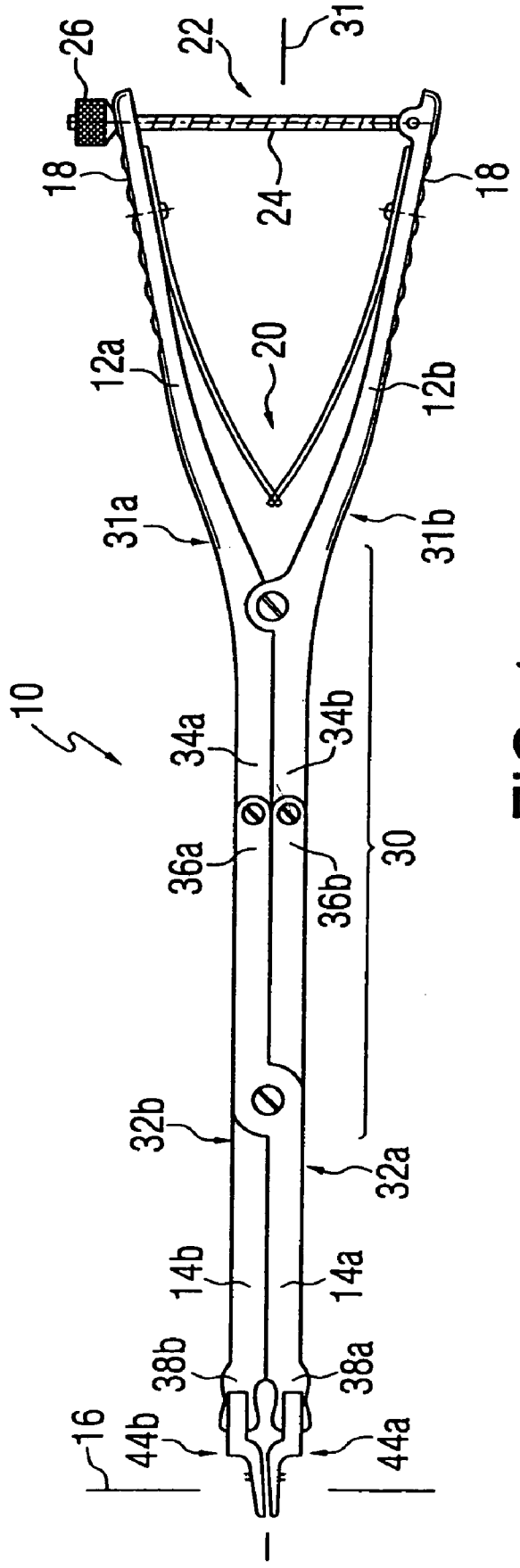

26
22
31
18
24
18
20
12a
12b
31a
31b
10
34a
34b
36a
36b
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32b
32a
14b
14a
38b
38a
16
44b
44a

FIG. 1

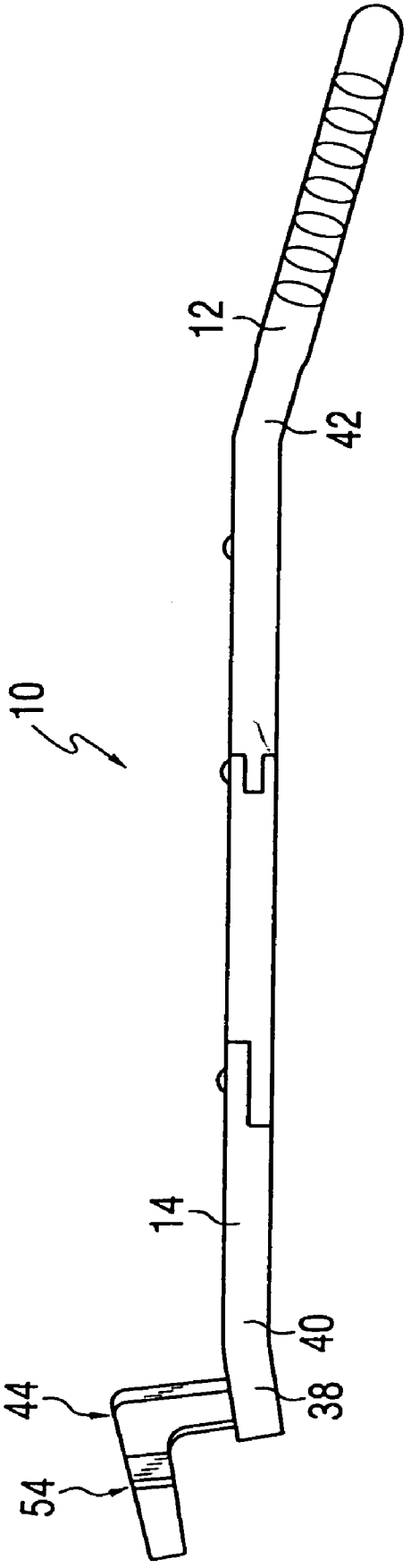


FIG. 2

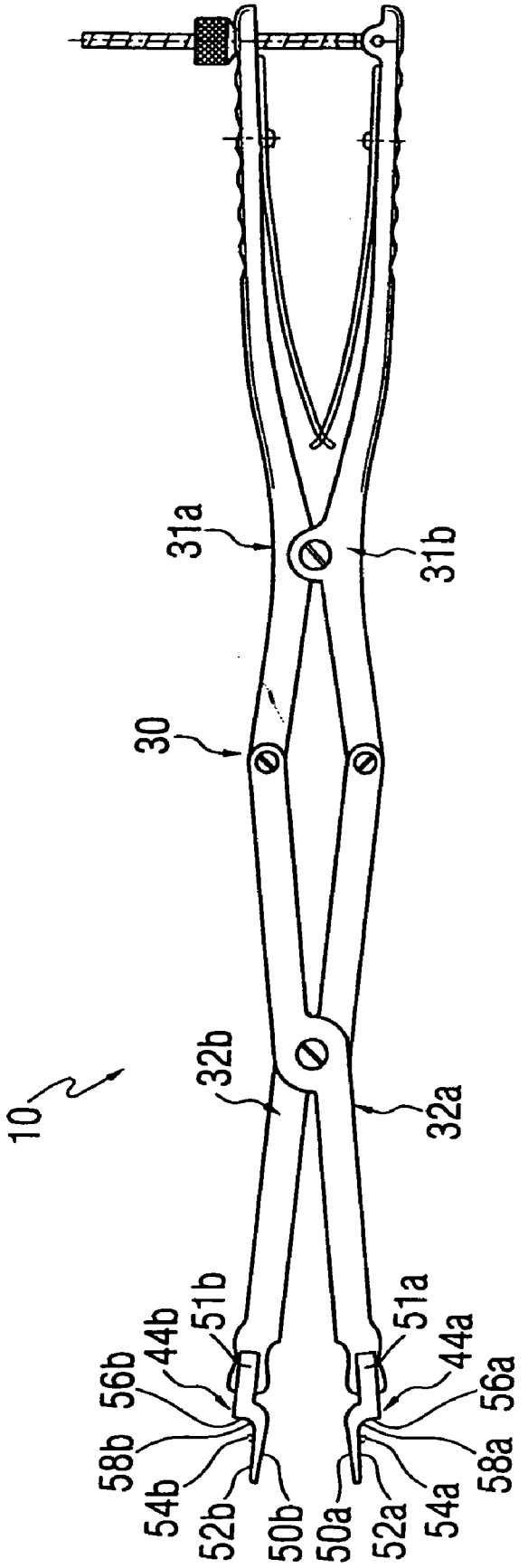

10
30
31a
31b
32a
32b
44a
44b
50a
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52a
52b
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54b
56a
56b
58a
58b

