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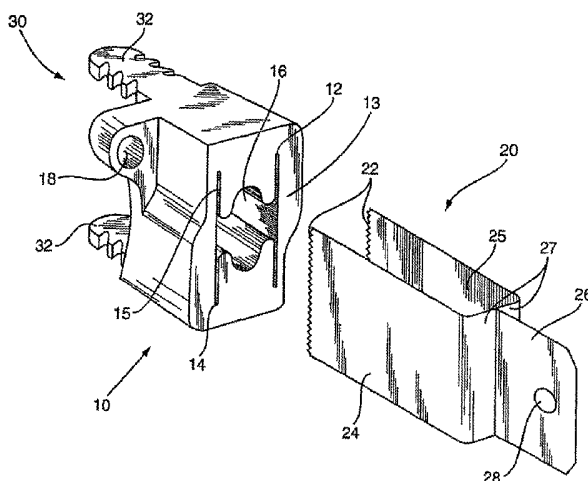
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(54) Title: GUIDE AND BLADE FOR CONTOURING VERTEBRAL BODIES



(57) Abstract: A guide (10) and a (20) blade for contouring vertebral bodies. The guide is sized to be mounted between two vertebral members and includes a pair of edges (12, 14) for receiving the blade. The pair of edges are spaced a distance apart for the first edge to align with a first vertebral member, and the second edge to align with a second vertebral member. The blade includes a pair of arms (24, 25) with at least one cutting edge (22). The arms are sized to fit within the pair of edges respectively. Using the blade and guide comprises inserting the guide adjacent to two vertebral members, and inserting the arms through the pair of edges to contour the ends of the members. In an embodiment with cutting edges at the distal ends of each of the arms, the two vertebral members can be contoured simultaneously.

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## GUIDE AND BLADE FOR CONTOURING VERTEBRAL BODIES

### Background of the Invention

5           Current surgical procedures often require a great deal of skill from the surgeon. The procedures may include making fine manipulations by hand using high-speed equipment. One example includes preparing opposing surfaces of vertebral members for receiving an intermediate device, such as preparing the end plates of adjacent vertebrae to receive a graft or interbody fusion device. Each of the end plates is contoured and shaped  
10           using a cutting instrument that is held and manipulated by the surgeon. The surgeon guides the cutting instrument by hand and relies upon experience and training to ensure the end plates are contoured correctly.

          It may be difficult for the surgeon to determine the amount of contouring and shaping required for each of the vertebral members. A trial-and-error routine is performed  
15           as the surgeon removes a first amount of material from one or both surfaces and determines whether the spacing is adequate for receiving the intermediate device. If the spacing is not adequate, the surgeon removes an additional amount from one or both of the surfaces. This routine continues until the proper amount has been removed and the surfaces are adequately prepared. The surgeon is careful not to remove too much from  
20           either surface, and instead tends to remove small increments.

### Summary of the Invention

          The present invention is directed to a device and method of preparing one or more vertebral members. The device includes a guide having a first edge for alignment relative  
25           to the first vertebral member, and a second edge for alignment relative to the second vertebral member. Embodiments of the edges include being part of individual slots within the guide, exposed edges, connected by an opening that extends between a portion of each of the slots, or may be part of a single enlarged opening. A blade is inserted into the first and second edges for contouring the vertebral members. The blade includes a first arm  
30           having a first cutting edge on the distal end, and a second arm having a second cutting

edge on the distal end. The arms are sized and spaced to correspond to the guides such that both blades are within the guide and contouring the vertebral bodies at the same time.

In some embodiments, the guide may include a spacer that extends outward from a rear face for mounting between the vertebral members. The spacer may include a single prong, or may include a number of prongs depending upon the application.

In one embodiment, the guide is connected to a handle. This allows for the surgeon to position the guide relative to the vertebral members without having their vision obscured by their hands. Additionally, the guide may be too small for the surgeon to hold and the guide provides for more secure gripping. The handle also allows the surgeon to feel the guide during the procedure.

In one embodiment, the blade includes a first arm with a cutting edge, and a second guide arm that does not include a cutting edge. The blade functions by the guide arm contacting the reference edges to position the cutting edge at the proper location relative to the vertebral member.

#### Brief Description of the Drawings

Figure 1 is a perspective view of a front of a guide and blade constructed according to one embodiment of the present invention;

Figure 2 is a perspective view of the rear of the guide illustrated in Figure 1;

Figure 3 is side view illustrating the guide and blade relative to two vertebral members according to one embodiment of the present invention;

Figure 4 is a front view of a guide constructed according to another embodiment of the present invention;

Figure 5 is a perspective view of a rear of the guide illustrated in Figure 4;

Figure 6 is a perspective view of a front of a guide constructed according to another embodiment of the present invention;

Figure 7 is a perspective view of the rear of an embodiment of the guide constructed according to another embodiment of the present invention;

Figure 8 is a perspective view of the blade constructed according to one embodiment of the present invention;

Figure 9 is a perspective view of a handle attached to a guide in accordance with one embodiment of the present invention;

Figure 10 is a perspective view of another embodiment of a guide constructed according to the present invention;

5 Figure 11 is a perspective view of another embodiment of the blade constructed according to the present invention;

#### Detailed Description

10 The present invention is directed to a guide 10 and a blade 20 for contouring vertebral bodies. The guide 10 is sized to be mounted between two vertebral members and has a pair of edges 12, 14 for receiving a blade 20 as illustrated in Figure 1. The pair of edges 12, 14 are spaced a distance apart for the first edge 12 to align with a first vertebral member, and the second edge 14 to align with a second vertebral member. The blade 20 includes a pair of cutting edges 22 sized to fit within the pair of edges 12, 14 respectively.  
15 The cutting edges 22 are positioned at a distal end of a pair of arms 24 with a mount 26 at the proximal end. Using the blade 20 and guide 10 comprises inserting the guide 10 adjacent to two vertebral members, and inserting the blades 20 through the pair of edges 12, 14. The edges 12, 14 are sized for the blades to move within and contour the members.

