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(54) Fusion cage for bone joints.

(57) A fusion basket (10) having an external, substantially continuous helical V-thread (12) by which it can be screwed into a bore after first forming in the bore mating female threads that bite into the cancellous regions.. Mating of the threads ensures that the fusion basket remains securely in place without compressing or splitting the recipient bone. Eventually, the ingrowth of bone through perforations (13) in the valley (14) of the thread forms a permanent interconnection between the two bony structures. When used to create bone ingrowth between adjacent vertebrae, the V-thread fusion basket is implanted in pairs on opposite sides of the disc space.

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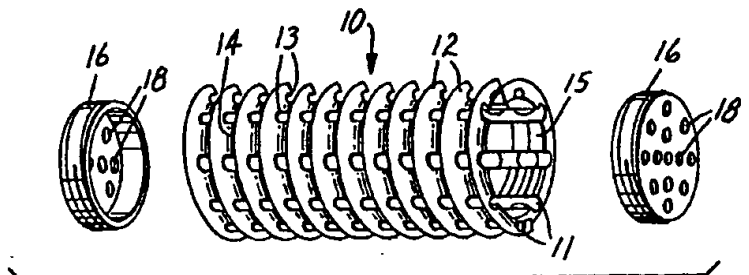

FIG.1

FUSION CAGE

The invention concerns method and apparatus for fusing two adjacent bony structures such as a bone joint, especially adjacent vertebrae of the spine.

BACKGROUND OF THE INVENTION

Subsequent to injury, disease or other degenerative disorder, the disc, a ligamentous cushion between vertebrae, may undergo a painful deterioration. The disc shrinks and flattens out, and the distance between the vertebral bodies begins to collapse. Subsequently, there may be a progressive degeneration leading to mechanical instability, where painful translocations occur between adjacent vertebrae. The movement-induced pain may be so disabling that in many such cases, the segmental motion must be eliminated. Thus, rigid fusions may be the only present means to stop the translocations and relieve the pain.

It is generally held that successful fusions demand a contiguous growth of bone to create a solid mass that will unite the movable elements into one unit. Otherwise, the fusion cannot achieve the tasks of pain reduction, maintenance of intervertebral height, and immobility of the segment. When fusion bone is first placed, it is soft and movable, having no cohesive strength. Therefore a variety of appliances have been developed that attempt to hold the segments quite still under conditions of normal spinal activity and daily stress. Bone graft material is placed between the segments, the outer or cortical surfaces of which have been removed or deeply scarified so as to promote the ingrowth of the graft into these recipient sites. Thus positioned, the bone graft slowly unites the segments. Such an appliance is not meant to permanently secure immobility of the segments. Bone ingrowth is required for this.

Dependency upon such an appliance as the sole stabilizer is ultimately unsuccessful due to the development of a mechanical gap or transition between the bone and the appliance, leading to structural failure of the bone and adjacent connective tissue. Such failure is seen in fractures, erosion, and absorption of bone with potential further collapse. The pain may also become progresively disabling.

Approximately 150,000 lumbar spinal fusions were performed in the USA during 1987, as reported by the American Hospital Association. There are many methods for intervertebral fusion. The most successful have achieved a success rate of about 90% in random cases. However, several of these techniques, especially those requiring complex appliances, are difficult to master and are hazardous to nerve and vessel structures normally lying close to the involved bones.

From a biomechanical point of view, the most important location of a spinal fusion is at the mechanical center of rotation between the vertebrae. This point is centered within the disc space. Therefore, an interbody fusion is the most rigid and thus the most sought after method among surgeons. Current methods of interbody fusions are, however, the most hazardous of all spinal fusion methods.

Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions. Typically, a plug, dowel, or segment of bone is driven tightly into a cavity carved inside the interbody, intradiscal space. Since there must be a bone-to-bone bridge created during the fusion process, connective tissue and discal tissue must be removed. Therefore, deep cuts within the bone must penetrate into the softer, cancellous region to promote bone growth across the space.

Intervertebral fusions using circular bone grafts have been reported in the orthopedic and neurosurgical literature for some years. B. R. Wiltberger in a paper published in Clinical Orthopedics, Vol. 35, pp. 69-79, 1964, reviewed various methods of intervertebral body fusion using posterior bone dowels driven firmly into a suitably smaller hole between the adjacent vertebrae. Upon doing so the dowel can split or crack or collapse. The stretched bone might also split and it can be compressed by the dowel to the point that it will not grow normally due to collapse of formerly open pores or vascular channels. If this occurs, there may be a late absorption of surrounding bone and the dowel might loosen, with a renewed danger of expulsion. See also a two-page brochure from Neurological Surgery Associates of Cincinnati, Inc. entitled "Posterior Lumbar Interbody Fusion Made Simple" which shows, after the bone dowel placement, the "(a)pplication of 5 mm dacron suture around spinous processes."

U.S. Patent 4,501,269 (Bagby) describes a surgical procedure for stabilizing the cervical spine of a horse and says that the procedure "is applicable to any human or animal joint formed by opposed contiguous bony surfaces which are covered and separated by intervening cartilage and are surrounded by ligaments which resist expansion of the joint. Specific examples of such joints are a spinal joint between adjacent vertebrae or the ankle joint. The process was developed to immediately stabilize the joint and to further promote ultimate

bone-to-bone fusion...The implanted structure is in the form of a perforated cylincrical bone basket which can be filled with bone fragments produced during the preparation of the joint. These bone fragments provide autogenous tissue to promote bone growth through the basket, as well as around it.

"The process involves the initial steps of surgically accessing the joint and removing intervening cartilage located between the contiguous bony surfaces. A transverse cylindrical opening is then bored across the contiguous bony surfaces. Immediate stabilization is achieved by driving into the cylindrical opening a hollow basket having a rigid perforated cylindrical wall whose outside diameter is slightly greater than the inside diameter of the cylindrical opening. The implanting of the basket spreads the bony surfaces apart in opposition to the resistance to expansion of the joint provided by the surrounding ligaments." (Col. 2, lines 26-55).

Vich, J. Neurosurg Vol. 63, pp. 750-753 (1983) describes a means for cervical spine fusion, using an anterior approach, by surgically implanting a cylindrical bone graft. "Screw threads are placed in the graft with a small, previously sterilized die. The grooves of the thread can be made as deep as required. The vertebral cervical bodies are prepared according to Cloward's technique. After a cylindrical bed has been drilled in the appropriate intervertebral bodies, the graft is screwed into place with instruments especially developed for this purpose." (P. 750). The Fig. 2 legend points out that a threaded graft dowel has a larger contact surface than a plain dowel and a greater resistance to pressure and sliding.

An additional desirable effect of an intervertebral fusion is the restoration or maintenance of a normal intervertebral spacing. Spreading devices are generally required in order to restore all or a part of the normal intradiscal height, in the process of placing the fusion material or applicance. When the procedure is performed using the commonly employed posterior approach, a variety of spreaders may be placed between various posterior bony elements normally attached to he vertebrae, such as, dorsal spinous processes or laminas. Using such spreaders, a forward tilt or wedging of the discal space occurs, with the posterior aspect of the space becoming more open than the anterior. When a bone graft of any shape is driven into a cavity that is wedged more open posteriorly between two opposing movable vertebrae, there is a strong propensity for the graft to be retropulsed during the postoperative recovery period as a result of to and fro movement between the opposing vertebrae. Thus, to aid in the prevention of graft expulsion, it would be desirable to have the cavity either maintain parallelism or be slightly narrower at its most posterior portion. Ventral to this cavity, the stout ligamentous disc anulus remains and prevents ventral migration of the graft into the retroperitoneal space. Further, there is value in restoring the original spinal lordotic curve, as the fusion grows; this requires that the cavity and the interbody fusion element be placed to promote a normal spinal anatomical position, that is, without wedging of the space in either direction.

BRIEF SUMMARY OF THE INVENTION

The invention provides a fusion basket or cage which, like the fusion basket of Bagby, is a perforate rigid cylinder that can be surgically inserted into a bore that has been formed in two adjacent bony structures such as two vertebrae. The fusion cage is then packed with bone chips or other bone-inducing substance, thus inviting ingrowth of live bone. The fusion cage of the invention differs from the fusion basket of Bagby by an external, substantially continuous helical V-thread by which it can be screwed into the bore, after first forming mating female threads in the bore. Mating of the threads ensures that the fusion basket remains securely in place, there being much less danger of splitting or compression atrophy of the recipient bone. Eventally, the ingrowth of bone through perforations in the valley of the thread forms a permanent interconnection between the two bony structures.

By V-thread is meant that the crown of the thread is sharp, although its valley preferably is blunt or rounded to permit the mating peaks of the female threads to have adequate strength. When the angle of the V-thread at its crown is about 60°, a preferred range of radii for the fillet in the valley is from 0.35 to 0.75 mm. The angle at the crown of the V-thread should be no more than 90°, because a sharper thread would increase the exposed interface surface of bone relative to the implant, thus increasing the opportunity for ingrowth. However, the angle at the crown should be at least 45°, because the pitch would be undesirably small if the angle were smaller. An unduly small pitch would entail weak female bone threads and create a danger of cross threading.

The perforations should be as large as possible as long as the fusion basket has adequate structural strength. When the surface of the fusion basket is projected onto the inner face of a cylinder, the projected perforations should comprise from 30% to 60% of the projected area, preferably about 50%. Individual apertures should be at least one mm both axially and transversely to permit good ingrowth of fresh bone, whereas the fusion basket might be unduly weakened if the apertures were

substantially more than 2 mm axially and 3 mm transversely when the angle of the V-thread at its crown is about 60°.

The novel fusion basket preferably is fitted with end caps, a first of which may be in place before the fusion basket is screwed into the recipient bone, and thus should have a maximum diameter no greater than the minor diameter of the V-thread of the fusion basket. The first end cap retains the bone-inducing sustance when it is packed into the fusion basket. The open end of the fusion basket may then be closed with a second end cap to hold the bone chips securely in place. The end caps may be imperforate but preferably have substantially the same perforation as does the fusion basket to permit bone or other tissue ingrowth through the end caps. However, end caps may not be necessary or, if used, they can be made of biodegradable material, even when the fusion basket is not.

Currently the novel V-thread fusion basket preferably is made of implantable-grade stainless steel. Titanium and ceramics are also useful, as are super-strength polymers or composites of polymers and high-strength filaments such as super-high-density polyethylene, glass, or graphite. Non-metallic composites have the preferred ability to pass x rays or magnetic beams without distortion, thus enhancing the preparation of scan images as compared to metallic fusion baskets. The fusion basket can be biodegradable, because it no longer is needed after the bone ingrowth has matured. When the fusion basket is not biodegradable, it can remain in place permanently after the ingrowth has taken place, in contrast to the need to remove many types of metallic supports or appliances that have heretofore been used to promote rigid fusions.

Useful bone-inducing substances include bone chips and bone substitutes or synthetic material, with or without bone activating matter, such as hydroxyapatite, bone morphologic protein, bone growth factor, or cartilage activation factor. Instead of being mixed with the bone-inducing substance, bone-activating matter can be coated onto the novel fusion basket, e.g., after being microencapsulated in a wax. When the fusion basket is made of an organic material, bone activating matter can be combined with the organic material before it is formed into the fusion basket.

For implantation between vertebrae of a person's lower back, two sizes of the novel fusion basket should suffice, one having a V-thread major diameter of 16 mm and the other a major diameter of 12 mm. Because the anterior-posterior dimension of a typical lower lumbar vertebra is about 30 mm, the length of the fusion basket preferably does not exceed 25 mm but is at least 20 mm in length to give sufficient contact as well as a good platform when implanted in pairs.

The crown of the V-thread of the novel fusion basket preferable is continuous, both for strength and for ease of insertion into the threaded bore. Preferably the V-thread has from 3 to 8 turns per cm. A smaller turn ratio may result in an undesirably large thread depth, penetrating too deeply into the cancellous bone. A larger turn ratio may unduly restrict the size of the performations.

The novel V-thread fusion basket can be implanted for fusing adjacent bony structures by the following method: (a) forming ain said bony structures a bore with a female thread that penetrates into their cancellous regions, (b) forming a rigid, perforate, cylindrical basket to have an external, substantially continuous helical V-thread that can mate with said female thread, (c) screwing the basket into said threaded bore, and (d) packing the basket with bone-inducing substance. When the bore to be formed in step (a) is to extend between adjacent vertebrae, there should be prior to step (a) the added step of spreading the vertebrae apart, preferably in a manner that maintains their parallelism, the fusion basket is implanted in pairs on opposite sides of the disc space.

The novel fusion basket should have a modulus of elasticity approximating that of the recipient bone, thus permitting it to flex along its length, consequently minimizing stresses at the bony interface between the graft and recipient bone. Although a fusion basket of substantially lower modulus of elasticity would provide the same desirable result, it might not have adequate structural strength.

The bore into which the V-thread fusion basket is to be inserted preferably is tapped by hand, using a slow motion to ensure against burning the bone. This freshens the bone margins of the bore so that if any bone had been burned by drilling to form the bore, it is now cut away slowly by hand. The tapping process is quite safe, in that the surgeon can feel the progress of the technique.

The V-thread fusion basket preferably is screwed by hand into the threaded bore, again permitting the surgeon to feel if the resistance is too great and that rethreading of the bore might be required. In contrast, a bone dowel typically is driven into a bore using a hammer, and in order to guard against an overly tight fit, the surgeon listens to the sound of the striking hammer and also monitors the degree of resistance.

When using the noval fusion basket to créat bone ingrowth between adjacent vertebrae, the fusion basket should be implanted in pairs on opposite sides of the disc space. Each is held in place by its V-thread, biting into female threads that penetrate into the cancellous bone of the inter-

posed vertebral bodies. Gravity, muscle pull, and elastic recoil of the spread (or stretched) outer disc anulus together exert force against each of the fusion baskets. Thus the fusion baskets are held in place by compression forces between the adjacent vertebrae.

To prevent distraction froces from possibly dislodging the fusion baskets, e.g., when the patient forward flexes, thus separating the posterior margins of the adjacent vertebrae, the dorsal processes may be tied or wrapped together. By another technique, screws placed through the appropriate facet jackets limit both flexion and extension motions.

A novel interbody spreader in the form of a scissors jack has been developed to maintain a desirable parallel attitude between the adjacent vertebrae while the bore is drilled and then tapped by a novel instrument. Another instrument that has been developed for use in the implantation of the novel fusion basket is a tapping instrument for forming helical threads in a bore in reciplent bone. This noval tapping instrument comprises

a hollow cylindrical shaft having a handle at one end and an external thread which is formed at the other end with at least one scallop that exposes a cutting edge, and

a pilot rod that slidably fits into said bore, projects beyond said other end of the hollow shaft, and is formed with a central recess that communicates with the scallop in the hollow shaft and provides a reservoir for detritus remvoed by said cutting edge, thus permitting the detritus to be carried away by removing the pilot rod from the the hollow shaft.

The portion of the pilot rod that projects beyond said other end of the hollow shaft preferably is threaded to carry detritus upwardly to the reservoir.

When using the novel tapping instrument to form female threads for an interbody fusion, the hollow shaft should have an odd number of scallops and cutting edges, preferably three because an odd number provides more equal removal of recipient bone on both sides of the bore than would an even number.

The novel tapping instrument and a novel wrench are illustrated in the drawing that also illustrates two V-thread fusion baskets of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawing, all figures of which are schematic,

Fig. 1 is an exploded isometric view of a first V-thread fusion basket of the invention and two perforated end caps;

Fig. 2 is an isometric view illustrating the formation of a body that can be cut to form a series of second V-thread fusion baskets of the invention;

Fig. 3 is an isometric view of a tap (partly cut away to reveal details of construction) for forming female thread in bores into which a V-thread fusion basket is to be inserted; and

Fig. 4 is an isometric view of a wrench for screwing a V-thread fusion basket into a threaded bore.

The fusion basket 10 of Fig. 1 was formed from a solid steel cylinder by drilling eight small, equally-spaced holes 11 in the axial direction, each hole being centered on a circle concentric with the axis of the cylinder. Then a large hole was drilled centered on the axis and having a radius substantially identical to that of the aforementioned circle. A V-thread 12 was then machined in the external surface of the cylinder, thus opening through that surface a perforation 13 extending through the rounded valley 14 of the V-thread at each crossing of the valley and one of the small holes 11. A screw thread 15 was then machined in the internal surface of the fusion basket to threadably receive an end cap 16 that has apertures 18 similar to those of a salt shaker. Snap-on end caps would also be useful.

In making a fusion basket by the technique described in the preceding paragraph, the small holes 11 could be enlarged to intersect each other, thus making it unnecessary to drill a central hole. Enlarged small holes would result in larger perforations 13.

Referring to Fig. 2, a series of fusion baskets can be made from a plurality of rods 22 of rectangular cross-section that can be continuously extruded and fed into each of eight keyways 23 in the surface of a mandrel 24. Simultaneously, a rod 26 of triangular cross-section is extruded, wrapped helically around the rectangular rods 22, and soldered or welded to each of the rectangular rods 22 at every crossing to provide an external V-thread. Upon emerging from the keyways, the resulting body is cut into individual fusion baskets each of which has a perforation 28 between adjacent turns of the V-thread-forming rod 26 wherever it bridges a gap between adjacent rectangular rods 22.

A fusion basket identical to that of Fig. 2 can be made from a hollow cylinder by machining an external V-thread and broaching a plurality of rectangular internal keyways.

Each of the fusion baskets of Figs. 1 and 2 could be made from a model by the lost-wax process.

The tapping isntrument 30 of Fig. 3 has a hollow cylindrical shaft 31 with a T-handle 32 at one end and an external thread 33 at the other end.

Slidably received within the hollow shaft is a pilot rod 34, one end 35 of which protrudes beyond the hollow shaft 31 and slidably fits into a bore that has been drilled into the recipient bone. At the other end of the pilot rod is a knurled cap 35A. Projecting from the threaded end of the hollow shaft 31 are cutting teeth 36 that enlarge the bore to the minor diameter of the external thread 33 of the hollow shaft 31. The threaded end of the hollow shaft also is formed with three symmetrical scallops 37 (one shown) to expose a cutting edge 38 at the leading edge of the external thread 33, which cutting edge forms female bone threads in the bore upon rotation of the hollow shaft.

Detritus created by tapping instrument 30 is deposited through the scallops 37 into a reservoir provided by a central recess 39 in the pilot rod 34. The end 35 of the pilot rod which extends from the recess 39 into the bore has external threads which, when the threaded pilot rod 34 is turned, carry detritus upwardly to be deposited through the scallops into the reservoir.

Upon rotating the hollow shaft 3I to form female bone threads in the bore, the surgeon can feel increased back pressure when the reservoir becomes full and should grasp the knurled cap 35A to remove and clean out the pilot rod. If the gummy nature of the detritus were to prevent the pilot rod from being easily pulled out of the hollow shaft, the knurled cap 35A could be removed to permit the hollow shaft 31 to be unscrewed from the threaded bore, leaving the pilot rod in place. The pilot rod then serves. as a guide if the bore has not yet been completely tapped and it is necessary to reinsert the hollow shaft to complete the tapping.

The wrench 40 of Fig. 4 has a cylindrical shaft 41 with a T-handle 42 at one end and an octagonal protuberance 44 at the other end. The corners of the protuberance 44 fit into recesses in the fusion basket to permit the fusion basket to be rotated by rotating the wrench. A spring-loaded ball 46 frictionally holds the protuberance in place when it is inserted into the fusion basket.

Implanting the Fusion Basket

In order to implant the novel fusion basket between adjacent vertebrae, soft, collagenous disc material is first removed from the intervertebral space. A small window is created in the overlying laminas of each side, namely, standard laminotomies. The neural tissues, dural sac and nerves, are retracted medially. The intervertebral space is cleaned of disc material in a standard surgical fashion. If the disc space has narrowed as a result of degeneration, a scissors-jack type vertebral spreader or a hydraulically inflated bladder is inserted on one (the first) side inside the disc space and opened until the space approximates the normal. This may be confirmed by a lateral x ray. The height of the disc space is measured on the x ray so that the proper sizes of drills, tap, and fusion basket may be chosen.

The opposite (second) side of the same disc space is then addressed. The nerve tissues on the first side are relaxed and then retracted medialward on the second side. A pilot drill (e.g., 5 mm or 8 mm diameter depending upon discal space height) cuts a small channel in the face of each of the vertebrae, penetrating the interdiscal space to a depth of about mm (the normal disc space is about 30 mm deep and 50 mm wide). A drill stop may be applied to the drill to prevent overboring the hole. A solid rod pilot is then inserted into the pilot hole and a pilot cutter (7 mm or 10 mm) is passed over it and brought downward to enlarge the pilot channels to slidably receive the pilot rod 35 of the tapping instrument 30 of Fig. 3. The cutting thread 33 (12 mm or 16 mm major diameter) cuts female bone threads through the opposing vertebral end plates and into both cancellous regions that will invite the ingrowth of new bone.

A V-thread fusion basket of the invention, with one end cap in place, is snapped onto the wrench 40 of Fig. 4 by which it is screwed by hand into the threaded intradiscal bore to its full depth. After removing the wrench, the basket is packed with bone chips or other bone-inducing substance, and the second end cap is applied to hold the bone chips securely in place.

After removing the vertebral spreader, the dura and nerves on the second side are relaxed and attention is once again directed to the first side which is drilled and tapped to receive a second fusion basket by the same procedure.

Over a period of several weeks, the bone from the vertebral bodies will grow through the perforations in the fusion baskets and unite with the bone-inducing substance inside them, creating a solid fusion.

It is believed that the novel fusion baskets will primarily be implanted by a posterior approach to the spine, although an anterior approach may be utilized, especially when applied to the cervical spine.

Example 1

The fusion basket of Fig. 1 has been machined from a cylinder of surgically implantable stainless steel to have the following dimensions:

diameter of starting cylinder 16 mm
length of cylinder 25 mm
diameter of each small hole 11 3 mm
diameter of circle on which holes 11 are centered 11.5 mm
diameter of central hole 11 mm
pitch of V-thread 12 2.5 mm/turn
angle at crown of thread 12 60°
fillet radius in valley of thread 12 0.4 mm
axial width of perforations 13 1.6 mm
circumferential breadth of perfs. 13 2.8 mm
when projected onto interior of a cylinder, % of area perforated 25%

A V-thread fusion basket identical in appearance to one produced as in Fig. 2 can be made from a hollow cylindrical tube. After machining an external thread, a plurality of rectangular keyways are broached in the inner surface to form perforations through the valley of the thread. A continuous technique for making a novel fusion basket starts with a continuous helical spring made from a triangular rod such as the rod 26 used in Fig. 2, then welding or soldering the inner-facing surface of the spring to a plurality of cylindrical wires, each extending parallel to the axis of the spring.

Claims

1. A fusion cage which is a hollow perforate rigid cylinder that can be surgically inserted into a bore that has been formed in two adjacent bony structures and filled and packed with bone chips, thus inviting ingrowth of live bone, wherein the improvement comprises: the fusion cage (a) has an extenal, substantially continuous helical V-thread by which it can be screwed into mating female threads formed in the bore and (b) is perforated in the valley between adjacent turns of the thread.

2. A fusion cage as defined in claim 1 wherein the V-thread is continuous and the angle at the crown of the V-thread is no more than 90°, but not less than 45°.

3. A fusion cage as defined in claim 2 wherein the angle at the crown of the V-thread is about 60°.

4. A fusion cage as defined in claim 2 wherein the V-thread has from 3 to 8 turns per cm.

5. A fusion cage as defined in claim 2 wherein the valley of the V-thread has a fillet, the radius of which is from 0.35 to 0.75 mm.

6. A fusion cage as defined in claim 1 wherein, when the surface of the fusion cage is projected onto the inner face of a cylinder, the perforations comprise from 30% to 60% of the projected area.

7. A fusion cage as defined in claim 1, which is fitted with removable perforated end caps.

8. A fusion cage as defined in claim 1, the major diameter of which is from 12 to 16 mm.

9. A fusion cage as defined in claim 1, made of implantable-grade stainless steel.

10. A fusion cage as defined in claim 1, made of biodegradable material.

11. A fusion cage as defined in claim 1, made of x-ray-transparent material.

12. A fusion cage that is a hollow rigid cylinder that is suitable for insertion during surgery into a bore that has been formed in adjacent bony structures and can contain bone inducing substances, thus inviting ingrowth of live bone, the fusion cage having an external, substantially continuous screw thread by which it can be screwed into mating female threads formed in the bore, and, having openings in the valley between turns of the thread.

13. A fusion cage as claimed in claim 12 having any one or more of the features as defined in claims 2 to 11.

14. A fusion cage as claimed in claim 12 or 13, wherein the screw thread is a V-thread.

15. A fusion cage as claimed in any one of the preceding claims for use in fusing adjacent bony structures.

16. A tapping instrument comprising a hollow cylindrical shaft having a handle at one end and an external thread which is formed at the other end with at least one scallop that exposes a cutting edge, and a pilot rod that slidably fits into said bore, projects beyond said other end of the hollow shaft, and is formed with a central recess that communicates with the scallop in the hollow shaft and provides a reservoir for detritus removed by said cutting edge, thus permitting the detritus to be carried away by removing the pilot rod from the hollow shaft.

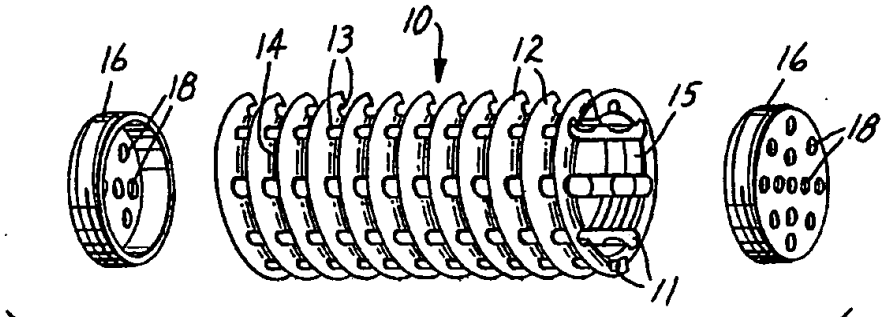

FIG.1

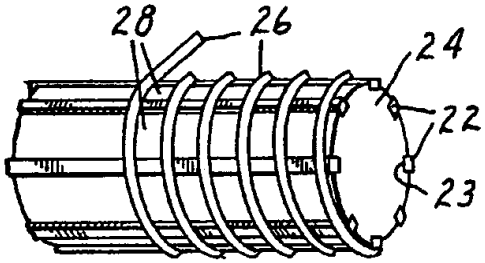

FIG.2

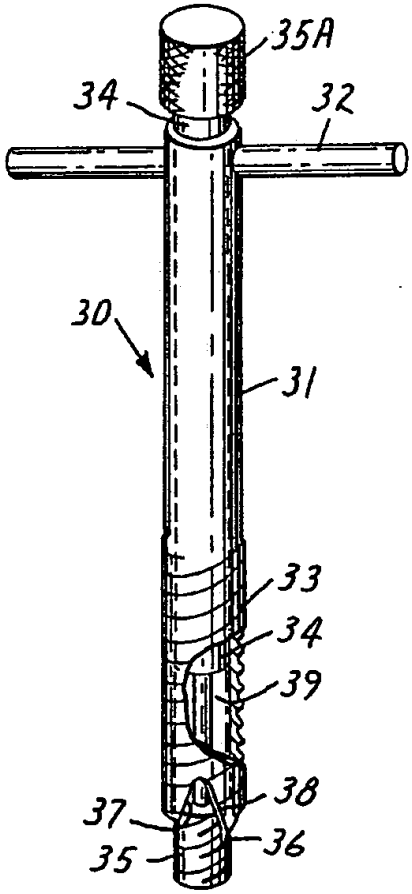

FIG.3

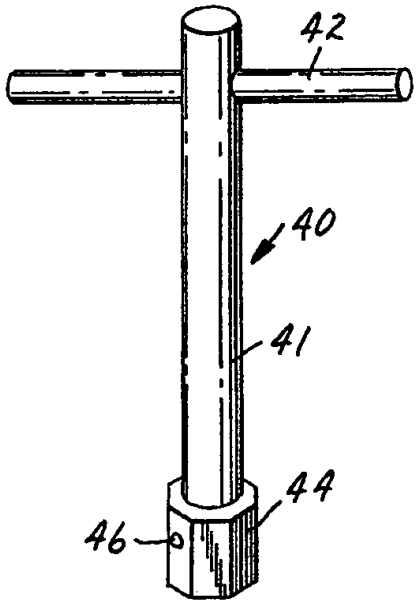

FIG.4

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 89 31 0572

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
D,Y	US-A-4 501 269 (BAGBY) * Complete document *	1,7,9, 10,12, 15	A 61 F 2/44
Y	DE-A-3 505 567 (VICH) * Claims; figures *	1,7,9, 10,12, 15	
A	-	16	
A	WO-A-8 707 827 (S + G IMPLANTS)		
A	EP-A-0 268 115 (BIEDERMANN)		

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 F

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	16-01-1990	SANCHEZ Y SANCHEZ J.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
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E : earlier patent document, but published on, or after the filing date
D : document cited in the application
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& : member of the same patent family, corresponding document

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(54) Wirbelkörperimplantat.

(57) Als Implantat für Wirbelsäulen wird eine Scheibe (11) vorgeschlagen, die alleine oder zu mehreren gestapelt (11 bis 14) zwischen Wirbelkörper einsetzbar sind. Einzelne Scheiben werden nach Bedarf von einem Strang abgeschnitten, wobei die Scheibendikke dem Einzelfall genau angepaßt werden kann. Diese Implantate eignen sich insbesondere für Halswirbel sowie als Ersatz nach der Entfernung von Bandscheiben. Für die Bildung eines Implantats aus mehreren übereinandergestapelten Scheiben kann ein entsprechendes Sortiment von Scheiben bereitgestellt werden, die sich sowohl im Durchmesser als auch in der Höhe unterscheiden. Für den jeweiligen Anwendungszweck werden demzufolge Scheiben mit entsprechender Dicke ausgesucht und zusammengesetzt, so daß sie insgesamt die erforderliche Höhe des Implantats ergeben. Verschraubungen und insbesondere längere Handhabungen im eingesetzten Zustand des Implantats sind bei dem erfindungsgemäßen Implantat nicht erforderlich.

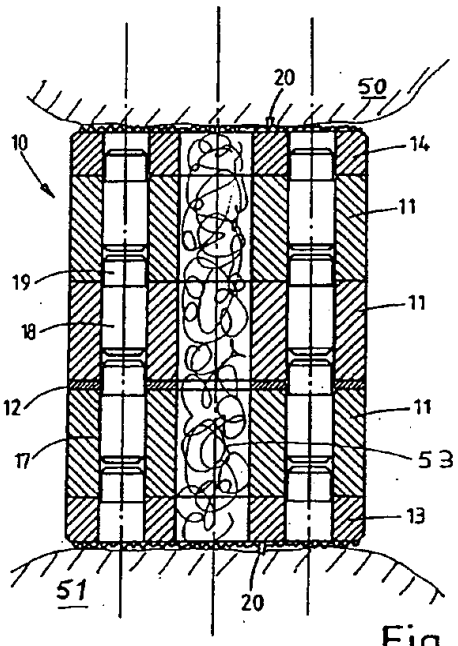

Fig.1

EP 0 517 030 A3

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EUROPÄISCHER RECHERCHENBERICHT

Nummer der Anmeldung

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EINSCHLÄGIGE DOKUMENTE

Kategorie	Kennzeichnung des Dokuments mit Angabe, soweit erforderlich, der maßgeblichen Teile	Betrifft Anspruch	KLASSIFIKATION DER ANMELDUNG (Int. Cl.5)
X,D A	WO-A-9 000 037 (MICHELSON) * Seite 11, Zeile 28 - Seite 16, Zeile 25; Abbildungen *	1,3,4 5	A61F2/44
X A	US-A-4 743 256 (BRANTIGAN) * Spalte 5, Zeile 33 - Zeile 65; Abbildungen 11,12 *	1,4 2,3	
A	US-A-3 867 728 (STUBSTAD) * Spalte 11, Zeile 3 - Zeile 27; Abbildung 18 *	1	
A	EP-A-0 307 241 (BRANTIGAN) * Spalte 11, Zeile 35 - Zeile 53; Abbildungen 18,19 *	3,5	
A	WO-A-8 805 312 (M. C. OY) * Abbildung 8C; Beispiel 8 *	6,8	
A	EP-A-0 197 441 (M.A.N. TECHNOLOGIE) * Seite 6, Zeile 20 - Seite 7, Zeile 4; Ansprüche 1,2; Abbildungen *	6,8	RECHERCHIERTE SACHGEBIETE (Int. Cl.5)
A	DE-A-2 426 814 (U.S. A. E. C.) * Abbildung; Beispiel 3 *	7	A61F
A	EP-A-0 302 719 (A.W. SHOWELL)		
A,D	DE-A-3 023 942 (WALDEMAR LINK)		

Der vorliegende Recherchenbericht wurde für alle Patentansprüche erstellt

Recherchenort	Abschlußdatum der Recherche	Prüfer
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KATEGORIE DER GENANNTEN DOKUMENTE

X : von besonderer Bedeutung allein betrachtet
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(54) Device for implantation for the purpose of limiting the movements between two vertebrae.

(57) The invention relates to a device for implantation for the purpose of limiting movements between two vertebrae, comprising at least two vertebra engaging elements each having a free end, and an elastic coupling element which is connected with the free ends of the vertebra engaging elements, the elastic coupling element being designed in such a manner that upon an increase of the distance between the free ends of the vertebra engaging elements starting from a neutral position the coupling element generates a force counteracting the increase and upon a decrease of the distance between the free ends of the vertebra engaging elements starting from the neutral position the coupling element generates a force counteracting the decrease.

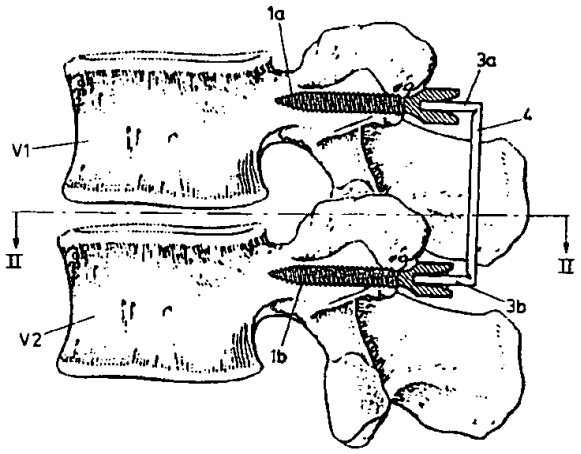

FIG.1

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This invention relates to a device to be implanted for the purpose of limiting movements between two vertebrae.

Heretofore, there have been only two forms of treating back complaints in the lower part of the back caused by an unstable vertebral column segment. Characteristic of an unstable vertebral column segment is that a slight displacement from the neutral position results in too great a change or an abnormal change in the shape of the vertebral column segment. The complaints of pain are treated on the one hand with conservative methods such as physiotherapy and anti-inflammatory injections and on the other with relatively aggressive methods based on arthrodesis, i.e. fusion of the unstable vertebral elements. Between these two treatment options lies a wide gap which could not be filled heretofore. This gap could very suitably be filled by implantation of a device permitting limited movement between the vertebrae.

Movement-limiting devices for vertebrae could also be very suitably fitted at the transition between vertebral column segments fused by arthrodesis and the non-fused vertebral column parts adjacent to these segments. The vertebrae located at the transition between a fused and a non-fused vertebral column part are loaded extra heavily since these vertebrae attempt to take up the movements which were previously taken up by the fused vertebral column part. In order to relieve these vertebrae and the surrounding muscles to some extent, a movement-limiting device could very effectively be employed at precisely that point.

In the case of knee joints, for instance, it is known to use elastic tensioning bands which are tensioned around the free ends of two joint engaging elements, such as for instance screws, which are each fitted in a joint member whose relative movements are to be limited. Such a device is described in EP-A-0 260 970. The drawback of devices functioning on the basis of elastic tensioning bands is that the movements of the joint members are counteracted in only one direction by a force produced by the tensioning bands, viz. in that direction in which the band is pulled taut. Movements by which the tension on the elastic bands is reduced are, of course, not limited and even promoted. Since vertebrae can move relative to each other in all directions, the principle of limiting the movements by means of elastic bands cannot successfully be transferred to the vertebral column.

Another drawback of the known devices equipped with elastic tensioning bands is that the tensioning bands, even when the joint members are disposed in the neutral position relative to each other, are under stress and therefore draw the joint members toward each other. The element which is to produce the counterpressure to keep the joint members spaced apart is formed by a cartilage part or a connective tissue structure such as, for instance, a meniscus or, when the device is applied to the vertebral column, an intervertebral disk. This cartilage part loses its elasticity under the influence of the continuous load and moreover becomes thinner in the course of time. As a result, the tension on the tensioning bands lessens, so that the device allows greater movement again and the chances of the tensioning bands coming off the free ends of the screws increase.

Further, the durability of the tensioning bands, typically made of rubber or plastic, is not sufficient to function satisfactorily for the rest of the patient's life under the fatigue loads exerted thereon.

The object of the invention is to provide a device for limiting movements between two vertebrae without the above-described disadvantages.

To that end, the device comprises at least two vertebra engaging elements each having a free end, and an elastic coupling element which is connected with the free ends of the vertebra engaging elements, the elastic coupling element being designed in such a manner that upon an increase of the distance between the free ends of the vertebra engaging elements starting from a neutral position the coupling element generates a force counteracting the increase, and upon a decrease of the distance between the free ends of the vertebra engaging elements starting from the neutral position the coupling element generates a force counteracting the decrease.

Such a device has the advantage that also in the case where the free ends of the vertebra engaging elements move towards each other, the coupling element will produce a force counteracting this movement. This provides the advantage that in the event of such movements the intervertebral disk is loaded to a lesser extent. Moreover, the coupling element need not exert any force on the vertebra engaging elements when they are in the neutral position. This prevents an additional force being exerted continuously on the intervertebral disk, so that the extent of thinning of the intervertebral disk over a particular period of time will be slight.

According to a further elaboration of the invention, it is particularly advantageous if the force counteracting the increase or decrease of the distance between the free ends of the vertebra engaging elements increases progressively with the amount of increase or decrease. Such progressive increase of the force upon an increase or decrease of the distance between the free ends of the vertebra engaging elements provides that the movement ends in a damped manner against a kind of end stop. Thus shock loads to which the vertebrae are

exposed are minimized.

In further elaboration of the invention, the device is characterized in that the counteractive force increases exponentially with the amount of increase or decrease of the distance between the free ends of the vertebra engaging elements.

Tests show that such exponential increase is highly satisfactory and that the occurrence of shock loads is thereby minimized.

The vertebra engaging elements will mainly be arranged on the dorsal side of the vertebral column. Accordingly, upon forward bending, also referred to as flexion, the distance between the free ends of the vertebra engaging elements increases while, conversely, upon straightening of the vertebral column, also referred to as extension, the distance between the free ends of the vertebra engaging elements decreases.

According to a further elaboration of the invention, it is particularly advantageous if the counteractive force arising upon a particular increase of the distance between the free ends of the vertebra engaging elements is smaller than the counteractive force arising upon an equally large decrease of that distance. The consequence of this is that unbending the vertebral column will require more effort than bending it, which corresponds with the natural situation in the case of a healthy vertebral column.

A first embodiment of the above-described device is characterized in that the coupling element comprises two flexible pins which are each rigidly connected by one end to the free end of a vertebra engaging element and are each connected at their other end to a rigid connecting member, each vertebra engaging element comprising at the free end thereof an internal cavity in which the pin extends at least partly, the internal surface of the cavity serving to support the pin during the bending thereof.

Such a device provides the advantage that all parts can be made of metal. Metal presents few problems in the natural environment in which the device is disposed. Rubber and plastic have a more limited resistance to fatigue than metal does, which is unfavorable in particular when they are employed as an elastic element. Accordingly, the first embodiment, in which no rubber or plastic is used, is particularly advantageous.

Preferably, the internal surface of the cavity in the vertebra engaging element is designed in such a manner that upon a greater amount of increase or decrease of the distance between the free ends of the vertebra engaging elements, i.e. upon a stronger bending of the pins, the pins abut against the internal surface over a greater part of their length.

Because upon the bending of the pin the pin abuts against the internal surface of the internal cavity over an increasingly greater part of its length, the force counteracting the bending increases progressively upon an increase of the bending. This is the result of the shortening of the flexible part of the pin. Through an appropriate design of the internal surface of the cavity in which the pin extends, it is, for instance, possible to obtain an exponential increase of the counteractive force upon an increase or decrease of the distance between the vertebra engaging elements starting from the neutral position thereof.

The flexible pin is preferably manufactured from memory metal, such as for instance a TiNi alloy. Such material provides the advantage that it can resist an elongation of approximately 8% in the elastic range. With a relatively short pin, which is necessary to limit the required overall space for the device, such an amount of elongation still enables a relatively large displacement of the free pin end relative to the clamped pin end.

In order to limit the undesirable build-up of moment in the memory metal pins and the rigid connecting member of the coupling element, it is particularly advantageous, in accordance with a further elaboration of the invention, when the rigid connecting member is pivotally connected to the free ends of the two flexible pins.

To limit the maximum elongation in the pins, it can be particularly advantageous, according to a further elaboration of the invention, if the pins are designed as a bundle of substantially parallel wire-shaped elements. Such bundle of wire-shaped elements can be bent to a considerable extent without the elongation in the individual wire-shaped elements becoming inadmissibly large. This provides that even in the case of extreme bending, the deformations still take place within the elastic range of the material.

A first alternative embodiment of the invention is characterized in that the coupling element comprises a rigid connecting member and two ball-and-socket joints, of which each ball in mounted condition is rigidly connected with an associated vertebra engaging element, while each socket is slidably connected with the rigid connecting member and in the neutral position is urged in an end position by biassed springing means.

Over the known device, this device has an important advantage in that both with flexion and with extension of the vertebral column, a force counteracting this flexion or extension is generated by the device.

In order to effect a progressive increase of the force counteracting the change in the distance between the free ends of the vertebra engaging elements, it is possible, in accordance with a further

elaboration of the invention, for the springing means to be formed by blocks made from rubber or plastic and accommodated in a chamber of the rigid connecting member. As long as the rubber or plastic blocks can still deform freely, the counteractive force will increase approximately linearly with the change in the distance between the free ends of the vertebra engaging elements. However, as soon as the blocks contact the walls of the chamber, the force counteracting the change in the distance will increase progressively due to the fact that the rubber blocks can no longer expand freely in particular directions.

In this connection, according to a further elaboration of the invention, the two sockets can each be positioned relative to the springing means in such a manner that upon an increase of the distance between the free ends of the vertebra engaging elements one socket is urged into the associated end position and the other socket moves from the end position against the spring pressure of the springing means associated with that socket, while upon a decrease of the distance between the free ends of the vertebra engaging elements the other socket is urged into the end position and the one socket moves from the end position against the spring pressure of the springing means associated with that one socket. Thus, both for an increase and for a decrease of the distance between the vertebra engaging elements, in each case only one of the blocks made of rubber or plastic is operative. By choosing, for instance, blocks having different spring characteristics, in this way the counteractive force upon a particular decrease of the distance can simply be different from the counteractive force upon an equally large increase of the distance between the free ends of the vertebra engaging elements. It can thus be provided that for flexion, for instance, less resistance has to be overcome than for a similar extension, which corresponds with the natural situation in the case of a healthy vertebral column.

In a third embodiment according to the invention, the coupling element comprises at least one spring element, manufactured from springing wire or sheet material, which is provided with a curvature, the or each spring element being connected at the free end thereof with the free ends of the vertebra engaging elements. Such element, manufactured from springing wire or sheet material and provided with a curvature, upon an increase of the distance between the free ends of the vertebra engaging elements, exerts on the vertebra engaging elements a force counteracting the increase of the distance. According as the distance between the free ends of the vertebra engaging elements increases, the curvature in the spring element is straightened, so that the spring arm becomes smaller and the force needed to further extend the spring increases progressively.

In order to provide that the counteractive force increases progressively also in the case where the free ends of the vertebra engaging elements move toward each other, it is particularly advantageous, in accordance with a further elaboration of the invention, if the coupling element comprises two spring elements, the curvatures of the two elements being so designed that upon a decrease of the distance between the free ends of the vertebra engaging elements the spring elements butt against each other. Owing to the fact that the springs butt against each other upon a particular reduction of the distance between the free ends of the vertebra engaging elements, much more counteractive force will have to be overcome to achieve a further reduction of the distance. Through the interaction between the two spring elements, in particular in that the spring elements must bend over a shorter part of their length, the spring characteristic will change markedly. This change of the spring characteristic results in a progressive increase of the counteractive force upon the decrease of the distance between the free ends of the vertebra engaging elements.

When the spring elements are designed as leaf springs, the chances of the spring elements sliding past each other rather than butting against each other are minimized.

To clarify the invention two exemplary embodiments of the device are described with reference to the drawing.

Fig. 1 is a lateral view of a part of the lumbar part of the vertebral column in which a first exemplary embodiment of the device is fitted;

Fig. 2 is a cranial view taken on line II-II of Fig. 1;

Fig. 3 is a side elevation of a first embodiment of the device in the neutral position;

Fig. 4 is a side elevation of the device, similar to that shown in Fig. 3, where the distance between the free ends of the vertebra engaging elements is reduced;

Fig. 5 is a side elevation of a second embodiment of the device according to the invention;

Fig. 6 is a top plan view of a third embodiment of the device;

Fig. 7 is a top plan view of a fourth embodiment of the device; and

Fig. 8 is a side elevation of the device shown in Figs. 6 and 7.

Fig. 1 shows the position of vertebra engaging elements 1a, 1b of the device according to the first exemplary embodiment, which is preferred, in two lumbar vertebrae V1, V2, located one above the other, while Fig. 2 shows the position of a vertebra engaging element 1b in cranial view.

In the exemplary embodiments shown, the vertebra engaging elements 1a, 1b are each designed as pedicle screws. It will be clear, however, that for the vertebra engaging elements other engagement constructions to be rigidly connected to the vertebrae can be used as well, such as for instance the transversal hook proposed in applicant's patent application EP-A-0 564 046.

Figs. 3 and 4 respectively show the device attached to the vertebrae in Figs. 1 and 2 in the neutral position and in a position where the distance between the free ends 2a, 2b of the pedicle screws 1a, 1b is reduced. When the vertebral column is in the natural position, the free ends 2a, 2b of the pedicle screws 1a, 1b are spaced apart a specific distance. In this situation the pedicle screws 1a, 1b are in the neutral position.

According to the invention, the device includes a coupling element which comprises two flexible pins 3a, 3b and a rigid connecting member 4. The flexible pins 3 are each rigidly connected by a first end to a pedicle screw 1 and connected by a second end to the rigid connecting member 4. The pedicle screws 1a, 1b are both provided, at the free end 2a, 2b thereof, with an internal cavity 5a, 5b in which the pin 3a, 3b extends at least over a part of its length. The internal surface of the cavity 5a, 5b is of such design that the pin 3a, 3b, upon being bent, abuts against and is supported by the internal surface of the cavity 5a, 5b. Preferably, the surface is so designed that upon a greater extent of increase or decrease of the distance between the free ends 2a, 2b of the pedicle screws 1a, 1b, i.e. upon a stronger bending of the pins 3a, 3b, the pins 3a, 3b abut against the internal surface of the cavities 5a, 5b over a greater part of their lengths.

Because the pins 3a, 3b, upon being bent further, abut against the internal surface of the cavities 5a, 5b over an increasingly greater part of their length, the length of the part of the pin 3a, 3b that can bend still further becomes increasingly shorter, so that the force which is required to effect such further bending increases progressively. A suitable internal surface of the cavity 5, in a sectional plane coinciding with the longitudinal centerplane of the pin 3a, 3b, can follow the contour of, for instance, a segment of a circle, a segment of a parabola or a like continuous contour.

It is clear that the contour of the internal surface need not be rotation-symmetrical with respect to the longitudinal axis of the pin 3. By choosing a non-rotation symmetrical contour, it can for instance be provided that the increase of the counteractive force upon a decrease of the distance between the free ends 2a, 2b of the pedicle screws 1a, 1b has a different curve than in the case where the distance is increased. Accordingly, it can thus be provided that more force is required for extension than for flexion.

The pin 3 can be secured in the cavity 5 by means of a securing bolt (not shown) extending transversely to the longitudinal axis of the pin 3. The pin 3 can also be connected with the free end 2 of the pedicle screw 1 by means of a press fit. Of course, other securing methods are possible as well.

In the exemplary embodiment shown, the pins 3 and the rigid connecting member 4 are constructed in one piece. The constriction 6 at the transition between the rigid connecting member 4 and the pins 3 creates the possibility of pivotal movement of the pins 3a, 3b relative to the rigid connecting member 4. It is clear that this possibility of pivotal movement can also be created in a different manner. Thus, the pins 3a, 3b may at the second end thereof be provided with a spherical body and the rigid connecting member 4 may be provided with cup-shaped cavities in which the spherical bodies are receivable. When placing the rigid connecting member 4, the spherical bodies are received in the cup-shaped cavities and thus form a ball-and-socket joint.

By manufacturing the pins 3 from memory metal, in particular from a TiNi alloy, a relatively short pin 3 yet enables a considerable elastic deformation of the pin and hence a relatively large displacement of the second end of the pins 3a, 3b through bending of the pins 3a, 3b. This is possible in that the memory metal features an elongation in the elastic range of 8%. For this application, no use is made of the mnemonic properties of the material.

