

(43) International Publication Date  
5 December 2013 (05.12.2013)

## (51) International Patent Classification:

A61F 2/46 (2006.01) A61B 17/88 (2006.01)  
A61F 2/44 (2006.01)

## (21) International Application Number:

PCT/IB2012/055693

## (22) International Filing Date:

18 October 2012 (18.10.2012)

## (25) Filing Language:

English

## (26) Publication Language:

English

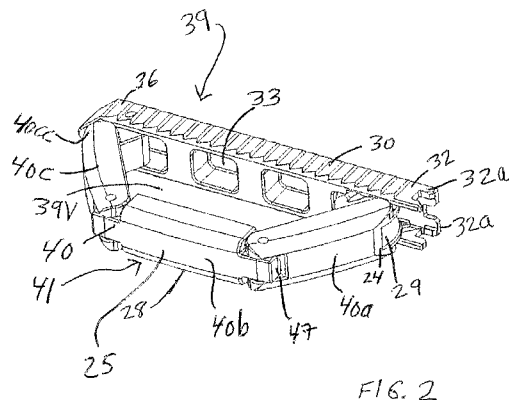
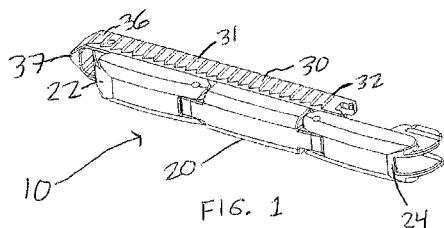
## (30) Priority Data:

61/652,345 29 May 2012 (29.05.2012) US  
61/707,963 30 September 2012 (30.09.2012) US

(71) Applicant: **NLT-SPINE LTD.** [IL/IL]; P.O.Box 2289,  
44641 Kfar Saba (IL).(72) Inventors: **SIEGAL, Tzony**; Moshav Shoeva, 90855 Sho-  
eva (IL). **LOEBL, Oded**; 18 Hasigalit St., 40600 Tel  
Mond (IL). **TOUBIA, Didier**; 11 Hagdud Haivri St.,  
43559 Raanana (IL).(74) Agent: **DR. MARK FRIEDMAN LTD.**; Moshe Aviv  
Tower, 54F, 7 Jabotinsky, 52520 Ramat Gan (IL).(81) Designated States (unless otherwise indicated, for every  
kind of national protection available): AE, AG, AL, AM,  
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,  
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,  
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,  
HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP,  
KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD,  
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI,  
NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU,  
RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ,  
TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA,  
ZM, ZW.(84) Designated States (unless otherwise indicated, for every  
kind of regional protection available): ARIPO (BW, GH,  
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,  
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,  
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,  
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,  
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,  
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,  
ML, MR, NE, SN, TD, TG).

## Published:

— with international search report (Art. 21(3))

(54) Title: **LATERALLY DEFLECTABLE IMPLANT**(57) Abstract: A laterally deflectable asymmetric implant  
(10) for implanting into a body may comprise a deflectable  
piece having distal and proximal ends (22,24) and assuming  
a straightened insertion state. The backbone (30) may abut or  
interconnect with said deflectable piece (20) at the distal end  
(22) of the deflectable piece. In a fully deflected state the im-  
plant may define an asymmetric shape, e. g. a D-shaped loop  
(39), defining an at least partially enclosed volume (39V).  
The deflectable piece may comprise a sequence of segments  
(40, 40a, 40b, 40c) interconnected at effective hinges (47).  
Longitudinal pressure applied to the proximal end (24) of the  
deflectable piece or applied to the backbone in an opposite  
direction may cause relative longitudinal movement between  
the backbone and the proximal end of the deflectable piece  
and may generate outward horizontal movement of the de-  
flectable piece away from the backbone. In one embodiment,  
the implant is implanted using lateral access into an anterior  
zone of a vertebra and deployed posteriorly.

## LATERALLY DEFLECTABLE IMPLANT

FIELD AND BACKGROUND OF THE INVENTION

The present invention generally relates to apparatus and methods for implants, and more particularly to apparatus and methods for implanting deflectable implants.

Minimally invasive and percutaneous subcutaneous procedures, which are performed through a small orifice in the skin, limit the size of the surgery tools and implants that are used. Hence it would be highly advantageous to develop implants that have small cross sections such that they can be inserted easily through a small orifice in the skin and be formed into their final functional expanded shape at the intended implantation site in the body. It would be highly advantageous to provide implants for spinal surgeries such as interbody fusion, motion preservation and vertebral augmentation that may be inserted into the body in minimally invasive procedures.

In addition, precise control over the location of an implant is vitally important to the success or failure of a spinal surgery. Undesired movement of the implant after placement, imprecise placement, improper or imprecise opening, expanding or other forming of the implant after insertion can result in the implant not being precisely where the user intended the implant to be and imperfect fusion. Differences of a millimeter can change an otherwise successful surgery into an unsuccessful surgery. Many prior art methods and apparatuses have been developed to control the exact placement and opening of implants, such as those used in surgery, for example spinal surgery. There is a compelling need for an implant and a method of its implantation that provides the greatest clinical benefit and allows the user to have precise control over the insertion, deployment and follow-up positioning and use of the implant.

Furthermore, there is a need for alternative approaches to insertion of implants into the body, for example in spinal surgery, since approaches through the front have disadvantages, for example since they require moving vital organs.

## SUMMARY OF THE PRESENT INVENTION

One aspect of the present invention is a laterally deflectable implant for implanting into a body, comprising a deflectable piece having a distal end and a proximal end and assuming a straightened or low curvature insertion state for insertion into the body; and a backbone configured to interconnect with or abut the deflectable piece, the backbone comprising a beam, a top of the beam configured to engage cortical bone in the body and receive an impact from a load of the cortical bone, the deflectable piece in a fully deflected state defining, together with said

backbone, an asymmetric loop wherein said asymmetric loop defines an at least partially enclosed volume, wherein longitudinal movement of the proximal end of the deflectable piece relative to at least a distal end of the backbone deflects the deflectable piece to the deflected state to form, with said backbone, the asymmetric loop, wherein the implant in a deflected state is asymmetric such that the implant does not have an axis of symmetry parallel to the backbone.

A further aspect of the present invention is a laterally deflectable implant for implanting into a body, comprising a deflectable piece having a distal end and a proximal end and assuming a straightened or low curvature insertion state for insertion into the body; and a backbone configured to interconnect with or abut the deflectable piece, the backbone having a first telescoping portion and a second telescoping portion, the deflectable piece in a fully deflected state defining, together with said backbone, an asymmetric loop wherein said asymmetric loop defines an at least partially enclosed volume, wherein longitudinal movement of the proximal end of the deflectable piece relative to at least a distal end of the backbone deflects the deflectable piece to the deflected state to form, with said backbone, the asymmetric loop, wherein the implant in a deflected state is asymmetric such that the implant does not have an axis of symmetry parallel to the backbone

A further aspect of the present invention is a method of implanting an implant into a body, comprising inserting the implant into an anterior portion of the body using lateral access while the implant is in a straightened or low curvature state, the implant having a backbone and a deflectable piece meeting the backbone at a distal end of the deflectable piece; and deploying the implant posteriorly by deflecting the deflectable piece.

A still further aspect of the present invention is a method of implanting an implant into a body, comprising inserting the implant into the body while the implant is in a straightened or low curvature state, the implant having a backbone and a deflectable piece, the backbone comprising a beam; anchoring the implant by situating the backbone on a cortical bone so that the backbone holds at least a majority of a load on the implant; and guiding the deflectable piece by holding the backbone stationary while applying longitudinal pressure to a proximal end of the deflectable piece so as to deflect the deflectable piece such that the deflectable piece together with the backbone form an asymmetric loop, the asymmetric loop defining an at least partially enclosed volume.

A yet still further aspect of the present invention is a method of implanting an implant into a body, comprising inserting the implant into the body while the implant is in a straightened or low curvature state, the implant having a backbone and a deflectable piece comprising a sequence of segments interconnected at effective hinges; having a distal segment of the sequence

meet the backbone at a distal end of the deflectable piece; and forming an asymmetric loop between the backbone and deflectable piece together by deflecting the deflectable piece such that a proximal end of the deflectable piece moves longitudinally relative to at least a distal end of the backbone and interconnects to the backbone.

A still further aspect of the present invention is a method of implanting implants into a body, comprising inserting into the body a first laterally deflectable implant that has a first backbone and a first deflectable piece while the first deflectable piece is in a straightened or low curvature insertion state; inserting into the body a second laterally deflectable implant that has a second backbone and a second deflectable piece while the second deflectable piece is in a straightened or low curvature insertion state and such that the first and second backbones are substantially parallel; deflecting the first and second laterally deflectable implants in opposite directions such that the first laterally deflectable implant defines a first asymmetric loop, said first asymmetric loop defines an at least partially enclosed volume and such that the second laterally deflectable implant defines a second asymmetric loop, said second asymmetric loop defines an at least partially enclosed volume.

A yet still further aspect of the present invention is a method of distracting intervertebral space between a first vertebra and a second vertebra, comprising inserting an implant into a body while the implant is in a straightened or low curvature state, the implant having a backbone and a deflectable piece meeting the backbone; and generating relative longitudinal movement between a proximal end of the deflectable piece and at least a distal end of the backbone so as to deflect the deflectable piece and distract an intervertebral space between the first and second vertebrae.

A further aspect of the present invention is a laterally deflectable implant for implanting into a body, comprising a deflectable piece having a distal end and a proximal end and assuming a straightened or low curvature insertion state for insertion into the body; and an anchor configured to interconnect with or abut the deflectable piece, the anchor comprising a beam, the anchor having a height that is at least as great as a maximum height of the deflectable piece and having a top, a width of the top at least half a height of the beam, the top configured to engage cortical bone in the body and receive an impact from a load of the cortical bone and hold at least half the load such that the anchor remains immobile while the deflectable piece deflects to a fully deflected state defining, together with said anchor, an asymmetric loop wherein said asymmetric loop defines an at least partially enclosed volume, wherein longitudinal movement of the proximal end of the deflectable piece relative to at least a distal end of the anchor deflects the deflectable piece to the deflected state to form, with said anchor, the asymmetric loop, wherein the implant in a deflected state is asymmetric such that the implant does not have an axis of

symmetry parallel to the anchor.

A further aspect of the present invention is a laterally deflectable implant for implanting into a body, comprising a deflectable piece having a distal end and a proximal end and assuming a straightened or low curvature insertion state for insertion into the body; and a backbone comprising a rotatable element and an annular element, the rotatable element attached to or abutting the deflectable piece and configured to move longitudinally by rotatingly engaging the annular element, the deflectable piece in a fully deflected state defining, together with said backbone, an asymmetric loop wherein said asymmetric loop defines an at least partially enclosed volume, wherein longitudinal movement of the proximal end of the deflectable piece relative to at least a distal end of the backbone deflects the deflectable piece to the deflected state to form, with said backbone, the asymmetric loop, wherein the implant in a deflected state is asymmetric such that the implant does not have an axis of symmetry parallel to the backbone.

These and other features, aspects and advantages of the present invention will become better understood with reference to the following drawings, descriptions and claims.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIG. 1 is an isometric view of an implant in a straightened configuration for example prior to insertion into a body or after insertion but prior to deflection, in accordance with one embodiment of the present invention;

FIG. 2 is an isometric view of the implant of FIG. 1 in a deflected state, in accordance with one embodiment of the present invention;

FIG. 3 is a top view of an implant in a straightened configuration for example prior to insertion into a body or after insertion but prior to deflection, in accordance with one embodiment of the present invention;

FIG. 4 is a top view of the implant of FIG. 3 in a deflected state, in accordance with one embodiment of the present invention;

FIG. 5A is an isometric view from the top of a deployer on a holder, in accordance with one embodiment of the present invention;

FIG. 5B is an isometric view from the bottom of a deployer on a holder, in accordance with one embodiment of the present invention;

FIG. 6 is an isometric view of a holder, in accordance with one embodiment of the present invention;

FIG. 7A is a top view of an implant showing a locking mechanism, in accordance with one embodiment of the present invention;

FIG. 7B is a top view as in FIG. 7A with a tooth in a slot in locked position, in accordance with one embodiment of the present invention;

FIG. 7C is a top view as in FIG. 7A with a tooth locked in a second locking position, in accordance with one embodiment of the present invention;

FIG. 8 is a front view of a straight beam used as a backbone for an implant and having anchoring ridges on a top and bottom surface, in accordance with one embodiment of the present invention;

FIG. 9 is an end view of an implant including a backbone and a deflectable piece, in accordance with one embodiment of the present invention;

FIG. 10 is an isometric view of a segment of a deflectable piece showing a curved exterior, in accordance with one embodiment of the present invention;

FIG. 11 is a top view of a vertebra showing the vertebral body divided into four equal zones;

FIG. 12 is a top view of an implant positioned over zone two of a vertebral body by lateral access, the implant in a straightened configuration and held by a holder; in accordance with one embodiment of the present invention;

FIG. 13 is a top view of the implant of FIG. 12 wherein the implant backbone is positioned over zone two of the vertebral body but the deflectable piece has been deflected into zone three by the deployer on the holder, in accordance with one embodiment of the present invention;

FIG. 14 is a top view of an implant positioned on the vertebral body as in FIG. 13, but with the holder and deployer having already been separated and removed from the implant, in accordance with one embodiment of the present invention;

FIG. 15 is a top view of an implant having a deflectable piece with two interconnected segments, in accordance one embodiment of the present invention;

FIG. 16 is a flow chart showing a method in accordance with one embodiment of the present invention;

FIG. 17 is a flow chart showing a further method in accordance with one embodiment of the present invention;

FIG. 18 is a flow chart showing a still further method in accordance with one embodiment of the present invention;

FIG. 19 is a flow chart showing a further method in accordance with one embodiment of the present invention;

FIG. 20 is a flow chart showing a still further method in accordance with one embodiment of the present invention;

FIG. 21 shows isometric views of an implant and a biocompatible-material-delivery device, in accordance with one embodiment of a system of the present invention;

FIG. 22A shows a laterally deflectable implant inserted through a TLIF approach, in accordance with one embodiment of the present invention;

FIG. 22B shows two laterally deflectable asymmetric implants alongside one another resulting from a PLIF insertion approach, in accordance with one embodiment of the present invention;

FIGS. 23A-B are side views of an implant, holder and deployer effectuating vertical distraction of the intervertebral space between endplates, in accordance with one embodiment of the present invention;

FIGS. 24A-B are top isometric views of an implant with two sequences of segments each with adjustable backbones, before and after deflection, in accordance with one embodiment of the present invention;

FIGS. 24C-E are top isometric views of an implant whose deflectable piece has two sequences of segments each deflected separately and independently using adjustable length backbones, in accordance with one embodiment of the present invention; and

FIG. 25A is an isometric view of an implant with an adjustable length backbone in a straightened state, in accordance with one embodiment of the present invention;

FIG. 25B is an isometric view of an implant with an adjustable length backbone after deflection, in accordance with one embodiment of the present invention;

FIG. 26A is an isometric view of an implant whose undeflected deflectable piece includes side panels useful for vertical distraction, in accordance with one embodiment of the present invention;

FIG. 26B is a vertical sectional view of the implant of FIG. 26A, in accordance with one embodiment of the present invention;

FIG. 26C is an isometric view of the implant of FIG. 26A after deflection of the deflectable piece, in accordance with one embodiment of the present invention;

FIG. 26D is a vertical sectional view of the implant as shown in FIG. 26C, in accordance with embodiment of the present invention;

FIG. 27A is an isometric view of an implant, deployment tube and holder shaft, in a straight configuration before deflection, in accordance with one embodiment of the present invention;

FIG. 27B is an isometric view of the implant, deployment tube and holder shaft of FIG. 27A after deflection, in accordance with one embodiment of the present invention;

FIG. 27C is an isometric view of the implant, detachment tube and holder shaft of FIG. 27A shown from an opposite side and before deflection, in accordance with one embodiment of the present invention;

FIG. 27D is an isometric view of the implant, deployment tube and holder shaft of FIG. 27C after deflection, in accordance with one embodiment of the present invention

FIG. 27E is a vertical sectional view of the implant, deployment tube and holder shaft of FIG. 27C with the implant in straightened configuration, in accordance with one embodiment of the present invention;

FIG. 27F is a vertical sectional view of the implant, deployment tube and holder shaft of FIG. 27C with the implant in partially deflected state, in accordance with one embodiment of the present invention;

FIG. 27G is a vertical sectional view of the implant, deployment tube and holder shaft of FIG. 27C with the implant in partially deflected state, in accordance with one embodiment of the present invention;

FIG. 27H is a vertical sectional view similar to FIG. 27G except with the deployment tube detached, in accordance with one embodiment of the present invention;

FIG. 27I is a vertical sectional view similar to FIG. 27G except with the deployment tube detached and the holder shaft also removed, in accordance with one embodiment of the present invention;

FIG. 27J is an isometric view of the deflected implant without the deployment tube or holder shaft and revealing the engagement teeth at the rear of the threaded tube; and

FIG. 27K is an isometric view of the end of a disconnected deployment tube showing its engagement teeth, in accordance with one embodiment of the present invention.

#### DETAILED DESCRIPTION OF THE INVENTION

The following detailed description is of the best currently contemplated modes of carrying out the invention. The description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the invention, since the scope of the invention is best defined by the appended claims.



The present invention generally provides a method and apparatus for laterally deflectable implants, and systems and methods for implanting deflectable implants having a loop structure in a human or animal body which may be asymmetric, for example D-shaped, in a deflected state. The implant may during its delivery assume a straightened or low-curvature configuration to facilitate delivery via a minimally invasive procedure. The implant may have a deflectable piece having a distal end and a proximal end and may have a backbone configured to meet (i.e. to abut or interconnect with) the distal end or the proximal end. The backbone may be a beam configured to hold a majority of the load of the implant and may for example have a height at least equal to a maximum height of a proximal segment of the deflectable piece or at least equal to a maximum height of the deflectable piece. The deflectable piece may be comprised of a sequence of two or more segments that may be interconnected to one another by effective hinges. The effective hinges may be integral hinges such as lateral cut-outs that close upon deflection or the effective hinges may be actual mechanical hinges between the segments. The deflectable piece may be interconnected with the backbone at the distal end and/or at the proximal end of the deflectable piece. If the deflectable piece is connected to the backbone at the distal end of the deflectable piece prior to deflection, then upon deflection, the deflectable piece may also be interconnected with said backbone at the proximal end of the deflectable piece. In a deflected state, for example a fully deflected state, the deflectable piece may define, together with said backbone, an asymmetric loop that defines an at least partially enclosed volume. To deflect, either longitudinal pressure may be applied to the proximal end of the deflectable piece or to the backbone so as to generate relative longitudinal movement between the proximal end and at least a distal end of the backbone. This may generate an outward horizontal movement of at least a central portion of the deflectable piece away from the backbone. The implant may be asymmetric about an axis defined by the direction of insertion and running from the proximal and distal ends and situated between the backbone and the deflectable piece.

In certain embodiments, the implant is arranged to open towards one side of the axis defined by the direction of insertion, and may be asymmetrical about that axis, as will be exemplified below.

In the context of the present description and claims, the word "loop" is used to refer to any structure in which following along the contiguous structure can lead back to the starting point while encircling at least one point lying outside the device, except that there may be a gap between a proximal end (or a distal end) of the deflectable piece and the backbone, most often the proximal end (or the distal end) of the backbone. Typically, and in one preferred embodiment, any such gap does not exceed 10% of a length of the backbone (in the case of

telescoping backbones, the length of the backbone when the implant is fully deflected). In other preferred embodiments, the loop is called a modified loop or asymmetric modified loop and does not exceed 15% or 20% or 25% or 50% or 75% of such length, depending upon the embodiment. In the event a modified loop is used, such modified loop may be used in conjunction with any other compatible feature or step of the present invention. In certain cases, completion of the loop may be in the form of a sliding joint. The word "loop" does not carry any implication of a circular or smooth shape, although such shapes are in certain cases preferred implementations of the loop structure when open. In still other preferred embodiments, the word "strict loop" is used to refer to any structure in which following along the contiguous structure can lead back to the starting point while encircling at least one point lying outside the device. Embodiments featuring strict loops may be used in conjunction with any other compatible feature or step of the present invention.

The term "low curvature" insertion state refers to a configuration of the deflectable piece of the implant in which at least one dimension of the deflectable piece, for example the width, other than the longitudinal dimension (i.e. the direction of elongation) of the implant, is significantly reduced, typically to less than 50% (and in some other preferred embodiments to less than 30% or in other preferred embodiments to less than 10%) of the corresponding dimension in its fully deflected state, in order to facilitate delivery through a small orifice. Note that a "straightened configuration" would not be reduced to 0% of the corresponding dimension due to the inherent width of the deflectable piece, even when not deflected at all. In the present context, moreover, the implant, which may comprise the deflectable piece and the backbone together, has a "low-profile" configuration in which preferably two transverse dimensions are small compared to the direction of elongation of the implant, for easy delivery in a minimally invasive procedure, and the implant device opens up in one or two transverse dimensions when deployed.

Particularly preferred but non-limiting examples of implementations include intervertebral implants for supplementing, supporting or replacing an intervertebral disc as part of a fusion procedure or as a motion preserving implant, and intravertebral implants for supporting or restoring a vertebral body. The deflectable implants may include a sequence of segments interconnected with effective hinges (such as conventional hinges or integral hinges) or may be formed with at least an elongated side without clearly distinguished segments.

According to certain embodiments of the present invention, the deflectable piece may comprise a sequence of segments. While a "sequence" means at least two segments, more preferably the sequence includes at least three, and in many preferred cases four or more

segments. The segments may be interconnected at effective hinges, the sequence assuming a straightened or low curvature insertion state for insertion into the body, and being deflectable to a deflected state, for example a fully deflected state, that may be defined by abutment of abutment features of adjacent of the segments.

According to certain embodiments of the present invention, an implant for interbody fusion is disclosed. The implant may be deflectable to a deflected loop, for example a fully deflected loop, inside the body, where the loop defines an enclosed volume (or an at least partially enclosed volume, for example if the loop is not a strict loop and has a gap) with the upper and lower surfaces of the body. The implant for interbody fusion further includes at least one opening in one or both of the elongated sides allowing access to the enclosed volume wherein the at least one opening is used to fill the enclosed volume in the fully deflected loop state with biocompatible filling materials for interbody fusion.

According to certain embodiments of the present invention, an implant for motion preservation is disclosed. The implant is deflectable to a deflected loop, for example a fully deflected loop, inside the body, where the loop defines an enclosed volume (or an at least partially enclosed volume, for example if the loop is not a strict loop and has a gap) with the upper and lower surfaces of the body. The implant for interbody fusion further includes at least one opening in one or both of the elongated sides allowing access to the enclosed volume wherein the at least one opening is used to fill the enclosed volume in the fully deflected loop state with inert biocompatible filling materials applicable for motion preservation.

According to certain embodiments of the present invention, an implant system for implanting implants described herein above is disclosed. The implant system includes further an injector containing filling materials such as but not limited to biocompatible materials, bone grafts, bone chips, bone-growth enhancing agents for interbody fusion or inert filling materials, such as cement for interbody fusion or for stabilizing compression fractures, or other nucleus reinforcement or replacement material for motion preservation.

