



(11) **EP 2 967 651 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:  
**02.09.2020 Bulletin 2020/36**

(21) Application number: **14762759.0**

(22) Date of filing: **14.03.2014**

(51) Int Cl.:  
**A61B 17/70 (2006.01)**

(86) International application number:  
**PCT/US2014/028767**

(87) International publication number:  
**WO 2014/144379 (18.09.2014 Gazette 2014/38)**

(54) **SPINAL STABILIZATION SYSTEM**

WIRBELSÄULENSTABILISIERUNGSSYSTEM  
SYSTÈME DE STABILISATION VERTÉBRALE

(84) Designated Contracting States:  
**AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR**

(30) Priority: **15.03.2013 US 201361794543 P**  
**13.03.2014 US 201414209138**

(43) Date of publication of application:  
**20.01.2016 Bulletin 2016/03**

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## Description

### CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application No. 61/794,543, filed March 15, 2013 and U.S. Non-Provisional Application No. 14/209,138 filed March 13, 2014.

### FIELD OF THE INVENTION

[0002] The present invention relates generally to the field of medical apparatus. More specifically, the present invention relates to systems for treating spinal conditions, and specifically for systems for stabilizing vertebrae in the spinal column. More specifically, the present invention relates to interlaminar vertebral stabilization devices for placement between adjacent vertebra and including supporting devices for stabilization of the vertebral segments above and below the vertebra being treated.

### BACKGROUND OF THE INVENTION

[0003] Injury to and/or diseases of the spine frequently result in damage to or abnormalities in the vertebrae, the intervertebral discs, the facet joints and to the connective tissue and ligaments around the spine. Such damage or abnormalities may result in spinal instability causing misalignment of the vertebral column and wear of the intervertebral discs and vertebral bony surfaces, a chronic and progressive deterioration which typically results in severe pain, loss or restriction of motion, and eventually, loss of mobility of the individual suffering from the condition.

[0004] One treatment option for addressing spinal disorders is via surgical intervention and the placement of fusion, stabilization and/or repair devices on or adjacent to the spine or between adjacent vertebrae. Certain surgical procedures are irreversible, for example, fusion techniques using bone grafts or synthetic implants to fuse vertebra, and may also significantly alter vertebral range of motion. Other procedures, for example procedures for installing spinal implants or pedicle screw systems for fixating two or more vertebrae, are intricate, time consuming and highly invasive. Alternative solutions include the insertion of interspinous or intra-laminar spacers in the space between adjacent vertebrae to control relative motion between and to stabilize the two vertebrae. However, the stabilization does not extend above or below the insertion point, leaving the remaining portions of the spinal column subject to unstable motion and the potential damage resulting therefrom.

[0005] Various prior art systems have attempted to address the problems described above. U.S. Patent No. 5,645,599 issued to Samani on July 8, 1997 (the '599 patent), discloses an interspinous implant device having a generally u-shaped, spring-like configuration for insertion between the spinal processes of adjacent vertebrae. Sa-

mani's device includes opposing pairs of upwardly and downwardly extending brackets adapted to be secured to the spinal process, thereby providing for flexible positioning of the adjacent vertebrae. However, the apparatus of the '599 patent does not attribute to the overall stability of the spinal column; its effect being limited to the two specific vertebrae to which it is attached. It is also difficult to attach multiple devices configured in accordance with Samani's disclosure at adjacent segments due to interference of the bracket portions.

[0006] Hochschuler et al disclose various intra-laminar stabilization systems in U. S. Patent Application Publication No. US 2009/0204150 published on August 13, 2009 (the '150 publication), and in U. S. Patent Application Publication No. US 2011/0106163 published on May 5, 2011 (the '163 publication). The '150 publication discloses a pair of oppositely disposed hook members that are translationally positioned on a rod and adapted to engage the laminar regions of adjacent vertebra and maintain a preselected spacing therebetween. However, the apparatus of the '150 publication does not stabilize other vertebrae in the spinal column, its effect being limited to the two adjacent vertebrae which it engages.

[0007] The Hochschuler et al. '163 publication discloses an interlaminar stabilizing system which includes a structure adapted to be disposed between two adjacent vertebrae as described above with respect to the apparatus of the '150 publication. The '163 structure further includes a support structure which is secured to the second vertebra to further restrict the interval spacing between the adjacent vertebrae. However, the system of the '163 disclosure also does not stabilize the vertebrae in the remaining portions of the spinal column for the reasons set forth above.

[0008] A further prior art fixing device for the spine is disclosed in WO2007/052975, which relates to a fixing device for attachment to adjacent vertebrae to prevent degenerative deformity of the spine after a back injury.

[0009] None of the known prior art systems address the problem of "transition syndrome" or "adjacent segment disease" associated with fusion of adjacent vertebrae. In fusion, if a motion segment is eliminated via fusion, the unfused adjacent segments above and below the fused vertebrae take up and bear the additional forces induced by bending and rotational movement of the spine, which may result in so-called "transition syndrome" over the long term. In addition, none of the prior art systems provide for augmenting previously installed spinal hardware to enhance stability, adjust intervertebral distraction, and so forth.

[0010] Accordingly, a need exists for an improved spinal stabilization system which provides both flexibility and stability to the spinal column and which addresses the combination of problems not solved by the prior art.

### SUMMARY OF THE INVENTION

[0011] It is therefore the object of the present invention

to provide an improved spinal stabilization system for maintaining preselected spacing and movement between adjacent vertebrae and also for providing overall stability to the spinal column.

**[0012]** The invention is defined in claim 1 while preferred embodiments are set forth in the dependent claims. Associated surgical methods are also described herein to aid understanding the invention. These methods do not form part of the claimed invention.

**[0013]** In an embodiment, a spinal stabilization system is provided which includes a blocking member to limit movement of adjacent vertebrae to prevent narrowing of the spinal canal and nerve compression. In yet another embodiment, a spinal stabilization system is provided which includes at least one adjustable cross-linking member to enhance stability of the spine.

**[0014]** These and other features of the present invention will be apparent from the accompanying description of the invention, diagrams and supplemental supporting materials provided herein.

### BRIEF DESCRIPTION OF THE DRAWINGS

#### **[0015]**

Fig. 1 is a front plan view of a spinal stabilization system of the present invention;

Fig. 2 is a side perspective view of a spinal stabilization system of the present invention;

Fig. 3 is a side plan view of a spinal stabilization system of the present invention;

Fig. 4 is a bottom perspective view of a spinal stabilization system of the present invention;

Fig. 5 is a top perspective view of a spinal stabilization system of the present invention;

Fig. 6 is an enlarged side plan view of a portion of the spinal stabilization system of the present invention shown in Fig. 3 showing an upper portion of the stabilization system affixed to a spinal column;

Fig. 7 is a side perspective view of a portion of the spinal stabilization system shown in Fig. 6;

Fig. 8 is an exploded front perspective view of a portion of the spinal stabilization system shown in Figs 6 and 7;

Fig. 9 is an exploded rear perspective view of a portion of the spinal stabilization system shown in Figs 6, 7 and 8;

Fig. 10 is a front plan view of a spinal stabilization system of the present invention affixed to a spinal

column;

Fig. 11 is a bottom front perspective view of a spinal stabilization system of the present invention affixed to a spinal column;

Fig. 12 is a top front perspective view of a spinal stabilization system of the present invention affixed to a spinal column;

Fig. 13 is a side perspective view of a spinal stabilization system of the present invention affixed to a spinal column.

### 15 DESCRIPTION OF THE INVENTION

**[0016]** It should be noted that the present description is by way of illustration only, and that the concepts and examples presented herein are not limited to use or application with any single system or methodology. Hence, while the details of the system and methods described herein are for the convenience of illustration and explanation with respect to the exemplary embodiments, the principles disclosed may be applied to other types of spinal stabilization systems without departing from the scope of the present invention.

**[0017]** Referring now to Figure 1, a spinal stabilization system according to an embodiment of the present invention is shown generally at 10 (which for purposes of brevity will be referred to herein as "the system"). The system includes a first interlamina member 12 adapted to be positioned between adjacent vertebra in a spinal column. As shown in greater detail in Figs. 6 and 7, the interlamina member 12 is shown positioned between a first vertebra 14 and a second adjacent vertebra 16 in a spinal column 18.