In order to implant the device, first the pedicle screws 1a, 1b are fitted at the appropriate points in two adjacent vertebrae V1, V2 (see Figs. 1, 2). Then the vertebral column is brought into the equilibrium or neutral position and the distance between the free ends 2a, 2b of the pedicle screws is accurately determined. Then a coupling element comprising the rigid connecting member 4 and the two pins 3a, 3b of the proper length is placed in the pedicle screws and secured, for instance by means of securing bolts or by tapping it home into a press fit.

Fig. 5 shows an alternative embodiment of a device according to the invention, which comprises two vertebra engaging elements in the form of pedicle screws 11a, 11b and a coupling element 12. The coupling element 12 comprises a rigid connecting member 13 and two ball-and-socket joints 14a, 14b, each comprising a ball 15a, 15b and a socket 16a, 16b. In mounted condition, each ball 15 is rigidly connected with the associated pedicle screw 11. Both sockets 16 are slidably connected with the rigid connecting member 13 and in a neutral position are urged in an end

position by biassed springing means 17a, 17b. Fig. 5 shows the device in the neutral position. In the exemplary embodiment shown, the springing means 17a, 17b are formed by blocks 17a, 17b manufactured from rubber or plastic and accommodated in a chamber 18a, 18b. A block 17 accommodated in the chamber 18 can initially deform freely, until the block contacts the walls of the chamber 18 and the deformation is influenced. Because of this influence, the force required for further deformation of the rubber block 17 increases progressively.

In the exemplary embodiment shown in Fig. 5 the two sockets 16a, 16b are each positioned relative to the springing means 17a, 17b in such a manner that upon an increase of the distance between the free ends 15a, 15b of the pedicle screws 11a, 11b one socket 16b is urged into the associated end position and the other socket 16a moves from the end position against the spring pressure of the springing means 17a associated with that socket 16a. Conversely, upon a decrease of the distance between the free ends 15a, 15b of the pedicle screws 11a, 11b, the above-mentioned other socket 16a is urged into the end position while the above-mentioned one socket 16b moves from the end position against the spring pressure of the springing means 16b associated with the one socket 16b.

Optionally, the elasticity of one rubber block 17a may be chosen differently from that of the other rubber block 17b. Thus it can be provided that a greater force is required for moving the free ends 15a, 15b of the pedicle screws 11a, 11b towards each other than for moving them apart.

In this embodiment, the pedicle screws 11a, 11b are each provided with a conical nut 19a, 19b, formed thereon, which facilitates tightening the pedicle screws 11a, 11b and which also serves as a stop. In the embodiment of Figs. 3 and 4, this conical stop is integrated into the free end 2a, 2b of the pedicle screw 1a, 1b.

In a third embodiment, which is shown in Figs. 6 and 8, the coupling element comprises a leaf spring 22 which is provided with a curvature. The leaf spring 22 is clamped in a slot in the free ends 23a, 23b of the vertebra engaging elements, which in this exemplary embodiment are designed as pedicle screws 21a, 21b. In the exemplary embodiment shown, the clamping is effected by means of locking screws 26. It will be clear that a press fit, soldering, welding or other jointing techniques also qualify for this purpose. Upon an increase of the distance between the free ends 23a, 23b of the pedicle screws 21a, 21b, the leaf spring 22 exerts on the pedicle screws a force counteracting the distance increase. According as the distance between the free ends 23a, 23b of the pedicle screws 21a, 21b increases, the curve in the leaf spring 22 is straightened, so that the spring arm becomes smaller and the force required to further extend the leaf spring increases progressively.

In order to effect the progressive increase of the counteractive force also in the case where the free ends 23a, 23b of the pedicle screws 21a, 21b move towards each other, in the fourth embodiment, shown in Fig. 7, the coupling element is made up of two leaf springs 24, 25. The curvatures of the two leaf springs 24, 25 are of such design that upon a decrease of the distance between the free ends 23a, 23b of the pedicle screws 21a, 21b the leaf springs 24, 25 butt against each other. Owing to the fact that the leaf springs 24, 25 will butt against each other upon a particular decrease of the distance between the free ends 23a, 23b of the pedicle screws 21a, 21b, a much greater counteractive force will have to be overcome for any further reduction of the distance. Through the interaction between the two leaf springs 24, 25 the spring characteristic thereof will change markedly, in particular because the leaf springs 24, 25 must bend over a shorter part of the length thereof. This change of the spring characteristic results in a progressive increase of the counteractive force upon a decrease of the distance between the free ends 23a, 23b of the pedicle screws 21a, 21b. It will be clear that the invention is not limited to the exemplary embodiments described but that various modifications are possible within the purview of the invention.

Claims

1. A device for implantation for the purpose of limiting movements between two vertebrae (V1, V2), comprising at least two vertebra engaging elements (1a, 1b; 11a, 11b) each having a free end (2a, 2b; 15a, 15b), and an elastic coupling element (3a, 3b, 4; 12) which is connected with the free ends (2a, 2b; 15a, 15b) of the vertebra engaging elements (1a, 1b; 11a, 11b), the elastic coupling element (3a, 3b, 4; 12) being designed in such a manner that upon an increase of the distance between the free ends (2a, 2b; 15a, 15b) of the vertebra engaging elements (1a, 1b; 11a, 11b) starting from a neutral position the coupling element (3a, 3b, 4; 12) generates a force counteracting the increase and upon a decrease of the distance between the free ends (2a, 2b; 15a, 15b) of the vertebra engaging elements (1a, 1b; 11a, 11b) starting from the neutral position the coupling element (3a, 3b, 4; 12) generates a force counteracting the decrease.

2. A device according to claim 1, characterized in that the force counteracting the increase or decrease of the distance between the free ends (2a, 2b; 15a, 15b) of the vertebra engaging elements (1a, 1b; 11a, 11b) increases progressively with the extent of increase or decrease.

3. A device according to claim 2, characterized in that the counteractive force increases exponentially with the extent of increase or decrease.

4. A device according to claim 2 or 3, characterized in that the counteractive force arising upon a particular increase of the distance between the free ends (2a, 2b; 15a, 15b) of the vertebra engaging elements (1a, 1b; 11a, 11b) is smaller than the counteractive force arising upon an equally large decrease of that distance.

5. A device according to any one of claims 1-4, characterized in that the coupling element (3a, 3b, 4) comprises two flexible pins (3a, 3b) which are each rigidly connected by one end with the free end (2a, 2b) of a vertebra engaging element (1a, 1b) and are each connected at the other end with a rigid connecting member (4), each vertebra engaging element (1a, 1b) at the free end (2a, 2b) thereof comprising an internal cavity (5) in which the pin (3a, 3b) extends at least partly, the internal surface of the cavity (5) serving to support the pin (3a, 3b) during the bending thereof.

6. A device according to claim 5, characterized in that the internal surface of the cavity (5) in the vertebra engaging element (1a, 1b) is designed in such a manner that upon a greater extent of increase or decrease of the distance between the free ends (2a, 2b) of the vertebra engaging elements (1a, 1b), i.e. upon stronger bending of the pins (3a, 3b), the pins (3a, 3b) abut against the internal surface over a greater part of their length.

7. A device according to claim 5 or 6, characterized in that the flexible pin (3a, 3b) is manufactured from memory metal, such as, for instance, a TiNi alloy.

8. A device according to any one of claims 5-7, characterized in that the rigid connecting member (4) is pivotally connected to the free ends of the two flexible pins (3a, 3b).

9. A device according to any one of claims 5-8, characterized in that the pins are designed as a bundle of substantially parallel wire-shaped elements.

10. A device according to any one of claims 1-4, characterized in that the coupling element (12) comprises a rigid connecting member (13) and two ball-and-socket joints (14a, 14b) each comprising a ball (15a, 15b) and a socket (16a, 16b), each ball (15a, 15b) in mounted condition being rigidly connected with an associated vertebra engaging element (11a, 11b), while each socket (16a, 16b) is slidably connected with the rigid connecting member (13) and in a neutral position is urged into an end position by biassed springing means (17a, 17b).

11. A device according to claim 10, characterized in that the springing means (17a, 17b) are formed by blocks (17a, 17b) made of rubber or plastic and accommodated in a chamber (18a, 18b) of the rigid connecting member (13).

12. A device according to claim 10 or 11, characterized in that the two sockets (16a, 16b) are each positioned relative to the springing means (17a, 17b) in such a manner that upon an increase of the distance between the free ends (15a, 15b) of the vertebra engaging elements (11a, 11b) one socket (16b) is urged into the associated end position and the other socket (16a) moves from the end position against the spring pressure of the springing means (17a) associated with that socket (16a), while upon a decrease of the distance between the free ends (15a, 15b) of the vertebra engaging elements (11a, 11b) said other socket (16a) is urged into the end position and said one socket (16b) moves from the end position against the spring pressure of the springing means (17b) associated with said one socket (16b).

13. A device according to any one of claims 1-4, characterized in that the coupling element comprises at least one spring element, manufactured from springing wire or sheet material, which is provided with a curvature, the or each spring element being connected at free ends thereof with the free ends of the vertebra engaging elements.

14. 14. A device according to claim 13, characterized in that the coupling element comprises two spring elements, the curvatures of the two elements being so designed that upon a decrease of the distance between the free ends of the vertebra engaging elements the spring

elements butt against each other.

15. 15. A device according to any one of claims 13 or 14, characterized in that the spring elements are designed as leaf springs.

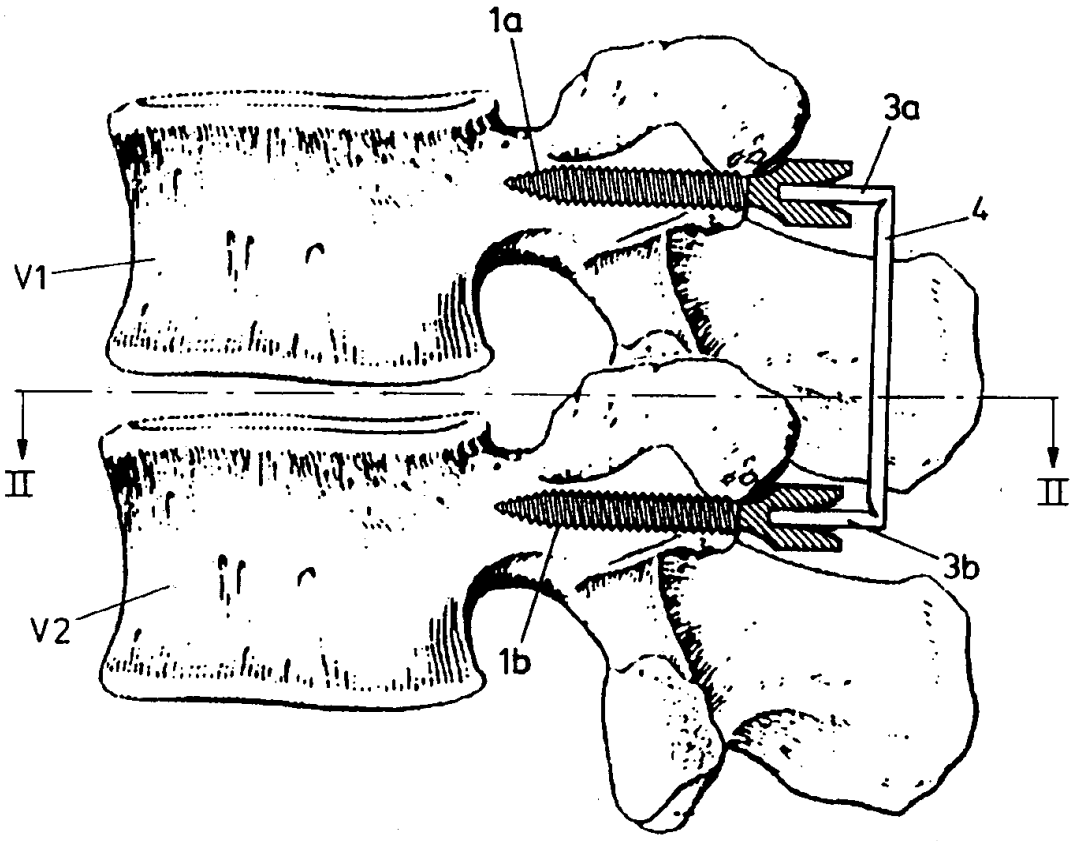

FIG.1

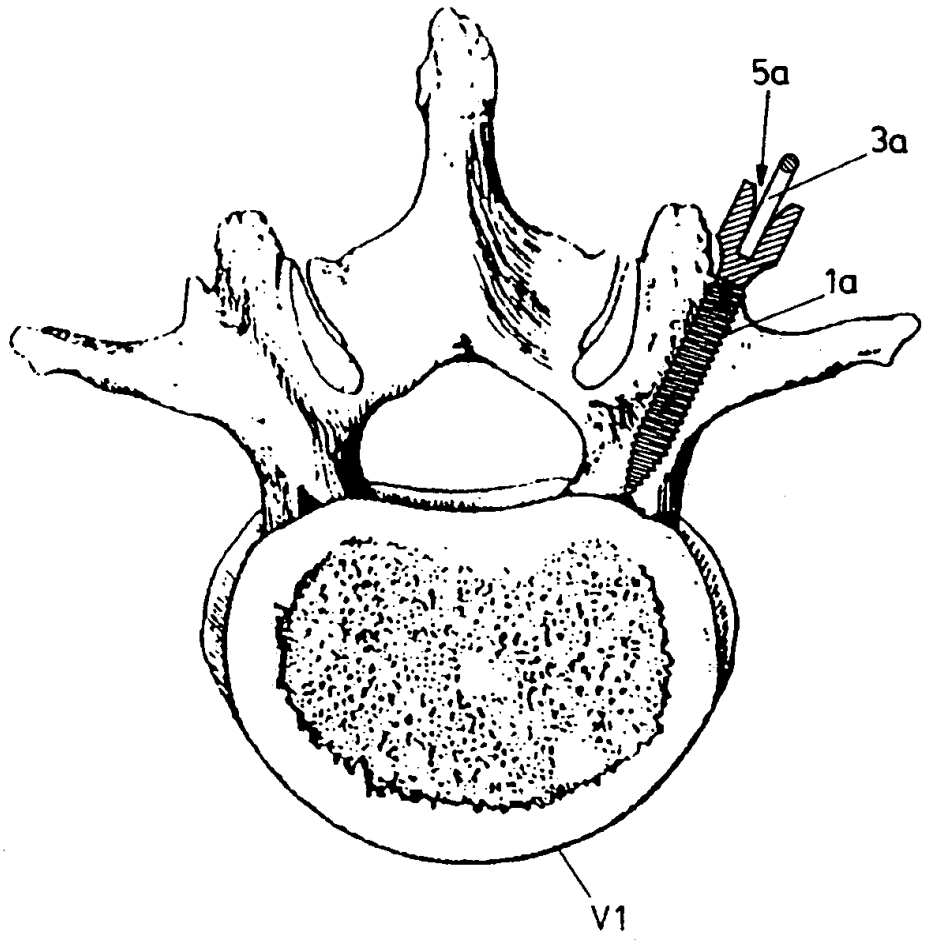

FIG.2

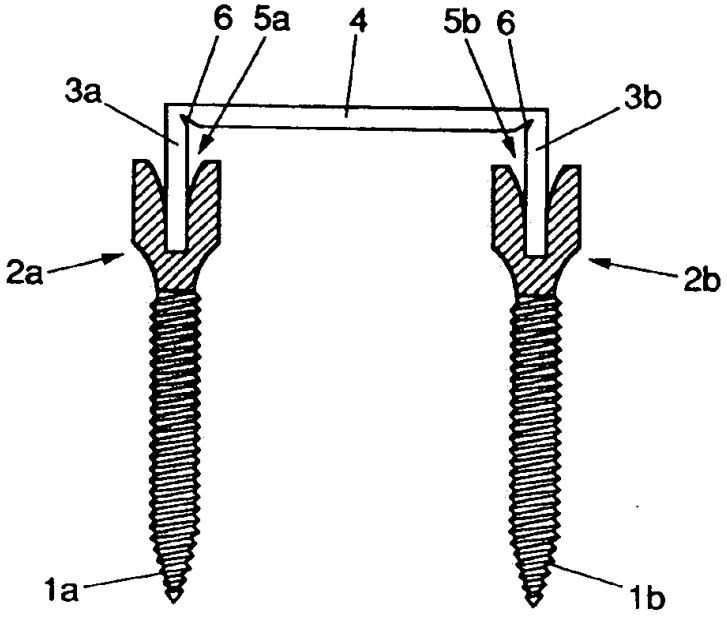

FIG. 3

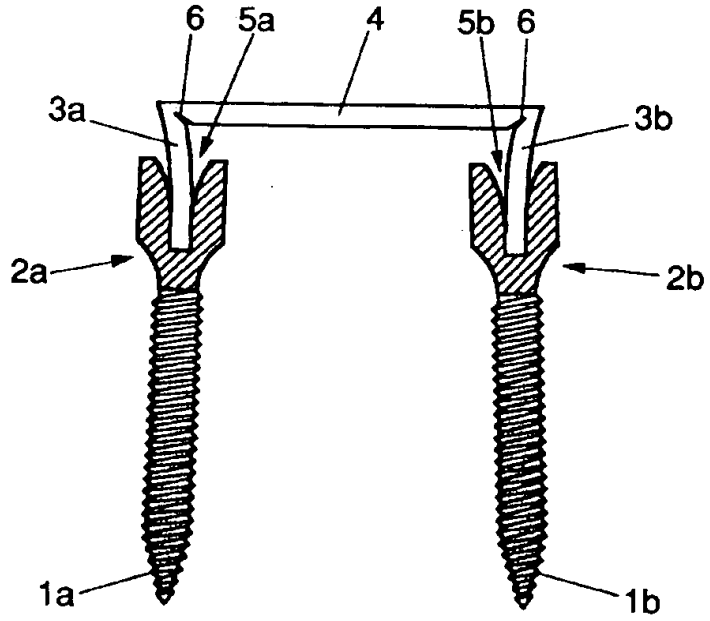

FIG. 4

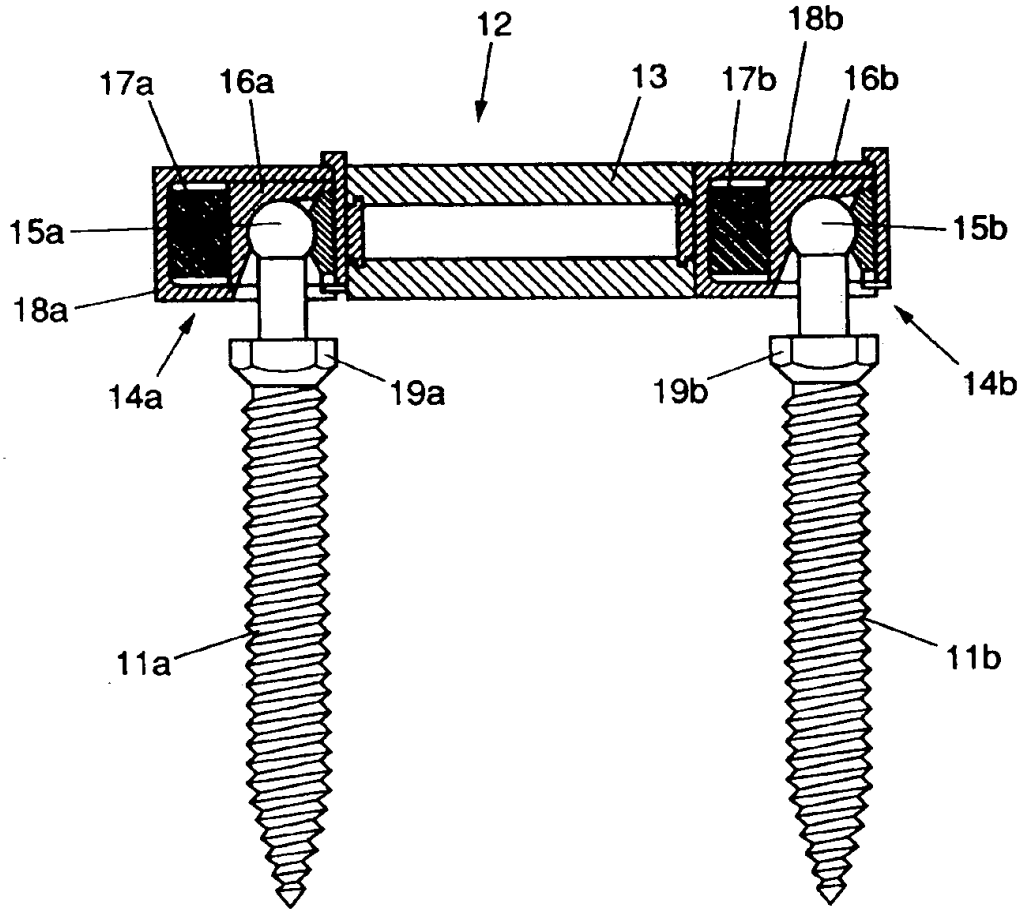
12
18b
17a
16a
13
17b
16b
15a
15b
18a
14a
19a
19b
14b
11a
11b

FIG. 5

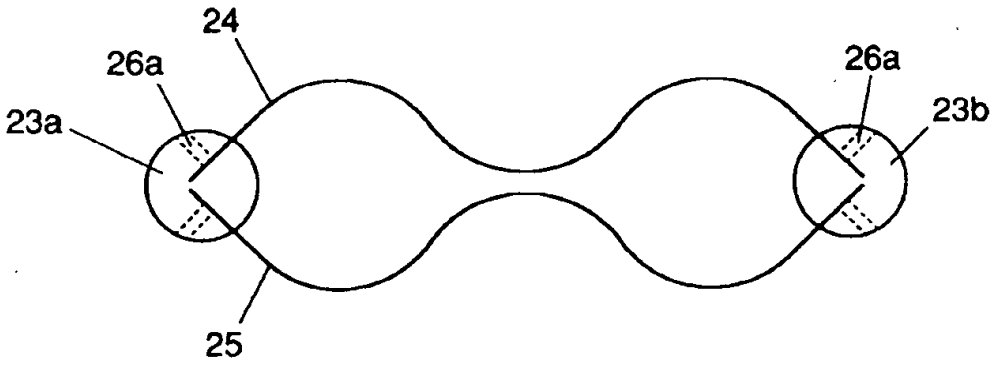
24
26a
26a
23a
23b
25

FIG. 7

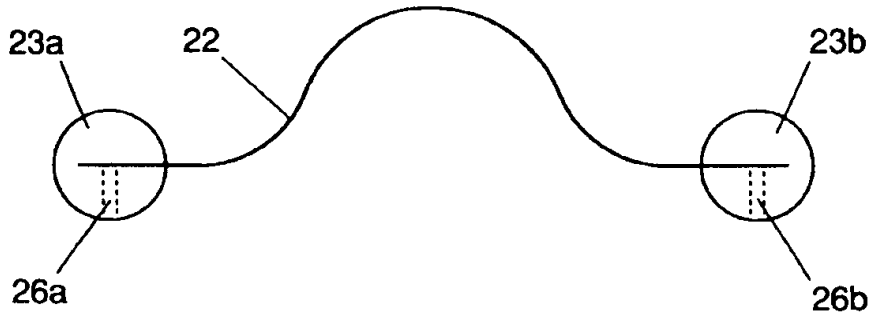

FIG. 6

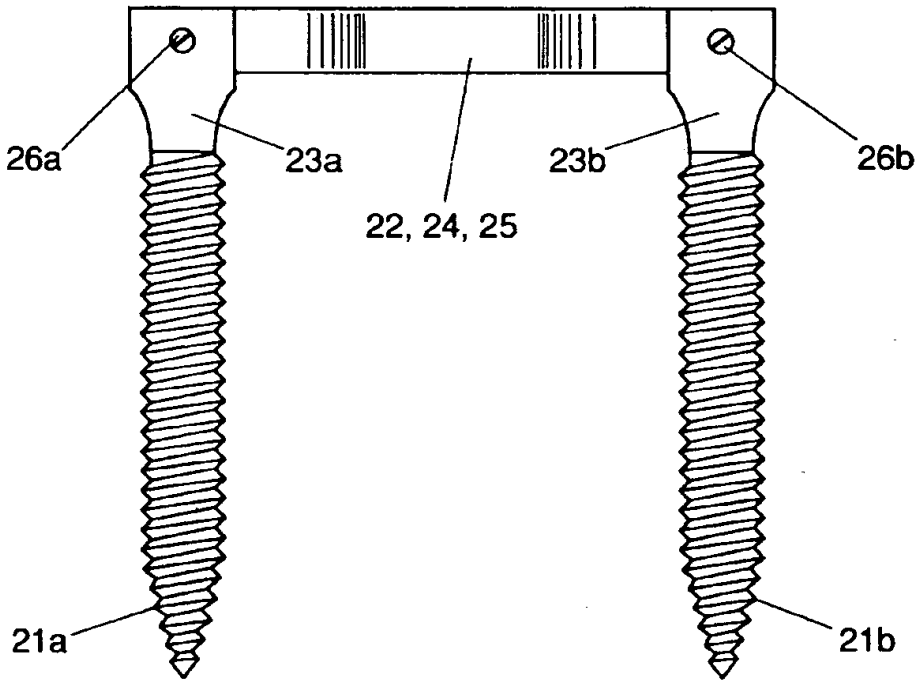

FIG. 8

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 95 20 0317

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	EP-A-0 576 379 (PSI) * abstract; figure 4 * * column 3, line 36 - line 44 * * column 4, line 10 - line 23 *	1-4, 10-12	A61B17/58
X	EP-A-0 516 567 (PSI) * column 5, line 41 - line 48 * * column 7, line 4 - line 6 * * figures 3,8-10 *	1,2,4,10	
X	EP-A-0 322 334 (COTE) * claim 1; figure 1 *	1,2,4	
X	FR-A-2 681 525 (MEDICAL OP) * abstract; figures *	1,2,13	
A	EP-A-0 140 790 (W.PEZE) * abstract; figures 1,3,9 * * page 10, line 8 - line 12 * * page 12, line 22 - line 28 *	7,9	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
P,X	FR-A-2 697 428 (A.ALBY) * abstract; figures 5,9 *	1-3, 10-12	A61B
P,X	EP-A-0 611 554 (PSI) * figures 3,4 *	1-3, 10-12	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	18 May 1995	Nice, P

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

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(54) Composite structure and method of forming same

(57) A method of forming a composite structure (60) comprises the steps of forming a radially inner portion (64) of a preform with braided reinforcing fibers extending substantially transverse to an axis of the preform and forming a radially outer portion (68) of the preform circumscribing the inner portion with braided reinforcing fibers extending substantially parallel to the axis of the preform. The preform is heated and consolidated in a mold into the composite structure. The composite structure has braided reinforcing fibers extending throughout a radially inner portion (60) substantially transverse to an axis of the structure along which the structure is subject to splitting to resist splitting of the composite structure along the axis and braided reinforcing fibers extending throughout a radially outer portion (68) substantially parallel to the axis to resist bending of the composite structure. The composite structure is particularly suitable for manufacturing a bone plate.

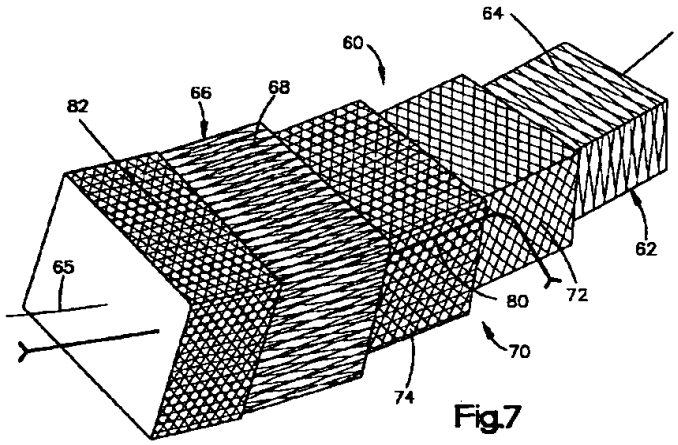

Fig.7

EP 0 706 876 A1

Description

Background of the Invention

The present invention relates to a composite structure, and in particular relates to a composite structure comprising matrix material with braided reinforcing fibers and a method of making the structure.

There are many known composite structures which comprise a fiber reinforced matrix material. A known composite structure comprises a laminated stack of layers of matrix material containing linearly oriented reinforcing fibers. The direction of orientation of the reinforcing fibers in one layer may be at a different angle relative to the direction of orientation of the reinforcing fibers in an adjacent layer. A disadvantage of a laminated stack of layers of a matrix material containing linearly oriented reinforcing fibers is that there is no fiber reinforcement in a direction perpendicular to the layers. A known way to strengthen the structure in the direction perpendicular to the layers is to stitch the layers together. A disadvantage in stitching the layers together is that the stitching process is labor and equipment intensive. Also, known fiber reinforced composite structures are made from knitted fibers and woven fibers which form a three-dimensional structure. However, the making of these composite structures is also labor and equipment intensive.

Summary of the Invention

In accordance with the present invention, a composite structure is made by a method which comprises the steps of braiding reinforcing fibers of a radially inner portion of a preform to extend substantially transverse to an axis of the preform along which the composite structure is subject to splitting. Reinforcing fibers of a radially outer portion circumscribing the radially inner portion are braided to extend substantially parallel to the axis of the preform. The preform is placed in a mold and heated to a temperature at which fibers which are to become the matrix material melt but the reinforcing fibers do not melt. The preform is consolidated in the mold. After heating and consolidating the preform, the composite structure is cooled so that a device such as a bone plate can be machined from the composite structure.

The composite structure comprises a radially inner portion of matrix material with braided reinforcing fibers extending throughout the inner portion substantially transverse to an axis of the composite structure along which the composite structure is subject to splitting to resist splitting of the composite structure. A radially outer portion of matrix material circumscribes the inner portion and has braided reinforcing fibers extending throughout the outer portion substantially parallel to the axis to resist bending of the composite structure.

The composite structure is similar to an I-beam in bending. The radially outer portions, like the outer webs of an I-beam, need the strength to resist bending of the composite structure because the stresses due to the bending are concentrated in the radially outer portions. The radially inner portion, like the connecting web of the I-beam, does not need to resist bending. The radially inner portion can be used to resist splitting of the composite structure.

The composite structure is machined into a bone plate for maintaining adjacent bone members, such as vertebrae or pieces of a broken bone, in a desired spatial relationship. When fasteners extend through openings in the bone plate to connect the bone plate to bone, the bone plate is subjected to clamping forces which could cause the bone plate to split along an axis. The braided reinforcing fibers in the radially inner portion of matrix material resist splitting of the bone plate due to the clamping forces applied to the bone plate by the fasteners. Furthermore, the braided reinforcing fibers extending through the radially outer portion resist bending of the bone plate and prevent movement between adjacent bone members which the bone plate is connected to.

A composite bone plate, as compared to a metal bone plate, is advantageous because it does not block the image of tissue on X-ray films and computerized tomography scans. A doctor can easily see if the pieces of a broken bone to which the composite bone plate is connected are healing properly or if adjacent vertebrae to which the composite bone plate is connected are fusing together properly. An X-ray marker, such as a titanium wire, may be braided into the composite bone plate so that a doctor may determine the position of the bone plate.

Another advantage of the composite bone plate is that the plate can be designed to prevent stress shielding. The stress-strain curve for bone has an initial region where some strain is achieved with very little stress. This initial region of the stress-strain curve is often called the "toe" of the stress-strain curve. At higher stresses, the curve becomes linear or proportional. The "toe" region allows for some deformation of the bone at low stress levels, while becoming more rigid at higher stresses, protecting against higher loads. The low stress deformation of bone is important in bone remodeling since the bone remodels to support applied loads.

When stiff metallic implants are connected to bone, the surrounding bone is shielded from applied stresses and the bone resorbs. If flexible implants are used, at high loads, the bone is deformed too much and damaged. The composite structure of the present invention is well suited for use as a bone plate since it can be made to have a stress-strain curve similar to that of bone, that is, with a low-stress "toe" region.

Contorted reinforcing fibers may be used in the composite structure to increase the size of the "toe" region. Twisted commingled yarn may be used in braiding the preform or the reinforcing fibers may be coiled, wavy, or kinked. With these

structures, the matrix material of the bone plate deforms at low stress levels while the reinforcing fibers begin to straighten out. At higher stress levels, the reinforcing fibers straighten out to pick up the load and the composite plate becomes stiffer.

Brief Description of the Drawings

The foregoing and other features of the present invention will become apparent to one skilled in the art upon consideration of the following description of the preferred embodiments of the invention with reference to the accompanying drawings, wherein:

Fig. 1 is a fragmentary view of a portion of a spinal column on which a composite bone plate constructed in accordance with the present invention has been installed to maintain vertebrae in a desired spatial relationship;
Fig. 2 is a sectional view, taken generally along the line 2-2 of Fig. 1, illustrating the manner in which fasteners are used to connect the composite bone plate with the vertebrae;
Fig. 3 is a plan view of the composite bone plate of Fig. 1;
Fig. 4 is a sectional view of the composite bone plate of Fig. 3 taken along the line 4-4 of Fig. 3;
Fig. 5 is a schematic view of a preform, partially cut away to show various layers of the preform, used in forming the composite bone plate of Fig. 1;
Fig. 6 is an enlarged plan view of a portion of a layer of the preform of Fig. 5;
Fig. 7 is a schematic perspective view of a composite structure, partially cut away to show various portions of the structure, from which the bone plate of Fig. 1 is machined; and
Fig. 8 is a graph showing the relationship between stress and strain for the composite structure of Fig. 7.

Description of the Preferred Embodiments of the Invention

A pair of surgically implantable composite bone plates 10 (Fig. 1) for correcting deformation and/or degeneration of a spinal column C are connected with several vertebrae V of the spinal column by fasteners 20. Each composite bone plate 10 is elongate and has a rectangular cross-section taken in a plane extending perpendicular to a longitudinal central axis 12 of the plate (Fig. 2). Each composite plate 10 is preferably curved to conform to a desired curvature of the spinal column C, as illustrated in Fig. 4. The composite bone plates 10 have sufficient strength and rigidity to maintain the vertebrae V in the desired relationship. Although the composite bone plates are shown maintaining vertebrae in a desired spatial relationship, they may be used for maintaining pieces of a broken bone in a desired relationship.

The composite bone plates 10 are connected to respective vertebrae V by fasteners 20 (Fig. 2) made of a suitable biocompatible material, such as titanium or stainless steel. Each of the fasteners 20 has a threaded inner end portion 22 having a coarse helical thread convolution 24 which engages the vertebra V. An outer end portion 26 of the fastener 20 is provided with a relatively fine thread which engages an internal thread convolution on a clamp nut 28 preferably made of a suitable biocompatible material, such as titanium coated with titanium nitride. Wrenching flats (not shown) are provided on the outermost end of the outer end portion 26 of the fastener 20. Torque is applied to these wrenching flats to turn the relatively coarse helical thread convolution 24 into the vertebra V. Once the fastener 20 has been connected to the vertebra and the composite bone plate 10, the outer end portion of the fastener may be cut away to minimize the overall length of the fastener.

An intermediate portion 32 is provided with wrenching flats which can be engaged to hold the fastener 20 against rotation when the clamp nut 28 is tightened. In addition, the intermediate portion 32 of the fastener has a flat outer side surface which abuttingly engages the composite bone plate 10. When the clamp nut 28 is tightened, the composite bone plate 10 is securely gripped between the clamp nut 28 and the intermediate portion 32 of the fastener 20.

Although it is contemplated that the fastener 20 could have many different constructions, it is preferred to construct the fastener 20 in accordance with U.S. Patent No. 4,854,311 which is assigned to the assignee of the present invention. Another possible fastener would include a piece with a plurality of ridges that mates with a plurality of ridges on the plate to prevent movement of the plate relative to the fastener.

Each of the composite bone plates 10 has a length which is at least sufficient to enable the bone plate to span at least two of the vertebrae V. In the embodiment of the invention illustrated in Fig. 1, the bone plates 10 span two vertebrae V. Of course, the length of the composite bone plates in any particular installation will depend upon the condition to be corrected and the number of vertebrae V to be held in a desired spatial relationship relative to each other by the composite bone plates. Preferably, each of the composite bone plates includes a titanium wire 80 (Fig. 2) extending along the longitudinal extent of the bone plate as an X-ray marker.

Each of the composite bone plates 10 is identical and includes at least one slot 40 (Figs. 3 and 4) and may include a circular opening 42 located adjacent an end portion of the bone plate. The bone plate 10 may have any number of slots for receiving fasteners depending on the length of the bone plate. The bone plate 10 has an upper surface 44 provided with spherical recesses 46 along the slot 40 defining a plurality of locations for receiving the fastener 20. If the bone plate 10 includes a circular opening 42, then upper surface 44 also includes a spherical recess 48 surrounding

the opening 42 for receiving a fastener 20. The spherical recesses 46 and 48 have a radius that is the same as a radius of a spherical surface of the clamp nut 28 and is approximately 16mm. The spherical recesses extend approximately 145° to help prevent splitting of the plate along the longitudinal axis 12 by directing most of the clamping forces applied to the plate in a direction normal to the surface 44 instead of transverse to the axis 12.

Preferably, a composite structure 60 from which the bone plate 10 is machined is formed by heating and consolidating a cylindrical braided preform 100 (Fig. 5) having a longitudinal axis 101. The preform 100 has a cross-section that forms a cross-section of a single composite structure 60 upon heating and consolidating the preform. The preform 100 may have any desired length to form one or a plurality of composite structures 60.

The preform 100 comprises a plurality of concentric layers of braided commingled yarn. The layers have varying braid angles with the inner layers having a large braid angle and the outer layers having a relatively small braid angle. The braid angle X is defined as half of the interlacing angle between yarns such as A and B, as shown in Fig. 6.

Preferably, the yarn is a commingled yarn known as Ultrapek/AS-4 Commingled Yarn manufactured by Cytec Inc., Anaheim, CA. Ultrapek/AS-4 Commingled Yarn comprises Ultrapek polymer fibers made from poly(ether ketone ether ketone ketone) by BASF Inc., Charlotte, NC commingled with AS-4 carbon fibers made from a polyacrylonitrile percurser by Hercules Advanced Materials and Systems Company, Magna, UT. The carbon fibers are the reinforcing fibers and the polymer fibers become matrix material when melted. Preferably, the reinforcing fibers are between 55% and 75% of the weight of the preform 100.

Alternatively, the material of which the yarn is made may be carbon fibers that have firmly adhering polymer powder bonded to the carbon fibers. Also, the material of which the yarn is made may be carbon fibers having a thin coating of polymer material. Also, the carbon fibers may be replaced with other carbon or graphite fibers or with glass fibers, silicon carbide fibers, or any other structural fibers. Also, the Ultrapek polymer may be replaced with other high performance and biocompatible polymers. These include, but are not limited to, other poly (aryl ether ketone)s such as PEEK, PEKK, and PEK, as well as poly (amide imide)s, poly (aryl sulfone)s, nylon, poly (butylene phthalate), poly (ethylene phthalate) and liquid crystal polymers or other similar polymers.

The preform 100 includes a radially inner plurality of concentric layers 102, one of which is shown in Figs. 5 and 6, of biaxially braided commingled yarn. The braid angle X of each of the layers 102 is between approximately 60° and 90°. It is desirable to have the braid angle as close to 90° as possible. Preferably, the inner plurality of concentric layers 102 comprises approximately one third of the thickness of the preform 100. The number of layers and the actual braid angle may vary depending on the braiding process.

An intermediate plurality of concentric layers 104 and 106 of braided yarn circumscribes the radially inner plurality of concentric layers 102. The braid angle of each of the layers of the intermediate plurality of concentric layers 104 and 106 is between approximately 40° and approximately 55°. The intermediate plurality of layers includes a first plurality of concentric layers 104, one of which is shown in Fig. 5, of biaxially braided yarn and a second plurality of concentric layers 106, one of which is shown in Fig. 5, of triaxially braided yarn circumscribing the first plurality of layers. Triaxially braided yarn has a pattern similar to the pattern of biaxially braided yarn shown in Fig. 6 with another system of yarn extending parallel to the longitudinal axis 101 of the preform 100 braided between the yarn extending transverse to the longitudinal axis.

The titanium wire 80 is braided into one of the second plurality of layers 106. Preferably, the intermediate plurality of layers 104 and 106 comprises approximately one third of the thickness of the preform 100. The actual number of intermediate layers 104 and 106 and the braid angle of the intermediate layers 104 and 106 may vary depending on the braiding process.

A radially outer plurality of concentric layers 110, one of which is shown in Fig. 5, of triaxially braided yarn circumscribes the intermediate plurality of layers 104 and 106. The braid angle of each of the layers of the outer plurality of concentric layers 110 is between approximately 0° and approximately 45°. It is desirable to have the braid angle as close to 0° as possible. Preferably, the outer plurality of concentric layers 110 comprises approximately one third of the thickness of the preform 100. The number of outer layers 110 and the actual braid angle of outer layers 110 may vary depending on the braiding process.

A radially outermost concentric layer 112 of triaxially braided yarn circumscribes the radially outer plurality of concentric layers 110. The outermost layer 112 has a braid angle of between approximately 40° and approximately 65°. The outermost layer 112 is tightly braided together so it does not come apart easily to provide for easy handling of the preform 100. Preferably, approximately half of the bias ends of the outermost layer 112 comprises a polymer yarn, the other half of the bias ends comprises Ultrapek/AS-4 commingled yarn and the axial ends comprise Ultrapek/AS-4 commingled yarn to provide a polymer rich surface of the composite structure 60.

Preferably, at least some of the reinforcing fibers are contorted prior to braiding the preform. The commingled yarn may be twisted, or coils, waves, or kinks may be formed in the reinforcing fibers. Therefore, the stress-strain curve (Fig. 7) of the composite structure has a "toe" region 200 and a linear region 202. At low stress levels the stress-strain curve is non-linear and at higher stress levels the stress and strain are approximately proportional. At low stresses the matrix material of the composite structure 60 deforms while the reinforcing fibers straighten out and at higher stresses the reinforcing fibers straighten and pick up the load.

EXAMPLES

Two examples of braided preforms from which composite bone plates have been formed are set forth below in Tables 1 and 2. The tables set out each concentric layer of the preform numbered from the radially innermost layer to the radially outermost layer. The braid angle and the picks per inch (ppi) for each layer are given in the tables. The picks per inch is defined as the distance between interlacing points and is labeled Y in Fig. 6.

TABLE 1

Layer	Braid Angle (deg.)	ppi
1	14	14
2	47	13
3	54	12
4	64	14
5	60	9
6	62	9
7	65	9
8	65	8
9	66	8
10	70	9
11	71	9
12	70	8
13	71	8
14	72	8
15	73	8
16	65	5
17	66	5
18	47	10
19	45	8
20	48	8.5
21	43	7
22	45	7
23	45	6.25
24	46	6.25
25	45	5.75
26	45	5.25
27	45	5
28	60	5

Layers 1-17 are biaxially braided with 4 bias ends. Layers 18-21 are biaxially braided with 16 bias ends. Layers 22 and 23 are triaxially braided with 16 bias ends and 16 axial ends. Layer 22 includes a bias end of titanium wire. Layers

24-27 are triaxially braided with 16 bias ends and 32 axial ends. Layer 28 is triaxially braided with 8 bias ends of commingled yarn, 24 bias ends of polymer yarn, and 48 axial ends of commingled yarn.

TABLE 2

Layer	Braid Angle (deg.)	ppi
1	33.4	14
2	50.8	13
3	65.5	14
4	71.4	14
5	72.2	12
6	74	12
7	75.8	12
8	77.8	12
9	59.1	4
10	60.1	4
11	54.7	4
12	44.1	2
13	44.8	2
14	45.1	8
15	26.6	3.5
16	25	3
17	26.6	3
18	30.1	3
19	22.2	2
20	28.8	2.5
21	30.2	2.5
22	64.2	7

Layers 1-13 are biaxially braided with 4 bias ends. Layers 14 and 15 are triaxially braided with 16 bias ends and 16 axial ends. Layer 14 includes an axial end of titanium wire. Layers 16-21 are triaxially braided with 16 bias ends and 32 axial ends. Layer 22 is triaxially braided with 8 bias ends of commingled yarn, 8 bias ends of polymer yarn, and 48 axial ends of commingled yarn.

In both examples the first few radially innermost layers have braid angles from 14° to 54°. These braid angles are a result of the braiding process and machinery. It is preferred that these innermost layers have a braid angle as close to 90° as possible.

After the preform 100 is formed, it is heated and consolidated into an elongate composite structure 60 from which the bone plate 10 is machined. The preform 100 may be cut into a plurality of lengths to form a plurality of composite structures 60. The preform 100 is placed into a mold and the mold is placed into a high temperature consolidation press with vacuum capability. The vacuum chamber of the press is evacuated, the temperature is set to 800°F, and the pressure is set to 500 lbs. closing force. It requires approximately one hour for the press to reach 800°F. As the press displacement decreases, showing consolidation of the preform, the pressure is increased to 7,000 lbs. The temperature and pressure are maintained for 45 minutes and then the heat is turned off and the press cooling is turned on. After the mold has reached ambient temperature, the press is opened, the mold is removed, and the consolidated composite structure 60

is removed from the mold. The composite structure 60 is then machined to form a desired bone plate 10. After the bone plate 10 is machined it is placed in an ultrasonic bath with acetone to remove any residual particulate debris.

The composite bone plate 10 is machined from the composite structure 60 (Fig. 7) comprising matrix material and reinforcing fibers. Preferably, the composite structure 60 is curved if the bone plate 10 is to be curved. The matrix material is the polymeric material, Ultrapek, and the reinforcing fibers are the AS-4 carbon fibers. Preferably, the reinforcing fibers make up between 55% and 75% of the weight of the composite structure 60.

The composite structure 60 includes a radially inner portion of matrix material 62 with a plurality of concentric layers 64, one of which is shown in Fig. 7, of biaxially braided reinforcing fibers extending throughout the inner portion. The reinforcing fibers in the radially inner portion of matrix material 62 extend substantially transverse to a longitudinal axis 65 of the composite structure 60 to resist splitting of the structure along the longitudinal axis 65 when connected to bone as a bone plate. The axis 65 of the composite structure 60 becomes the axis 12 of the bone plate 10. The reinforcing fibers in the radially inner portion 62 have a braid angle between approximately 60° and 90°. It is desirable to have the braid angle as close to 90° as possible.

The composite structure 60 has a radially outer portion of matrix material 66 which circumscribes the radially inner portion of matrix material 62. A plurality of concentric layers 68, one of which is shown in Fig. 7, of triaxially braided reinforcing fibers extend throughout the radially outer portion of matrix material 66 substantially parallel to the longitudinal axis 65 to resist bending of the composite structure. The reinforcing fibers in the outer portion 66 have a braid angle between 0° and approximately 45°. It is desirable to have the braid angle as close to 0° as possible.

The composite structure 60 also includes an intermediate portion of matrix material 70 circumscribing the inner portion of matrix material 62 and circumscribed by the outer portion of matrix material 66. A plurality of concentric layers 72 and 74 of braided reinforcing fibers extend throughout the intermediate portion 70 and have a braid angle between approximately 40° and approximately 55°. A first plurality of concentric layers 72, one of which is shown in Fig. 7, of braided reinforcing fibers of the intermediate portion 70 are biaxially braided. A second plurality of concentric layers 74, one of which is shown in Fig. 7, of braided reinforcing fibers of the intermediate portion 70 circumscribes the first plurality of concentric layers 72 of the intermediate portion and are triaxially braided. The titanium wire 80 extends through the intermediate portion 70 and substantially parallel to the longitudinal axis 65 of the composite structure 60 to act as an X-ray marker.

The composite structure 60 has a radially outermost layer 82 of braided reinforcing fibers. The radially outermost layer 82 circumscribes the radially outer portion of matrix material 66. The radially outermost layer 82 is triaxially braided and has a braid angle between approximately 40° and approximately 60°.

From the above description of the invention, those skilled in the art will perceive improvements, changes and modifications. Such improvements, changes and modifications within the skill of the art are intended to be covered by the appended claims.

Claims

1. A composite structure comprising:
   a radially inner portion of matrix material;
   a radially outer portion of matrix material circumscribing said inner portion;
   braided reinforcing fibers extending throughout said inner portion substantially transverse to an axis along which said composite structure is subject to splitting to resist splitting of said composite structure along said axis; and
   braided reinforcing fibers extending throughout said outer portion substantially parallel to said axis to resist bending of said composite structure;
   said directions of said reinforcing fibers resulting from heating and consolidating a preform made of matrix material and braided reinforcing fibers.

2. A composite structure as set forth in claim 1 wherein said reinforcing fibers in said inner portion have a braid angle between approximately 60° and 90° and said reinforcing fibers in said outer portion have a braid angle between 0° and approximately 45°.

3. A composite structure as set forth in claim 2 further including an intermediate portion of matrix material circumscribed by said outer portion of matrix material and circumscribing said inner portion of matrix material and braided reinforcing fibers extending throughout said intermediate portion, said reinforcing fibers in said intermediate portion having a braid angle between approximately 40° and approximately 55°.

4. A composite structure as set forth in claim 3 wherein each of said inner, intermediate, and outer portions includes a plurality of concentric layers of braided reinforcing fibers.

5. A composite structure as set forth in claim 4 wherein said plurality of concentric layers of reinforcing fibers in said inner portion are biaxially braided.

6. A composite structure as set forth in claim 5 wherein said intermediate portion includes a first plurality of concentric layers of biaxially braided reinforcing fibers and a second plurality of concentric layers of triaxially braided reinforcing fibers, said second plurality of concentric layers of reinforcing fibers circumscribing said first plurality of concentric layers of reinforcing fibers in said intermediate portion.

7. A composite structure as set forth in claim 6 wherein said plurality of concentric layers of reinforcing fibers in said outer portion are triaxially braided.

8. A composite structure as set forth in claim 3 further including a titanium wire extending through said intermediate portion.