In contrast to prior art implants, which may be straight or circular or of other various shapes, the present implant may be asymmetric, such as D-shaped and may, in a deflected state, comprise an asymmetric loop that may define an at least partially enclosed volume. For example, the implant of the present invention may be comprised of (i) a deflectable piece and (ii) a backbone that is not deflectable or at least not normally deflected. In still further contrast to prior art implants, the deflectable piece may be comprised of a sequence of segments that may be interconnected at effective hinges. In some preferred embodiments, and in contrast to prior art implants, the effective hinges may be lateral cut-outs, for example triangular lateral cut-outs that

may close upon deflection. The deflected state, for example the fully deflected state, may be defined by abutment of abutment features (for example surfaces, which may also be called abutment surfaces) of adjacent segments of the sequence. In further contrast to prior art implants, in which the implant opens using a tensioning element or a mechanical linkage, the implant of the present invention may open upon longitudinal pressure applied either to a proximal end of the deflectable piece or to the backbone to generate relative longitudinal movement between at least a distal end of the backbone and the proximal end of the deflectable piece. In contrast to the manner of opening prior art implants, this application of longitudinal pressure may generate relative longitudinal movement between the proximal end of the deflectable piece and at least a distal end of the backbone and may generate an outward horizontal movement (transverse to the longitudinal movement and in a preferred embodiment along a plane of or substantially parallel to an intervertebral disc) of at least a central portion of the deflectable piece away from the backbone, thereby deflecting the deflectable piece to the deflected state to form, with said backbone, an asymmetric loop, such as a D-shaped loop. This may be accomplished in part because in contrast to prior art implants, in which a proximal end of a deflectable portion is either free or interconnected, the implant of the present invention may have a deflectable piece that is free on its proximal end prior to insertion and prior to and during at least a portion of its deflection but meeting (abutting or interconnected to) the backbone at a distal end after the deflection, or at least during the deflection. In further contrast to prior art implants, which may be symmetric and may expand symmetrically after insertion, the implant of the present invention may be asymmetric along an axis defined by a direction of insertion and running between a proximal and distal end of the deflectable piece and situated between the backbone and deflectable piece. Accordingly, the implant of the present invention may expand asymmetrically by deflection of the deflectable piece on only one side of the axis. In further contrast to prior art implants, the height of the backbone may in certain preferred embodiments be at least as great as the deflectable piece (or, in other preferred embodiments, at least as great as a proximal segment of the deflectable piece). In still further contrast to prior art implants, at least one segment may have a curved exterior and/or may have an elliptical and/or anatomically shaped cross-section, at least at a top, bottom and at least one side (i.e. the at least one segment has a cross-section that corresponds to an ellipse at a top, a bottom and at least one side of the at least one segment). Furthermore, in contrast to method of implanting in the prior art, the method of implanting of the present invention may involve inserting the implant laterally, which has clinical benefits, such as avoiding the nerve root, avoiding major blood vessels, eliminating the need for a facetectomy, and allowing very large implants to be implanted to afford greater stability. In further contrast to

prior art implantation methods, the method of implanting of the present invention in certain preferred embodiments may involve initially inserting the implant into an anterior portion of a spine and then deployed posteriorly. For example, the implant may be laterally inserted into zone two of the spinal column and then deflected into zone three and/or zone four. In other preferred embodiments, the method of the present invention may involve inserting posteriorly and then deflecting anteriorly. In further contrast to prior art methods, the method of the present invention may involve setting an initial position of the backbone so as to pre-define the final position of the implant. For example, the backbone may be held stationary during deflection of the deflectable piece. In further contrast to prior art methods of implantation, the backbone may be configured to hold at least a majority of the load of the implant and may be configured to be emplaced under or between cortical bone to receive the impact of such load. For example, the backbone may be a solid beam whose width may be at least half the height of the backbone (or in other preferred embodiments, at least two-thirds or at least three-quarters or in some preferred embodiments between one times the height and one and a half times the height or in other preferred embodiments between one half times and one and one half times the height). In still further contrast to prior art implants and methods, one method of the present invention may involve inserting two laterally deflectable implants so that their backbones may be substantially parallel and may be alongside one another and then deflecting each of the implants in opposite lateral directions to define two asymmetric loops. In further contrast to the prior art implantation methods wherein deflection of the implant is lateral or radial, one embodiment of the present invention is a method of implantation involving inserting the implant in a straightened or low curvature state and deflecting vertically to distract an intervertebral space between two discs of a spine. In still further contrast to implantation methods of the prior art, one embodiment of the present invention may involve separately deflecting different sequences of interconnected segments of the deflectable piece of the implant, wherein the different sequences combines comprise the deflectable piece. One application of this is to deflect the implant so as to form a "B" shaped implant. In still further to prior art implant that deflect, the implant of the present invention may utilize a backbone that telescopes to adjust its length and thereby generate the relative longitudinal movement between the proximal end of the deflectable piece and at least a distal end of the backbone.

The principles and operation of an apparatus and method for a laterally deflectable implant according to the present invention may be better understood with reference to the drawings and the accompanying description.

As shown in FIG. 1, a laterally deflectable implant may be in a straightened or low

curvature insertion state for insertion into the body. In this case, the implant 10 is in a straightened insertion state. Implant 10 may comprise a deflectable piece 20 that may have a distal end 22 and a proximal end 24 and a backbone 30 that may be configured to meet (i.e. abut or interconnect with) deflectable piece 20, for example at the distal end 22 of deflectable piece 20 (or at the proximal end 24). According to certain embodiments, a deflectable piece 20 may be formed of a single body of flexible material and may have at least a first and a second elongated side.

Backbone 30 is typically generally straight and normally is not configured to deflect.

Backbone 30 may abut or interconnect with deflectable piece at a distal end 36 of backbone 30 (or at a different portion of backbone 30). Typically this positioning may be such that deflectable piece 20 is interconnected with backbone 30 or else deflectable piece 20 may merely abut backbone 30. If the backbone and deflectable piece are abutting without an interconnection, this may still allow application of longitudinal pressure against deflectable piece 20 or backbone 30 to cause relative longitudinal movement of proximal end 24 relative to at least a distal end 36 of backbone 30 causing deflection of deflectable piece 20. "Distal end" of backbone 30 is defined to mean the last 10% of backbone 30. In other preferred embodiments, the relative longitudinal movement of proximal end 24 is relative to at least a "distal part" of the backbone, which may be the last 5%, or in other preferred embodiments the last 15%, or the last quarter, or the last third, or the last 40%, or in still other preferred embodiments the region of attachment of the distal segment to the backbone. In some preferred embodiments, the proximal end 24 of deflectable piece 20 moves longitudinally relative to the entire backbone 30 (particularly when the backbone is not an adjustable length backbone).

In some preferred embodiments, deflectable piece 20 and backbone 30 are interconnected even before insertion of the implant 10 into the body. In other preferred embodiments, backbone 30 may be inserted into the body first and then deflectable piece 20 may be inserted so as to interconnect along a rail on backbone 30, for example sliding along the rail longitudinally until deflectable piece 20 abuts a tip 37 of backbone 30. Deflectable piece 20 may be hingedly interconnected with backbone 30 at distal end 22 of the deflectable piece, as shown in FIG. 2. Note that when deflectable piece 30 is in a straightened (or low curvature) configuration, implant 10 is said to also be in a straightened (or low curvature) configuration.

When deflectable piece 20 is in its straightened or low curvature configuration, backbone 30 may extend alongside deflectable piece 20, as shown in FIG. 1. When deflectable piece 20 is in its deflected state, backbone 30 may be alongside only the ends 22, 24 of deflectable piece 20 and backbone 30 may extend from the distal end 22 of the deflectable piece 20 to the proximal

end 24 thereof.

As shown in FIG. 2, in addition to abutting or interconnecting with backbone at one end such as a distal end of backbone, deflectable piece 20 in a deflected state, for example after insertion, may also be interconnected (for example hingedly) with said backbone 30 at the proximal end 24 of deflectable piece 20 and backbone 30 may then extend between the distal end 22 and the point of interconnection which may be proximal end 24 of the deflectable piece 20. In some preferred embodiments, for example as shown in FIG. 1, the proximal end 24 of deflectable piece 20 is not in contact with the backbone prior to deflection of the deflectable piece 20.

When deflected, for example when fully deflected, the deflectable piece 20 may define, together with backbone 30, an asymmetric loop 39 (or asymmetric modified loop), which may be D-shaped. D-shaped loop 39 may define an at least partially enclosed volume 39V. When the deflectable piece 20 of implant 10 is fully deflected, the asymmetric loop may in some embodiments have a toroidal shape, for example a ring toroid or an oval toroid (or in other embodiments a toroidal polyhedron). The interconnection between proximal end 24 of deflectable piece 20 and backbone 30 may typically occur at or near the completion of the deflection, although this is not a requirement or a limitation of implant 10. In addition, in some preferred embodiments, asymmetric loop 39 may not be fully closed – for example even in a fully deflected state there may be a gap between backbone 30 and the proximal end 24 of deflectable piece 20. Typically, any such gap does not exceed 10% of a length of the backbone (in the case of telescoping backbones, the length of the backbone when the implant is fully deflected) and in other preferred embodiments, does not exceed 15% or 20% or 25% of such length.

As shown in FIG. 2, deflectable piece 20 may comprise a sequence 41 of segments 40, for example segments 40a, 40b and 40c. “Segments 40” is used to refer in general to the segments 40a, 40b, 40c, etc. Segments 40 may be interconnected with one another at effective hinges 47 for example effective hinges 47a, 47b, etc. As shown in FIG. 3, the effective hinges 47 may be comprised of lateral cut-outs 48a, 48b, 48c between segments 40a, 40b, 40c and 40d. The lateral cut-outs 48a-c may be triangular or substantially triangular and as shown in FIG. 4 may close upon deflection. In some preferred embodiments, the sequence 41 of segments 40 is deflectable to a deflected state, for example a fully deflected state, defined at least partially by abutment of abutment features 43 (for example surfaces) of adjacent segments of the sequence 41 of segments 40. The abutment features 43 may function as a limiter feature to prevent rotation about the hinges beyond the desirable range in either clockwise or counterclockwise

direction(s). In embodiments without cut-outs, another limiting feature may be used, for example a limiter built-in to the hinge (not shown). In order to improve robustness of the torque of the segments 40, the segments 40 may be interconnected to one another by interdigitation, for example interlocking fingers.

If deflectable piece 20 is comprised of segments 40, then proximal end 24 of deflectable piece 20 is a part of the most proximal segment 40a. For clarity, as shown in FIG. 2, middle segment 40b may have a side surface 25.

In order for the deflectable piece 20 to change from the straightened or low curvature state shown in FIG. 1 to the deflected state, for example the fully deflected state, shown in FIG. 2, longitudinal pressure may be applied to the proximal end 24 of the deflectable piece 20. As shown in FIGS. 5A-5B, this may be accomplished with a deployer or "pusher" component 60 which may be a separate component or may be located on a holder 50 (FIG. 6). Application of the longitudinal pressure may generate relative longitudinal movement between the proximal end 24 and backbone 30 to cause deflection of deflectable piece 20. In addition, the longitudinal pressure may generate an outward horizontal (lateral) movement (transverse to the longitudinal movement and, in a preferred embodiment, along a plane of or substantially parallel to an intervertebral disc) of at least a portion 28 of the deflectable piece 20 away from the backbone 30, thereby deflecting the deflectable piece 20 to the deflected state to form the asymmetric loop 39 together with backbone 30. The portion 28 referred to may be a central portion of deflectable piece 20, which in this context is not in any way limited to a portion that is right in the middle of deflectable piece 20 or necessarily in a middle segment 40 of the deflectable piece 20. Rather, the central portion is any portion that is not at the very remote end at the distal end 22 and not at the very remote end at the proximal end 24 of deflectable piece 20.

If deflectable piece 20 is not made up of segments, then the central portion 28 may be thought of as a bow expanding outward with the ends fixed. In some embodiments, the outward expansion, i.e. the deflection of the deflectable piece 20, may be centered at a point that is not at the midpoint between the distal and proximal ends 22, 24. The deflection of deflectable piece 20 allows the deflectable piece together with the backbone to form a loop, and in particular a D-shaped loop.

Instead of longitudinal pressure applied against proximal end 24, for example to push proximal end 24, there may be longitudinal pressure applied to backbone 30, for example to pull a distal end 32 of backbone 30. In general, in either case, relative longitudinal movement between backbone 30 and proximal end 24 of deflectable piece 20 may be generated to deflect deflectable piece 20 to its deflected state and thereby form asymmetric loop 39.



As shown in FIGS. 25A-25B, backbone 30 may be adjustable in length. Accordingly, in embodiments in which the length of backbone 30 is adjustable and this adjustability is utilized to generate relative longitudinal movement between a proximal end of deflectable piece 20 and at least a distal end of the backbone, the proximal end 24 of deflectable piece 20 may be in contact with backbone 30 (and in fact may be attached to backbone 30) even before deflection of deflectable piece 20. For example, backbone 30 may include a first telescoping portion 88a of the backbone 30 that telescopes into or with a second telescoping portion 88b of backbone 30. As seen in FIG. 25B, the proximal end 24 of deflectable piece 20 may be attached to first telescoping portion 88a of the backbone such that deflection of the deflectable piece 20 is actuated by moving the first telescoping portion 88a relative to the second telescoping portion 88b of backbone 30. Although the number of telescoping portions in backbone 30 has been described as two, this number can also be greater than two, such as three, four or higher numbers. First and second telescoping portions 88a, 88b may be linearly aligned (i.e. collinear) as part of backbone 30. Furthermore, in a preferred embodiment, when first and second telescoping portions 88a, 88b telescope within one another, they do so without one telescoping portion sticking out the other longitudinal end of the other telescoping portion. In preferred embodiments, first and second telescoping portions maintain substantially equal heights even when telescoping within one another (since for example the outer surfaces of each may not participate in the telescoping).

In FIGS. 24A-E, the deflectable piece 20 is comprised of a first sequence of segments associated with first and second telescoping portions 88a, 88b of the backbone 30 and is comprised of a second sequence 41 of segments associated with third and fourth telescoping portions 88a, 88b of the backbone.

As shown by FIGS. 27A-K, the present invention may utilize in any suitable embodiment of implant 10 (or method or assembly) an implant 10 having an adjustable-in-length backbone 30 in which axial movement between parts of the backbone 30 is accompanied by relative rotation of the parts. The backbone may comprise a rotatable element 93 and an annular element 95, the rotatable element attached to or abutting the deflectable piece and configured to move longitudinally by rotatingly engaging the annular element. Rotatable element 93 may be a tube 93 such as a threaded tube 93 that is threaded at a distal portion 93a thereof, such as at a tip 93a. The annular element 95 may be a threaded nut 95, such as a female threaded nut, that receives the rotational movement of the threaded tube. Threaded nut 95 may be fixed. This embodiment resembles telescoping but differs from "telescoping" (which typically involves axial movement of a part within a part without accompanying rotation of these parts) since here, besides

longitudinal/axial movement of a part of backbone 30 within another part, there may also be rotation of at least one part of the backbone 30, and typically rotational engagement or relative rotation between that one part and at least one other part of the backbone 30.

As shown in FIG. 27A, a pin 96 may be used to connect a segment 40a (which in the view of FIG. 27A is a distal segment) of deflectable piece 20 to backbone 30. Furthermore, a proximal axis/axle 97 may be used to attach a proximal end of rotatable element 93 to deflectable piece 20, for example to proximal segment 40c, or in general to a proximal part of deflectable piece 20. Since the rotatable element is attached to (or abutting) the proximal part of the deflectable piece, the deflectable piece may move longitudinally relative to at least a distal end of the backbone when the rotatable piece 93 advances longitudinally with respect to annular element 95.

An implant assembly 1000 (FIG. 27C) may include an implant 10 with this kind of adjustable-in-length backbone 30 and may further include a holder shaft 92 running through the backbone 30, the holder shaft 92 including a holder shaft tail 92a jutting out a proximal end of the implant. Such an assembly may further comprise a deployment tube 91 enclosing the holder shaft tail 92a and being operatively engaged to the rotatable element 93 to rotate the rotatable element 93.

FIG. 27E is a vertical sectional view of an implant 10 whose deflectable piece 20 comprises segments 40a, 40b, 40c and whose backbone comprises a threaded tube 93 and a female threaded nut 95. In practice, a user may first insert a holder shaft 92 through implant 10, for example through the entire length of implant 10. The holder shaft 92 may connect to a distal tip of implant 10. The holder shaft 92 may have a holder shaft tail 92a that sticks out the proximal end of implant 10 and may attach to a handle (see FIGS. 5A-6). The user may then attach a deployment tube 91 over holder shaft tail 92a such that engagement teeth 91b of the deployment tube 91 mate with engagement teeth 93b at the proximal end of threaded tube 93, as seen in FIGS. 27G-27K, especially FIGS. 27J-27K.

Accordingly, the present invention may be described as a laterally deflectable implant for implanting into a body, comprising a deflectable piece having a distal end and a proximal end and assuming a straightened or low curvature insertion state for insertion into the body; and a backbone comprising a rotatable element and an annular element, the rotatable element attached to or abutting the deflectable piece and configured to move longitudinally by rotatingly engaging the annular element, the deflectable piece in a fully deflected state defining, together with said backbone, an asymmetric loop wherein said asymmetric loop defines an at least partially enclosed volume, wherein longitudinal movement of the proximal end of the deflectable piece

relative to at least a distal end of the backbone deflects the deflectable piece to the deflected state to form, with said backbone, the asymmetric loop, wherein the implant in a deflected state is asymmetric such that the implant does not have an axis of symmetry parallel to the backbone.

It should be understood that the embodiments in which the length of the backbone 30 is adjustable may have any of the other structural features of implant 10 described herein, and may be used in any of the methods described below, although as indicated such embodiments typically would not employ a deflectable piece 20 whose proximal end 24 is not in contact with the backbone 30 of the implant prior to deflection.

Furthermore, in this patent application in general, the structural features and method steps described in the context of one embodiment, or illustrated in a drawing of one embodiment, are not limited to that embodiment and may be adapted to any of the implants, methods, assemblies or systems described herein, unless otherwise indicated.

Asymmetric loop 39 may assume other shapes besides a D-shape such as rectangular, trapezoidal, triangular and B-shaped (i.e. two D-shaped implants with backbones that are substantially aligned). Moreover, in certain preferred embodiments, there may be two implants lined up such that the backbones 30 of each implant are substantially parallel or alongside one another such that the two implants together form two D-shapes. Moreover, "D-shape" does not require a perfect D. There could be a slight projection of backbone 30 beyond where backbone 30 meets deflectable piece 20 on the proximal and/or distal end.

As seen from FIG. 1, proximal end 24 of deflectable piece 20 may be a free proximal end during insertion of the implant, i.e. not connected to backbone 30 or to another element of implant or of holder 50 or deployer 60. Proximal end 24 may be free proximal end during at least a majority of the deflection of the deflectable piece, the majority measured by reference to how great of an outward horizontal distance the deflectable piece 20 has moved. In some preferred embodiments, proximal end 24 is attached to backbone 30 at or near the end of the application of longitudinal pressure by deployer 60. Accordingly, proximal end 24 may be free other than in the deflected state, for example the fully deflected state, of the deflectable piece 20. In other preferred embodiments, however, proximal end 24 may be free even in the fully deflected state.

As shown in FIG. 2 and FIG. 7B, in some preferred embodiments, a proximal end 24 of deflectable piece 20 may interconnect with the backbone at a proximal end of backbone 30, for example at the culmination of the deflection of deflectable piece 20. Typically, backbone 30 is not configured to deflect and is normally rigid. Nonetheless, in order to facilitate locking or other engagement to deflectable piece 20, backbone 30 could for example have a slit allowing at

least a portion of backbone 30 to bend, for example up to 15 or 20 rotational degrees of the longitudinal axis of backbone 30 (as measured from a distal to a proximal end of backbone 30), so as to facilitate engagement of a proximal end of deflectable piece 20 to backbone 30, for example at the culmination of the deflection of deflectable piece 20. In this version, backbone 30 would resume its original shape after the engagement with deflectable piece 20.

As can be seen from FIGS. 1-2, since backbone 30 and deflectable piece 20 are not identical, implant 10 may be asymmetric about a longitudinal axis running from one end of deflectable piece 20 to the other (for example in a direction of insertion of the implant 10) when the implant 10 is in a deflected state. The asymmetry may be particularly pronounced for example when the longitudinal axis is situated between the deflectable piece 20 and the backbone 30, for example where the backbone, deflectable piece and longitudinal axis are all on substantially one plane. The implant (and the loop) in a deflected state may be asymmetric such that the implant (and the loop) does not have an axis of symmetry parallel to the backbone 30.

The implant 10, including the backbone 30 and deflectable piece 20, may be made of any suitable biocompatible material (i.e. titanium, PEEK, shape memory alloy, steel, cobalt-chrome alloy etc.). The cross-section of implant 10 may be straight, as shown in FIGS. 1-2, or may be angled to create a lordotic angle between the vertebral bodies. Optionally, the lordotic angle may be created by having segments (of deflectable piece 20) of varying or graduated heights within the same implant 10.

An end 32 (FIG. 2) of backbone 30 (for example proximal end 32) may interface with a holder instrument 50 (see FIG. 6 and FIG. 12) that holds implant 10. As seen from FIG. 6, holder 50 may be an elongated instrument and may be made of metals, polymers or a combination of materials. One end 52 (i.e. a distal end) of holder 50 may have one or more such interfaces with functions such as anti-rotation of implant device 10 on the instrument 50, quick connect/quick release or other attachment/release method of the implant 10. For example, the anti-rotation feature 32a on the proximal end 32 of backbone 32 may interface with an anti-rotation feature on the distal end of holder 50. There may be separate features for attachment and release of implant 10 from the holder instrument 50. There may be a feature designed to minimize user error in attaching implant device 10 to the holder 50. The interface features may appear on corresponding ends of the holder 50 and backbone 30. The proximal end 54 of holder 50 may have a surface for pushing or tapping to effectuate advancing the implant 10 into the desired location in the body. The interface on distal end 52 may be connected to a component(s) 66 (i.e. a knob, button, dial, handle, etc.) on the proximal end 54 so that the user can perform the necessary functions to the implant 10 (connect, deploy, disconnect, etc.).

As shown in FIG. 5A, deployer 60 may have a component for aligning or directing a biocompatible material such as bone into the window 29 of deflectable piece 20 or of a segment(s) of the sequence 41 of segments 40. Deployer 60 may be integrally formed as part of the holder 50 and located on holder 50 or may be a separate instrument, or in a third possibility, deployer 60 may be attached to holder 50 intraoperatively. Deployer 60 may have a distal end 62 that interfaces with a proximal portion of deflectable piece 20, in particular in certain preferred embodiments with a segment of implant 10, most likely proximal end 24 forming part of proximal segment 40a of implant 10. When the deployer 60 is advanced longitudinally, deployer 60 pushes or moves the proximal end 24, this causes deflection of the deflectable piece 20 to the deflected state. As seen from FIG. 5A, deployer 60 may be advanced axially by squeezing or pushing handles 66 located on the holder and deployer 60. The handles may be fixed on the holder 50 and deployer 60 or may be removable. The handle 66 may have a spring component (not shown) to return the handles 66 to their original position after squeezing/pushing them to advance the deployer 60. The holder 50 and/or deployer 60 described in FIGS. 5A-6 may be utilized with any suitable implant or method or assembly or system described in this patent application, although for embodiments in which the backbone 30 is telescoping, the deployer 60 would more typically interact directly with backbone 30 rather than directly with deflectable piece 20 (although even in this telescoping backbone embodiment a deployer 60 could instead interact directly with deflectable piece 20). Furthermore, the adjustable in length backbone embodiment shown in FIGS. 27A-K may utilize its own suitable holder shaft 92 and deployment tube 91, as described therein, and the deployment tube 91 used for this embodiment may interact directly with the backbone or backbone element (i.e. threaded tube 93), as described.