**[0018]** The system further includes a second interlamina member 20 adapted to be positioned between the second vertebra 16 and a third vertebra 22 in the spinal column 18. Both the first and second interlamina members are operatively connected to a support structure shown generally at numeral 25 in Fig. 1. By way of example, in the embodiment shown, the support structure and the first interlamina member are integrally formed from a single piece of material such as titanium or stainless steel suitable for use as a medical implant device. However, it is to be understood that other means for connecting the interlamina device to the support structure such as hinges, pins, threaded fasteners and the like may also be used without departing from the scope of the invention.

**[0019]** The support structure 25 comprises a pair of support members or guide rods 28 secured to the first interlamina support member 12 and extending in a direction upwardly therefrom substantially parallel to one another. The second interlamina member 20 includes a body portion 21 of a preselected thickness  $t$ , which is most clearly illustrated in Fig. 9. Thickness  $t$  is selected

based upon the spacing between the second and third vertebrae and is intended to be smaller in size than the spacing to allow for flexion of the spinal column 18.

**[0020]** The body portion 21 further includes a pair of oppositely positioned ears 30 extending laterally outwardly from the body portion in opposing directions, each of the ears containing an aperture 32 structured and arranged to slideably receive one of the support members or guide rods 28. As will be discussed in greater detail below, the second interlaminar member is movably supported by upwardly extending support members or guide rods, and the position of the second interlaminar member 20 relative to the first interlaminar member 12 may be adjusted depending upon the dimensions of the specific spinal column on which the system is installed and the range of motion desired. Once the position of the second interlaminar member 20 has been selected, it is locked in place by a pair of set screws or other suitable fastening means 34 extending through each of the ears 30 and adapted to releaseably engage the respective guide rod extending therethrough.

**[0021]** Referring now to Figs. 2, 3, 7 and 8, the first interlaminar member is 12 depicted in greater detail. The first interlaminar member comprises a U-shaped body 40 defined by an elastic midsection 42, two spaced apart end portions 44, and a pair of juxtaposed legs 46, each leg extending substantially parallel to one another from one of the respective end portions in a direction generally outwardly away from the spinal column 18 (Fig. 7) and spaced apart a preselected distance  $d$ . Distance  $d$  is determined by the size of the first interlaminar member, which, in turn, is selected based upon the spacing between the first and second vertebrae. The first interlaminar member is intended to fuse the first and second vertebrae. Accordingly, it is sized to be a tight fit, and the elastic properties of the U-shaped body 40 act as a spring or shock absorber in the interface between the two vertebrae. Further, the uppermost one of the legs 46 is longer than the lower one of the legs, thereby forming a handle 48 which may be used to insert and position the system during surgery.

**[0022]** Referring again to Fig. 1, the support structure 25 further includes a T-shaped frame member 50 operatively connected to the first and second interlaminar members 12 and 20 and extends generally downwardly therefrom in a direction substantially parallel to the spinal column 18. The T-shaped frame member includes an elongate body 52 having first and second end portions 54, 56, the first end portion being operatively connected to the first interlaminar member 12, and an elongate cross member 58. The cross member has first and second end portions 60, 62 and a midpoint 64 and is structured and arranged to be connected to the second end portion 56 of the body 52 at approximately the midpoint 64. Each of the ends 60, 62 of the cross member 58 are adapted to receive and adjustably secure first and second support members 66 and 68 respectively. In the embodiment shown, each of the end portions 60, 62 have an aperture

70, 72 formed therein respectively for receiving one of the support members 66, 68, each of which may be held in a preselected position by a set screw 74.

**[0023]** In the embodiment shown, by way of example only and not of limitation, the support members are in the form of guide rods 66, 68, each guide rod having an upper end 76 and a lower end 78. Each of the upper and lower ends of the support members 66, 68 has a securing device 80 slideably positioned thereon and adapted to be secured thereto by means of set screws 82. By way of example, each of the securing devices is shown in the form of a pedicle screw 84, each pedicle screw being structured and arranged to be secured to one of the vertebrae of the spinal column 18.

**[0024]** The installation and operation of the spinal support system 10 of the present invention are illustrated in greater detail in Figs. 6, 7, and 10-13. The system advantageously may be installed where other spinal fusion devices or similar medical apparatus are already in place to add stability to the spinal column above and below the installation point, to control flexion and/or rotational movement of the spine or selected vertebrae with respect to one another, and to prevent impingement of adjacent vertebrae, spinal processes, pedicle screws and medical hardware on one another. By way of example, as best shown in Figs. 6 and 7, a surgeon may insert the support structure 25 into the space between adjacent vertebrae 14 and 16 by gripping handle 48 and making the insertion. The tight fitting U-shaped body 40 not only serves to control any motion between the adjacent vertebrae or even eliminate it entirely, thereby effectively fusing the vertebrae, but also serves as a dampening cushion or spring device by virtue of the spring-like elasticity of the body 40 translated to the vertebrae via legs 46. Thereafter, the second interlaminar member 20 may be selectively positioned intermediate vertebra 16 and vertebra 22 to permit flexion on a forward direction but to limit extension in the rearward direction and to limit compression of the spinal segment, thereby imparting enhanced stability to the spinal column above the fused vertebrae.

**[0025]** In a similar manner, support structure 25, via the T-shaped frame member 50 and support members or guide rods 66 and 68, provides support to the spinal processes located below the fused vertebrae 14 and 16. As shown in Figs. 10-13, the pedicle screws 80 may be positioned in first vertebra 14 and in either vertebra 15 immediately adjacent to vertebra 14, or at a lower level as shown by vertebra 17, thus extending the stabilizing effect of the novel support system of the present invention to multiple levels in the spinal column 18.

**[0026]** More than one level may be addressed simply by lengthening the rods 66 and 68 and slideably positioning multiple pedicle screws 80 thereon for selective positioning along the spinal column.

**[0027]** In one example, the cross member midpoint 64 may be configured, structured and arranged to be adjustably (e.g., pivotably or translatably) connected or secured to the second end portion 56 of the body 52 at

approximately the midpoint 64 in order to allow a surgeon during the course of the surgical procedure to adjust and align components of the implant in relation to the patient's bony anatomy and in relation to support members 66 and 68.

**[0028]** In another example, elongate body 52 may be comprised of multiple pieces. For example, one or more linear racks may be configured in operable relation with gear mechanisms, thereby forming a ratchet device (not shown), in order to extend the distance between first and second end portions 54 and 56 thereby permitting a surgeon during the course of the surgical procedure to adjust and align components of the implant in relation to the patient's bony anatomy and subsequently securing them in place. For example, a ratchet mechanism configuration may permit the surgeon to progressively extend elements of the implant to better appose a lamina.

**[0029]** In yet another example, each of the ends 60, 62 of the cross member 58 may be configured to permit a degree of adjustability (e.g., pivotably or translatably) to receive and adjustably secure first and second support members 66 and 68 respectively. For example any crosslink variable adjustment mechanism or fastener known in the art may be employed to accomplish the desired fixation between the ends 60, 62 of the cross member 58 and first and second support members 66 and 68.

**[0030]** According to particular embodiments, interlaminar member 20 may be configured to permit connection to guide rods 28 via an approach that is substantially perpendicular to the longitudinal axis of guide rods 28. In other words, after the other components of the system have been implanted via a posterior approach to the posterior aspect of the spine the interlaminar member 20 may follow a generally similar approach trajectory and then secured to the guide rods 28 with, e.g., set screws in a similar manner to the engagement between the ends 60, 62 of the cross member 58 and first and second support members 56 and 68. Furthermore, in another example, an interlaminar member 20 may be used alone (and may alternatively be configured to be similar to the U-shaped body 40) and may be directly engaged with a first and second support members 66 and 68 and positioned between the lamina and spinous processes of the spine.

**[0031]** In particular examples, the different elements of the system may be configured with tool engagement features in order to permit a surgeon to grasp the implant with a tool assembly or insertion tool to ease implantation of the various components. For example, the insertion tool may be configured as a pair of pliers or hemostats. As another example, a threaded portion of a tool assembly may reversibly secure to a complementary threaded portion of the implant in order to ease implantation. E.g., a tool assembly may be comprised of a cannulated shaft with a retainer shaft housed substantially within, the retainer shaft further configured with a threaded portion at its distal end which may extend out of a distal end of the retainer shaft and a handle located and attached to a

proximal end of the retainer shaft; the distal end of the retainer shaft may have a feature that permits rotation of the retainer shaft via another tool, such as the mechanical arrangement that exists between a wrench and nut, in order to secure the tool assembly to the implant. After implantation of the implant the tool assembly may be decoupled and removed.