9. A composite structure as set forth in claim 2 further including a radially outermost portion circumscribing said outer portion, said outermost portion including braided reinforcing fibers with a braid angle between approximately 40° and approximately 65°.

10. A composite structure as set forth in claim 1 including a plurality of openings for receiving fasteners.

11. A composite structure as set forth in claim 10 wherein said openings are defined by spherical recesses in a side surface of said composite structure which define a plurality of locations for receiving fasteners, each of said recesses defining a spherical arc extending approximately 145°.

12. A composite structure as set forth in claim 11 wherein at least one of said openings is a slot, said recesses defining a plurality of locations along said slot for receiving fasteners.

13. A composite structure as set forth in claim 12 further including a round opening located at an axial end portion of said structure.

14. A composite structure as set forth in claim 1 wherein said reinforcing fibers are between 55% and 75% of the weight of said composite structure.

15. A composite structure as set forth in claim 1 wherein at least some of said reinforcing fibers are contorted.

16. A composite structure as set forth in claim 15 wherein said at least some of said reinforcing fibers are coiled.

17. A composite structure as set forth in claim 15 wherein said at least some of said reinforcing fibers are twisted.

18. A method of forming a composite structure which in use is subject to splitting along an axis and bending, said method comprising the steps of:

providing a radially inner portion of a preform with a first plurality of braided reinforcing fibers extending substantially transverse to the axis;

providing a radially outer portion of the preform circumscribing the inner portion with a second plurality of braided reinforcing fibers extending substantially parallel to the axis; and

heating and consolidating the preform to form a matrix with the first and second plurality of braided reinforcing fibers extending through inner and outer portions of the matrix material, respectively.

19. A method as set forth in claim 18 including braiding the first plurality of reinforcing fibers of the inner portion of the preform with a braid angle between approximately 60° and 90° and braiding the second plurality of reinforcing fibers of the outer portion with a braid angle between 0° and approximately 45°.

20. A method as set forth in claim 19 including providing an intermediate portion of the preform circumscribed by the outer portion and circumscribing the inner portion with a third plurality of braided reinforcing fibers having a braid angle between approximately 40° and approximately 55°.

21. A method as set forth in claim 20 including providing a radially outermost portion of the preform circumscribing the outer portion with braided reinforcing fibers having a braid angle between approximately 40° and approximately 65°.

22. A method as set forth in claim 21 including braiding approximately 50% of bias ends of the radially outermost portion with matrix yarn, approximately 50% of the bias ends of the radially outermost portion with commingled matrix and reinforcing fiber yarn, and axial ends of the radially outermost portion with commingled matrix and reinforcing fiber yarn.

23. A method as set forth in claim 20 including forming each of the inner, intermediate, and outer portions to be approximately one third the thickness of the preform.

24. A method as set forth in claim 20 including forming each of the inner, intermediate, and outer portions out of a plurality of concentric layers of braided fibers.

25. A method as set forth in claim 24 including biaxially braiding the plurality of concentric layers of the inner portion.

26. A method as set forth in claim 24 including biaxially braiding a first plurality of concentric layers of the intermediate portion and triaxially braiding a second plurality of concentric layers of the intermediate portion circumscribing the first plurality of concentric layers of the intermediate portion.

27. A method as set forth in claim 24 including triaxially braiding the plurality of concentric layers of the outer portion.

28. A method as set forth in claim 24 including braiding a titanium wire into the intermediate portion.

29. A method as set forth in claim 18 including contorting at least some of the reinforcing fibers prior to braiding.

30. A method as set forth in claim 29 wherein said step of contorting the reinforcing fibers includes forming coils in the reinforcing fibers.

31. A method as set forth in claim 29 including forming the preform with commingled yarn.

32. A method as set forth in claim 31 wherein the step of contorting the reinforcing fibers includes twisting the commingled yarn.

33. A method as set forth in claim 18 including forming a plurality of openings in the composite structure for receiving fasteners.

34. A method as set forth in claim 33 including forming spherical recesses extending approximately 145° in a side surface of the composite structure to define a plurality of locations for receiving fasteners.

35. A method as set forth in claim 34 including forming a slot with at least two recesses defining locations for receiving fasteners.

36. A method as set forth in claim 35 including forming a round opening at an axial end portion of the composite structure for receiving one fastener.

37. A method as set forth in claim 18 further including forming the composite structure with the reinforcing fibers making up between 55% and 75% of the weight of the composite structure.

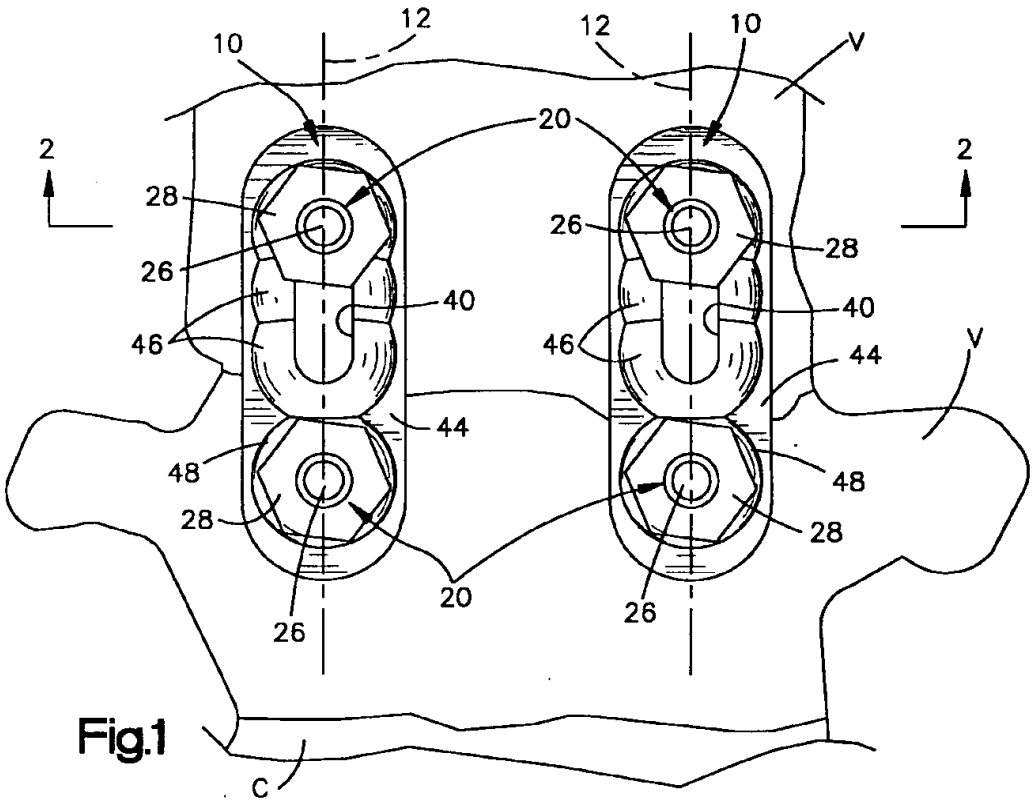
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Fig.1

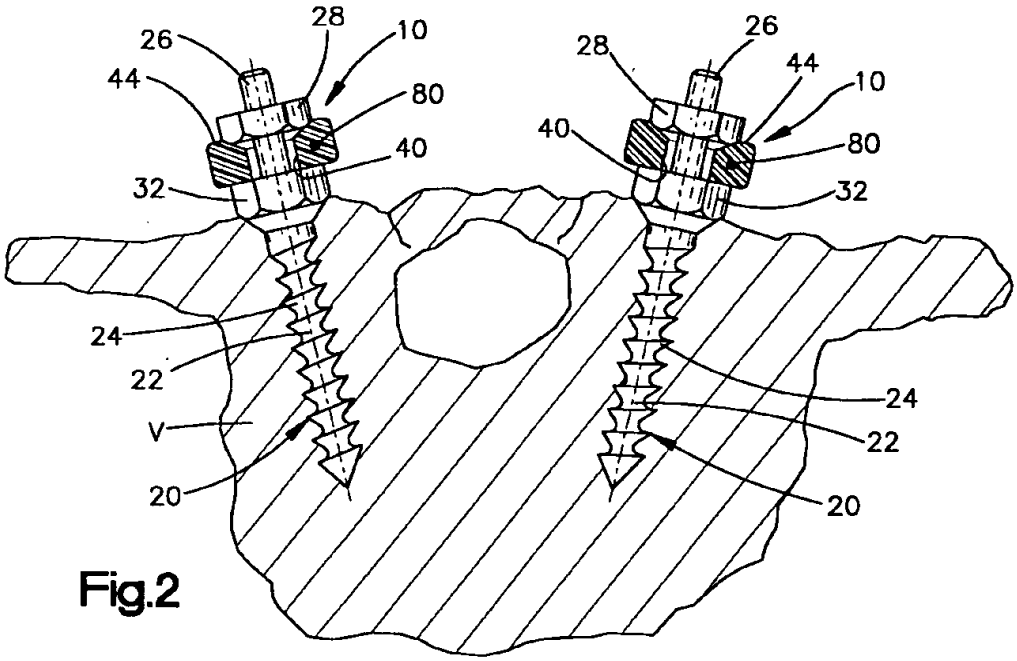
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Fig.2

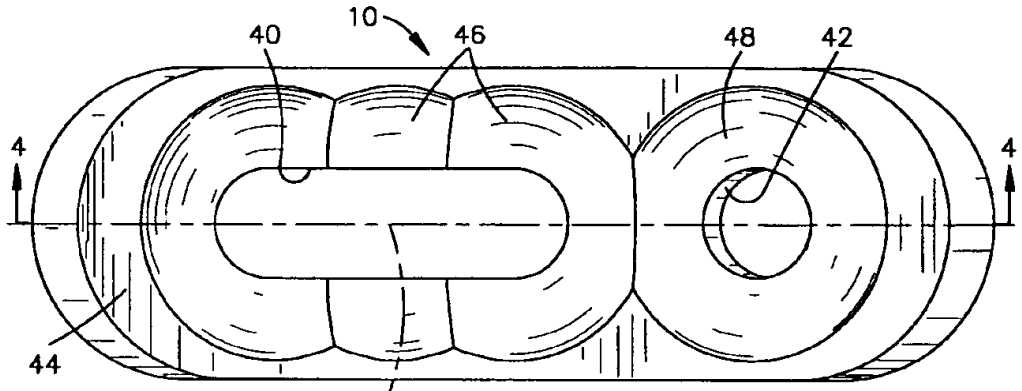

Fig.3

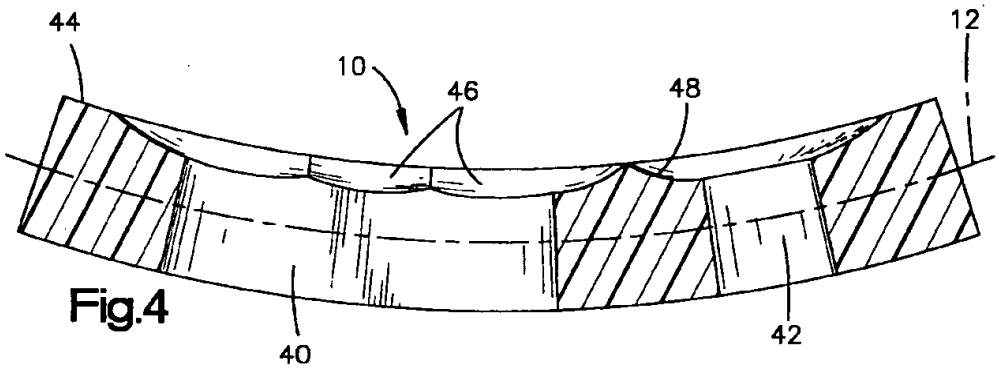

Fig.4

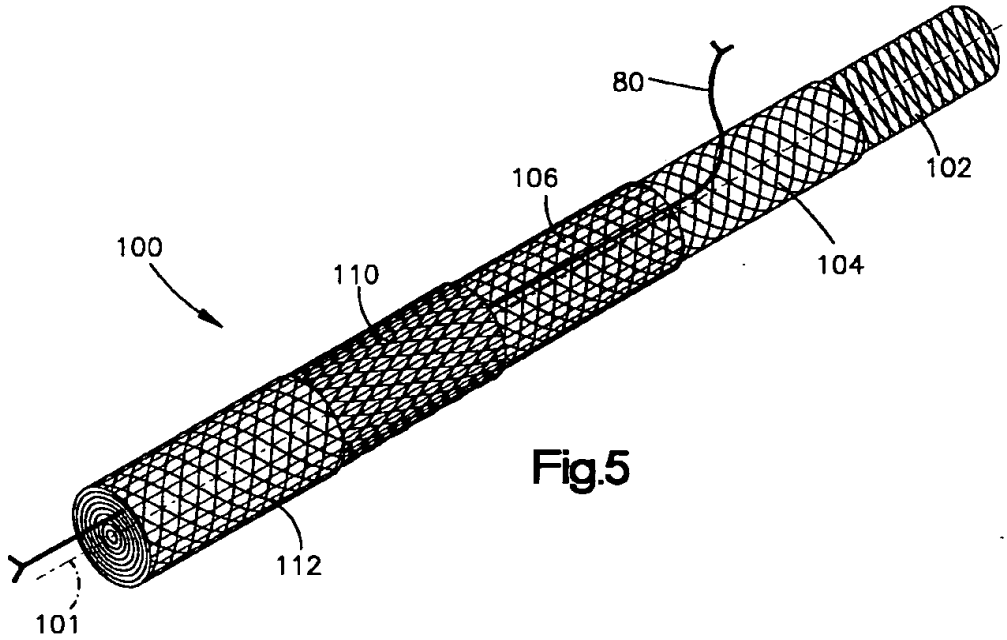

Fig.5

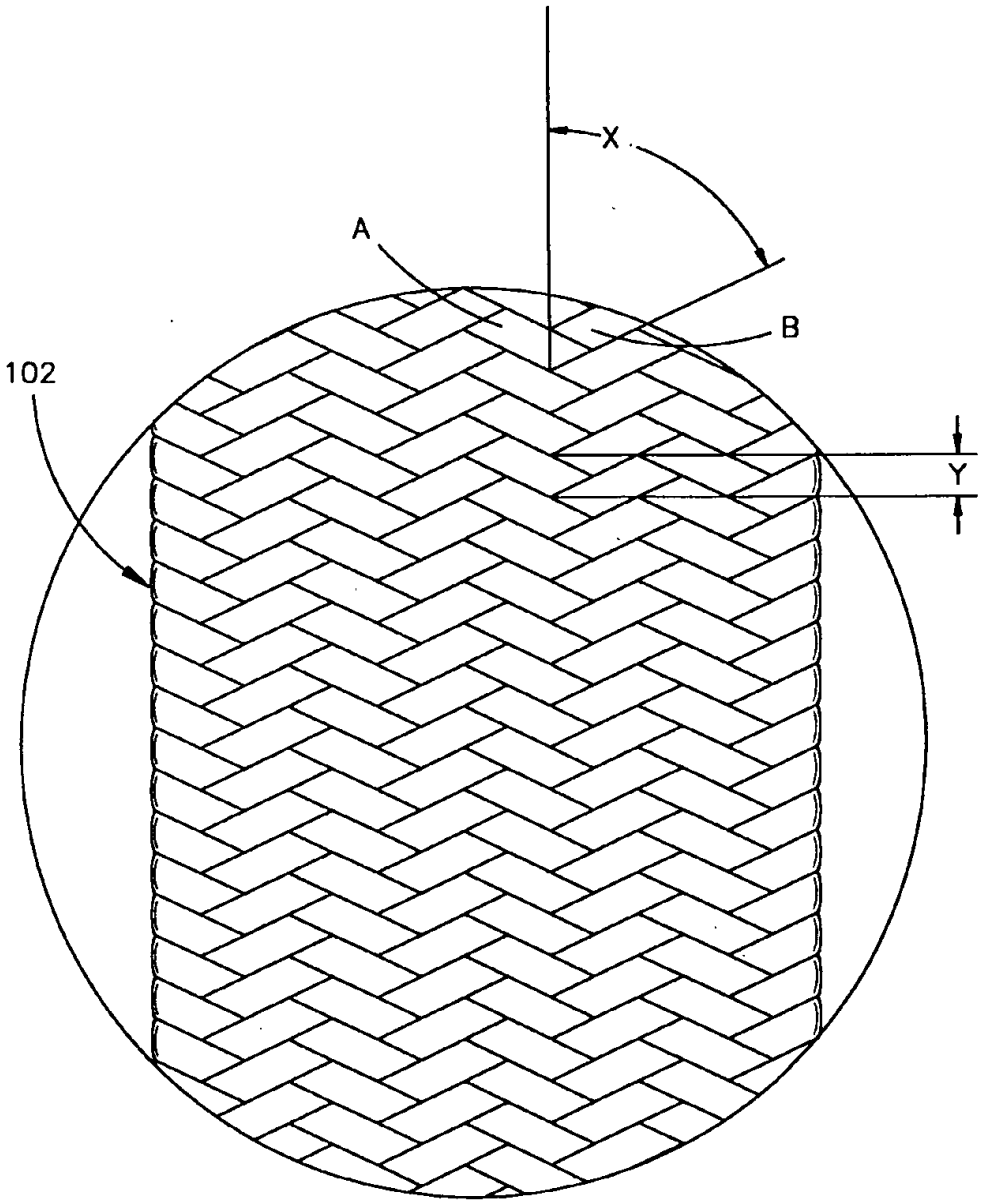

Fig.6

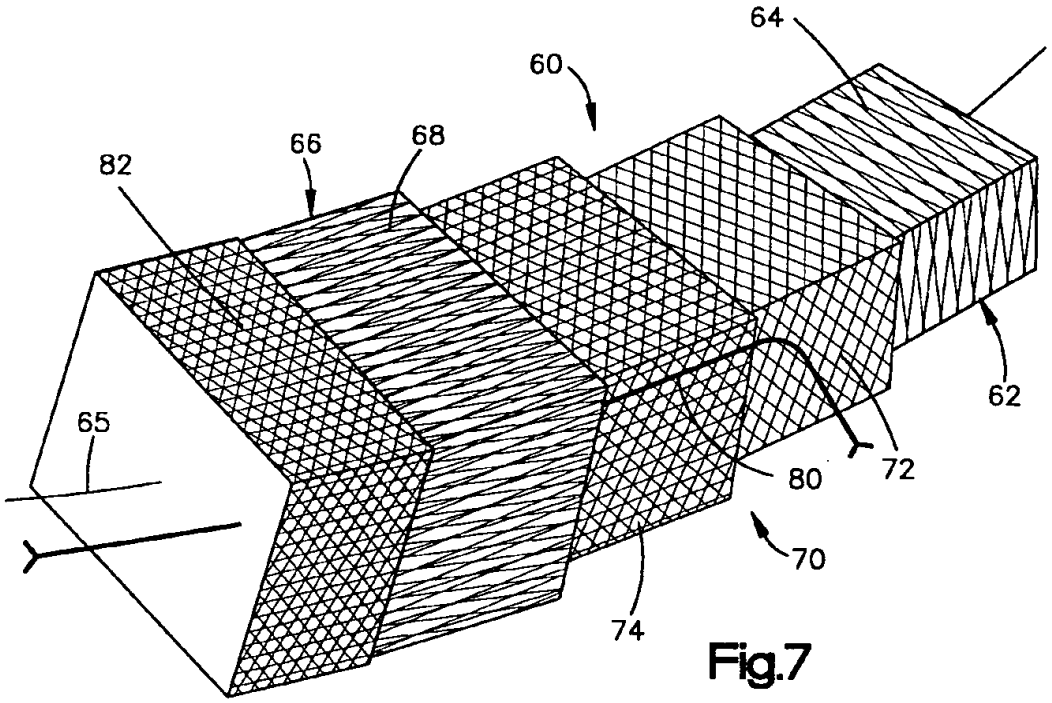
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Fig.7

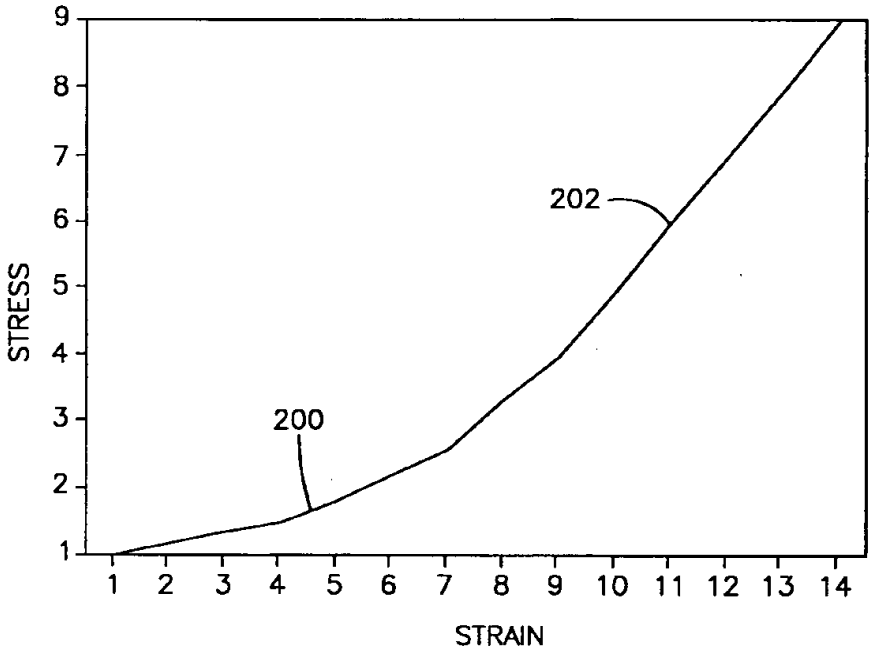
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Fig.8

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 95 11 4530

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Y	EP-A-0 285 156 (DU PONT) 5 October 1988 * example 1 *	18-21, 23-27,37	B29C70/34 B29C70/22 B29B11/16
X Y	WO-A-93 13733 (DU PONT) 22 July 1993 * page 19, line 29 - page 21, line 5; claims 20,21 *	1-5,9,14 18-21, 23-27,37	
X Y	WO-A-93 19699 (HOWMEDICA) 14 October 1993 * page 9, line 17 - line 34 * * page 3, line 29 - line 31 *	1-5,9,14 18-21, 23-27,37	
X	EP-A-0 127 553 (VERRE TISSE SA) 5 December 1984 * the whole document *	1-5,9,14	
A	WO-A-92 11128 (ALLIED SIGNAL INC) 9 July 1992 * the whole document *	6,7,26, 27	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6) B29C B29B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	30 January 1996	Van Wallene, A

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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(54) Conically-shaped fusion cage and method of implantation

(57) A fusion cage 20 for vertebral body fusion is conically-shaped. A thread 40 is formed as part of the external conical surface of the fusion cage. Apertures 54 are defined through the fusion cage in order to provide for contact between the engaged vertebral bone structures and bone growth inducing substances packed within the fusion cage. The fusion cage is introduced and maintains or increases the lordosis between adjacent vertebral bone structures.

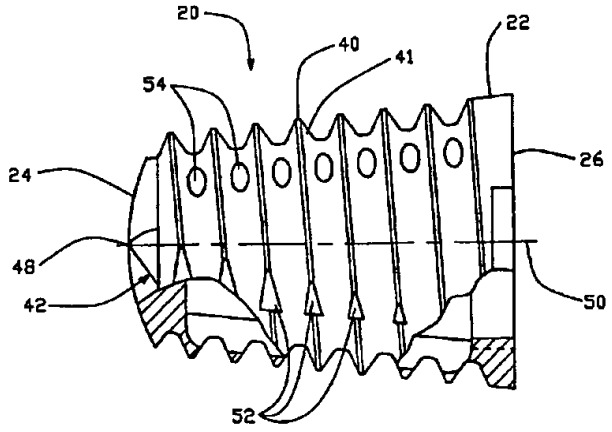

FIG.—1

EP 0 716 840 A2

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Description

BACKGROUND

Field of the Invention

The present invention is directed to devices and methods for facilitating the fusing of bone structures and more particularly the fusing together of adjacent vertebral bodies or bone structures.

Background of the Invention

Technical literature and patent documents disclose a number of devices and methods for fusing bones together. One such device which has proven to be successful is disclosed in U.S. Patent 4,961,740, entitled "V-THREAD FUSION CAGE AND METHOD OF FUSING A BONE JOINT," which patent has been assigned the present assignee and which patent is incorporated herein by reference. The referenced patent discloses a fusion cage which is preferably cylindrical and has a thread formed as part of the external cylindrical surface. The fusion cage defines an internal cavity and apertures through the wall of the cage which communicate the external cylindrical surface with the internal cavity. The apertures are formed in the valleys of the thread. Normally two such cages are used to stabilized and fuse together adjacent vertebral bodies or bone structures.

In practice, using a posterior approach, a patient's vertebral bone structures are exposed and degenerate disk material located between the vertebral bone structures is removed. A threaded tap is used to tap a complementary thread in the upper and lower vertebral bone structures preparatory to the insertion of the above fusion cage. Once such tapping has been accomplished, using an introduction tool, the fusion cage is screwed into the space between the adjacent vertebral bone structures. The thread bites into the bone of the upper and lower vertebral bone structures, stabilizing the bone structures, and preventing the fusion cage from working out of this position due to patient movement. Generally two such fusion cages are applied using this technique. Once the two implants have been positioned, then bone growth inducing substances, such as bone chips, are packed into the internal cavity of the fusion cages. These bone growth inducing substances come into immediate contact with the bone from the vertebral bone structures which project into the internal cavity through the apertures. Such projection of bone is due to the fact that the apertures are formed in the valleys of the external thread of the fusion cage. Such immediate bone to bone contact between the vertebral bone structures and the bone pack within the fusion cages results in more rapid propagation of bone cells between the adjacent vertebral bone structures and thus a more rapid fusion of the adjacent vertebral bone structures.

It is to be understood that in the above method, bone growth inducing substances can be prepacked into the cages before the cages are implanted between the vertebral body structures.

Summary of the Invention

The present invention is directed to a fusion cage which has been designed to be implanted using principally a posterior approach to the vertebral bone structures.

In a first embodiment of the present invention, the fusion cage includes a cage body having a proximal end and a distal end, said distal end having a diameter which is larger than the diameter of the proximal end. The distal end further is rounded with for example a bull nose in order to facilitate the insertion of the cage body relative to one or more bone structures. The distal end could alternatively have a snub nose with or without a starter turn of a thread. The snub nose has a starter diameter that is smaller than the diameter of the distal end. The cage body is preferably conically-shaped. This shape is particularly advantageous due to the fact that the normal lordosis of the vertebral bone structures defines a wedged-shape space for a vertebral disk between, for example, lumbar vertebrae. Accordingly, the conically-shaped body cage can be sized and selected in order to maintain or enlarge upon the normal lordosis.

In a second embodiment of the present invention the cage body can include a cylindrically-shaped portion and a conically-shaped portion. The cylindrically-shaped portion is located adjacent to the distal end and the conically-shaped portion extends from the cylindrically-shaped portion and tapers toward the proximal end.

In a third embodiment of the present invention, a fusion cage includes a cage body having a proximal end and a distal end with the proximal end having a diameter which is smaller than the diameter of the distal end. The distal end has a flute formed therein. Additionally, the cage body has an outer surface and at least one flute formed in the outer surface. These flutes act as a relief much as the flute placed on self-tapping screws in order to facilitate the insertion of the fusion cage using a twisting motion between two vertebral bone structures.

In a fourth embodiment of the invention, a fusion cage includes a cage body having a proximal end and a distal end, the proximal end having a diameter which is smaller than the diameter of the distal end. The cage body has an outer surface and a thread formed as part of the outer surface. The thread aids the cage body in being inserted. As the cage is inserted, it gradually spreads apart the vertebral bone structures in order to regain or enlarge the natural lordosis of the adjacent vertebral bone structures. As with other embodiments of the present invention, flutes can be provided in the thread in order to allow for enhanced thread tapping by the cage and for a smoother insertion of the fusion cage between the vertebral bone structures. Preferably two or three flutes would be formed spaced about the fusion cage in order that one flute would be engaging with or adjacent to an upper vertebral bone structures with another flute

being engaging with or adjacent to a lower vertebral bone structure. Such a relationship maintains alignment of the fusion cage and prevent wandering as the fusion cage is introduced between the two vertebral bone structures. Without two or more flutes, wandering might occur due to the fact that the thread is only substantially engaged with the vertebral bone structures and not with the disk material between the vertebral bone structures, which disk material does not provide support to the thread.

In a further aspect of the invention, any of the above embodiments can be provided with a plurality of apertures through the fusion cage and an internal cavity with the apertures communicating between the internal cavity and the external surface of the fusion cage. Bone growth inducing substances, such as bone chips, can be packed into the internal cavity either before the fusion cage is inserted or after the fusion cage has reached a final insertion position, or packed in both before and after. The bone chips come in contact with the vertebral bone structures through the apertures in order to facilitate fusion between the adjacent vertebral bone structures.

In another aspect of the invention which can be included in any of the above embodiments, the cage body can have a round or bull nose distal end with one or more flutes formed in the round or bull nose distal end in order to enhance the self-tapping nature of the fusion cage and to prevent the cage from wandering.

In yet another aspect of the invention, introduction tools allow the fusion cage to be accurately positioned between the vertebral bone structures. A preferred introduction tool allows for the cage to be implanted and thereafter allows an end cap of the cage to be conveniently removed, if desired, in order to place bone growth inducing substances in the cage.

The method of the present invention affords access to adjacent vertebral bone structures using an posterior approach and procedure. Such posterior approach and procedure can be performed percutaneously using a minimally invasive technique with an introduction set including cannulas. Such a procedure is minimally invasive as the tissues can be spread using a set of cannula of increasing size and a small opening thereby developed through which a fusion cage can be inserted. Such a procedure is less traumatic to the tissue than an alternate posterior approach and procedure, also known as an posterior lumbar interbody fusion, where an incision is made, through the tissues. It is to be understood however that either posterior approach and procedure can be used with the fusion cage and fall within the scope of the invention.

After such access, using preferably a minimally invasive technique, degenerate disk material can be removed and, using a cannula and insertion tool, an appropriately shaped fusion cage can be screwed into place between the vertebral bone structures in order to stabilize the vertebral bone structures and allow for fusion. Either preparatory to insertion of the fusion cage or after it has been inserted, bone chips or other bone growth inducing substances can be inserted into the fusion cage to promote bone to bone contact and subsequent fusion.

It is to be understood that although the above-embodiments have been described with respect to the fusion of adjacent vertebral bodies or bone structures, that the present invention can be used (1) to fuse together a variety of bone structures, in addition (2) to being fused to one bone structure and used as, for example, a base for an implant or (3) to being used to reunite the pieces of a broken bone.

Other objects and advantages of the invention can be obtained through a review of the specification and the figures.

Brief Description of the Figure

Anterior Fusion Cage:

Figure 1 is a partially sectional side view of an embodiment of the anterior fusion cage of the invention.

Figure 2 depicts a left end (distal end) view of the fusion cage of Figure 1.

Figure 3 depicts a right end (proximal end) view of the fusion cage of Figure 1.

Figure 4 depicts a view through line 4-4 of the fusion cage of Figure 1.

Figure 5 depicts the fusion cage of Figure 1 in conjunction with an introduction tool.

Figure 6 depicts an alternative embodiment of the introduction tool.

Figures 7, 8, and 9 depict progressive stages in the method of inserting the anterior fusion cage between adjacent vertebral bone structures.

Figure 10 depicts a side view of an alternative embodiment of the anterior fusion cage of the invention.

Figure 11 depicts the left end (distal end) view of the fusion cage of Figure 10.

Figure 12 depicts the right end (proximal end) view of the fusion cage of Figure 10.

Figure 13 depicts a side view of yet another embodiment of the anterior fusion cage of the present invention.

Figure 14 depicts a left distal end (distal end) view of the fusion cage of the invention of Figure 13.

Figure 15 depicts a right end (proximal end) view of the fusion cage of the invention of Figure 13.

Figure 16 depicts a sectional view taken through line 16-16 of Figure 13.

Posterior Fusion Cage:

Figure 17 is a partially sectional side view of an embodiment of the posterior fusion cage of the invention.

Figure 18 depicts a left end (distal end) view of the fusion cage of Figure 17.

Figure 19 depicts a right end (proximal end) view of the fusion cage of Figure 17.

Figure 20 depicts a view through line 20-20 of the fusion cage of Figure 17.

Figures 21, 22, and 23 depict progressive stages in the method of inserting the posterior fusion cage between adjacent vertebral bone structures using the cage depicted in Figure 25.

Figure 24 depicts a side view of an alternative embodiment of the posterior fusion cage of the invention.

Figure 25 depicts a side view of another embodiment of the posterior fusion cage of the invention.

Figure 26 depicts a left end (distal end) view of the embodiment of the fusion cage of Figure 25.

Figure 27 depicts the fusion cage of Figure 25 in conjunction with a new preferred insertion tool that can preferably be used with the anterior fusion cages of Figure 1, 10 and 13, and with the posterior fusion cages of Figure 17 and 25.

Figure 28 depicts an end view of the insertion tool of Figure 27 along line 28-28.

Figure 29 depicts a partially broken away view of the fusion cage and the insertion tool of Figure 27 connected together.

Figure 30 depicts a perspective view of the end of the insertion tool depicted in Figure 28.

Figure 31 depicts a partially sectional view of the handle of the insertion tool of Figure 27.

Detailed Description of the Preferred Embodiment

Anterior Fusion Cage:

With respect to the figures in a particular Figure 1, a side view of the preferred embodiment of the fusion cage 20 is depicted. Fusion cage 20 includes a fusion cage body 22 which in this preferred embodiment is provided in the shape of a cone. Fusion cage 20 includes a distal end 24 and a proximal end 26. The distal end 24 in a preferred embodiment is rounded or bull nosed in order to facilitate the insertion of the fusion cage 20 relative to one or more bone structures. The proximal end 26 includes an opening 28 which communicates with an internal cavity 30 defined by the fusion cage 20. The opening 28 in a preferred embodiment is threaded so that it can receive an end cap or plug 32 (Figure 5). End cap 32 is used to close off the proximal end 26 and retain bone growth inducing substances packed therein as described herein-below. As can be seen in Figure 5, end cap 32 includes a threaded bore 34 which is designed to receive an insertion tool. The threaded bore 34 has an initial unthreaded, square or hex-shaped section 35 which can be used with a socket wrench to tightly position end cap 32 in opening 28 and which can be engaged by a preferred insertion tool of Figure 27. Further the unthreaded portion of bore 34 could equally be cylindrical with an irregularity to allow for mating with an insertion tool, as well as having a variety of other shapes. The proximal end 26 further define first and second peripheral indentations 36, 38. These peripheral indentations 36, 38 receive tangs from an insertion tool as described hereinbelow for facilitating the insertion of the fusion cage 20.

A thread 40 is defined as part of the outer cylindrical surface 41 of the body 22. It is to be understood that the thread can be replaced with a plurality of discrete threads or a plurality of projections, ridges, protrusions, barbs, or spurs and be within the spirit and scope of the invention.

The rounded distal end 24, and at least some of the turns of thread 40 defined flutes or relief grooves 42, 44, and 46. (Figures 1, 2.) In a preferred embodiment, flutes 42, 44, and 46 meet at a central point 48 of the distal end 24 on the longitudal axis 50 of the fusion cage 20. In other embodiments the flutes can be smaller and not extend all the way to the central point 48 on the longitude axis 50. Still in other embodiments, the flutes can be eliminated from the distal end 24 and such embodiments are still within the spirit and scope of the invention.

The flutes extend from the distal end 24 toward the proximal end 26 as shown in Figure 1 with respect to flute 42. These flutes are defined by the sections 52 which are removed from the thread. In a preferred embodiment, the flutes become narrower as they approach the proximal end 26 due to the fact that thread relief for purposes of self-tapping becomes less important as the cage reaches a final resting position. As shown in other embodiments, the flutes can be deeper and extend from the distal end completely to the proximal end. Still further in other embodiments the flutes can be confined to the first several turns of the thread adjacent to the distal end and/or to just the distal end.

As can be seen in Figures 1, 4, a plurality of apertures 54 are provided through wall 56 of the fusion cage 20. In a preferred embodiment, these apertures 54 are formed by broaching grooves 58 in the internal surface 60 of the internal cavity 30. The effect of such broaching is to remove material from the valleys between the turns of the thread 40, thus defining the aperture 54. The advantages of such an arrangement are taught by the above-referenced U.S. Patent No. 4,961,740, which patent is incorporated herein by reference and allows for immediate bone to bone contact between the vertebral bodies or bone structures and the bone packed within the internal cavity 30 of the fusion cage 20.

The apertures 54 in a preferred embodiment increase in size from smaller apertures closer to the distal end 24 to a larger aperture closer to the proximal end 26. This increase in size allows for more bone to bone contact. Alternatively in the embodiment as shown in Figure 1, all the apertures are of the same size.

As can be seen in Figure 4, the apertures are clustered about a transverse axis 51, both at the upper and lower end of the axis. This is so that in position, the apertures come into contact with the upper and lower vertebral bone structures (Figure 9) to encourage bone growth through the fusion cage from the vertebral bone structures. The lateral section of the fusion cage found along the other transverse access 53 do not have apertures in order to prevent growth of disk material which might interfere with the bone fusing process.

A preferred embodiment of the conically-shaped fusion cage 20 includes a fusion cage which is 23 mil-

limeters in length having a distal end 24 with a diameter of 14 millimeters and a proximal end 26 with a diameter of 18 millimeters. The cage body is a right circular cone. The thread has a pitch of 30° and there are ten turns per inch with a thread depth of .053 inches. Further the cage is made of a titanium metal or alloy such as Ti64. Preferably this and the other disclosed fusion cages disclosed are machined. However, the processes such as molding, casting, or sintering can be used to accomplished formation of the fusion cages.

The cage is inserted between vertebral bodies using an insertion tool 62 (Figure 5). Insertion tool 62 includes an inner handle 64 and an outer handle 66. The outer handle includes a bore 68 for receiving the inner handle 64. Handles 64, 66 include knobs 70, 72 respectively. The distal end of inner handle 64 defines a threaded shaft 74, having a reverse thread to facilitate easy removal, and the distal end of handle 66 define a cylindrical disk 76 which has first and second tangs 78, 80, projecting from the peripheral edge of the cylindrical disk 76. These tangs 78, 80 are designed to mate with the peripheral indentation 36, 38 of the fusion cage 20. For purposes of inserting the fusion cage between the vertebral bodies, the end cap 32 is inserted into the fusion cage 20 as shown in Figure 5. Then the threaded shaft 74 of the inner handle is introduced into the threaded bore 34 of the end cap 32. After this is accomplished, the outer handle 66 is slid over the inner handle 64 and the tangs 78, 80 are positioned into engagement with the indentations 36, 38. In this arrangement, the fusion cage 20 can be anteriorly inserted into the space between the vertebral body structure using the insertion tool 62.

An alternative embodiment of the insertion tool is shown in Figure 6. In this figure, insertion tool 82 includes a handle 84 with a knob 86. At the end of the insertion tool 82 distal from the knob 86 is a cylindrical disk 88 which has first and second tangs 90, 92, which have the same function as the above tangs 78, 80. Extending from the center of the cylindrical disk 88 along the centerline of the insertion tool 82 is a shaft 94 which has a ball detent 96. For use with insertion tool 82, the threaded bore 34 of the end cap 32 would be replaced with a bore having a lip which could engage with the ball detent 96 of the insertion tool 82.

It is to be understood that the insertion tool depicted in Figure 27 and described below is preferable to the above described insertion tools for both the anterior fusion cages and the below described posterior fusion cages.

The method for inserting the fusion cage 20 of Figure 1 using an anterior approach and procedure to the vertebral bodies is as follows. It is to be understood that although the focus of this discussion is on a laparoscopic procedure, that the anterior approach and procedure can also include a more invasive procedure where a long incision is made in the abdomen wall.

With an anterior approach, using an introduction set such as described by way of example only, in U.S. Patent 4,863,430, entitled "INTRODUCTION SET WITH FLEXIBLE TROCAR WITH CURVED CANNULA," which is incorporated by reference, but however with larger diameter instruments, an amount of disk material is removed between the two vertebral bodies or bone structures which are to be fused together. This procedure is accomplished through a cannula position adjacent to the vertebral bone structures. With the same or a larger diameter cannula, the fusion cage 20 can be introduced adjacent to the vertebral bone structures. In a first procedure, the fusion cage is packed with bone growth substances and the end cap 32 is affixed to the fusion cage 20. Insertion tool 62 is then secured to the fusion cage 20 and the fusion cage is guided through the cannula to a location adjacent to the upper and lower vertebral body such as presented schematically in Figures 7, 8, 9, by upper body 98 and lower body 100. In the initial position as shown in Figure 7, the fusion cage 20 is adjacent to the anterior surfaces 102, 104 of the vertebral bodies 98, 100. As the introduction tool is turned, the thread 40 of the fusion cage 20 bites into the vertebral bodies 98, 100. Further turning of the introduction tool causes the fusion cage to move through the position shown in Figure 8 to the final resting position shown in Figure 9, where the distal end 24 is moved adjacent to the posterior sections 106, 108 of the vertebral bone structures 98, 100. As this occurs, the fusion cage 20 increases the lordosis or spacing between the vertebral bodies, basically distracting the vertebral bodies and causing the vertebral bodies to pivot about the posterior sections 106, 108, with such posterior sections acting like a hinge. It is noted that most of the distraction occurs adjacent to the anterior sections, but that distractions also occur at the posterior sections where the hinged effect is exhibited. Preferably, the lordosis is increased over the normal lordosis in order to stabilize the vertebral bone structures prior to fusion occurring. Stabilization occurs due to the fact that increased lordosis places additional stress on the anterior longitudinal ligaments which are part of the anatomy holding the vertebral bodies in place.

Once the fusion cage 20 is appropriately positioned, the handle 64 of the insertion tool 62 is unscrewed from the cap 32 and the fusion handle 62 is pulled away from the fusion cage.

An alternative embodiment of a fusion cage 200 is shown in Figures 10, 11, and 12. Fusion cage 200 includes a distal end 202 and an a proximal end 204. Fusion cage 200 includes an internal cavity 206. End caps not shown can be used to close the ports 208, 210 of distal and proximal ends 202, 204. A thread 212 is defined on the external conical surface 214 of the fusion cage 200. Defined by the thread 212 are first and second flutes 216, 218, which in this embodiment extend from the distal end 202 to the proximal end 204. These flutes provide thread relief allowing the fusion cage 200 to be self-tapping.

The fusion cage 200 includes a plurality of elongated apertures 220 which are formed through the side walls of a fusion cage 200. The elongated apertures 202 are formed in such a way that the internal conical surface

214 is spaced away from the internal surface 224 of the internal cavity 206 by the thickness of the sidewall 222.

A further embodiment of the invention is shown in Figures 13, 14, 15 and 16. In Figure 16 the fusion cage 300 has distal and proximal ends 302 and 304 respectively. The fusion cage 300 defines an internal cavity 306, and ports 308 and 310 defined through the distal and proximal ends 302 and 304 respectfully. A thread 312 is defined as part of the external conical surface 314 of the fusion cage 200. First, second and third flutes 316, 318, and 320, are defined in the thread 312 from the distal end 302 to the proximal end 304. These flutes give the fusion cage 300 an enhanced self-tapping advantage. These flutes are equally spaced about the fusion cage 300 in a manner similar to the flutes of the fusion cage embodiment 20 in Figure 1.

A plurality of aperture 322 is provided through the external conical surface 314 of the fusion cage 300 and through the side wall 324 opening into the internal cavity 306. Accordingly, at the location of the aperture 322 the external surface 314 is held away from the internal surface 326 by the thickness of the side wall 324.

Posterior Fusion Cage:

With respect to the figures in a particular Figure 17, a side view of the preferred embodiment of the posterior fusion cage 420 is depicted. Fusion cage 420 includes a fusion cage body 422 which in this preferred embodiment is provided with a conically-shaped portion 423 and a cylindrically-shaped portion 425. It is to be understood that alternatively the entire body 422 can be conically-shaped. Further, as appropriate the shape of the cage body 422 can be more complex with various conical and/or cylindrical configurations. Fusion cage 420 includes a distal end 424 and a proximal end 426. The distal end 424 in a preferred embodiment is rounded or bull nosed in order to facilitate the insertion of the fusion cage 420 relative to one or more bone structures. The proximal end 426 includes an opening 428 (Figure 19) which communicates with an internal cavity 430 (Figure 20) defined by the fusion cage 420. The opening 428 in a preferred embodiment is threaded so that it can receive an end cap or plug such as 32 of the embodiment in Figure 5. End cap is used to close off the proximal end 426 and retain bone growth inducing substances, such as bone chips, packed therein as described herein-below. As can be seen in the embodiment of Figure 5, end cap 32 includes a threaded bore 34 which is designed to receive an insertion tool. The threaded bore 34 has an initial unthreaded, square or hex-shaped portion 35 which can be used with a socket wrench to tightly position end cap 32 in opening 428 and which can also be engaged by the insertion tool of Figure 27 described below. Portion 35 can be otherwise shaped as described above.

The proximal end 426 of the embodiment of Figure 19 further define first and second peripheral indentations 436, 438 which are centered about transverse axis 453. These peripheral indentations 436, 438 receive tangs from an insertion tool as described below for facilitating the insertion of the fusion cage 420. These identifications are also used to line up the cage 420 for proper insertion between the vertebral bodies as discussed below.

A thread 440 is defined as part of the outer cylindrical surface 441 of the body 422. It is to be understood that the thread can be replaced with a plurality of interrupted or discrete threads or a plurality of projections, ridges, protrusions, barbs, or spurs and be within the spirit and scope of the invention.

The rounded distal end 424, and at least some of the turns of thread 440 can in a preferred embodiment can define flutes or relief grooves 442, 444, and 446 (Figures 24, 25). It is to be understood that in alternative embodiments the flutes can be eliminated from the distal end 424 and the thread 440, since for example, the bore for the insertion of the fusion cage 420 between the vertebral bodies can be pre-tapped. Still in alternative embodiment, the flutes on the distal end can remain to assist in the insertion of the cage 420 between the vertebral bodies. In a preferred embodiment, flutes 442, 444, and 446 meet at a central point 448 of the distal end 424 on the longitudal axis 450 of the fusion cage 420. In other embodiments the flutes can be smaller and not extend all the way to the central point 448 on the longitude axis 450. Still as indicated above in other embodiments, the flutes can be eliminated from the distal end 424 and the thread 440 and such embodiments are still within the spirit and scope of the invention.

The flutes can extend from the distal end 424 toward the proximal end 426 as shown in the alternative embodiment in Figure 24 with respect to flute 542. These flutes are defined by the sections 552 which are removed from the thread. In this embodiment, the flutes become narrower as they approach the proximal end 526 due to the fact that thread relief for purposes of self-tapping becomes less important as the cage reaches a final resting position. As shown in other embodiments, the flutes can be deeper and extend from the distal end completely to the proximal end. Still further in other embodiments the flutes can be confined to the first several turns of the thread adjacent to the distal end and/or to just the distal end.

With respect to Figures 17, 20, a plurality of apertures 454 are provided through wall 456 of the fusion cage 420. In a preferred embodiment, these apertures 454 are formed by broaching grooves 458 in the internal surface 460 of the internal cavity 430. The effect of such broaching is to remove material from the valleys between the turns of the thread 440, thus defining the aperture 454. The advantages of such an arrangement are taught by the above-referenced U.S. Patent No. 4,961,740, which patent is incorporated herein by reference and allows for immediate bone to bone contact between the vertebral bodies or bone structures and the bone packed within the internal cavity 430 of the fusion cage 420.

The apertures 454 in a preferred embodiment increase in size from smaller apertures closer to the

proximal end 426 to a larger aperture closer to the distal end 424. This increase in size allows for more bone to bone contact. Alternatively in the embodiment as shown in Figure 17, all the apertures are of the same size.

As can be seen in Figure 20, the apertures are clustered about a transverse axis 451, both at the upper and lower end of the axis. This is so that in position, the apertures come into contact with the upper and lower vertebral bone structures (Figure 23) to encourage bone growth through the fusion cage from the vertebral bone structures. The lateral sections of the fusion cage found along the other transverse axis 453 do not have apertures in order to prevent growth of disk material which might interfere with the bone fusing process. As can be seen viewing both Figures 19 and 20 together, the indentation 436 and 438 are centered on the axis 453 with the aperture 454 centered on axis 451. Axis 451 is preferably perpendicular to axis 453. The insertion tool has tangs that are inserted in indentation 436 and 438. Accordingly, the position of the insertion tool defines the position of the apertures 454 in that upon insertion the apertures 454 can be put in contact with the upper and lower vertebral bodies to allow bone ingrowth and prevent lateral ingrowth of disk material.

A preferred embodiment of the conically-shaped fusion cage 420 includes a fusion cage which is 28 millimeters in length having a distal end 424 with a diameter of 16 millimeters and a proximal end 426 with a diameter of 14 millimeters. The cage body is a right cylinder from the distal end 424 extending toward the proximal end 426 for four turns of thread 440. Then the cage 420 becomes a right cone from the remaining five turns of thread 440 until thread 440 terminates at proximal end 426. This conically-shaped portion is defined by relief 455 of 3.2°.. The thread has a pitch of 30° and there are ten turns per inch with a thread depth of .053 inches. Further the cage is made of a titanium metal or alloy such as Ti64. Preferably this and the other disclosed fusion cages disclosed are machined. However, the processes such as molding, casting or sintering can be used to accomplished formation of the fusion cages.

