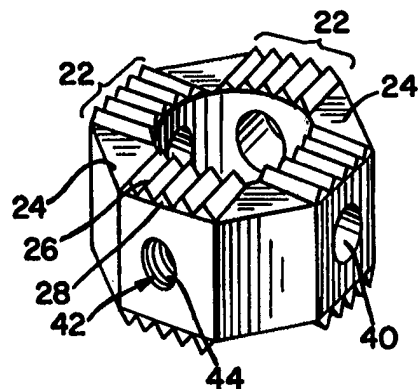




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US98/04777 (22) International Filing Date: 12 March 1998 (12.03.98) (30) Priority Data: 08/823,509 24 March 1997 (24.03.97) US (71)(72) Applicant and Inventor: HAIDER, Thomas, T. [US/US]; 2357 Knob Hill Drive, Riverside, CA 92506 (US). (74) Agent: JACKSON, Harold, L.; Jackson Law Corporation, Suite N, 14751 Plaza Drive, Tustin, CA 92780 (US).		(81) Designated States: CN, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>
(54) Title: SPINAL IMMOBILIZATION DEVICE AND METHOD (57) Abstract A spinal immobilization device in the form of a hollow cage (18), available in a plurality of lengths, is provided to support adjacent bone segments and allow the segments to fuse together. The bone segments are prepared to receive one of the cages by forming parallel faces (66, 68) between adjacent segments via bone shaving instruments (52). A cage is chosen from a plurality of cages having different lengths such that the length of the cage is slightly greater than the distance between the prepared face of the adjacent bone segments. Bone material is placed within the cavity of the cage (30) to facilitate bone migration and fusion between the adjacent bone segments. The cage includes serration (22) at each end for burrowing into the bone segments to maintain the cage in position during the fusion process.		



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DescriptionSPINAL IMMOBILIZATION DEVICE AND METHOD1 TECHNICAL FIELD

The present invention relates to a spinal immobilization device and a surgical method of employing the device to facilitate the fusion of bone segments to correct medical conditions such as degenerative disc diseases.

5 BACKGROUND ART

A degenerative disc disease is characterized by a disorder which effects the proper functioning of a disc between two adjacent bones. There are numerous reasons for this which include herniated, ruptured, or slipped discs. Due to the defect in the disc, the vertebrae goes out of alignment and tends to produce problems with posture and pain.

In many cases the deviated arrangement of the vertebrae can lead to a visible contortion of the spine resulting in disorders such as idiocies (a swayed back posture), kyphosis (shoulders being rolled forward), and scoliosis (sideways curvature of the spine). This exaggerated posture can have bleak social consequences and comport a potentially negative psychological perspective to the person affected. Yet this is but one detrimental result of the disorder.

As the vertebrae go out of alignment, the spinal cord and related nerves are necessarily effected. This can lead to pain as the nerves are moved out of place and more force is placed upon them. The pain is also increased as movement will tend to irritate the already abnormal condition.

Surgical stabilization techniques have been employed to correct these conditions. This involves the use of an immobilization device which both secures the spine in position and promotes fusion of the adjacent bone segments. The goal being a return of the curvature of the spine to a more normal condition and the reduction of physical pain.

In practice, a partial discectomy (removal of the disc material) is performed to remove enough disc material to allow the insertion of the immobilization device. Then the opposing surfaces of adjacent bone segments may be cut to allow for the
5 insertion of the immobilization device. The device may be filled with bone material before insertion so that the bone can fuse from the bone segments through the device.

One such method uses a hollow circular post with threads on the outside. The opposing bone surfaces are cut in a
10 semicircular shape to accommodate the device. This type of shaping of the bone surfaces tends to cut deeply into the body of the vertebrae due to the arc of the circle. The result is that the strongest part of the body of the vertebrae (i.e., the outside layer) is weakened, because of the removal of so much
15 bone to accommodate the circular shape.

The device is filled with bone material and then screwed in the space created between the bone segments. Another drawback to this device is that the threads are not secured into place resulting in a tendency of the device to unscrew and become
20 dislodged; thus defeating both the structural support and bone fusing objectives.

For example, the device, upon movement from its initially placed position, can intrude upon and irritate soft tissues within the body. This can lead to further pain and other
25 complications that require surgery to correct. Furthermore, each surgery presents a patient with a risk of danger including the risk of being under anesthesia and related problems.