In certain preferred embodiments, the implant 10 in its final position may protrude beyond the vertebrae on the ipsi (proximal to the holder/deployer) and/or contra lateral side.

As shown in FIGS. 1-2, the height of backbone 30 may be at least as great as the maximum height of the deflectable piece 20. In some preferred embodiments, the deflectable piece 20 is comprised of a sequence of segments and a height of the backbone 30 is at least a maximum height of the proximal segment, which in some preferred embodiments may be a segment that interconnects with backbone 30, for example upon deflection of deflectable piece 20.

Typically, backbone 30 may be elongated. Backbone 30 may be a beam, such as a solid beam or a beam that is mostly solid, or solid except for particular openings. "Solid" does not preclude being solid with openings. A "beam" as used in this patent application is defined to

have two dimensions other than its length such that an average size of one of those two dimensions is at least 30% of an average size of the second of those two dimensions of the beam. As shown in FIG. 8, for example, a straight beam used as backbone 30 may have anchoring ridges 38 on a top surface 31 and on a bottom surface 34. This beam may be used in motion preservation implants of the present invention. The top 31 of the beam 30 (i.e. the backbone 30) may be configured to engage cortical bone in the body and receive an impact from a load of the cortical bone.

Deflectable piece 20 may have a height, a width and a length. The length of deflectable piece 20 may be along a direction of insertion of the implant and may be by far the largest dimension. In some preferred embodiments, backbone 30 may be configured such that the width of the backbone (the dimension transverse to the height and transverse to the length) is at least half as large as a height of the backbone, or in other preferred embodiments at least three-quarters as large as the height, or between one half and one and a half the height in other preferred embodiments. The "height" of the backbone 30 is defined to mean the dimension perpendicular to the plane in which the implant 10 device opens. The "width" of the backbone 30 is the dimension transverse to the elongated length of the implant (and is parallel to the axis referenced herein that runs from the proximal and distal ends of the deflectable piece and is situated between the backbone and the deflectable piece). The width of backbone 30 allows it to withstand a load. Although in general backbone 30 may be hollow, solid or partially hollow, in preferred embodiments, backbone 30 may be configured to hold at least a majority (or in some other preferred embodiments at least two-thirds or at least three-quarters) of a load held by the implant 10. Implant 10 may be placed under cortical bone (for example the bone of a spinal disc adjacent a vertebral body) and the top surface 31 of the beam may be configured to engage cortical bone in the body and receive an impact from a load of the cortical bone. Implant 10 may be anatomically shaped to similarly match the contour of the vertebral endplate.

In motion preservation implants 10, the brunt of the necessary impact to cross the annulus to the contralateral side may be carried by the straight beam. The beam 30 may take its seat on the annular ring after proper sizing is performed. Stability of the implant relies on the initial small aperture in the annulus to allow passage of the implant – and then the gradual sinking of the ridges 38 along the beam 30 into the surrounding tissues. The beam is the most anteriorly located part of the implant 10, mechanically supporting the lordosing effect. Accordingly, the height of the beam may be greater than the height of the deflectable piece.

As shown in FIGS. 1-2, backbone 30 may have a window 33 or an opening to allow biocompatible material (such bone graft) to pass into the anterior area of the vertebral body, i.e.

zone one. Backbone 30 may also have a contoured tip 37 (FIG. 1), for example in the form of a bullet nose, to ease insertion of the implant device 10 in between hard tissue (i.e. two adjacent vertebral bodies). Backbone 30 may also have ridges 38, as shown in FIGS. 3-4 on a surface (for example top surface 31 or a bottom surface or side surface) that comes into contact with the tissue of the body in order to prevent movement in an undesired direction. Ridges 38 may be in the form of teeth, pyramids, knurls or similar structures. Ridges 38 may be perpendicular to a length of the backbone, as shown in FIGS. 3-4, or the ridges 38 may be parallel to such length, at an angle, in a combination of directions, and may be on all or only part of the surface. Furthermore, the ridges 38 may vary in height or may be of the same height, and ridges 38 may be straight or curved.

In a preferred embodiment, there is at least one opening 29 (FIG. 2) in the sequence 41 of segments 40 to allow access to the at least partially enclosed volume in the loop for insertion of biocompatible material such as bone graft. In a preferred embodiment, the opening 29 is in a proximal segment 40a or in another segment 40. In other embodiments, opening 29 can be between adjacent segments 40.

Proximal segment 40a (or in embodiments without segments, proximal end 24) may have an interface with pusher component 60 (FIGS. 5A-5B) which allows the segments 40 to be pushed and advanced from the straight configuration to the deflected or fully deflected state.

In some preferred embodiments, deflectable piece 20, which may be comprised of the sequence 41 of segments 40, is resiliently biased towards the fully deflected state, and is temporarily deformed to the insertion state. In this case, a guide may maintain deflectable piece 20 straight during insertion and removal of the guide then permits deflection of the deflectable piece 20, for example by deflection of segments 40, to an original shape. In this sense, the deflectable piece 20 exhibits elastic memory.

As shown in FIGS. 9-10, which is an end view of the backbone 30 and deflectable piece 20, a hollow 45 (i.e. a cavity 45) of at least one segment 40 of the sequence 41 may be cut out to allow axial flexibility of the implant 10 in response to the repeated impacts of axial loading. The term "axial loading" as used herein means loading in the height direction (i.e. perpendicular to the plane in which the implant 10 opens). Backbone 30 may also have a hollow cut-out 35, as shown in FIG. 9. As also shown in FIGS. 9-10, at least one segment of the sequence may also have a lateral cut-out 44 extending to the hollow 45. At least one segment 40 (and in some preferred embodiments all segments or all except one segment) may have a curved exterior. As shown in FIGS. 9-10, the at least one segment may have an elliptical cross-section at a top, a bottom and at least one side of the at least one segment, that is the at least one segment may have

a cross-section that corresponds to an ellipse at a top, a bottom and at least one side of the at least one segment. This may be useful for flexibility for axial loading in the case of motion preservation implants. In addition, deflectable piece 20, and in particular segments 40, may have curved edges to form a bullet nose shape (i.e. similar to such a shape in backbone 30) in order to ease the deployment of the device 10 in-between hard tissue (for example two adjacent vertebral bodies) in the body. As with the other structural features described herein, the hollow cut-out, lateral cut-out, curved exterior and other structural features shown in FIGS. 8-10 may be applied to the deflectable piece 20 (segmented or non-segmented) and backbone 20 (whether or not adjustable in length) of any suitable implant, method step, assembly or system described in this patent application. In addition, although the drawings herein for the most part illustrate implants with a segmented deflectable piece in the various embodiments herein, the deflectable piece 20 may be a flexible non-segmented piece, as described herein.

As shown in FIGS. 12-13, the present invention may also be described as an implant system comprising the implant 10 and further comprising an elongated conduit for inserting said implant in said straightened insertion state into the body. As shown in FIG. 21, the present invention may also be described as a system 94 comprising the implant 10 and further comprising a delivery device such as an injector 83 containing filling material selected from the group consisting of: biocompatible materials, bone grafts, bone chips, bone-growth enhancing agents for interbody fusion, cement and filling materials for motion preservation. Injector 83 may include a body 83A, a plunger 83B and a cartridge 83C. As shown in the lower depiction of the delivery device 83, injector may also include a tip 83D that passes through body 83A and cartridge 83C. Cartridge 83C may be a tube with one end to fit the window 29 of implant 10 and the other end to attach to the remainder of device 83. Plunger 83B may interface or connect with implant holder 50 (FIG. 6 and FIG. 12) and other delivery instruments. After the cartridge 83C is filled with the biocompatible material such as bone graft, cartridge 83C may be attached to the body 83A of delivery device 83 at a time when the plunger 83B is in the "back" position. The device is then positioned so that the distal tip of the cartridge 83C is placed at the delivery window 29 of implant 10. The plunger 83B is then advanced so that it pushes the biocompatible material through cartridge 83C and into the implant 10. The device 83 may then be removed. If additional biocompatible material is needed, such material may be inserted into cartridge 83C and the remaining steps repeated as necessary.

As shown in FIGS. 7A-7C, implant 10 may also comprise a locking arrangement to retain said implant in the pre-defined deflected state or range and/or to prevent undesired motion between backbone 30 and deflectable piece 20 (or at least one segment 40 of deflectable piece



20). The locking arrangement may include at least one element selected from: cords, cables, strips, hooks, ratchets, interconnections and snaps. Locking mechanism 70 may be on segments 40. For example, as shown in FIG. 7A, backbone 30 has slots 76A, 76B or other female elements into which a one or more teeth 75 (FIG. 7B) mate. Teeth 75 may project from a segment 40, for example on an internal side of segment 40. FIG. 7C depicts teeth 75 positioned in an optional second locking position by mating with a second slot 76b on backbone 30. Although the locking mechanism 70 illustrated in FIGS. 7A-7C has been described in the context of the specific implant shown in these figures, it should be emphasized that, as with other structural features described herein, this locking mechanism 70 or another locking arrangement described herein may be utilized on any suitable implant or assembly or system or method step outlined in this patent application.

Optionally, there may be locking mechanisms between segments to provide segmental interlocking. In embodiments where deflectable piece 20 is not comprised of separate segments, but rather is comprised of a single flexible piece of material, deflectable piece 20 may deflect by deforming reversibly.

As shown in FIG. 11, in the lumbar vertebral, the area between the anterior and posterior edges of the vertebral body (VB) 80 may be divided into four equal zones. As shown by the flow chart of FIG. 16, the present invention may be described as a method 100 of implanting an implant 10 into a body. Method 100 may have a step 110 of inserting the implant into an anterior portion of the body using lateral access while the implant is in a straightened or low curvature state, as shown in FIG. 12. The implant may have a backbone 30 and a deflectable piece 20 meeting (i.e. interconnected to or abutting) the backbone at a distal end 22 of the deflectable piece. The backbone 30 may be positioned, in a preferred embodiment, on the vertebral lips (apophyseal ring) or within the confines of the annulus. The deflectable piece 20 used in this method (and other methods) may be comprised of a sequence of segments 40 and in general may be structured as described above for implant 10.

Method 100 may also have a step 120 of deploying the implant, for example posteriorly, by deflecting the deflectable piece, as shown in FIG. 13. For example, step 110 may involve inserting the implant onto zone two of the intervertebral disc and step 120 may involve deploying the deflectable piece posteriorly onto zone three and/or zone four of the intervertebral disc.

The deflecting of deflectable piece 20 may deflect implant 10 into an asymmetric, for example D-shaped, loop by applying longitudinal pressure to the proximal end of the deflectable piece or by applying longitudinal pressure to the backbone 30 to pull the backbone. In either

case, this may generate relative longitudinal movement between the proximal end and at least a distal end of the backbone and may generate an outward horizontal movement of at least a portion (for example a central portion) of the deflectable piece away from the backbone. As shown in FIGS. 12-13, this deflection may be accomplished without a tensioning element and without a mechanical linkage. For example, as shown in FIG. 12-13, the application of longitudinal pressure may be achieved by using a pusher/deployer to apply longitudinal pressure to a proximal end (which may be a proximal segment) of the deflectable piece after insertion. Deflecting the deflectable piece by applying longitudinal pressure to a proximal end of the deflectable piece or to a proximal end of the backbone (for example in an opposite direction for example by pulling the backbone) may generate relative longitudinal movement between the proximal end of the deflectable piece 20 and at least a distal end of the backbone and move at least a portion of the deflectable piece away from the backbone. Furthermore, if deflectable piece 20 is made up of segments 40 with cut-outs, then deflecting the implant into an asymmetric loop, such as a D-shaped loop, by applying the longitudinal pressure to the proximal end 24 of deflectable piece 20 (or to the backbone in an opposite direction) to generate relative longitudinal movement between the backbone and the proximal end 24 may close or partially close cut-outs between segments of a sequence of segments of the deflectable piece, as shown in FIGS. 3-4. By setting an initial position of the backbone the user may be able to pre-define a final position of the implant in a deflected state.

After deflection, the holder and deployer may be separated and removed from the implant in a separate step. The implant device would then remain between the vertebral body shown in the FIGS. 11-13 and the one above it (not shown).

As shown by the flow chart of FIG. 17, the present invention may also be described by a further method 200 of implanting an implant into a body. Method 200 may involve a step 210 of inserting the implant into the body while the implant is in a straightened or low curvature state, the implant having a backbone and a deflectable piece, wherein the backbone comprises a beam. Method 200 may also have a step 220 of anchoring the implant by situating the backbone 30 on a cortical bone so that the backbone holds at least a majority of a load of the implant, or in other preferred embodiments at least two-thirds of the load. In order to accomplish this (or for other reasons) method 200 may also involve configuring the backbone so that a height of the backbone is at least a maximum height of the deflectable piece. To allow the backbone to carry the desired load, method 200 may involve configuring the backbone so that a width of the backbone is at least half as large as a height of the backbone, or configuring the backbone so that a width of the backbone is at least three-quarters as large as a height of the backbone, or

configuring the backbone as a solid beam (or a solid beam with openings appropriate for delivery of biocompatible material or instruments). Method 200 (or any of the other methods herein) may also involve a further step of inserting a biocompatible material into the at least partially enclosed volume through a window in the implant.

Step 230 may involve guiding the deflectable piece by causing relative longitudinal movement between a proximal end of the deflectable piece and the backbone either by holding the backbone stationary while applying longitudinal pressure to a proximal end of the deflectable piece or by pulling the backbone while the deflectable piece is stationary or by closing a telescoping backbone. This may deflect the deflectable piece such that the deflectable piece together with the backbone form an asymmetric loop, for example a D-shaped loop, the asymmetric loop defining an at least partially enclosed volume.

As shown by the flow chart of FIG. 18, the present invention may also be described as a further method 300 of implanting an implant into a body. Method 300 may include a step 310 of inserting the implant into a portion of the body while the implant is in a straightened or low curvature state, the implant having a backbone and a deflectable piece, for example comprising a sequence of segments interconnected at effective hinges. A further step 320 may involve having a distal end (for example a distal segment) of the sequence meet the backbone (i.e. by abutting or being interconnected to the backbone) at a distal end of the deflectable piece. This may occur prior to insertion (with the backbone or after insertion of the implant). A further step 330 may involve deploying the implant so as to form a loop between the backbone and deflectable piece together by deflecting the deflectable piece such that a proximal end of the deflectable piece moves longitudinally relative to at least a distal end of the backbone (by either applying longitudinal pressure to the proximal end, for example while holding the backbone stationary, or by pulling the backbone for example while holding the proximal end stationary or for example by closing a telescoping backbone). The proximal end may also interconnect to the backbone.

In some preferred embodiments, method 300 may also have a step of inserting the implant onto an intervertebral disc using lateral access to the disc and then deploying the implant posteriorly if the implant was inserted onto an anterior portion of the disc and anteriorly if the implant was inserted onto the posterior portion of the disc. It should be fully understood, however, that in other preferred embodiments, an approach other than lateral access may be used to insert the implant into the body.

Method 300 may also have a step of locking the implant to prevent undesired motion of the deflectable piece relative to the backbone. Another step of method 300 may be applying

longitudinal pressure to a proximal segment of a sequence of segments comprising the deflectable piece so as to deflect the deflectable piece such that the deflectable piece together with the backbone form an asymmetric loop such as D-shaped loop, the asymmetric loop defining an at least partially enclosed volume. Method 300 may involve a step of configuring the backbone so that a width of the backbone is at least half as large as a height of the backbone, or in other preferred embodiments at least two-thirds as large, at least three-quarters as large, at least equal to, or between half and one and a half the height. Method 300 may also involve deploying the implant while the backbone is maintained stationary along an axis defined by a direction of insertion.

As shown by the flow chart of FIG. 19 and the device shown in FIG. 22, the present invention may also be described as a method 400 of implanting implants into a body. Method 400 may have a step 410 of inserting into the body a first laterally deflectable implant that has a first backbone and a first deflectable piece while the first deflectable piece is in a straightened or low curvature insertion state. A further step 420 may be inserting into the body a second laterally deflectable implant that has a second backbone and a second deflectable piece while the second deflectable piece is in a straightened or low curvature insertion state and such that the first and second backbones are between the first and second deflectable pieces. In a preferred embodiment, the second laterally deflectable implant is inserted into the body such that the first backbone and the second backbone are substantially parallel. "Substantially parallel" is defined to mean parallel or within 20 rotational degrees of being perfectly parallel. In a preferred embodiment, the first and second backbones are within five rotational degrees (or ten rotational degrees or fifteen rotational degrees in other preferred embodiments) of being perfectly parallel. In a preferred embodiment, the inserting of the first and second laterally deflectable implants in the body may be implemented so that the first and second backbones are between the first and second deflectable pieces, as shown in FIG. 22.

Method 400 may also involve a step 430 of deflecting the first and second laterally deflectable implants in opposite directions such that the first laterally deflectable implant defines a first asymmetric loop (which may be D-shaped), said first asymmetric loop defines an at least partially enclosed volume and such that the second laterally deflectable implant defines a second asymmetric loop (which may be D-shaped), said second asymmetric loop defines an at least partially enclosed volume. In one preferred embodiment, the shapes of the first and second asymmetric loops are the same (i.e. D-shaped and D-shaped, rectangular and rectangular, etc.) although in other preferred embodiments, one can be D-shaped and the other rectangular or another asymmetric shape.

A further step of method 400 may be generating relative longitudinal movement between at least a distal end of the first backbone and a proximal end of the first deflectable piece to deflect the first deflectable piece and generating relative longitudinal movement between at least a distal end of the second backbone and a proximal end of the second deflectable piece to deflect the second deflectable piece.

Method 400 may be useful for two implants inserted in parallel fashion through a PLIF, as shown in FIG. 22B.

Furthermore, as shown by the flow chart of FIG. 20 and the device shown in FIGS. 23A-B, the present invention may also be described as a method 500 of distracting intervertebral space 73 between discs or between first and second vertebrae 81, 82. Method 500 may have a step 510 of inserting an implant 10 structured as described herein into a body while the implant 10 is in a straightened or low curvature state, the implant having a backbone 30 and a deflectable piece 20 meeting the backbone (interconnected or abutting).

In other preferred embodiments, instead of inserting implant 10, step 510 may involve inserting an instrument assembly including an element having the structure of implant 10 (although by right it is not called an implant since it is not implanted into the body but rather inserted and removed), together with an integrally formed deployer and a holder. This instrument assembly would be removed after distraction is performed and its purpose may have been merely to assess the size of a possible distraction involving an implant.

Method 500 may have a further step 520 of generating relative longitudinal movement between a proximal end of the deflectable piece and at least a distal end of the backbone so as to deflect the deflectable piece and distract an intervertebral space between the first and second vertebrae (for example between adjacent vertebrae).

Method 500 may also have a step of inserting the implant into the body such that the backbone of the implant is abutting or facing an endplate of one vertebra and the deflectable piece is abutting or facing an endplate of a second vertebra. This may be implemented by for example inserting the implant 10 vertically into a vertebral body that has collapsed and the using step 520 to generate relative longitudinal movement between a proximal end of the deflectable piece and at least a distal end of the backbone so as to deflect the deflectable piece and distract endplates of the same vertebra (such as to restore vertebral height in VCF). For example, prior to inserting the implant, the implant may be configured so that upon insertion the implant is already oriented vertically such that the backbone is abutting or facing an endplate of one vertebra and the deflectable piece is abutting or facing an endplate of a second vertebra.

The relative longitudinal movement may be generated using application of longitudinal

pressure, for example against the proximal end 24 or against the backbone, for example as described herein, or using another method described herein. In a preferred embodiment of method 500, the deflecting of the deflectable piece is such that the backbone together with the deflectable piece defines an asymmetric loop, the asymmetric loop defining an at least partially enclosed loop.

The deflectable piece of the implant may be deflected in any of the manners that are described herein.

In order to distract the intervertebral space (i.e. increase the distance) between the first and second vertebra, since the implant 600 is oriented vertically, in some preferred embodiments as shown in FIGS. 26A-D, the deflectable piece may incorporate side panels 621 to help define the at least partially enclosed volume. Side panels 621 may extend from deflectable piece 620 (for example from a middle segment or from a segment that is not a first or last segment of deflectable piece 620) to backbone 630 and may overlap with the backbone 630 to form a continuous enclosure for the at least partially enclosed volume. In FIG. 26C, the side panels 621 may overlap the sides 631, 634 of backbone 630 (which sides in the horizontal orientation of implant 10 are referred to as the top surface 31 and bottom surface 34 of backbone 30) whereas in the deflected configuration shown in FIG. 26B the side panels 621 may overlap only a portion (in the vertical dimension for example between vertebra) of sides 631, 634 of backbone 30. This is sufficient to form the at least partially enclosed volume, and in particular to form a hollow chamber defined by the backbone and by the deflectable piece or a portion (for example a middle segment) of the deflectable piece. Accordingly, after deflection of the deflectable piece, backbone 630 of implant 600 may be abutting or facing an endplate of one vertebra of the first and second vertebra and deflectable piece 620 may be abutting or facing an endplate of another vertebra of the first and second vertebra. Furthermore, backbone 630 and deflectable piece 620 together may form, after deflection of the deflectable piece, a chamber that is enclosed other than on a surface facing an endplate of one vertebra of the first and second vertebra (which surface has an opening for example opening 623) and other than on a surface facing an endplate of another vertebra of the first and second vertebra (which surface has an opening). In contrast to this embodiment, note that in the horizontally oriented embodiments of implant 10 the "sides" of the implant 10 are normally covered by the endplates or other bodily material of the body of the subject.

An opening in a surface of the deflectable piece and an opening in a surface of the backbone may define an unobstructed path between the deflectable piece and backbone through the at least partially enclosed volume. For example, as can be seen from FIGS. 26A-D, there

may be an unobstructed or direct path from an opening 623 in a top surface 625 of a middle segment 40b of deflectable piece 20 to an opening in a bottom surface of backbone 30. This direct path or passage is useful where fusion is employed since it may allow fusion of bone or other biocompatible material with endplates of adjacent vertebrae. For clarity, it is noted that the bottom surface of backbone 630 would be called the rear surface in embodiments showing the implant 10 in a horizontal orientation. In addition, "top" surface 625 is called "top" by reference to the vertical orientation shown in FIGS. 26A-D yet it corresponds to side surface 25 of middle segment 40b in the implant 10 of FIG. 2 which depicts an implant 10 in the horizontal orientation.

It is emphasized that FIGS. 26A-D happen to show the vertically oriented implant with the side panels in the context of a telescoping backbone 630 and a deflectable piece 620 having three segments, 640a, 640b, 640c, but none of these features (that the backbone 630 is telescoping, that the deflectable piece 620 is segmented and that the deflectable piece 620 has three segments rather than two, four, five, etc.) are required aspects of this embodiment. If for example deflectable piece 630 is segmented, the opening in the top surface of deflectable piece 630 would normally be in the top surface of a segment other than the first and last segment, although this is not a required limitation either. Furthermore, the vertically oriented embodiment of the implant may define a loop that is not a strict loop as defined herein (i.e. may have a gap) and may incorporate any other suitable feature described in the context of other embodiments.