FIG. 3

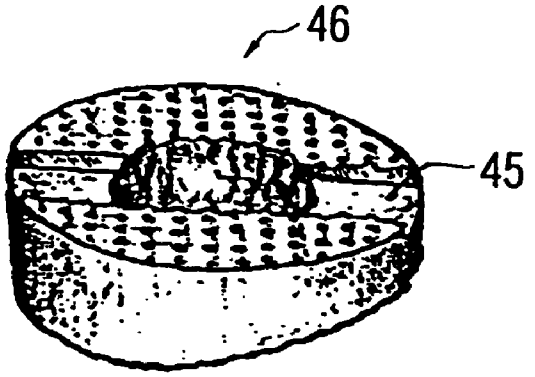


FIG. 4

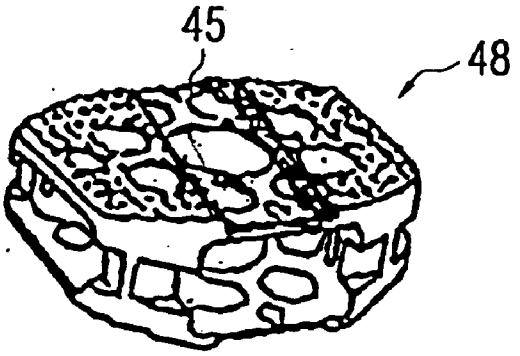


FIG. 5

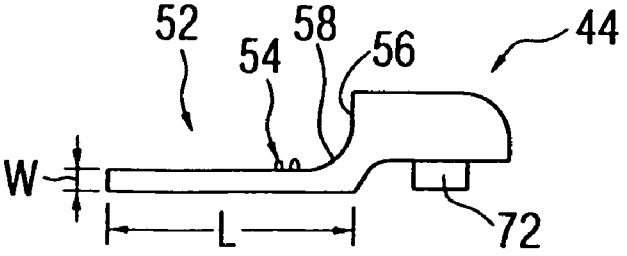


FIG. 6

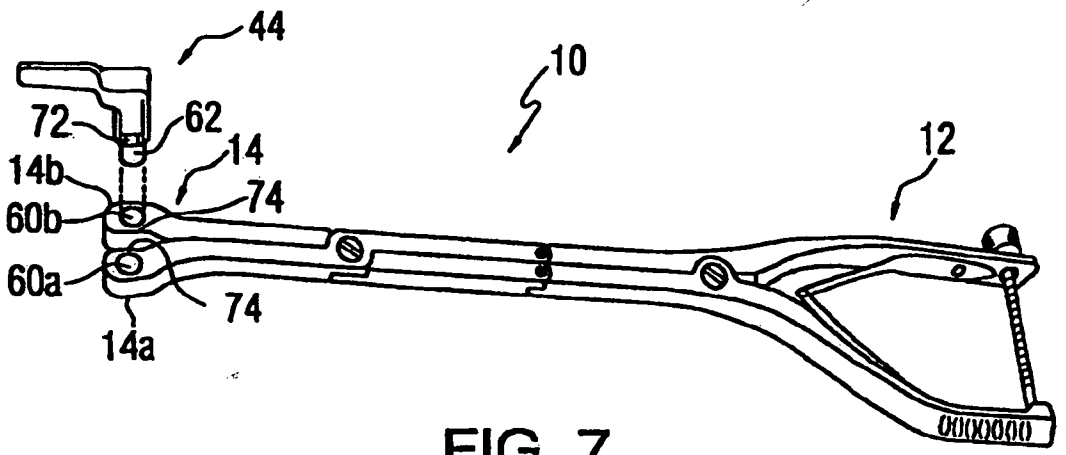


FIG. 7

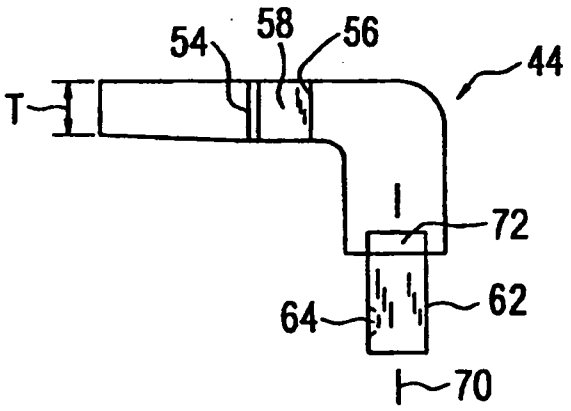


FIG. 8

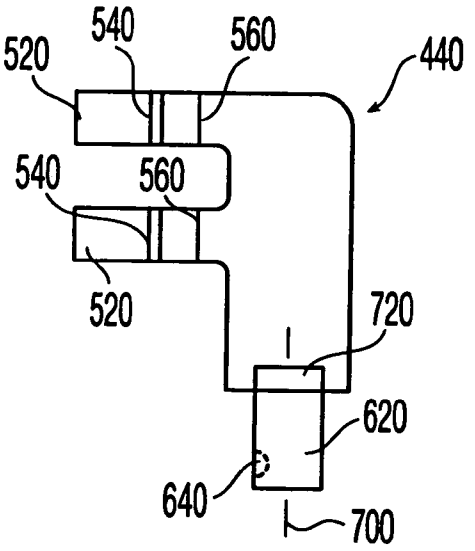


FIG. 8a