Another method uses a hollow circular metal cage. The cage is filled with bone material and at least one end of the cage is
30 cut to a length approximating the distance between the segments to be immobilized. The cutting operation is often imprecise resulting in a length which is either too short or too long for the space between the bone segments. Also, the tool used to cut the cage tends to produce a sharp surface on the end of the cage.
35 This sharp surface has a tendency to cut into the bone so that the cage fails to adequately correct the spinal displacement when

it digs too deeply into the bone. As a result, the spine may not be corrected completely and the pain is not effectively eradicated. Also, the structural integrity of the bone may be further compromised by the deeply cutting edges.

5 The problems associated with the metal cage may require further surgery for correction. Again, this presents the patient with the risk of further complications. For example, the cage may be difficult to remove if it is buried deeply within the bone due to the cutting produced by the sharp edges.

10 There is a need for a spinal immobilization device, and method of utilizing the device, that results in a more secure placement than can be achieved with a screw type device and does not undermine the support of the spine by cutting too deeply into the bone as with the prior art metal cage.

15 SUMMARY OF THE INVENTION

 The present invention addresses the stabilization of bone segments. This is accomplished through the use of an immobilization device, composed of a cage chosen from a number of cages of different lengths, and a method of; preparing the bone
20 surfaces for receiving the cage, choosing the proper length cage, and installing the cage.

 Disc material between adjoining bone segments is removed in an area that approximates the external volume of the cage. Then the opposing sides of adjacent bone segments are shaved using a
25 bone shaving device. Initially the opposing bone segments need not be parallel and in many cases will not be. The bone is shaved to provide opposing substantially parallel surfaces that will receive the cage. Due to the use of a flat surface, the amount of bone removed (particularly from the hardest proximal
30 end of the spinal segments) is minimized and the structural integrity of the hardest part of the bone is maintained. The cavity produced by removing the disc material and shaved bone closely resembles the shape of the cage.

After the cavity is created, the distance between the opposing parallel surfaces of the bone segments is measured. A variety of cages of varying lengths are made available so that at least one will approximate the height of the cavity. The
5 advantage of using a pre-formed cage is twofold.

First, the difficulty encountered when cutting a cage to a specific length in the operating facility is negated. Such a cutting operation tends to leave sharp edges that dig deeply into the bone, thus compromising the procedure. Second, the imprecise
10 cutting operation in the field is eliminated. Also, since the cage is not screwed into the cavity, the problem of a screw becoming unloosened and unscrewing the device into soft tissue is eliminated.

The top and bottom of each of the several cages (of
15 different lengths) has groups of ridges or serrations separated by substantially flat areas. The ridges are designed to come into contact with and burrow into the bone. These ridges have a short height which is adequate for engaging the bone and securing the cage in a single position, but not enough to deeply penetrate
20 to a point that compromises the structural integrity of the bone. The flat surfaces between the groups of ridges and the valleys between the ridge peaks act to limit the penetration of the ridges into the bone.

A cage is chosen that is slightly longer than the height of
25 the cavity to accommodate the minor penetration of the ridges of the cage into the bone. Bone material is then placed in the hollow center of the chosen cage to allow for bone fusion. A placement assembly is inserted into the cage and is used to position the cages between the bone segments.

30 The placement of the selected cage requires application of force on a placement assembly which is fitted (e.g., via a threaded connected) into a tool engaging surface formed on one side of the cage). When the cage is in position, it fits securely in a single place and cannot be dislodged in the same
35 manner as a screw can become unscrewed. When securely situated, the placement assembly is then removed and the cage is left to

facilitate bone fusion and stabilization of the bone segments.

The spinal immobilization device of the present invention and the method of installing the same may best be understood by reference to the following description taken in conjunction with the accompanying drawings in which like elements or features are designated by the same reference numerals.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevational view of the cage with the placement tool engaging surface in the foreground;

Figure 2 is a perspective view of the cage of Figure 1;

Figure 3 is top view of the cage;

Figure 4 is a top cross sectional axial view of the cage taken along line 4-4 of figure 1;

Figure 5 is a top plan view of another embodiment of the cage having a narrow width;

Figure 6 is a side elevational view of the cage of Figure 5 with the bone engaging surface and side wall perforations visible;

Figure 7 is a top plan view of another embodiment of the cage having an internal polygonal, i.e., octagonal, surface;

Figure 8 is a side elevational view of the cage of Figure 7 with the side wall perforations showing;

Figure 9 is a side elevational view of a bone shaving device entering a patient's body and in preparation of shaving the opposing surfaces of spinal bone segments;

Figure 10 is a perspective view of one type of bone shaving device suitable for use in the present invention;

Figure 11 is a perspective view of another type of bone shaving device;

Figure 12 is a top plan view of the bone shaving device of figure 10 shaving the upper face of one spinal segment;

Figure 13 is a side elevation view of a group of cages of varying lengths supported on a rod;

Figure 14 is a side elevation view of the placement assembly engaging the cage and in preparation for placement of the cage between a cavity formed between adjacent bone segments;

Figure 15 is a top plan view of the cage in place on the upper face of the lower bone segment; and

Figure 16 is a side elevation view of the cage in place.