20 The guide 10 is constructed of a rigid material, such as stainless steel. The guide 10 is sized such that the first and second edges 12, 14 position the blade at the proper placement relative to the vertebral members and support the blade 20 during the contouring operation. The guide 10 may also act as a spacer to position the two vertebral members an appropriate distance apart for performing the contouring process. In one  
25 embodiment, guide 10 is constructed of a unitary member. In another embodiment, guide 10 is an assembled part comprising two or more different sections.

The first and second edges 12, 14 extend through the guide 10 and position and support the blade 20 while contouring the vertebral members. In the embodiment illustrated in Figures 1 and 2, the first and second edges 12, 14 are part of slots 13, 15  
30 respectively, that have a width to receive the blade 20. In this embodiment, the first and second edges 12, 14 may be either the interior or exterior edge of the slots 13, 15. The

slots 13, 15 have a length and a width greater than the blade 20 to provide room for the blade 20 to operate during the contouring process. The slots 13, 15 may be sized for the blade 20 to reciprocate back and forth, up and down, or various other cutting techniques that are well known in the art. Slots 13, 15 may have a variety of widths for alignment relative to the vertebral members. The first and second edges 12,14 may have a variety of shapes depending upon the specific application. In the embodiment illustrated in Figures 1 and 2, the first and second edges 12, 14 are parallel to contour parallel ends of the adjacent vertebral members. In the embodiment of Figures 1 and 2, the first and second edges 12,14 are straight. However, depending upon the application, other embodiments may be included such as curved edges and jagged edges. In one embodiment, the blade 20 is shaped to conform to the shape of the edges 12, 14.

In some embodiments, an opening 16 extends between the first and second edges 12, 14. The opening 16 is sized for the surgeon to visually observe the contouring process. The opening 16 further allows for access to the vertebral members for irrigation and bone removal during the contouring process. Opening 16 may have a variety of sizes and shapes depending upon the application. Opening 16 may extend to include the first and second edges 12,14 as illustrated in Figures 1 and 2. In another embodiment, opening 16 is positioned between the first and second edges 12, 14.

In one embodiment such as illustrated in Figures 1 and 2, a spacer 30 extends from a rear face of the guide 10 for spacing the vertebral members. Spacer 30 may have a variety of shapes to fit between the vertebral members and space them a predetermined distance apart. Spacer 30 is spaced between the first and second edges 12, 14 to not interfere with access to the vertebral members during the contouring. In another manner, the distance between the first and second edges 12, 14 is about equal to or greater than the width of the spacer 30. In one embodiment, the distance between the first and second edges 12, 14 is about the same as the width of the spacer 30 such that the reference edges 12, 14 align with the edges of the vertebral members to contour only a small amount. In another embodiment, the distance between the first and second edges 12, 14 is greater than the width of the spacers 30 such that reference edges 12, 14 align further on the vertebral members to contour a larger amount.

In one embodiment illustrated in Figures 1 and 2, spacer 30 includes two prongs 32 that extend outward from the guide 10. Each prong includes jagged edges 34 to reduce the likelihood of the guide 10 inadvertently moving from between the vertebral members. In this embodiment, the jagged edges are angled from the ends toward the guide body such that insertion of the prongs 32 is not made more difficult or troublesome than with smooth edges. The angled edges 34 catch on the vertebral members to prevent inadvertent removal.

Apertures 18 may be positioned for attaching the guide 10 to the vertebral members. Apertures 18 may be spaced at a variety of locations about the guide 10. In one embodiment illustrated in Figures 1 and 2, apertures 18 are located on opposite edges such that a first aperture is aligned with a first vertebral body and a second aperture is aligned with a second vertebral body. Each aperture 18 is sized to receive a fastener 19 for connection to the vertebral members.

In one embodiment, blade 20 comprises first and second arms 24, 25 extending a distance apart by a span 27. A mount 26 is positioned opposite the arms 24, 25 for attachment to a drive source. In one embodiment, arms 24, 25 are the same length such that cutting edges 22 at the distal end are aligned and contour the vertebral members to the same depth. The arms 24, 25 are spaced a distance apart to align respectively with the first and second edges 12, 14. In one embodiment, arms 24, 25 are parallel and span 27 is substantially perpendicular. The height of the blade 20 is the distance extending between the edges 22 and the span 27. During use, the span 27 may contact the front face of the guide 10 to control the depth of contouring of the vertebral members.

In one embodiment, cutting edges 22 include a plurality of individual teeth that contact the vertebral members. In one embodiment, cutting edges 22 are substantially straight. In another embodiment, cutting edges 22 have an arc such that the midsection extends outward from the mount 26 a greater distance than the outer edges. The amount of arc may vary depending upon the application. Other types of cutting edges 22 with different teeth sizes and orientations are known and may be used in the present invention.

Mount 26 provides for attaching the blade 20 to a power device. Mount 26 may have a variety of shapes and sizes, such as a single outwardly extending fin as illustrated

in Figure 1. Apertures 28 may be positioned for attaching the blade 20 to the power device.