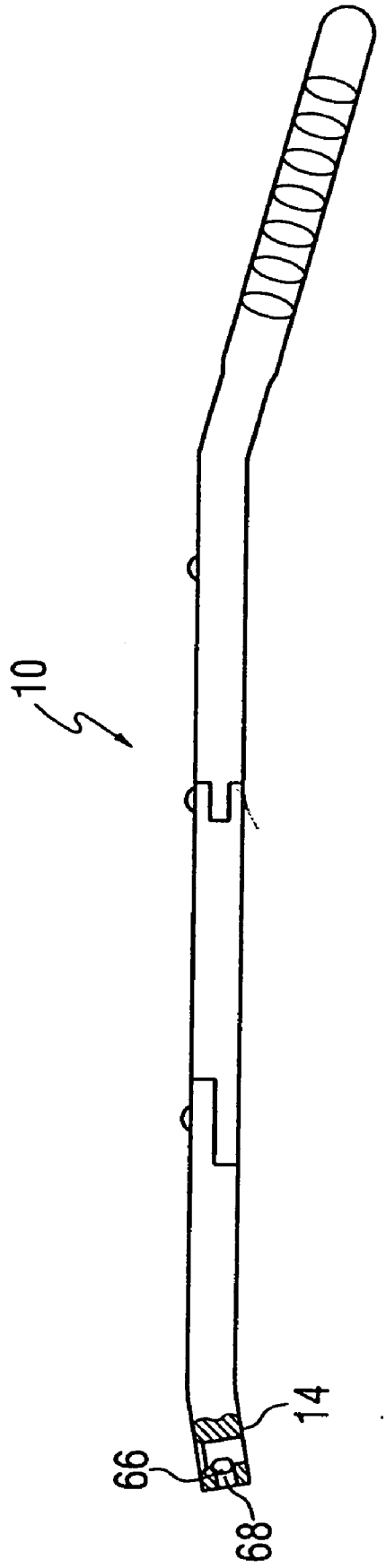


FIG. 9

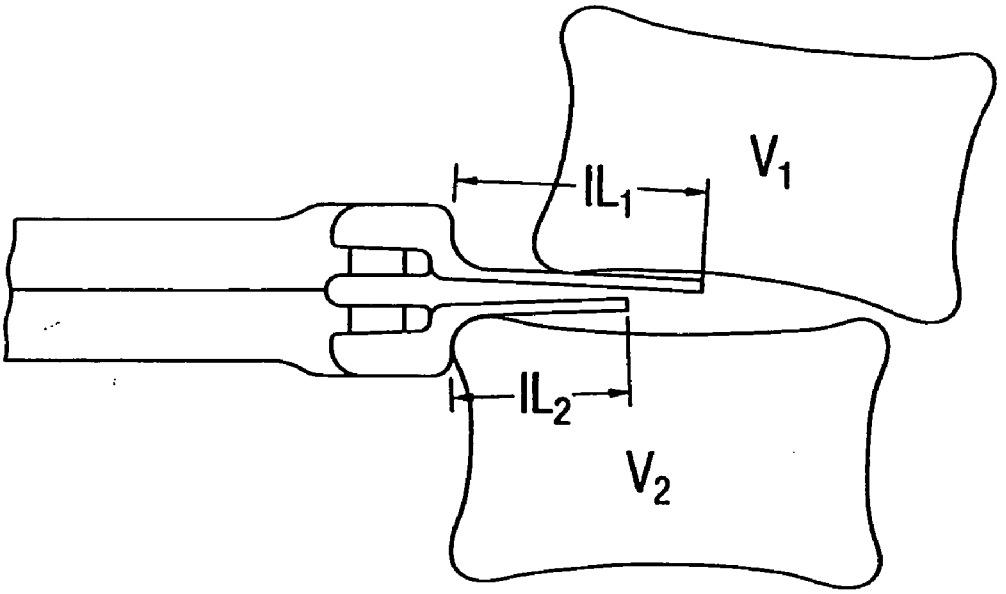


FIG. 10

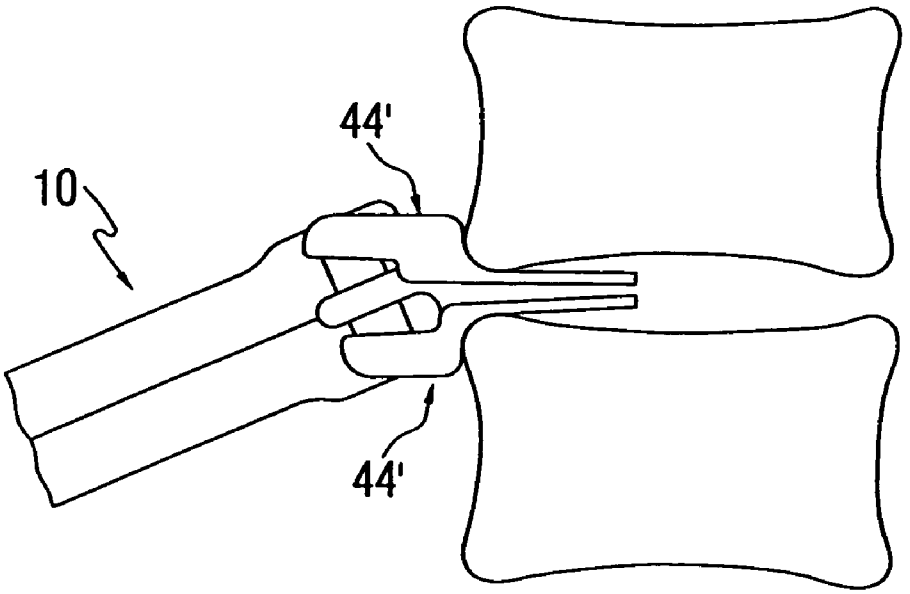


FIG. 11

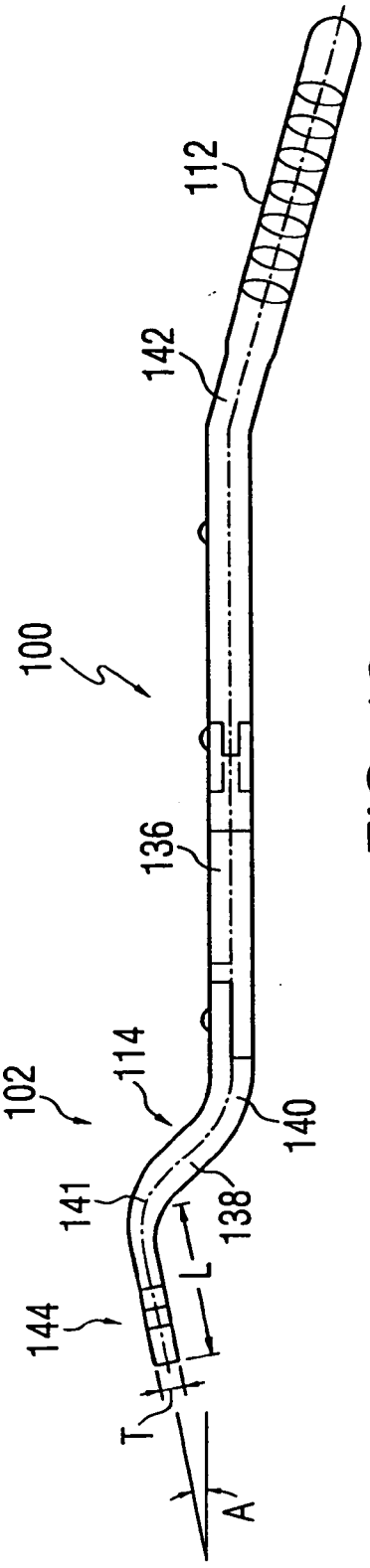

100
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141
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144
T
A