DESCRIPTION OF THE PREFERRED EMBODIMENT

5 Referring now to the drawings and particularly to Figures 1-4, a spinal immobilization device in accordance with the present invention comprises a cage 18 having a peripheral wall 19 which terminates at an upper first end 20 and at a lower or second end 21. A longitudinal axis x-x extends through the center of the
10 cage at right angles to the planes passing through the ends 20, 21, as illustrated. Groups of ridges or serrations 22 are provided on each end of the cage. Turning now to Figure 3, the groups of ridges 22 are separated by flat surface areas 24. As illustrated in Figure 2, the individual ridges are composed of
15 peaks 26, which extend above the flat surfaces 24 and valleys 28 with the bottom of the valley being about level with the flat surfaces 24 as shown.

The ridges are adapted to engage the bone and penetrate to a depth adequate to secure the cage in place. The flat surfaces
20 between the groups of ridges and the valleys act to halt the boring of the ridge peaks into the bone. This control of depth penetration of the ridges insures that the structural integrity of the bone is not compromised.

As illustrated in Figure 5, the cage is hollow thus forming
25 a cavity 30 therein. This cavity is adapted to receive bone material which will migrate through the cavity and fuse adjacent bone segments. The peripheral wall 19 has an inner surface 32 and an outer surface 34. The inner and outer surfaces have a polygonal shape with the shape of the outer surface being in the
30 form of an octagon while the inner surface is in the form of a circle.

There are perforations 40 extending through the wall 19, i.e., from the outer surface to the inner surface, as illustrated in Figures 2 and 4. The shape and size of the perforations or
35 holes are sufficient to allow for the bone material within the hollow cavity to migrate out of the cage and fuse with the

adjacent bone segments. By the same token, bone material may migrate into the cavity during the fusion process.

The cage is provided with a tool engaging surface 42 which comprises a threaded opening 44 as is illustrated in Figures 2, 3 and 4. A placement assembly or tool 46 (Fig. 14) is used between the spinal segments after such segments have been properly prepared, as will be explained in more detail. The placement assembly 46 is in the form of an elongated rod 47 with a threaded end 48 that engages the threads of the tool engaging surface 42 on the cage.

The peripheral wall of the cage has an inside diameter (ID) and an outside diameter (OD) as shown in Figure 3. Figure 3 further illustrates the width (W) of the cage. The width of the cage is determined by the strength of the material from which the cage is made and perhaps the amount of flat surface 20 needed to restrict the progress of the ridges within the bone. The cage of Figures 1-4 is preferably made of a thermoplastic material containing or impregnated with carbon fibers to provide the necessary strength to support the spinal segments during the fusion process. Most preferably such a carbon fiber/plastic material has a modulus of elasticity approximating or similar to the modulus of elasticity of the spinal bone segments. For example, the elastic modulus of the carbon fiber/plastic material may be within the range of 4 to 8 or more. Cortical bone has an elastic modulus of about 12-18. The similarity of the elastic modulus served to reduce stress shielding.

Figures 5, 6, 7 and 8 illustrate alternative embodiments of a cage manufactured of a metal such as titanium (Figures 7 and 8) or stainless steel (Figures 5 and 6). The peaks within a group of ridges of all of the embodiments are preferably equally spaced as illustrated at F in Figure 6. The peaks are preferably spaced apart at a distance within the range of about .05 to 2.0mm and most preferably about 1.0mm. The height of the peaks (H) is measured from the bottom (or valley) of a ridge (which is substantially coplanar with the flat surface 24) to the top of a peak. The height H of the peaks is preferably within the range

of about 0.3 to 2.0mm and most preferably about 1.0mm.