The cage is inserted between vertebral bodies using a preferred insertion tool 700 shown in Figure 27. Insertion tool 700 includes a handle 702 with an outer shaft 704 extending therefrom. The handle 702 includes first and second wings 706, 708 which make the handle easier to grab. The outer shank 704 is hollow and disposed within the outer shaft is an intermediate shaft 710 which can be seen extending from the cage engaging in 712 of the shaft 704. The cage engaging end 712 includes first and second tangs 714, 716 which can be inserted in the indentation of the cage such as for example indentations 436, 438, as shown in Figure 19, and indentations 636 and 638 shown in Figure 27. The end of shaft 710 includes a square-shaped drive 718 which engages the square-shaped unthreaded portion of the otherwise threaded bore such as bore 34 of an end cap such as end cap 32 as shown in Figure 5. This same end cap can be used in the end of fusion cage 620. Alternatively, the square drive can be hexagonal shape with the unthreaded portion of the bore 34 being hexagonal shaped to provide the necessary mating arrangement. Other mating shapes can also be used. A first knurled knob 720 is secured to immediate shaft 710 in order to provide a mechanism for rotating intermediate shaft 710 inside of outer shank 704. As can be seen in Figure 31, the intermediate shank 710 is spring biased relative to the handle 702 with a spring 722. Spring 722 is imbedded in a bore 724 of handle 702. In Figure 31, the first knurled knob 720 and the shank 710 are pulled back and thus compress the spring 722. In Figure 27, the first knurled knob 720 is released and the spring (not shown) is uncompressed.

An inner shaft 726 is located within a bore 728 of the intermediate shaft 710. The inner shaft 726 ends in a threaded portion 730 (Figure 30). The other end of inner shaft 726 is secured to the second knurled knob 732. Inner shaft 726 is free to rotate, through the use of the second knurled knob 72, within the bore 728 of the intermediate shaft 710. In addition the inner shaft 728 has limited freedom of motion along the longitudinal axis of the inner shaft 726.

The operation of the insertion tool 700 is as follows. With the insertion tool 700 not secured to a fusion cage, the insertion tool is as depicted in Figure 27 with the threaded portion 730 being either received entirely within bore 728 or extending a minimal amount out of bore 728. With the end cap secured in the fusion cage, the exposed square drive 718 is mated with the square portion of the bore in the end cap. The tangs 712, 714 are aligned with the indentations 636 and 638 and the tool is pushed in so that the tang 712, 714 are received in the indentations 636, 638. As this occurs, the knurled knob 730 moves up to the position as shown in Figure 29 and 31, compressing the spring. After this occurs, the second knurled knob 732 can be turned clockwise in order to engage the threaded portion 730 of the inner shaft 726 with the threaded portion of the bore of the end cap. This draws the fusion cage securely to the insertion tool 700 as shown in Figure 29. In this position, the cage is ready for insertion between the vertebral bodies. The handle 702 is then used to screw the cage between the vertebral bodies into the final resting position. Once the cage is in the final resting position, second knurled knob 732 is turned counter-clockwise in order to back the threaded 730 out of the threaded portion of the bore of the end cap. As this occurs, the spring 722 causes the square drive 718 to push against the end cap maintaining the end cap in its position relative to the fusion cage until the threaded portion 730 disengages itself from the threaded portion of the end cap, and the insertion tool 700 is disengaged from the fusion cage and can be removed. Thus the square drive, which is spring loaded, prevents the end cap on the cage from screwing out when the insertion tool is removed from the cage.

Should it be desired to move the end cap with the fusion cage in place, the square drive 718 can be inserted into the square portion of the threaded bore.

The threaded portion 730 of the inner shaft 726 can then be screwed into engagement with the threaded portion of the threaded bore of the end cap, preferably with the tangs unaligned with the indentations. The first knurled knob 720 can then be turned in order to back the cap out of the fusion cage. A reverse of this operation can be used to insert the end cap into the fusion cage after additional bone growth inducing substances are packed into the fusion cage.

The method for inserting the fusion cage 420 of Figure 17 using a posterior approach and procedure to the vertebral bodies is as follows. Both a minimally invasive procedure and a more invasive procedure where a long incision is made in the back can be used.

With a posterior approach, using an introduction set such as described by way of example only, in U.S. Patent 4,863,430, entitled "INTRODUCTION SET WITH FLEXIBLE TROCAR WITH CURVED CANNULA," which is incorporated by reference, but however with larger diameter instruments, an amount of disk material is removed between the two vertebral bodies or bone structures which are to be fused together. This procedure is accomplished through a cannula position adjacent to the vertebral bone structures. Then if required a thread is tapped in the upper and lower vertebral bodies. With the same or a larger diameter cannula, the fusion cage 420, or alternatively the preferred fusion cage 620 of Figure 25, can be introduced adjacent to the vertebral bone structures. In a first procedure, the fusion cage is packed with bone growth substances and the end cap is affixed to the fusion cage 620. Insertion tool 700 is then secured to the fusion cage 620 and the fusion cage is guided through the cannula to a location adjacent to the upper and lower vertebral body such as presented schematically in Figures 21, 22, 23, by upper body 498 and lower body 500. In the initial position as shown in Figure 21, the fusion cage 620 is adjacent to the posterior sections 502, 504 of the vertebral bodies 498, 500. As the introduction tool is turned, the thread 640 (Figure 25) of the fusion cage 620 bites into the vertebral bodies 498, 500. Further turning of the introduction tool causes the fusion cage to move through the position shown in Figure 22 to the final resting position shown in Figure 23, where the distal end 624 is moved adjacent to the anterior sections 506, 508 of the vertebral bone structures 498, 500. As this occurs, the fusion cage 620 increases the lordosis or spacing between the vertebral bodies, basically distracting the vertebral bodies. It is noted that most of the distraction occurs adjacent to the anterior sections, but that distraction also occur at the posterior sections. Preferably, the lordosis is increased over the normal lordosis in order to stabilize the vertebral bone structures prior to fusion occurring. Stabilization occurs due to the fact that increased lordosis places additional stress on the anterior longitudinal ligaments which are part of the anatomy holding the vertebral bodies in place.

Once the fusion cage 620 is appropriately positioned, the insertion tool 700 is unscrewed from the cap and the insertion tool 700 is pulled away from the fusion cage.

It is to be understood that the cage can be implanted without the use of a cannula by making a larger incision in the back. With this arrangement the bone chips would more often be packed into the cage after the cage reaches its final position and then an end cap would be secured t the cage. In the final position apertures 454 or 654 (embodiment of Figure 25) would be positioned adjacent vertebral bodies 498 and 500. No matter which procedure is used to insert the cage 420 or 620, it is advantageous to provide a bore between the vertebral bodies that is less than the diameter of the distal end 424. Thus, for a cage 420 or a cage 620 with a distal end having an 18 diameter, the bore would be 14 millimeters. Inserting the cage 420 or the cage 620 would cause the vertebral bodies to be distracted (Figure 22) and then rock back (Figure 23) onto the conically-shaped portion of the fusion cage 420.

An alternative embodiment of a fusion cage 520 is shown in Figures 24. Fusion cage 520 includes a distal end 524 and an a proximal end 526. A thread 540 is defined on the external surface of the fusion cage 520. Defined by the thread 540 are flutes 542, 544, 546, which in this embodiment extend from the distal end 524 toward the proximal end 526. These flutes provide thread relief 552 allowing the fusion cage 520 to be self-tapping

Still an alternative and preferred embodiment of the invention as mentioned above is shown in Figure 25. In this embodiment the fusion cage 620 includes a blunt or flat distal end 624 and a proximal end 626. As in the other embodiments, the fusion cage is conically-shaped, and includes a thread 640 and aperture 654.

Figure 26 includes a view of the distal end 624 of the fusion cage 620. This distal end 624 uses a snub nosed portion that is closed. The diameter of the snub nosed portion 660 is smaller than the largest root of the thread 640 at the distal end 624. As can be seen in Figure 26, the thread 640 has a starter portion or starter turn 641 which includes approximately the first half turn of the thread 640. The diameter of the starter portion 641, as can be seen Figure 26, is substantially less than the outside diameter of the four turns of thread 640 which comprised the cylindrical portion 625. From the cylindrical portion 625, the cage 620 and the thread 640 taper off to the proximal end 626 and define the conically-shaped portion 623.

The starter turn 641 of thread 640, as the name implies, assist in promoting the proper engagement of the thread 640 with the upper and lower vertebral bodies. In this embodiment, as in prior embodiments, the distal end has a diameter of approximately 16 millimeters. The diameter of the snub nosed portion 660 is about 10 millimeters.

Industrial Applicability

The present invention affords the advantages of a fusion cage which can be introduced through a posterior

approach in order to maintain or increase lordosis between adjacent vertebral bodies. The fusion cage has the advantage of being conically-shaped and self-tapping through the use of external flutes. The flutes additionally assist in keeping the fusion cage aligned and centered as the cage is being inserted between the vertebral bone structures.

Other advantages, aspects, and objects of the invention can be obtained through a review of the claims and the appended figures.

Additional embodiments of the invention can be constructed and fall within the scope of the claims.

Claims

1. A fusion cage for promoting fusion with one or more bone structures comprising:
   a cage body having a proximal end and a distal end, said proximal end having a diameter which is smaller than a diameter of said distal end; and
   said distal end being rounded in order to facilitate insertion relative to one or more bone structures.

2. A fusion cage for promoting fusion with one or more bone structures comprising:
   a cage body having a proximal end and a distal end, said proximal end having a diameter which is smaller than a diameter of said distal end; and
   said cage body having an outer surface and at least one flute formed in the outer surface.

3. A fusion cage for promoting fusion with one or more bone structures comprising:
   a cage body having a proximal end and a distal end, said proximal end having a diameter which is smaller than a diameter of said distal end; and
   said cage body having a outer surface and a thread formed into said outer surface.

4. The fusion cage of claims 1, 2 or 3 wherein:
   said cage has a cylindrically-shaped portion located adjacent to the distal end and a conically-shaped portion located adjacent to the proximal end.

5. The fusion cage of claim 4 wherein:
   a thread is defined by the cylindrically-shaped portion and the conically-shaped portion.

6. The fusion cage of any of the preceding claims wherein:
   said cage body has a thread formed on an outer surface and at least one flute formed in the thread.

7. The fusion cage of claim 6 wherein the flute is formed in the distal end in order to facilitate the insertion of the fusion cage in the one or more bone structures, the flute extending from the distal end toward the proximal end.

8. The fusion cage of any of the preceding claims including:
   at least three flutes formed in the outer surface being equally spaced about said distal end.

9. The fusion cage of any of preceding claims wherein:
   said cage body has an outer surface and an internal cavity; and
   a plurality of apertures are formed through the cage body which communicate said outer surface with said internal cavity.

10. The fusion cage of any of the preceding claims wherein said cage body is a right circular cone.

11. The fusion cage of any of the preceding claims further comprising a thread with a plurality of turns found on the outer surface, and the flute is formed in at least one of said turns.

12. The fusion cage of any of the preceding claims in combination with an insertion tool, said fusion cage including:
   said proximal end having an opening which communicates with an internal cavity;
   an end cap which can fit into said opening in order to close off said internal cavity;
   said proximal end including at least one insertion tool receiving indentation;
   said end cap including an insertion tool receiving threaded bore with an unthreaded portion with an irregularity; and
   said insertion tool including:
   a tang for being received in said indentation and a threaded shaft for being received in said threaded bore, and a shaft for mating with the unthreaded portion, said insertion tool for being engaged with said fusion cage for inserting said fusion cage relative to the one or more bone structures.

13. The fusion cage of claim 9 including:
   said apertures increase in size from the distal end toward the proximal end.

14. A fusion cage for promoting fusion with one or more bone structures comprising:
   a cage body having a proximal end and a distal end;
   said cage body having a longitudinal axis, and a first transverse axis which is perpendicular to the longitudinal axis and a second transverse axis which is perpendicular to both the longitudinal axis and the first transverse axis;
   a position indicator located at said proximal end, which position indicator is located along the first

transverse axis; and

said cage body having a plurality of apertures for promoting bone growth into the cage body, which apertures are located only substantially along the second transverse axis between the proximal end and the distal end.

15. The fusion cage of claim 14 wherein:

said position indicator includes an indentation into said proximal end.

16. The fusion cage of claim 15 wherein:

said distal end has a snub nose extending therefrom in order to facilitate insertion relative to one or more bone structures the snub nose having a diameter which is less than the diameter of the distal end.

17. The fusion cage of claims 14, 15 or 16 wherein:

the cage body includes a thread which has a starter turn located at the distal end, the starter turn of the thread extends from the snub nose in order to facilitate insertion relative to the one or more bone structures.

18. A fusion cage in combination with an insertion tool comprising:

said fusion cage having a cage body with a distal end and a proximal end, said proximal end including at least one insertion tool receiving indentation;

said proximal end including an insertion tool receiving threaded bore having an unthreaded portion with at least one irregularity; and

said insertion tool having a first shaft with a tang that can be received in said indentation, a second shaft with a portion which can mate with the unthreaded portion of the bore with the irregularity, and a third shaft with a threaded portion which can mate with the threaded bore.

19. The fusion cage and insertion tool combination of claim 18 wherein:

said second and said third shafts can rotate relative to the first shaft and relative to each other.

20. The fusion cage and insertion tool combination of claim 19 wherein:

one of said second and third shafts is biased relative to the other of said second and third shafts.

21. The fusion cage and insertion tool combination of claim 20 wherein:

said fusion cage includes an end cap which in part comprises said proximal end, and wherein said end cap includes said threaded bore, and wherein said end cap can be selectively removed from the remainder of the proximal end.

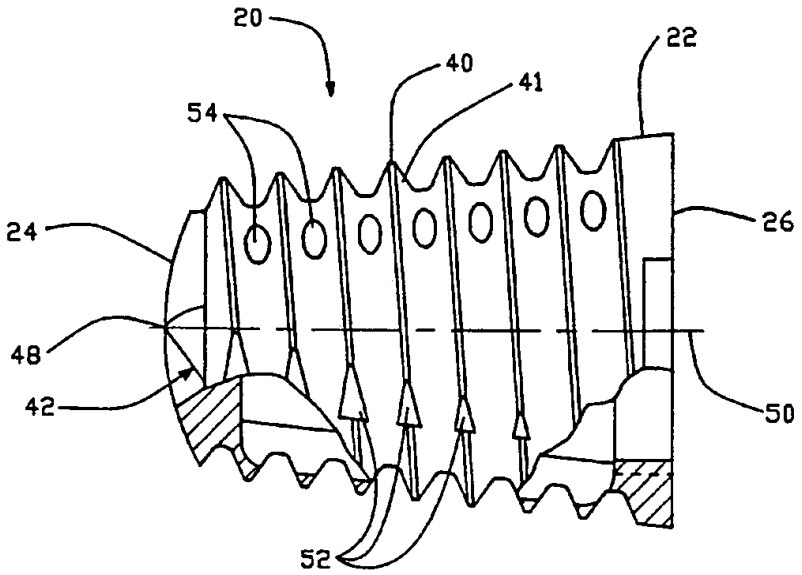

FIG.—1

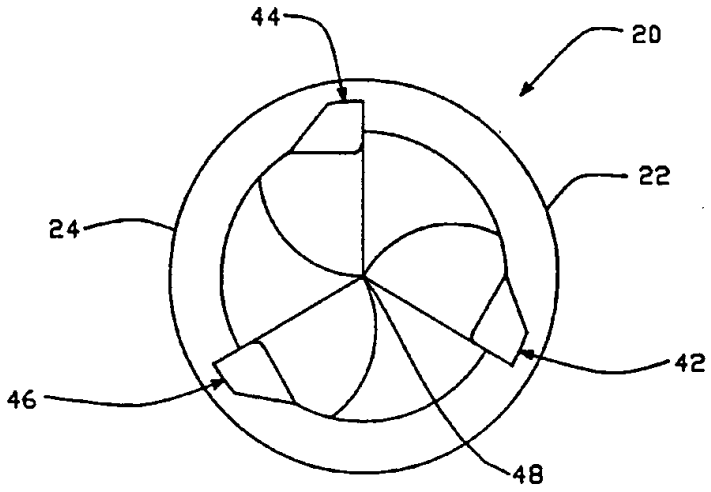

FIG.—2

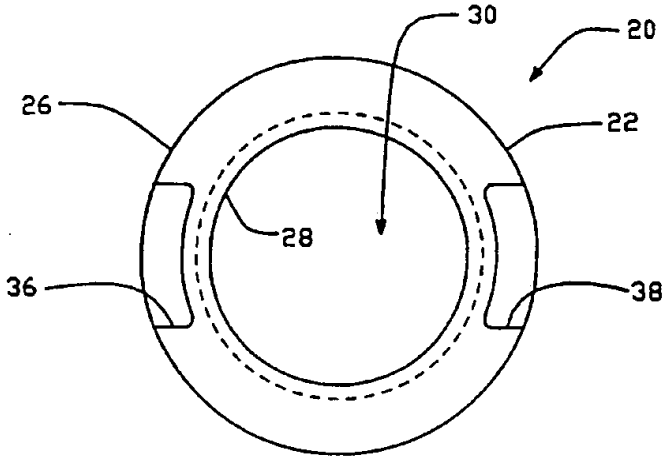

FIG.—3

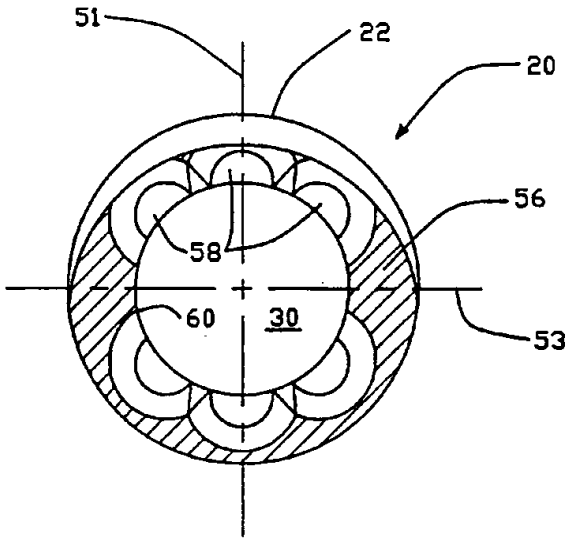

FIG.—4

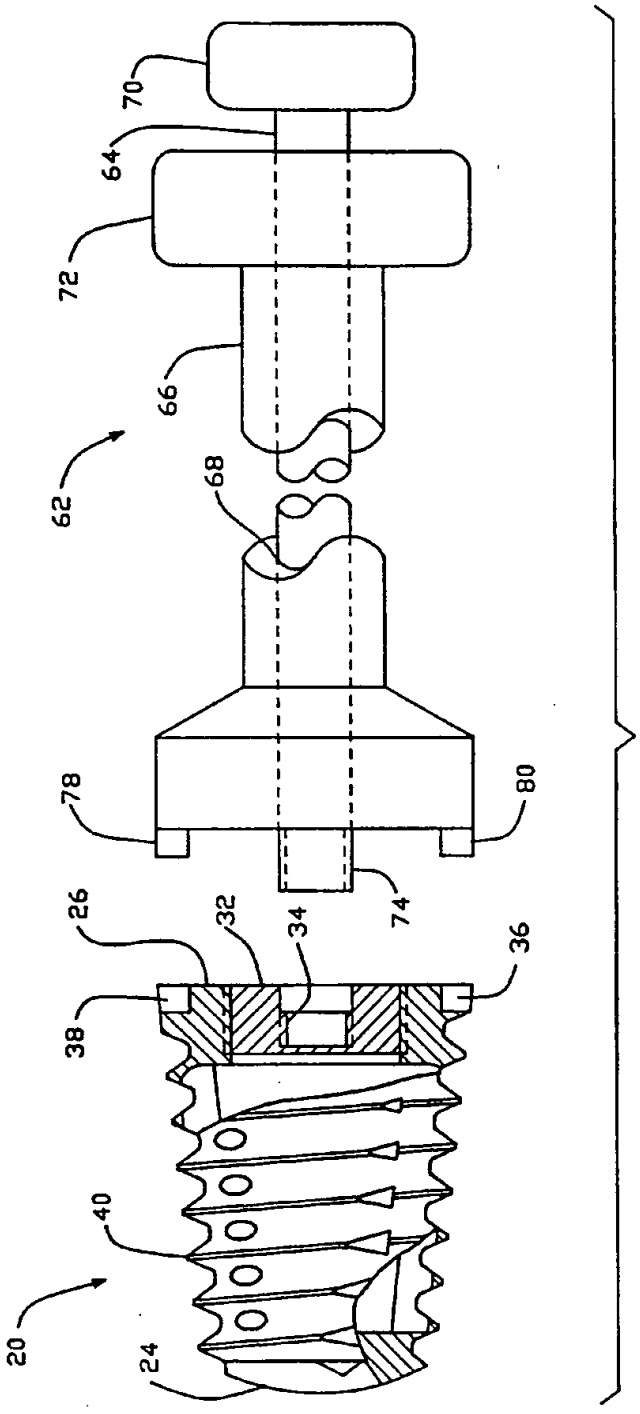

FIG.—5

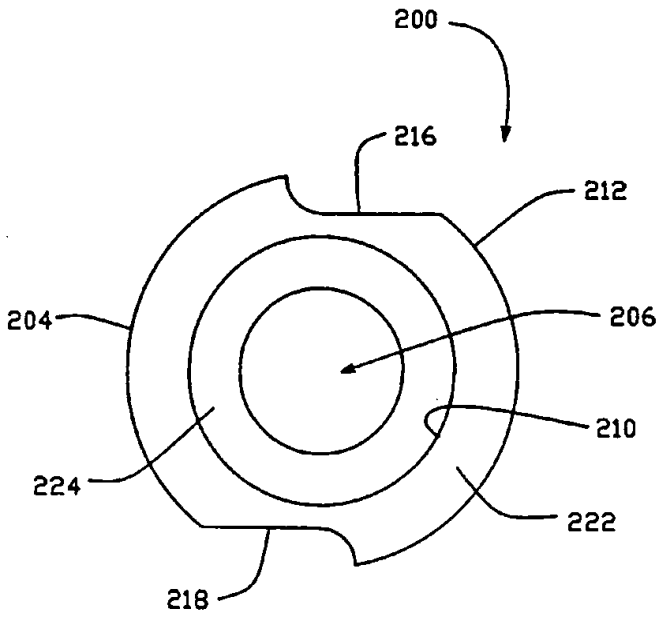

FIG.-12

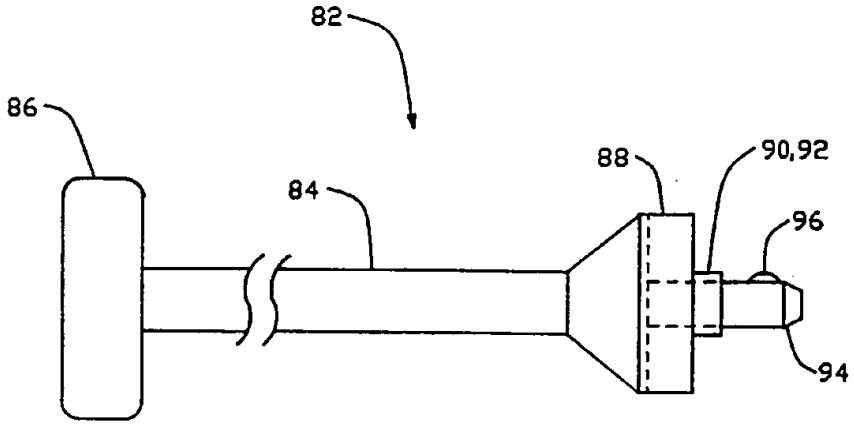

FIG.-6

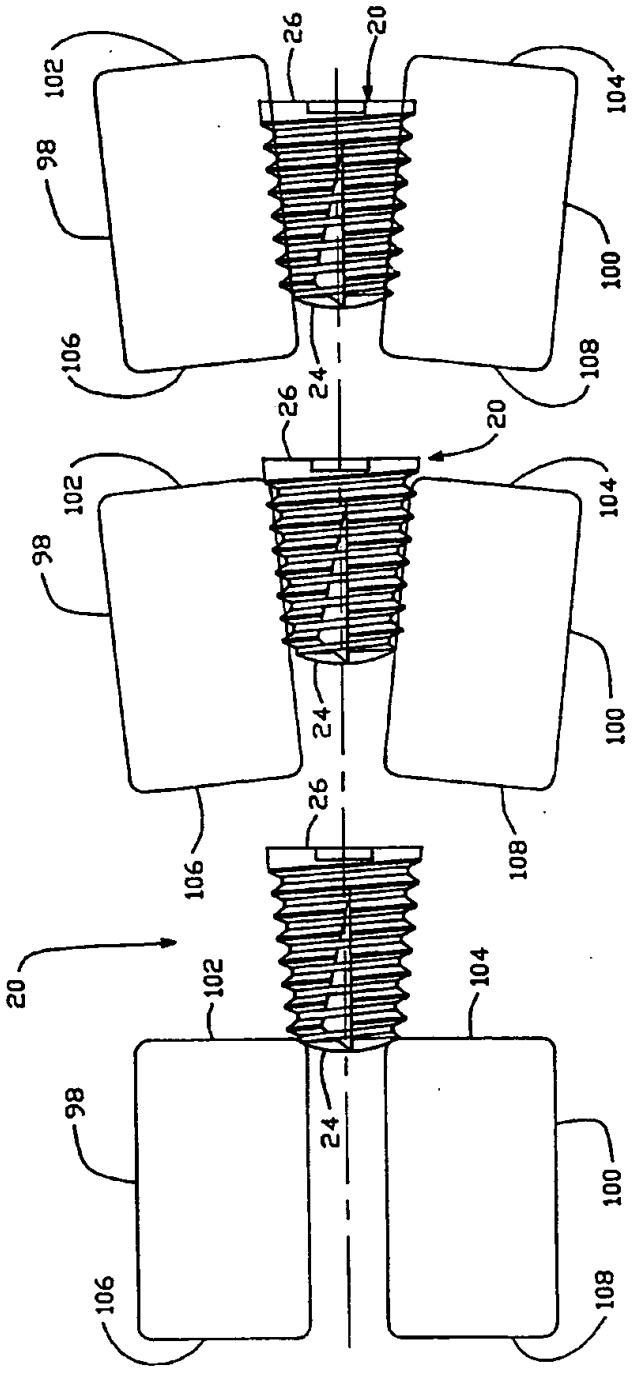

FIG.—7

FIG.—8

FIG.—9

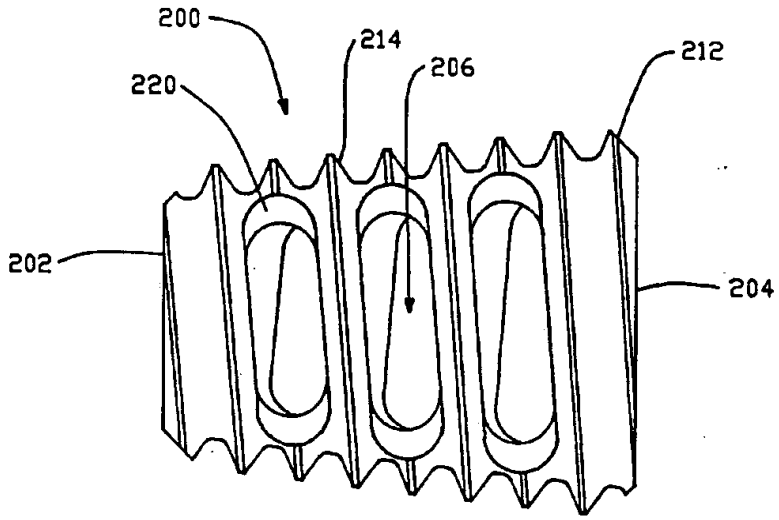

FIG.—10

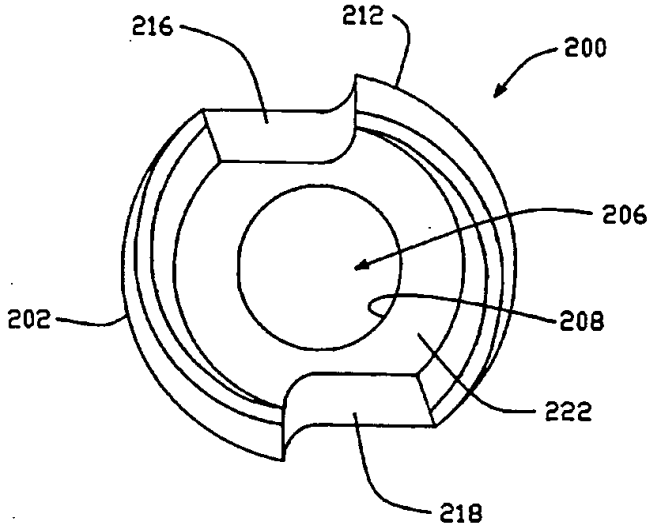

FIG.—11

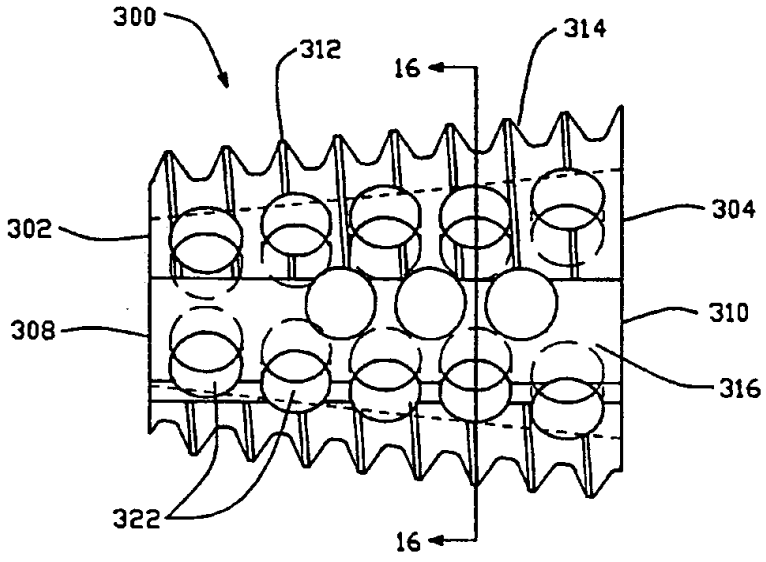

FIG.—13

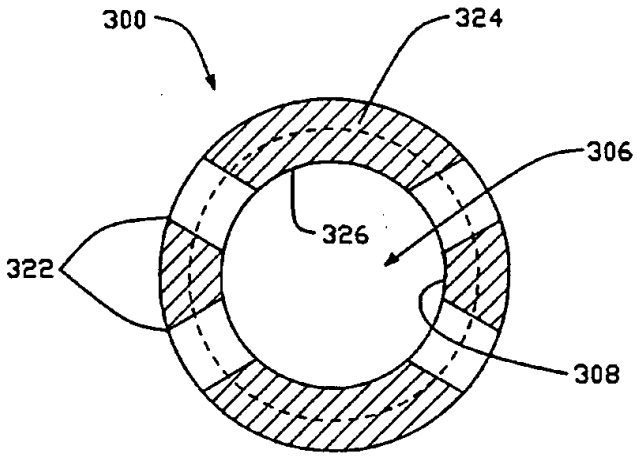

FIG.—16

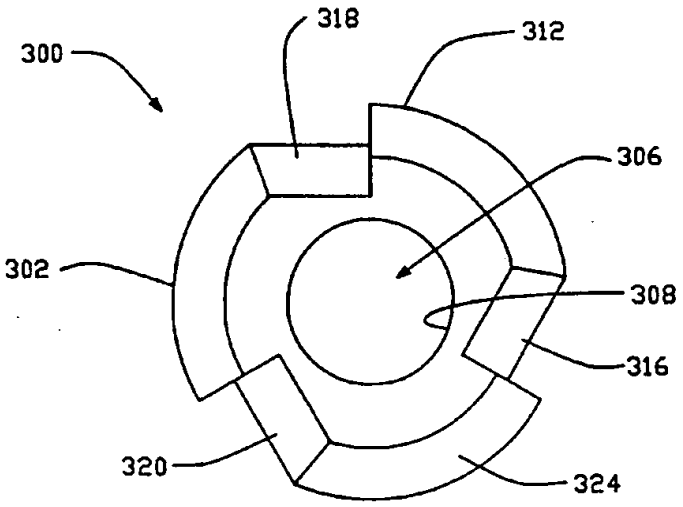
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FIG.—14

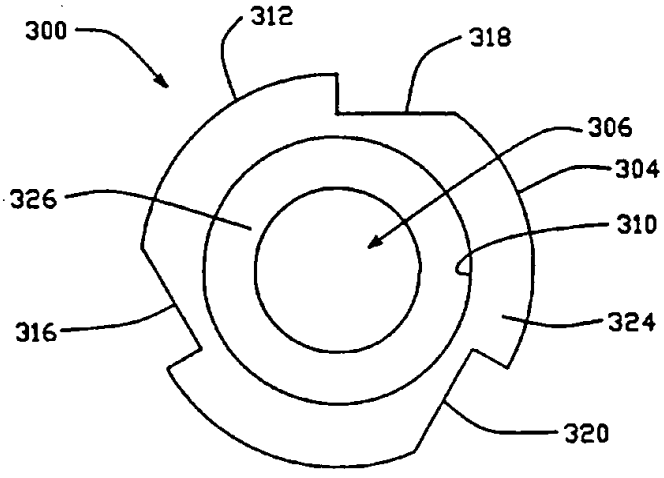
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FIG.—15

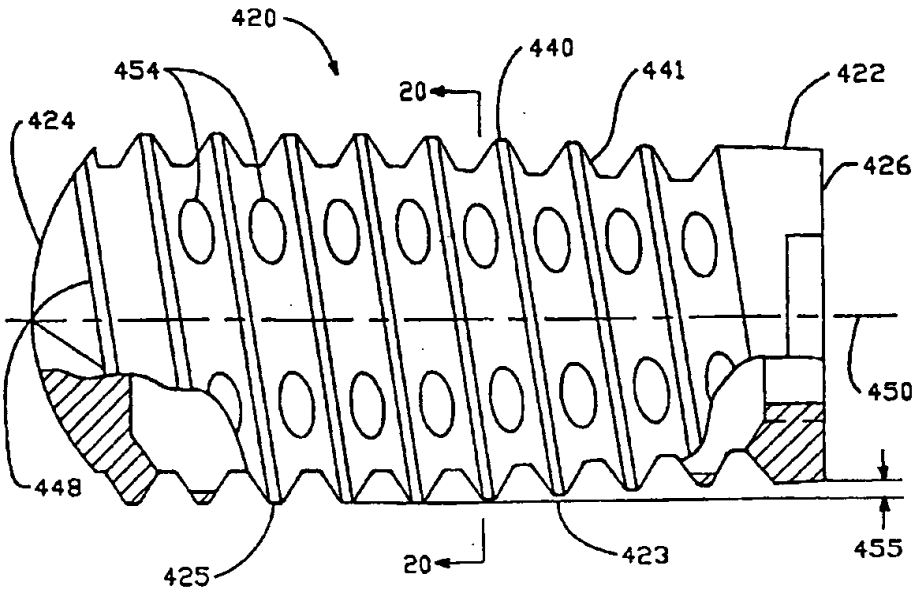
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FIG.—17

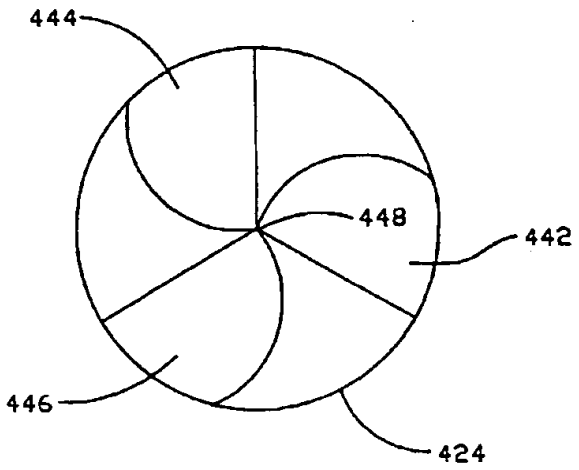
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FIG.—18

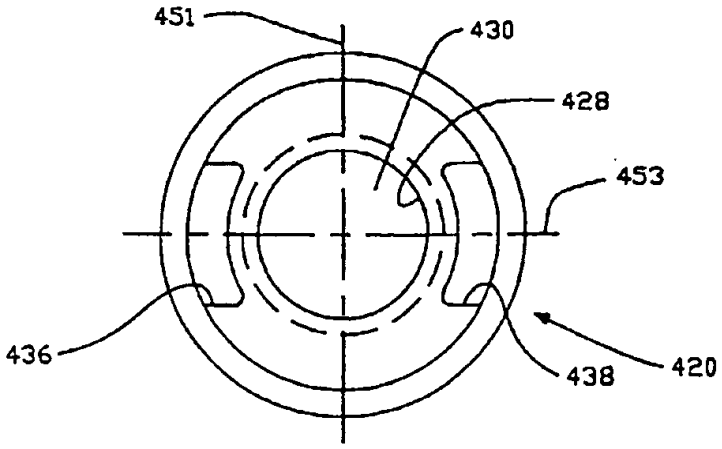

FIG.—19

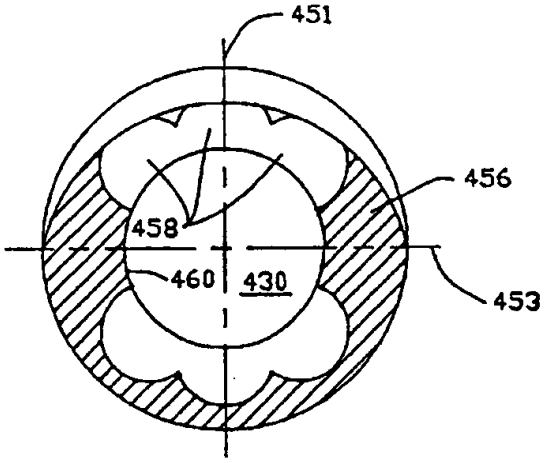

FIG.—20

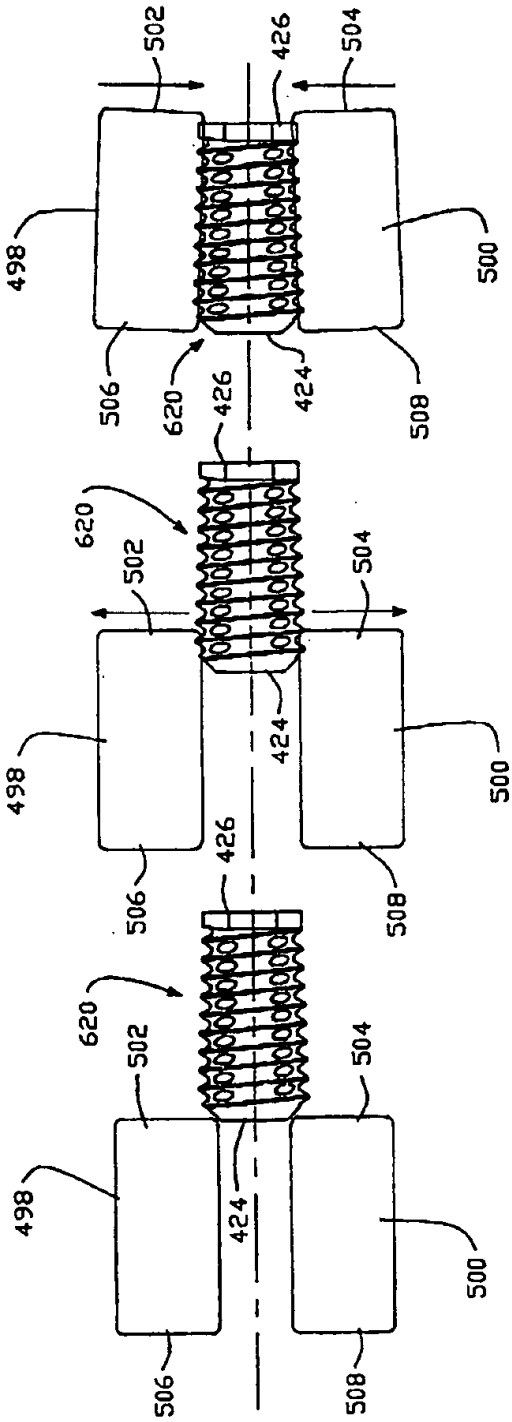

FIG.—23

FIG.—22

FIG.—21

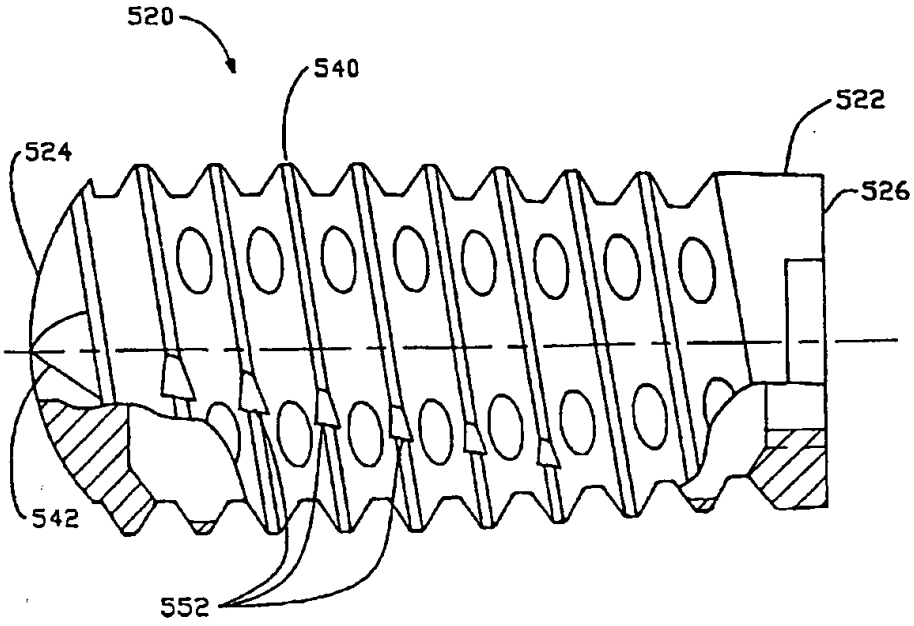

FIG.—24

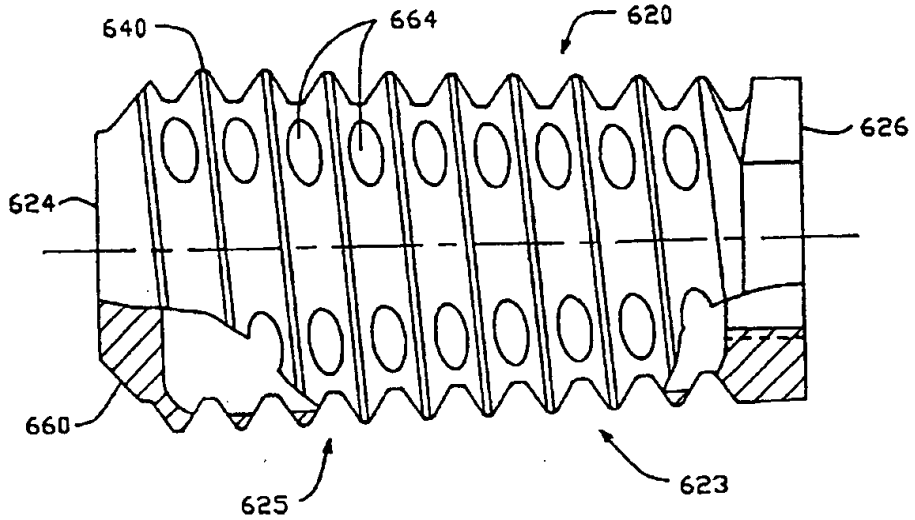

FIG.—25

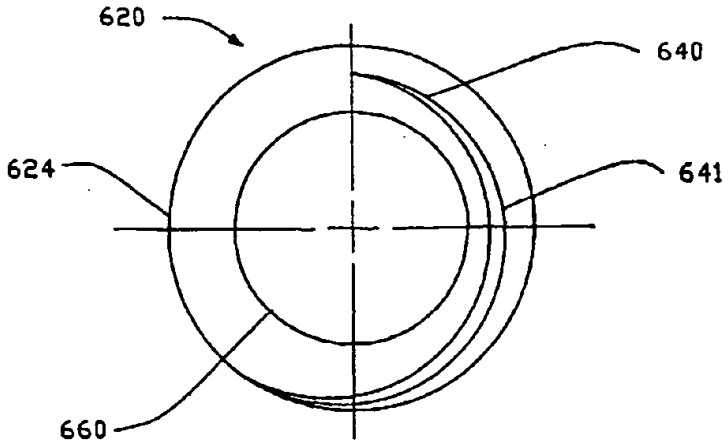
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FIG.—26

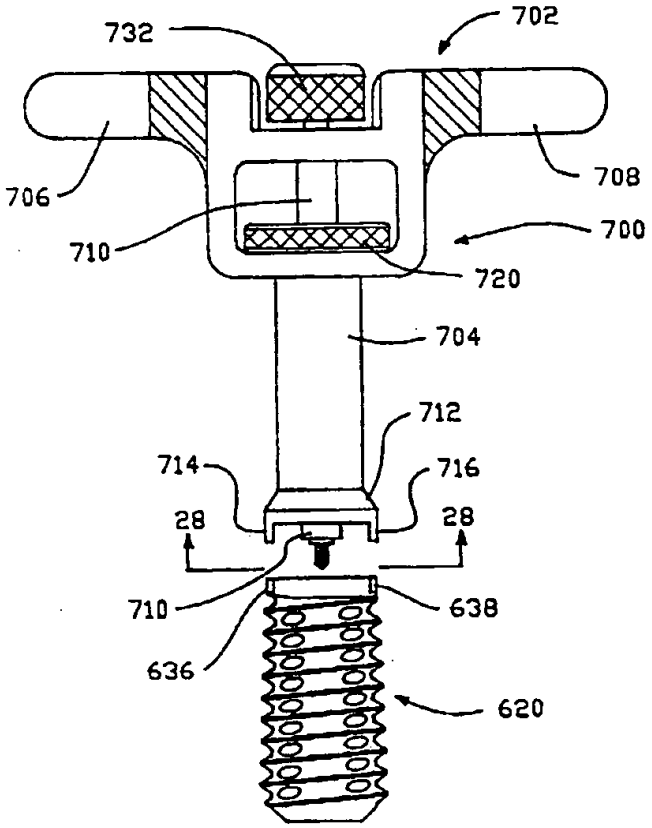
732
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FIG.—27

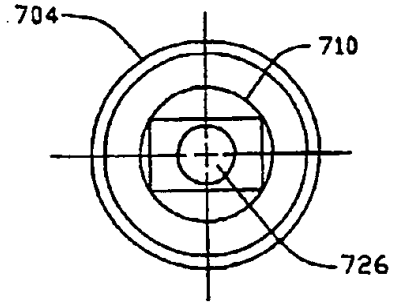

FIG.—28

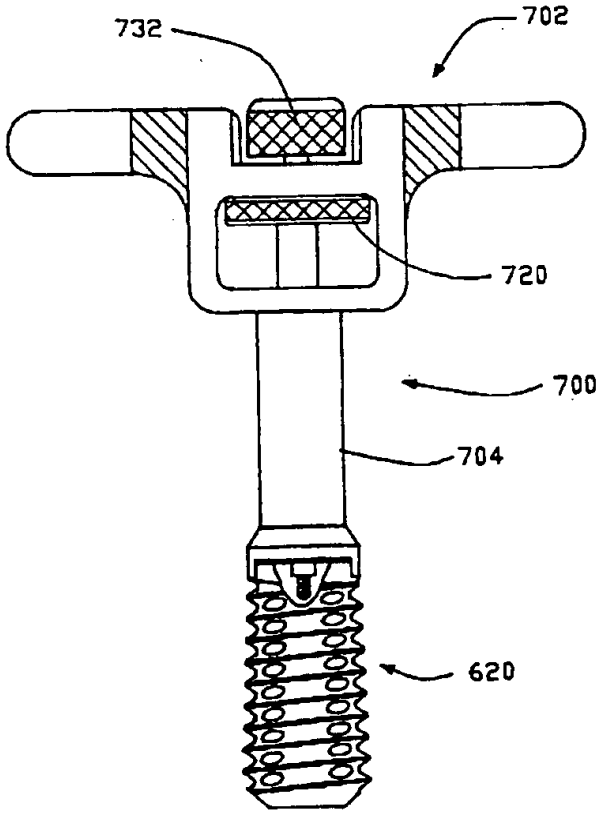

FIG.—29

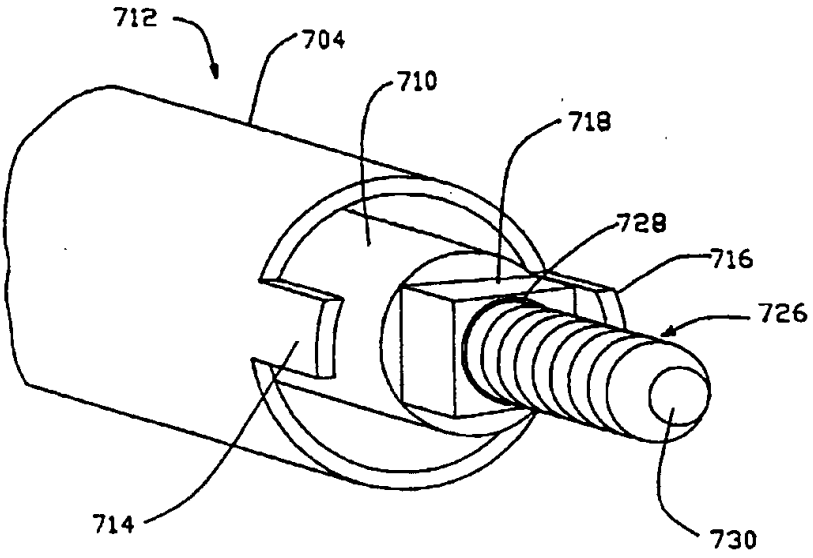

FIG.—30

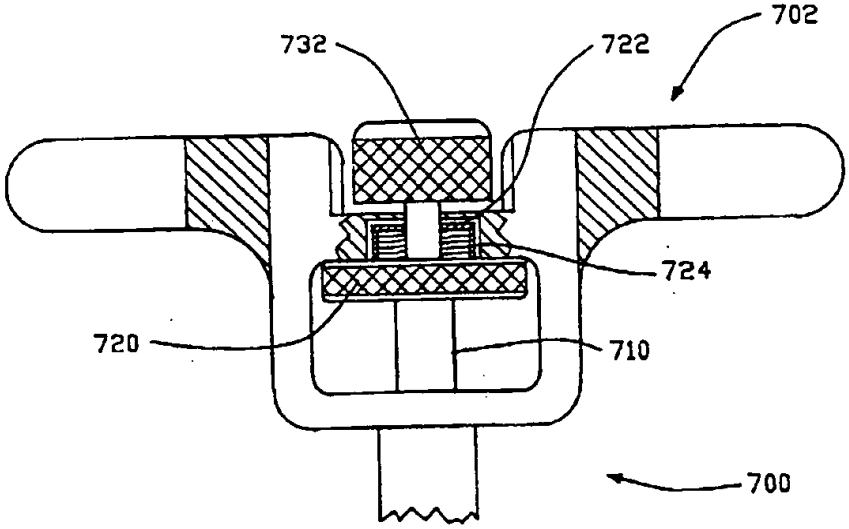

FIG.—31

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(54) Transverse connection for spinal jobs

(57) Four versions of clamps originally slidable along two generally parallel spinal rods (12,13) are swivel connected to three versions of transverse connectors (19) located between the rods (12,13). Set screws (31) lock the transverse connectors (19) to the clamps (22). Two of the clamp versions use interfitting rotational index locking detents at the swivel connections to fix the final orientation of the transverse connector (19) relative to the spinal rods (12,13). The other two clamp versions use locking tapers to lock the rotational index positions at the swivel connections to fix the final orientation of the transverse connector (19) relative to the spinal rods (12,13). One clamp version uses a separate set screw to fix the clamp on the spinal rod. One transverse connector has an open clamping head for installation directly onto the spinal rod without sliding it onto the rod from one end or the other.