FIG. 12

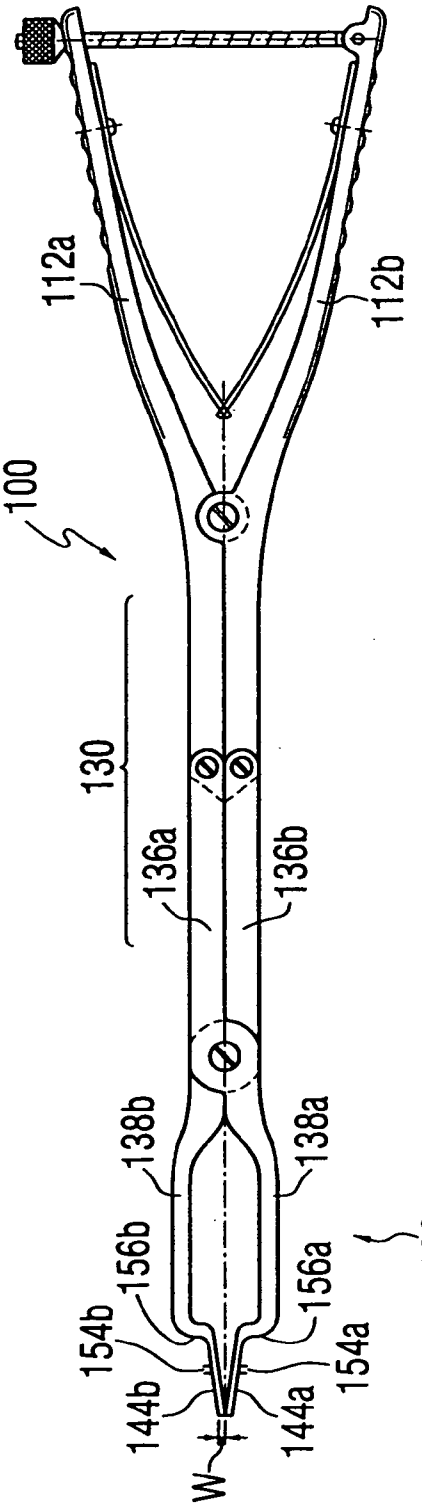

100
112a
112b
130
136a
136b
138b
138a
156b
156a
154b
154a
144b
144a
W
102

FIG. 13

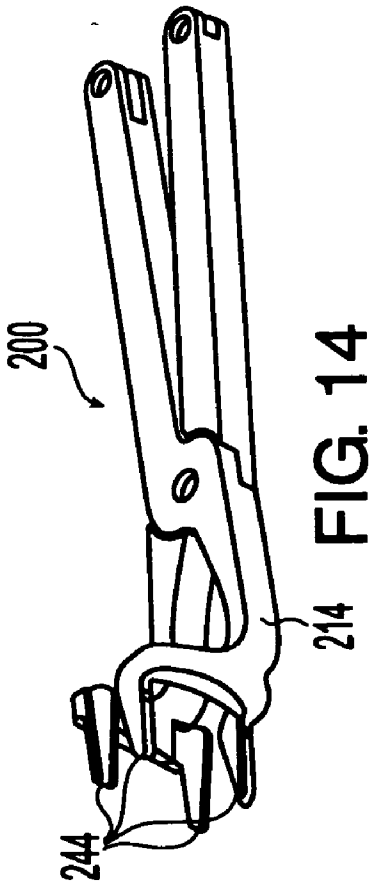


FIG. 14

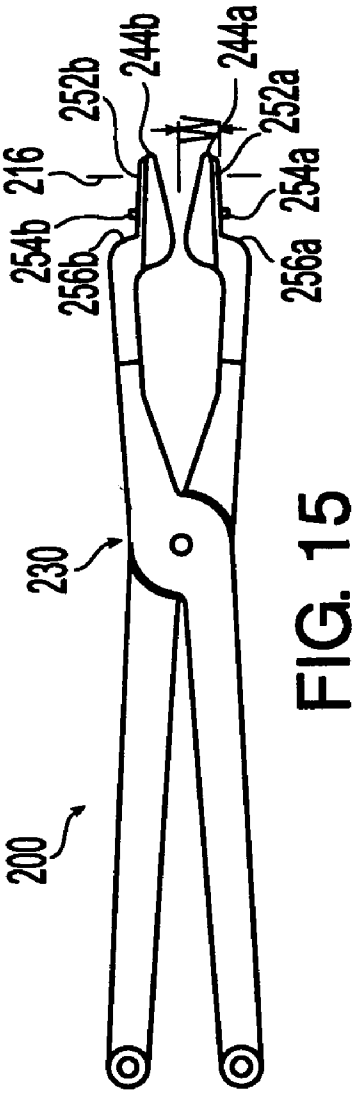


FIG. 15

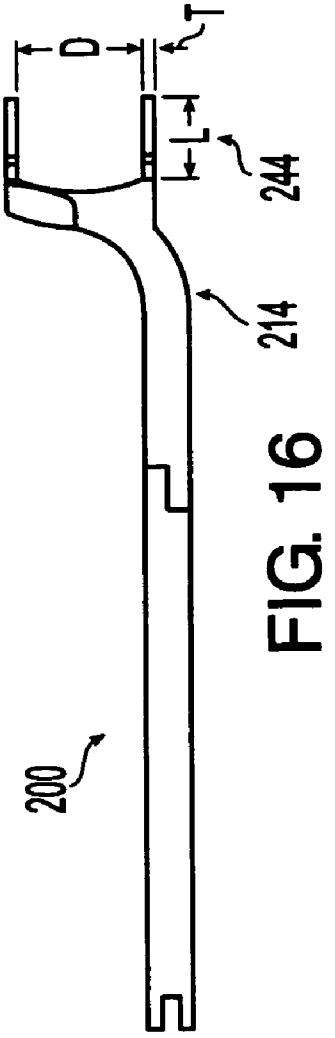


FIG. 16

SPINAL DISC SPACE DISTRACTOR

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application is a continuation of copending U.S. patent application Ser. No. 09/879,911, filed Jun. 14, 2001, which is a continuation of U.S. patent application Ser. No. 09/411,161, filed Oct. 1, 1999, now U.S. Pat. No. 6,261,296, which claims priority to U.S. Provisional Application No. 60/102,669, filed Oct. 2, 1998, which are incorporated by reference herein in their entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to a device and method for spreading apart adjacent vertebrae of a vertebral column so that an implant may be inserted therebetween. More particularly, the present invention relates to a distractor device shaped and configured for minimally invasive insertion and use, such as for distraction of vertebrae using an anterior or anterolateral approach.

BACKGROUND OF THE INVENTION

[0003] Back pain can be caused by either one or a combination of the following: a loss of disc height, compression of nerve roots, degenerative disc disease, spondylolisthesis, and other causes. The current standard of treatment for people suffering from severe back pain requiring surgical intervention due to different types of pathology is by intervertebral fusion. Intervertebral fusion is achieved by fusing two adjacent vertebral bodies together by removing the affected disc and inserting a suitably sized implant into the disc space that allows for bone to grow between the two vertebral bodies bridging the gap left by the disc removal.

[0004] Known intervertebral fusion procedures typically involve the steps of removing a portion or all of the affected disc material, spreading apart adjacent vertebrae with a distractor, and inserting an implant into the space previously occupied by the removed disc material. This procedure can be done either from the front of the patient (anterior interbody fusion) or from the back (posterior interbody fusion). If done from the front, it is important to reduce the size of the distractor so that the procedure is as minimally invasive as possible and thus minimally interferes with and traumatizes the organs and vasculature between the vertebral region being treated and the insertion point. Posterior fusion can utilize larger implants and tools since the insertion space is more accommodating.

[0005] Current implants used for interbody fusion include allograft rings/dowels and cages such as threaded cages. However, the technique for the insertion of these implants generally does not achieve distraction because of their height limitations, thus making it difficult to restore the natural disc height. The force necessary to insert these implants (such as by drilling and tapping) may cause damage to the vertebrae or vertebral endplates at the insertion site. Moreover, allograft products and cages made out of other brittle materials (e.g., carbon fiber and ceramics) may break during insertion, particularly when distraction is not used and external force is necessary to insert the implant. Threaded cages on the other hand do not restore lordosis, and do not allow for atraumatic distraction to restore disc height. Thus, there remains a need for improvements in this area.

SUMMARY OF THE INVENTION

[0006] In accordance with the principles of the present invention, a spinal disc distractor is provided to allow for an implant insertion technique to be performed during distraction of the disc space. The implants are slid into the disc space between the distractor blades, preferably while the blades are in contact with the upper and lower surfaces of the adjacent vertebral bodies. The distractor of the present invention is formed to be as minimally invasive and atraumatic as possible such that it may readily be used in an anterior or anterolaterial approach. Thus, the distractor of the present invention is configured to be used in the confined spaces of the human anatomy through a small surgical incision and permits the use of laparoscopic approaches like Balloon Assisted Endoscopic Retroperitoneal Gasless ("BERG").

[0007] In a preferred embodiment, the distractor of the present invention has a scissor-like configuration with a pair of handles pivotally connected together. A distractor jaw is coupled to a distal end of each handle such that movement of the handles together draws the jaws apart to separate the vertebrae being treated. In an even more preferred embodiment, the jaws and handles are pivotally coupled together in a double-acting scissor-like configuration to further reduce the space required to move the jaws apart and thus further minimize the invasiveness of the device and procedure.

[0008] Although the handles, jaws, and distractor mechanism of the present invention may all lie in the same plane, in order to facilitate visualization of the treatment site during distraction and insertion of an implant, at least the handles may be angled away from the plane of the distractor jaws. In a preferred embodiment, the distractor mechanism is angled downwardly with respect to the jaws and the handles are angled downwardly with respect to the distractor mechanism to further enhance visualization and also to permit greater space for the implant holder adjacent the proximal end of the distractor during insertion of the implant.

[0009] A locking mechanism preferably is provided adjacent to or in the handle to maintain distraction. The locking mechanism may include a spindle or threaded bolt mounted on a first handle and passing through the second handle. An internally threaded speed nut is rotatably mounted on the threaded bolt such that movement of the speed nut along the bolt selectively inhibits movement of the second handle away from the first handle and thus maintains the vertebrae at the desired distracted position.

[0010] The blades of the distractor of the present invention are configured to increase versatility of the distractor. In a first embodiment of the present invention, the blades are removably coupled to the distractor jaws. Thus, the blades may be changed, as necessary or desired, for a given procedure or patient.

[0011] In another embodiment, the blades of the distractor are gradually curved to be out of the plane of the distractor mechanism. Because of the gradual curve, the distal end of the jaws may safely be manipulated through the patient's body with as minimal contact as possible with organs and vasculature including major blood vessels such as the vena cava and aorta. Moreover, such curvature permits insertion through a smaller incision because of the increased manipulability of the gradually curved blades through small openings and spaces.

[0012] In yet another embodiment, the blades of the distractor are configured to permit insertion of any type of implant. In particular, although certain implants may be provided with slots for engagement with a surface of the distractor blades during insertion, other implants do not have such slots. The blades of the third embodiment of the present invention are configured and sufficiently spaced apart to permit insertion of either type of implant, regardless of whether slots are provided for engaging distractor blades. The spaced apart blades may be fixed with respect to the distractor jaws, or alternatively may be removably coupled to the distractor jaws.