A method of preparing adjacent bone segments for receiving the cage will now be described. The distance between the adjacent faces or surfaces of the spinal bone segments as viewed from the anterior side of the body, i.e., from the abdominal or chest area towards the spine, atypically decreases from the front to the back as is illustrated in Figure 9. Thus, the opening between adjacent segments, in the absence of intervening disc material, is wedge shaped.

To accommodate a spinal segment supporting cage of uniform length, without adversely affecting the proper spinal alignment, it is necessary to shave the adjacent faces of the segments to provide an appropriate cavity therebetween. Such a cavity needs to be bounded at the top and bottom by substantially parallel planes so that when the cage is inserted the desired spinal alignment is achieved. The sides of the cavity must, of course, accommodate the lateral dimensions of the cage. Such a cavity is sometimes hereinafter referred to as a polyhedron cavity.

The preparation of the bone segments is achieved through the use of a bone shaving device 52 (Fig. 9) as will be explained in more detail. The bone shaving device 52 is inserted through the anterior body portion 50 of a patient with a sharp end 60 thereof (Fig. 10) engaging the lower face 54 of the upper segment 55 as well as the upper face 56 of the lower bone segment 57 of the spinal vertebrates. Figures 10 and 11 illustrate varieties of the shape of the cutting surface 60 and graduated measurement markings 58 in the form of millimeter measurements from the distal end 61 of the instrument to allow the surgeon to determine the amount of penetration of the instrument within the bone segments by means of appropriate imaging devices such as flourscopes.

Figure 12 illustrates the movement of the bone shaving instrument within the body portion of a vertebra 62. The lateral motion of the instrument removes bone from the faces of the adjacent bone segments. The top 54 and bottom 56 faces of the vertebrates are not initially parallel as explained above.

The shaving is performed to create two surfaces which are parallel and thus capable of receiving the cage.

Depending upon the relative angle between the original facing surfaces of the bone, the amount of bone necessary to be shaved will vary. However, less bone needs to be removed than with procedures utilizing other support devices, such as the cylindrical threaded posts, due to the availability of a variety of sizes of cages as illustrated in Figure 13. The variety of cages allows for the forming of a cavity with as little shaving as possible. I have found that cages having lengths of about 8mm, 10mm, 12mm, 14mm and 16mm fulfill the needs of most spinal immobilization procedures.

The advantage to a minimal shaving becomes clear because of the varying density and strength of the bone segments. The outside of the bone appears to be the toughest and provides the greatest load carrying capacity as compared to the interior bone structure. By providing cages of varying height less of the structurally significant bone needs to be shaved away. This translates into an increased support over other procedures which need to tailor the bone to a particular support device. The result of the shaving produces a polygonal cavity 64, as illustrated in Figure 14. Once the cavity is formed, the distance between the adjacent shaved faces 66 and 68 is measured as is illustrated in Figure 14. It should be noted that the height of the cavity can be measured, for example, by means of an instrument of the type shown in Figure 11 or by any other appropriate method.

This measurement is compared to the lengths (L) of a number of cages provided in Figure 13. A cage is chosen such that the length (L) is slightly more than the distance (Ch) by such an amount as to allow the ridges to penetrate the bone while preserving the proper spinal alignment.

Figure 14 illustrates the placement assembly engaged with the cage in preparation for inserting the cage into the cavity. Since the cage is slightly longer than the height of the cavity, force must be applied to the placement assembly to insert the

cage securely within the cavity. The placement assembly is then removed from the cage and the cage is left securely in place between the bone segments as illustrated in Figure 16.

5 The parameters of the present device may be altered in numerous ways without departing from the spirit and scope of the invention as defined in the appended claims. Therefore, it is intended that the drawings be interpreted as illustrative and not in any way viewed as being a limitation on the invention.

CLAIMS:

1. A spinal immobilization device for structurally supporting and accommodating fusion of spinal segments comprising:

5 a cage having a first and second ends and a longitudinal axis extending perpendicular to the ends, the first and second ends having groups of ridges separated by substantially flat surfaces, the ridges being formed by alternating peaks and valleys, the peaks extending above the flat surfaces and being adapted to engage and burrow into the bone to firmly secure the
10 cage between the bone segments, the flat surfaces being adapted to limit the depth of the penetration of the peaks into the bone, the cage being hollow for receiving bone material, the cage further defining an inner and an outer surface extending between the ends and having a plurality of perforations extending from
15 the outer surface to the inner surface adapted to allow for migration and fusion of bone material between the bone segments and the bone material within the hollow cage.