As shown in FIG. 26A, moreover, a first segment 640a may have a hole 629 for insertion of biocompatible material such as bone graft, autograft, allograft, etc. Furthermore, as shown in FIGS. 26C-D, the two telescoping portions 688a, 688b of the telescoping backbone 630 may have one or more holes 689 and/or threading to interface with a holder 650 and/or deployer 660 mechanism or instrument such as described herein with respect to implant 10 (see FIGS. 5A-6).

In a still further method of the present invention shown in FIGS. 24C-E, in which deflectable piece 20 is comprised of at least four segments 40, the deflection of deflectable piece 20 may occur separately with respect to two sequences 41 of segments 40. As shown in FIG. 24C, implant and deflectable piece 20 are initially straight, for example for insertion. As shown in FIG. 24D, the two most proximal segments 40a, 40b forming a first sequence 41 of segments 40 are then deflected, for example by actuating the telescoping feature of backbone 30 (or in other preferred embodiments by applying longitudinal pressure to a proximal end 40cc (see FIG. 2) of segment 40c or possibly by pulling backbone 30). More distal segments 40c, 40d remain straight. As shown in FIG. 24E, deflection of segments 40c, 40d forming a second sequence 41 of segments 40 may then be effectuated by applying longitudinal pressure or actuating the

telescoping feature. In the implant depicted in FIGS. 24C-E, backbone 30 is telescoping and is of adjustable length. Hence, the deflection may be generated by application of longitudinal pressure, such as against a proximal end 32 of backbone 30 or by an internal mechanism of backbone 30 that actuates the telescoping of backbone 30.

FIGS. 24A-B are similar to FIGS. 24C-E except that in FIGS. 24A-B, each sequence 41 of segments of the deflectable piece 20 has three interconnected segments rather than two. In addition, the telescoping of the backbone 30 in FIGS. 24A-B of each sequence may derive from a common actuator deflecting simultaneously or may be actuated and deflected separately whereas in FIGS. 24C-E, the deflection of the separate sequences 41 are necessarily occurring separately.

As shown by FIGS. 27A-K, the present invention may also involve a method of implanting an implant comprising inserting a holder shaft 92 into an implant 10 of the kind shown in FIGS. 27A-K. The method may also have a step of attaching a deployment tube 91 to the rear of the rotatable element (i.e. the threaded tube 93). A further step may involve deflecting the implant by actuating (i.e. rotating) the deployment tube 91 so as to rotate the rotatable element 93, thereby advancing the rotatable element longitudinally/axially relative to the annular element (i.e. threaded nut). Since the rotatable element is attached to (or abutting) the proximal part of the deflectable piece, the deflectable piece may move longitudinally relative to at least a distal end of the backbone. In another step, after deflection of the implant 10, the user may then disconnect the deployment tube 91. The user may also then disconnect the holder shaft 92.

It should be understood that one or more steps of the methods described herein may be combined. Furthermore, any suitable embodiment of implant 10 described herein consistent with the steps of a particular method may be used in any such method. It should also be understood that the term "backbone" 30 used as an element of the implant 10 is not related in meaning to the "backbone" of a spine of a person into which such an implant may, in some embodiments, be implanted.

As noted, in general the methods and apparatus of the present invention are not limited to insertion of the implant through lateral access into the body, and other insertion routes may be used, for example through the back as in posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF). Furthermore, the term "laterally" in the phrase "laterally deflectable implant" has no connection or relation with the route of insertion such as insertion through "lateral" access. In fact, the direction of the lateral access is along the direction of insertion of the implant and this direction is considered to be longitudinal as discussed herein.



Rather, “laterally deflectable” refers to a direction of the deflection of the deflectable piece 20 and imposes no limitation as to whether the implant deflects in the horizontal or vertical orientation.

Furthermore, the terms “vertical” and “vertically” as used herein refer to the orientation in either a sagittal plane, a plane parallel to the sagittal plane, a frontal/coronal plane or a plane parallel to the frontal/coronal plane (the exception being the term “vertical sectional view” in the Brief Description of the Drawings which has its ordinary meaning in relation to the view of the implant or other structure). The terms “horizontal orientation”, “horizontally oriented”, in contrast, refer to horizontal or transverse planes perpendicular to the “vertical”, as used herein. Accordingly, this patent application describes an implant that may be deflectable in the horizontal orientation but may also be deflectable in the vertical orientation for example when used for vertical distraction.

The present invention may also be described as a laterally deflectable implant 10 for implanting into a body, comprising a deflectable piece 20 having a distal end and a proximal end and assuming a straightened or low curvature insertion state for insertion into the body and an anchor 30 (also called a backbone 30) configured to interconnect with or abut the deflectable piece 20. The anchor 30 may comprise a beam having two dimensions other than its length such that an average size of one of those two dimensions is at least 30% of an average size of the second of those two dimensions of the beam. Beam 30 may have a height that is at least as great as a maximum height of the deflectable piece 20. The top of the beam may have a width equal to at least half the height of the beam (and in other versions at least three-quarters or at least the full height of the beam). As a result of the height of the beam relative to the height of the deflectable piece and as a result of the width of the top of the beam, and the fact that the top of the beam may be configured to engage cortical bone in the body and receive an impact from a load of the cortical bone, and hold at least half (and in other preferred embodiments at least three-quarters) of the total load on the implant from the cortical bone, the anchor may remain immobile holding the load while the deflectable piece deflects to a fully deflected state. This may allow the anchor 30 to function as a guide that may allow the user to define the final location of the implant by setting the initial location of the anchor.

In some versions of this preferred embodiment, the proximal end 24 of deflectable piece 20 may remain unconnected to the anchor 30 until the deflectable piece 20 is fully deflected. The fully deflected state may define an asymmetric loop together with the anchor. As in other embodiments, the asymmetric loop may define an at least partially enclosed volume, and longitudinal movement of the proximal end of the deflectable piece relative to at least a distal

end of the anchor may deflect the deflectable piece to the deflected state to form, with said anchor, the asymmetric loop. The implant in a deflected state may be asymmetric such that the implant does not have an axis of symmetry parallel to the anchor.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made. Therefore, the claimed invention as recited in the claims that follow is not limited to the embodiments described herein.

## WHAT IS CLAIMED IS:

1. A laterally deflectable implant for implanting into a body, comprising:  
a deflectable piece having a distal end and a proximal end and assuming a straightened or low curvature insertion state for insertion into the body; and  
a backbone configured to interconnect with or abut the deflectable piece, the proximal end of the deflectable piece not in contact with the backbone prior to deflection of the deflectable piece,  
the deflectable piece in a fully deflected state defining, together with said backbone, an asymmetric loop wherein said asymmetric loop defines an at least partially enclosed volume,  
wherein longitudinal movement of the proximal end of the deflectable piece relative to at least a distal end of the backbone deflects the deflectable piece to the deflected state to form, with said backbone, the asymmetric loop,  
wherein the implant in a deflected state is asymmetric such that the implant does not have an axis of symmetry parallel to the backbone.
2. The implant of claim 1, wherein the backbone abuts the deflectable piece at the distal end of the deflectable piece.
3. The implant of claim 2, wherein the deflectable piece in a deflected state, after insertion, is interconnected with said backbone at the proximal end of the deflectable piece,
4. The implant of claim 1, wherein the asymmetric loop is D-shaped.
5. The implant of claim 1, further comprising the deflectable piece comprising a sequence of segments, said segments interconnected at effective hinges.
6. The implant of claim 5, wherein the effective hinges are comprised of lateral cut-outs.
7. The implant of claim 6, wherein the lateral cut-outs are triangular.
8. The implant of claim 5, wherein the deflectable piece is hingedly interconnected with said backbone at the distal end of the deflectable piece.
9. The implant of claim 5, further comprising  
said sequence of segments being deflectable to a fully deflected state defined at least partially by abutment of abutment features of adjacent segments of the sequence of segments.
10. The implant of claim 5, wherein said sequence is resiliently biased towards said deflected state, and is temporarily deformed to said insertion state.
11. The implant of claim 5, wherein said implant comprises further at least one opening in said sequence of segments to allow access to the at least partially enclosed volume in said loop.

12. The implant of claim 5, wherein a hollow of a segment of the sequence is cut out to allow flexibility of the implant for axial loading.

13. The implant of claim 12, wherein at least one segment of the sequence has a lateral cut-out extending to the hollow.

14. The implant of claim 5, wherein at least one segment has a curved exterior.

15. The implant of claim 14, wherein the at least one segment has a cross-section that corresponds to an ellipse at a top, a bottom and at least one side of the at least one segment.

16. The implant of claim 1, wherein a height of the backbone is at least a maximum height of the deflectable piece.

17. The implant of claim 1, wherein the backbone is configured to hold at least a majority of a load held by the implant.

18. The implant of claim 1, wherein the backbone has a width at least equal to a half of a height of the backbone.

19. The implant of claim 1, wherein the backbone has a width at least equal to a half of a height of the backbone.

20. The implant of claim 1, wherein the backbone has a width at least equal to a height of the backbone.

21. The implant of claim 1, wherein the backbone comprises a beam, a top of the beam configured to engage cortical bone in the body and receive an impact from a load of the cortical bone.

22. The implant of claim 1, wherein the proximal end of the deflectable piece is a free proximal end before insertion of the implant.

23. The implant of claim 22, wherein the proximal end is a free proximal end during at least a majority of the deflection of the deflectable piece, the majority measured by reference to a distance of the outward horizontal movement.

24. The implant of claim 22, wherein the proximal end is free other than in the fully deflected state of the deflectable piece.

25. The implant of claim 1, wherein the deflection includes an outward horizontal movement of at least a portion of the deflectable piece away from the backbone.

26. The implant of claim 1, wherein the deflectable piece deflects by deforming reversibly.

27. An implant system comprising the implant of claim 1, and further comprising an elongated conduit for inserting said implant in said straightened insertion state into the body.

28. An implant system comprising the implant of claim 1, and further comprising an injector containing filling material selected from the group consisting of: biocompatible materials, bone grafts, bone chips, bone-growth enhancing agents for interbody fusion, cements and filling materials for motion preservation.

29. The implant of claim 1, further comprising a locking arrangement to retain said implant in said deflected state, and wherein said locking arrangement includes at least one element selected from the group consisting of: cords, cables, strips, interconnections and snaps.

30. The implant of claim 1, wherein said fully deflected loop has a toroidal shape selected from the group consisting of ring toroids and oval toroids.

31. The implant of claim 1, wherein the implant is deflectable into an asymmetric loop by applying longitudinal pressure without a tensioning element to either a proximal end of the deflectable piece or to a proximal end of the backbone.

32. The implant of claim 1, wherein a length of the backbone is adjustable.

33. The implant of claim 1, further comprising the at least partially enclosed volume defined further by side panels extending between the deflectable piece and the backbone.

34. The implant of claim 33, wherein an opening in a surface of the deflectable piece and an opening in a surface of the backbone define an unobstructed path between the deflectable piece and backbone through the at least partially enclosed volume.

35. A laterally deflectable implant for implanting into a body, comprising:

a deflectable piece having a distal end and a proximal end and assuming a straightened or low curvature insertion state for insertion into the body; and

a backbone configured to interconnect with or abut the deflectable piece, the backbone having a first telescoping portion and a second telescoping portion,

the deflectable piece in a fully deflected state defining, together with said backbone, an asymmetric loop wherein said asymmetric loop defines an at least partially enclosed volume,

wherein longitudinal movement of the proximal end of the deflectable piece relative to at least a distal end of the backbone deflects the deflectable piece to the deflected state to form, with said backbone, the asymmetric loop,

wherein the implant in a deflected state is asymmetric such that the implant does not have an axis of symmetry parallel to the backbone.

36. The implant of claim 35, wherein the proximal end of the deflectable piece is attached to the first telescoping portion of the backbone and wherein deflection of the deflectable piece is actuated by moving the first telescoping portion of the backbone relative to the second telescoping portion of the backbone.

37. The implant of claim 35, wherein the deflectable piece is comprised of a first sequence of segments associated with first and second telescoping portions of the backbone and is comprised of a second sequence of segments associated with third and fourth telescoping portions of the backbone.

38. The implant of claim 35, wherein the asymmetric loop is an asymmetric strict loop.

39. The implant of claim 35, further comprising the at least partially enclosed volume defined further by side panels extending between the deflectable piece and the backbone.

40. The implant of claim 35, wherein an opening in a surface of the deflectable piece and an opening in a surface of the backbone define an unobstructed path between the deflectable piece and backbone through the at least partially enclosed volume.

41. A method of implanting an implant into a body, comprising:

inserting the implant into an anterior portion of the body using lateral access while the implant is in a straightened or low curvature state, the implant having a backbone and a deflectable piece meeting the backbone at a distal end of the deflectable piece; and

deploying the implant posteriorly by deflecting the deflectable piece.

42. The method of claim 41, further comprising

inserting the implant onto zone two of an intervertebral disc and

deploying the deflectable piece posteriorly into zone three and/or zone four of the intervertebral disc.

43. The method of claim 41, further comprising

setting an initial position of the backbone so as to pre-define a final position of the implant in a deflected state.

44. The method of claim 41, further comprising deflecting the implant into an asymmetric loop by applying longitudinal pressure without a tensioning element to either a proximal end of the deflectable piece or to a proximal end of the backbone.

45. The method of claim 44, further comprising deflecting the implant into the asymmetric loop such that longitudinal pressure applied to the proximal end of the deflectable piece generates relative longitudinal movement between the proximal end and at least a distal end of the backbone and generates an outward horizontal movement of at least a central portion of the deflectable piece away from the backbone.

46. The method of claim 44, further comprising deflecting the implant into an asymmetric loop by applying the longitudinal pressure to a proximal end of the deflectable piece to close or partially close cut-outs between segments of a sequence of segments of the deflectable piece.

47. The method of claim 41, further comprising

deflecting the deflectable piece by applying longitudinal pressure to a proximal end of the deflectable piece to move the proximal end relative to at least a distal end of the backbone longitudinally and move at least a portion of the deflectable piece away from the at least a distal end of the backbone.

48. A method of implanting an implant into a body, comprising:

inserting the implant into the body while the implant is in a straightened or low curvature state, the implant having a backbone and a deflectable piece, the backbone comprising a beam;

anchoring the implant by situating the backbone on a cortical bone so that the backbone holds at least a majority of a load on the implant; and

guiding the deflectable piece by holding the backbone stationary while applying longitudinal pressure to a proximal end of the deflectable piece so as to deflect the deflectable piece such that the deflectable piece together with the backbone form an asymmetric loop, the asymmetric loop defining an at least partially enclosed volume.

49. The method of claim 48, further comprising

inserting a biocompatible material to the at least partially enclosed volume through a window in the implant.

50. The method of claim 48, further comprising

configuring the backbone so that a height of the backbone is at least a maximum height of the deflectable piece.

51. The method of claim 48, further comprising configuring the deflectable piece to be comprised of a sequence of segments interconnected at effective hinges and configuring the backbone so that a height of the backbone is at least a maximum height of a proximal segment of the deflectable piece.

52. The method of claim 48, further comprising

configuring the backbone to hold at least two-thirds of the load on the implant.

53. The method of claim 48, further comprising

configuring the backbone so that a width of the backbone is at least half as large as a height of the backbone.

54. The method of claim 48, further comprising

configuring the backbone so that a width of the backbone is at least three-quarters as large as a height of the backbone.

55. The method of claim 48, further comprising configuring the backbone as a solid beam.

56. A method of implanting an implant into a body, comprising:

inserting the implant into the body while the implant is in a straightened or low curvature state, the implant having a backbone and a deflectable piece comprising a sequence of segments interconnected at effective hinges;

having a distal segment of the sequence meet the backbone at a distal end of the deflectable piece; and

forming an asymmetric loop between the backbone and deflectable piece together by deflecting the deflectable piece such that a proximal end of the deflectable piece moves longitudinally relative to at least a distal end of the backbone and interconnects to the backbone.

57. The method of claim 56, further comprising

inserting the implant onto an intervertebral disc using a lateral access to the disc and then deploying the implant posteriorly if the implant was inserted onto an anterior portion of the disc and anteriorly if the implant was inserted onto a posterior portion of the disc.

58. The method of claim 56, further comprising

locking the implant to prevent undesired motion of the deflectable piece relative to the backbone.

59. The method of claim 56, further comprising

applying longitudinal pressure to a proximal segment of a sequence of segments comprising the deflectable piece so as to deflect the deflectable piece such that the deflectable piece together with the backbone forms a D-shaped loop, the D-shaped loop defining an at least partially enclosed volume.

60. The method of claim 56, further comprising

configuring the backbone so that a width of the backbone is at least half as large as a height of the backbone.

61. The method of claim 56, further comprising

deploying the implant while the backbone is maintained stationary along an axis defined by a direction of insertion.

62. A method of implanting implants into a body, comprising:

inserting into the body a first laterally deflectable implant that has a first backbone and a first deflectable piece while the first deflectable piece is in a straightened or low curvature insertion state;



inserting into the body a second laterally deflectable implant that has a second backbone and a second deflectable piece while the second deflectable piece is in a straightened or low curvature insertion state and such that the first and second backbones are substantially parallel;

deflecting the first and second laterally deflectable implants in opposite directions such that the first laterally deflectable implant defines a first asymmetric loop, said first asymmetric loop defines an at least partially enclosed volume and such that the second laterally deflectable implant defines a second asymmetric loop, said second asymmetric loop defines an at least partially enclosed volume.

63. The method of claim 62, further comprising

generating relative longitudinal movement between at least a distal end of the first backbone and a proximal end of the first deflectable piece to deflect the first deflectable piece and

generating relative longitudinal movement between at least a distal end of the second backbone and a proximal end of the second deflectable piece to deflect the second deflectable piece.

64. The method of claim 62, further comprising inserting the first and second laterally deflectable implants so that the first and second backbones are between the first and second deflectable pieces.

65. A method of distracting intervertebral space between a first vertebra and a second vertebra, comprising:

inserting an implant into a body while the implant is in a straightened or low curvature state, the implant having a backbone and a deflectable piece meeting the backbone; and

generating relative longitudinal movement between a proximal end of the deflectable piece and at least a distal end of the backbone so as to deflect the deflectable piece and distract an intervertebral space between the first and second vertebrae.

66. The method of claim 65, further comprising inserting the implant into the body such that the backbone of the implant is abutting or facing an endplate of one vertebra of the first and second vertebra and the deflectable piece is abutting or facing an endplate of another vertebra of the first and second vertebra.

67. The method of claim 65, further comprising prior to inserting the implant, configuring the implant so that upon insertion the implant is oriented vertically such that the backbone is abutting or facing an endplate of one vertebra and the deflectable piece is abutting or facing an endplate of a second vertebra.

68. The method of claim 65, further comprising deflecting the deflectable piece so that the backbone together with the deflectable piece defines an asymmetric loop, the asymmetric loop defining an at least partially enclosed loop.

69. The method of claim 65, further comprising after deflection of the deflectable piece the backbone of the implant is abutting or facing an endplate of one vertebra of the first and second vertebra and the deflectable piece is abutting or facing an endplate of another vertebra of the first and second vertebra.

70. The method of claim 65, further comprising the backbone and deflectable piece together forming, after deflection of the deflectable piece, a chamber that is enclosed other than on a surface facing an endplate of one vertebra of the first and second vertebra and other than on a surface facing an endplate of another vertebra of the first and second vertebra.

71. A laterally deflectable implant for implanting into a body, comprising:

a deflectable piece having a distal end and a proximal end and assuming a straightened or low curvature insertion state for insertion into the body; and

an anchor configured to interconnect with or abut the deflectable piece, the anchor comprising a beam,

the anchor having a height that is at least as great as a maximum height of the deflectable piece and having a top, a width of the top at least half a height of the beam, the top configured to engage cortical bone in the body and receive an impact from a load of the cortical bone and hold at least half the load such that the anchor remains immobile while the deflectable piece deflects to a fully deflected state defining, together with said anchor, an asymmetric loop wherein said asymmetric loop defines an at least partially enclosed volume,

wherein longitudinal movement of the proximal end of the deflectable piece relative to at least a distal end of the anchor deflects the deflectable piece to the deflected state to form, with said anchor, the asymmetric loop,

wherein the implant in a deflected state is asymmetric such that the implant does not have an axis of symmetry parallel to the anchor.