Figure 3 illustrates one embodiment of the guide 10 and blade 20 in use. A first vertebral member 210 and a second vertebral member 220 are separated with a disc space 230 positioned therebetween. Guide 10 is attached via fasteners 19 extending through the apertures 18 into the first and second vertebral members 210, 220. Prongs 32 are positioned within the disc space 230 and space apart the first and second vertebral members 210, 220. With the guide 10 attached, the first edge 12 is positioned relative to the first vertebral member 210 and the second edge 14 is positioned relative to the second vertebral member 220. Blade 20 is inserted within the guide 10 with the first arm 24 aligned with the first edge 12 and the second arm 25 aligned with the second edge 14. The blade arms 24, 25 are sized to extend through the guide such that the cutting edges 22 contact the vertebral members 210, 220. In this embodiment, end plates within the vertebral members 210, 220 are contoured. The blade 20 is configured such that both vertebral members 210, 220 are contoured concurrently.

Figures 4 and 5 illustrate another embodiment of the guide 10. The guide 10 includes first and second edges 12, 14 separated a distance apart by a solid guide body. The slots including the first and second edges 12, 14 may have a variety of widths depending upon the application. This embodiment does not include an opening. Figure 5 illustrates a rear view having a pair of spacers 32 that extend outward from a rear face of the guide 10. The spacers 32 are spaced inward from the edges of the guide 10 at points directly between the first and second edges 12, 14. Figure 6 illustrates another embodiment with the guide 10 having a single opening 16 that includes the first and second edges 12, 14. The first and second edges 12, 14 are for positioning and supporting the blade 20. The single opening 16 provides for visual assistance and access to the vertebral members during the contouring process.

Figure 7 illustrates another embodiment featuring a single spacer 32 extending outward from a rear face of the guide 10. The spacer 32 is positioned between the first and second edges 12, 14. The spacer 32 has a smooth tapered edge that narrows to a rounded end 36. The rounded end 36 eases the insertion between the vertebral members. The spacer 32 is aligned parallel with the first and second edges 12, 14. The spacer 32 has



a width  $w$  sized to space the vertebral members a distance apart to align the first edge 12 with the first vertebral body and the second edge 14 with the second vertebral body.

Figure 10 illustrates another embodiment of the guide 10 having exposed first and second edges 12, 14. Edges 12, 14 are spaced a desired distance apart to support and  
5 guide the blade 20. In one embodiment, stop edges 11 are positioned on one or both ends of the edges 12, 14 to control the extent of blade 20 movement. Stop edges 11 prevent the blade 20 from inadvertently contacting sections of the vertebral members that are not to be contoured. In another embodiment, there are no stop edges 11. Handle 54 may be  
10 attached to the guide 10 to position the edges 12, 14. A spacer 32 extends outward from one side of the guide 10. The spacer 32 may have a variety of widths, including a first and second edge that align substantially edges 12, 14, and a width with first and second edges each being positioned within edges 12, 14. In another embodiment (not illustrated), there is no spacer 32.

Figure 9 illustrates a handle 50 attached to the guide 10. The handle 50 allows the  
15 surgeon to position and hold the guide 10 relative to the vertebral members. The handle 50 provides for the surgeon to use tactile senses to position the guide 10. A grip 52 may further assist the surgeon with the feel of the instrument. In one embodiment, grip 52 is off-center from the guide 10 such that the surgeon can visually see the guide 10 when holding the grip 52. The elongated arm 54 may have a variety of sizes and configurations.  
20 In one embodiment as illustrated in Figure 9, a distal end of the elongated arm 54 attaches to a side wall of the guide 10. In one handle embodiment, the guide 10 includes a spacer 30. In another embodiment, the guide 10 does not include a spacer 30. The handle 50 may be attached to a variety of different guides 10.

A variety of different power sources may drive the blade 20. Embodiments  
25 include a rechargeable battery, gas turbine mechanism, and any standard electrical source, such as 110 volt, 60 cycle power sources, with or without a transformer to reduce the voltage as necessary. In one embodiment, the blade 20 is oscillated back and forth in a direction parallel with or aligned with the first and second edges 12, 14. In another  
30 embodiment, blade 20 is oscillated in an in-and-out direction substantially perpendicular to the first and second edges 12, 14.

In one embodiment as illustrated in Figure 8, blade 20 is constructed of a single piece of material having a fold that comprises the edge of the mount 26. In this embodiment, the arms 24, 25 and span 27 is a single ply, with the mount 26 being a double play. In another embodiment as illustrated in Figure 1, the mount 26 is a separate piece that is attached to the span 27 and arms 24, 25.

Figure 11 illustrates another embodiment of a blade 20. The blade comprises a first arm 24 with cutting edge 22. A second arm comprises a guide arm 29 sized to contact a first or second edge 12, 14 to position the first arm 24. Guide arm 29 does not include a cutting edge 22. The guide arm 29 is sized to contact one of the reference edges 12, 14 and may have a number of different shapes and sizes. The guide arm 29 may have a variety of lengths, provided it is not of such a length to contact the vertebral members and interfere with the contouring process. In the guide of Figure 10, the span 27 may be wider than the distance between the reference edges 12, 14. The cutting edge 22 of the first arm 24 is aligned by the guide arm 29 contacting one of the reference edges 12 or 14 as the first arm 24 may be spaced from and not contact the other reference edge 12 or 14.