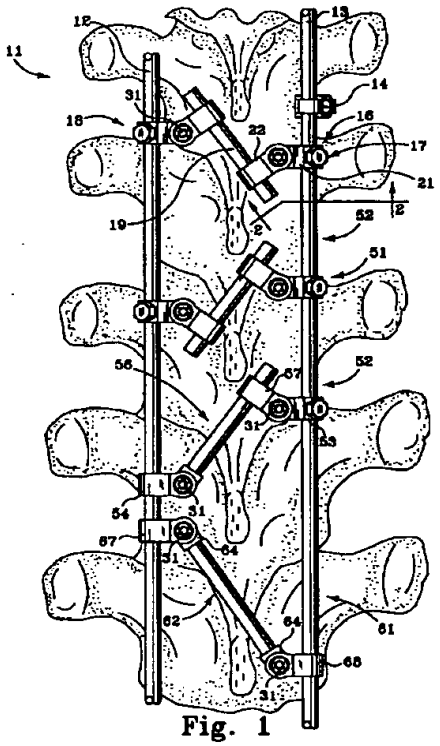

Fig. 1

EP 0 737 448 A1

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Description

BACKGROUND OF THE INVENTION

Field of the Invention:

This invention relates generally to spinal osteosynthesis, and more particularly to a system for making connections between two spinal rods.

Description of the Prior Art:

In spinal osteosynthesis, there are many cases in which implanted apparatus include laterally spaced implanted rods. Usually the positioning of the rods relative to each other must be stabilized, and various devices are used for that purpose. In U. S. Patent No. 5,005,562 issued April 9, 1991 to Yves Cotrel, transverse threaded rods 22 have hooks 23 screwed onto them. The hooks are fixed to the spinal rods 3 by hexagonal headed set screws or bolts. In U. S. Patent No. 5,261,907 issued November 16, 1993 to Vignaud et al., the pedicular screw 3 is anchored in bone and is attached to ring 9 by screwing down screw 6 which simultaneously spreads the screw head 5 to lock on ring 9, and also clamps the rod 2. Transverse rods 10, fixed in the rings 9, are received in clamping collar 11 and, when oriented in desired position, are fixed in collar 11 by the common clamping screw 12. There has remained a need for a device enabling rigid connection between two rods and which accommodates some variation in initial relative positioning of the rods, does not require mounting directly to screws such as in Vignaud et al., enables passage between vertebrae, and has minimal bulk. The present invention is addressed to that need.

SUMMARY OF THE INVENTION

Described briefly, according to a typical embodiment of the present invention, clamps originally slidable along two generally parallel spinal rods are swivel connected to a transverse connector located between the rods. Set screws lock the transverse connector to the clamps. One embodiment of clamp uses a separate set screw to fix the clamp on the spinal rod. The clamps use interfitting rotational index locking detents at the swivel connections to fix the final orientation of the transverse connector relative to the spinal rods. Other embodiments use locking tapers to lock the rotational index positions at the swivel connections to fix the final orientation of the transverse connector relative to the spinal rods.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a fragmentary posterior view of a spinal column with a corrective implant system incorporating transverse connection devices according to various embodiments of the present invention.

FIG. 2 is a view taken at line 2--2 in FIG. 1 and viewed in the direction of the arrows.

FIG. 3 is a view of a portion of one of the pivot assemblies.

FIG. 4 is a view similar to FIG. 1 but showing a still further embodiment.

FIG. 5 is a sectional view taken at line 5--5 in FIG. 4 and viewed in the direction of the arrows.

FIG. 6 is a fragmentary section of the assembly of FIG. 5.

FIG. 7A is an elevational view of one connector rod embodiment.

FIG. 7B is a top plan view of the FIG. 7A component.

FIG. 8 is an elevational view of another connector rod embodiment.

FIG. 9 is a view similar to FIG. 6 but of a still further connector assembly.

FIG. 10 is a much enlarged view of a break-off set screw used in the system.

FIG. 11 is a view similar to FIGS. 1 and 4 but showing a lateral connector with an open clamp to one of the spinal rods.

FIG. 12 is an exploded view of the lateral connector with the open clamp.

DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring now to the drawings in detail, in FIG. 1 there is the spinal column shown generally at 11 with two spinal rods 12 and 13 thereon and, for purposes of illustration, one hook assembly 14 securing the rod 13 to one of the bones. It should be understood that the rods can be secured in several additional places to the spinal column by appropriate hooks such as are well known in the art, some examples of which are shown in the above-mentioned Cotrel patent and others in the TSRH Spinal Implant System described in the "Surgical Technical Manual" of Danek Medical, Inc. published in 1990, the disclosure of which is incorporated herein by reference. That particular literature describes CROSSLINK devices to provide fixed spacing between rods 12 and 13.

Several different embodiments of the present invention are illustrated in FIG. 1 herein, and another embodiment is shown in FIG. 2. Conditions to be treated in

different cases may indicate the desirability of using only one embodiment or other combinations of various embodiments of the present invention.

The first embodiment to be described will be the transverse connector assembly 16 which includes two pivot assemblies 17 and 18 which are identical although differently oriented, and a transverse connector rod 19. The pivot assembly 17, which will be described as exemplary, includes the connector pivot base 21 and the U-clamp 22. The components are better shown in FIGS. 2 and 3. The pivot base 21 includes the aperture through which the spinal rod 13 extends. The set screw 23 is threaded into the boss 24 of the pivot base 21. There are axially extending serrations or teeth 26 in the spinal rod receiving aperture in the pivot base to assist in securing the pivot base on the rod when the screw 23 is tightened onto the rod.

The other portion of the pivot base has an aperture through it receiving a set screw 31 which serves first as a pivot pin, and then as a clamping screw. On the upper and lower faces 27 and 28, respectively, there are grooves extending radially from the axis 29 of the pin receiving aperture, thus providing a rotary indexing detent system.

The other portion of the pivot assembly 17 is the U-clamp 22. This clamp is secured to the transverse connector rod 19 and to the pivot base by set screw 31 which, as shown in FIG. 10, has a hexagonal head 32, a peripheral notch 33 immediately below the head, a flange 34, a smooth shank 36 and threaded distal lower end 37. The notch provides a break-off feature to prevent excessive tightening. A circular aperture 38 through the head provides access to a number 10 TORX socket 41 in the top of that portion of the set screw immediately below the notch 33. In the assembly, the threaded portion is passed freely through the aperture 42 in the top of the U-clamp (FIG. 3) and threaded into the threaded portion 43 in the bottom of the U-clamp to thereby assemble the U-clamp to the pivot base. The U-clamp has two sets of axially extending teeth 44 and 46, similar to the teeth in the spinal rod receiving bore of the pivot base. These U-clamp teeth 44 and 46 grip transverse connector rod 19 when the clamp is tightened.

Once the orientation of the clamp on the pivot base has been established and deemed acceptable by the surgeon, it is essential that the orientation remain constant. For that purpose, there are four ribs 47 on the U-clamp. Two of these, spaced diametrically apart, face downward from the top of the clamp, and two of them face upward from the bottom of the clamp. These ribs or ridges seat in the grooves in the upper and lower faces 27 and 28, respectively, of the pivot base. The grooves are in a sunburst array around the axis 29 of the pin receiving aperture in the pivot base. The ability to interfit the ridges 47 of U-clamp 22 in the grooves in the top and bottom surfaces of the pivot base enables locking these two parts in any of many possible rotational index positions chosen by the surgeon.

The pivot assembly 18 on the spinal rod 12 is exactly the same as assembly 17 just described on spinal rod 13. The orientation is different as shown in FIG. 1, with the transverse connector rod 19 spanning the gap between the two U-clamps on the respective pivot assemblies. It is a feature of this invention that there is great freedom of discretion in the location and orientation of the pivot assemblies and the transverse connector. The assembly allows for the necessary degrees of tilt, rotation and angulation in three planes to make connections possible regardless of what the anatomy instrumented or deformity treated might be. It allows for dynamic diagonal transverse connections with both distraction and compression force applications. The sequence of tightening the set screws 23 for the pivot bases to the spinal rods and screws 31 for the U-clamps to the pivot bases can be selected in accordance with the preferences of the surgeon, to provide the best possible relationship of the parts. At such time as the desired relationship of the U-clamps to the pivot bases has been determined, the set screws 31 can be tightened by a hexagonal wrench on the heads 32. They are designed to break at the notch 33 to avoid excessive application of tightening torque. If, at some later time, it is desired to remove the set screws, a suitable TORX wrench can be used in the socket 41 for that purpose.

Referring further to FIG. 1, there is a second transverse connector assembly 51 shown connected between the two rods 12 and 13. The components of this connector assembly are exactly the same as those for the assembly 16, the only difference being that the pivot base on the right-hand rod is above that on the left-hand rod.

Referring still further to FIG. 1, there is a third transverse connector assembly 52. This one is different from the first two in several respects. A pivot base and U-clamp assembly 53 is secured to the rod 13 in the same manner as described above with reference to the assembly 17. But on the other rod 12, the pivot assembly has only the U-clamp portion 54 of an assembly such as 53. The U-clamp 54 is exactly like U-clamp 22. Instead of the transverse connector rod 19 previously described, the transverse connector 56 as shown in FIG. 7A and 7B has a cylindrical rod portion 58 and, at one end of it, there is a double faced swivel head portion 59 having an upper surface 61 and lower surface 62, both of which have the radially extending grooves in a sunburst array as was described above for the pivot base 21. These are received in the U-clamp 54 just as the comparable portion of the pivot base 21 is received in the U-clamp 22. This swivel connection is secured in the same way with the same type of set screw 31 as described above. The cylindrical portion 58 of the rod is received through the U-clamp 57 (which is exactly like U-clamps 54 and 22) and is secured in the same way as described above for the rod 19 in U-clamp 22.

Referring further to FIG. 1, a fourth transverse connector assembly 61 is shown connected between the rods 12 and 13. In this example, the transverse connec-

tor 62 is as shown in FIG. 8 and is similar to connector 56 described above, but the cylindrical rod portion 63 has swivel head portions 64 at both ends. These are like the swivel head 59 at the end of the rod 58 and are received in U-clamps 67 and 68 on rods 12 and 13, respectively. Set screws 31 are used in both of the U-clamps to clamp them to the swivel heads 64 of the rod 62 when the desired spacing and location of the rod 62 have been determined. U-clamps 67 and 68 are like U-clamp 22 and the clamping is the same as described above for fixing the U-clamp 22 to pivot 21.

Referring now to FIG. 4, spinal rods 72 and 73 are shown. It should be understood that the spinal rods in FIGS. 1 and 2 can be closer together or farther apart, and the only resulting change would be the orientation of the connector assemblies and the transverse rod between them. Therefore, any of the three different connector assemblies in FIG. 1 can be used with a greater or lesser spacing between the spinal rods. This is true of the embodiment shown in FIG. 4. The transverse connector assembly in FIG. 4 appears very similar to and is similarly oriented to that shown at the top of FIG. 1., but there are some differences, as can be better understood by reference to FIGS. 5 and 6. In this case, the transverse rod 76 can be the same as rod 19 in FIG. 1. But the pivot assembly 77 includes two clamps 78 and 79. In a sense, both of these clamps 78 and 79 might be considered U-clamps. But to distinguish them, the clamp 78 will be referred to as split clamp and 79 as a U-clamp. Clamp 78 has the longitudinally or axially extending alternate ridges or grooves or (teeth) 81 therein to tightly engage the spinal rod 73 when clamped shut. Similarly, clamp 79 has the axially extending alternate ridges and grooves 82 for gripping tightly on transverse rod 76 when the assembly is clamped together. For clamping the assembly together, a set screw 83 is used and is provided with a Morse taper on its exterior surface 84 received in a matching Morse taper 85 in the upper finger of clamp 79, and matching Morse taper 86 in the clamp 78. The threads 87 on the lower end of the set screw 83 are threaded into the threads 88 of the clamp 79. A Morse taper is also provided on surface 91 of the clamp 78 so that it does not matter whether the clamp is used as shown or upside down, as the set screw 83 will lock in whichever of the apertures 86 or 91 is at the top. The set screw 83 can be provided with a break off head as described above with reference to the set screw 31, or with simply a TORX or hexagonal socket 92 therein. Upon reception of the clamps 78 and 79 on rods 73 and 76, respectively, and upon suitable orientation of the rods with respect to each other and the suitable orientation of the clamps on the rods, the set screws can be tightened to clamp both of the clamps onto their respective rods, with the set screws locking in their respective tapers such as 86 in the upper finger of clamp 78 and surface 85 in the upper finger of clamp 79. The connector clamp assembly 93 on rod 72 is exactly the same as clamp assembly 77 on rod 73 and is clamped to rod 72 and rod 76 in the same way. A shallow, semi-circular channel 94, half of which is on the lower finger of clamp 78 and half on the upper finger of clamp 78, extends around the entire exposed surface of the two fingers so as to accommodate the rod 76 during the swiveling of the clamp 79 on clamp 78 before locking the two together with the set screw.

Referring now to FIG. 9, a variation of the embodiment of FIGS. 5 and 6 is shown. In this pivot assembly example, the spinal rod 97 and the transverse rod 76 are associated with two clamps, one being clamp 78 as previously described with reference to FIGS. 5 and 6, but the other being a U-clamp 99 which is different from clamp 79. One of the differences is the fact that the upper finger 101 thereof has the aperture 102 which is a straight walled cylindrical aperture and does not lock on the taper 84 of the locking screw 83. Another difference is that there is a tapered aperture with a Morse taper at 103 in the lower finger of the clamp. The locking screw 83 is the same as that in the previously described embodiment, except that in this embodiment it has an upper flange 104 to engage and bear on the upper surface of the upper finger 101. The threaded end of this screw is received in a lock nut 106 which has a tapered external surface 107, and a flange 108 on its lower end. Therefore, when this assembly is to be clamped on the rods 97 and 76, the screw 83 is turned down to engagement of the threads thereon with the threads in the bore of the nut 106 which then jams in the Morse taper in the lower finger of the clamp 99 and, upon sufficient tightening, the flange 104 on the head of screw 83 will pull the clamp 99 into clamping engagement with rod 76. The engagement of the Morse taper 84 on the screw 83 with the taper 86 in the clamp 78 will pull that clamp tightly onto rod 97 and lock the screw in the clamp. The edges 109 at the bottom of the aperture in the lower finger of clamp 99 can be bent over to trap the flange 108 of the lock nut in the assembly so that it does not fall out before the screw threads engage it.

Referring now to Figs. 11 and 12, the spinal rods 112 and 113 can be considered comparable and situated similarly to those in Figs. 1 and 4, for example. A U-clamp 114 is secured to rod 113. This clamp can be identical to clamp 22 shown in Figs. 1-3 but, instead of being secured to the transverse rod as in those figures, it is secured directly to the spinal rod 113. A pivot base 116 is mounted to the U-clamp 114. This pivot base is identical to pivot base 21 in Figs. 1 and 2. It is mounted to the U-clamp 114 in exactly the same way and secured by the set screw 117, which simultaneously secures the U-clamp 114 to the spinal rod 113. In this example, in contrast to the Fig. 1 illustration, the U-clamp and the pivot base are shown at 90° with respect to each other but, as in the previous example, the angle between the parts, once established as desired, is fixed by the ribs on the U-clamp received in the grooves in the pivot base to securely maintain that angular relationship.

The transverse connector rod 118 is received and fixed in the aperture of the pivot base 116 by the set

screw 119 in exactly the same manner as the spinal rod 13 is secured in pivot base 21 by set screw 23 in Fig. 2. This transverse connector rod 118 is integral with the connector base 121 of the open-type connector clamp assembly 122 which includes a connector cap 123 secured to the base and to the spinal rod 112 by the set screw 124.

Referring now to Fig. 12, the transverse connector rod-base and clamp assembly 122 is shown in three pieces, with the connector rod 118 and base 121 separate from the cap 123 and set screw 124. The rod 118 itself has a knurled surface as does the groove 126 in the base. Similarly, although not shown, the groove 127 in the cap is knurled. As may be evident from the description to this point, the base is open so that it can be installed on the spinal rod in a transverse direction without having to slide it axially down the length of the rod. In other words, the entrance gap to the spinal rod receiver channel is wide enough for the spinal rod to be received in it in the direction of arrow 129. Grooves 131 are provided at each side of the spinal rod receiver channel. The lower surface of each groove has a slight concave curve to it, and the flange 132 at the top of the base at each side of the channel entrance has a convex curve to it. Similarly, the cap 123 has a flange 133 at each side which extends parallel to the axis of the rod receiving channel 127, whereby the cap can be installed into the base in the direction of arrow 136, with the flanges on the cap received in the grooves 131 outboard of the flanges 132 on the base, the flanges 132 of the base being received in the grooves 134 in the cap. Because of the fact that the top of flange 133, bottom of flange 132 and the bottom of the groove 134 in the cap and the bottom of the groove 131 in the base are all curved, so is the bottom 137 of the cap. Therefore a slight rocking motion of the cap as it is inserted in the direction of arrow 136 into the base, will occur. Therefore, the total clearance between the cylinder formed by the rod receiving channel 127 in the cap and the rod receiving channel 126 in the base will be enough to admit the cap into the base when the base has been positioned in place under the spinal rod. Following the installation, the set screw 124 is tightened in the threads 138 in the set screw receiver aperture in the cap. Accordingly, the set screw drives the spinal rod tightly against the bottom of channel 126 in the base. The bottom of the set screw is pointed as at 139 to avoid any axial slippage along the spinal rod. Axial movement of the base along the spinal rod is limited not only by the friction between the channel bottom and the rod but also by the fact that, due to the curvature in the flanges and receiver grooves in the base and the cap, axial movement of the base cannot take place without tending to rotate it about the axis of the rod 118. This movement is resisted not only by the rod 112 itself, but also by the clamping of the transverse rod 118 in the pivot base and by the pivot base being clamped in the U-clamp 114. Therefore, once the set screws 117, 119 and 124 are secured, movement is securely resisted in all directions.

The material for all of the components may be the same. For one example, connector 56 is a solid unit of 316L ASTM F138 grade 2 cold rolled 900/1050 MPa material. It is machined to provide the rod portion 58 and head portion 59. The spinal rods and transverse rods can be smooth, shot peened, or knurled. The transverse rods such as 19 and 58 can be cut off to a desired length.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

Claims

1. In a system for spinal osteosynthesis including two generally parallel spinal rods implanted adjacent a spinal column, apparatus for making a rigid connection between the rods and comprising:

   first and second connectors slidable along the first and second rods, respectively;

   a transverse connector located between the rods and swivel connected to the first and second connectors;

   two fasteners;

   one of the fasteners connecting the first connector to the transverse connector, the other of the fasteners connecting the second connector to the transverse connector;

   and

   swivel orientation locks at the locations of the connection of the transverse connector to the first and second connectors for locking said connector at variable orientations.

2. The apparatus of claim 1 and further comprising: third and fourth fasteners, the third fastener clamping the first connector to the first rod, and the fourth fastener clamping the second connector to the second rod.

3. The apparatus of claim 1 and wherein:

   the first connector is a pivot base having upper and lower indexing detent recesses circularly-spaced around a pivot aperture, the apparatus further comprising:

   a U-clamp pivotally mounted to the pivot base and having detent projections thereon receivable in the detent recesses,

   one of the fasteners being a set screw operable to drive at least one of the detent projections into one of the detent recesses to thereupon prevent the U-clamp from pivoting on the pivot about the aperture.

4. The apparatus of claim 3 and wherein:
the U-clamp has upper and lower arms,
the detent recesses are grooves extending radially outward from the pivot aperture
the upper arm having an aperture therein receiving the one set screw therein, and the lower arm having screw threads therein receiving threads of the one set screw,
the upper arm having a lower surface with at least one of the detent projections thereon projecting downward therefrom into one of the detent recesses of the pivot base,
the lower arm having an upper surface with at least one of the detent projections thereon projecting upward therefrom into one of the detent recesses of the pivot base.

5. The apparatus of claim 4 and wherein:
the U-clamp has a semicylindrical portion thereof with a cylindrical axis, and has a plurality of teeth therein extending parallel to the axis thereof and gripping a rod.

6. The apparatus of claim 5 and wherein:
the one set screw is a break-off set screw.

7. The apparatus of claim 1 and wherein:
the first connector is a pivot base in the form of a split clamp having upper and lower arms, the apparatus further comprising:
a U-clamp having a portion received on the split clamp and a portion receiving the transverse connector therein; and
the fastener connecting the pivot base to the transverse connector is a set screw which has a tapered portion and a threaded portion, and at least one of the split clamp and the U-clamp has a taper matching and locking on the tapered portion of the set screw.

8. The apparatus of claim 7 and wherein:
the matching taper is in the upper arm.

9. The apparatus of claim 8 and wherein:
the U-clamp has an upper arm and a lower arm, the upper arm having an aperture therein receiving a portion of the set screw therethrough, the aperture having a tapered internal wall matching the taper of the set screw, and the lower arm having an aperture therein with threads receiving the threaded portion of the set screw whereby, upon advancing the threaded portion of the set screw in the lower arm threads, the clamps are locked to each other and the split clamp is locked on the spinal rod and the U-shaped clamp is locked on the transverse connector.

10. The apparatus of claim 8 and wherein:
the set screw has an upper flange engageable with the top of the upper arm of the split clamp;
the U-clamp has an upper arm and a lower arm and an aperture in the lower arm and which has a taper therein, the apparatus further comprising:
a nut received in the aperture in the lower arm of the U-clamp, the nut having an external taper matching the taper in the lower arm of the U-clamp, and the nut having internal threads receiving the threaded portion of the set screw whereby the set screw is securable in the nut and the nut is lockable in the taper in the lower arm of the U-clamp and the taper on the set screw is lockable in the taper in the upper arm of the split clamp to thereby lock the clamps to each other and lock the split clamp on the spinal rod and lock the U-clamp on the transverse connector.

11. The apparatus of claim 1 and wherein:
the first and second connectors are pivot bases and the fasteners are set screws threaded through the pivot bases and operable to fix the pivot bases on their respective rods, the apparatus further comprising:
first and second swivel clamps pivotally mounted to the first and second pivot bases;
the transverse connector being a rod extending through the first and second clamps; and
third and fourth set screws serve as clamp set screws and connect the clamps to their respective pivot bases and lock the clamps on the pivot bases and on the transverse connector rod.

12. The apparatus of claim 11 and wherein:
the clamps and transverse connector rod are disposed between the first and second spinal rods.

13. The apparatus of claim 10 and wherein:
each of the clamps has an interface with the pivot base

14. The apparatus of claim 13 and wherein:
the interfaces between the clamps and pivot bases have interengaging detents providing interference between the clamp and respective pivot base when the clamp set screw is tightened, to prevent swiveling of the clamp on the pivot base.

15. The apparatus of claim 1 and wherein:
the first connector is a U-clamp having an upper arm and a lower arm;
the swivel orientation locks include detents on the transverse connector and on the U-clamp.

16. The apparatus of claim 15 and wherein:
the detents include detent ridges and grooves on the transverse connector and detent ridges on the U-clamp.

17. The apparatus of claim 16 and wherein:

the transverse connector has a rod portion and a head portion at an end of the rod portion, the head portion having top and bottom surfaces and an aperture through them, and

the detent ridges and grooves extend radially outward from the aperture on the top and bottom surfaces of the head portion.

18. The apparatus of claim 17 and wherein:

the one fastener is a set screw and has threads threaded into the lower arm of the U-clamp and has a bearing surface bearing downward on the upper arm of the U-clamp and holds at least one detent ridge of the U-clamp in at least one detent groove of the connector rod head to prevent swiveling of the rod about the aperture in the U-clamp.

19. In a system for spinal osteosynthesis including first and second generally parallel spinal rods implanted adjacent a spinal column, apparatus for making a rigid connection between the rods and comprising:

first and second connectors slidable along the first and second rods, respectively;

a transverse connector located between the rods and swivel connected to at least one of the first and second connectors;

two fasteners;

one of the fasteners connecting the first connector to the transverse connector, the other of the fasteners connecting the second connector to the transverse connector;

and

swivel orientation locks at the location of the connection of the transverse connector and the one of the connectors for locking said transverse connector at different orientations with respect to the second rod.

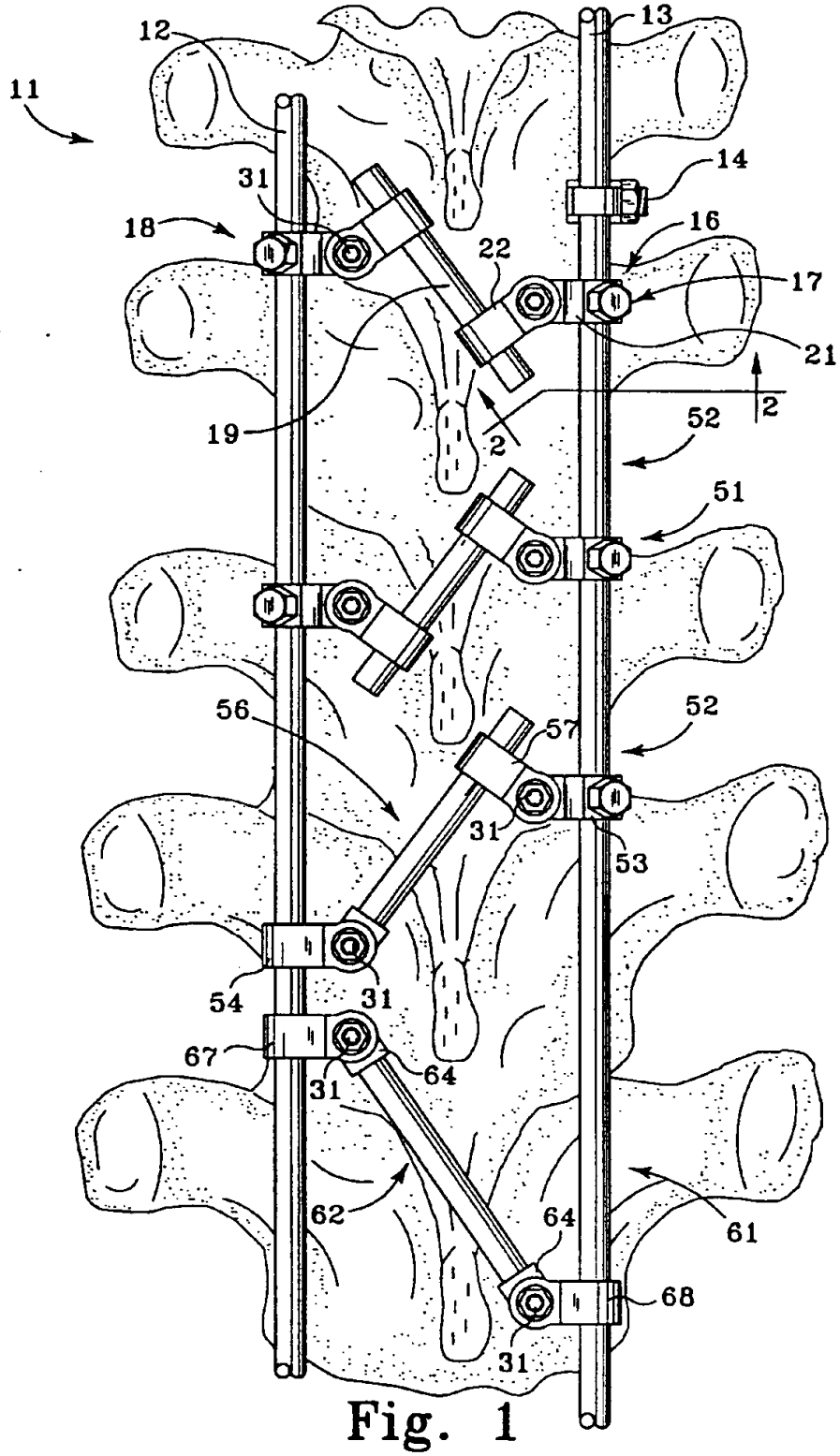
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Fig. 1

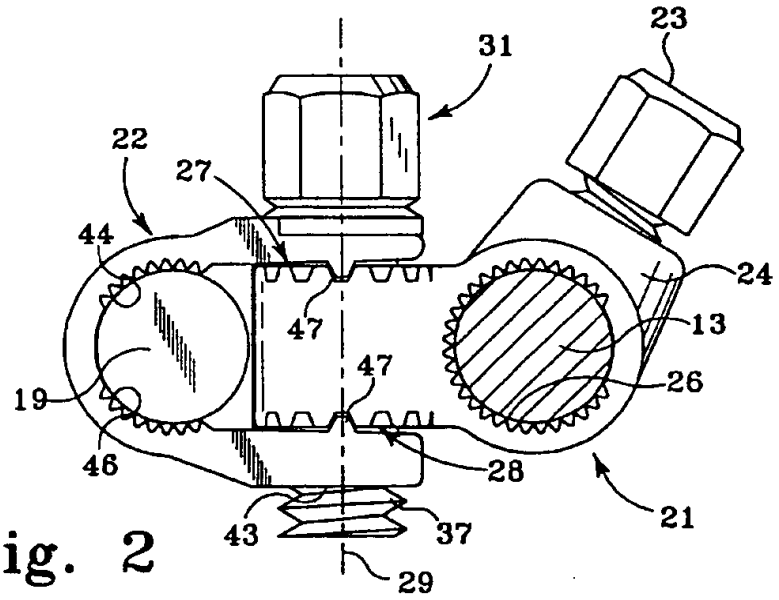

Fig. 2

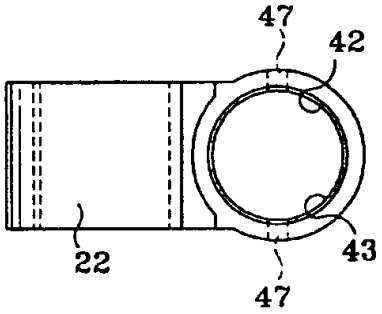

Fig. 3

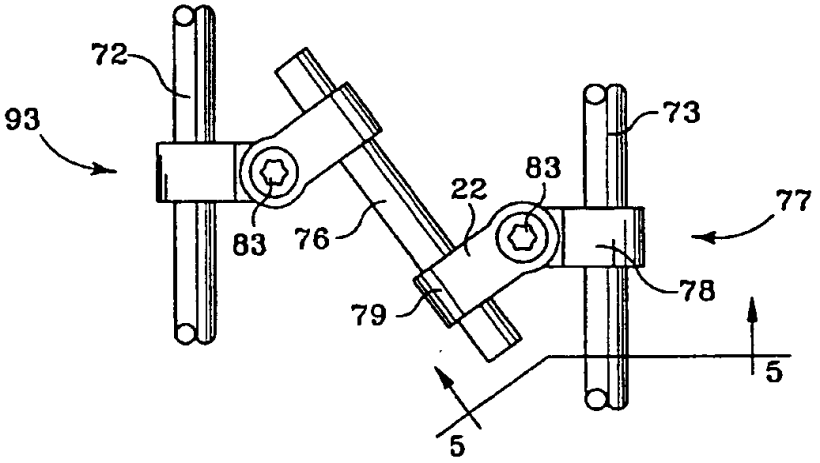

Fig. 4

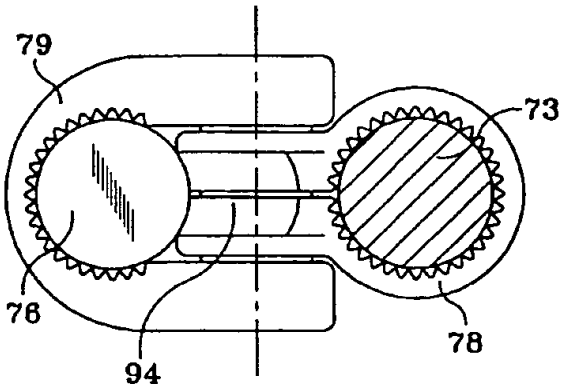

Fig. 5

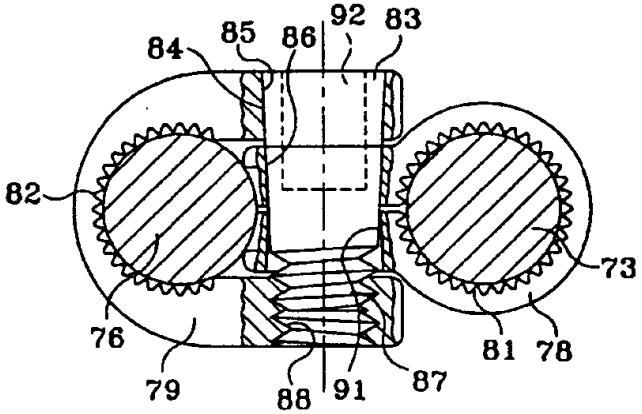

Fig. 6

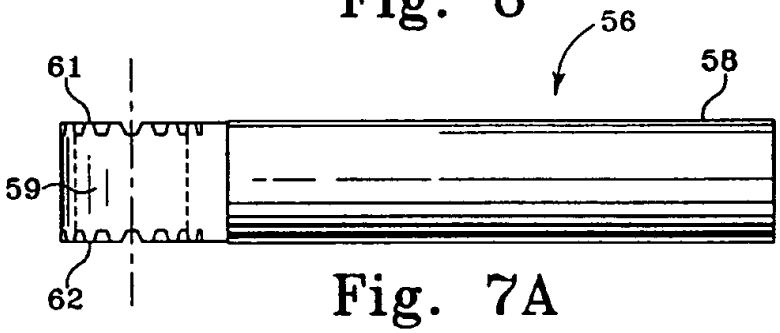

Fig. 7A

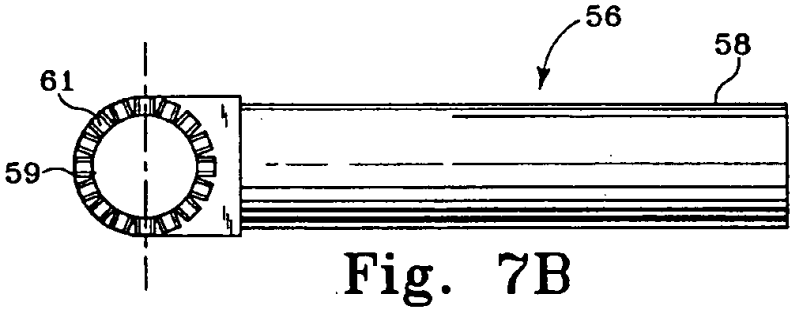

Fig. 7B

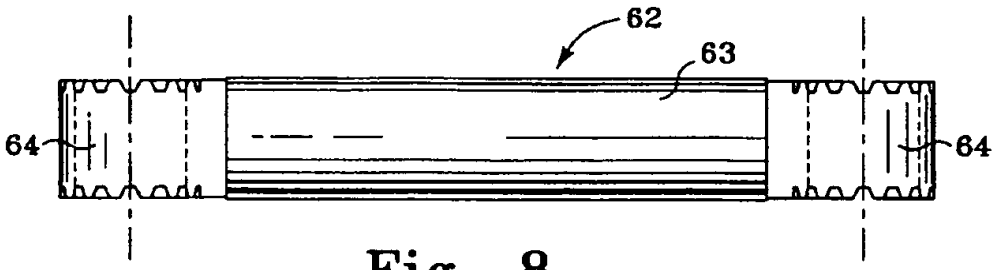

Fig. 8

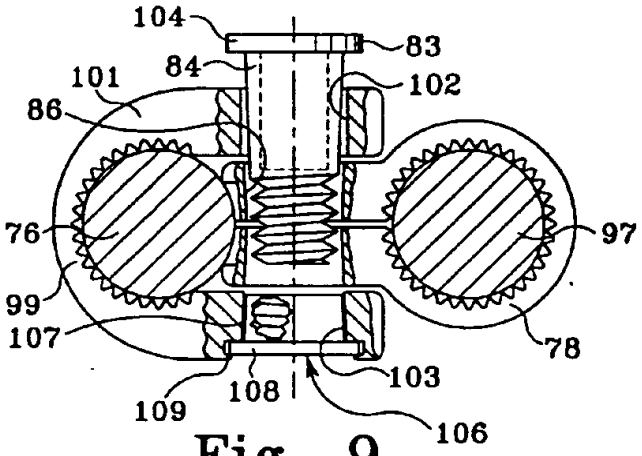

Fig. 9

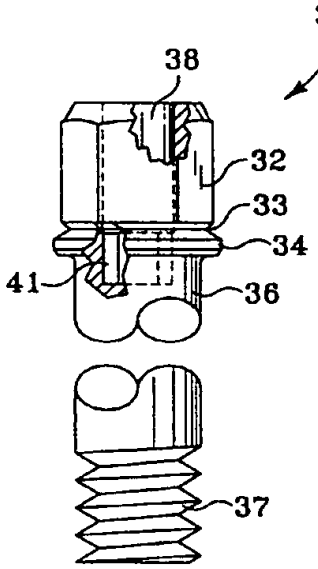

Fig. 10

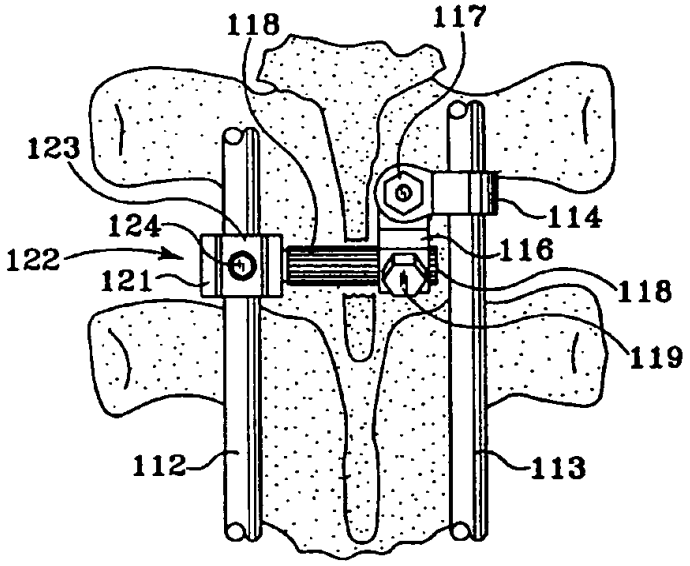
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Fig. 11

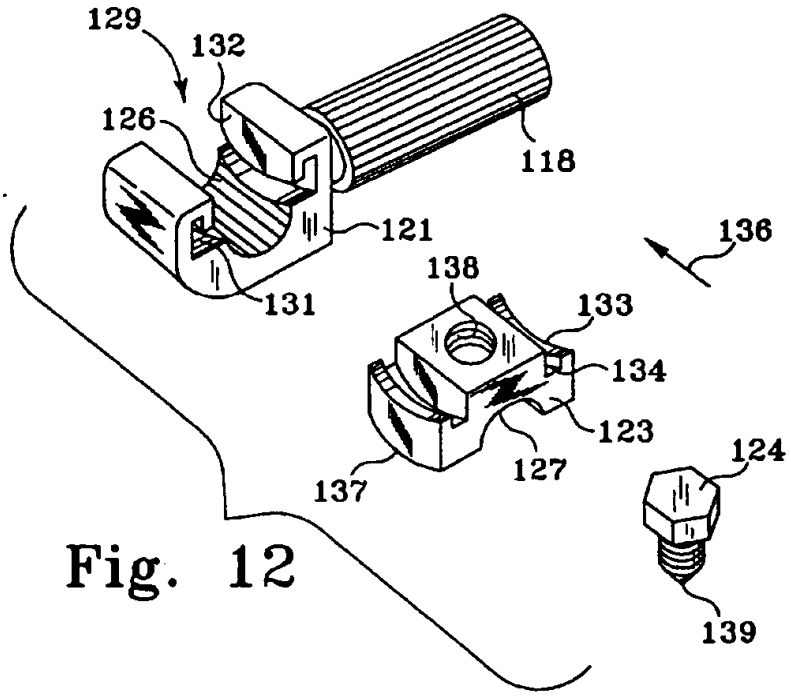
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Fig. 12

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 96 30 1739

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	EP-A-0 418 387 (V KURGANSKY NAUCHNY TS VOSSTAN) 27 March 1991 * column 8, line 2 - line 17; claim 4; figure 7 *	1,19	A61B17/70
A	US-A-5 254 118 (MIRKOVIC SRDJIAN) 19 October 1993 * column 2, line 13 - line 26; figures *	1,15,19	
D,A	US-A-5 261 907 (VIGNAUD JEAN L ET AL) 16 November 1993 * column 3, line 10 - line 47; figures *	1,19	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	1 July 1996	Neumann, E

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
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T : theory or principle underlying the invention
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L : document cited for other reasons

& : member of the same patent family, corresponding document

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(54) Method and instrumentation for surgical implant insertion

(57) A surgical retractor including a sleeve member having two opposed retractor arms (20) at its distal end portion. By inserting the retractor arms of the retractor within a space defined between adjacent bony structures, first and second supporting surfaces (20a, 20b) of each retractor arm respectively engage the opposed structures thereby distracting the structures, for performing a surgical procedure. A method for inserting a spinal implant is also disclosed. Instrumentation for performing the procedure is also disclosed.

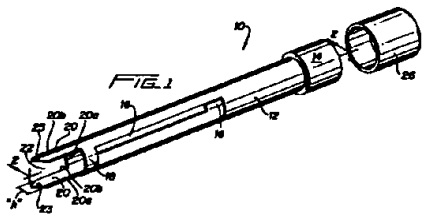

FIG. 1

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Description

BACKGROUND

1. Technical Field

The present disclosure generally relates to a method and associated instrumentation for implant insertion and, in particular, to a method and instrumentation for insertion of spinal implants to facilitate fusion of adjacent vertebral bodies.

2. Background of the Related Art

A large number of orthopedic procedures involve the insertion of either natural or prosthetic implants into bone or associated tissues. These procedures include, for example, ligament repair, joint repair or replacement, non-union fractures, facial reconstruction, spinal stabilization and spinal fusion. In a typical procedure, an insert, dowel or screw is inserted into a prepared bore formed in the bone or tissues to facilitate repair and healing. See, for example, U.S. Patent Nos.: 5,470,334 to Ross et al.; 5,454,811 to Huebner; 5,480,403 to Lee et al.; 5,40_,805 to Warren; 5,358,511 to Gatturna et al.; and 4,877,020 to Vich.

Some implants are particularly configured with cavities and bores to facilitate bony in growth and enhance anchoring of the implant at the insertion site. See, for example, U.S. Patent Nos.: 4,328,593 to Sutter et al.; 4,936,851 to Fox et al.; and 4,878,915 to Brantigan. Implants in the form of fusion cages having internal cavities to receive bone growth stimulation materials such as bone chips and fragments are disclosed, for example, in U.S. Patent Nos.: 4,501,269 to Bagby; 4,961,740 to Ray et al.; 5,015,247 to Michaelson; and 5,489,307 to Kuslich et al. These types of implants are particularly well suited for intervertebral spinal fusion procedures necessitated by injury, disease or some degenerative disorder of the spinal disc. Subsequently, there may be progressive degeneration leading to mechanical instability between adjacent vertebrae necessitating direct fusion of the vertebrae while maintaining a pre-defined intervertebral space. This fusion may be accomplished by the insertion of one or more of the specialized implants as discussed above and also discussed in commonly assigned U.S. Patent No. 5,026,373, the contents of which are incorporated herein by reference.

Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions of the lumbar spine. Fusions in the cervical area of the spine are primarily performed using a posterior approach. Typically, an implant such as a plug, dowel, prosthesis or cage is inserted into a preformed cavity inside the interbody, interdiscal space. Since it is desirable in these procedures to promote a "bone to bone" bridge, connective tissue and at least a portion of the distal tissue is removed. Preferably, relatively deep cuts are made in the adjacent bones in order to penetrate into the softer, more vascularized cancellous region to facilitate bone growth across the implant.

One of the more critical tasks performed in the insertion of a surgical fusion implant, particularly, in intervertebral spinal fusion, is the formation of the implant receiving cavity or bore between/within the adjacent vertebrae. More particularly, the drilled bore must be equally centered within the intervertebral space and preferably parallel to the vertebral end plates to ensure removal of equal portions of bone from the adjacent vertebrae throughout the length of the cut and subsequent appropriate seating of the implant relative to the vertebral bodies.

Surgical instruments for spinal fusion implant insertion are known. For example, U.S. Patent No. 5,484,437 to Michelson discloses a method and apparatus incorporating an outer and an inner sleeve arrangement. The outer sleeve is positioned over the spinal distractor and has teeth at one end which are driven directly into the posterior surface of the adjacent vertebrae. The inner sleeve is positioned within the outer sleeve and serves to guide instruments such as a drill used to form the implant receiving bore. U.S. Patent Nos.: 5,487,307 to Kuslich et al.; 5,015,247 to Michelson; and 4,878,915 to Brantigan also disclose outer sleeves with teeth mounted to the vertebrae. Other arrangements include the use of guide rods which are placed in pilot holes formed in the vertebral bodies. The guide rods guide a bore forming hollow drill into the intervertebrai space.

Although some current instrumentation and methods associated therewith for enhancing the placement of spinal fusion implants have been generally effective for their intended purposes, there exists certain limitations with the design of this instrumentation which detract from their usefulness. For example, the arrangement disclosed in the Michelson '437 patent and similar arrangements do not provide for automatic alignment of the outer sleeve to ensure that the bore formed by a drill introduced into the outer sleeve is in optimal alignment for a tapping procedure (if required) and reception of the spinal implant. Rather, such orientation is dependent directly upon the skill of the surgeon. Moreover, the outer sleeve, which is mounted via teeth only at its extreme distal end to the posterior surface of the adjacent vertebrae, is subject to disorientation or dislodgment during insertion and/or removal of the drill and/or tapping instrument. The use of guide rods increases the number of steps required to implant the fusion cage.

Accordingly, the present disclosure is directed to a method and associated instrumentation to facilitate the introduction of a fusion implant, which ensures optimal alignment of the drilled bore for reception of the fusion implant and, if appropriate, for bore tapping procedures. The instrumentation of the present disclosure also reduces the number of steps required for implantation of the fusion cage.

SUMMARY

Generally, the present disclosure is related to a method for performing a surgical procedure. The method includes the steps of providing a surgical retractor having proximal and distal end portions and having an opening therethrough to receive instrumentation, the distal end portion configured for insertion at least partially into an intervertebral space between adjacent opposed vertebrae. The method further includes the steps of at least partially inserting the retractor into the intervertebral space to distract adjacent vertebral and performing the surgical procedure with instrumentation inserted through the retractor. The surgical procedure particularly contemplated includes introducing a fusion implant through the surgical retractor and within the space defined between the distracted vertebrae.

The present disclosure is also directed to a method for effecting fusion of adjacent vertebral bodies, including the steps of accessing the intervertebral disc space, providing a retractor including a retractor sleeve having proximal and distal end portions with the distal end portion having opposed retractor arms extending in a general longitudinal direction, positioning the retractor arms within the intervertebral disc space whereby first and second supporting surfaces of each arm contact and distract opposed vertebral bodies, introducing a drill instrument into the sleeve and advancing the drill instrument within the sleeve to the intervertebral disc space, forming with the drill instrument a bore that penetrates at least partially into each opposed vertebral body, removing the drill instrument from the sleeve and introducing a fusion implant into the bore. The preferred method may further include the steps of introducing a tap instrument into the sleeve and advancing the tap instrument within the sleeve to the disc space, tapping with the tap instrument a thread within the bore such that the thread communicates into the opposing vertebral bodies, removing the tap from the retractor sleeve, introducing a fusion implant having a cage body with an external thread into the bore and screwing the cage body into the threaded bore.