72. A laterally deflectable implant for implanting into a body, comprising:

a deflectable piece having a distal end and a proximal end and assuming a straightened or low curvature insertion state for insertion into the body; and

a backbone comprising a rotatable element and an annular element, the rotatable element attached to or abutting the deflectable piece and configured to move longitudinally by rotatingly engaging the annular element,

the deflectable piece in a fully deflected state defining, together with said backbone, an

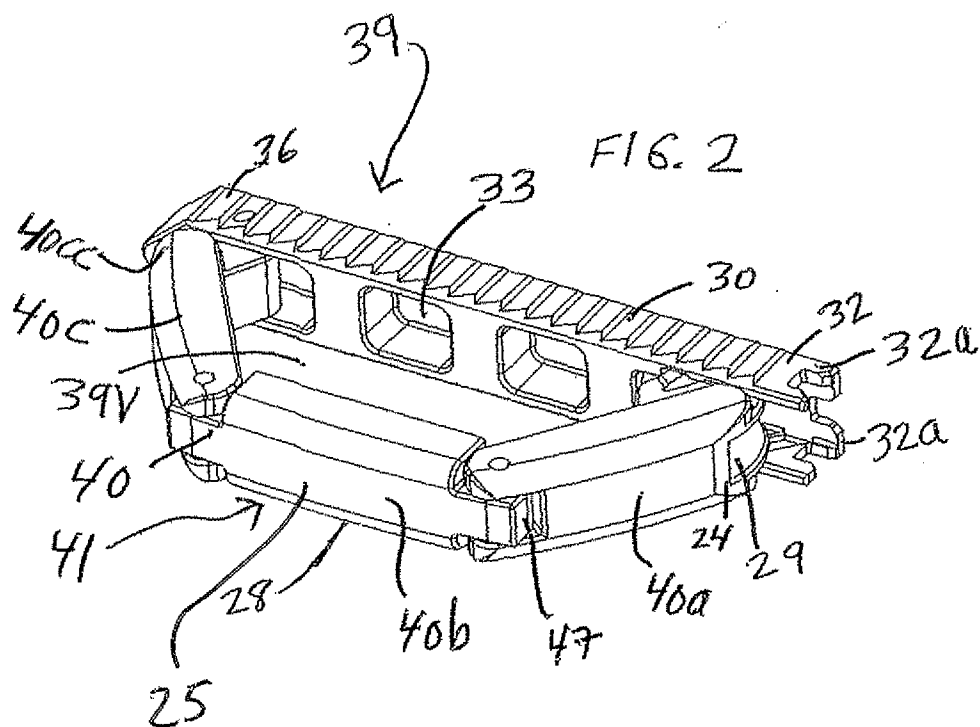
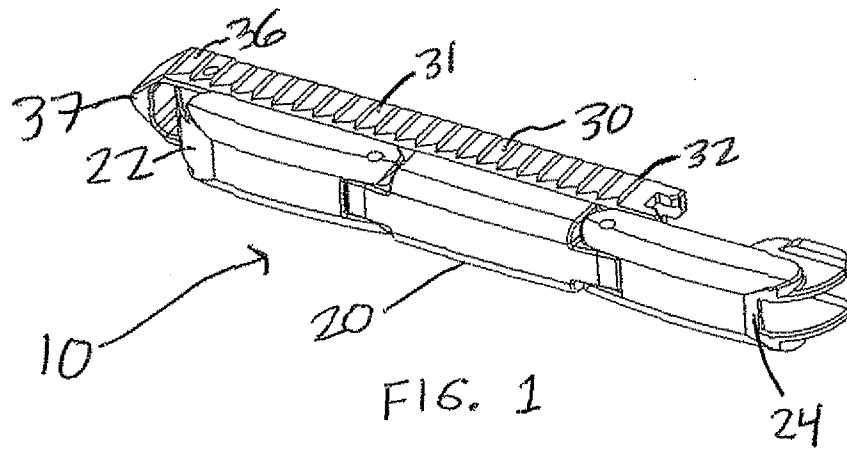
asymmetric loop wherein said asymmetric loop defines an at least partially enclosed volume,

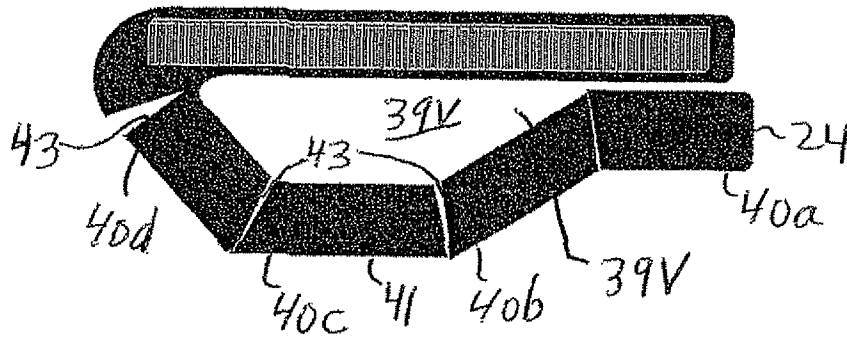
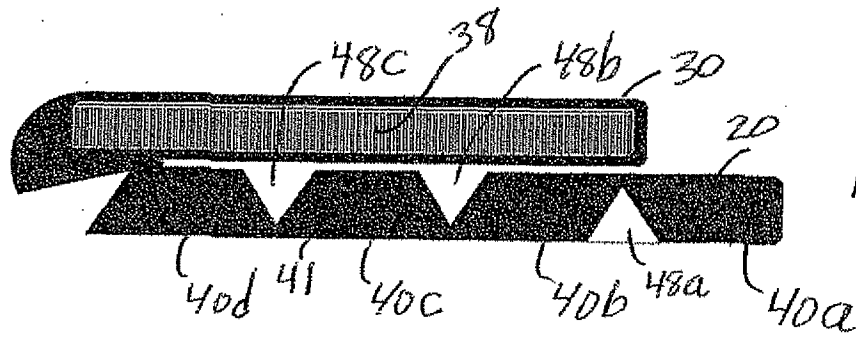
wherein longitudinal movement of the proximal end of the deflectable piece relative to at least a distal end of the backbone deflects the deflectable piece to the deflected state to form, with said backbone, the asymmetric loop,

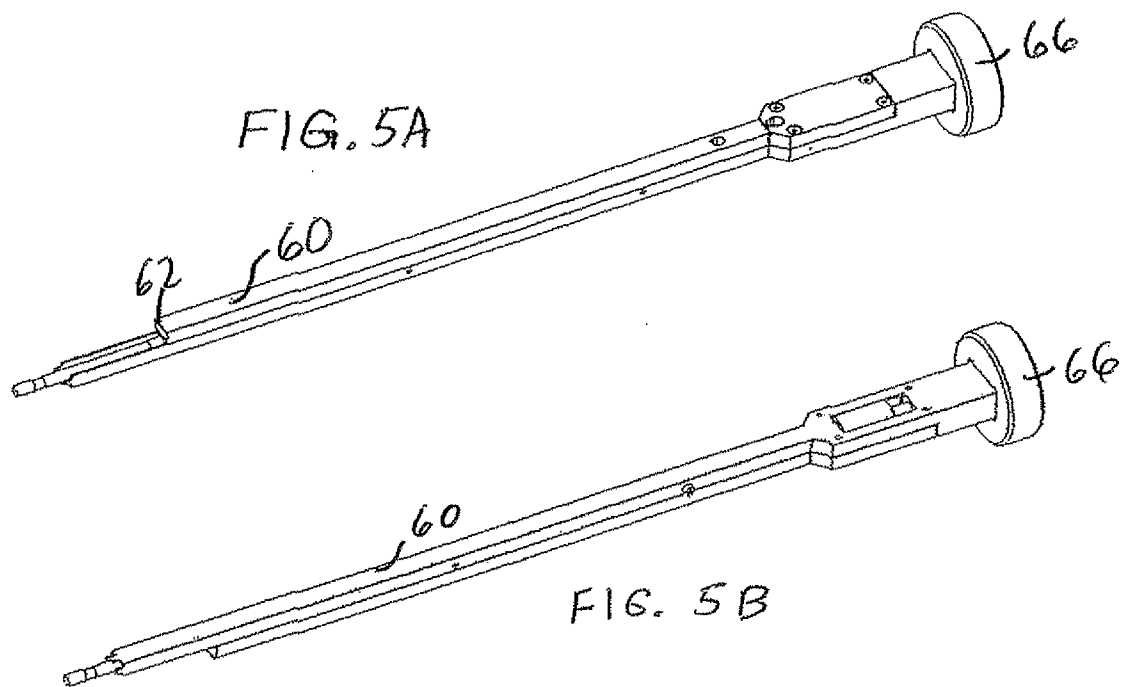
wherein the implant in a deflected state is asymmetric such that the implant does not have an axis of symmetry parallel to the backbone.

73. An implant assembly comprising the implant of claim 72, and further comprising a holder shaft running through the backbone, the holder shaft including a holder shaft tail jutting out a proximal end of the implant, the assembly further comprising a deployment tube enclosing the holder shaft tail and being operatively engaged to the rotatable element to rotate the rotatable element.

74. The implant of claim 72, wherein the rotatable element is a threaded tube and the annular element is a threaded nut.







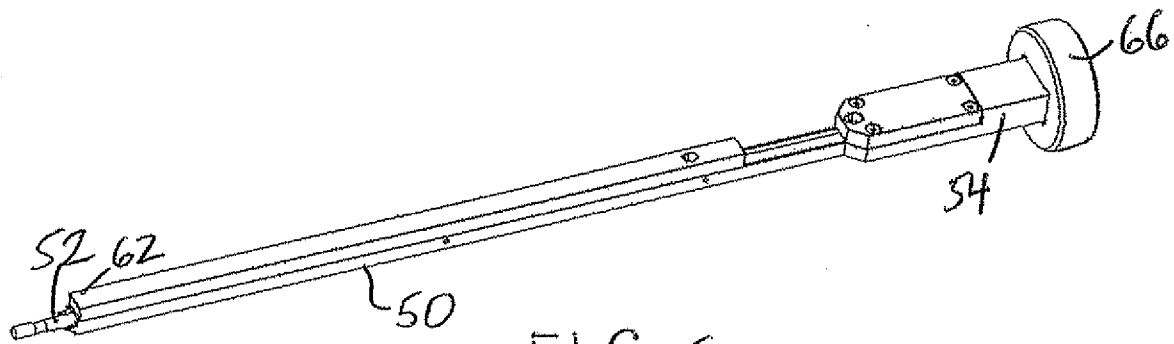


FIG. 6

FIG. 7A

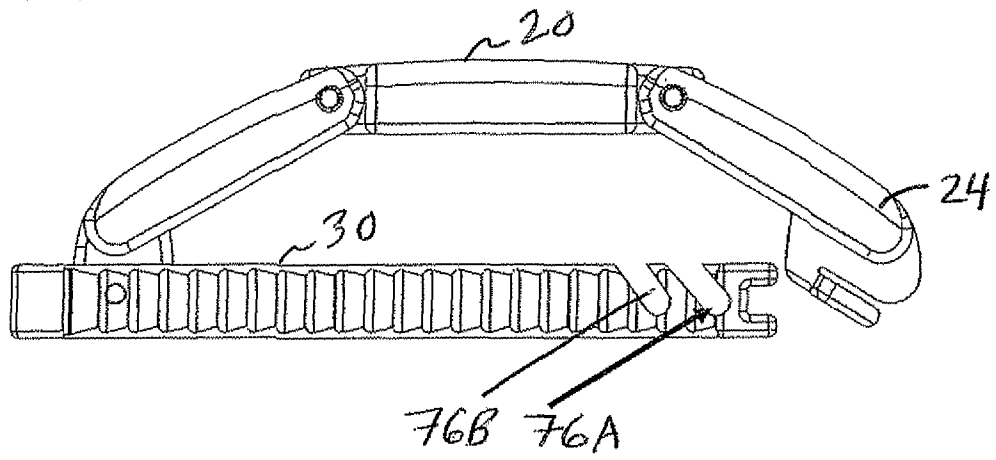


FIG. 7B

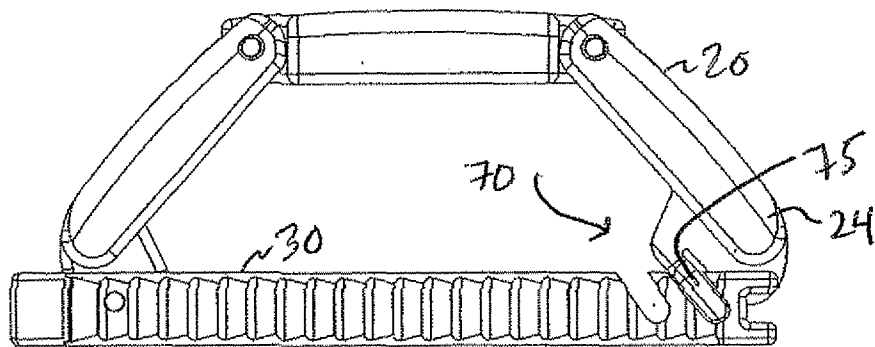


FIG. 7C

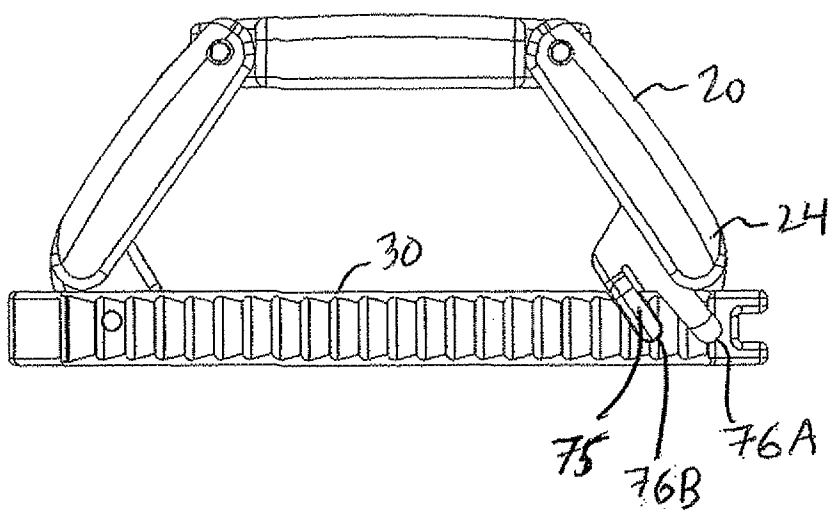




FIG. 8

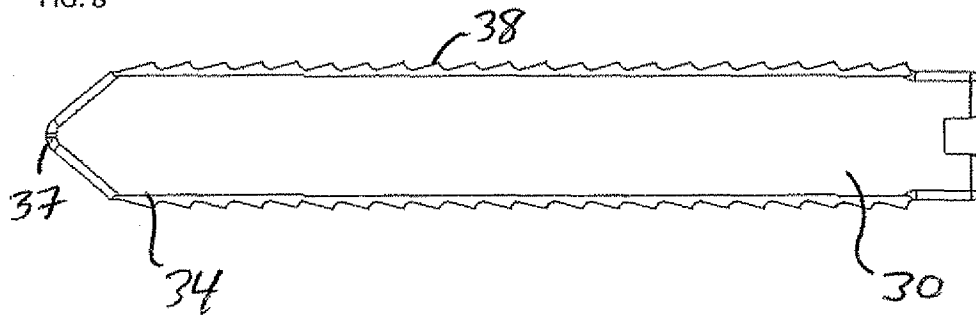


FIG. 9

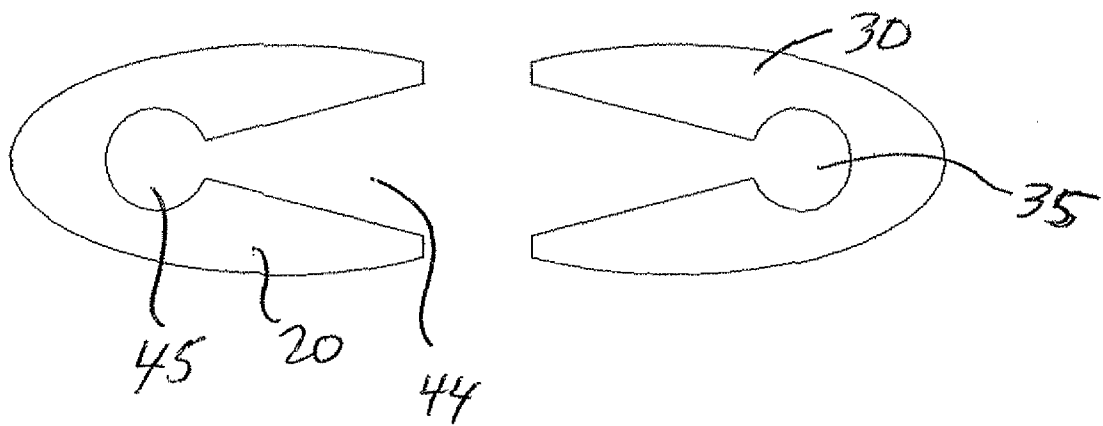
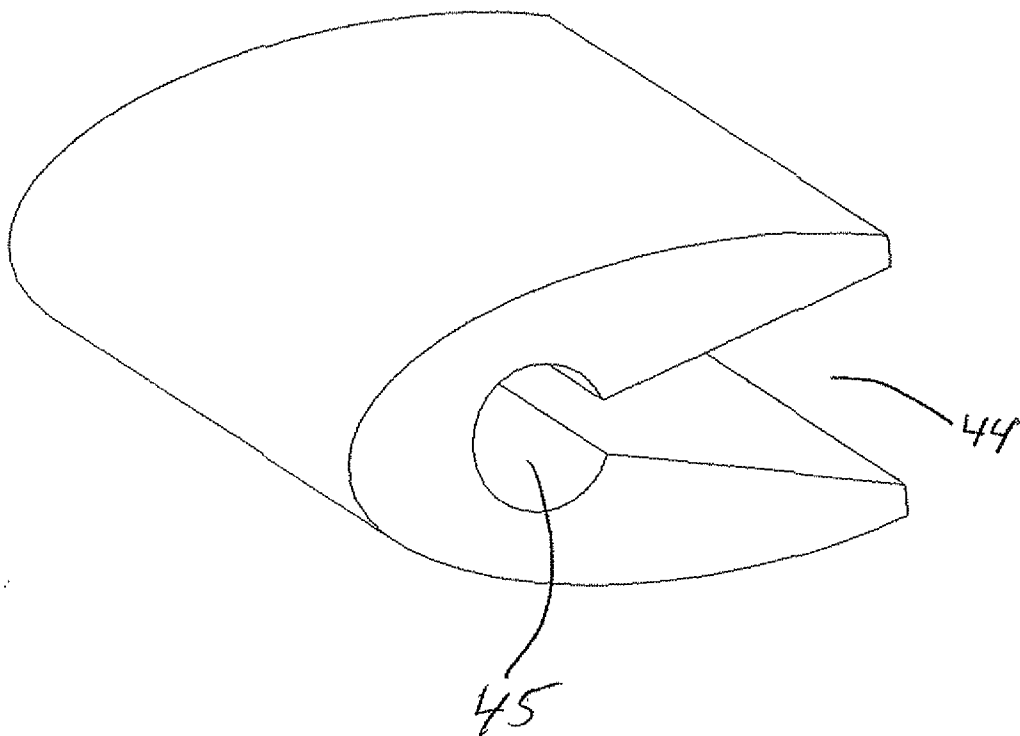
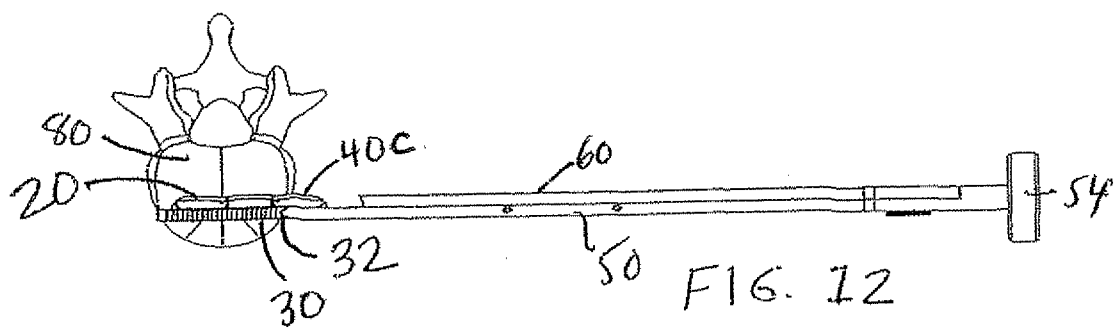
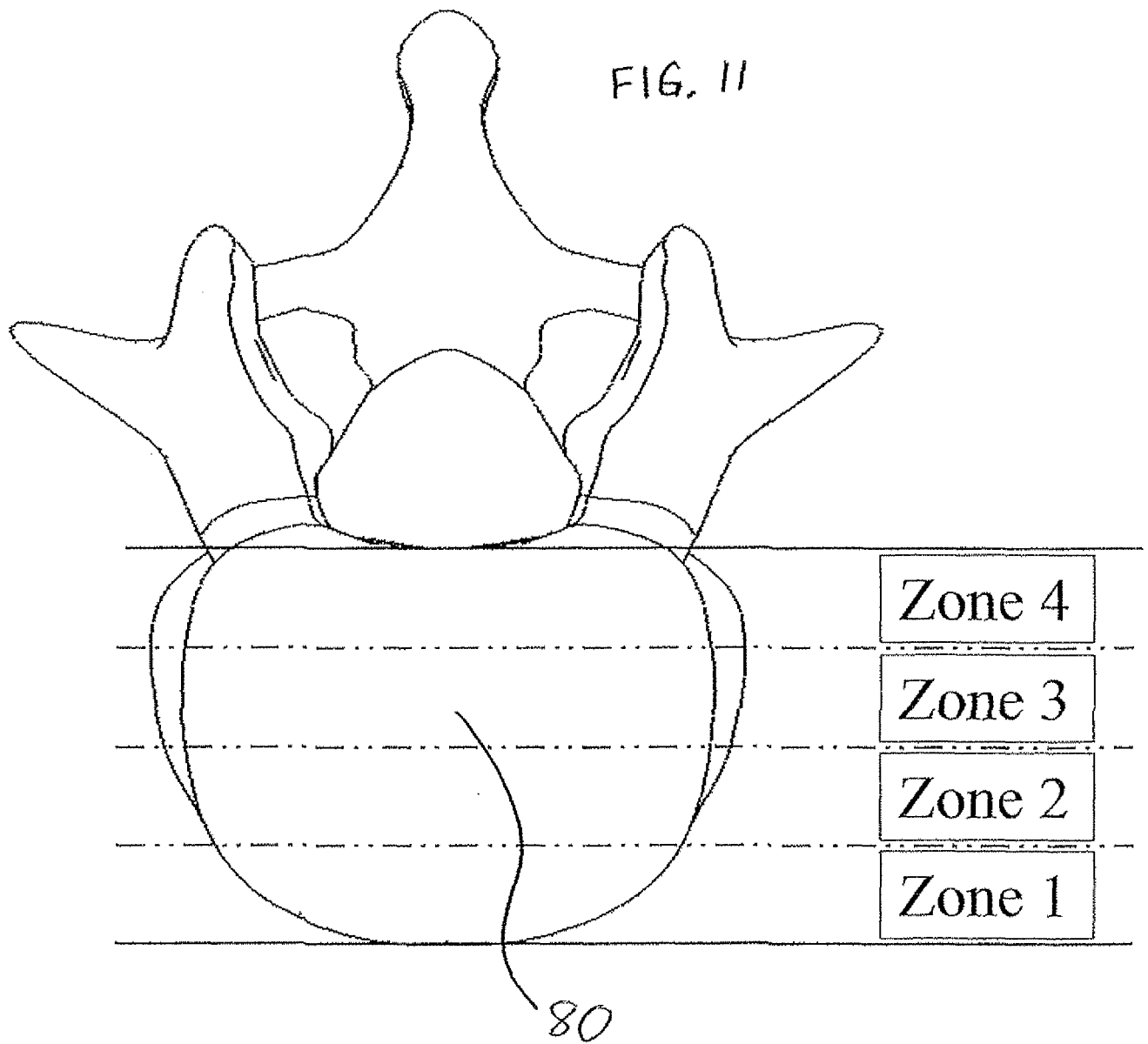
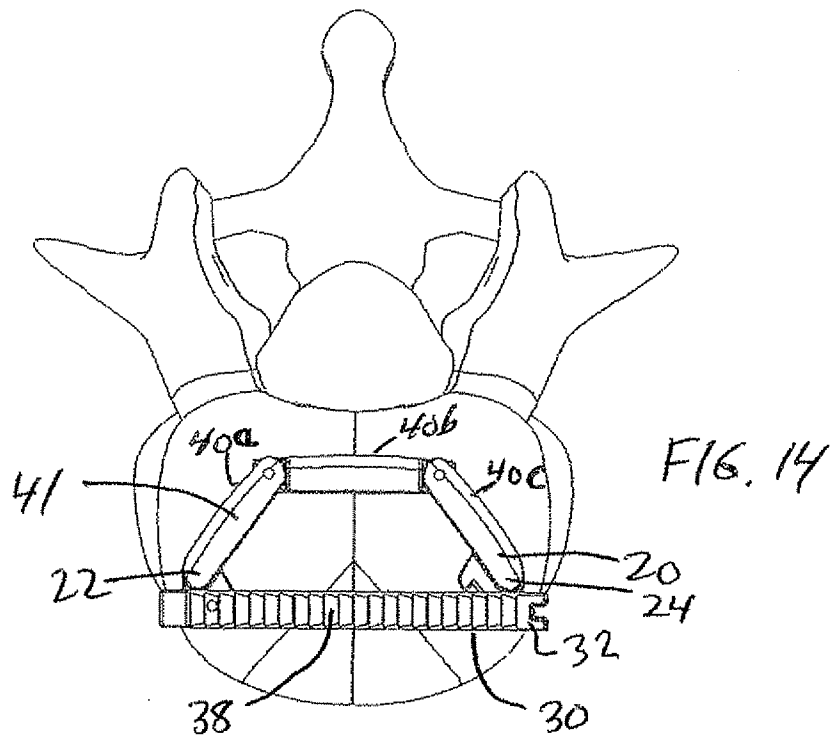
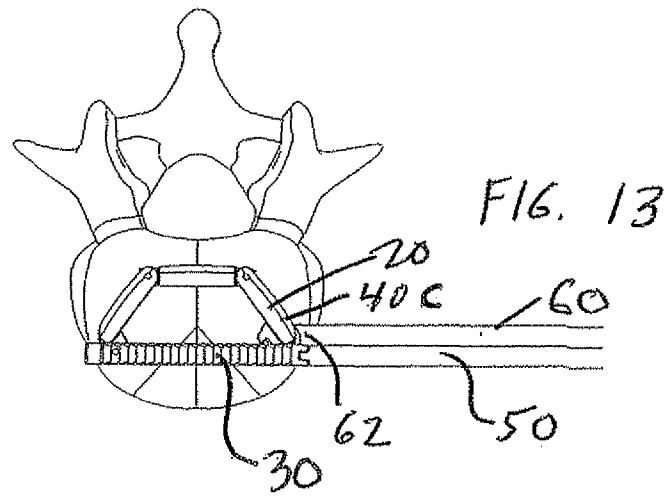