## 10 Claims

1. A spinal stabilization system (10) comprising:

a first interlaminar member (12) adapted to be positioned between a first vertebra (14) and a second vertebra (16) in a spinal column, the first interlaminar member including a U-shaped body (40) having an elastic midsection (42), and two spaced apart end portions (44), and a pair of juxtaposed legs (46) extending substantially parallel to one another from one of the respective ends in a direction generally outwardly away from the spinal column; a second interlaminar member (20) adapted to be positioned between the second vertebra (16) and a third vertebra (22) positioned adjacent to and above the second vertebra in the spinal column; and a support structure (25) operatively connectable to the first and second interlaminar members, the second vertebra and at least one vertebra positioned below the second vertebra in the spinal column, the support structure including a T-shaped frame member (50) operatively connected to the first and second interlaminar members and extending generally downwardly therefrom in a direction substantially parallel to the direction of the spinal column, the T-shaped frame member including an elongate body (52) having first and second end portions (54, 56) the first end portion being operatively connected to the first interlaminar member, and an elongate cross member (58) having first and second end portions (60, 62) and a midpoint (64), the elongate cross member being operatively connected approximately at the midpoint to the second end portion of the elongate body (52).

2. The system of claim 1, wherein the support structure includes a pair of support members (28) secured to the first interlaminar member and extending upwardly therefrom in a direction substantially parallel to one another.

3. The system of claim 2, wherein the second interlaminar member is moveably supported by the upwardly extending support members.

4. The system of claim 1, wherein the first interlaminar member is structured and arranged to fit tightly between the first vertebra and the second vertebra.
5. The system of claim 1, wherein the second interlaminar support member is structured and arranged to fit loosely between the second vertebra and the third vertebra.
6. The system of claim 1, further including first and second support members (66, 68) adjustably secured to the first and second ends of the elongate cross member respectively.
7. The system of claim 6, wherein each of the first and second support members includes an upper and a lower end, each of the upper and lower ends having a securing device slideably positioned thereon, each securing device being structured and arranged to be secured to a vertebra in the spinal column.

#### Patentansprüche

1. Wirbelsäulenstabilisierungssystem (10), umfassend:
  - ein erstes interlaminares Element (12), das angepasst ist, um zwischen einem ersten Wirbel (14) und einem zweiten Wirbel (16) in einer Wirbelsäule positioniert zu werden, wobei das erste interlaminares Element einen U-förmigen Körper (40) mit einem elastischen Mittelteil (42) einschließt sowie zwei voneinander beabstandete Endabschnitte (44) und ein Paar nebeneinander angeordneter Beine (46), die sich von einem der jeweiligen Enden im Wesentlichen parallel zueinander in einer Richtung erstrecken, die im Allgemeinen von der Wirbelsäule nach außen weg weist;
  - ein zweites interlaminares Element (20), das angepasst ist, um zwischen dem zweiten Wirbel (16) und einem dritten Wirbel (22) positioniert zu werden, der benachbart zu und über dem zweiten Wirbel in der Wirbelsäule positioniert ist; und
  - eine Stützstruktur (25), die operativ mit dem ersten und zweiten interlaminaren Element, dem zweiten Wirbel und mindestens einem Wirbel, der unterhalb des zweiten Wirbels in der Wirbelsäule positioniert ist, verbunden werden kann, wobei die Stützstruktur ein T-förmiges Rahmenelement (50) einschließt, das operativ mit dem ersten und zweiten interlaminaren Element verbunden ist und sich von diesen im Allgemeinen nach unten in einer Richtung im Wesentlichen parallel zur Wirbelsäule erstreckt, wobei das T-förmige Rahmenelement einen länglichen Kör-

per (52) mit einem ersten und einem zweiten Endabschnitt (54, 56) einschließt, wobei der erste Endabschnitt operativ mit dem ersten interlaminaren Element verbunden ist, sowie ein längliches Querelement (58) mit einem ersten und einem zweiten Endabschnitt (60, 62) und einem i-Mittelpunkt (64), wobei das längliche Querelement ungefähr in der Mitte mit dem zweiten Endabschnitt des länglichen Körpers (52) operativ verbunden ist.

2. System nach Anspruch 1, wobei die Stützstruktur ein Paar von Stützelementen (28) einschließt, die an dem ersten interlaminaren Element befestigt sind und sich von dort nach oben in einer Richtung im Wesentlichen parallel zueinander erstrecken.
3. System nach Anspruch 2, wobei das zweite interlaminares Element beweglich von den sich nach oben erstreckenden Stützelementen getragen wird.
4. System nach Anspruch 1, wobei das erste interlaminares Element so strukturiert und angeordnet ist, dass es fest zwischen dem ersten Wirbel und dem zweiten Wirbel sitzt.
5. System nach Anspruch 1, wobei das zweite interlaminares Stützelement so strukturiert und angeordnet ist, dass es lose zwischen dem zweiten Wirbel und dem dritten Wirbel sitzt.
6. System nach Anspruch 1, ferner einschließend erste und zweite Stützelemente (66, 68), die einstellbar an dem ersten bzw. zweiten Ende des länglichen Querelements befestigt sind.
7. System nach Anspruch 6, wobei jedes der ersten und zweiten Stützelemente ein oberes und ein unteres Ende einschließt, wobei jedes der oberen und unteren Enden eine Sicherungsvorrichtung aufweist, die verschiebbar darauf positioniert ist, wobei jede Sicherungsvorrichtung so strukturiert und angeordnet ist, dass sie an einem Wirbel der Wirbelsäule befestigt werden kann.

#### Revendications

1. Système de stabilisation vertébrale (10) comprenant :
  - un premier élément interlaminaire (12) adapté pour être positionné entre une première vertèbre (14) et une deuxième vertèbre (16) dans une colonne vertébrale, le premier élément interlaminaire comportant un corps en U (40) ayant une section médiane élastique (42), et deux parties d'extrémité espacées (44), et une paire de

- jambes juxtaposées (46) s'étendant sensiblement parallèlement l'une à l'autre à partir de l'une des extrémités respectives dans une direction généralement à l'extérieur de la colonne vertébrale ;
- un second élément interlaminaire (20) adapté pour être positionné entre la deuxième vertèbre (16) et une troisième vertèbre (22) positionnée adjacente et au-dessus de la deuxième vertèbre dans la colonne vertébrale ; et
- une structure de support (25) pouvant être reliée de manière fonctionnelle aux premier et second éléments interlaminaires, la deuxième vertèbre et au moins une vertèbre positionnée sous la deuxième vertèbre dans la colonne vertébrale, la structure de support comportant un élément de cadre en forme de T (50) relié de manière fonctionnelle aux premier et second éléments interlaminaires et s'étendant généralement vers le bas à partir de ceux-ci dans une direction sensiblement parallèle à la direction de la colonne vertébrale, l'élément de cadre en forme de T comportant un corps allongé (52) ayant des première et seconde parties d'extrémité (54, 56), la première partie d'extrémité étant reliée de manière fonctionnelle au premier élément interlaminaire, et un élément transversal allongé (58) ayant des première et seconde parties d'extrémité (60, 62) et un point médian (64), l'élément transversal allongé étant relié de manière fonctionnelle approximativement au niveau du point médian de la seconde partie d'extrémité du corps allongé (52).
2. Système selon la revendication 1, dans lequel la structure de support comporte une paire d'éléments de support (28) fixés au premier élément interlaminaire et s'étendant vers le haut de celui-ci dans une direction sensiblement parallèle à l'autre.
3. Système selon la revendication 2, dans lequel le second élément interlaminaire est supporté de manière mobile par les éléments de support s'étendant vers le haut.
4. Système selon la revendication 1, dans lequel le premier élément interlaminaire est structuré et disposé pour s'ajuster étroitement entre la première vertèbre et la deuxième vertèbre.
5. Système selon la revendication 1, dans lequel le second élément de support interlaminaire est structuré et disposé pour s'ajuster librement entre la deuxième vertèbre et la troisième vertèbre.
6. Système selon la revendication 1, comportant en outre des premier et second éléments de support (66, 68) fixés de manière réglable aux première et

seconde extrémités de l'élément transversal allongé respectivement.