[0013] The spinal disc distractor of the present invention is thus designed to distract disc space atraumatically with respect to both the vertebrae and the implant during endplate preparation, implant sizing, and implant insertion. The distractor may be used in a straight anterior, anterolateral, or lateral approach, and may be used in either an open or a laparoscopic procedure. Moreover, the distractor is designed to ensure the selection of an anatomically correct implant size by permitting the annulus to be fully stretched so that the largest possible implant may be inserted and compressed upon release of the vertebrae, thereby enhancing stability and assuring correct placement of the implant. Thus, the present invention permits disc height and lordosis to be restored. The jaws are shaped and configured to preserve the endplate and the vertebral body during distraction, as well as to permit insertion of an implant during distraction. The risk of breakage of allograft implants and other cages made from brittle materials during insertion is thereby reduced.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The detailed description will be better understood in conjunction with the accompanying drawings, wherein like reference characters represent like elements, as follows:

[0015] **FIG. 1** is a top elevational view of a distractor with removable blades formed in accordance with the principles of the present invention;

[0016] **FIG. 2** is a side elevational view of the distractor of **FIG. 1**;

[0017] **FIG. 3** is a top elevational view of the distractor of **FIG. 1** in a working configuration with the jaws separated for distraction;

[0018] **FIG. 4** is a perspective view of a femoral ring implant which may be used with a distractor formed in accordance with the principles of the present invention;

[0019] **FIG. 5** is a perspective view of a cage implant which may be used with a distractor formed in accordance with the principles of the present invention;

[0020] **FIG. 6** is an isolated top elevational view of the blade of the distractor of **FIG. 1**;

[0021] **FIG. 7** is a perspective exploded view of the distractor of **FIG. 1**;

[0022] **FIG. 8** is a side elevational view of the blade of the distractor of **FIG. 1**;

[0023] **FIG. 8***a* is an isolated top elevation view of spaced apart blades of an alternate distractor in accordance with the present invention;

[0024] **FIG. 9** is a side elevational view partially in cross-section of the distractor of **FIG. 1** with the blade removed;

[0025] **FIG. 10** is a schematic illustration of the distractor of **FIG. 1** with blades of different lengths in use;

[0026] **FIG. 11** is a schematic illustration of the distractor of **FIG. 1** with blades in use which are positioned at an angle which is not parallel with the distractor mechanism;

[0027] **FIG. 12** is a side elevational view of a distractor with curved blades formed in accordance with the principles of the present invention;

[0028] **FIG. 13** is a top elevational view of the distractor of **FIG. 12**;

[0029] **FIG. 14** is a side elevational view of a distractor with a pair of blades coupled to each handle in accordance with the principles of the present invention;

[0030] **FIG. 15** is a top elevational view of the distractor of **FIG. 14**; and

[0031] **FIG. 16** is a front perspective view of the distractor of **FIG. 14**.

DETAILED DESCRIPTION OF THE INVENTION

[0032] In accordance with the principles of the present invention, a distractor **10** is provided with a pair of handles **12***a*, **12***b* movable with respect to each other to actuate a pair of jaws **14***a*, **14***b* coupled thereto, as shown in **FIG. 1**. Although distractor **10** may be used for a variety of procedures, a preferred procedure for which distractor **10** is used is spinal disc distraction. Thus, distractor **10** is preferably configured such that actuation of handles **12** (**12***a*, **12***b*) moves jaws **14** (**14***a*, **14***b*) apart substantially along distraction axis **16** to a working position corresponding to the desired resulting relative position of the endplates. For example, the blades may be moved to a substantially parallel or lordotic position to separate adjacent vertebrae to be treated.

[0033] In order to be optimally useful for use in an anterior approach, handles **12** and jaws **14** are configured to move jaws **14** apart along distraction axis **16** a sufficient amount to adequately separate adjacent vertebrae to be treated (typically 5 mm-20 mm, most typically 13 mm-15 mm) yet to occupy a minimal amount of space within the insertion region during the procedure. Thus, handles **12** and jaws **14** preferably are pivotally coupled together in a scissors configuration such that movement of handles **12***a* and **12***b* together causes jaws **14***a* and **14***b* to move apart and effect distraction of vertebrae between which jaws **14** are positioned. Thus, proximal ends **18** of handles **12** are configured to facilitate gripping. In a preferred embodiment, the outer surface of handle proximal ends **18** are contoured to increase user comfort, as shown in **FIG. 2**.

[0034] A biasing element **20**, such as a pair of leaf springs, maintains handles **12***a*, **12***b* in a spaced apart configuration such that jaws **14***a*, **14***b* are close together, ready for insertion through a small incision and narrow passage through the patient in the neutral configuration of **FIG. 1**. A locking mechanism **22** is provided to counteract biasing element **20** as desired, such as to maintain jaws **14** at a desired spaced

apart position for operation on the distracted vertebral region. Locking element may be in any desired configuration, such as a threaded bolt **24** coupled (typically pivotally) to one handle and slidably passing through the other handle, and a locking nut **26** threadedly and rotatably mounted on the end of bolt **24** extending past the other handle (i.e., the portion not between handles **14**). Movement of nut **26**, as a result of rotation, along bolt **24** thus shortens the length of bolt **24** between handles **14** and prevents the handles from moving apart, thus maintaining handles **12** in a position closer together than the neutral position.

[**0035**] A distractor mechanism **30** is provided such that movement of handles **12** to actuate distractor mechanism **30** causes jaws **14** to move apart to effect distraction of adjacent elements such as vertebrae. Distractor mechanism **30** may have a simple scissors configuration (such as in **FIGS. 14-16** described below) such that handle **12***a* and jaw **14***a* are at opposite ends of a first lever arm and handle **12***b* and jaw **14***b* are on opposite ends of a second lever arm pivotally coupled to the first lever arm. In a preferred embodiment, distractor mechanism **30** is in the form of a double-acting scissor configuration having greater than one pivot point, thus reducing the amount of space required along distraction axis **16** and laterally away from distractor mechanism longitudinal axis **31** to effectuate distraction. As may be appreciated with reference to **FIGS. 1 and 3**, in order to form a double-acting scissor configuration, handles **12** and jaws **14** are provided on separate lever arms which are pivotally coupled together. In particular, handle **12***a* is formed at a proximal end of proximal lever arm **31***a*, handle **12***b* is formed at a proximal end of lever arm **31***b*, jaw **14***a* is formed at a distal end of distal lever arm **32***a*, and jaw **14***b* is formed at a distal end of distal lever arm **32***b*. Distal end **34***a* of proximal lever arm **31***a* is pivotally coupled to proximal end **36***a* of distal lever arm **32***a* and distal end **34***b* of proximal lever arm **31***b* is pivotally coupled to proximal end **36***b* of distal lever arm **32***b*. In order to actuate the double-acting mechanism to effectuate distraction and hence movement of jaws **14***a*, **14***b* apart upon movement of handles **12***a*, **12***b* together, one set of lever arms is laterally pivotally coupled together and the other set of lever arms is crosswise pivotally coupled together. In distractor mechanism **30** of **FIGS. 1 and 3**, proximal lever arms **31***a*, **31***b* are laterally pivotally coupled together and distal lever arms **32***a*, **32***b* are crossed over each other and pivotally coupled together. However, it will be appreciated that, instead, proximal lever arm **31***a*, **31***b* may be crossed-over each other and distal lever arms **32***a*, **32***b* may be laterally pivotally coupled. The double-acting configuration breaks the pivoting action into two components, reducing the total movement of distractor mechanism **30** required along distraction axis **16**.

[**0036**] An additional feature of distractor **10** which facilitates use thereof during distraction is the relative offset positions of jaws **14***a*, **14***b*, handles **12***a*, **12***b*, and distractor mechanism **30** with respect to one another, as may be appreciated in the side elevational view of **FIG. 2**. In particular, in a preferred embodiment, distal jaw ends **38***a*, **38***b* are to be positioned to properly distract adjacent vertebrae and distractor mechanism **30** and handles **12***a*, **12***b* are offset relative to distal jaw ends **38***a*, **38***b* to permit optimal visualization of distal jaw ends **38***a*, **38***b* from the proximal end of distractor **10** (outside the patient's body) during distraction. For example, a distal bend **40** may be provided immediately proximal of distal jaw ends **38***a*, **38***b*, as may be appreciated with reference to **FIG. 2**. Thus, the remainder of distractor **10** (i.e., the proximal portions of distractor **10** such as distractor mechanism **30** and handles **12***a*, **12***b*) is in a different plane from the plane of distal jaw ends **38***a*, **38***b* and the distraction site. With such an offset, visualization of the distraction site and of insertion of the implant therein is enhanced. Additionally or alternatively, a proximal bend **42** may be provided immediately distal of handles **12***a*, **12***b* such that proximal handle ends **18***a*, **18***b* are not in the same plane as distal jaw ends **38***a*, **38***b* and the distraction site. The provision of either or both of bends **40**, **42** causes at least a proximal portion of distractor **10** to be in a plane different from the plane of distal jaw ends **38***a*, **38***b* and the distraction site such that the line of site to view distraction is not obstructed by the distractor. Moreover, such offset of portions of distractor **10**, such as distractor mechanism **30** and handles **12***a*, **12***b*, from the distal jaw ends **38** accommodate an implant holder for insertion of the implant to permit a substantially straight insertion of the implant holder. Bend **40** may be between 0°-30°, most preferably 10°, and bend **42** may be between 0°-30°, most preferably 15°, to achieve the desired improved visualization and increased area for the implant holder.