In one embodiment, the first and second arms 24, 25, or the first arm 24 and guide arm 29 are spread apart wider than the distance between the first and second reference edges 12, 14. In this embodiment, the position of the blade performing the contouring is accomplished by the opposite reference edge. By way of example using the guide illustrated in Figure 10 and the blade illustrated in Figure 1, the first arm 24 and second arm 25 are spaced apart a distance greater than the distance between the reference edges 12, 14. When the first arm 24 and cutting edge 22 is contouring the vertebral member at a point spaced from the first reference edge 12, the position of the contouring is aligned by the second arm 25 contacting the second reference edge 14. The opposite vertebral member may then be contoured by the second arm 24 at a position aligned by the first arm 24 contacting the first reference edge 12. In the embodiment of the blade illustrated in Figure 11, cutting edge 22 is first aligned by the guide arm 29 contacting the first reference edge 12, and then contouring the opposite vertebral member by the guide arm 29 contacting the second reference edge 14. This embodiment may be accomplished using an opened sided guide as illustrated in Figure 10, or a closed sided guide with adequately wide slots such as illustrated in Figure 1.

In one embodiment of using the guide 10 and blade 20, the guide 10 is positioned relative to the two vertebral members. In one embodiment, the guide 10 is attached to the vertebral members by inserting fasteners through apertures 18 within the guide body and into the members. In another embodiment, the guide 10 is attached to a handle 50 and the surgeon holds the guide 10 in position.

Once the guide 10 is properly positioned, the blade 20 is inserted into the guide 10. In one embodiment, the blade 20 includes two opposing arms 24, 25 that align against a first and second edge 12, 14 respectively that extend through the guide 10. The arms 24, 25 each include cutting edges 22 and the vertebral members are contoured at the same time. In this embodiment, the first and second edges 12, 14 locate and support the arms 24, 25 to ensure the proper location and amount of contouring is performed. The edges 12, 14 are sized to allow the blade 10 to move to contour the members. Movement may be oscillating, reciprocating, vibratory, and other known manners. In another embodiment, a first arm 24 contacts a first edge 12 to position a cutting edge 22 on the second arm 25 to contour a first vertebral body. The blade 20 is then re-adjusted with the first arm contacting the second edge to position the cutting edge 22 on the second arm 25 to contour the second vertebral body. Various other manners of orientating and using the guide 10 and blade 20 are disclosed, as these embodiments are merely examples to illustrate several manners of using the invention.

The present invention may be carried out in other specific ways than those herein set forth without departing from the scope and essential characteristics of the invention. The present invention may be used for other applications such as for knee surgery, elbow surgery, and others. In one embodiment, the process of contouring the vertebral members comprises using a plurality of different blades 20 each having increasingly longer arms 24, 25. The vertebral members may already be distracted by other means prior to the application of the guide and blade. The blades are inserted into the guide in order to increase the depth of the contouring until the correct amount has been obtained. In another embodiment, no spacer 30 is positioned on the rear face of the guide 10. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, and all changes coming within the meaning and equivalency range of the appended claims are intended to be embraced therein.

What is claimed is:

1. A device for contouring first and second vertebral members comprising:

5 a guide sized to be positioned adjacent to the two vertebral members, the guide comprising a first edge and a second edge spaced a predetermined distance apart; and

10 a blade comprising a first arm and a second arm each with cutting edges on a distal end and each having a height greater than a guide height, the first arm and the second arm being spaced apart the predetermined distance, the first arm having a length less than the first edge and the second arm comprising a length less than the second edge for the blade to move back and forth along the first edge and the second edge with the cutting edges contacting the first and second vertebral members to contour the first and second vertebral members.

15 2. The device of claim 1, wherein the first edge and the second edge of the opening have the same length.

3. The device of claim 1, wherein the first edge and the second edge are formed from a single opening within the guide.

20 4. The device of claim 1, wherein the first edge comprises a first slot positioned adjacent to a first edge of the guide and the second edge comprises a second slot positioned adjacent to a second edge of the guide.

25 5. The device of claim 1, further comprising a spacer extending outward from a rear face of the guide to space apart the first vertebral member and the second vertebral member, the spacer being positioned between the first edge and the second edge.

30 6. The device of claim 5, wherein the spacer comprises two extensions extending outward from the rear face, the extensions having a substantially identical shape and size.

7. The device of claim 5, wherein the spacer has a first surface to contact the first vertebral member and a second surface to contact the second vertebral member, the first and second surfaces being parallel with the first and second edges.

5 8. The device of claim 5, wherein the spacer has a first surface to contact the first vertebral member and a second surface to contact the second vertebral member, the first and second surfaces being perpendicular with the first and second edges.

10 9. The device of claim 5, wherein the spacer further comprises a jagged surface comprising a plurality of angled edges.

10. The device of claim 1, further comprising a handle attached to the guide.

15 11. The device of claim 1, wherein the guide further comprises apertures sized to receive fasteners to mount the guide to the first and second vertebral members.

12. The device of claim 1, wherein the blade first arm and second arm are parallel.

20 13. The device of claim 1, wherein the blade is constructed of a single piece of material.

14. The device of claim 1, further comprising stop edges positioned on the ends of the first edge and the second edge.

25 15. A guide for preparing vertebral members within a patient, the guide comprising:  
a body having a rear face for placing towards the vertebral members, a front face for placing outward from the vertebral members, and a side face extending between the front face and the rear face;  
a spacer extending outward from the rear face to be inserted between the vertebral members;  
30 a first edge and a second edge each extending from the front face to the rear face, the first edge and second edge being parallel; and

an elongated handle having a first end mounted to the side face of the body and a second end comprising a grip and being distanced from the first end.

16. The guide of claim 15, wherein the grip is off-center from the guide.

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17. A device for contouring first and second vertebral members comprising:

a guide having a length to extend between the first and second vertebral members, the guide comprising

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a first edge and a second edge in parallel alignment and each extending through a height of the guide, the first edge and the second edge being distance a predetermined distance apart;

15

a spacer extending outward from a rear face of the guide and having a first surface to contact the first vertebral member and a second surface to contact the second vertebral member, the second vertebral member, the first surface and the second surface being spaced apart a distance less than the predetermined distance; and

20

a blade having a first arm with a first cutting surface and a second arm with a second cutting surface, the first arm and the second arm being in parallel alignment, the first arm and the second arm each having a height greater than the height of the guide.