7. Système selon la revendication 6, dans lequel chacun des premier et second éléments de support comporte une extrémité supérieure et une extrémité inférieure, chacune des extrémités supérieure et inférieure ayant un dispositif de fixation positionné de manière coulissante sur celles-ci, chaque dispositif de fixation étant structuré et disposé pour être fixé à une vertèbre dans la colonne vertébrale.

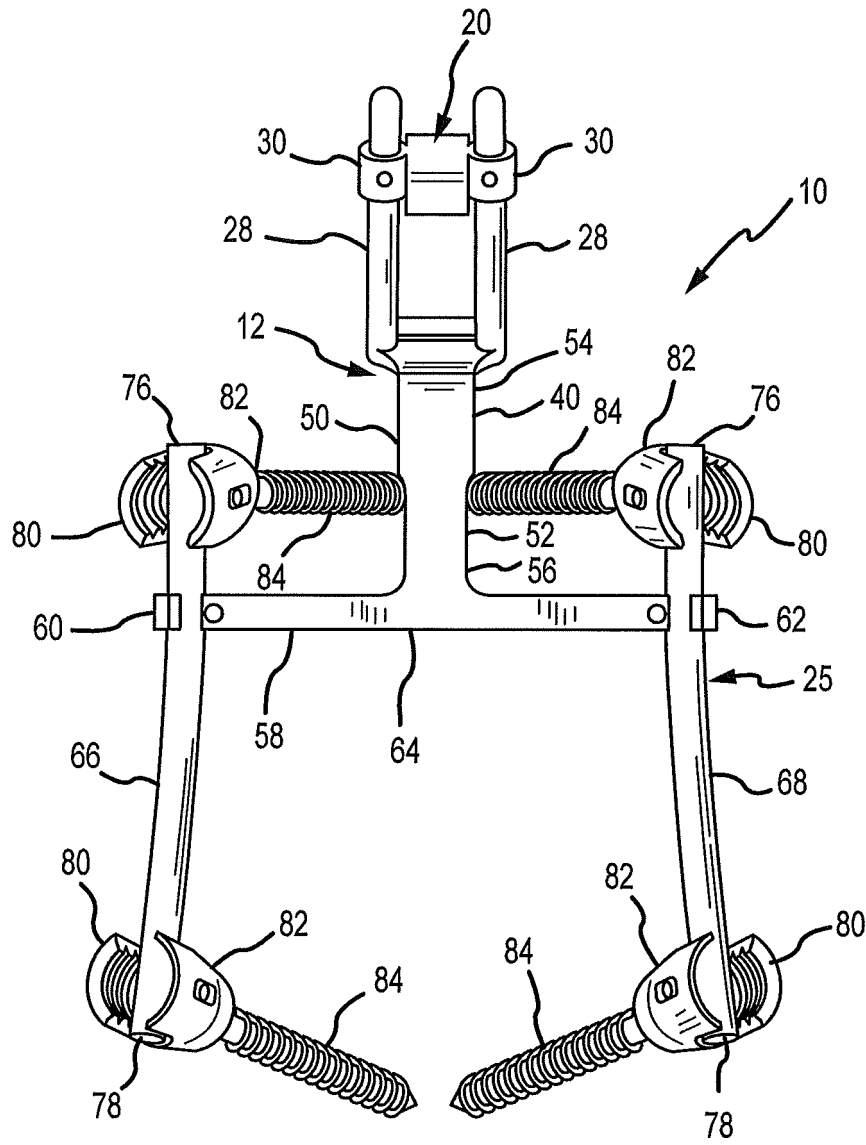


FIG.1