[**0037**] A distractor provided in accordance with the principles of the present invention is configured to distract adjacent vertebrae so that an implant may be inserted therebetween. Preferably, each jaw of a distractor formed in accordance with the principles of the present invention is provided with a blade shaped and configured to contact a vertebral endplate and also to permit insertion of an implant therebetween. Once the implant is properly positioned between the vertebral endplates, the distractor, along with its blades, may be removed from the distraction site in the patient.

[**0038**] In the embodiment of **FIGS. 1-3**, blades **44***a*, **44***b* are provided on jaws **14***a*, **14***b*, respectively, to engage the vertebrae to be distracted. Blades **44***a*, **44***b* are shown in **FIG. 8** and described in detail below. Alternatively, the spaced apart blades **440** of **FIG. 8***a* may be provided on jaws **14***a*, **14***b* as described in more detail below. In a preferred embodiment, blades **44***a*, **44***b* are configured and shaped to correspond to a slot **45** in an implant such as cage **46** of **FIG. 4** or femoral ring **48** of **FIG. 5**. Thus, as the selected implant is moved toward the treatment site with a desired insertion tool, implant contacting surfaces **50***a*, **50***b* (**FIG. 3**) of blades **44***a*, **44***b* contact respective slots **45**. Preferably, implant contacting surfaces **50***a*, **50***b* of blades **44***a*, **44***b* are closer together than the point of connection **51***a*, **51***b* of blades **44***a*, **44***b* to respective jaws **14***a*, **14***b*. Thus, jaws **14***a*, **14***b* are sufficiently spaced apart to permit insertion of the thickest dimension of the implant therebetween, yet blades **44***a*, **44***b* are closer together to account for the narrower dimension of the implant in the region of slots **45** and thereby to securely grasp the implant via slots **45**.

[**0039**] Blades **44** may converge toward each other in a distal direction before actuation of distractor mechanism **30** as may be appreciated with reference to **FIG. 1**. Thus, upon actuation of distractor mechanism **30** and pivoting apart of jaws **14**, blades **44**, and particularly outwardly facing distracting surfaces **52***a*, **52***b* (positioned to contact the endplates in the treatment site), may be moved into an orientation appropriate for the vertebral region being treated. For

example, actuation of distractor mechanism **30** may move distracting surfaces **52***a*, **52***b* into a parallel orientation with respect to each other to securely engage endplates which are parallel with respect to each other.

[**0040**] Distracting surfaces **52***a*, **52***b* of blades **44***a*, **44***b* preferably are shaped to securely engage the vertebrae being treated, particularly the endplates thereof. In a preferred embodiment, distracting surfaces **52***a*, **52***b* are configured to securely engage the anterior lip of the vertebral endplates being treated, as shown in the isolated view of blade **44** in **FIG. 6**. For instance, distracting surfaces **52***a*, **52***b* may be provided with vertebral engagers **54***a*, **54***b* **(FIGS. 2 and 6)**, such as in the form of ridges, which engage the endplates. Transverse engagement walls **56***a*, **56***b* **(FIGS. 2 and 6)** may be spaced from vertebral engagers **54***a*, **54***b* such that an anterior lip of the vertebral endplates fits therebetween. Engagement surface **58***a*, **58***b* **(FIGS. 2 and 6)** between vertebral engagers **54***a*, **54***b* and engagement walls **56***a*, **56***b* preferably is curved to accommodate the anterior lip of the vertebral endplates as well as to provide a smooth transition from distracting surfaces **52***a*, **52***b* to transverse engagement walls **56***a*, **56***b*.

[**0041**] In accordance with the principles of the present invention, the distractor blades preferably are configured to increase versatility of use of the distractor of the present invention. It will be appreciated that distractor **10** preferably is formed from a surgical grade sterilizable metal such that the same distractor may be used for different patients. In order to increase the versatility of distractor **10** and its usefulness for different patients and situations, at least one of blades **44***a*, **44***b* may be removably coupled to its respective jaw **14***a*, **14***b*, as illustrated in **FIG. 7**. Thus, in such embodiment, jaws **14***a*, **14***b* are provided with a socket **60***a*, **60***b* shaped to receive a mounting post **62** of a blade **44**, as shown in **FIGS. 7 and 8**. Post **62** may be releasably held within a bore **60** of a jaw **14** in any desired manner. For example, a ball detent attachment may be formed by providing a depression **64** in post **62** **(FIG. 8)** for matingly receiving a biased detent ball **66** housed within a transverse bore **68** in jaw **14** **(FIG. 9)**. Blade post **62** preferably is fitted within socket **60** to permit pivotable movement of blade **44** about longitudinal axis **70** of blade post **62**. Such pivotable movement facilitates manipulation of blade **44** with respect to the vertebral endplates to ease removal of blade **44** and distractor **10**. If desired, in order to limit the range of pivotal motion of blade **44**, a stop plate **72** **(FIGS. 6-8)** may be provided on post **62** to fit within range limiting groove **74** **(FIG. 7)** in jaw **14**. Stop plate **72** extends transversely from post **62**, as may be appreciated with reference to **FIG. 6** and has stop surfaces **76***a*, **76***b* engaging respective range limiting surfaces **78***a*, **78***b* of range limiting groove **74**. The spaced apart blades **(FIG. 8***a*) are similarly configured having a mating portion in the form of a post **620** for reception in bore **60** in jaw **14**. The post **620** of blades **440** is shown preferably including a depression **640** for a ball detent attachment within bore or socket **60** and a stop plate **720** for limiting the range of pivotal motion of blade **620** about the longitudinal axis **700**. Blades **440** are also shown having distracting surfaces **520** which may preferably further include vertebral engagers **540** and transverse engagement walls **560**.

[**0042**] Removable attachment of blades **44** to jaws **14** permits a plurality of differently configured blades to be used with distractor **10** depending on the situation or application. For example, the size of the blade may be selected based on the implant to be inserted, different implants potentially having differently sized slots for receiving a distractor blade. The size of the blade may also be selected depending on the size of the vertebrae being treated or the curvature of the vertebral column. For example, it may be desirable to select blades of different insertion lengths IL_1, IL_2, as shown in **FIG. 10**, to account for spondylolisthesis which results in one vertebra V_1 being closer to the distractor than the other vertebra V_2. Blade selection may also depend on the vertebral region being treated, which may affect the difficulty of the approach. For example, in the pelvic region organs and bony structures may complicate insertion and the use of blades **44'** which are angled, such as 20°-30°, with respect to the longitudinal axis **31** of distractor mechanism **30** may be desired. Such angled blades **44'** would permit an angled approach of distractor **10** to avoid bony structures such as the pelvis. It will be appreciated that the spaced apart blades **440** of varying lengths may be selected for use with distractor **10** or may be angled with respect to the longitudinal axis of distractor mechanism **30**.

[**0043**] Although the removability of blades **44** of distractor **10** provides a significant versatility advantage over prior art distractors having blades which are rigidly and fixedly connected to the remaining elements of the distractor, versatility is achievable in accordance with the principles of the present invention in other manners as well. For instance, distal end **102** of distractor **100** of **FIGS. 12 and 13** is curved such that blades **144** lie in a plane spaced from the remainder of distractor **100** (i.e., the proximal portions of distractor **100** such as distractor mechanism **130** and handles **112**). Such curvature provide several advantages over prior art distractors thus increasing versatility thereof.

[**0044**] For instance, in prior art distractors, the insertion hole commonly is sized to accommodate the distance between spaced apart elements of the distractor. However, the gradual and smooth curvature of jaws **114** and blades **144** permits distractor **100** to be manipulated to fit through the insertion hole such as by "snaking" distractor **100** through. Thus, the curvature of jaws **114** of distractor is selected and configured such that the insertion hole may be sized based on the single element of the distractor with the largest cross-section. Additionally, the curvature of jaws **114** and blades **144** is smooth and selected such that upon insertion, no sharp edges are present which may injure vasculature, organs, etc., along the insertion path. The curvature thus is sufficiently gentle and wide such that jaws **114** and blades **144** are readily manipulated through the patient's body without causing internal injuries or damage. Preferably the curvature has an S-shape to permit such manipulation and rounded surfaces.