2. The spinal immobilization device of claim 1 wherein the cage further defines a tool engaging surface disposed between the
20 first and second ends for receiving a placement tool to facilitate insertion of the cage between bone segments such that the longitudinal axis of the cage is generally perpendicular to the exposed faces of the opposing bone segments.

3. A spinal immobilization device according to claim 2
25 wherein the peaks are equally spaced and the distance between two adjacent peaks within a group of ridges is within a range of about 0.5 to 2.0 millimeters.

4. A spinal immobilization device according to claim 3
wherein the peaks extend beyond the first and second ends within
30 a range of about 0.3 to 2.0 millimeters defining a height of the ridges.

5. A spinal immobilization device according to claim 4
wherein the length of the cage is within a range of about 5 to 20 millimeters.

6. A spinal immobilization device according to claim 1 wherein the cage has an outside diameter of about 18-25 millimeters.

7. A spinal immobilization device according to claim 1 wherein the cage has an inside diameter within the range of about 12-20 millimeters.

8. A spinal immobilization device according to claim 2 wherein the cage is made of a carbon fiber polymer product having a modulus of elasticity similar to that of the bone segments.

9. A spinal immobilization device according to claim 2 wherein the cage is made of a titanium alloy.

10. A spinal immobilization device according to claim 2 wherein the cage is made of a stainless steel.

11. A method of immobilizing and enhancing the ultimate of fusion of adjacent spinal bone segments comprising:

forming a polyhedron cavity between the bone segments at the point where the faces of the bone segments are opposing one another;

measuring the height of the cavity formed between the adjacent bone segments;

providing a plurality of hollow cages of varying lengths; selecting one of the cages such that the length is chosen to be slightly greater than the height of the cavity;

inserting bone material into the hollow cage to facilitate bone migration and bone fusion between the bone segments; and placing the cage within the polyhedron cavity.

12. A method of immobilizing segments of bone according to claim 11 wherein the step of forming the polyhedron cavity includes:

using a bone shaving device to shave opposing bone surfaces to obtain flat parallel shaved surfaces with a distance between the flat parallel shaved surfaces being slightly less than the length of at least one cage from the plurality of cages and wherein the opposing flat parallel shaved surfaces form part of the polyhedron cavity being adapted to receive the cage.

13. A method of immobilizing segments of bone according to claim 12 wherein the cages have a longitudinal axis and are provided with a threaded tool engaging surface disposed on one side of the cage intermediate the ends thereof and further including:

inserting the selected cage between adjacent bone segments by the utilization of a placement assembly, the placement assembly having a first end and a second end, the first end having a handle, the second being threaded and adapted to engage the threaded tool engaging surface of the cage, the placement assembly being used to force the cage within the polyhedron cavity to correctly situate the cage such that the longitudinal axis is in line with the opposing bone segments in a manner which engages the ridges into the flat parallel shaved surfaces of the bones and facilitates a fastening of the spinal immobilization device into place.

14. A method of immobilizing segments of bone according to claim 13 wherein the cages have groups of serrations at each end with flat areas disposed between the groups of serrations.

15. A spinal immobilization device for insertion between the adjacent spinal bone segments from which a degraded disk or portion thereof has been removed to structurally support the segments in a spaced apart relationship and accommodate fusion of such segments comprising:

a hollow cage having a longitudinal axis and a peripheral wall surrounding the axis, the peripheral wall terminating at first and second ends located in planes which are generally perpendicular to the axis, each end defining a plurality of groups of serrations separated by substantially flat surface areas, the serrations being adapted to engage and burrow into the bone segments, the interposed flat surface areas being adapted to inhibit the penetration of the cage into the bone, the interior of the cage being adapted to receive bone material for accommodating the fusion process.

16. The invention of claim 15 wherein the peripheral wall is in the form of a hexagon.

17. The invention of claim 15 wherein the peripheral wall defines a plurality of opening therein to accommodate the egress and ingress of bone material for enhancing the fusion of the spinal segments.