The preferred fusion implant has a plurality of openings extending through the cage body whereby bone-growth inducing substances may be introduced into the cage body of the fusion implant to fuse with the adjacent vertebral bodies.

The present disclosure is also directed to instrumentation utilized to perform the spinal fusion implant surgery. In particular, a surgical retractor is provided including an elongated member having proximal and distal end portions and defining a longitudinal passageway for reception of surgical instrumentation. The distal end portion of the member includes first and second retractor arms extending in a general longitudinal direction. Each retractor arm has first and second supporting surfaces for engaging opposed adjacent tissue portions, e.g. opposed vertebral bodies. Each retractor arm defines a dimension between the first and second supporting surfaces sufficient to distract the opposed tissue portions, e.g. vertebral bodies, upon insertion thereof The retractor arms may each possess distal tapered portions for facilitating insertion into the intervertebral space. The first and second supporting surfaces of each retractor arm are preferably in general parallel relation to each other and the longitudinal axis of the sleeve member and in a preferred embodiment are substantially planar.

The present disclosure is also directed to a surgical tapping instrument for tapping an internal thread within a bore defined in adjacent vertebral bodies. The tapping instrument includes an elongated frame defining a longitudinal axis and having a distal tapping head. The tapping head includes a tapping thread for tapping a thread within the bony tissue and at least one conveyance channel having a directional component transverse to the longitudinal axis and dimensioned to collect bone material removed during the tapping procedure.

Other instrumentation to facilitate spinal implant insertion is also disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the disclosure are described hereinbelow with reference to the drawings wherein:

FIG. 1 illustrates a surgical retractor constructed in accordance with the principles of the present disclosure and utilized in distracting adjacent bony structures;

FIG. 2 is a cross-sectional view of the retractor taken along the lines 2-2 of FIG. 1;

FIG. 3A is a perspective view of a drilling instrument utilized in drilling a bore within the adjacent bony structures;

FIG. 3B is a cross-sectional view of the drilling instrument taken along the lines 3B-3B of FIG. 3A;

FIG. 4A is an axial plan view of the drilling head of the drilling instrument;

FIG. 4B is a side plan view of the distal end portion of the drilling head illustrating the end and side cutting surfaces of the drilling head;

FIG. 5 is a perspective view of a tapping instrument utilized in tapping an internal thread in the bore formed by the drilling instrument;

FIG. 6 is an axial plan view of the tapping head of the tapping instrument of FIG. 5;

FIG. 7A is a perspective view of an insertion instrument and a detached T-handle utilized in inserting an implant within the tapped bore formed by the tapping instrument;

FIG. 7B is an enlarged cross-sectional view illustrating a mounting arrangement for mounting the T-handle to the insertion instrument with the mounting mechanism in a disengaged position;

FIG. 7C is a view similar to the view of FIG. 7B illustrating the mounting mechanism in an engaged

position;

FIG. 8 is a perspective view of the implant to be inserted into the tapped bore formed between the adjacent bony structures;

FIG. 9 is a perspective view of the implant of FIG. 8 illustrating the body and detached end cap;

FIG. 10A is a perspective view illustrating mounting the distal end of insertion instrument of FIG. 7A to the implant of FIG. 8;

FIG. 10B is a cross-sectional view illustrating engagement of the spring-loaded ball detent of the insertion instrument with the interior surface of the implant;

FIG. 11 is a side plan view illustrating positioning of the retractor of FIG. 1 within an intervertebral space between adjacent vertebrae in accordance with a preferred method for inserting the implant;

FIG. 12 is a side plan view illustrating insertion of the drilling instrument of FIG. 3 into the retractor to drill a bore within the adjacent vertebrae;

FIG. 13 is a side plan view illustrating insertion of the tapping instrument of FIG. 5 into the retractor to tap an internal thread in the bore;

FIG. 14 is a side plan view illustrating insertion of the insertion instrument with mounted implant through the retractor and placement of the implant within the tapped bore;

FIG. 15 is a side plan view of a syringe containing bone inducing substances;

FIG. 16 is a side plan view illustrating loading of the bone-inducing substances into the implant with the use of forceps;

FIG. 17 is a side plan view of a cap mounting instrument utilized in mounting the implant end cap onto the body of the implant;

FIG. 18 is an axial plan view of the mounting head of the mounting instrument of FIG. 17;

FIG. 19 is a perspective view of the mounting head and the end cap;

FIG. 20 is a view illustrating insertion of the mounting instrument and end cap within the surgical site to mount the end cap to the body of the implant; and

FIG. 21 is an enlarged top view in partial cross-section of a pair of implants positioned into the intervertebral space of a lumbar spinal section.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

The preferred embodiments of the method and instrumentation disclosed herein are discussed in terms of orthopedic spinal fusion procedures and instrumentation. It is also envisioned, however, that the disclosure is applicable to a wide variety of procedures including, but, not limited to ligament repair, joint repair or replacement, non-union fractures, facial reconstruction and spinal stabilization. In addition, it is believed that the present method and instrumentation finds application in both open and minimally invasive procedures including endoscopic and arthroscopic procedures wherein access to the surgical site is achieved through a cannula or small incision.

The following discussion includes a description of each instrument utilized in performing a spinal fusion followed by a description of the preferred method for spinal fusion utilizing the instrumentation in accordance with the present disclosure.

In the discussion which follows, the term "proximal", as is traditional, will refer to the portion of the structure which is closer to the operator, while the term "distal" will refer to the portion which is further from the operator.

Referring now to the drawings in which like reference numerals identify similar or identical elements throughout the several views, FIG. 1 illustrates in perspective view a surgical retractor of the present disclosure. Retractor 10 is particularly contemplated for distracting adjacent bony structures, e.g., adjacent opposed vertebral bodies, to facilitate the insertion and application of an implant, for providing a cannula for insertion of the instruments, and for ensuring proper alignment of the instrumentation and accurate insertion of the implant. Although described for spinal procedures, it is envisioned that retractor 10 may also be utilized to distract other structures as well including joints, ligaments, etc...

Referring now to FIGS. 1-2, retractor 10 includes sleeve 12 defining longitudinal axis "a" and having enlarged head 14 disposed at a proximal end thereof. Sleeve 12 defines a longitudinal opening extending therethrough to receive surgical instrumentation described below. Sleeve 12 and enlarged head 14 are preferably monolithically formed of a suitable rigid material including stainless steel, aluminum alloy or the like. Sleeve 12 may be formed of a suitable polymeric material as well. Sleeve 12 may be a variety of sizes including, for example, 12 mm, 14 mm, 16 mm and 18mm in diameter. The retractor size utilized will generally correspond to the diameter of the instrumentation and/or implant to be applied.

Sleeve 12 may include first and second longitudinally extending openings 16 formed in its outer wall. Openings 16 are diametrically arranged with relation to each other and terminate at their distal ends in collar 18. Each opening 16 extends radially for about between 10%-50% the circumference or perimeter of sleeve 12 and longitudinally for greater than 50% the length of sleeve 12. Openings 16 are contemplated to permit the lateral introduction of surgical instrumentation required to carry out the fusion procedure as an alternative to introducing the instrumentation through the open proximal end of sleeve 12. These openings 16 also enhance illumination at the surgical site.

Sleeve 12 further includes first and second diametrically opposed retractor arms or tangs 20. Retractor arms 20 extend distally from collar 18 in a general longitudinal direction parallel to one another and define longitudinal slotted portion 22. Each arm 20 has an arcuate

outer surface (i.e., defining a radius of curvature substantially equivalent to the radius of curvature of the remaining portion of the sleeve). Each retractor arm 20 has first and second vertebrae supporting surfaces 20a, 20b in general parallel relation to each other and preferably parallel to the longitudinal axis of sleeve 12. In the illustrated embodiment, supporting surfaces 20a, 20b are substantially planar. The height "h" of each arm 20 (i.e., the distance between supporting surfaces 20a, 20b) corresponds to the height of the intended distraction distance between adjacent tissue portions, i.e. adjacent vertebrae. For example, in spinal fusion application, the height "h" of each arm 20 ranges from about .3 to .4 inches and more preferably from about 0.28 to about 0.35 inches. One skilled in the art will readily appreciate that this dimension can be varied as needed depending upon the procedure. Each arm 20 further includes tapered end portions 23 defining a generally V-shaped configuration. End portions 24 facilitate insertion of retractor arms 20 within the surgical site, e.g., within the intervertebral space.

Referring still to FIGS. 1-2, an impact end cap 26 is positionable over enlarged head 14 and preferably has an inner diameter approximating the outer diameter of the head 14 to form a releasable frictional fit between the two components. Impact cap 26 is intended to receive the impact of a driving instrument used to insert retractor 10 within the bony tissue as will be discussed. Such impaction, drives the arms 20 of sleeve 12 into the disc space (with the height h spanning the space) and distracts the opposing vertebrae bodies as surfaces 20a engage the upper (or lower) vertebral body and surface 20b engages the opposing vertebral body, thereby firmly mounting the retractor 20 to maintain its alignment and orientation and ensure that an equal amount of material is cut on both vertebral end plates when a drill is inserted therethrough (described below).

Referring now to FIGS. 3A-3B, the drilling instrument used to form a bore between/within the adjacent vertebrae will be described. Drilling instrument 40 includes drill shaft 42 and extension shaft 44 which is connectable to the drill shaft 42. Drill shaft 42 has an internally threaded bore 46 at its proximal end and drill bit 48 mounted at its distal end. Extension shaft 44 has a proximal mounting section 50 which cooperatively engages corresponding structure of a T-handle (the distal portion of the T-handle is depicted in FIG. 3A) to mount the handle to the extension shaft 44. The particular mounting arrangement utilized to effect the mounting of the T-handle to extension shaft 44 will be discussed in greater detail hereinbelow with later reference to Figs. 7A-7C. Extension shaft 44 further includes collar 52 and distal threaded portion 54 extending from the collar 52. Collar 52 includes an internal thread which cooperates with threaded portion 54 to mount the collar 52 to extension shaft 44. Collar 52 is preferably fixedly mounted to threaded portion 54 by welding or the like. Distal threaded portion 52 cooperatively engages internal threaded bore 46 of drill shaft 42 to connect the two components.

Extension shaft 44 has first and second collars 56, 58 which are threaded on threaded portion 54. Each collar 56, 58 is moveable on threaded portion 54 between a position adjacent stationery collar 52 and a position adjacent drill shaft 42. First collar 56 serves as a positioning collar, i.e., by adjusting the positioning of first collar 56 on threaded portion 54, the depth of penetration of drill shaft 42 into the bony structures may be adjusted. Second collar 58 serves as a locking collar to selectively lock the first collar 56 at the predetermined location on threaded portion 54. In particular, when drilling instrument 40 is inserted within sleeve 12 of the retractor of FIG. 1, positioning collar 56 engages the proximal end face of enlarged head 14, thus, precluding further distal advancement of drilling instrument 40 within the bony structures. Thus, by selectively adjusting the location of positioning collar 56 on threaded portion 54 and locking the collar 56 with locking collar 58 at the desired position, the length (depth) of the bore formed in the bony structures (e.g., vertebrae) is readily controllable. Thus, the depth of the hole is predetermined to accommodate the length of the fusion cage to be implanted. Extension shaft 44 also includes depth markings 60 on its outer surface. Depth markings 60 are calibrated to indicate to the surgeon the degree of penetration of drill shaft 42, thus, further assisting the surgeon in monitoring the length of the bore formed by drilling instrument 40.

Referring now to FIGS. 4A-4B, drill bit 48 includes a twin cutting surface design incorporating end cutting edges 62 located on flutes 64 and side cutting edges 66. These edges 62, 66 cooperate to shear or cut the tissue rather than tear or pull the soft tissue as in conventional bone drills. The end cutting edge 62 cleanly cuts the soft disc material as the side cutting edges 66 cut the end plates substantially simultaneously. Thus, the bore formed by drill bit 48 is clean and exceptionally precise and less manual pressure on the drill is required to form the hole. As depicted in FIG. 4B, which is an enlarged view of the distal end portion of drill bit 48, the drill bit 48 defines the following parameters. Angle "a" is the degree of forward projection of the outer peripheral surface of the distal end of the drill bit 48 relative to a plane "t" transverse to the longitudinal axis "1" defined by the radial center of the drill bit 48. Angle "a" ranges from about 0 • to about 10 • and is preferably about 2 • . Angle "B" is the degree of the angle of attack for end cutting edges 62 relative to the transverse plane "t" and ranges from about 2 • to about 15 • , and is preferably about 5 • . Angle "O" is the degree of twist defined by side cutting edges 62 relative to the transverse plane "t" and ranges from about 15 • to about 60 • , and is preferably about 45 • .

Referring now to FIGS. 5-6, tapping instrument for forming an internal thread within the drilled bore will be discussed. Tapping instrument 70 includes proximal mounting portion 72 which cooperatively engages T handle (discussed below) and distal tapping thread por-

tion 74. Distal tapping thread portion 74 includes threaded cutting edges 76 and at least one spiral conveyance channel [3 are shown] extending longitudinally from the distal end of tapping thread portion 74 to the proximal end of the thread portion 74. The conveyance channels having a directional component transverse to the longitudinal axis and preferably in the form of a helical groove. Conveyance channel 78 is dimensioned to receive bone material deburred by the cutting edges 76 during the tapping procedure and to continually transmit the bone material proximally through the channel 78 to avoid undesired material build-up at the tapping site. In this manner, tapping instrument 70 may be used to completely tap the internal thread within the bore without interruption of the tapping procedure.

Tapping instrument 70 further includes annular rings 80 integrally formed at an intermediate portion of the instrument. Annular rings 80 facilitate grasping engagement of tapping instrument 70 by the user. Several depth markings 82 are provided on the external surface of the tapping instrument 70. Depth markings 82 indicate the depth of insertion of tapping instrument 70 within the retractor 10 of FIG. 1 and the bore defined in the adjacent bony structures. Bevel 75 facilitates insertion of the tapping instrument 70 into the retractor 10.

Referring now to FIGS. 7A-7C, the insertion instrument for inserting the fusion implant into the tapped bore and the T-handle will be discussed. Insertion instrument 100 includes elongated member 102 having handle mounting section 104 at its proximal end and rounded head 108 at its distal end. Although the elongated member 102 is shown having sections of different diameters, in an alternate embodiment, the elongated member 102 is of substantially uniform diameter between its proximal and distal end portions. Handle mounting section 104 is configured to engage T-handle 110 to mount the T-handle to the insertion instrument. In a preferred mounting arrangement, T-handle 110 includes handle body 112, a first sleeve 114 mounted to the body 112 and a second sleeve 116 mounted with respect to the first sleeve 114. First sleeve 114 has an inner surface correspondingly dimensioned to engage hexagonal portion 118 of handle mounting section 104. An internal spring loaded ball system 120 is defined adjacent second sleeve 116 and is configured to engage an annular groove 122 defined in handle mounting section 104. Second sleeve 116 is mounted for relative movement between an unlocked position (FIG. 7B) and a locked position (FIG. 7C). In the locked position, ball system 120 is forced radially inwardly into annular groove 122. Spring 124 normally biases second sleeve 116 to the locked position. As depicted in FIG. 7B, in the unlocked position, second sleeve 116 is retracted to release ball system from annular groove 122.

Handle mounting section 104 of insertion instrument 100 is identical to the mounting sections 50, 72 of drilling instrument 40 and tapping instrument 40, 70, respectively. Thus, T-handle 110 may be mounted and used with drilling instrument 40 and tapping instrument 70 in an identical manner.

Referring now to FIGS. 8-9, one type of implant designed for use in spinal fusion procedures and with which the instrumentation of the present disclosure can be used is illustrated. This implant is generally disclosed in U.S. Patent No. 5,026,373 to Ray, the contents of which are incorporated herein by reference, and is commonly referred to as a "fusion cage".

Implant or fusion cage 200 includes body portion 202 having an internal cavity or hole 204 for accommodating bone-growth inducing substances. One end 206 of cage body 202 is closed and defines a rounded or bull-nosed configuration to facilitate insertion of the fusion cage relative to one or more bony structures. The other end 208 defines an opening which communicates with internal cavity 204. The outer surface of the cage body 202 includes a single continuous thread 208 (preferably V-shaped) having a plurality of raised turns with valleys defined between adjacent turns.

A plurality of perforations 210 are disposed within the threads and extend through the outer surface of the cage body 202 to provide direct communication between the outer surface and the inner cavity 204. The perforations 210 permit immediate contact between the bone growth inducing substances within the inner cavity 204 and the bone structure when the cage body 202 is mated to the bone structure, e.g., adjacent vertebrae. An end cap 212 is mountable to the open end of cage body 202 to enclose the bone-growth inducing substances within the interior cavity. End cap 212 is preferably fabricated from a flexible polymeric material such as polyethylene and is dimensioned to snap into a groove or recess 214 defined in the interior end of cage body 202. End cap 212 includes an axial opening 216 and four equidistally spaced peripheral notches 218.

Referring now to FIGS. 10A-10B, to mount the insertion instrument 100 of FIG. 7A to fusion cage 200, the rounded head 108 of the instrument 100 is positioned within the interior cavity 204 of cage body 202 with diametrically opposed slots 109 (only one is shown) engaging the longitudinal ribs 203 formed within the cage body 202. Once mounted, the cage body 202 is rotated by rotation of the instrument 110. Head 108 may be inserted within interior cavity 204 to a position almost adjacent closed end 206. A spring loaded ball detent system 126 associated with the rounded head 108 frictionally retains the head 108 within cage body 202 as depicted in FIG. 10B. A pair of opposed alignment bars 119 (only one is shown) formed on elongated shaft 102 (Fig. 7A) are positioned in substantial alignment with slots 109 to indicate to the user the orientation of the fusion cage 200.

Application of Instrumentation

The use of the instrumentation kit in conjunction with the insertion of the fusion cage 200 of FIG. 8 into an intervertebral space defined between adjacent lumbar vertebrae will be described. The subsequent

description will be particularly focused on an open posterior spinal fusion procedure, however, it is to be appreciated that an anterior approach is contemplated as well.

The intervertebral space is accessed utilizing appropriate retractors, e.g., laminar retractors, dural extractors to expose the posterior vertebral surface. Thereafter, retractor 10 of FIG. 1 with impactor cap 26 mounted thereon is positioned adjacent the intervertebral space. With reference to FIG. 11, retractor arms 20 are inserted within the intervertebral space and the retractor 10 is gently impacted into the space with a mallet. The preferred orientation of retractor arms 20 within the intervertebral space is shown in FIG. 11. As shown, retractor arms 20 are arranged such that first and second supporting surfaces 20a, 20b of each retractor arm respectively engages the opposed vertebral bodies V_1, V_2. Upon insertion of retractor arms 20, the vertebral bodies V_1, V_2 are distracted whereby the retractor arms 20 become firmly lodged within the intervertebral space. The arrangement of retractor arms 20 provides a double point contact with each vertebral body (curved end plate), i.e., the first supporting surfaces 20a of retractor arms 20 engage vertebral body V_1 at two different locations and in spaced relation. The second supporting surface 20b engage vertebral body V_2 in the same manner. Thus, the load exerted by vertebral bodies V_1, V_2 is distributed at two different locations on retractor 10 and along the entire lengths of the supporting surfaces 20a, 20b thereby firmly and uniformly loading the retractor 10 in the intervertebral space. It is also to be noted that as discussed above, the particular arrangement of the retractor arms 20 within the intervertebral space automatically appropriately aligns retractor 10 with relation to the vertebral bodies V_1, V_2, i.e., in parallel relation with the vertebral end plates for the subsequent drilling process. Tapered surfaces 24 of retractor arms 20 facilitate entry of the retractor arms 20 into the intervertebral space. The depth of penetration of retractor arms 20 is limited by collar 18 as described above.

Referring now to FIG. 12, the drilling instrument of FIG. 3A is now used to prepare the disc space and vertebral end plates for insertion of the fusion implant. The cutting depth of drilling instrument 40 is adjusted as desired (i.e., to correspond to the length of the fusion cage) by adjusting the positional collar 56 and securing the collar 56 at the desired position with locking collar 58 as described above. With the T-handle 110 mounted to drilling instrument 40 in the manner described above, the instrument is introduced into retractor 10 and advanced to contact the posterior surface of the vertebral bodies V_1, V_2. Drill bit 48 communicates with vertebral bodies V_1, V_2 through slotted opening 22 defined between retractor arms 20 (FIG. 1). Drilling instrument 40 is advanced into the intervertebral space by rotating T-handle 110 in the direction indicated by the directional arrow of FIG. 12 until positional collar 56 engages the proximal end of enlarged head 18 of the retractor 10. This shears the soft tissue and cuts the bone as described above. Depth markings 60 are also monitored to further assist the surgeon. Thereafter, drilling instrument 40 is removed by rotating T-handle 110 in the opposite direction and the instrument 40 is removed from the retractor 10.

When juxtaposed sides of the adjacent vertebral disc have been adequately prepared by drilling the holes and completely removing any remaining soft tissue, tapping instrument 70 of FIG. 5 is selected and attached to the T-handle 110. The purpose of the tapping instrument 70 is to cut the threads into the opposing vertebral endplates. This ensures that the implant will be positioned correctly and will have the correct purchase into the endplates for immediate bone graft material to endplate contact. With reference now to FIG. 13, tapping instrument 70 is inserted into retractor 10 and positioned adjacent the drilled bone. With retractor 10 as a direct guide, T-handle 110 is rotated in the direction of the directional arrow of FIG. 13 while simultaneously applying sufficient downward (distal) pressure on the T-handle 110 to advance the tapping instrument 70 and promote even purchase into the endplates. Upon advancement of the tapping instrument 70, the deburred bone chips collect within conveyance channel 78 of tapping head 74, and are conveyed proximally during rotational movement of the tapping head away from the tapping site. Tapping instrument 70 is advanced into the bone until the desired depth has been achieved, which occurs when the distal end of tapping head 74 "bottoms out" on the bone. To further ensure that the tapping instrument 70 reaches the proper depth, the depth markings 82 on tapping instrument 70 are also monitored. Tapping head 74 communicates with vertebral bodies V_1, V_2 through slotted openings 22 defined between the retractor arms 20. When tapping instrument 70 reaches the appropriate depth, the tapping instrument 70 is rotated via T-handle 110 in an opposite direction to back the instrument out of the bone and the instrument 70 is removed from the retractor 10.

With reference now to FIG. 14, attention is focused on the insertion of the selected fusion implant 200. Cage body 202 is mounted onto insertion instrument in the manner described in connection with FIGS. 10A-10B. With T-handle 110 attached in the manner described above, insertion instrument 100 with mounted cage body 202 is inserted into retractor 10 and the cage body 202 is positioned within the tapped bore by rotating insertion instrument in the direction depicted in FIG. 14. Cage body 202 is advanced until it is completely seated with the bore. The indicator lines on insertion instrument 100 assist the surgeon in determining when the cage is in proper position. Alignment bars 119 indicate to the user the orientation of the cage to assist in ensuring that the perforations 210 are in communication with the vertebral end plates when the cage is finally positioned. Insertion instrument 100 is then removed from retractor 10.

With reference now to FIG. 15, bone growth induc-

ing substances are harvested from, e.g., the illiac crest, and can be packed into a syringe body or tube "s" (as shown in FIG. 15) or other holding device. As depicted in FIG. 16, with the use of forceps "f", the bone growth inducing substances are removed from the syringe "s" and introduced into the cage body 202 until the cage body 202 is completely filled with bone growth inducing substances. The bone growth inducing substances can be lightly impacted to pack the cage.

With reference to FIGS. 17-19, after filling cage body 202, the end cap 212 is mounted to the cage body 202. A preferred instrument 300 for applying end cap 212 includes handle 302 and elongated portion 304 connected to the handle and extending distally therefrom. At the distal end of elongated portion 304 is mounting head or section 306. Mounting head 306 includes distal annular portion 308 with annular nub 310 projecting therefrom and four equidistantly spaced flanges 312. Flanges 312 extend in a radial direction and are preferably spaced about 90_ apart as best depicted in FIG. 17. Flanges 312 engage the end cap 312 to limit proximal flexure of the end cap 312 as it is mounted to the cage body 202. In the mounted condition of end cap 212 onto instrument 300, annular nub 310 of the instrument 300 is received within annular opening 216 of end cap 212. Preferably, annular nub 310 and opening 216 are correspondingly dimensioned such that a friction fit between the two components is established.

With reference now to FIG. 20, instrument 300 with mounted end cap 212 is introduced into the operative site and advanced to cage body 202. Thereafter, end cap 212 is mounted to cage body 202 by inserting the end cap 212 within the interior cavity whereby the end cap 212 snaps into correspondingly dimensioned groove 214 (FIG. 9) defined in the cage body 202. During insertion, the peripheral area of end cap 212 is permitted to deform due in part to the flexible characteristics of its material of fabrication and to notches 216, thus enabling the end cap 212 to pass within the cage body 202. It is to be noted that during insertion, flanges 312 of instrument 300 (FIG. 19) prevent any tendency of end cap 212 to rotate relative to the instrument. With end cap 212 mounted within cage body 202, instrument 300 is removed.

FIG. 21 illustrates two lateral fusion implants 200 inserted within the lumbar intervertebral space. The second fusion cage 200 is inserted in accordance with the method and instruments previously discussed.

While the above description contains many specifics, these specifics should not be construed as limitations on the scope of the disclosure, but merely as exemplifications of preferred embodiments thereof For example, the forceps and/or end cap insertion tool can be inserted through the retractor 10 prior to removal of the retractor 10. Those skilled in the art will envision many other possible variations that are within the scope of the claims appended hereto. The claims identify embodiments of the invention additional to those described in detail above.

Claims

1. A surgical retractor instrument comprising an elongated member having proximal and distal end portions and defining a longitudinal passageway for reception of surgical instrumentation, the distal end portion having first and second retractor arms extending in a general longitudinal direction, each retractor arm having first and second supporting surfaces for engaging opposed adjacent tissue portions, each retractor arm defining a dimension between the first and second supporting surfaces sufficient to distract the opposed tissue portions upon insertion thereof

2. The surgical retractor according to claim 1 wherein the first and second supporting surfaces of each retractor arm are substantially planar.

3. The surgical retractor according to claim 1 or 2 wherein each retractor arm has a tapered end portion for facilitating insertion into the intervertebral space.

4. A surgical retractor for use in distracting adjacent vertebrae, the retractor comprising:

   an elongate body having a proximal end and a distal end and defining a longitudinal passageway therebetween; and
   first and second retractor arms extending longitudinally from the distal end of the elongate body, each retractor arm defining a first vertebra supporting surface and a second vertebra supporting surface, the first and second vertebra supporting surfaces of each retractor arm being spaced thereon at a predetermined distraction distance.

5. The surgical retractor according to claim 4 wherein the retractor arms each possess distal tapered portions for facilitating insertion into the intervertebral space.

6. The surgical retractor according to claim 4 or 5 wherein the first and second supporting surfaces of each retractor arm are in general parallel relation.

7. The surgical retractor according to claim 6 wherein the first and second supporting surfaces of each retractor arm are in general parallel relation to a longitudinal axis of the elongate body.

8. The surgical retractor according to any one of the preceding claims wherein the elongate body includes at least one longitudinal opening defined in an intermediate wall portion.

9. A surgical tapping instrument for tapping an internal thread within a bore defined in bony tissue, comprising an elongated frame defining a longitudinal axis and having a distal tapping head, the tapping head including a tapping thread for tapping a thread within the bony structure and at least one conveyance channel dimensioned to collect bone material removed during the tapping procedure, the one conveyance channel having a directional component transverse to the longitudinal axis.

10. The surgical tapping instrument according to claim 9 wherein the one conveyance channel is a helical groove.

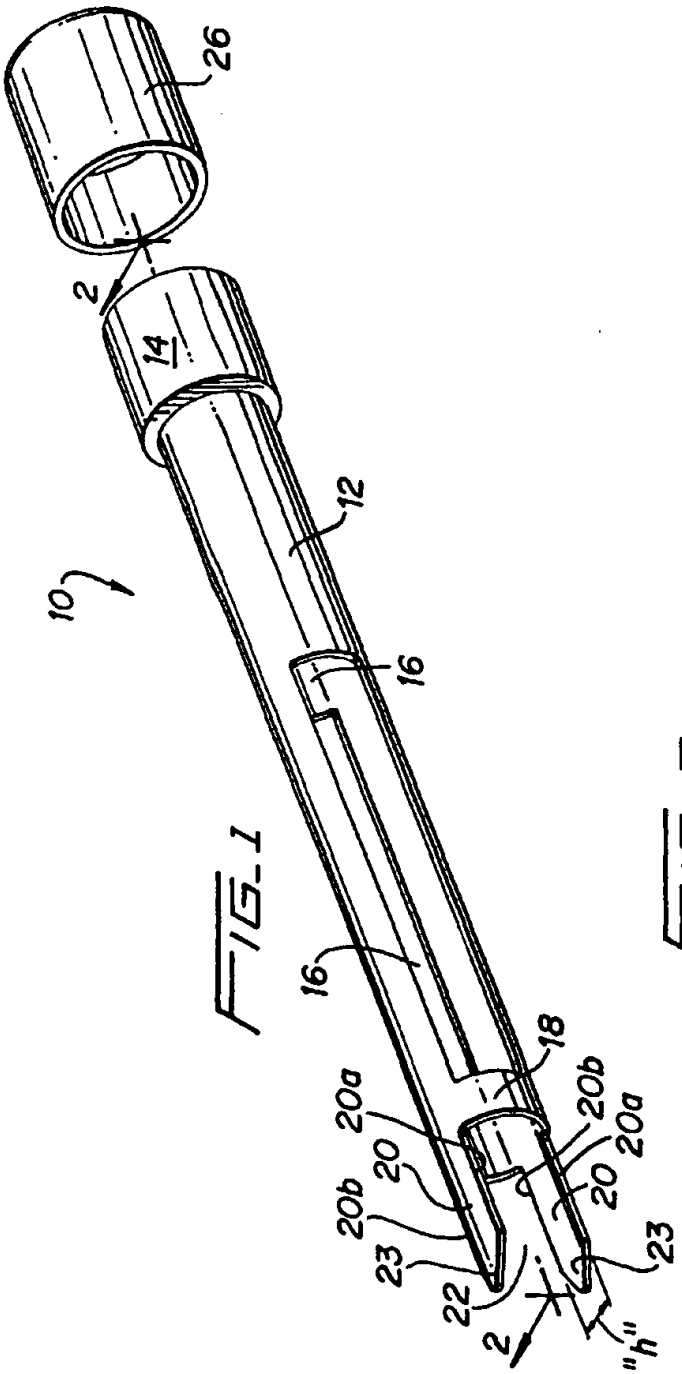

26
2
14
12
10
16
16
18
20a
20b
20
20b
20a
20
23
23
22
2
"h"

FIG_1

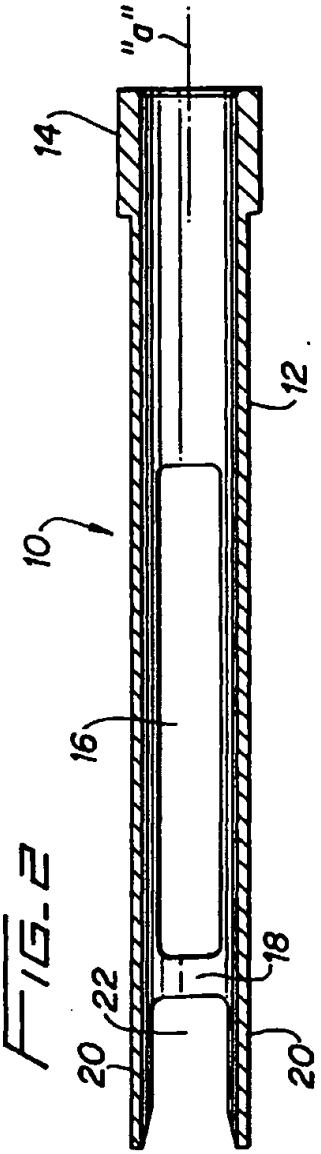

"a"
14
12
10
16
18
22
20
20

FIG_2

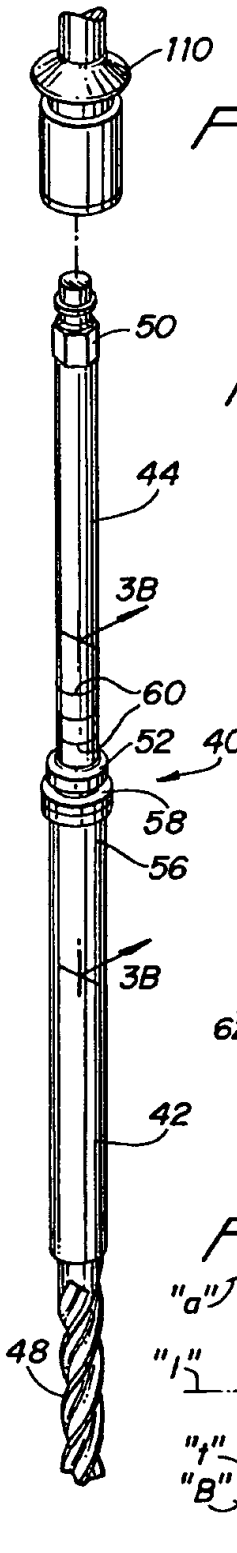


FIG. 3A

FIG. 3B

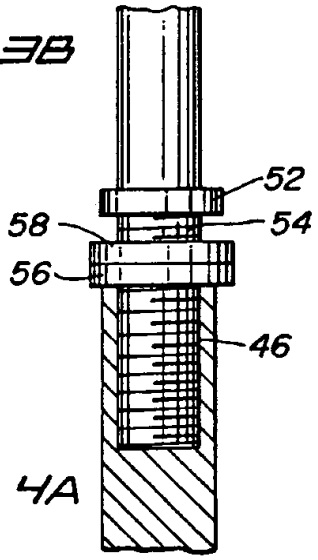


FIG. 4A

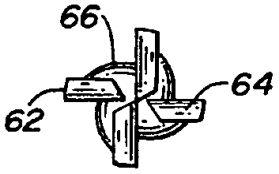


FIG. 4B

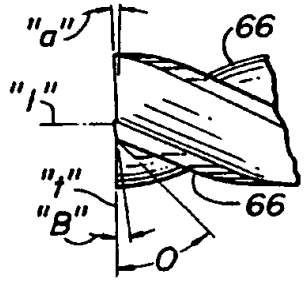


FIG. 5

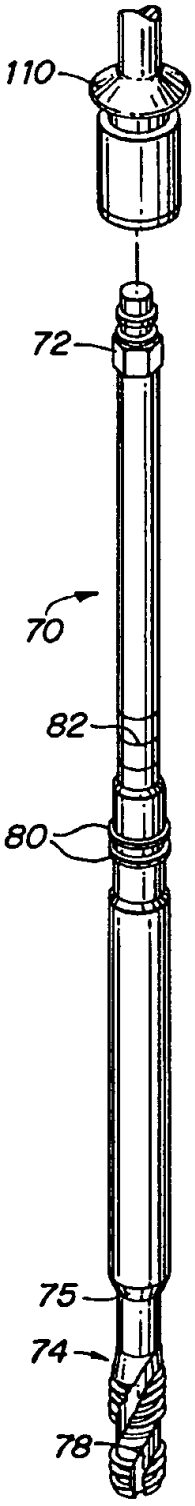
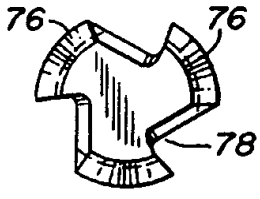


FIG. 6



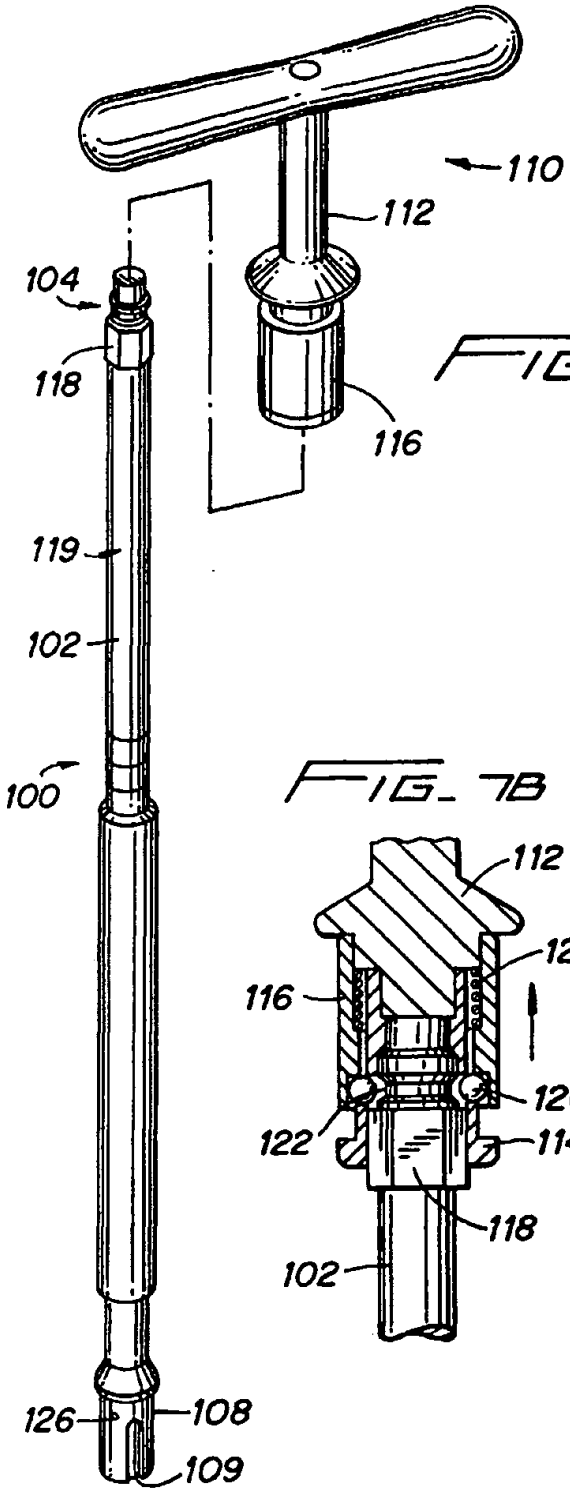


FIG. 7A

FIG. 7B

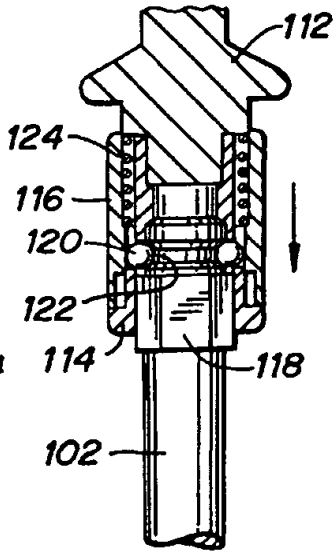


FIG. 7C

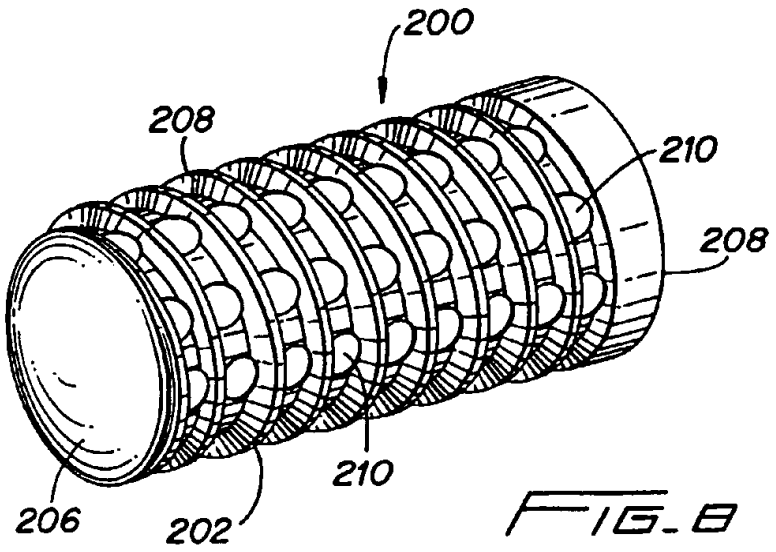
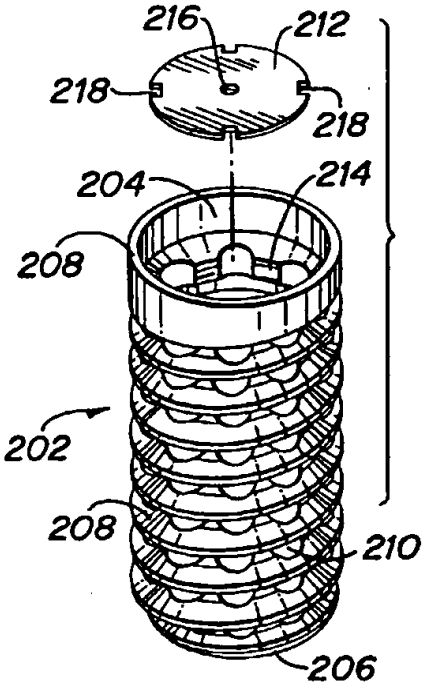

200
208
210
208
210
206
202

FIG_8


216
212
218
218
204
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202
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206

FIG_9

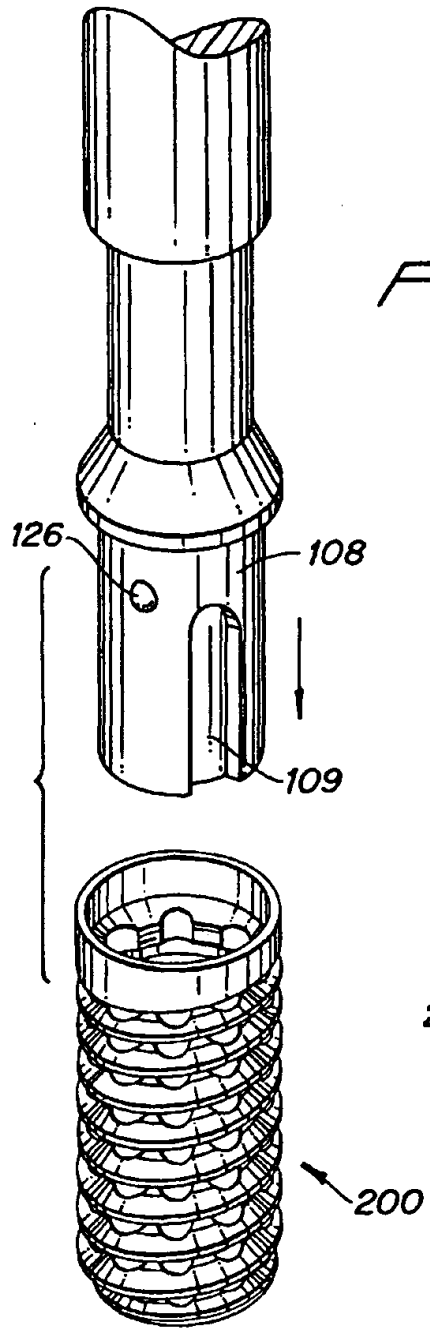
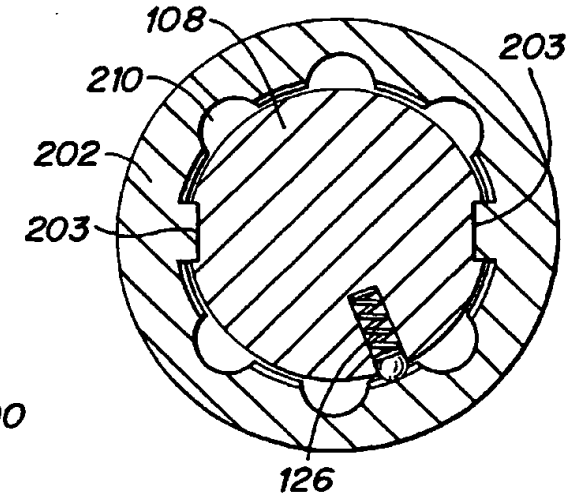