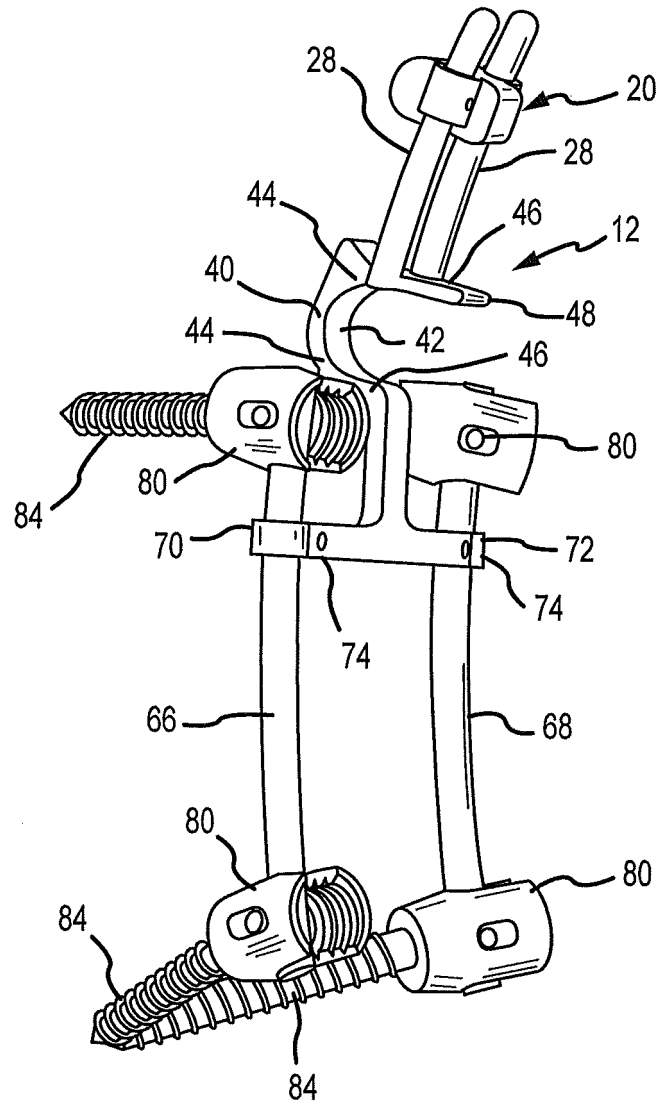


FIG.2

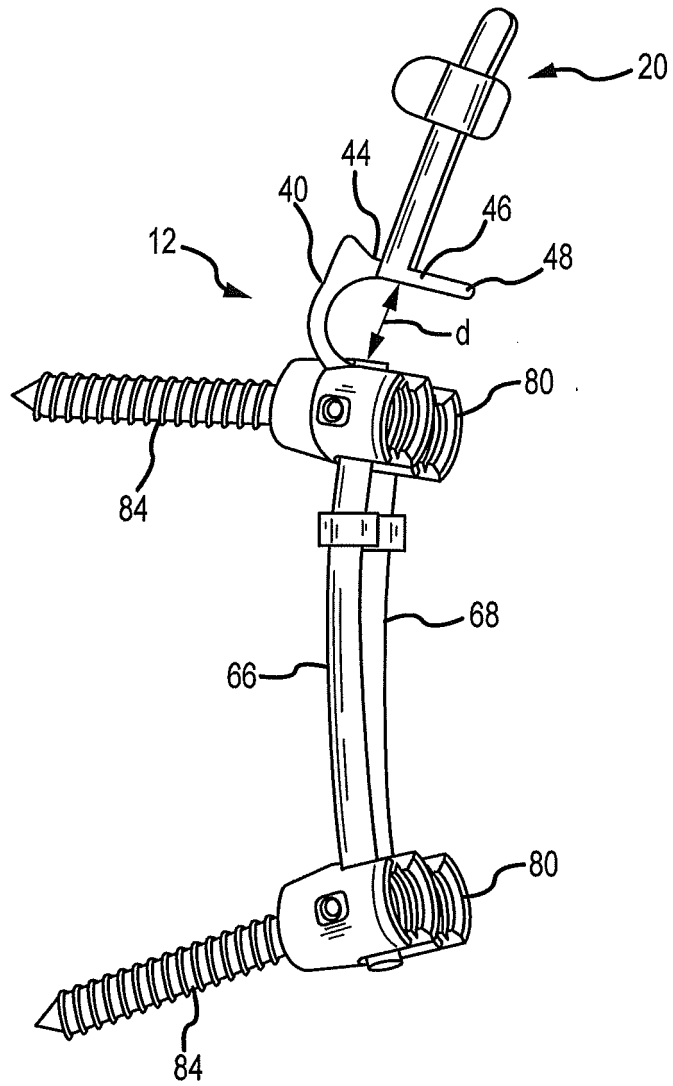


FIG.3

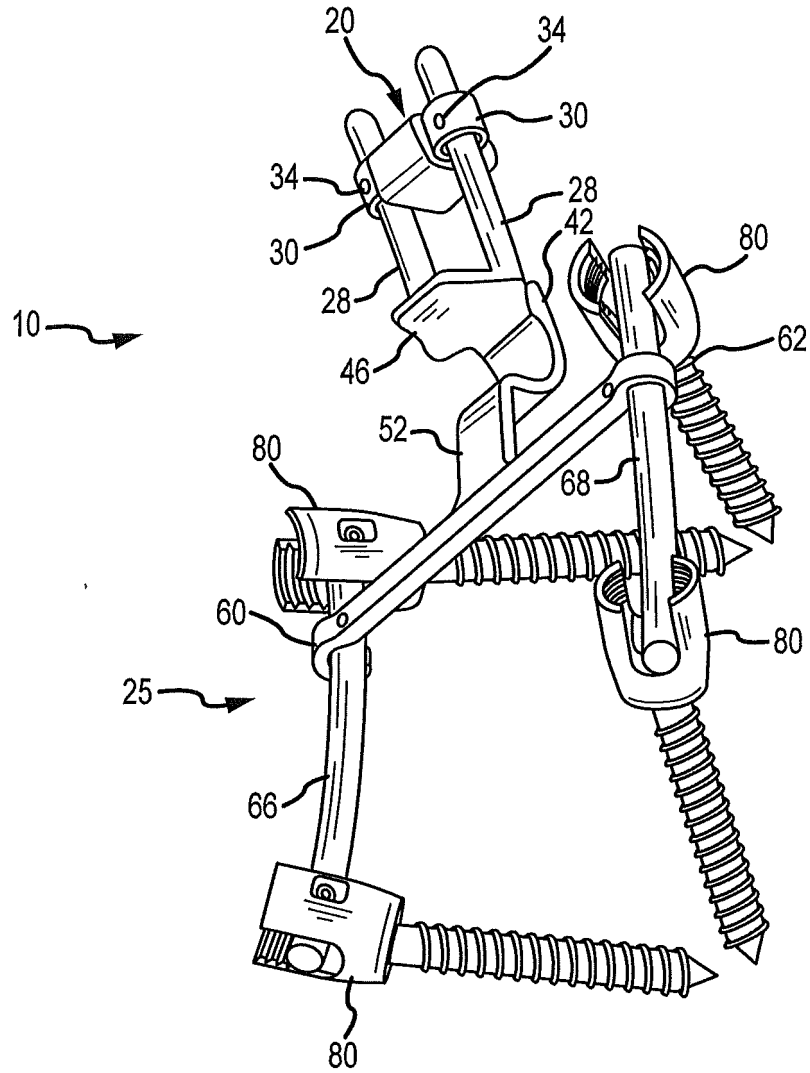


FIG.4

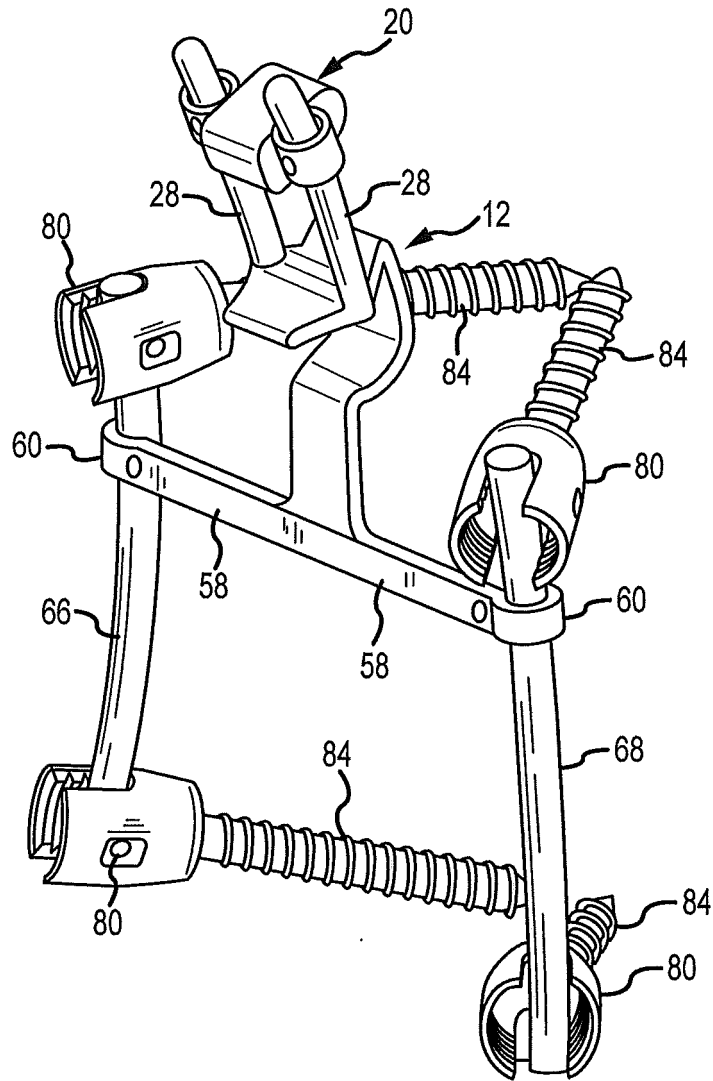


FIG.5

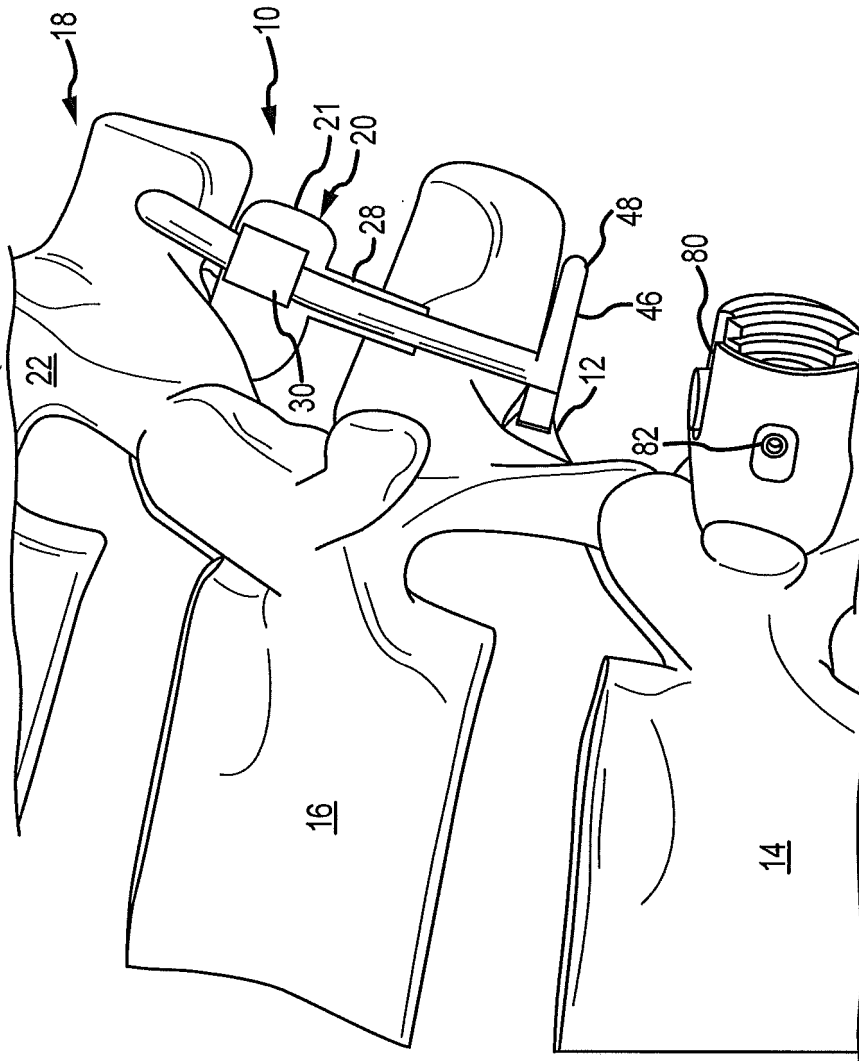