[**0045**] In order to provide the above-described curvature in the distal end of distractor **100**, a smooth (e.g., radiused without sharp edges) curve **140** which gradually results in distal jaw ends **138** being at an obtuse angle with respect to proximal jaw ends **136** may be provided in jaws **114**. Additionally, a similarly smooth and gradual curve **141** preferably is provided between distal jaw ends **138** and blades **144** to result in at least a proximal portion of distractor **100** being in a different plane from that of blades **144** for enhanced visualization as described with respect to bend **40** of distractor **10**. Preferably, curve **141** results in an

angle A between blades **144** and proximal jaw ends **136** of between 0°-30° and most preferably 10°. A bend **142** may also be provided in handles **112** such that proximal handle ends **118***a*, **118***b* are not in the same plane as distal jaw ends **138***a*, **138***b* and the distraction site to further enhance visualization, as described above with respect to bend **42** of distractor **10**. Bend **142** may be between 0°-30° and most preferably 15°.

[**0046**] It will be appreciated that distractor mechanism **130** is similar to distractor mechanism **30** and the description of distractor mechanism **30** thus is applicable to distractor mechanism **130** and is not repeated herein. Preferably, if distractor mechanism **130** is similar to distractor mechanism **30**, then blades **144***a*, **144***b* converge towards each other in a distal direction, as may be appreciated with reference to **FIG. 13**, as do blades **44** to permit a relative working orientation appropriate for the treatment site, as described above.

[**0047**] Like blades **44** of distractor **10**, blades **144***a*, **144***b* preferably are closer together than distal jaw ends **138***a*, **138***b*, as may be appreciated with reference to **FIG. 13**, such that blades **144***a*, **144***b* securely fit within slots **45** of an implant (as in **FIGS. 4 and 5**) to grasp the implant yet jaws **114** permit insertion of an implant therethrough. Additionally, vertebral engagers **154***a*, **154***b* and transverse engagement walls **156***a*, **156***b*, similar to above-described vertebral engagers **54***a*, **54***b* and transverse engagement walls **56***a*, **56***b*, may be provided to enhance engagement of blades **144***a*, **144***b* with the endplates at the treatment site as described above in connection with distractor **10**. However, unlike blades **44** of distractor **10**, blades **144** of distractor **100** preferably are fixedly secured to jaws **114**, such as by formation of blades **144** and jaws **114** as a unitary piece. Thus, distractor **100** may readily be used in severely calcified areas requiring significant strength and durability of the distractor blades. Alternatively, blades **144** may be configured substantially similarly to blades **440** of **FIG. 8***a*.

[**0048**] The dimensions of blades **44***a*, **44***b* of distractor **10** and blades **144***a*, **144***b* of distractor **100** are preferably similar. The thickness T (**FIGS. 8 and 12**) of blades **44***a*, **44***b*, **144***a*, **144***b* (e.g., the working surface, distracting surfaces **52***a*, **52***b*) is preferably approximately 2-15 mm and most preferably approximately 6-10 mm. The width W (**FIGS. 6 and 13**) of blades **44***a*, **44***b*, **144***a*, **144***b* is preferably approximately 0.5-4 mm and most preferably approximately 1.5-1.8 mm. The length L (**FIGS. 6 and 12**) of blades **44***a*, **44***b*, **144***a*, **144***b* is preferably approximately 5-50 mm and most preferably approximately 25-35 mm.

[**0049**] Versatility of a distractor formed in accordance with the principles of the present invention may alternatively be achieved by the provision of a distractor **200** as shown in **FIGS. 14-16** with jaws **214** which permit insertion of any kind of implant, including those not provided with slots as described above with respect to implants **46**, **48** of **FIGS. 4 and 5**. Accordingly, each jaw **214** has a pair of blades **244** sufficiently spaced apart to permit insertion of an implant therebetween without necessarily contacting the implant. Most preferably, blades **244***a*, **244***b* are spaced apart a distance D (**FIG. 16**) to permit insertion of an implant with a medial-lateral width and/or an anterior-posterior width of at least 50% of the corresponding dimension (i.e., medial-lateral or anterior-posterior) of the endplates between which the implant is to be inserted.

[**0050**] As may be appreciated upon comparison of **FIGS. 12 and 13**, blades **244** have a width W along distraction axis **216** greater than thickness T perpendicular to distraction axis **216** (along the working surface). Such dimension minimizes distracting surfaces **252***a*, **252***b* to minimize the surface of the endplates contacted by blades **244** and to permit sufficient space for insertion of an implant between blades **244**. Thus, contact thickness T of distracting surfaces **252***a*, **252***b* is selected to be as small as possible (such that a minimum amount of annulus need be removed and a sufficient amount of space is provided for the insertion of an implant between blades **244***a*, **244***b*) while still permitting safe distraction of adjacent vertebrae without causing damage thereto. Additionally, the width W of blades **244** along distraction axis **216** preferably is selected to ensure the strength of blades **244** so that blades **244** do not deform or buckle during distraction despite the relatively small thickness T of distracting surfaces **252***a*, **252***b*. Preferred dimensions are approximately 3-15 mm (most preferably approximately 7-10 mm) for width W and approximately 0.5-8 mm (most preferably approximately 1.5-3 mm) for thickness T. Because of such dimensions, blades **244***a*, **244***b* preferably overlap one another when distractor mechanism **230** is in a neutral configuration (with blades **244***a*, **244***b* are in their closest relative positions), thereby minimizing the space along distraction axis **216** occupied by blades **244***a*, **244***b* and the size of the insertion path necessary for insertion of blades **244** into the treatment site. The length L of blades **244**, like length L of blades **44** and **144**, is preferably approximately 5-50 mm and most preferably approximately 25-35 mm.

[**0051**] Vertebral engagers **254***a*, **254***b* and transverse engagement walls **256***a*, **256***b*, similar to above-described vertebral engagers **54***a*, **54***b* and transverse engagement walls **56***a*, **56***b*, may be provided to enhance engagement of blades **244***a*, **244***b* with the endplates at the treatment site as described above in connection with distractor **10**. Blades **244** of distractor **200** preferably are fixedly secured to jaws **214**, such as by formation of blades **244** and jaws **214** as a unitary piece. Thus, distractor **200** may readily be used in severely calcified areas requiring significant strength and durability of the distractor blades. Alternatively, blades **244** may be configured similarly to blades **440** so as to be removably coupled with jaws **214**.

[**0052**] It will be appreciated that distractor mechanism **130** is similar to distractor mechanism **30** and the description of distractor mechanism **30** thus is applicable to distractor mechanism **130** and is not repeated herein.

[**0053**] It will also be appreciated that distractor mechanism **230** of distractor **200** may be a simple scissors configuration with handles **212** and jaws **214** formed along the same lever element, as may be appreciated with reference to **FIGS. 12 and 14**. However, distractor mechanism **230** may instead have substantially the same configuration as distractor mechanism **30** of distractor **10** or distractor mechanism **130** of distractor **100**. The description of distractor mechanism **30** thus is applicable to distractor mechanism **230** and is not repeated herein. Conversely, it will be appreciated that distractor mechanism **30** or distractor mechanism **130** may have substantially the same configuration as distractor mechanism **230**. Preferably, if distractor mechanism **230** is either scissors-type configuration (single scissors as in **FIGS. 12-14** or double-scissors as in distractor mechanisms

30 and **130**), then blades **244** converge towards each other in a distal direction as do blades **44** to permit a relative working orientation appropriate for the treatment site, as described above.

[**0054**] While the foregoing description and drawings represent the preferred embodiments of the present invention, it will be understood that various additions and/or substitutions may be made therein without departing from the spirit and scope of the present invention as defined in the accompanying claims. One skilled in the art will appreciate that the invention may be used with many modifications of structure, forms, arrangement, proportions, materials, and components and otherwise, used in the practice of the invention and which are particularly adapted to specific environments and operative requirements, without departing from the principles of the present invention. The presently disclosed embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims, and not limited to the foregoing description.