FIG_10A

FIG_10B



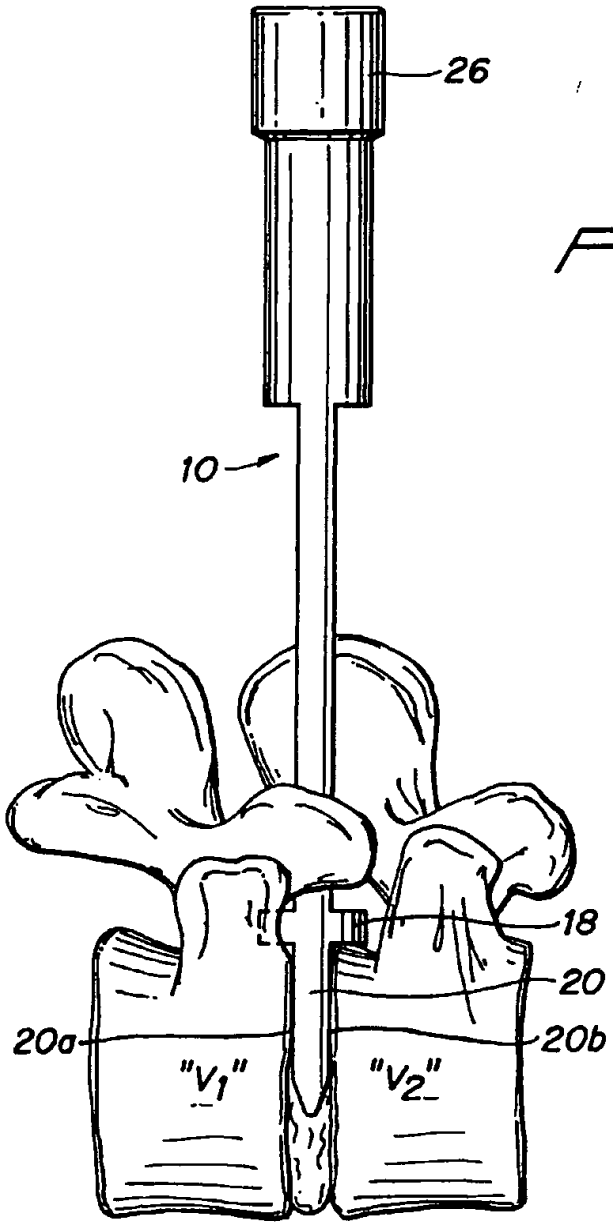


FIG_11

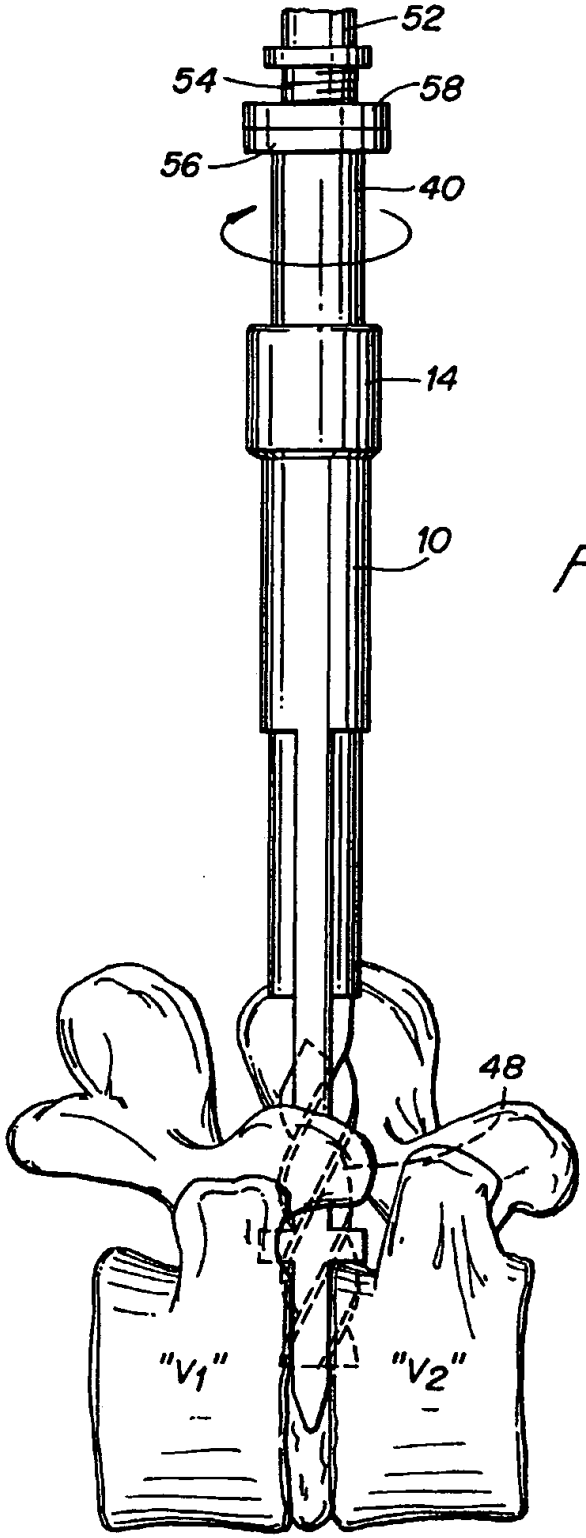


FIG_12

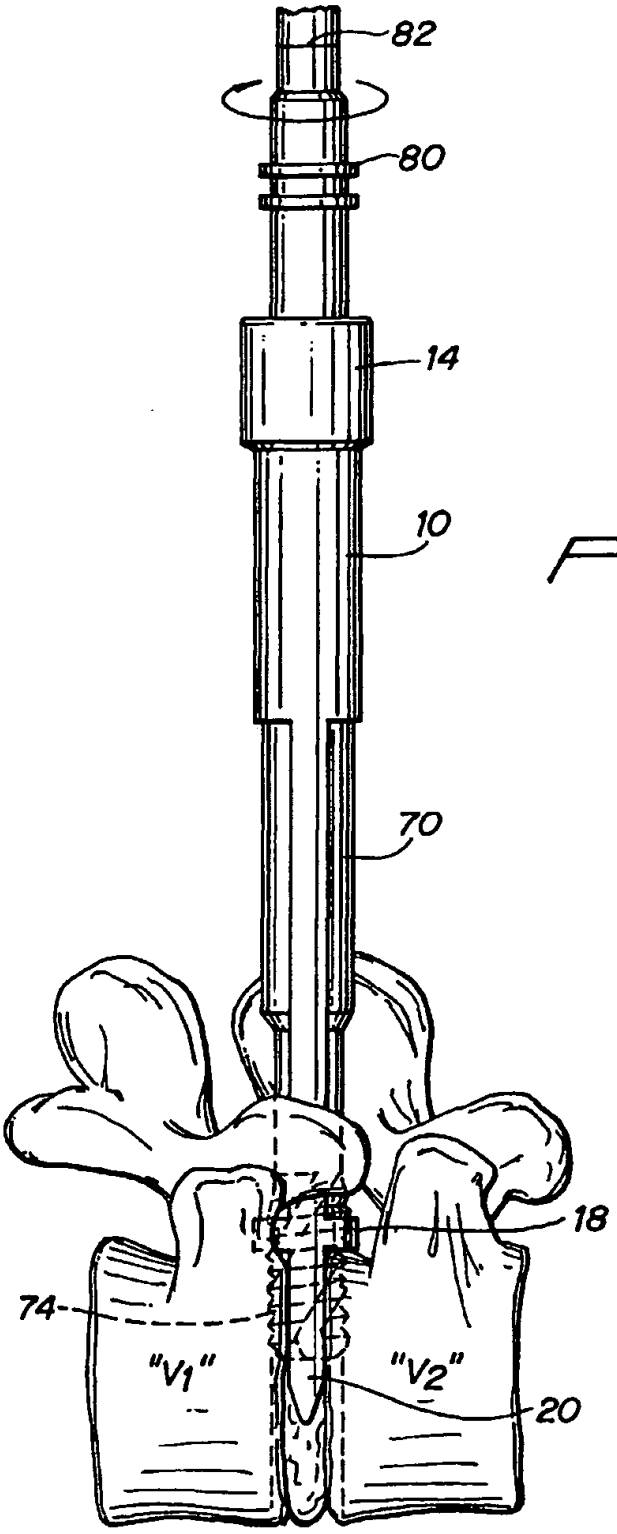


FIG_13

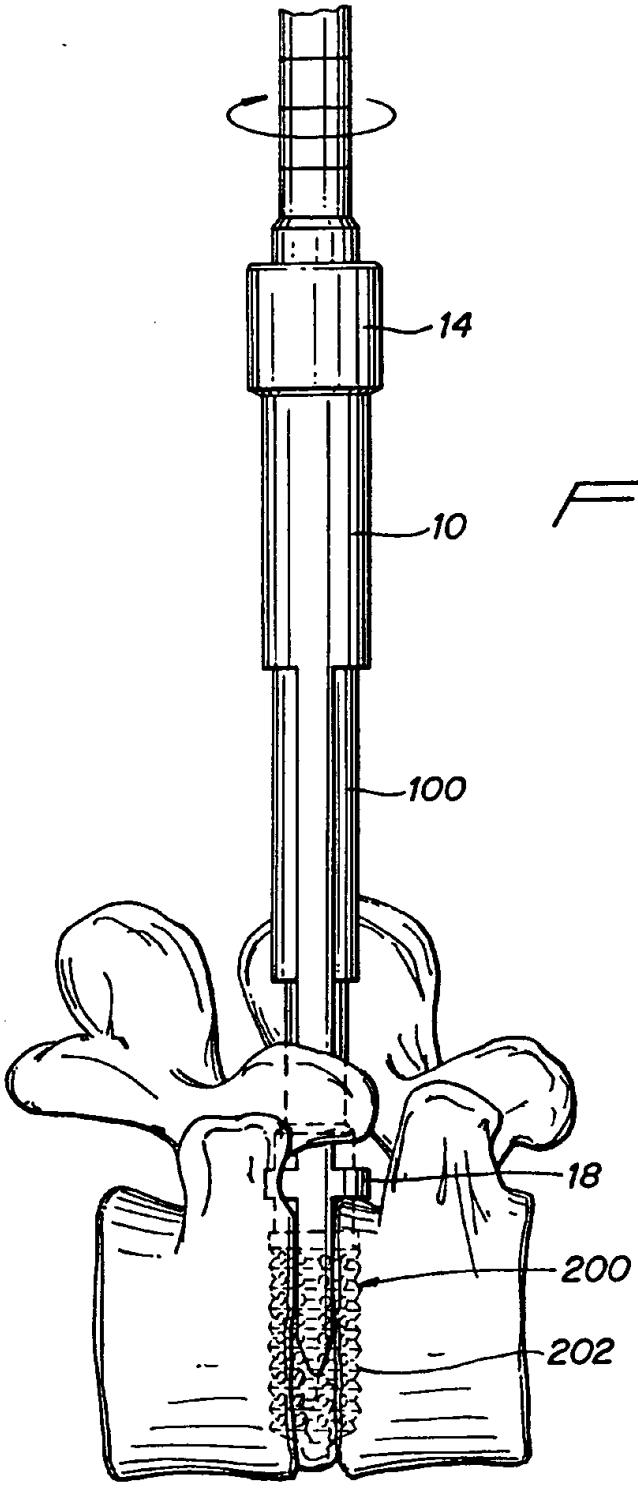


FIG_14

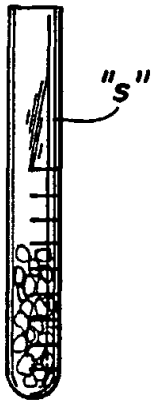
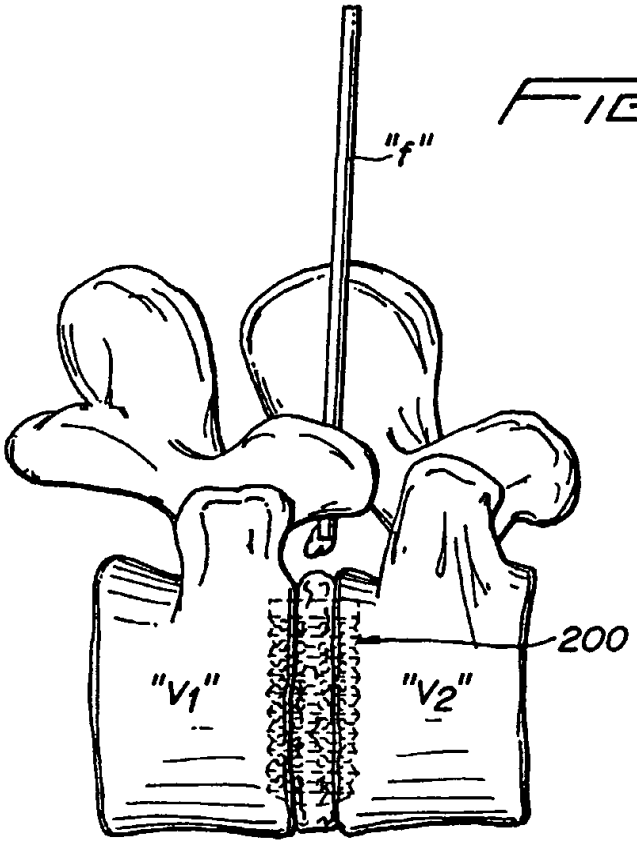


FIG_15

FIG_16



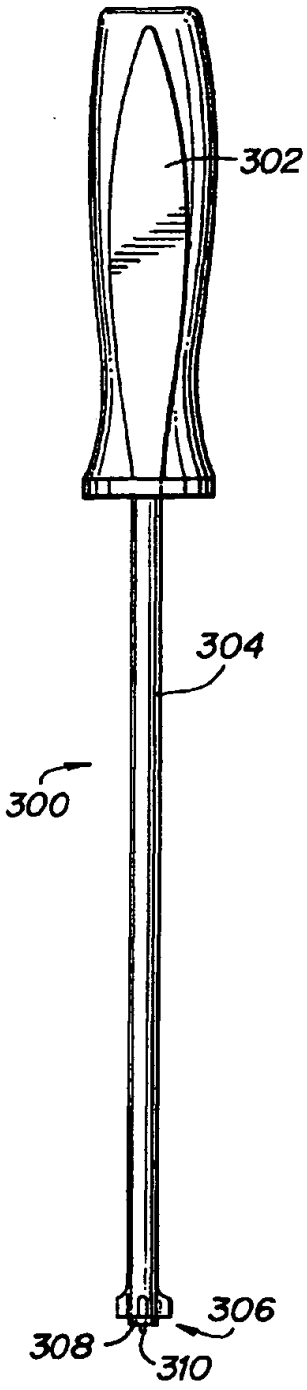


FIG_18

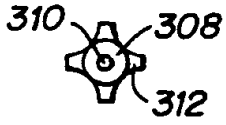


FIG_17

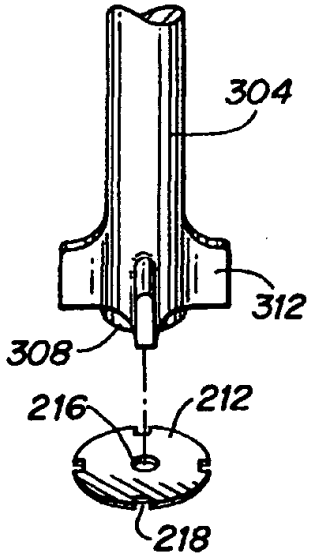


FIG_19

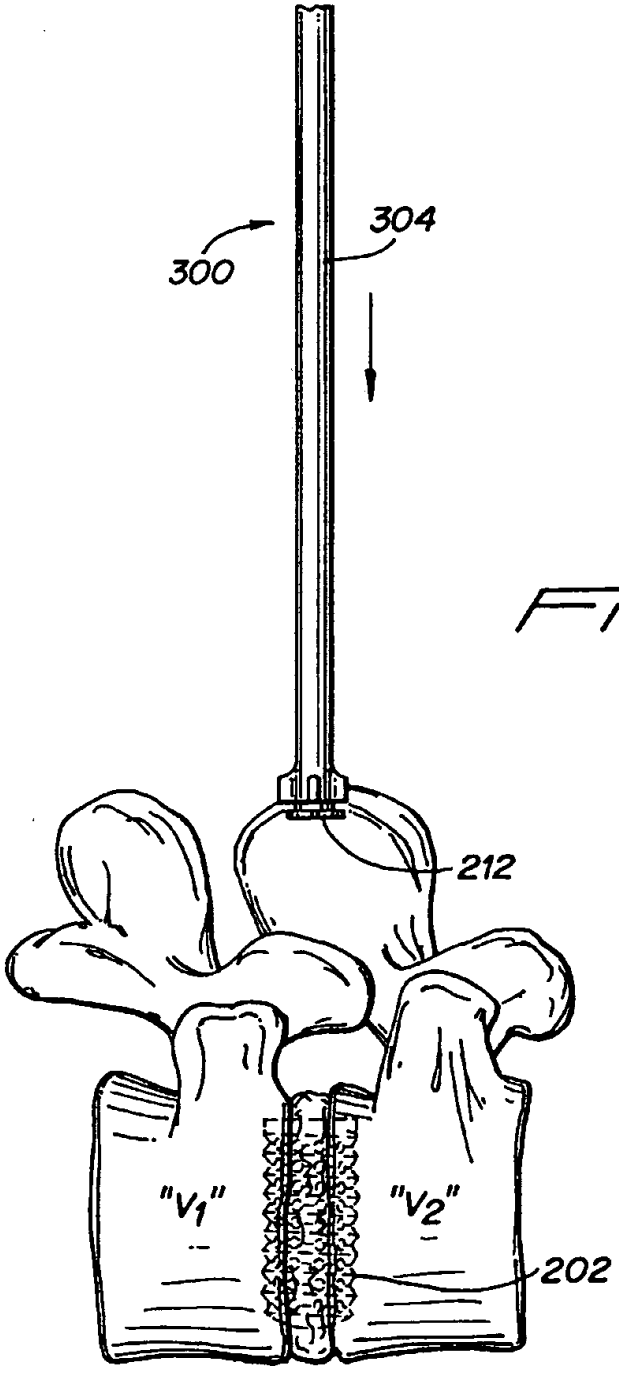
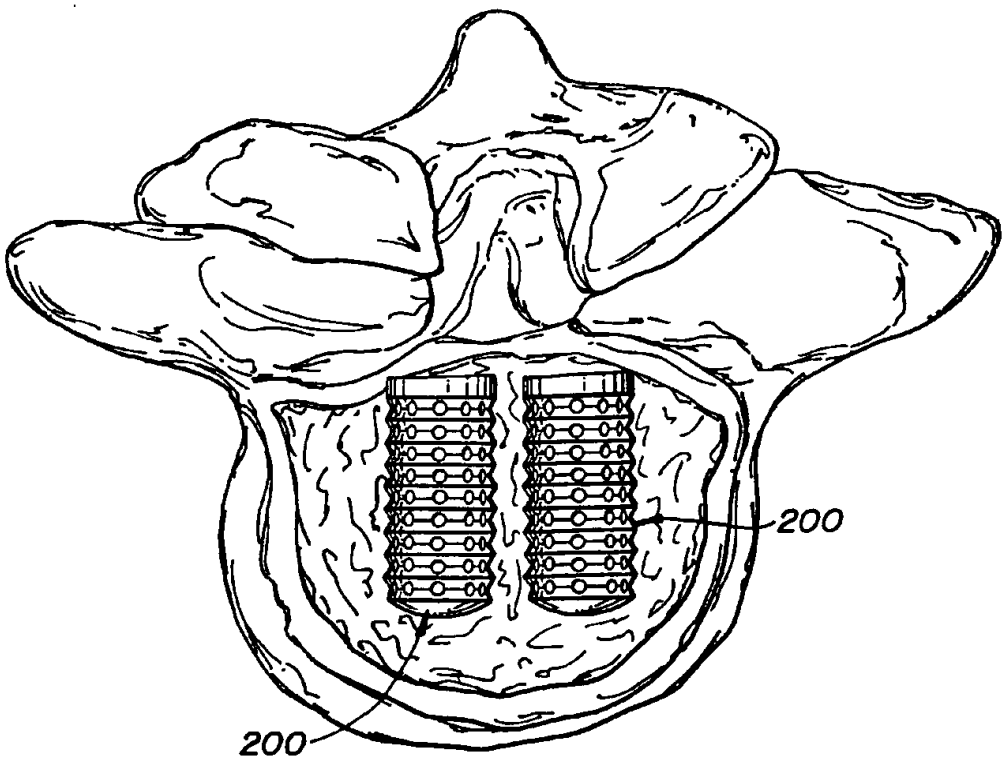


FIG.20

FIG. 21



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(30) Priority: **31.05.1996 US 65398**

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(54) An apparatus for retaining bone portions in a desired spatial relationship

(57) An apparatus for retaining first and second bone portions in a desired spatial relationship comprises a first member positionable along the first and second bone portions. A second member connectable with the first bone portion has surface means defining an opening. A fastener is extendable through the opening in the second member to connect the second member to the first bone portion. The fastener has a first portion for engaging the first bone portion and a second portion for clamping the first member against the second member to fix the first and second members against relative movement. The first member is also connected to the second bone portion.

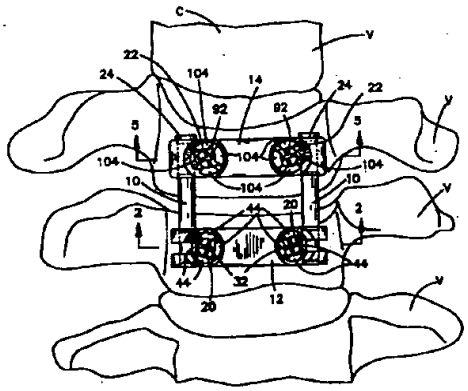

Fig.1

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European Patent Office

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DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	WO 95 08298 A (BECKERS ET AL.) * the whole document *	1,5,7	A61B17/70
A	US 4 611 581 A (STEFFEE) * column 5, line 61 - column 6, line 57; figures *	1,2,5,6	
A	WO 96 08206 A (SMITH & NEPHEW RICHARDS INC.) * the whole document *	1,2,5,6	
A	FR 2 615 095 A (SOCIÉTÉ DE FABRICATION DE MATERIEL ORTHOPEDIQUE) * abstract; figures *	1,5,7	
A	WO 91 11967 A (VIGNAUD ET AL.) * abstract; figures *	1,5	
A	US 4 289 123 A (DUNN) * figures *		

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A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	18 February 1998	Giménez Burgos, R

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O : non-written disclosure
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T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
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- **Wefers, Michael H.**
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- **Smith, Aaron C.**
  Gibsonia, Pennsylvania 15044 (US)

(74) Representative:
Rottmann, Maximilian R.
c/o Rottmann, Zimmermann + Partner AG
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(54) An apparatus comprising a plate and a fastener for connecting the plate to a bone portion

(57) An apparatus comprises a member connectable with a bone portion and having surface means defining an opening. A fastener is extendable through the opening in the member to connect the member to the bone portion. The fastener has a first portion for engaging the bone portion, a second portion, and a longitudinal axis. The second portion of the fastener is expandable into engagement with the surface means defining the opening to prevent relative movement between the fastener and the member. The fastener includes an expander for expanding the second portion into engagement with the surface means defining the first opening. The fastener is positionable in any one of a plurality of positions relative to the member in which the longitudinal axis of the fastener extends at an angle relative to the axis of the opening.

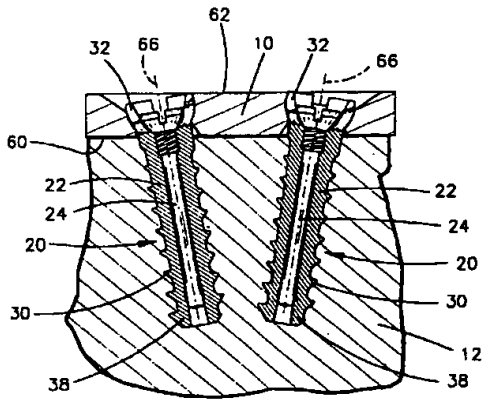

Fig.2

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European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 97 10 7977

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	WO 88 03781 A (RAVEH) * the whole document * ---	1-9	A61B17/80
A	WO 96 08206 A (SMITH & NEPHEW RICHARDS INC.) * the whole document * ---	1-9	
A	US 4 611 581 A (STEFFEE) * column 5, line 61 - column 6, line 57; figures * -----		

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	18 February 1998	Giménez Burgos, R

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& : member of the same patent family, corresponding document

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(30) Priority: **05.06.1996 US 658749**

(71) Applicant: **ACROMED CORPORATION**
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(54) Spinal column retaining apparatus

(57) An apparatus for retaining vertebrae in a desired spatial relationship. The apparatus includes a fastener which cooperates with a connector assembly, a longitudinal member which is positionable along the spinal column at a location offset from the fastener, and a connector assembly which connects the fastener with the longitudinal member. The connector assembly includes a transverse member, a retainer block, and a set screw. The transverse member and retainer block have mating teeth. When the desired spatial relationship is achieved, the set screw is tightened thereby engaging the teeth and providing for a rigid locked assembly.

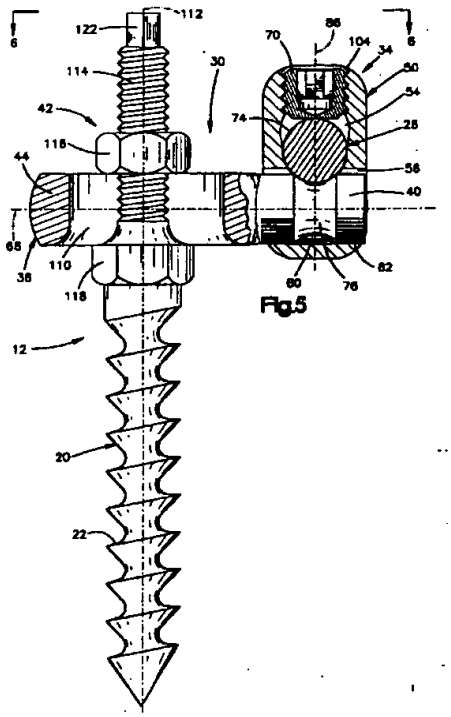

Fig.5

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European Patent Office

EUROPEAN SEARCH REPORT

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DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	US 5 474 551 A (FINN ET AL.) * the whole document *	1,2,4	A61B17/70
Y		3,5-17	
D,Y	US 5 053 034 A (OLERUD) * column 2, line 21-52 * * column 3, line 23 - column 4, line 3; figures *	3,12-17	
A		7,8	
Y	US 5 282 801 A (SHERMAN) * column 5, line 33 - column 7, line 12; figures 5-7 *	5-10	
D,Y	US 5 129 900 A (ASHER ET AL.) * column 3, line 43-62; figures 1-4 *	11	
A		14	
D,A	US 5 254 118 A (MIRKOVIC) * abstract; figures *		

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	18 February 1998	Giménez Burgos, R

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& : member of the same patent family, corresponding document

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(30) Priority: **30.05.1997 US 48045 P**

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(72) Inventors:
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(74) Representative: **Marsh, Roy David et al**
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(54) Instrumentation for implant insertion

(57) A surgical retractor instrument includes at least two elongate members disposed in side by side relation. Each elongate member has proximal and distal end portions and defines a longitudinal passageway for reception of surgical instrumentation. The distal end portion of each elongated member is configured for insertion at least partially within a space defined between adjacent tissue portions, preferably, adjacent vertebrae. The distal end portion includes at least two retractor arms extending in a general longitudinal direction. Each retractor arm has first and second supporting surfaces for engaging opposed adjacent tissue portions, and defines a dimension between the first and second supporting surfaces sufficient to distract the opposed tissue portions upon insertion thereof.

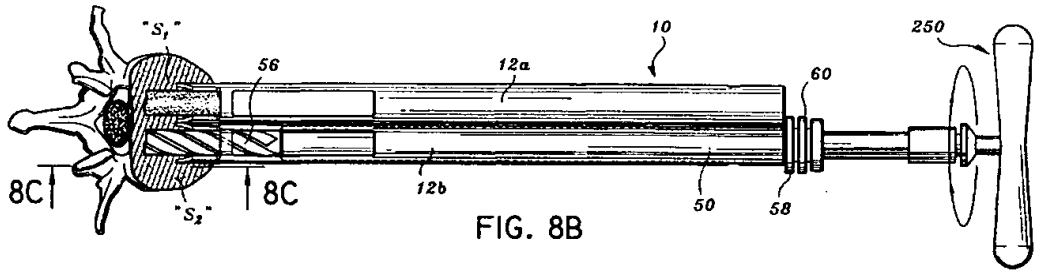

FIG. 8B

EP 0 880 938 A1

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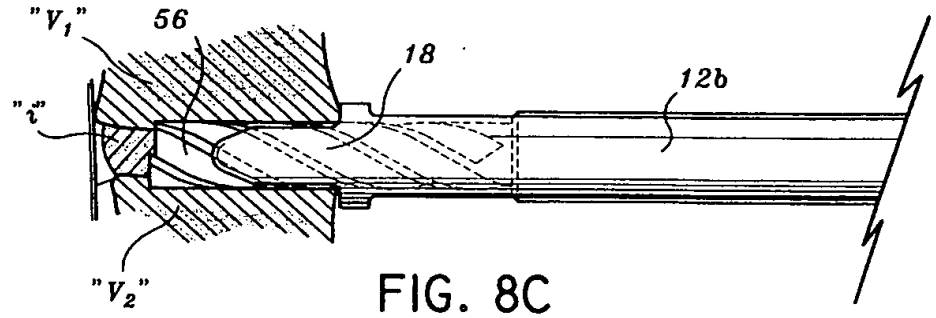


FIG. 8C

Description

BACKGROUND

1. Technical Field

The present disclosure generally relates to a method and associated instrumentation for implant insertion and, in particular, to a method and instrumentation for insertion of a pair of spinal implants to facilitate fusion of adjacent vertebral bodies.

2. Background of the Related Art

A large number of orthopedic procedures involve the insertion of either natural or prosthetic implants into bone or associated tissues. These procedures include, for example, ligament repair, joint repair or replacement, non-union fractures, facial reconstruction, spinal stabilization and spinal fusion. In a typical procedure, an insert, dowel or screw is inserted into a prepared bore formed in the bone or tissues to facilitate repair and healing. See, for example, U.S. Patent Nos.: 5,470,334 to Ross et al.; 5,454,811 to Huebner; 5,480,403 to Lee et al.; 5,358,511 to Gatturna et al.; and 4,877,020 to Vich.

Some implants are particularly configured with cavities and bores to facilitate bony ingrowth and enhance anchoring of the implant at the insertion site. See, for example, U.S. Patent Nos.: 4,328,593 to Sutter et al.; 4,936,851 to Fox et al.; and 4,878,915 to Brantigan. Other specialized implants include fusion cages having internal cavities to receive bone growth stimulation materials such as bone chips and fragments. See, for example, U.S. Patent Nos.: 4,501,269 to Bagby; 4,961,740 to Ray et al.; 5,015,247 to Michelson; and 5,489,307 to Kuslich et al. These types of implants are particularly well suited for intervertebral spinal fusion procedures necessitated by injury, disease or some degenerative disorder of the spinal disc. Subsequently, there may be progressive degeneration leading to mechanical instability between adjacent vertebrae necessitating direct fusion of the vertebrae while maintaining a pre-defined intervertebral space. This fusion may be accomplished by the insertion of one or more of the specialized implants as discussed above and also discussed U.S. Patent No. 5,026,373, the contents of which are incorporated herein by reference.

Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions of the lumbar spine. Fusions in the cervical area of the spine are primarily performed using posterior and anterior approaches as well. Typically, an implant such as a plug, dowel, prosthesis or cage is inserted into a preformed cavity inside the interbody, interdiscal space. Since it is desirable in these procedures to promote a "bone to bone" bridge, connective tissue and at least a portion of the distal tissue is removed. Preferably, relatively deep cuts are made in the adjacent bones in order to penetrate into the softer, more vascularized cancellous region to facilitate bone growth across the implant.

One of the more critical tasks performed in the insertion of a surgical fusion implant, particularly, in intervertebral spinal fusion, is the formation of the implant receiving cavity or bore within the adjacent vertebrae. More particularly, the drilled bore must be equally centered within the intervertebral space and preferably parallel to the vertebral end plates to ensure removal of equal portions of bone from the adjacent vertebrae throughout the length of the cut and subsequent appropriate seating of the implant relative to the vertebral bodies.

Surgical instruments for facilitating spinal fusion implant insertion are known. For example, U.S. Patent No. 5,484,437 to Michelson discloses a method and apparatus incorporating an outer and an inner sleeve arrangement. The outer sleeve has teeth at one end which are driven directly into the posterior surface of the adjacent vertebrae. The inner sleeve is positioned within the outer sleeve and serves to guide instruments such as a drill used to form the implant receiving bore. U.S. Patent Nos.: 5,487,307 to Kuslich et al.; 5,015,247 to Michelson; and 4,878,915 to Brantigan disclose similar arrangements. Other arrangements include the use of guide rods which are placed in pilot holes formed in the vertebral bodies. The guide rods guide a bore forming hollow drill into the intervertebral space.

Although current instrumentation and methods associated therewith for enhancing the placement of spinal fusion implants have been generally effective for their intended purposes, there exists certain limitations with the design of this instrumentation which detract from their usefulness. For example, the arrangement disclosed in the Michelson '437 patent and similar arrangements do not provide for automatic alignment of the outer sleeve to ensure that the bore formed by a drill introduced into the outer sleeve is in optimal alignment for a tapping procedure (if required) and reception of the spinal implant. Rather, such orientation is dependent directly upon the skill of the surgeon. Moreover, the outer sleeve, which is mounted only at its extreme distal end to the posterior surface of the adjacent vertebrae, is subject to disorientation or dislodgment during insertion and/or removal of the drill and/or tapping instrument. Similarly, the use of guide rods increases the number of steps required to implant the fusion cage and is also subject to possible misalignment.

In many surgical implant techniques, two implants are inserted within the intervertebral space in side-by-side or lateral relation to fully support the adjacent vertebrae across the span of the intervertebral space. In accordance with these techniques, a first lateral side of the intervertebral space is prepared, e.g., by removing excess disc material and drilling/tapping a bore to receive the implant followed by insertion of the implant. Thereafter, the second lateral side is prepared for implant insertion in the same manner. During the initial

preparation of the first lateral side of the intervertebral space, however, the adjacent vertebrae are subjected to displacement in both the lateral and longitudinal direction. This may cause additional movement of the vertebral portion disposed on the other (second) lateral side of the intervertebral space.

U.S. Patent No. 5,489,307 to Kuslich discloses a surgical method for implanting two spinal implants into a disc space utilizing a distraction spacer which is inserted initially within one side of the intervertebral space. The rigid distraction spacer is intended to act against the vertebral end plates of the adjacent vertebrae to urge the vertebrae apart while the second side of the intervertebral space is prepared, by drilling/tapping, to receive an implant. Once the implant is inserted, the distraction spacer is removed and the side left unoccupied by removal of the spacer is prepared to receive the second implant.

The present disclosure is directed to a method and associated instrumentation to facilitate the introduction of at least two fusion implants, which maintains the desired disc height across the span of the intervertebral space and thereby ensures optimal alignment of each drilled bore for reception of the fusion implant.

SUMMARY

In one preferred embodiment, a surgical retractor instrument is disclosed. The retractor instrument includes at least two elongated members connected to each other in side by side relation. Each elongated member has proximal and distal end portions and defines a longitudinal passageway for reception of surgical instrumentation. The distal end portion of each elongated member is configured for insertion at least partially within a space defined between adjacent tissue portions. Preferably, the distal end portion of each elongated member includes at least one retractor arm extending in a general longitudinal direction. Each retractor arm has first and second supporting surfaces for engaging opposed adjacent tissue portions, and defines a dimension between the first and second supporting surfaces sufficient to distract the opposed tissue portions upon insertion thereof. The first and second supporting surfaces of each retractor arm may be substantially planar. The retractor arms may be dimensioned between the first and second supporting surfaces to distract adjacent vertebrae. In an alternate embodiment two spaced apart retractor arms extend from the distal end portion of each elongated member.

In another preferred embodiment, a surgical retractor for use in distracting adjacent vertebrae includes first and second elongate sleeve members connected to each other in side by side relation. Each sleeve member has a proximal end and a distal end and defines a longitudinal passageway therebetween. At least two retractor arms extend longitudinally from the distal end of the retractor. Each retractor arm defines a first vertebra supporting surface and a second vertebra supporting surface portion. The first and second vertebra supporting surfaces of each retractor arm are spaced thereon at a predetermined distraction distance.

In an alternate embodiment, a spacer member is disposed between the first and second sleeve members to space the sleeve members at a predetermined distance.

A method for performing a surgical procedure with the surgical retractor is also disclosed. The method includes the steps of providing a surgical retractor including at least two elongate members connected to each other along longitudinal portions thereof and having proximal and distal end portions with an opening therethrough to receive instrumentation, the distal end portion of each elongate member configured for insertion at least partially into an intervertebral space between adjacent opposed vertebrae, inserting the distal end of the two elongate members of the retractor to distract lateral sides of the intervertebral space and performing the surgical procedure adjacent the distracted vertebrae. The distal end portion of at the retractor may include two spaced apart retractor arms having first and second supporting surfaces and wherein the step of distracting includes inserting the retractor arms within the intervertebral space whereby the first and second supporting surfaces of each retractor arm respectively engage the adjacent opposed vertebrae. Surgical instrumentation may be inserted within the opening of one of the elongate members to perform the surgical procedure. In a preferred embodiment, a fusion implant is inserted through the opening of the one elongate member and between the distracted vertebrae to effect fusion thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the disclosure are described hereinbelow with reference to the drawings wherein:

FIG. 1 illustrates a double surgical retractor constructed in accordance with the principles of the present disclosure and utilized in distracting adjacent bony structures, particularly adjacent vertebrae, and having first and second retractor sleeves;
FIG. 2 is a top plan view of the double retractor of FIG. 1;
FIG. 3 is a side plan view of the double retractor;
FIG. 4 is a cross-sectional view of the double retractor taken along the lines 4-4 of FIG. 3;
FIG. 5 is a perspective view of a surgical kit for performing a spinal fusion procedure illustrating, from bottom to top, the double retractor of FIG. 1, an implant insertion apparatus, a surgical tap instrument, a drill instrument and a T-shaped handle;
FIG. 6 is a view illustrating a portion of the vertebral column;

FIG. 7 is a side view illustrating insertion of the double retractor of FIG. 1 within an intervertebral space defined between adjacent vertebrae;

FIG. 8A is a view of the intervertebral space taken along the lines 8A-8A of FIG. 6 illustrating insertion of the drill instrument through a first retractor sleeve of the double retractor to drill a bore adjacent a first lateral side of the adjacent vertebrae;

FIG. 8B is a view similar to the view of FIG. 8A illustrating insertion of the drill instrument within the second retractor sleeve to drill a bore adjacent a second lateral side of the adjacent vertebrae;

FIG. 8C is a view taken along the lines 8C-8C of FIG. 8B further illustrating advancement of the drill instrument within the intervertebral space defined between adjacent vertebrae;

FIG. 9A is a view similar to the view of FIG. 8A illustrating insertion of the tap instrument within the first retractor sleeve for tapping the bore formed in the first lateral side of the adjacent vertebrae by the drill instrument;

FIG. 9B is a view similar to the view of FIG. 9A illustrating insertion of the tap instrument within the second retractor sleeve for tapping the bore formed in the second lateral side of the adjacent vertebrae by the drill instrument;

FIG. 10 is a view similar to the view of FIG. 8A illustrating insertion of the implant insertion instrument with mounted fusion implant within the retractor to mount the implant within the tapped bore;

FIG. 11 is a view taken along the lines 11-11 of FIG. 10 further illustrating insertion of the implant insertion instrument within the intervertebral space defined between adjacent vertebrae;

FIG. 12 is a cross-sectional view illustrating the insertion of two implants within the intervertebral space;

FIG. 13 is a perspective view of an alternate embodiment of the double surgical retractor of FIG. 1 having a spacing member interposed between the retractor sleeves to laterally displace the two retractor sleeves;

FIG. 14 is a top plan view of the double retractor of FIG. 13;

FIG. 15 is a view of the double retractor of FIG. 13 taken along the lines 15-15 of FIG. 14;

FIG. 16 is a top plan view of another alternate embodiment of the double surgical retractor having a curved engagement surface;

FIG. 17 is a perspective view of yet another alternate embodiment of the double surgical retractor having two retractor arms; and

FIG. 18 is a top plan view of the double surgical retractor of FIG. 17.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

The preferred embodiments of the method and instrumentation disclosed herein are discussed in terms of orthopedic spinal fusion procedures and instrumentation. It is also envisioned, however, that the disclosure is applicable to a wide variety of procedures including, but, not limited to ligament repair, joint repair or replacement, non-union fractures, facial reconstruction and spinal stabilization. In addition, it is believed that the present method and instrumentation finds application in both open and minimally invasive procedures including endoscopic and arthroscopic procedures wherein access to the surgical site is achieved through a cannula or small incision.

The following discussion will include a description of each instrument utilized in performing a spinal fusion method followed by a description of the preferred method for spinal fusion utilizing the instrumentation in accordance with the present disclosure.

In the discussion which follows, the term "proximal", as is traditional, will refer to the portion of the structure which is closest to the operator, while the term "distal" will refer to the portion which is furthest from the operator.

Referring now to the drawings in which like reference numerals identify similar or identical elements throughout the several views, FIG. 1 illustrates in perspective view a preferred embodiment of the double surgical retractor of the present disclosure. Double retractor 10 is particularly contemplated for distracting adjacent bony structures, e.g., adjacent vertebral bodies, to facilitate the insertion and application of a pair of implants. However, it is envisioned that double retractor 10 may also be utilized to distract other structures as well including joints, ligaments, etc... Other applications for retractor 10 are also contemplated.

Referring now to FIGS. 1-2, double retractor 10 includes first and second retractor sleeves 12a, 12b connected to each other along adjacent peripheral portions as shown. Retractor sleeves 12a, 12b may be formed of any suitable rigid material including stainless steel, titanium, aluminum or a suitable polymeric material and formed by injection molded techniques. Retractor sleeves 12a, 12b may be two separate components connected to each other by conventional means including adhesives, welding or the like or may be a single monolithic unit.

Each retractor sleeve 12a, 12b is similar in configuration to the retractor sleeve disclosed in U.S. patent Application Serial No. 08/615,379, filed March 14, 1996, the contents of which are incorporated herein by reference. Each sleeve 12a, 12b may be a variety of sizes such as 12 mm, 14 mm, 16 mm and 18 mm in diameter. The retractor size utilized will generally correspond to the size of the fusion implant to be applied. As shown, each retractor sleeve 12a, 12b has a longitudinal pas-

sageway extending from the proximal to the distal end portion to receive surgical instrumentation therethrough to carry out the fusion procedure.

With reference now to FIGS. 1-4, each sleeve 12a, 12b may optionally include first and second longitudinally extending openings 14 formed in its outer wall. Openings 14 are diametrically arranged with relation to each other and terminate at their distal ends in circumferential collar 16. Each opening 14 preferably extends radially for about between 15%-40% the circumference or perimeter of sleeve 12a, 12b and longitudinally preferably for about 25% the length of sleeve 12a, 12b. Openings 14 are contemplated to permit the introduction of surgical instrumentation if necessary to assist in carrying out the fusion procedure.

Each sleeve 12a, 12b further includes first and second diametrically opposed retractor arms 18. Retractor arms 18 extend distally from collar 16 in a general longitudinal direction and are spaced from each other. Each arm 18 has an arcuate outer surface (i.e., defining a radius of curvature substantially equivalent to the radius of curvature of the remaining portion of the sleeve). Each retractor arm 18 has first and second supporting surfaces 18a, 18b in general parallel relation to each other and preferably to the longitudinal axes "a" of each sleeve 12a, 12b. The supporting surfaces 18a, 18b are preferably substantially planar. The height "h" of each arm 18 (i.e., the distance between supporting surfaces 18a, 18b) corresponds to the height of the space between adjacent bony structures to be distracted. For example, in spinal fusion application, the height "h" of each arm 18 preferably ranges from about 0.28 to about 0.35 inches. Each arm 18 further includes tapered end portions 20 defining a generally V-shaped configuration. End portions 20 facilitate insertion of retractor arms 18 within the surgical site, e.g., within the intervertebral space.

As depicted in FIG. 5, retractor 10 may further include impactor head 22 which is correspondingly dimensioned to fit over the proximal ends of retractor sleeves 12a, 12b. Impactor head 22 is dimensioned to slide onto retractor 10 and form a friction fit therebetween. Impactor head 22 may further include an inner shelf which engages the proximal end faces of retractor sleeves 12a, 12b. In the alternative, impactor head 22 may be closed at its proximal end.

Referring still to FIG. 5, the various instruments utilized in performing a double spinal fusion procedure with the retractor 10 of the present disclosure are illustrated. These instruments include surgical drill 50, tap instrument 100, implant insertion instrument 150, fusion implant 200 and T-shaped handle 250 which is used to actuate each of the instruments.

Surgical drill 50 is disclosed in the previously incorporated '379 application. Drill 50 includes drill shaft 52, extension shaft 54 and drill bit 56 mounted at the distal end of the drill shaft 52. Extension shaft 54 has first and second collars 58, 60 which cooperate to control the depth of penetration of drill shaft 52 and drill bit 56 into the adjacent vertebrae. Drill shaft 52 includes a hexagonal-shaped head 62 at its proximal end to mount T-handle 250.

Tap instrument 100 is also disclosed in the '379 application. Tap instrument 100 is utilized for forming an internal thread within the drilled bore formed by the drill instrument 50. Tap instrument 100 includes elongated member 102 having hex head 104 at its proximal end to engage T-shaped handle 250. Tap instrument 100 further includes distal tapping threaded portion 106. Distal tapping portion 106 includes a plurality of conveyance channels (one is shown) 108 extending longitudinally through the cutting thread. Each conveyance channel 108 has a directional component parallel to the longitudinal axis and a directional component transverse to the longitudinal axis. Each conveyance channel 108 encompasses approximately an arc of about 1/3 the outer circumference of the tapping portion 106. Conveyance channels 108 are each dimensioned to receive bone material deburred by the cutting edges during the tapping procedure and to continually transmit the bone material proximally through the channel to avoid undesired material build up at the tapping site. In this manner, tap instrument 100 may be used to completely tap the internal thread within the bore without interruption of the tapping procedure.

Implant insertion instrument 150 is configured for mounting and inserting fusion implant 200 within the intervertebral space. Insertion instrument 150 includes elongated shaft 152 having hex-head mounting section 154 at its proximal end and cylindrical collar 156 at its distal end. Cylindrical collar 156 is dimensioned to be received within the cavity of fusion implant 200. A spring ball detent mechanism 158 is disposed within cylindrical collar 156 to releasably engage implant 200. Detent mechanism 158 is preferably spring-biased outwardly to engage corresponding structure defined within fusion implant 200 such as a recess or aperture formed in an interior wall thereof. Any type of detent mechanism 158 suitable for this intended purpose may be utilized. Collar 156 may further include a pair of longitudinal grooves 160 which engage corresponding structure of implant 200 (e.g., inner longitudinal rails) to rotatably fix the implant on the collar, i.e., to prevent rotational movement of the implant 200 on the collar. Other insertion instruments and arrangements are also envisioned.

Implant 200 is uniquely designed for use in spinal fusion procedures. This implant 200 is generally disclosed in U.S. Patent No. 5,026,373 to Ray, the contents of which have been previously incorporated herein by reference, and is commonly referred to as a "fusion cage". Implant or fusion cage 200 includes a cylindrical cage body 202 having an internal cavity or hole for accommodating bone-growth inducing substances. One end of cage body 202 is closed and defines a rounded or bull-nosed configuration to facilitate insertion of the fusion cage relative to one or more bony structures. The

other end defines an opening which communicates with the internal cavity. The outer surface of the cage body 202 includes a single continuous thread (preferably V-shaped) having a plurality of raised turns with valleys defined between adjacent turns.

A plurality of perforations are disposed within the thread and extend through the outer surface of the cage body 202 to provide direct communication between the outer surface and internal cavity. The perforations permit immediate contact between the bone growth inducing substances within the inner cavity and the bone structure when the cage body 202 is mated to the bone structure, e.g., adjacent vertebrae. An end cap (not shown) may be mountable to the open end of cage body 202 to enclose the bone-growth inducing substances within the interior cavity.

T-shaped handle 250 includes mounting portion 252 defining hexagonal-shaped recess 254 which receives the corresponding structure of drill instrument 50, tap instrument 100 and implant insertion instrument 150.

Operation of the Instrumentation

The use of the instrumentation in conjunction with the insertion of a pair of fusion implants 200 into an intervertebral space defined between adjacent vertebrae will be described. The subsequent description will be particularly focused on an anterior procedure for spinal surgery although a posterior approach is envisioned as well.

With reference to FIG. 6, which depicts a portion of the vertebral column, a targeted intervertebral space "i" defined between adjacent vertebrae "V_1, V_2" is accessed utilizing appropriate retractors, e.g., laminal retractors, dural extractors.

As depicted in FIG. 7, impactor head 22 is placed on the proximal end of retractor sleeves 12a, 12b. Retractor 10 is manipulated to align retractor arms 18 within the desired intervertebral space "i" defined between adjacent vertebrae "V_1, V_2". Preferably, retractor 10 is arranged such that retractor sleeve 12a is adjacent a first lateral side "S_1" of the intervertebral space "i" and retractor sleeve 12b is adjacent a second lateral side "S_2" of the intervertebral space "i". Thereafter, retractor arms 18 are advanced into the intervertebral space "i" whereby first and second supporting surfaces 18a, 18b of each retractor arm 18 respectively engage the opposed vertebral bodies "V_1, V_2". Retractor arms 18 are preferably dimensioned to slightly distract the adjacent vertebrae "V_1, V_2". However, alternatively, it is envisioned that retractor arms 18 may be configured to cause no distracting movement of the vertebrae "V_1, V_2". Once inserted, retractor arms 18 effectively stabilize the adjacent vertebrae "V_1, V_2" across the span of the intervertebral space "i". Preferably, during insertion, retractor 10 is driven distally, by e.g., impacting impactor head 22 with a standard mallet "m" as depicted in FIG. 7, which thereby drives retractor arms 18 within the adjacent vertebrae "V_1, V_2". Tapered end portions 20 of retractor arms 18 facilitate advancement within the intervertebral space "i".

Referring now to FIG. 8A, with retractor arms 18 of retractor sleeves 12a, 12b in their appropriate positions within the intervertebral space "i", attention is directed to drilling a bore in the first lateral side "S_1" of the intervertebral space "i". The cutting depth of drill instrument 50 is adjusted as desired (i.e., to correspond to the length of the fusion implant) by adjusting collars 58, 60. With the T-handle 250 mounted to drill instrument 50, the instrument is introduced into the axial bore of retractor sleeves 12a and advanced to contact the anterior surface of the vertebral bodies, "V_1, V_2". Drill 50 is advanced into the intervertebral space "i" adjacent the first lateral side "S_1" by rotating T-handle 250 such that drill bit 56 shears the soft tissue and cuts the bone of the adjacent vertebrae "V_1, V_2" thereby forming a bore which extends into the adjacent vertebrae "V_1, V_2". Drill 50 is then removed from retractor sleeve 12a. The drilling procedure is then repeated by insertion of drill instrument 50 within the second retractor sleeve 12b to form a bore within the adjacent vertebra "V_1, V_2" proximate the second lateral side "S_2" as depicted in FIGS. 8B-8C.

Referring now to FIG. 9A, tap instrument 100 is selected and attached to the T-handle 250. Tap instrument 100 is inserted into first retractor sleeve 12a and positioned adjacent the drilled bore formed in the adjacent vertebrae "V_1, V_2" by the surgical drill 50. With retractor sleeve 12a as a direct guide, T-handle 250 is rotated in the direction of the directional arrow of FIG. 9A while simultaneously applying sufficient downward pressure on the T-handle to advance the tap instrument 100 and promote even purchase into the endplates. Upon advancement of the tap instrument 100, the deburred bone chips collect within conveyance channel 108 of tapping head 106, and are conveyed proximally during rotational movement of the tapping head 106 away from the tapping site. Tap instrument 100 is advanced into the bone until the desired depth has been achieved, which occurs when the distal end of tapping head 108 "bottoms out" on the bone. When tap instrument 100 reaches the appropriate depth, the tap instrument 100 is rotated via T-handle 250 in an opposite direction to back the instrument out of the bore. The tapping procedure is then repeated by insertion of tap instrument 100 within the second retractor sleeve 12b to form a bore within the adjacent vertebrae "V_1, V_2" proximate the second lateral side as depicted in FIG. 9B. It is to be appreciated that in procedures where a self-tapping implant is utilized the tapping of the bores with tap instrument 100 is not necessary.

With reference now to FIG. 10, attention is focused on the insertion of fusion implant 200. FIG. 10 shows a first fusion implant 10 already applied within the bore proximate the first lateral side "S_1" of the intervertebral

space i. To apply the fusion implant, cage body 202 of the fusion implant 200 is mounted onto insertion instrument 150 by positioning the cage body 202 onto mounting collar 156 of the instrument to permit spring ball detent mechanism 158 to releasably engage corresponding structure of the implant body 202. This assembly is attached to T-handle 250. Insertion instrument 150 with mounted cage body 202 is inserted into retractor sleeve 12b of retractor 10 and the cage body 202 is positioned within the tapped bore by rotating insertion instrument 150 in the direction depicted in FIG. 10. Cage body 202 is advanced until it is completely seated with the bore as shown in FIG. 11. Insertion instrument 600 is then removed from retractor 100.

At this point in the procedure, bone growth inducing substances may be harvested from, e.g., the iliac crest, and packed into the cage body 202 of implant 200 until the cage body 202 is completely filled with bone growth inducing substances. An end cap may then be mounted to the cage body 202. Retractor 10 is then removed. It is also contemplated that the implant could be at least partially packed with bone growth inducing substances prior to insertion.

FIG. 12 illustrates the two lateral fusion implants 200 inserted within the intervertebral space in accordance with the afore-described procedure.

Thus, retractor 10 of the present disclosure maintains a desired spacing between the adjacent vertebra "V_1, V_2" across the lateral span of the intervertebral space during the entire spinal fusion procedure to facilitate insertion of the two implants 200. With the double sleeve arrangement 12a, 12b, additional retracting movement of the adjacent vertebra "V_1, V_2" is not required for drilling/tapping procedures and during insertion of the pair of implants 200. Moreover, the double sleeve arrangement ensures optical alignment of each drilled bore and placement of the two fusion implants 200. The double sleeve arrangement also reduces operating time since insertion of a separate retractor and/or distraction spacer is not required.