FIG.6

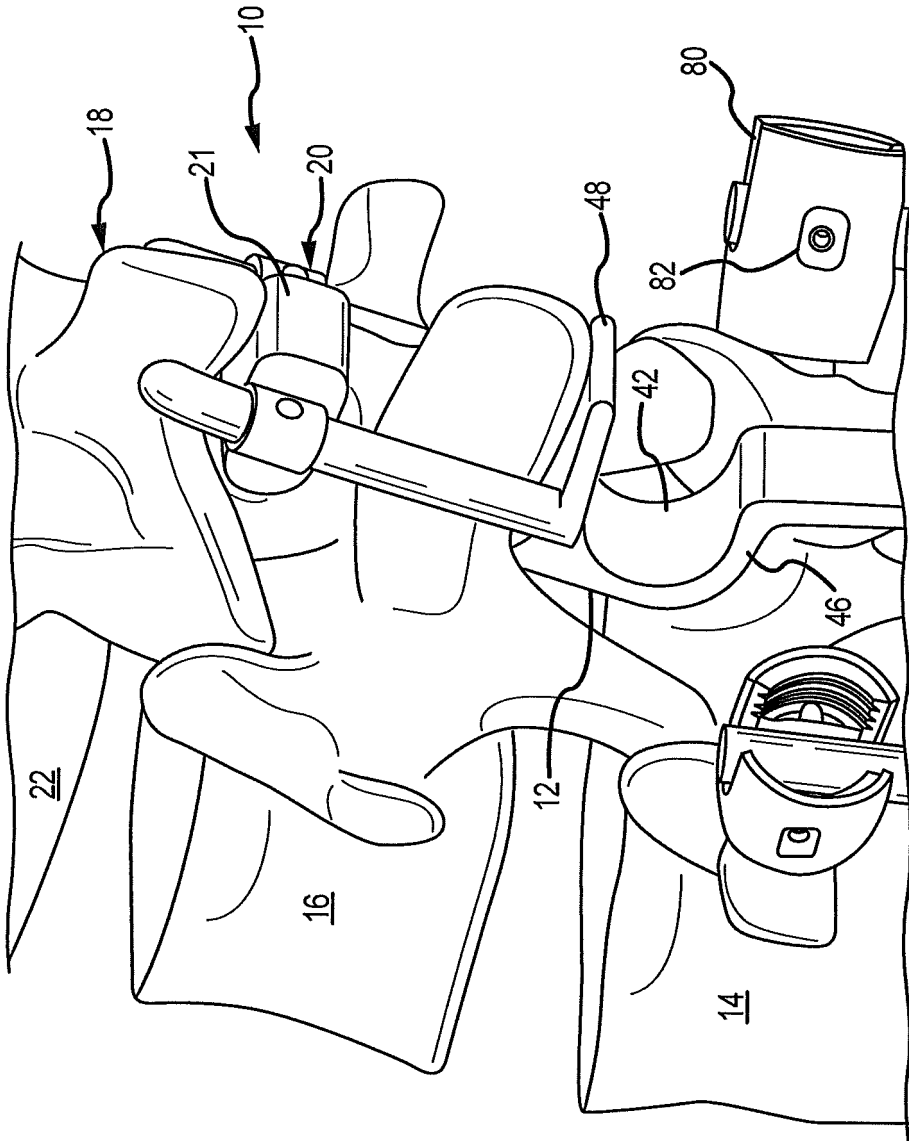


FIG.7

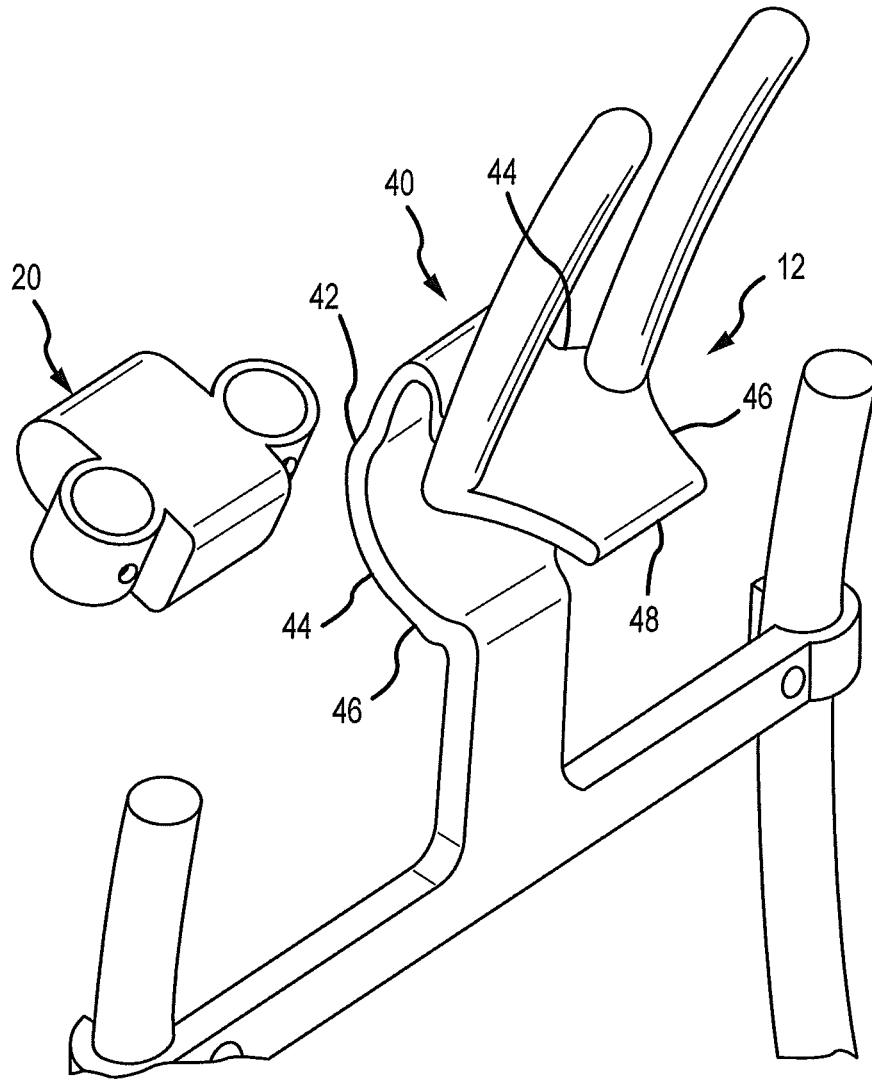


FIG. 8

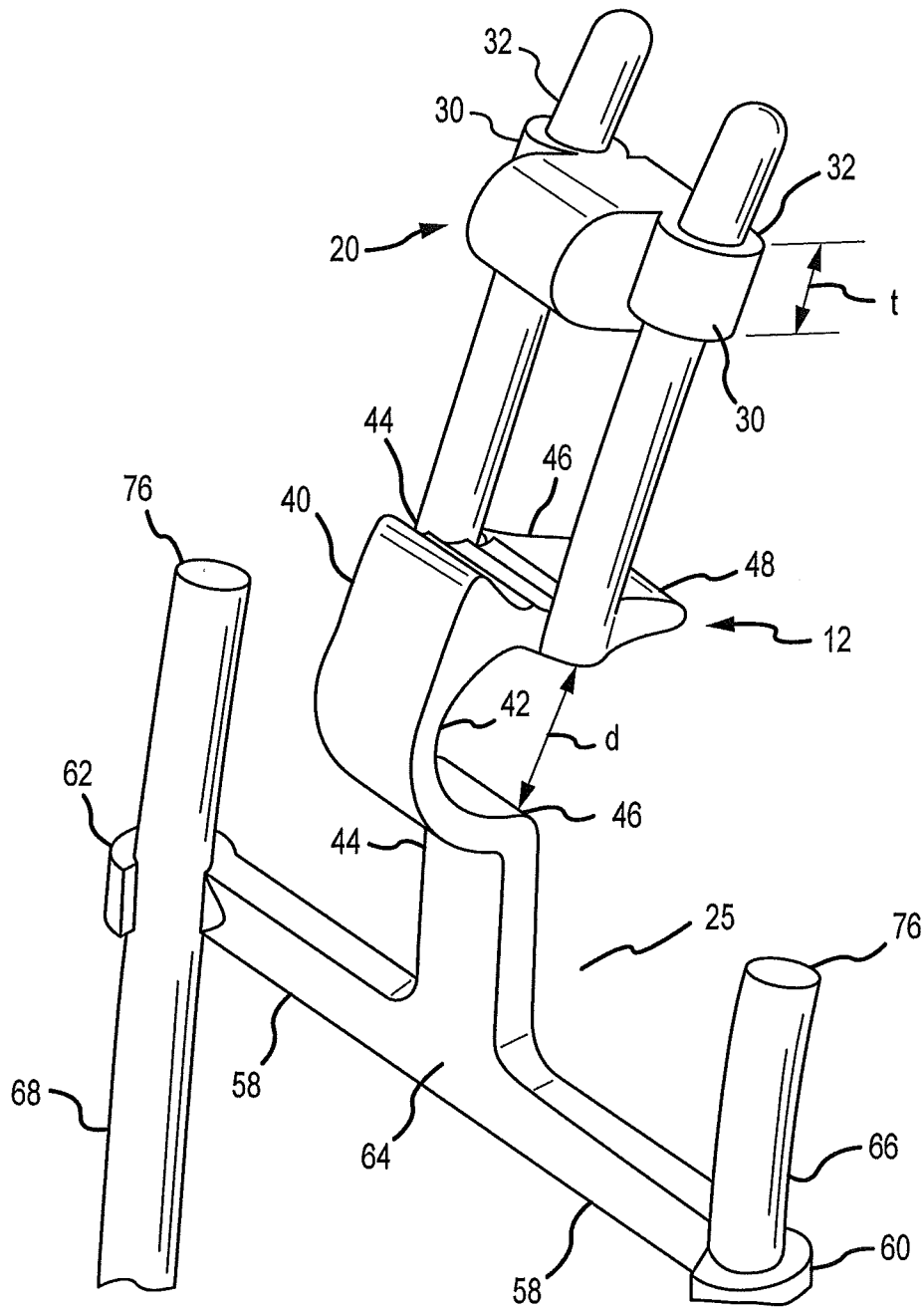


FIG. 9



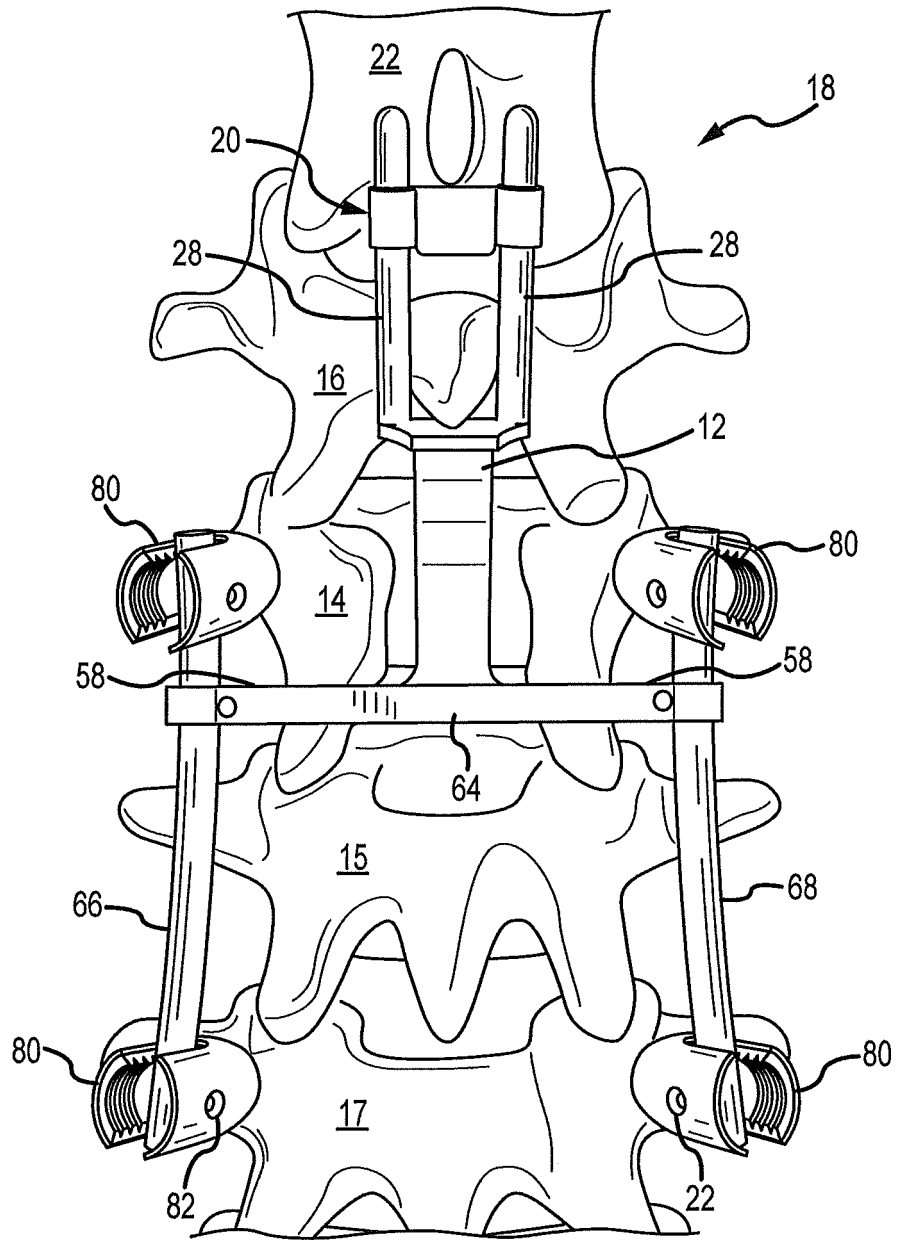


FIG.10