What is claimed is:

1. A distractor comprising:

first and second handles;

first and second jaws respectively associated with said first and second handles;

a first set of blades extending from said first jaw; said first set of blades comprising at least a first blade and a second blade, said first and second blades being separated by a dimension sufficient to permit the complete insertion of an entire bone fusion implant therebetween;

a second set of blades extending from said second jaw; said second set of blades comprising at least a first blade and a second blade, said first and second blades being separated by a dimension sufficient to permit the complete insertion of the implant therebetween; and

a distractor mechanism coupled between said handles and said jaws such that movement of said handles actuates said distractor mechanism to move said jaws apart,

wherein said first and second sets of blades are configured and adapted to contact anatomical elements to be distracted and permit the complete insertion of the entire bone fusion implant between said anatomical elements.

2. The distractor of claim 1, wherein the distractor mechanism includes an open position in which said first set of blades is spaced relative to said second set of blades, and a closed position in which at least a portion of said first set of blades contacts at least a portion of said second set of blades; and

the first set of blades includes at least a portion that is spaced from at least a portion of the second set of blades when the distractor is in the closed position to permit placement of an implant therebetween for insertion between said anatomical elements.

3. The distractor of claim 1, wherein the distractor mechanism includes an open position in which said first set of blades is spaced relative to said second set of blades, and a closed position in which at least a portion of said first set of blades contacts at least a portion of said second set of blades; and

the first jaw includes at least a portion that is spaced relative to at least a portion of the second jaw when the distractor is in the closed position to permit the placement of an implant prior to insertion between the first and second set of blades.

4. The distractor of claim 1, wherein the first set of blades lie in the same plane and the second set of blades lie in the same plane; and the at least first and second blades of each set are laterally spaced relative to one another.

5. The distractor of claim 1, wherein the first set of blades has an insertion length and the second set of blades has an insertion length, and the insertion length of the first set of blades is different from the insertion length of the second set of blades.

6. The distractor of claim 1, wherein the first and second set of blades are integrally attached to their respective first and second jaws.

7. The distractor of claim 1, wherein at least one of the first and second sets of blades is removably attached to its respective first and second jaws.

8. The distractor of claim 1, wherein the distractor mechanism further comprises:

a pair of first and second proximal lever arms each having proximal and distal ends; and

a pair of first and second distal lever arms each having proximal and distal ends,

wherein:

said first handle is located at said proximal end of said first proximal lever arm;

said second handle is located at said proximal end of said second proximal lever arm;

said first jaw is located at said distal end of said first distal lever arm;

said second jaw is located at said distal end of said second distal lever arm;

one of said pair of proximal lever arms and said pair of distal lever arms is crosswise pivotally coupled; and

the other of said pair of proximal lever arms and said pair of distal lever arms is laterally pivotally coupled.

9. The distractor of claim 1, wherein the first and second jaws each include a mating fixture and the first and second set of blades each include a mating portion, wherein each mating portion is shaped for removable association with each mating fixture.

10. The distractor of claim 9, wherein each mating portion is a post and each mating fixture is a socket.

11. The distractor of claim 9, wherein each mating portion is a socket and each mating portion is a post.

12. The distractor of claim 9, wherein the mating fixture is positioned on an upper surface of the first and second jaws and at least a portion of the first and second blades extends substantially perpendicular to the upper surface of the first and second jaws.

13. The distractor of claim 1, wherein the first and second jaws are removably associated with the first and second handles.

14. The distractor of claim 1, wherein the first and second set of blades are removably associated with the first and second jaws.

15. The distractor of claim 9, further comprising a locking mechanism for locking the position of the mating portion relative to the mating fixture.

16. The distractor of claim 15, wherein the locking mechanism includes a ball portion.

17. The distractor of claim 1, wherein at least a portion of the first set of blades extends at a first angle relative to the first jaw and at least a portion of the second set of blades extends at a second angle relative to the second jaw.

18. The distractor of claim 17, wherein the first angle is substantially the same as the second angle.

19. The distractor of claim 17, wherein the first and second angles range from about 20° to 30° relative to a longitudinal axis of the distractor mechanism.

20. The distractor of claim 1, wherein the first and second set of blades include at least one curved portion.

21. The distractor of claim 1, wherein the first and second jaws include at least one curved portion.

22. A method of distracting adjacent vertebrae comprising the steps of:

providing a distractor comprising first and second handles, first and second jaws respectively coupled to said first and second handles, a first set of spaced apart blades extending from said first jaw, a second set of spaced apart blades extending from said second jaw, and a distractor mechanism coupled between said handles and said jaws;

positioning said first set of spaced apart blades in contact against spaced apart ends of a first vertebral endplate;

positioning said second set of spaced apart blades in contact against spaced apart ends of a second vertebral endplate adjacent and facing said first vertebral endplate;

actuating said distractor mechanism to distract said first and second vertebral endplates; and

inserting an implant between said first and second sets of blades and said first and second vertebral endplates.

23. A distractor comprising:

first and second handles;

first and second jaws respectively associated with said first and second handles;

a first set of blades extending from said first jaw, a second set of blades extending from said second jaw, said first and second sets of blades each comprise at least first and second blades spaced apart to contact anatomical elements to be distracted and permit insertion of an implant between said anatomical elements; and

a distractor mechanism coupled between said handles and said jaws such that movement of said handles actuates said distractor mechanism to move said jaws,

wherein the distractor mechanism further comprises:

a pair of first and second proximal lever arms each having proximal and distal ends; and

a pair of first and second distal lever arms each having proximal and distal ends,

wherein:

said first handle is located at said proximal end of said first proximal lever arm;

said second handle is located at said proximal end of said second proximal lever arm;

said first jaw is located at said distal end of said first distal lever arm;

said second jaw is located at said distal end of said second distal lever arm;

one of said pair of proximal lever arms and said pair of distal lever arms is crosswise pivotally coupled; and

the other of said pair of proximal lever arms and said pair of distal lever arms is laterally pivotally coupled.

24. The distractor of claim 23, wherein the distractor mechanism includes an open position in which said first set of blades is spaced relative to said second set of blades, and a closed position in which at least a portion of said first set of blades contacts at least a portion of said second set of blades; and

the first set of blades includes at least a portion that is spaced from at least a portion of the second set of blades when the distractor is in the closed position to permit placement of an implant therebetween for insertion between said anatomical elements.

25. The distractor of claim 23, wherein the distractor mechanism includes an open position in which said first set of blades is spaced relative to said second set of blades, and a closed position in which at least a portion of said first set of blades contacts at least a portion of said second set of blades; and

the first jaw includes at least a portion that is spaced relative to at least a portion of the second jaw when the distractor is in the closed position to permit the placement of an implant prior to insertion between the first and second set of blades.

26. A distractor comprising:

a proximal end having first and second handles located in a first plane;

a distal end having first and second jaws respectively associated with said first and second handles, said first and second jaws located in a second plane different from the first;

a first set of blades extending from said first jaw, a second set of blades extending from said second jaw, said first and second sets of blades each comprise at least first and second blades spaced apart to contact anatomical elements to be distracted and permit insertion of an implant between said first and second set of blades and said anatomical elements; and

a distractor mechanism coupled between said handles and said jaws such that movement of said handles actuates said distractor mechanism to move said jaws apart,

wherein the first plane is angled with respect to the second plane so as to permit visualization of the blades from the proximal end.

27. The distractor of claim 26, wherein at least one of the first and second sets of blades is removably attached to its respective first and second jaws.

28. The distractor of claim 26, wherein the first and second jaws are removably associated with the first and second handles.

29. The distractor of claim 26, wherein the first and second set of blades are removably associated with the first and second jaws.

30. The distractor of claim 26, wherein the first plane and the second plane form an angle therebetween ranging from about 5° to about 30°.

31. The distractor of claim 30, wherein the angle ranges from about 5° to about 20°.

32. The distractor of claim 30, wherein the angle is substantially 15°.

33. The distractor of claim 1, wherein the dimension separating the first set of blades is substantially identical to the dimension separating the second set of blades.

34. The distractor of claim 1, wherein the implant does not engage the first and second set of blades when the implant is inserted between said anatomical elements.

35. The distractor of claim 1, wherein the implant does not contact the first and second set of blades when the implant is inserted between said anatomical elements.

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