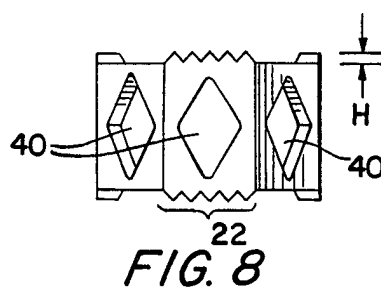
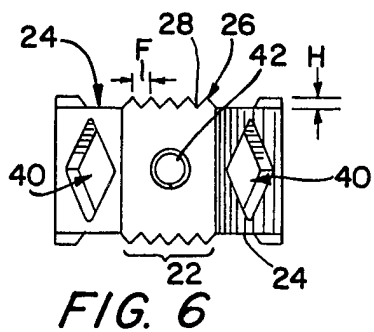
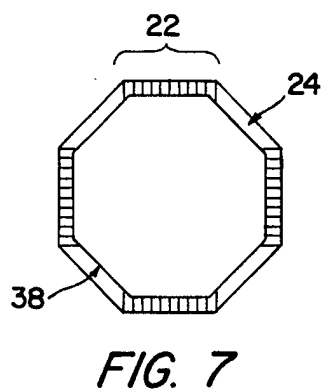
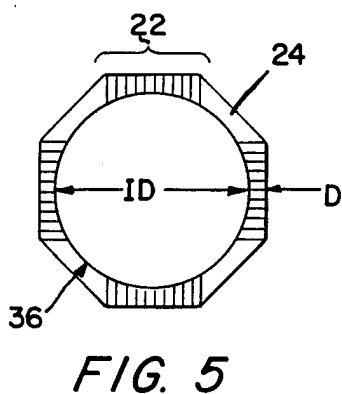
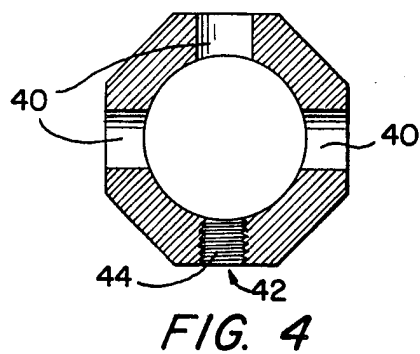
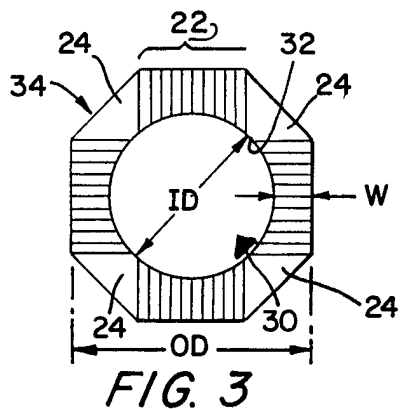
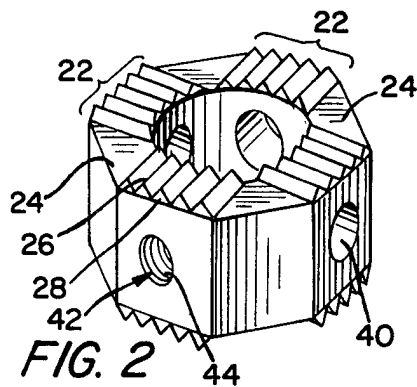
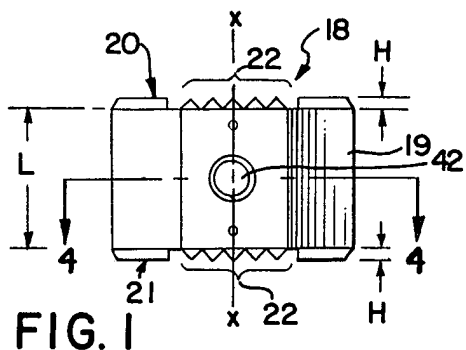
5 18. The invention of claim 17 wherein the ridges have a height within the range of about 0.5 to 2.0 mm.

19. The invention of claim 18 wherein the cage has a length within the range of about 6.0 to 20 mm.

10 20. The invention of claim 19 wherein the cage is made of a rigid thermoplastic material impregnated with carbon fibers.