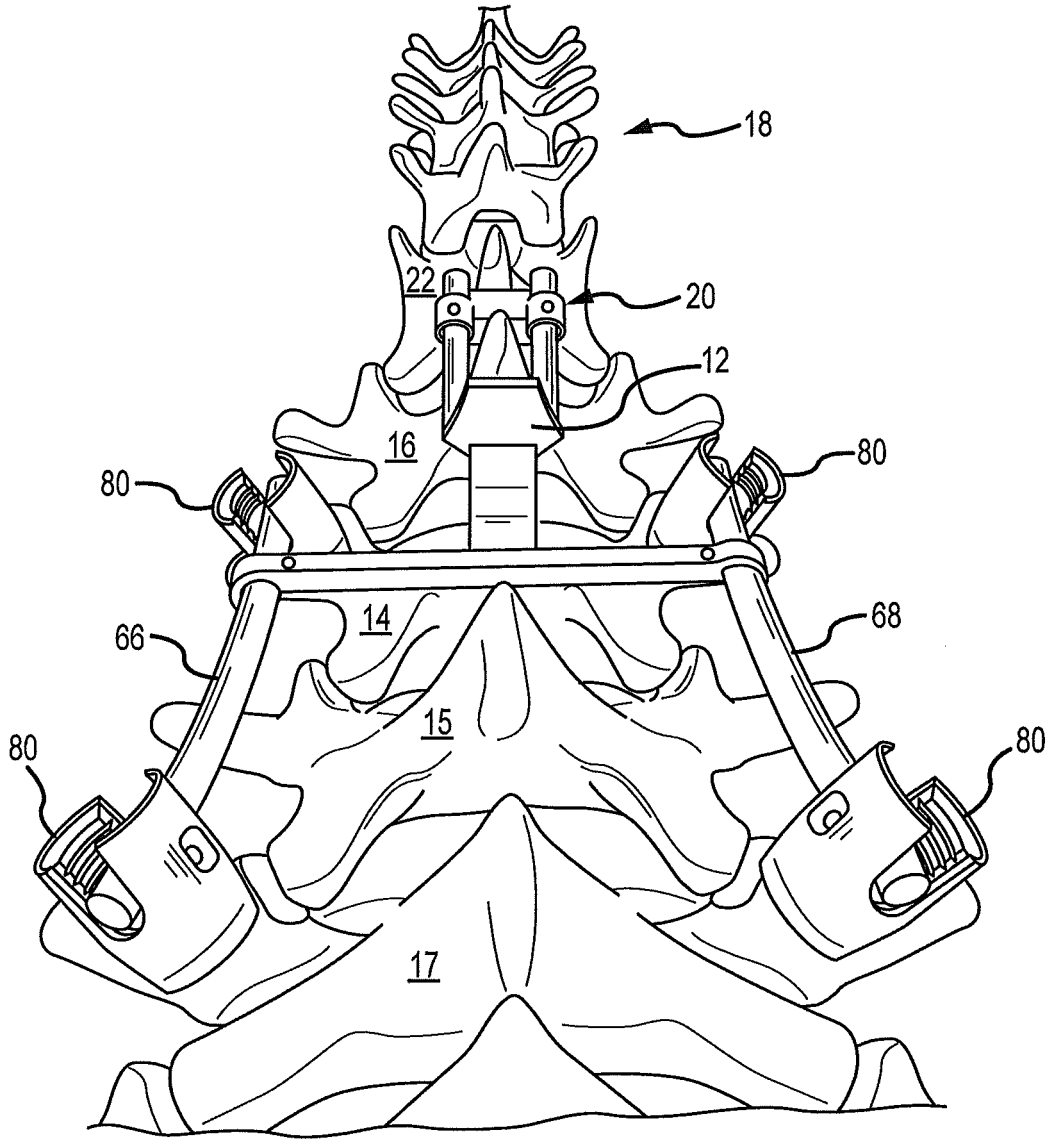


FIG. 11

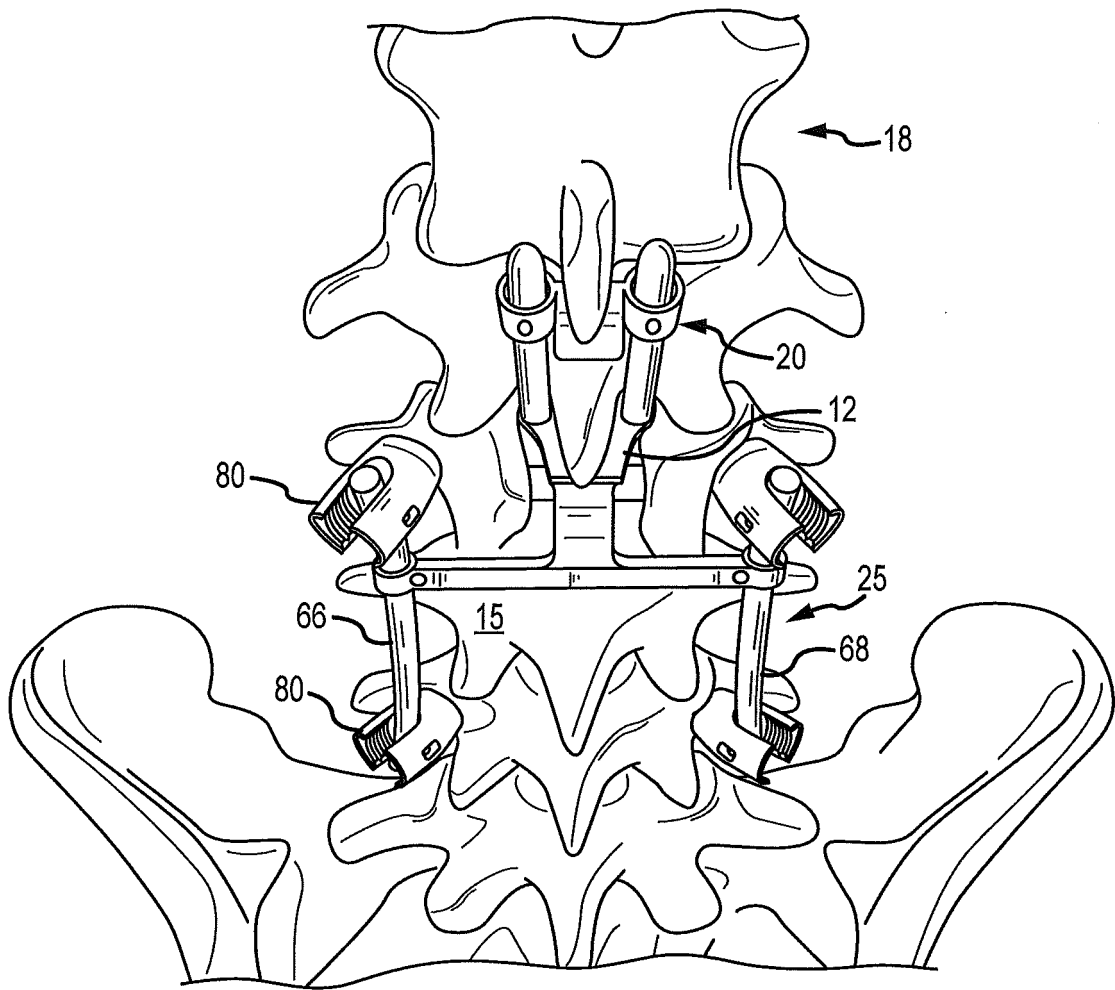


FIG.12

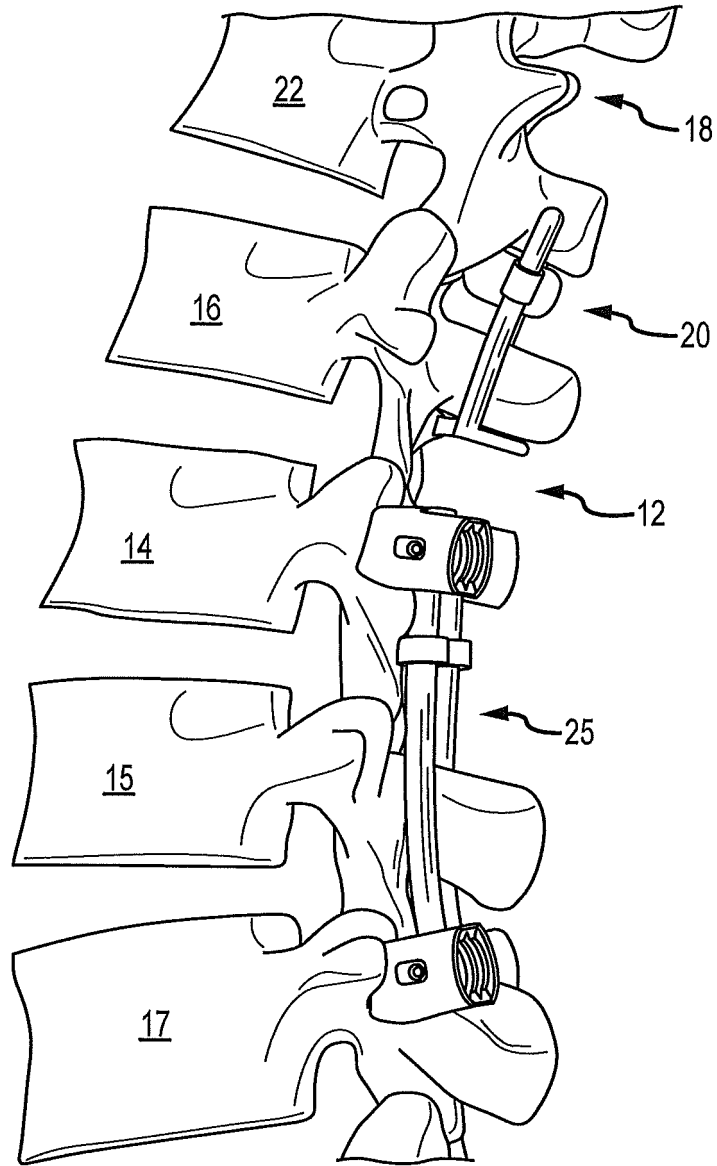


FIG.13

**REFERENCES CITED IN THE DESCRIPTION**

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