18. The device of claim 17, wherein the spacer comprises a single prong extending outward from the rear face of the guide.

25

19. The device of claim 17, wherein the spacer comprises a pair of prongs extending outward from the rear face of the guide.

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20. The device of claim 17, wherein the first and second edges are contained within a single opening extending through the height of the guide.

21. A device for contouring vertebral members comprising:

a body having a rear face for placing towards the vertebral members and a front face for placing outward from the vertebral members;

5 a first edge and a second edge each extending through the body between the rear face and the front face;

a blade comprising a first arm and a second arm, the first arm having a length greater than a distance between the front face and the rear face and comprising a cutting surface along a distal edge, the second arm being shorter than the first arm and comprising a contact surface for contacting the first edge and the second edge.

10

22. The device of claim 21, wherein a span member extends between the first arm and the second arm, the first arm and second arm being spaced apart a predetermined distance.

23. The device of claim 22, wherein the first arm and the second arm are spaced apart a distance greater than between the first edge and the second edge.

15

24. A method of contouring first and second vertebral members, the method comprising the steps of:

aligning a guide along the vertebral members by aligning a first edge of the guide relative to the first vertebral member and aligning a second edge of the guide relative to the second vertebral member;

20

inserting a blade into the guide with a first arm and a first cutting edge extending into the first edge and a second arm and a second cutting edge extending into the second edge; and

25

simultaneously contouring the vertebral members by moving the first cutting edge along the first vertebral member and moving the second cutting edge along the second vertebral member.

25. The method of claim 24, further comprising holding the guide relative to the vertebral bodies while simultaneously contouring the vertebral members.

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26. The method of claim 24, further comprising attaching the guide to a handle and manipulating the guide by moving the handle.

5 27. The method of claim 24, further comprising attaching the guide to a handle and tactilely feeling the guide contacting the vertebral members.

28. A method of contouring first and second vertebral members comprising the steps of:  
aligning a guide along the vertebral members, the guide comprising a first edge  
and a second edge;

10 positioning a first blade arm against the first edge with a blade cutting edge positioned relative to the first vertebral member;

contouring the first vertebral member by moving the first blade arm along the first edge with the blade cutting edge contacting the first vertebral member;

15 positioning the first blade arm against the second edge with the blade cutting edge positioned relative to the second vertebral member; and

contouring the second vertebral member by moving the first blade arm along the second edge with the blade cutting edge contacting the second vertebral member.

20 29. The method of claim 28, further comprising attaching the guide to the vertebral members.

30. The method of claim 28, further comprising contacting the first blade arm with stop edges on the guide to control a lateral extent of contouring.