FIG. 10







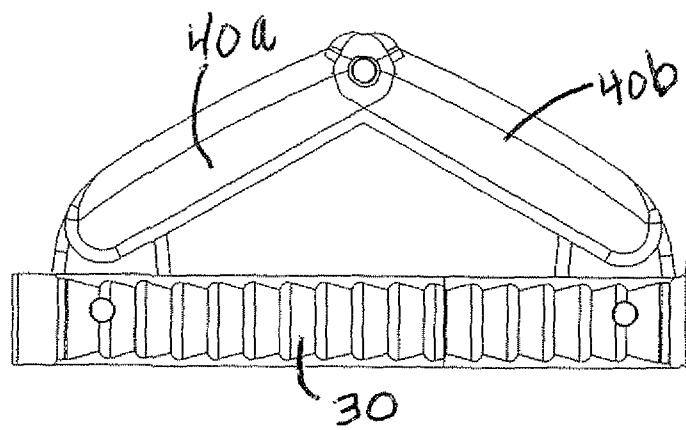


FIG. 15

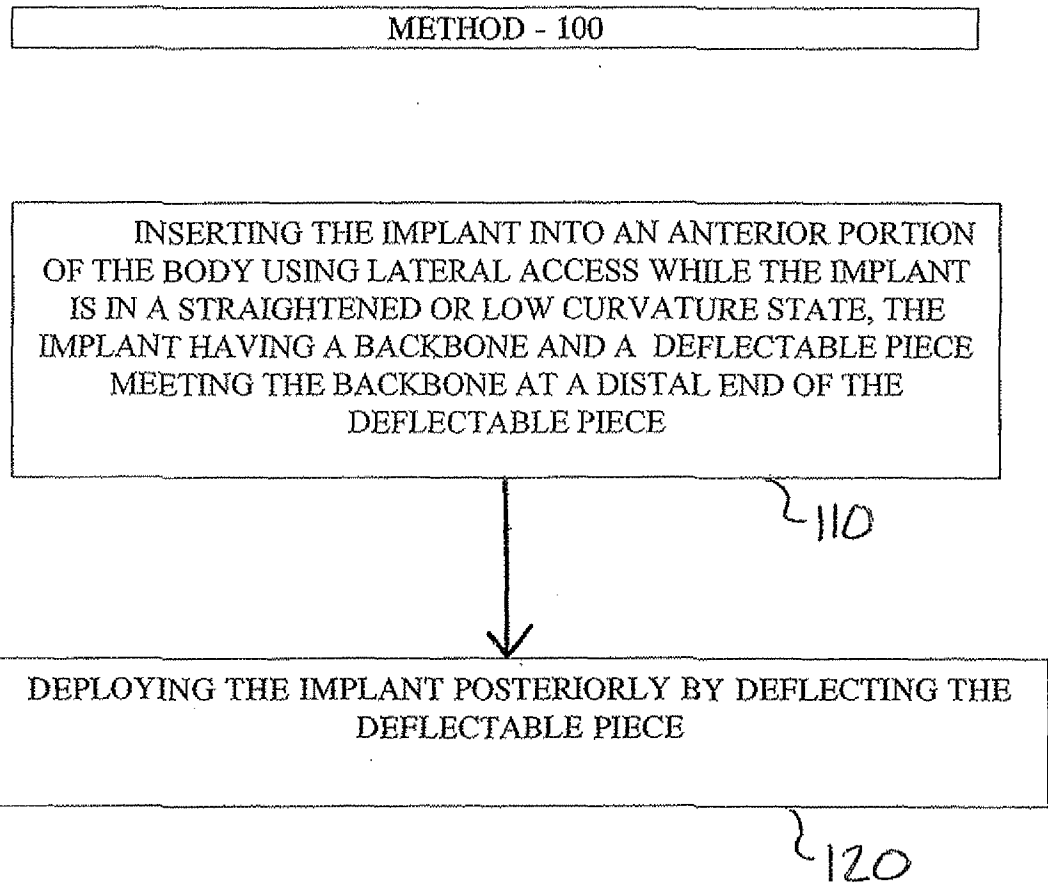


FIG. 16

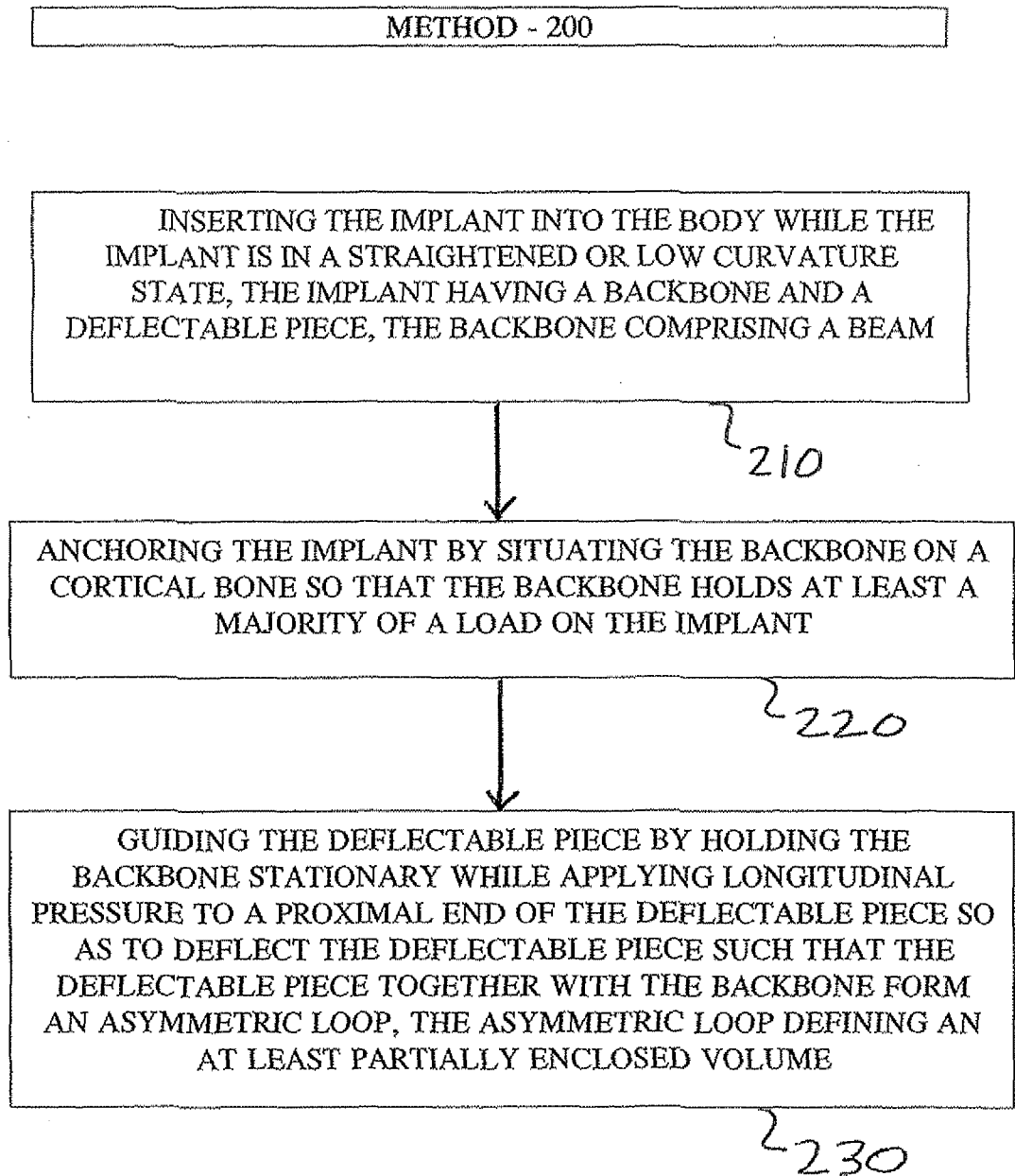


FIG. 17

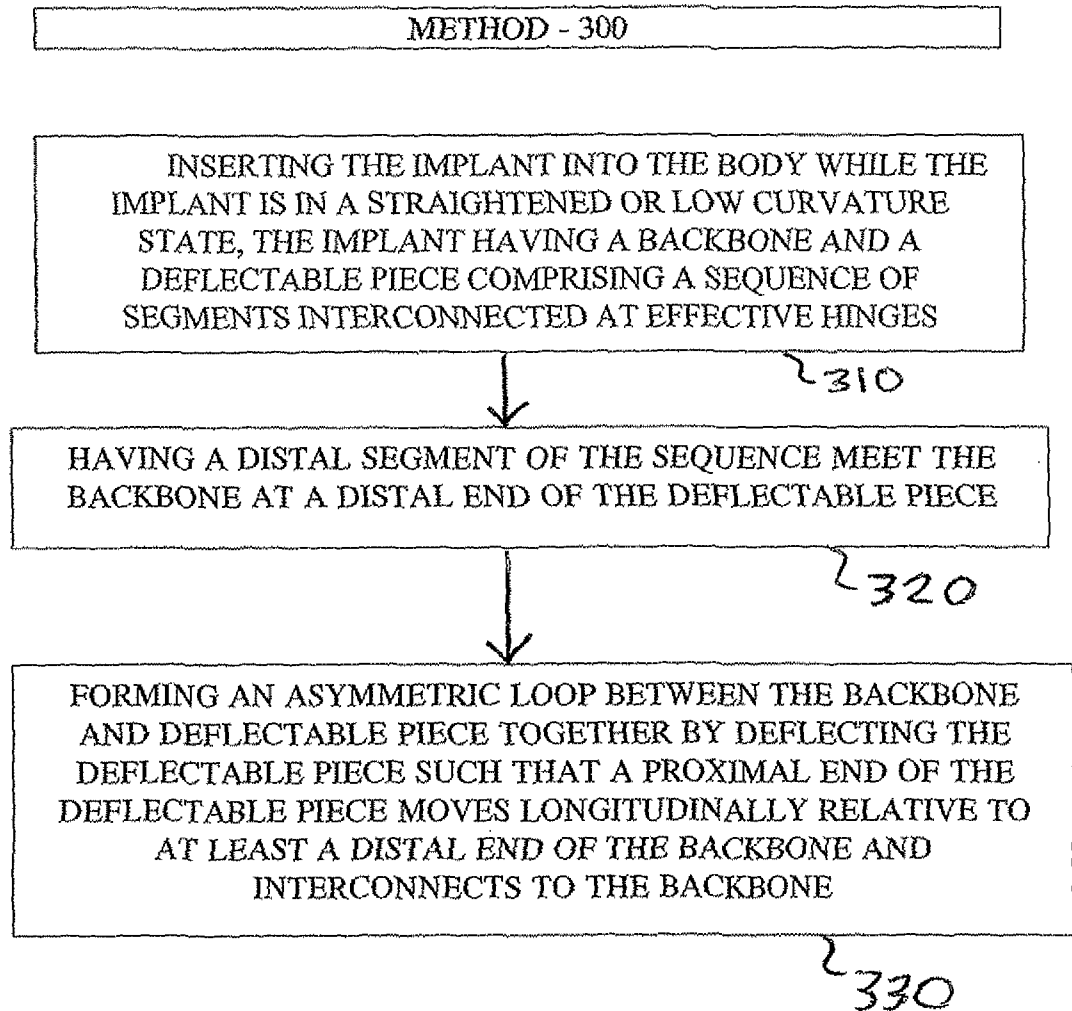


FIG. 18

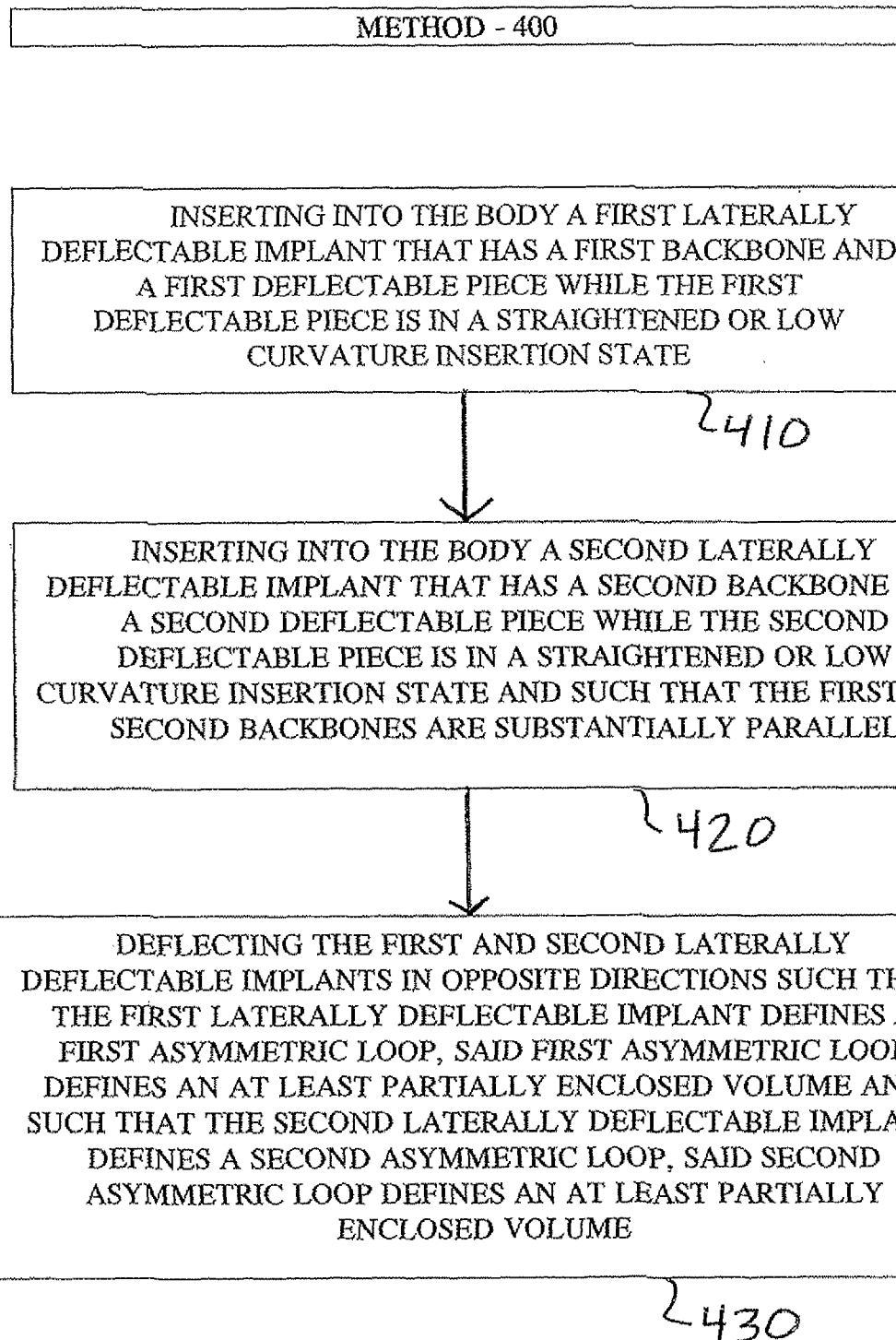


FIG. 19



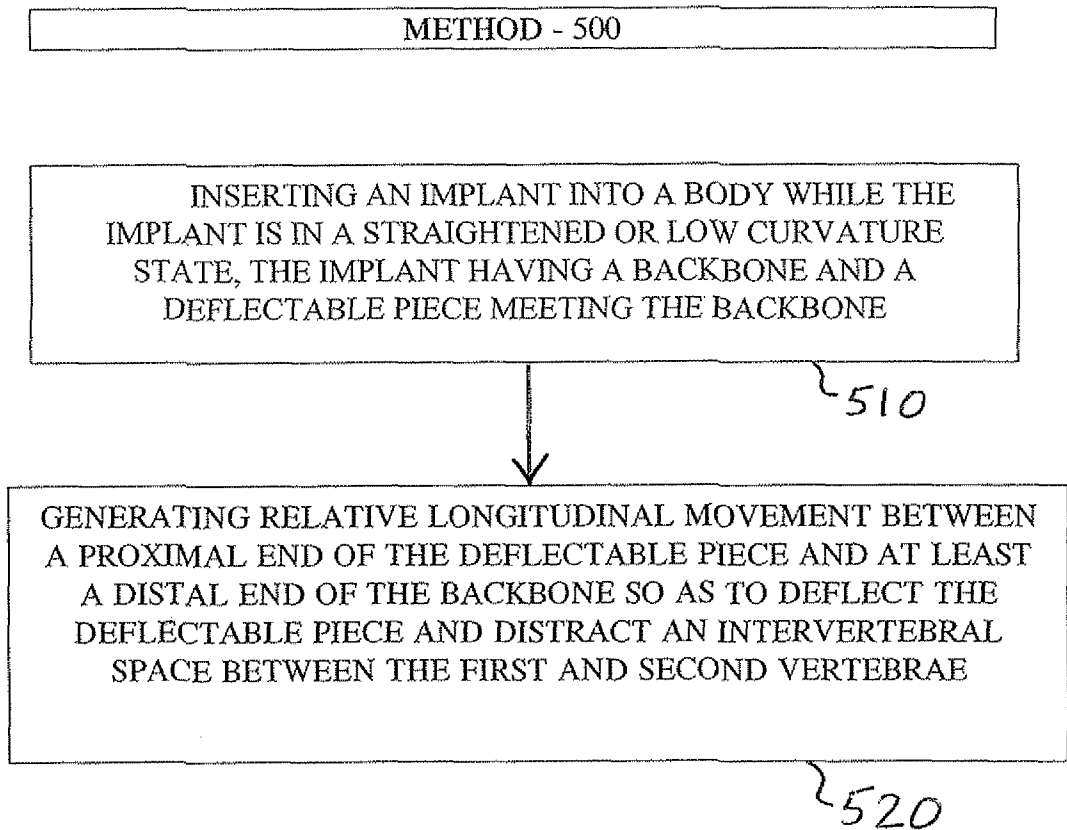


FIG. 20

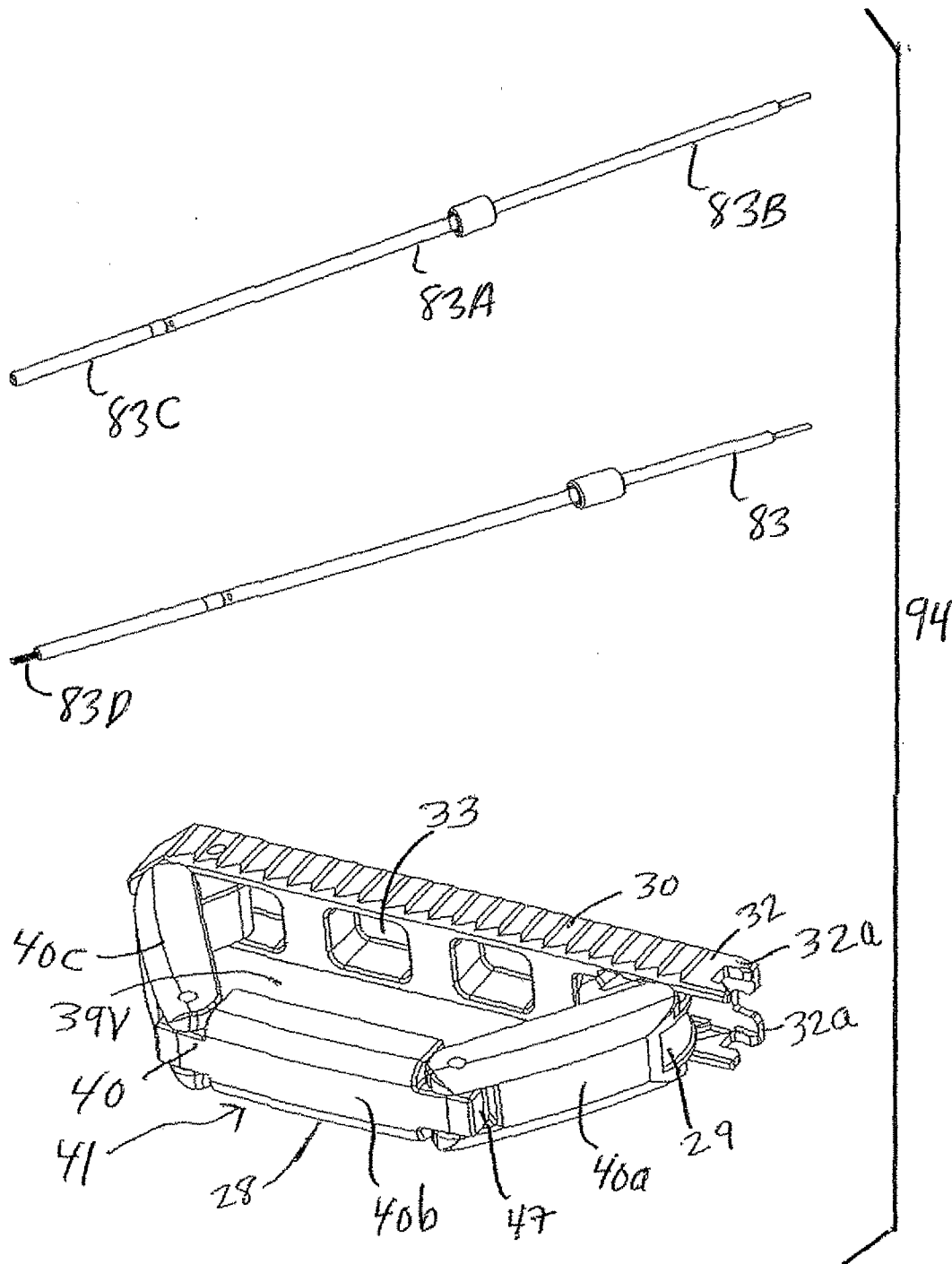


FIG. 21

FIG. 22A

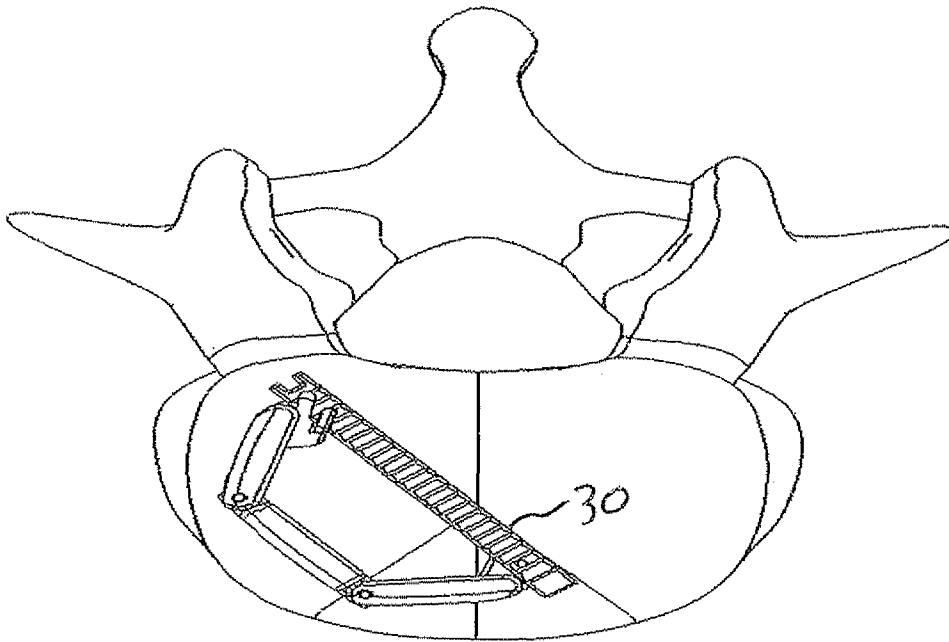


FIG. 22B

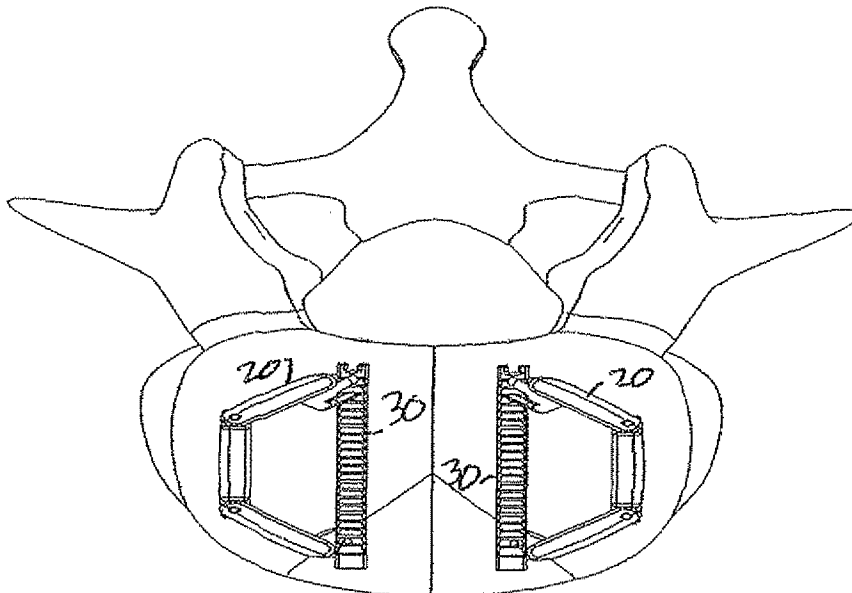


FIG. 23A

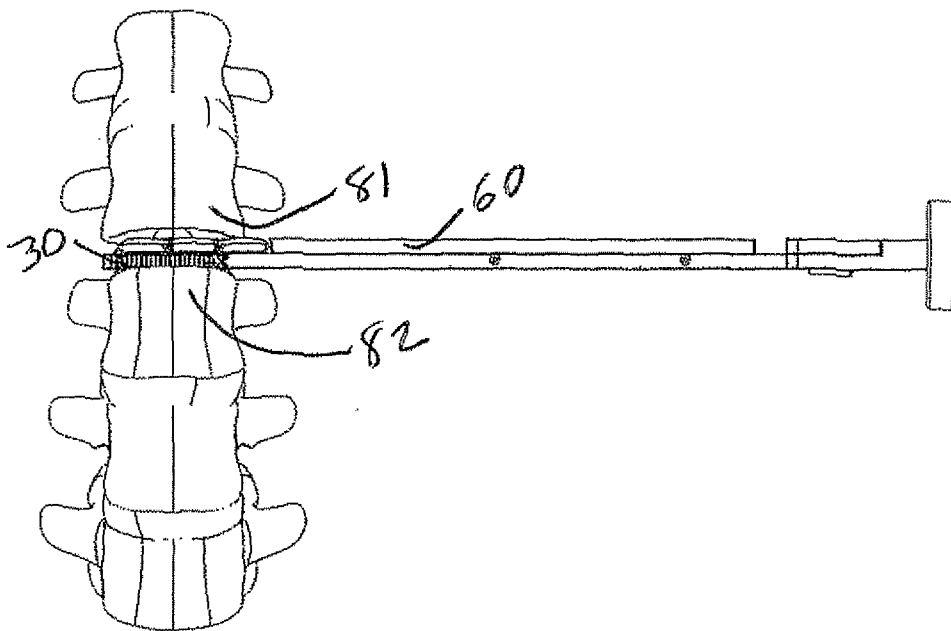


FIG. 23B

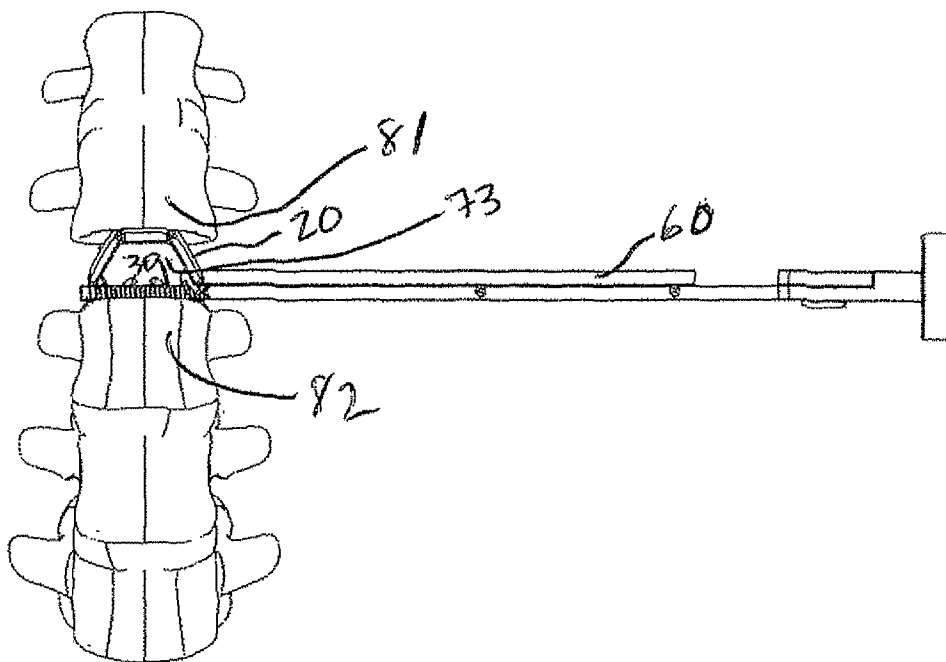


FIG. 24A

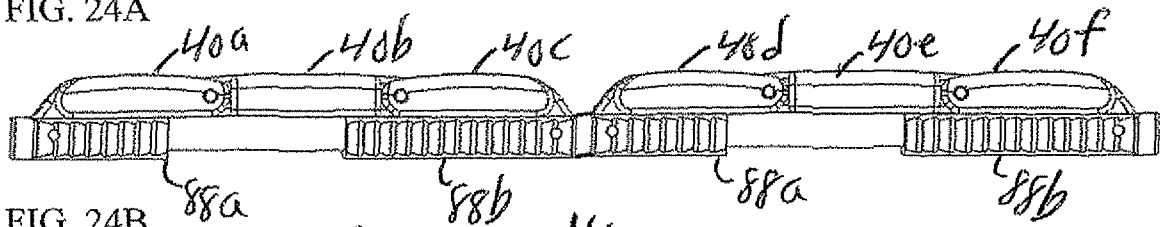


FIG. 24B

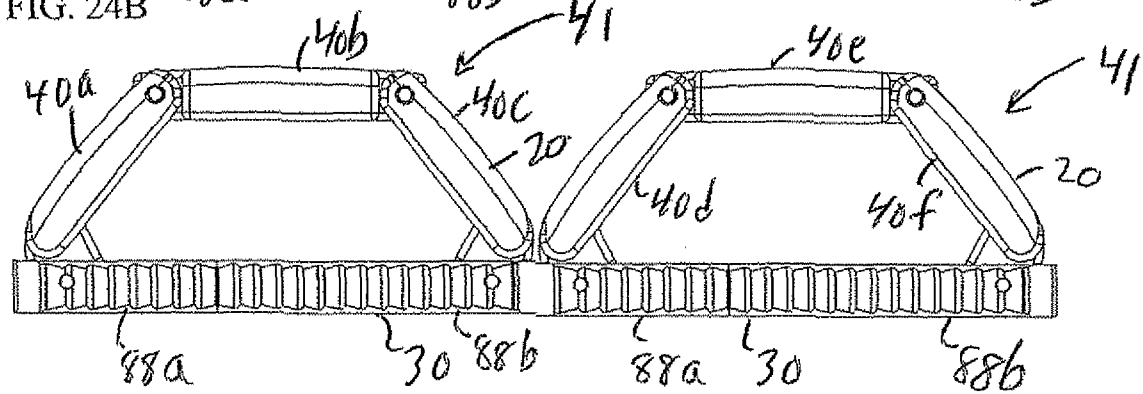


FIG. 24C

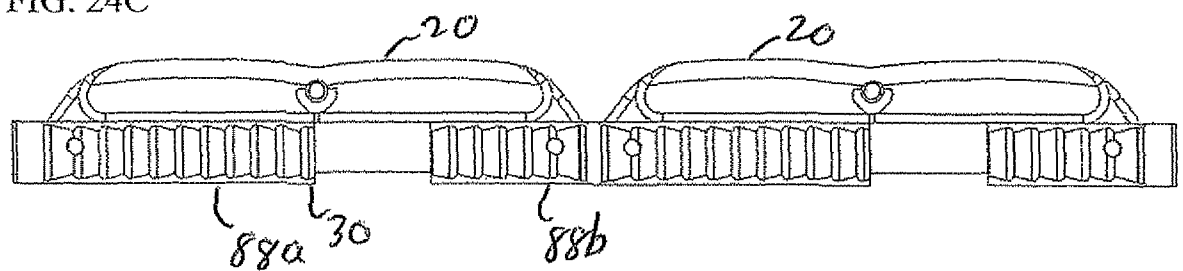


FIG. 24D

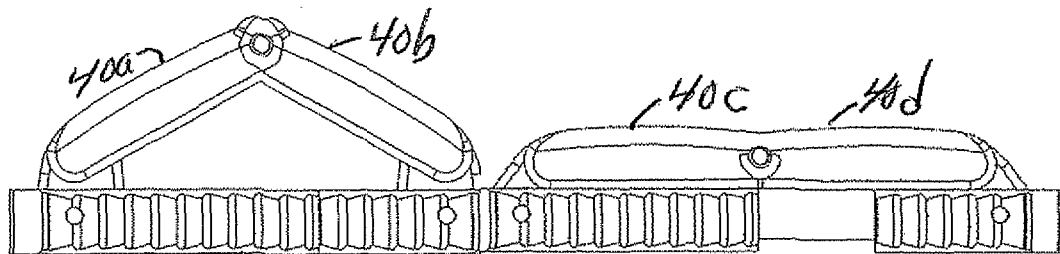


FIG. 24E

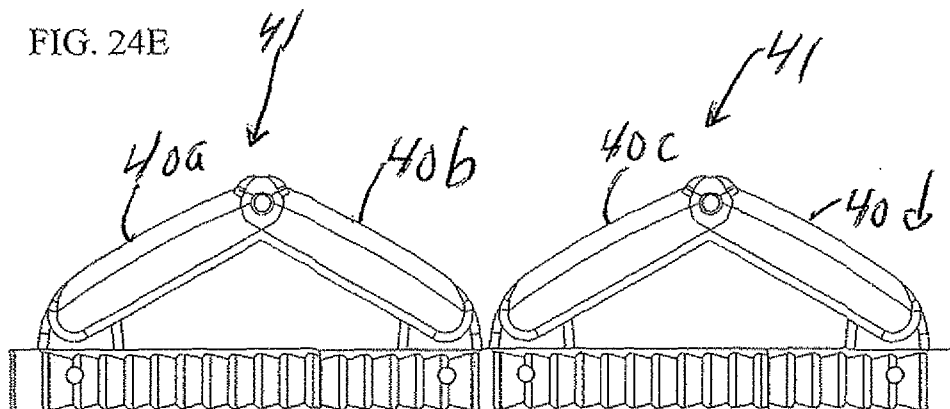


FIG. 25A

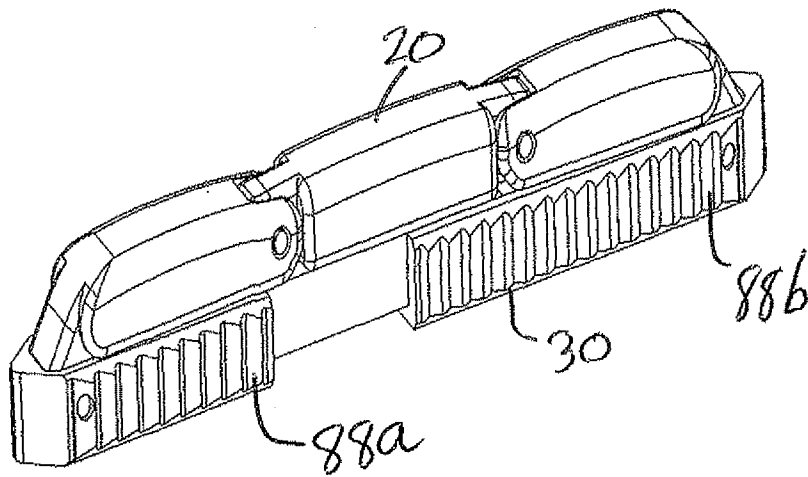


FIG. 25B

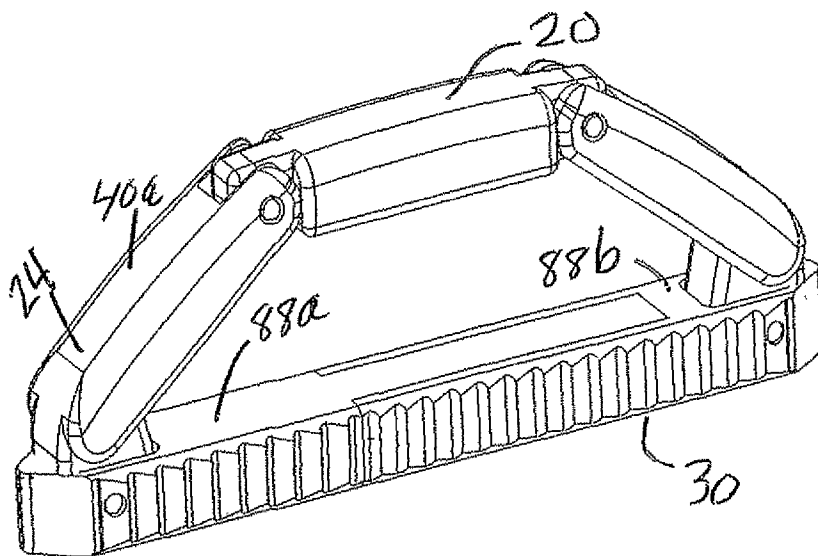


FIG. 26A

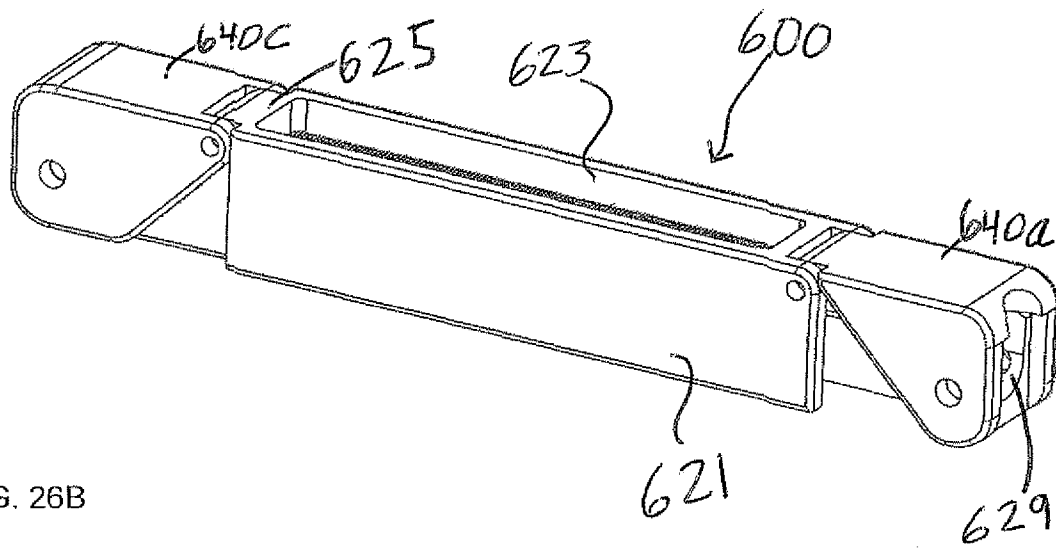


FIG. 26B

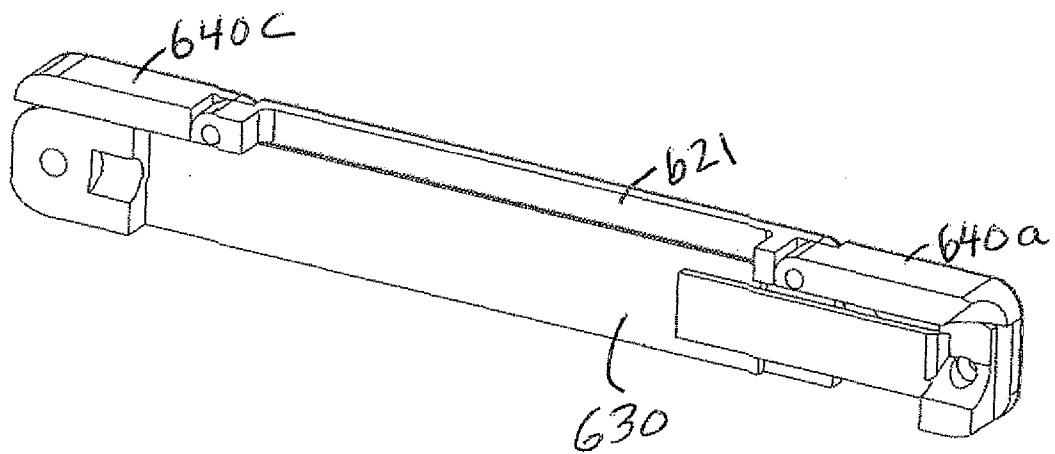


FIG. 26C

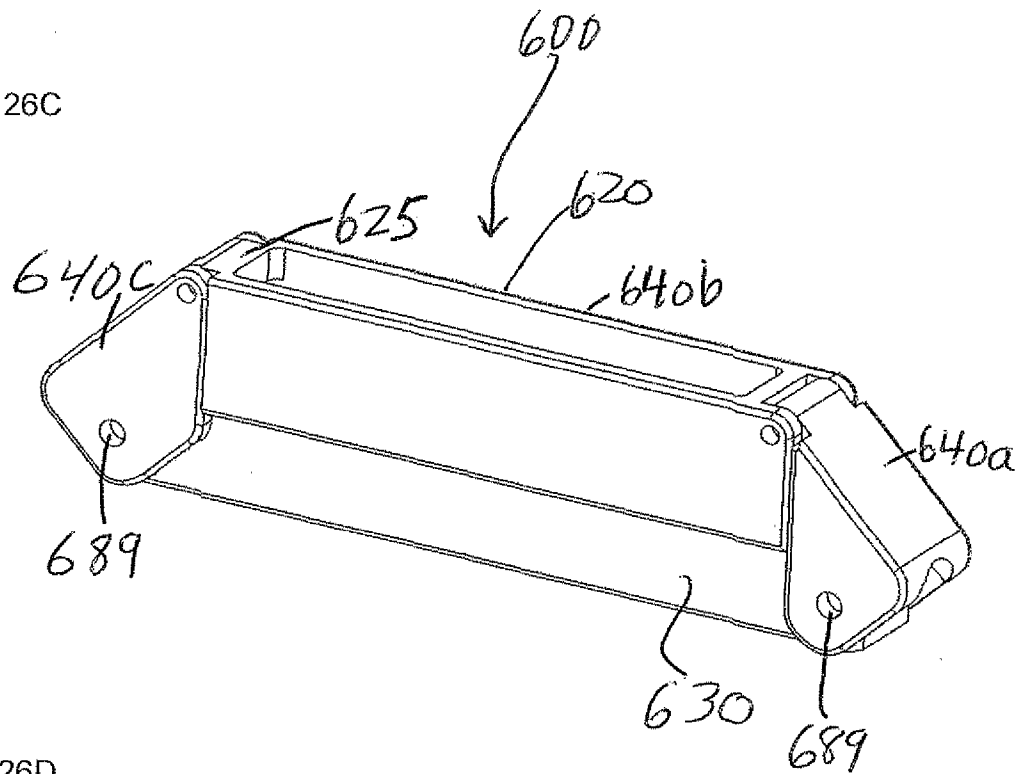


FIG. 26D

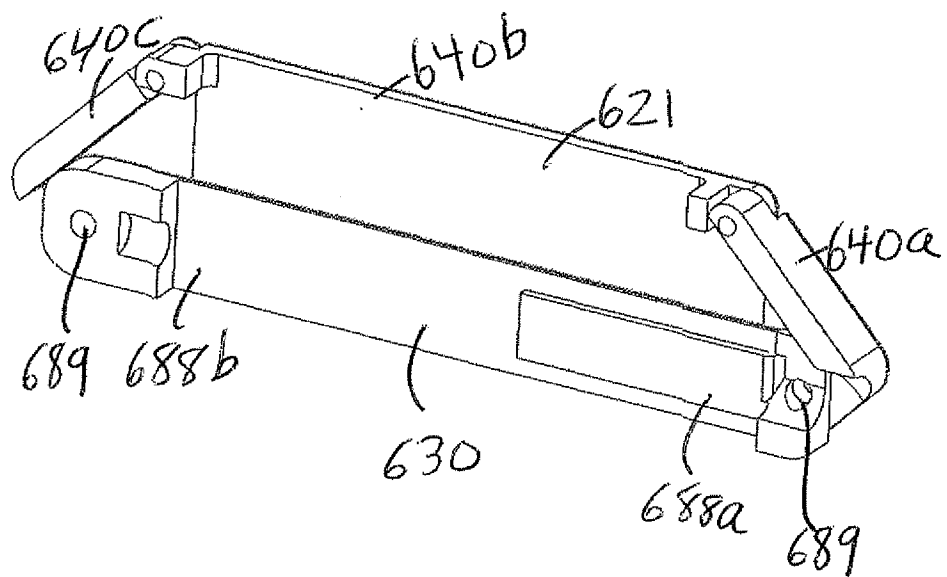




FIG. 27A

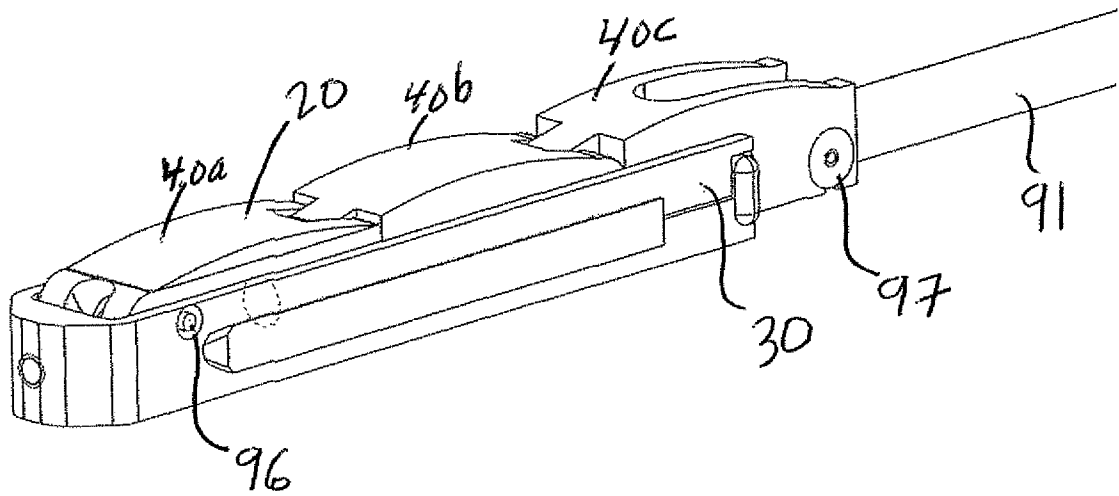
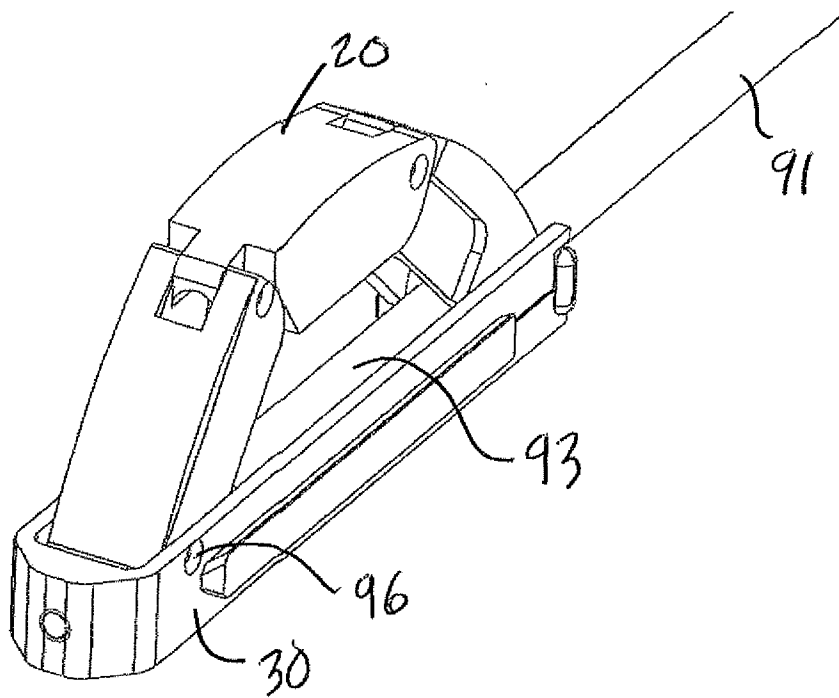


FIG. 27B



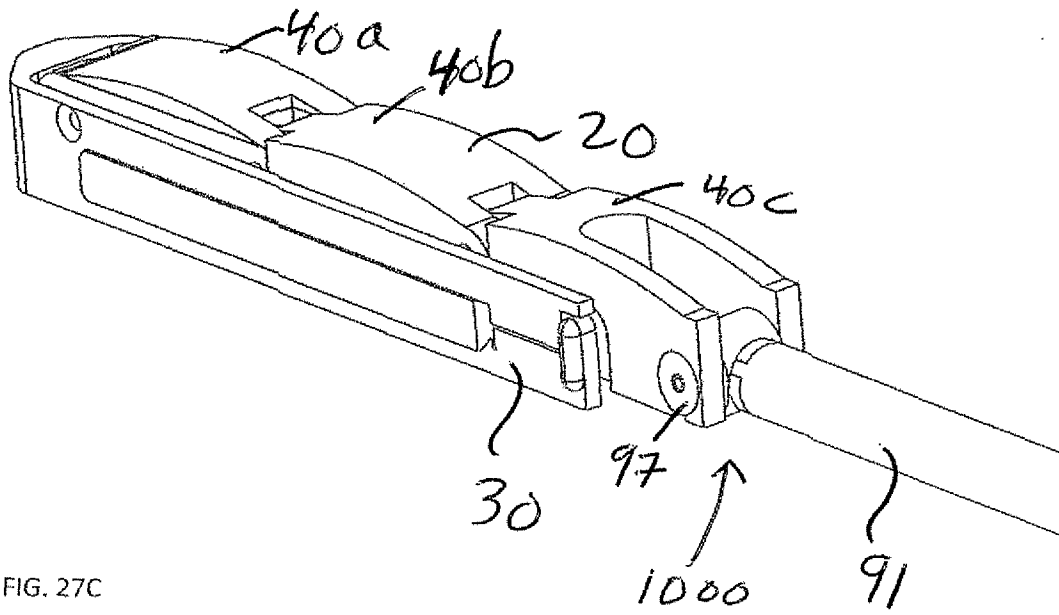


FIG. 27C

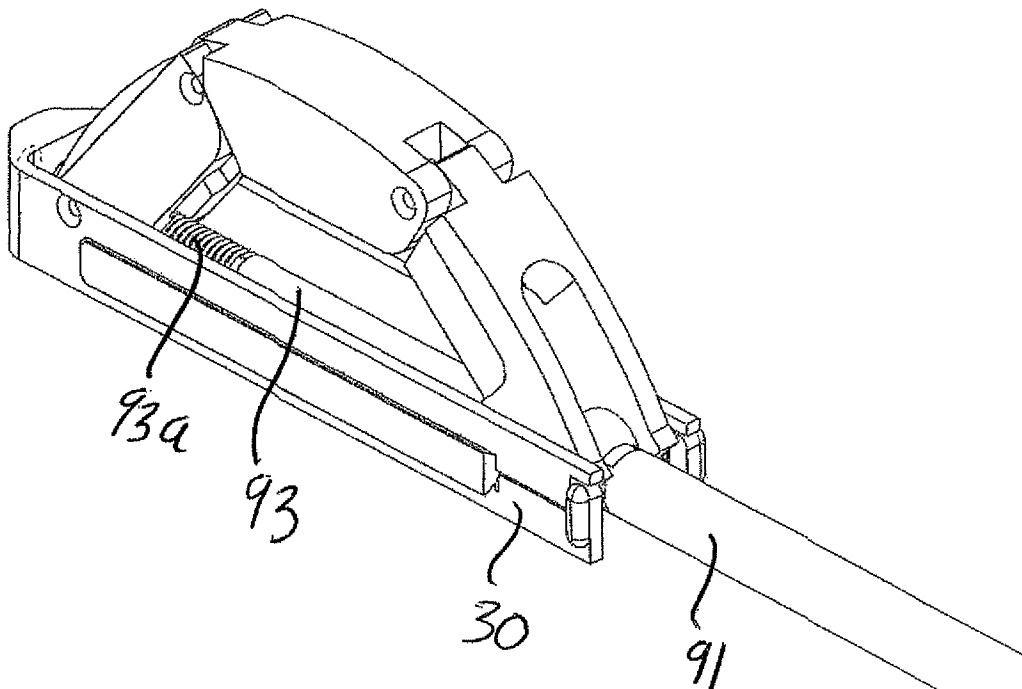


FIG. 27D

FIG. 27E

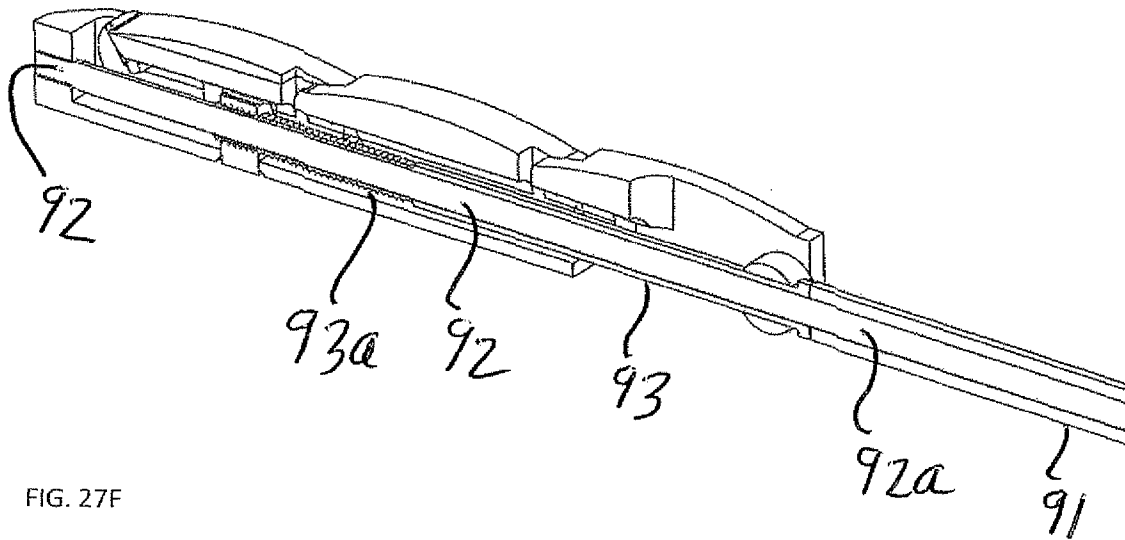


FIG. 27F

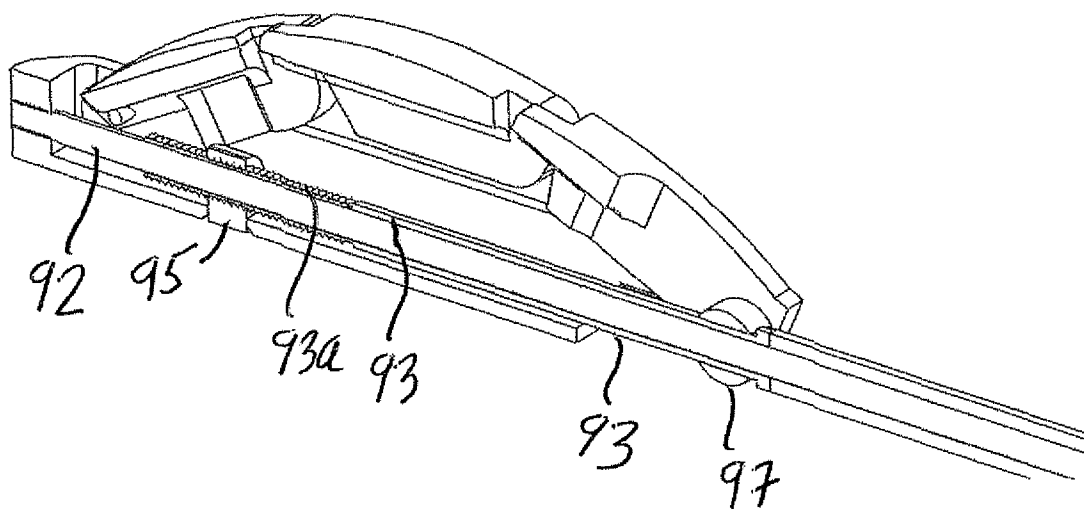


FIG. 27G

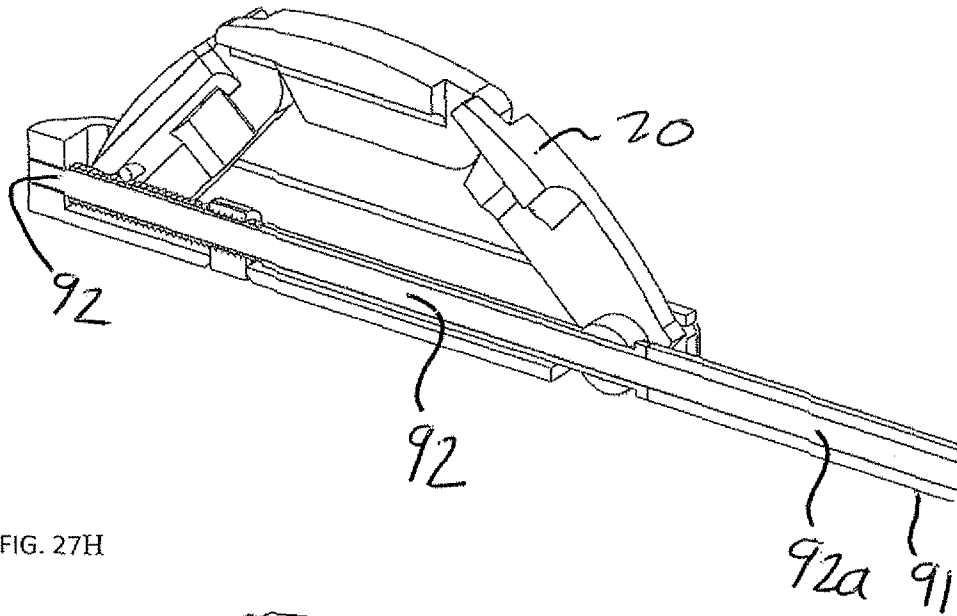


FIG. 27H

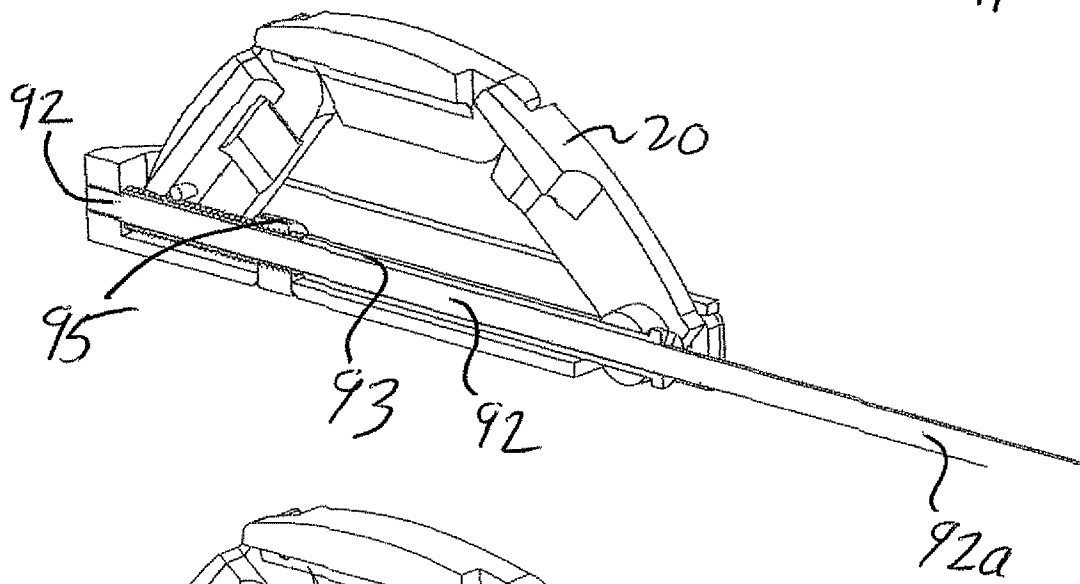


FIG. 27I

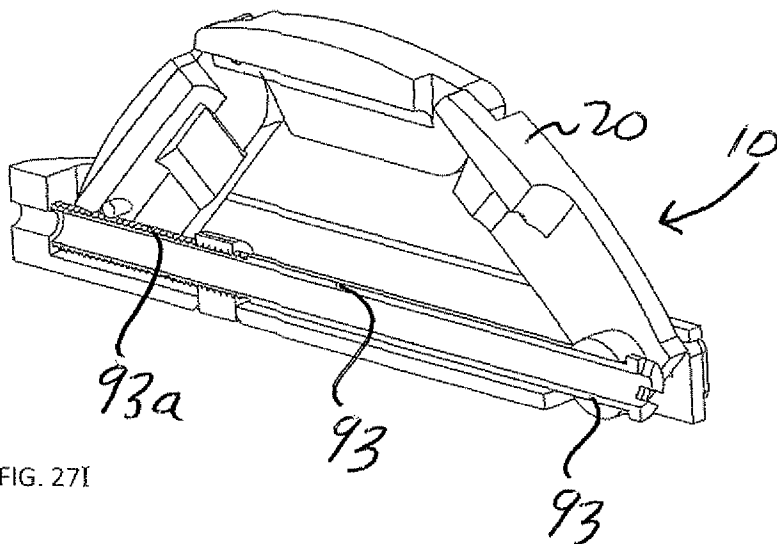


FIG. 27J

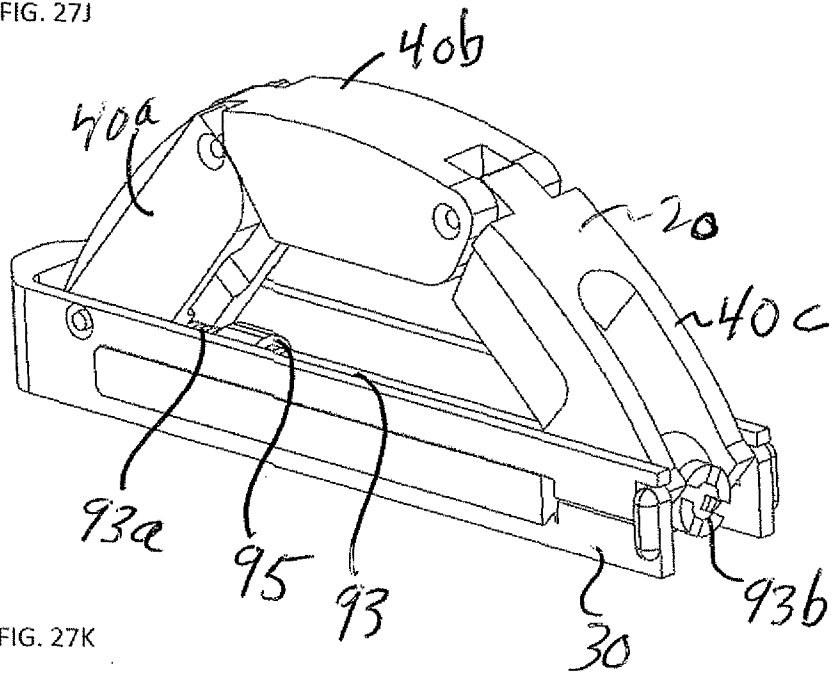