21. The invention of claim 19 wherein the cage is made of metal.

22. The invention of claim 21 wherein the cage is made of titanium.



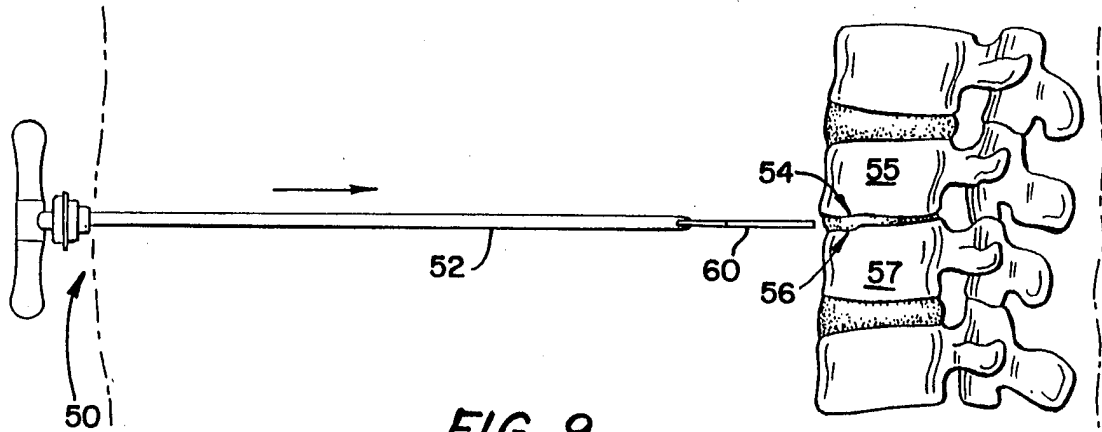


FIG. 9

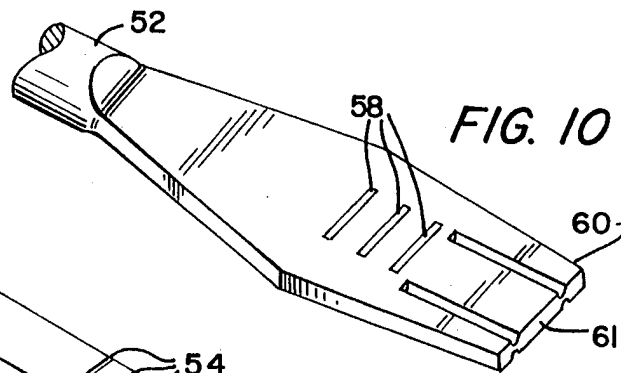


FIG. 10

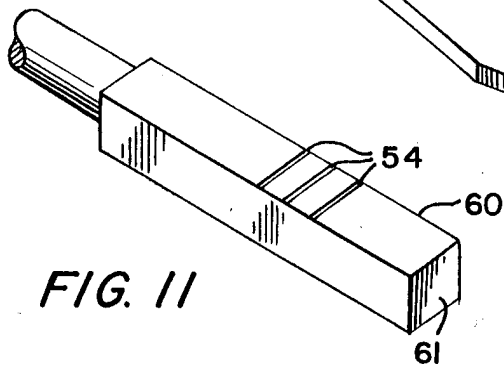


FIG. 11

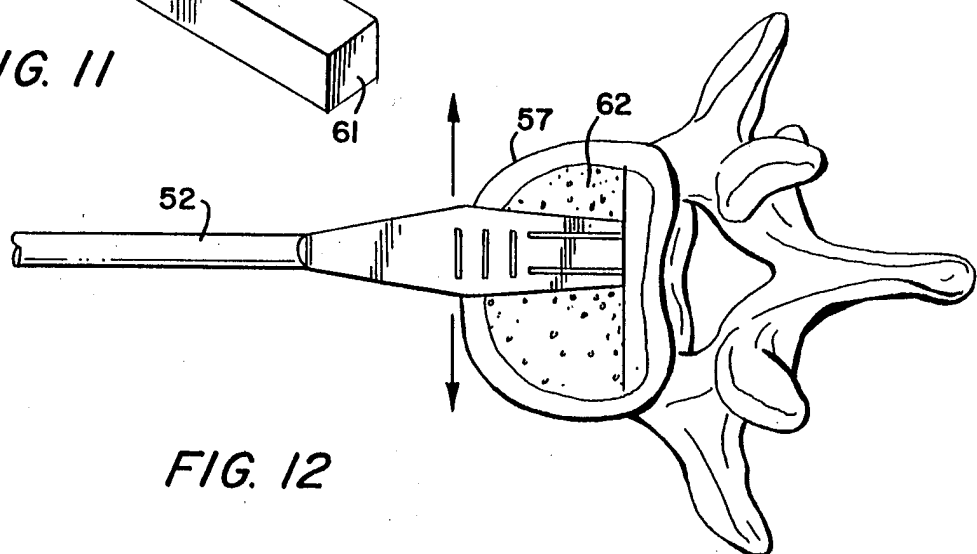


FIG. 12

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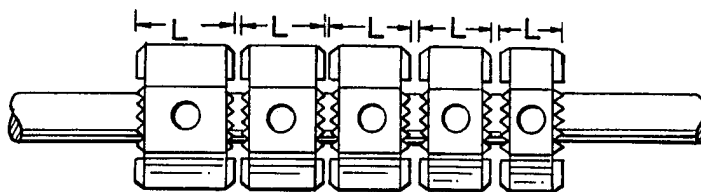