25



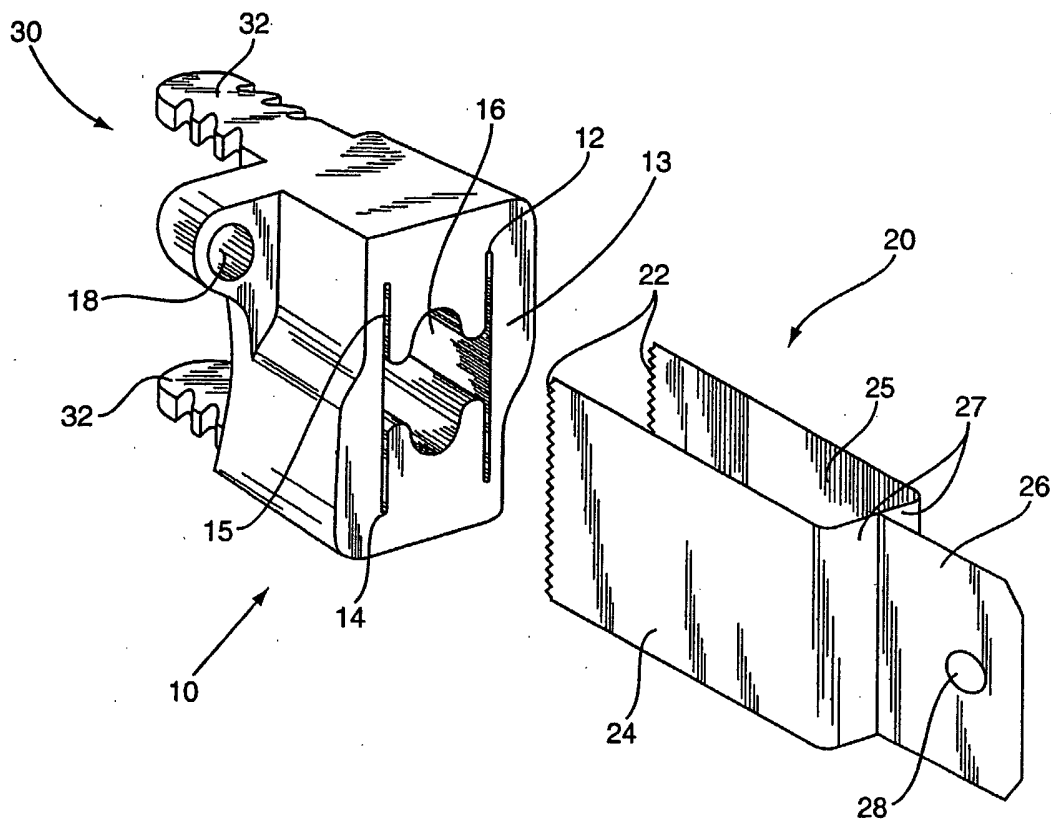


FIG. 1

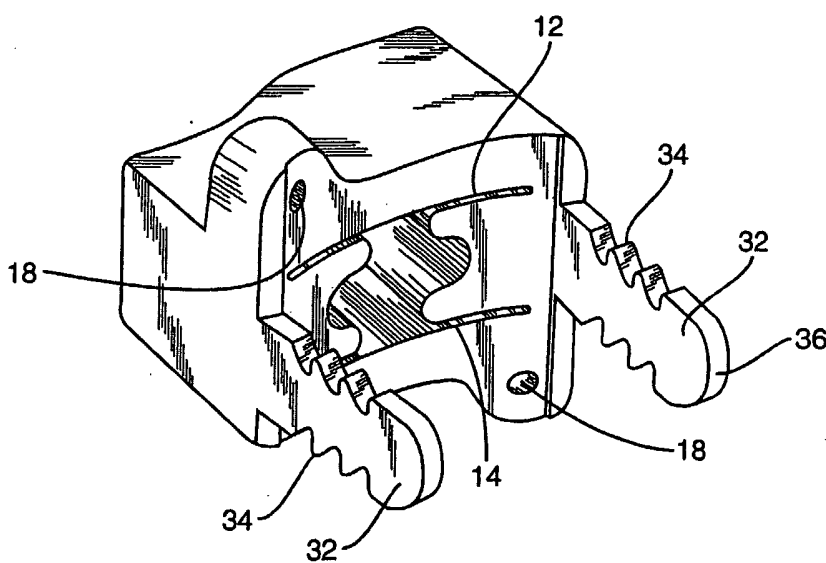
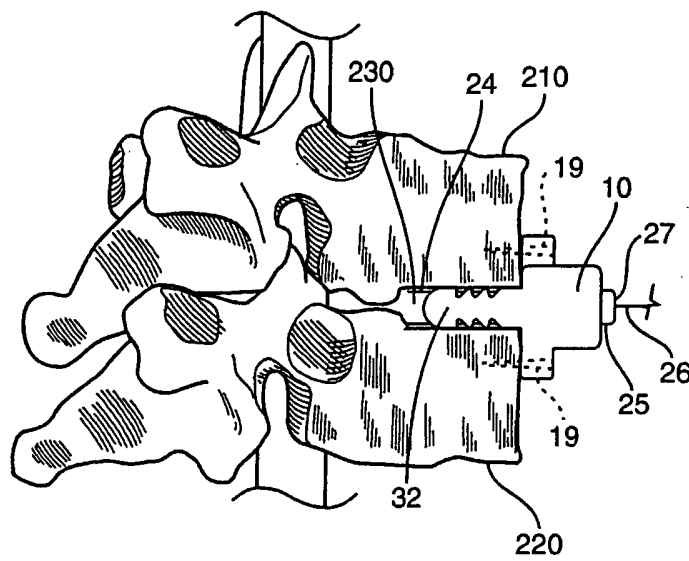
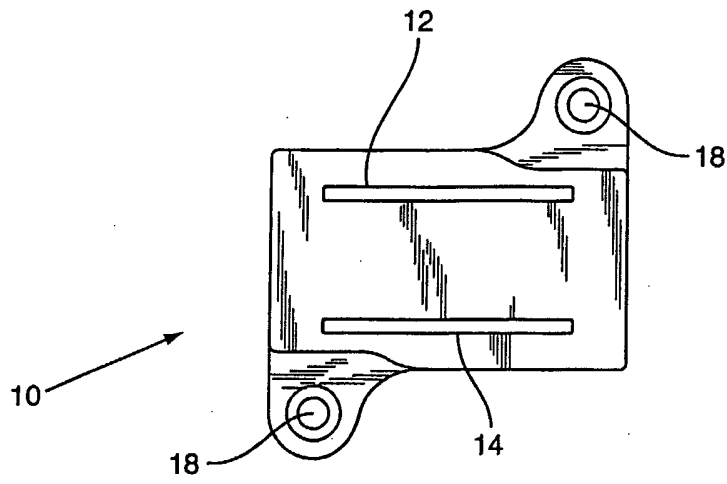