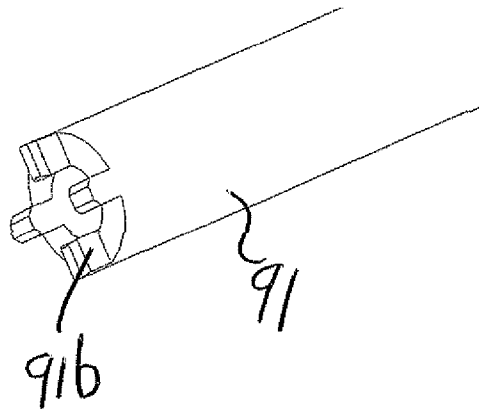


FIG. 27K



# INTERNATIONAL SEARCH REPORT

International application No  
PCT/IB2012/055693

A. CLASSIFICATION OF SUBJECT MATTER  
INV. A61F2/46 A61F2/44 A61B17/88  
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EP0-Internal, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/093072 A1 (SIEGAL T) 21 April 2011 (2011-04-21)  paragraphs [0069] - [0075]; claims; figures 21-36 -----	1,4-10, 12-14, 16-24, 26-31, 33,35, 36,38,39
X	WO 2008/084479 A2 (NONLINEAR TECH LTD) 17 July 2008 (2008-07-17)  claims; figures ----- -/--	1,4-10, 12-14, 16-24, 26-31, 33,35, 36,38,39

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

8 February 2013

Date of mailing of the international search report

18/02/2013

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040,  
Fax: (+31-70) 340-3016

Authorized officer

Kühne, H

# INTERNATIONAL SEARCH REPORT

International application No  
PCT/IB2012/055693

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	W0 2012/011078 A1 (SIEGAL TZONY ET AL) 26 January 2012 (2012-01-26)  page 7, line 8 - page 22, line 6; claims; figures 1-4,6,7  -----	1,4-10, 12-14, 16-24, 26-31, 33,35, 36,38,39
X	W0 2006/066228 A2 (INNOVATIVE SPINAL TECH) 22 June 2006 (2006-06-22) paragraphs [0060] - [0067]; claims; figures 12a-13e  -----	1
A	W0 2012/007918 A2 (NONLINEAR TECH LTD) 19 January 2012 (2012-01-19) claims; figures  -----	1-40
A	US 2008/243255 A1 (BUTLER M S ET AL) 2 October 2008 (2008-10-02) claims; figures  -----	1-40
A	US 2009/157084 A1 (AALSMA A M M ET AL) 18 June 2009 (2009-06-18) claims; figures  -----	1-40
A	W0 03/003951 A1 (BAAT MED ENG BV) 16 January 2003 (2003-01-16) claims; figures  -----	1-40