FIG. 13

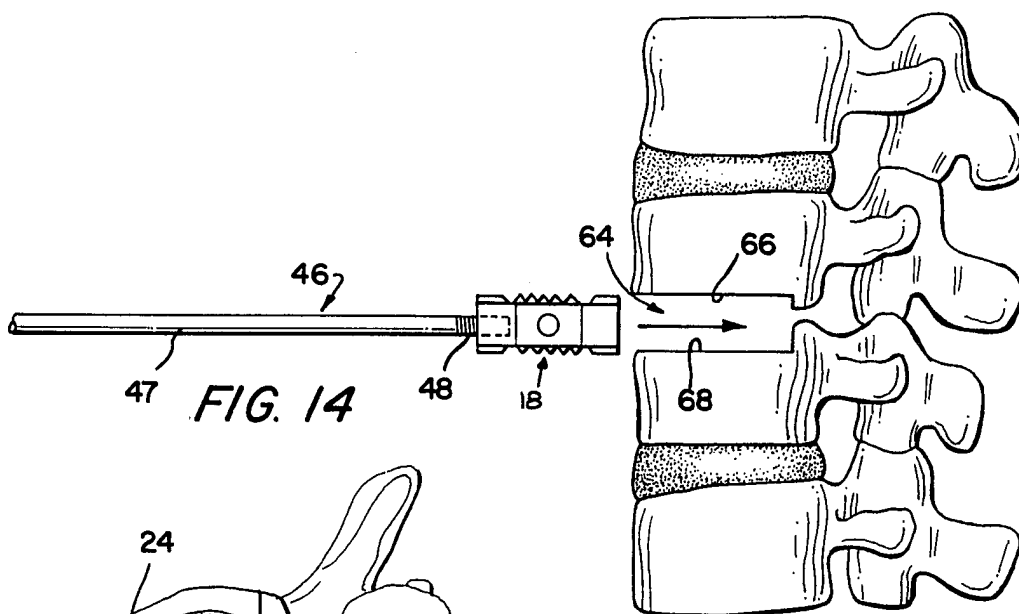


FIG. 14

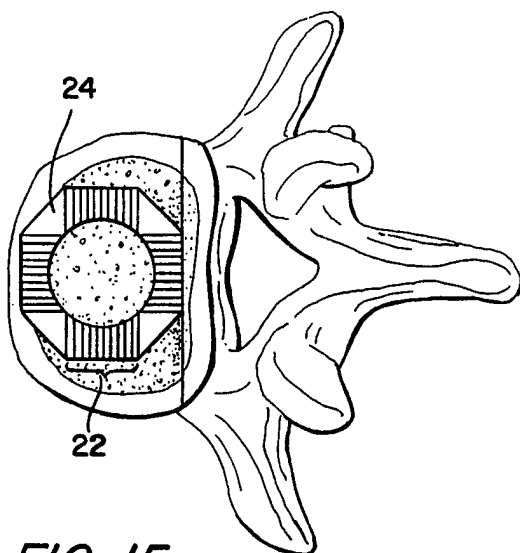


FIG. 15

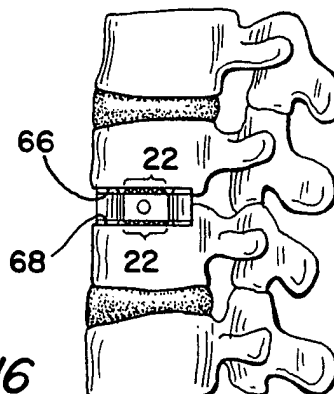


FIG. 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/04777

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/70

US CL :606/61

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)

U.S. : 606/60, 61; 623/17

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,192,327 A (BRANTIGAN) 09 March 1993, Figs. 1-14, col. 1 lines 30-43, col. 2 lines 19-22, col. 3 lines 9-18, col. 4 lines 50-56, col. 5 lines 22-29, and Abstract.	1, 2, 8-10, 15, 17 ----- 3-7, 11-14, 16, 18-22
Y	US 4,834,757 A (BRANTIGAN) 30 May 1989, col. 3 lines 17-38.	11-14



Further documents are listed in the continuation of Box C.



See patent family annex.

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