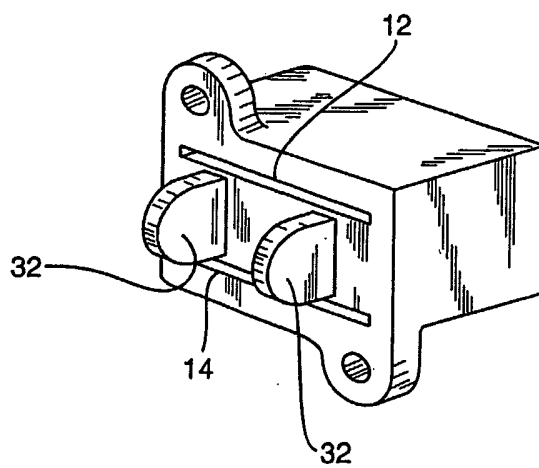
FIG. 2



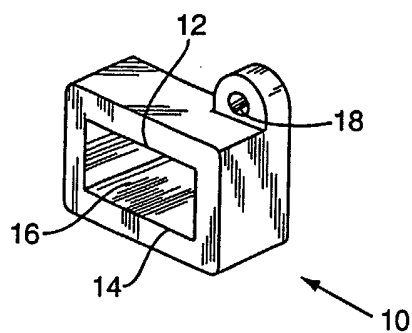
**FIG. 3**



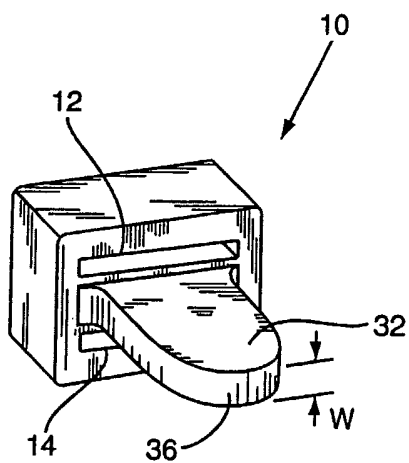
**FIG. 4**



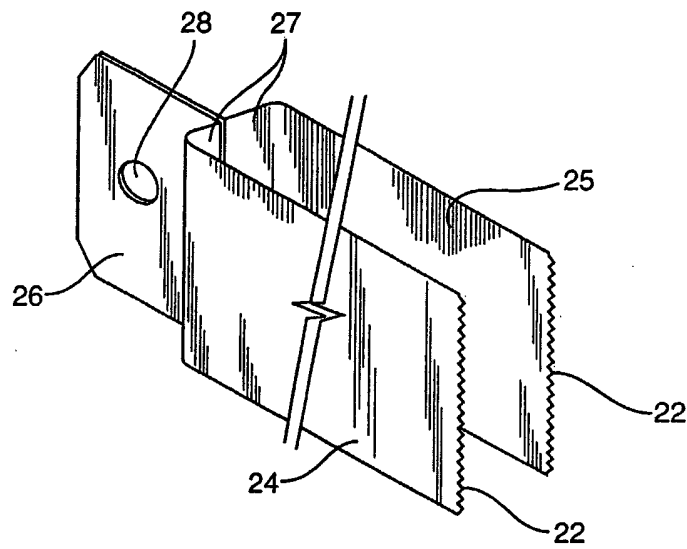
**FIG. 5**



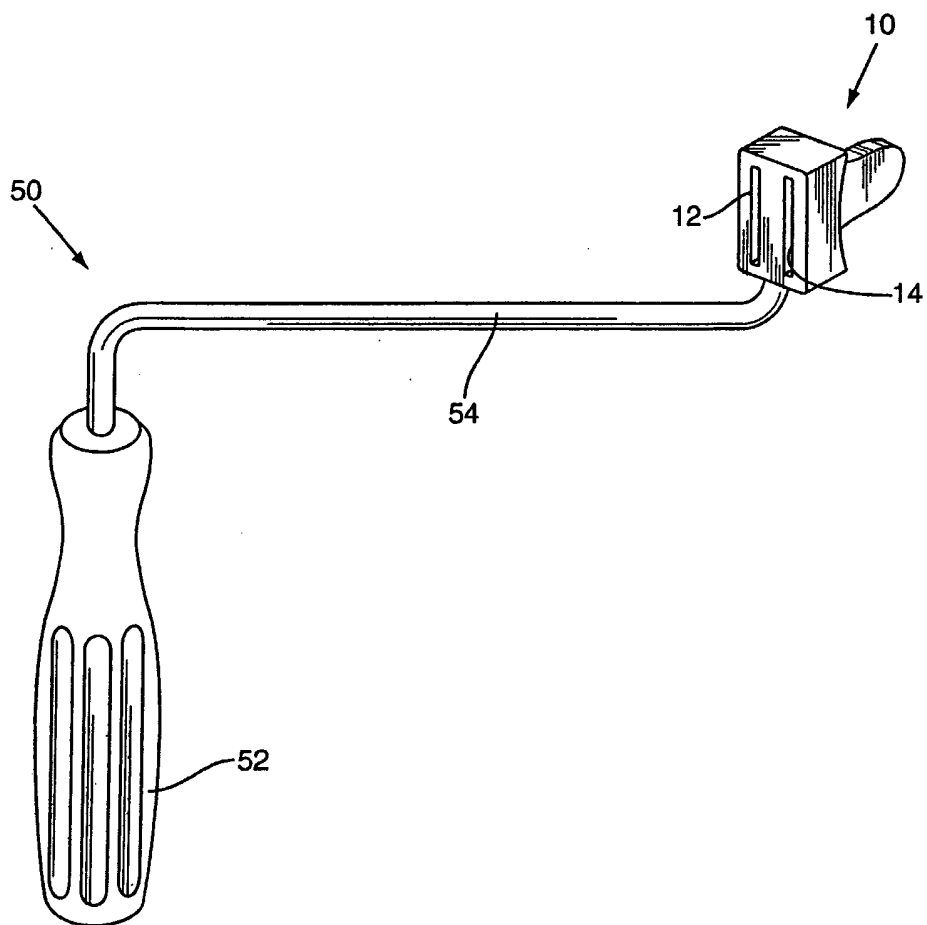
**FIG. 6**



**FIG. 7**



**FIG. 8**



**FIG. 9**

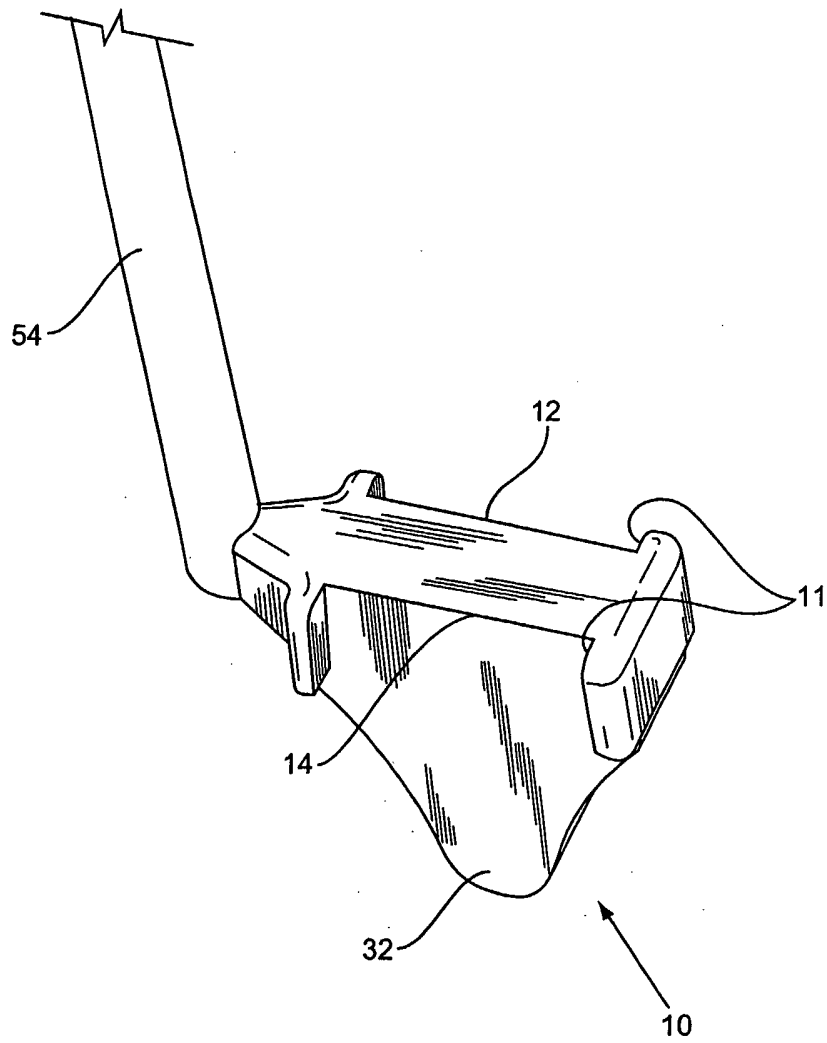
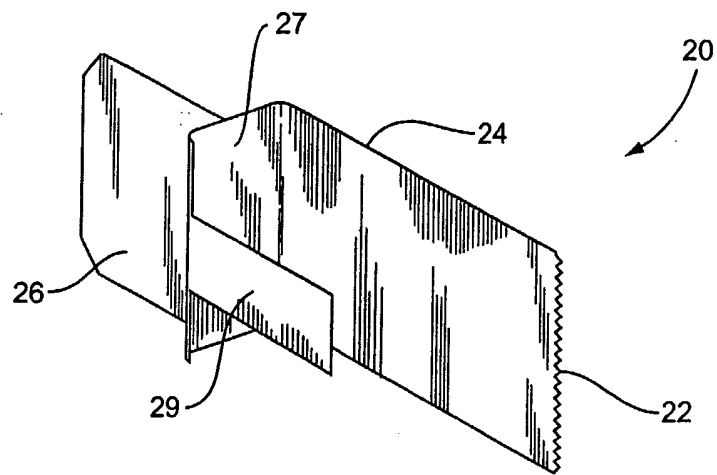


FIG. 10



**FIG. 11**

INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 03/19137

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61B17/14 A61B17/15

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)  
IPC 7 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 practical, search terms used)  
EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 93 25157 A (RADERMACHER KLAUS ;STAUDTE HANS WALTER (DE); RAU GUENTER (DE)) 23 December 1993 (1993-12-23)	15,16
A	column 13, line 4-10 -column 22-23; figures 1B,6B,9,12B	1-14, 17-23
Y	WO 01 62166 A (DERIDDER STEVEN D ;SDGI HOLDINGS INC (US); LANGE ERIC C (US); MCGA) 30 August 2001 (2001-08-30)	15,16
A	column 11-12 -column 18-19; figures 3,5A,5C,6C,16,29	1-14, 17-23
A	US 5 423 825 A (LEVINE ANDREW S) 13 June 1995 (1995-06-13) column 6-7 -column 10, line 60-63; figure 1	1-14, 17-23
	-/--	

Further documents are listed in the continuation of box C.  Patent family members are listed in 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 document 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.
- \*Z\* document member of the same patent family

Date of the actual completion of the international search <b>7 October 2003</b>	Date of mailing of the international search report <b>23/10/2003</b>
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Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer <b>Assion, J-C</b>
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## INTERNATIONAL SEARCH REPORT

Internatio plication No  
PCT/US 03/19137

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US H571 H (HOLLINGER ET AL.) 7 February 1989 (1989-02-07) column 1, line 30-38 -column 3; figure 1 ---	1-14, 17-23
A	US 2002/058944 A1 (MICHELSON GARY K) 16 May 2002 (2002-05-16) paragraph '0003! - paragraphs '0051!-'0064!; figures 5-8 -----	1-23

INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 03/19137

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 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.: 24-30  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
  
- 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 II Observations where unity of invention is lacking (Continuation of item 2 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 fee, this Authority did not invite payment of any additional fee.
  
- 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.
- No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

Internatic	lication No
PCT/US 03/19137	

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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WO 0162166	A	30-08-2001	AU 4161201 A CA 2395390 A1 EP 1259175 A2 JP 2003523257 T WO 0162166 A2 US 2003032962 A1	03-09-2001 30-08-2001 27-11-2002 05-08-2003 30-08-2001 13-02-2003
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US H571	H	07-02-1989	NONE	
US 2002058944	A1	16-05-2002	NONE	