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2012/055693

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011093072 A1	21-04-2011	NONE	
-----			
WO 2008084479 A2	17-07-2008	EP 2099390 A2	16-09-2009
		WO 2008084479 A2	17-07-2008
-----			
WO 2012011078 A1	26-01-2012	AU 2011281170 A1	31-01-2013
		WO 2012011078 A1	26-01-2012
-----			
WO 2006066228 A2	22-06-2006	US 2006142858 A1	29-06-2006
		WO 2006066228 A2	22-06-2006
-----			
WO 2012007918 A2	19-01-2012	AU 2011277927 A1	31-01-2013
		WO 2012007918 A2	19-01-2012
-----			
US 2008243255 A1	02-10-2008	US 2008243255 A1	02-10-2008
		WO 2008121317 A1	09-10-2008
-----			
US 2009157084 A1	18-06-2009	NONE	
-----			
WO 03003951 A1	16-01-2003	AT 326196 T	15-06-2006
		AU 2002315942 B2	20-03-2008
		BR 0210769 A	20-07-2004
		DE 60211514 T2	10-05-2007
		EP 1401361 A1	31-03-2004
		ES 2265508 T3	16-02-2007
		JP 4237613 B2	11-03-2009
		JP 2004530527 A	07-10-2004
		NL 1018438 C1	08-01-2003
		US 2005261683 A1	24-11-2005
		WO 03003951 A1	16-01-2003
-----			



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/IB2012/055693

### Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 41-74  
because they relate to subject matter not required to be searched by this Authority, namely:  

No International Preliminary Examining Authority shall be required to search an international application on an international application if, and to the extent to which, its subject matter are methods for treatment of the human or animal body by surgery (Rule 39.1(iv) PCT).
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box No. III Observations where unity of invention is lacking (Continuation of Item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.