Referring now to FIGS. 13-15, an alternate embodiment of the surgical retractor 10 of the present disclosure is illustrated. This retractor is similar to the retractor disclosed in connection with FIG. 1 except for the rib or spacer 24 between first and second retractor sleeves 12a, 12b. Rib 24, interposed between retractor sleeves 12a, 12b, is dimensioned to increase the lateral spacing of retractor sleeves 12a, 12b and arms 18. An increase in the lateral spacing of sleeves 12a, 12b may be desirable to correspond to the size of the vertebrae targeted during the procedure. Moreover, an increase in lateral spacing, in effect, displaces the location of the pair of implants. Although shown as one single rib extending substantially the lengths of retractor sleeves 12a, 12b, connecting rib 24 may extend for only a portion of the length of retractor 10. Several connecting ribs 24 may alternatively be provided as well. In a preferred embodiment, connecting rib 24 is integrally formed with retractor sleeves 12a, 12b as a single monolithic unit although it is envisioned that the rib 24 may be a separate component connected to each sleeve 12a, 12b by welding, adhesives, etc...

FIG. 16 illustrates an alternate embodiment of the double surgical retractor of the present disclosure. Double retractor 10' is identical to retractor 10 of Figure 1 except that surfaces 70a, 70b of each retractor sleeve 12a', 12b' are curved to better conform to the curvature of the anterior aspect of the vertebral body.

Another alternate embodiment of the surgical double retractor is illustrated in FIG. 17 and designated by reference numeral 80. Retractor 80 has two sleeves 82a and 82b. It differs from the other embodiments in that each sleeve 82a, 82b has only one retractor arm 84a, 84b, respectively. That is, the two central adjacent arms are eliminated, thereby reducing the extent of the anterior ligament removed during retractor insertion. Retractor 80 otherwise functions in the same manner as retractor 10 with each sleeve providing a cannula for insertion of the aforedescribed instrumentation and arms 84a, 84b providing vertebral distraction. As shown in FIG. 18, retractor 80 preferably has a concave surface 80b to complement the natural shape of the vertebral body.

The claims which follow identify embodiments of the invention additional to those described in detail above.

Claims

1. A surgical retractor instrument comprising two elongate members disposed in side by side relation, each elongate member having proximal and distal end portions and defining a longitudinal passageway for reception of surgical instrumentation, the distal end portion of each elongate member configured for insertion at least partially within a space defined between adjacent tissue portions.

2. The surgical retractor according to claim 1 wherein the distal end portion of each elongate member includes at least one retractor arm extending in a general longitudinal direction, each retractor arm having first and second supporting surfaces for engaging opposed adjacent tissue portion, each retractor arm defining a dimension between the first and second supporting surfaces sufficient to distract the opposed tissue portions upon insertion thereof.

3. The surgical retractor according to claim 2 wherein the dimension defined between the first and second supporting surfaces of each retractor arm is sufficient to distract adjacent vertebrae.

4. The surgical retractor according to claim 1, 2 or 3 wherein the first and second supporting surfaces of each retractor arm are substantially planar.

5. The surgical retractor according to any one of the preceding claims, wherein each retractor arm has a tapered end portion for facilitating insertion between the tissue portions.

6. The surgical retractor according to any one of the preceding claims, wherein the distal end portion of each elongate member has two retractor arms.

7. The surgical retractor according to any one of the preceding claims, wherein the two elongate members are monolithically formed.

8. The surgical retractor according to any one of the preceding claims, wherein the two elongated members are welded to each other.

9. A surgical retractor for use in distracting adjacent vertebrae comprising first and second elongate sleeve members arranged in side by side relation, each sleeve member having a proximal end and a distal end portion and defining a longitudinal passageway therebetween and at least one retractor arm extending longitudinally from the distal end portion of each sleeve member, each retractor arm defining a first vertebra supporting surface and a second vertebra supporting surface, the first and second vertebra supporting surfaces of each retractor arm being spaced thereon at a predetermined distraction distance.

10. The surgical retractor according to claim 9 wherein the distal end of each elongated member has two retractor arms, each arm having distal tapered portions for facilitating insertion.

11. The surgical retractor according to claim 9 wherein the retractor arms each possess distal tapered portions for facilitating insertion into the intervertebral space.

12. The surgical retractor according to claim 9, 10 or 11 wherein the first and second supporting surfaces of each retractor arm are in general parallel relation.

13. The surgical retractor according to claim 12 wherein the first and second supporting surfaces of each retractor arm are in general parallel relation to the longitudinal axis of the elongate body.

14. The surgical retractor according to any one of claims 9 to 13 wherein each sleeve member includes at least one longitudinal opening defined in an intermediate wall portion thereof for reception of surgical instrumentation.

15. The surgical retractor according to any one of claims 9 to 14 wherein a distal surface of each sleeve member is concave.

16. The surgical retractor according to any one of claims 9 to 15 including a spacer member disposed between the first and second sleeve members to increase the distance between the sleeve members.

17. The surgical retractor according to any one of claims 9 to 16 wherein the first and second sleeve members are welded to each other.

18. The surgical retractor according to any one of claims 9 to 17 wherein the first and second sleeve members are monolithically formed.

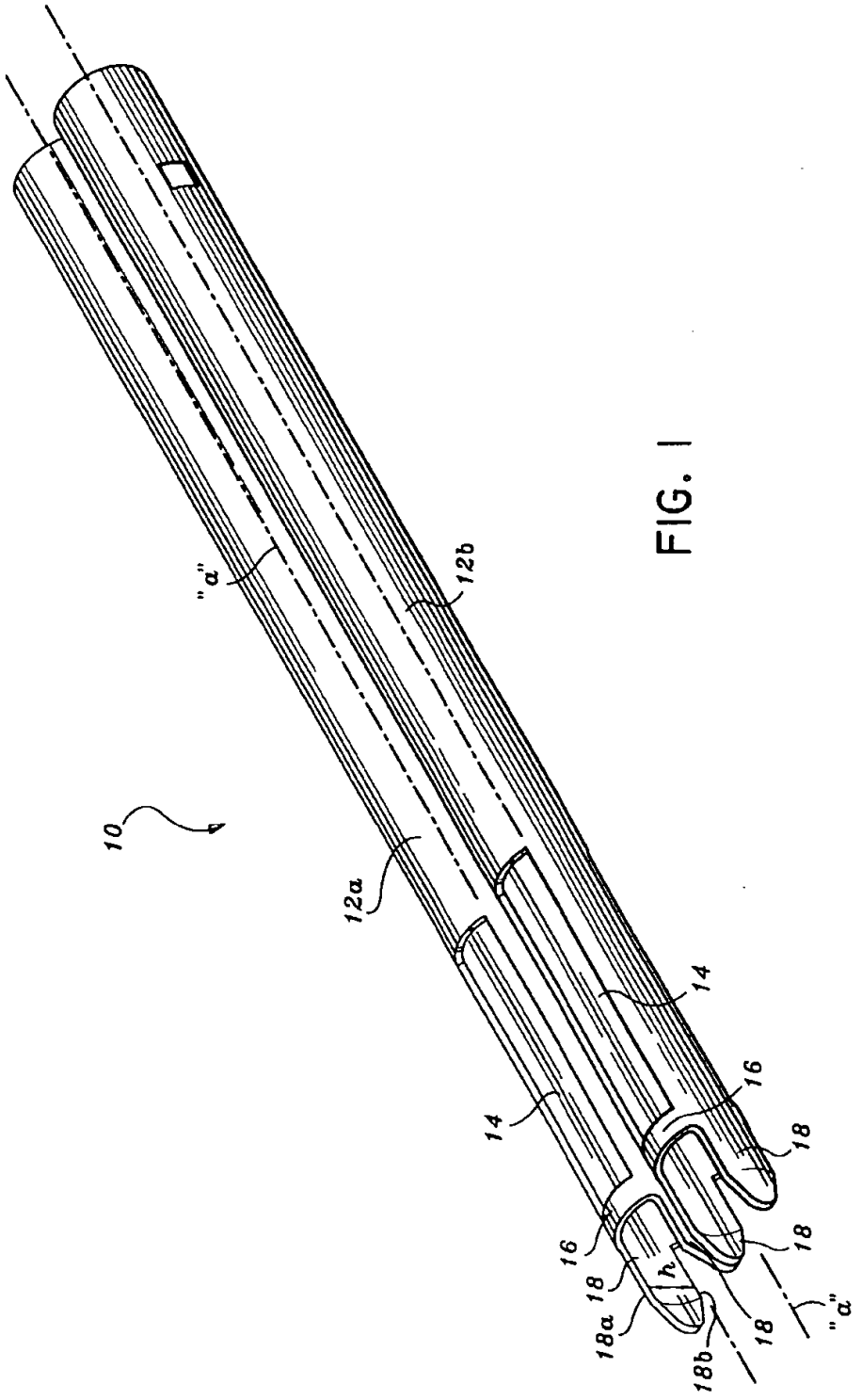


FIG. 1

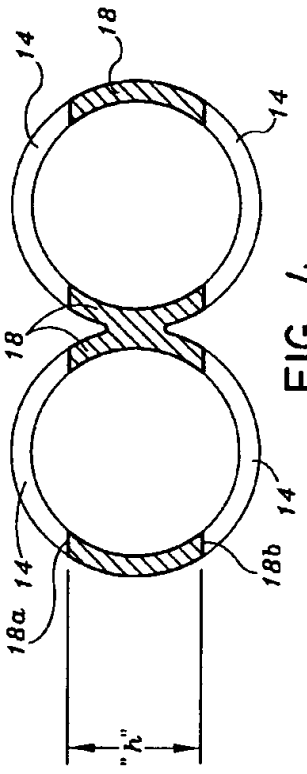


FIG. 4

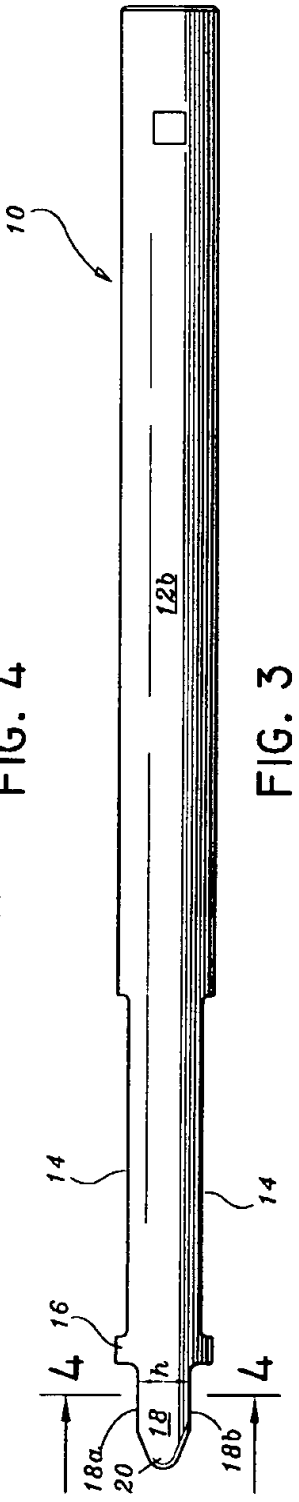


FIG. 3

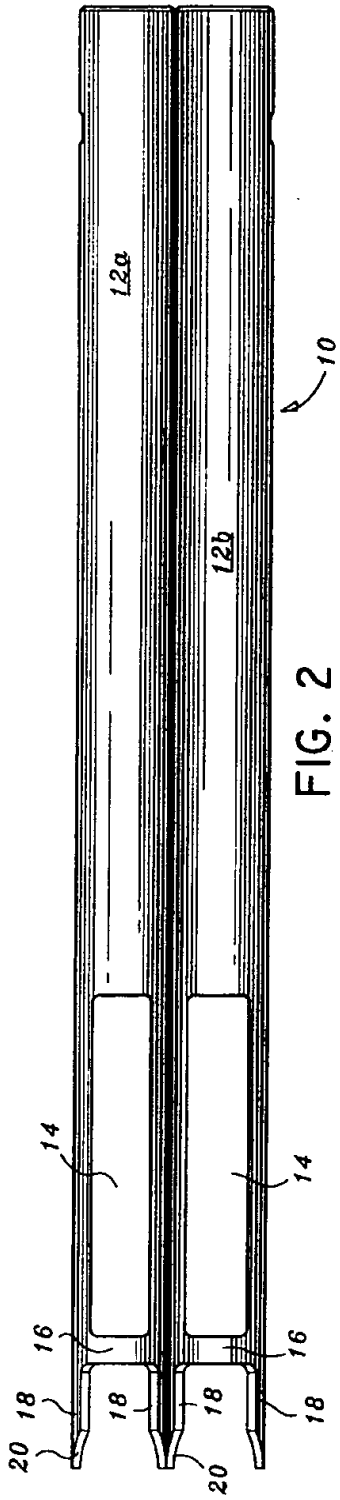


FIG. 2

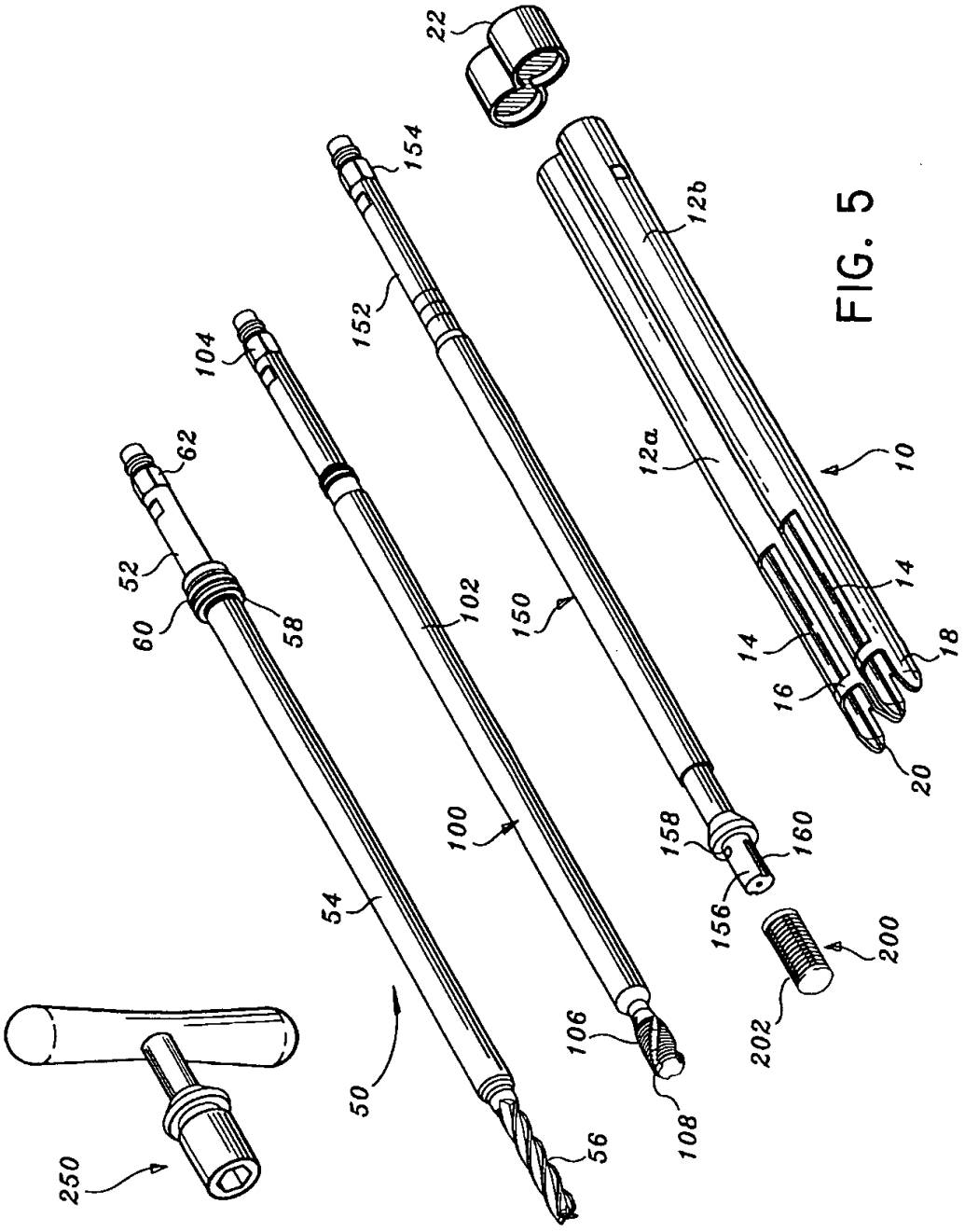

22
154
152
104
62
52
60
58
102
150
12b
12a
10
14
14
16
18
20
100
158
160
156
200
202
54
106
108
50
56
250

FIG. 5

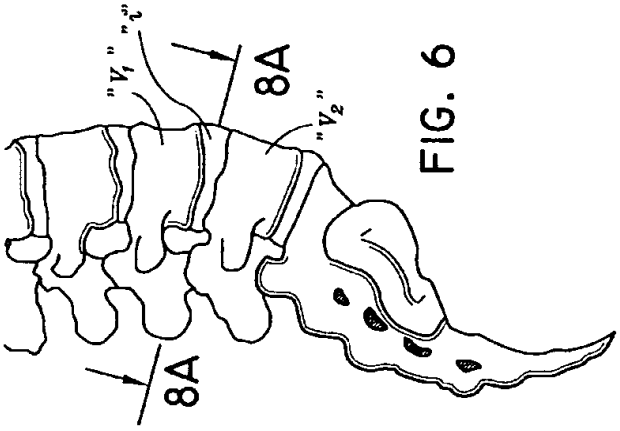


FIG. 6

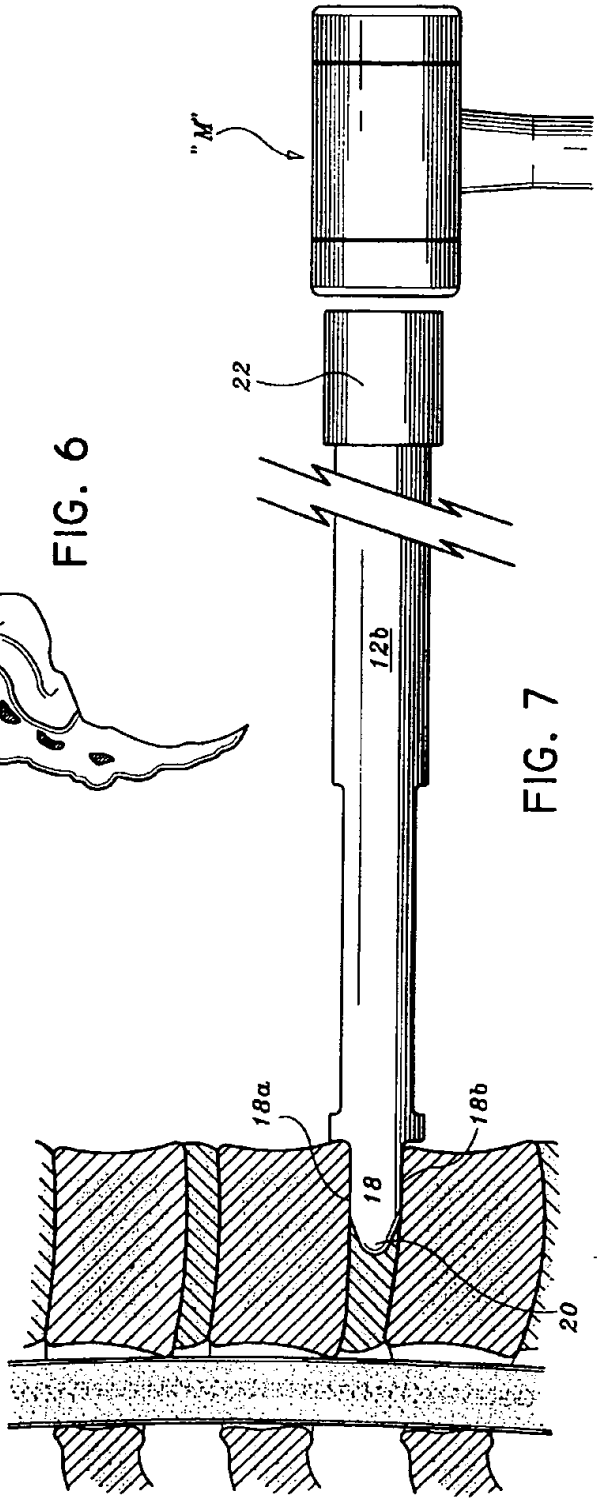


FIG. 7

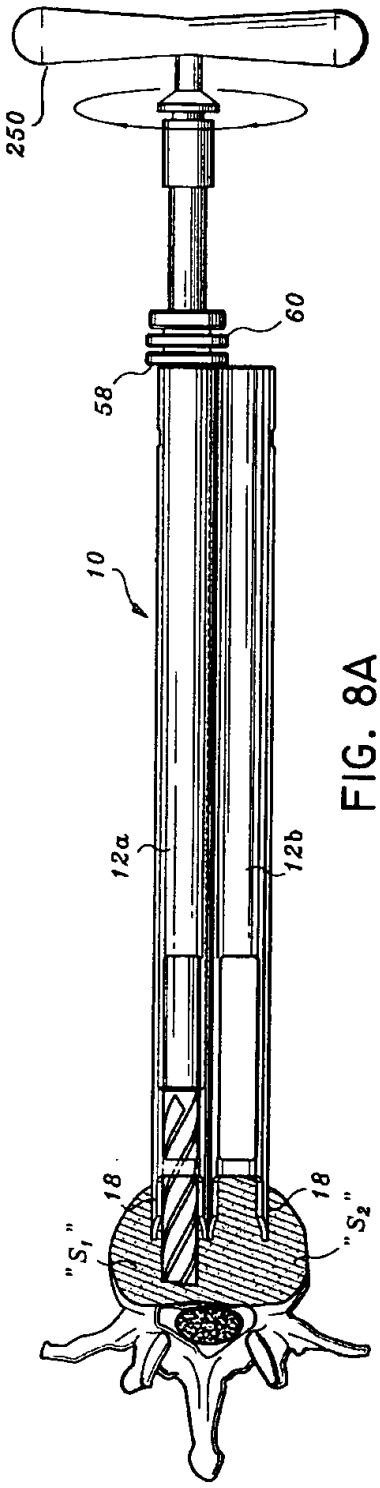
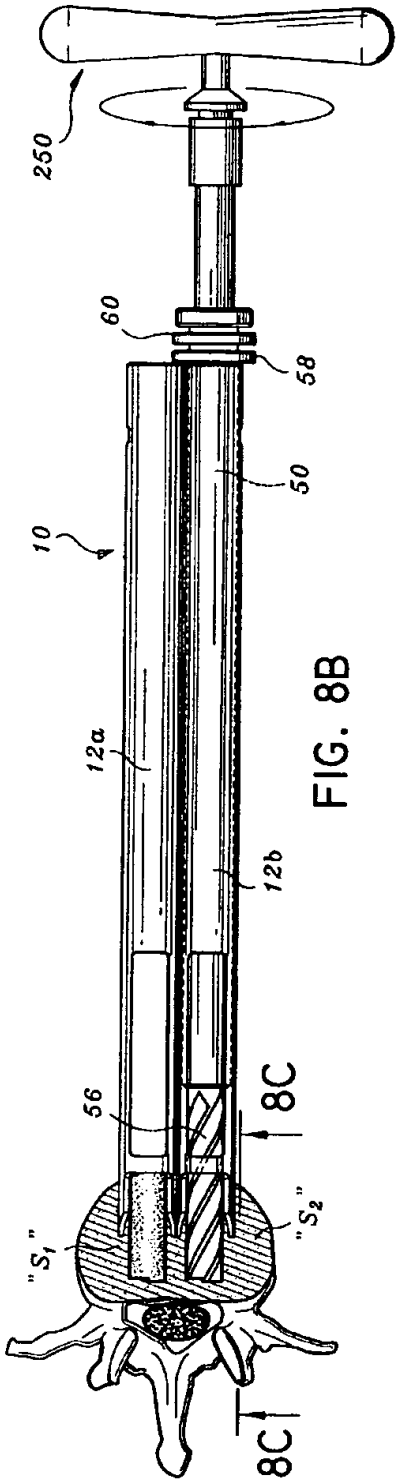

250
60
58
10
12a
12b
18
18
"S1"
"S2"

FIG. 8A


250
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58
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10
12a
12b
56
8C
8C
"S1"
"S2"

FIG. 8B

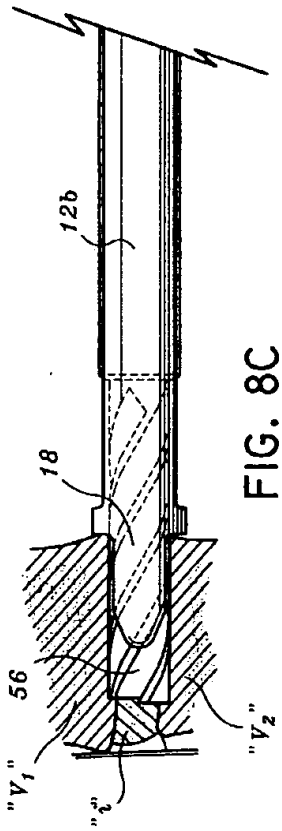

FIG. 8C

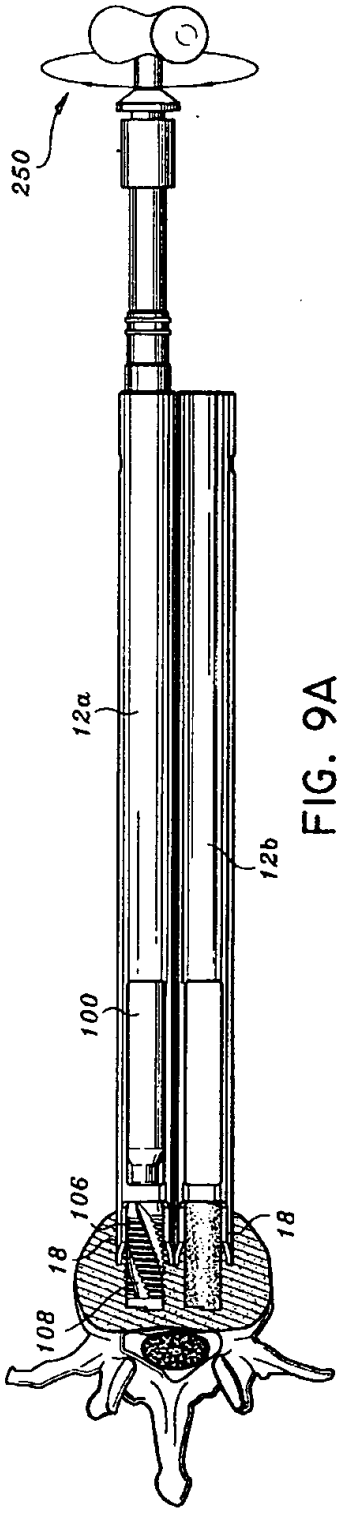

FIG. 9A

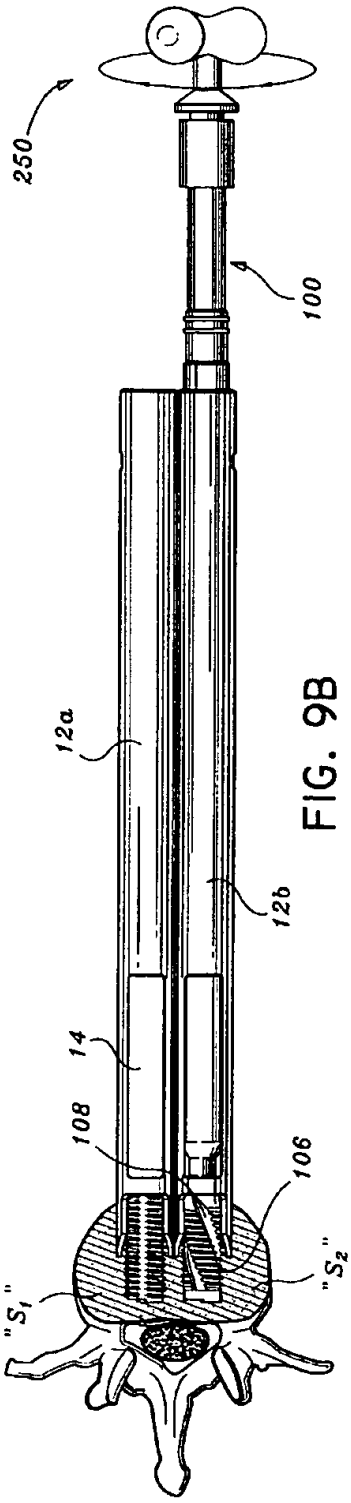

FIG. 9B

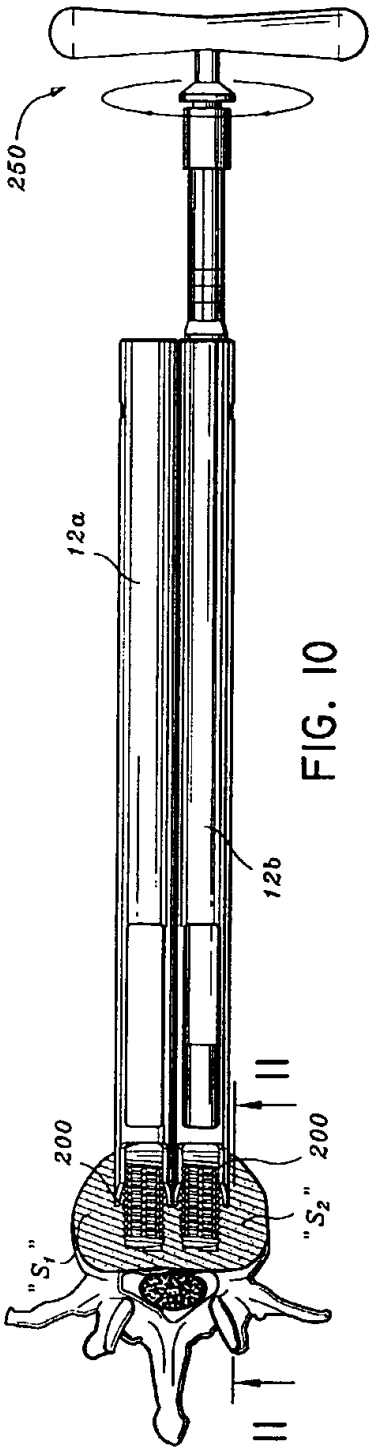

FIG. 10

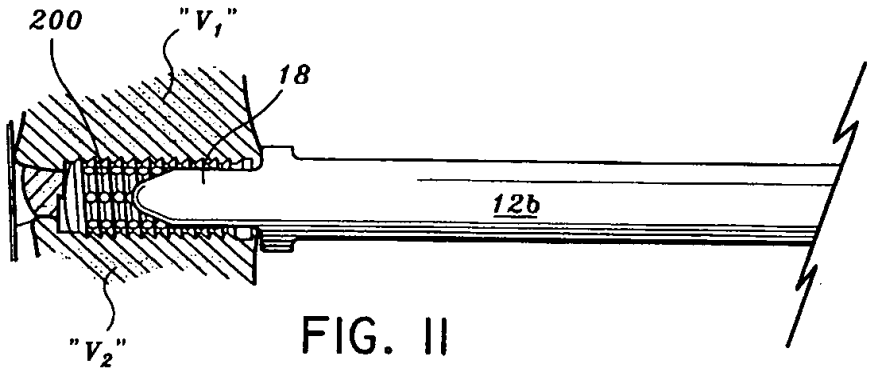

FIG. 11

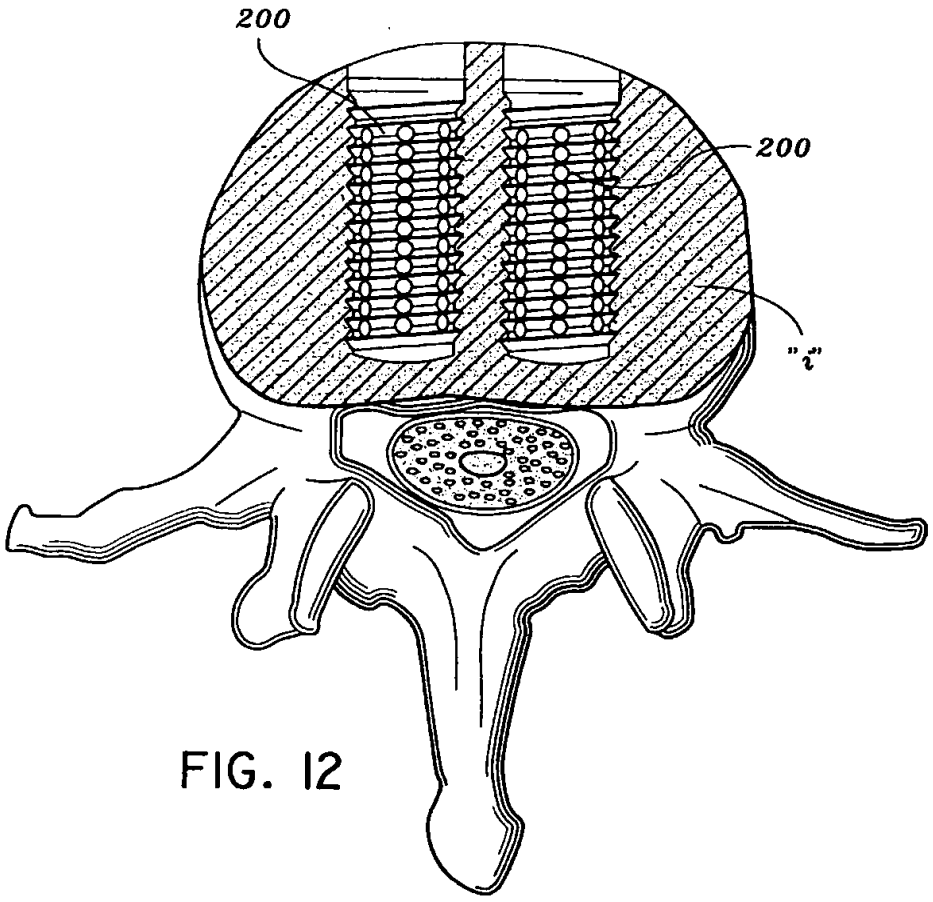

FIG. 12

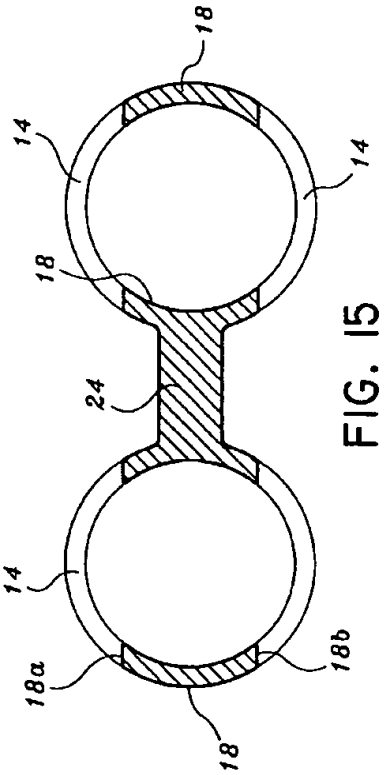

FIG. 15

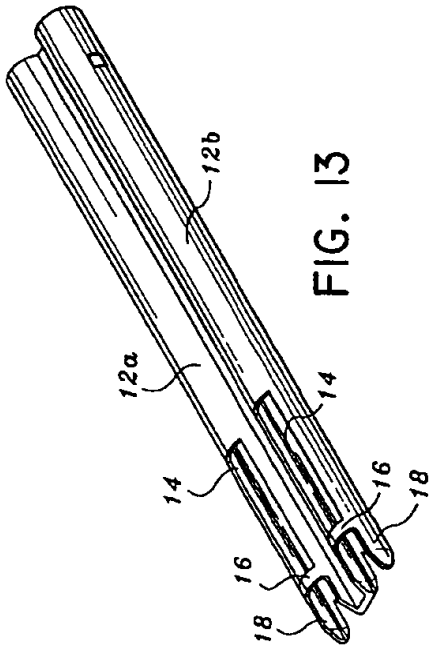

FIG. 13

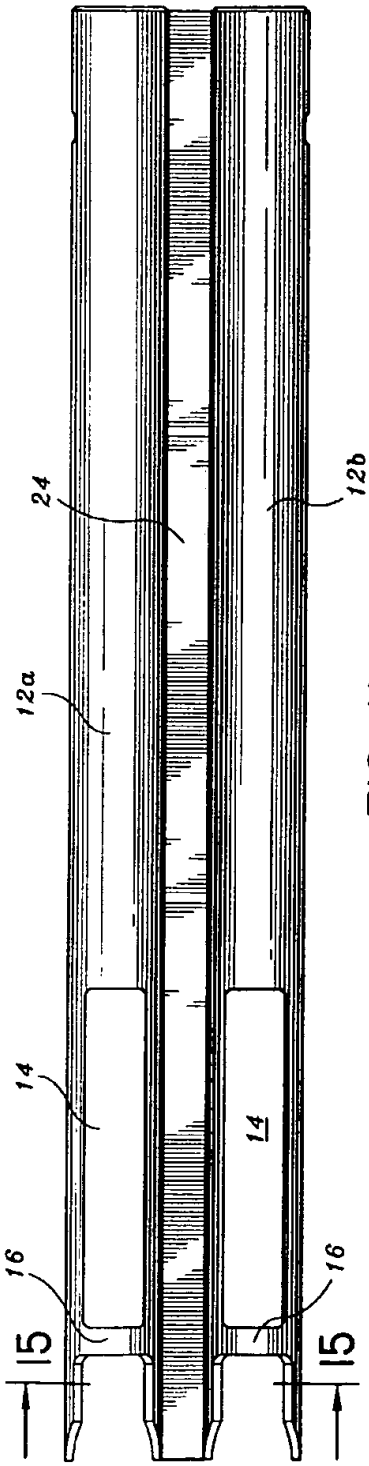

FIG. 14

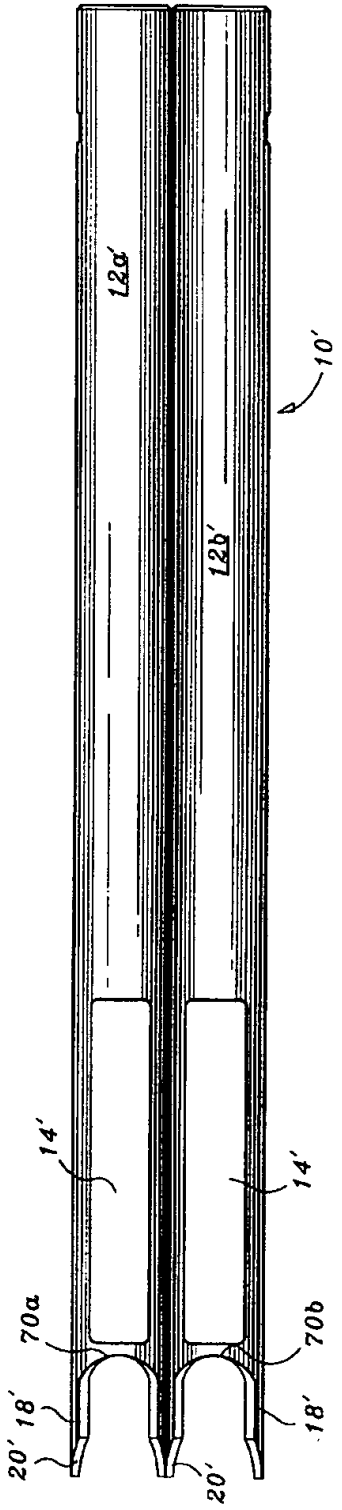

FIG. 16

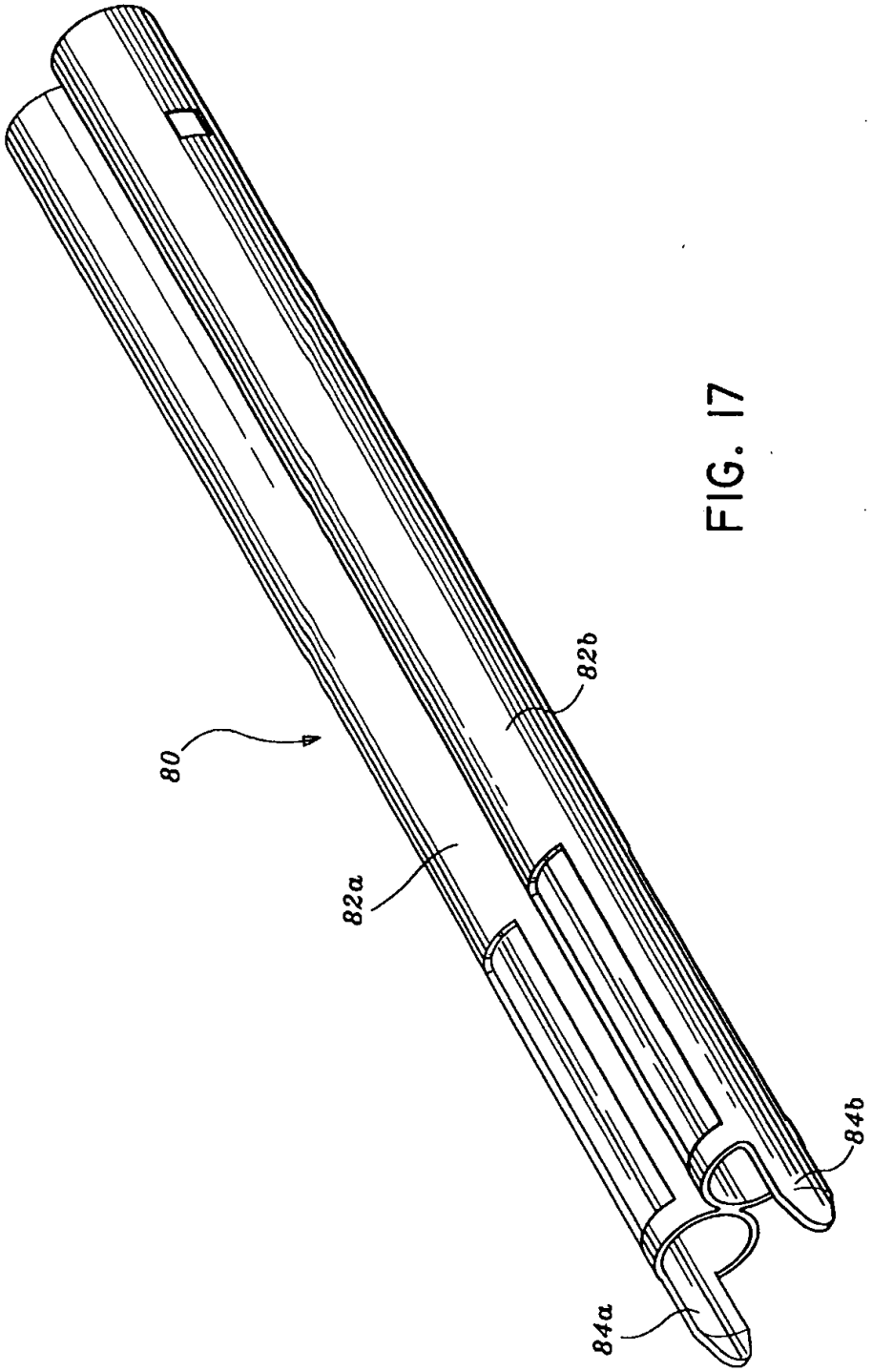

FIG. 17

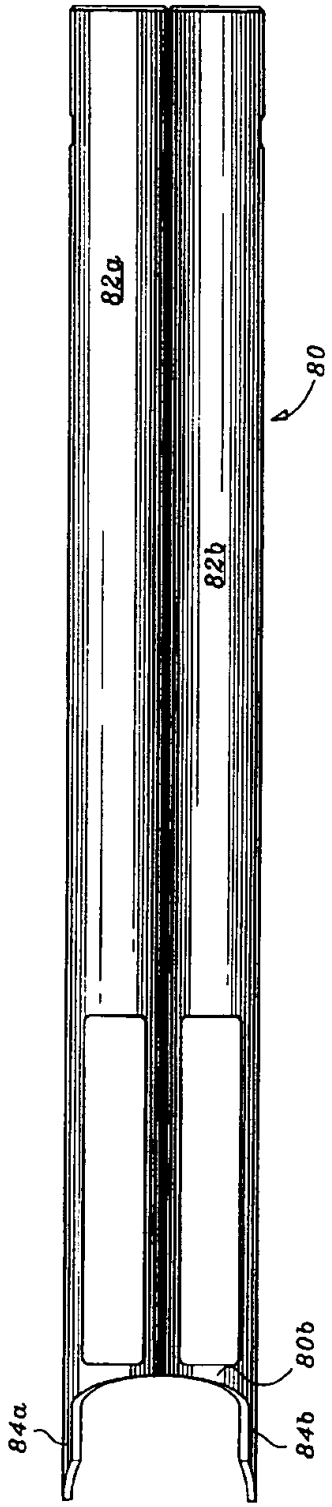

FIG. 18

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 98 10 9238

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	WO 96 27345 A (MICHELSON) 12 September 1996 * page 88, last paragraph - page 91, paragraph 2; figures 25-27,33-35 *	1-18	A61B17/02 A61F2/46
X A	US 5 571 109 A (BERTAGNOLI) 5 November 1996 * column 7, line 55 - column 8, line 25; figure 1 *	1-4,7,8 16	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61B
A61F

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	4 September 1998	Barton, S

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
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T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

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(22) International Filing Date: 31 January 2000 (31.01.2000)

(30) Priority Data:
299 01 724.9 02 February 1999 (02.02.1999) DE

(60) Parent Application or Grant
SYNTHES AG CHUR [/]; (). SYNTHES (U.S.A.) [/]; (). STEINER, Béatrice [/]; (). HEHLI, Markus [/]; (). AEBI, Max [/]; (). STEFFEN, Thomas [/]; (). STEINER, Béatrice [/]; (). HEHLI, Markus [/]; (). AEBI, Max [/]; (). STEFFEN, Thomas [/]; (). LUSUARDI, Werther ; ().

Published

(54) Title: DEVICE WITH A FLEXIBLE SHAFT FOR REMOVING BONE GRAFTS

(54) Titre: DISPOSITIF A ARBRE FLEXIBLE POUR PRELEVER DES COPEAUX D'OS

(57) Abstract

The invention relates to a device for removing bone grafts, comprising a cutting tool (16) with a cutting head (1), a longitudinal shaft (8) attached to the cutting head (1) and driving means (14) for the rotational movement of the cutting tool (16), wherein the bone grafts that have been cut by the cutting head (1) can be conveyed through a continuos bore (10) in the cutting tool (16), the shaft (8) is elastically mounted on a part (22) attached to the cutting head (1) enabling torsion and/or bending around the longitudinal axis, the device can additionally comprise a vacuum container (17) and the shaft (8) can also be attached to the container (17) during cutting and removal of bone grafts by the end (21) which is distant from the cutting head (1).

(57) Abrégé

L'invention concerne un dispositif permettant de prélever des copeaux d'os, qui comporte un outil de coupe (16) pourvu d'une tête de coupe (1), d'une tige (8) longitudinale raccordée à la tête de coupe (1), et des moyens d'entraînement (14) servant à l'entraînement en rotation de l'outil de coupe (16). Les copeaux d'os enlevés par la tête de coupe (1) peuvent être transportés depuis ladite tête de coupe (1) à travers un alésage (10) traversant de l'outil de coupe (16). La tige (8) est, en ce qui concerne la torsion et/ou la flexion autour de l'axe longitudinal, montée élastiquement sur une partie (22) raccordée à la tête de coupe (1). Le dispositif peut en outre comprendre une enceinte (17) à vide et la tige (8) peut être, à son extrémité (21) éloignée de la tête de coupe (1), raccordée à ladite enceinte (17) même pendant le prélèvement par découpe de copeaux d'os.

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(54) Title: DEVICE WITH A FLEXIBLE SHAFT FOR REMOVING BONE GRAFTS

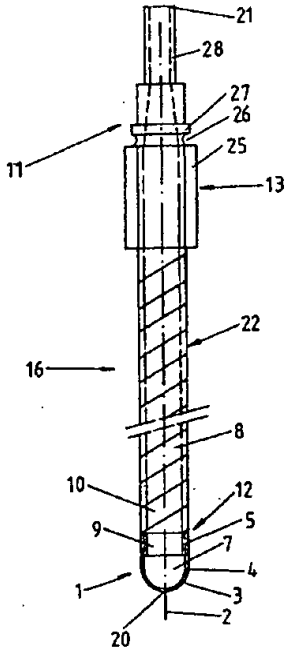
(54) Bezeichnung: VORRICHTUNG MIT FLEXIBLER WELLE ZUR GEWINNUNG VON KNOCHENSPÄNEN

(57) Abstract

The invention relates to a device for removing bone grafts, comprising a cutting tool (16) with a cutting head (1), a longitudinal shaft (8) attached to the cutting head (1) and driving means (14) for the rotational movement of the cutting tool (16), wherein the bone grafts that have been cut by the cutting head (1) can be conveyed through a continuos bore (10) in the cutting tool (16), the shaft (8) is elastically mounted on a part (22) attached to the cutting head (1) enabling torsion and/or bending around the longitudinal axis, the device can additionally comprise a vacuum container (17) and the shaft (8) can also be attached to the container (17) during cutting and removal of bone grafts by the end (21) which is distant from the cutting head (1).

(57) Zusammenfassung

Vorrichtung zur Gewinnung von Knochenspänen, welche ein Schneidwerkzeug (16) mit einem Schneidkopf (1), einem an den Schneidkopf (1) anschliessenden longitudinalen Schaft (8) und Antriebsmittel (14) zur rotativen Bewegung des Schneidwerkzeuges (16), umfasst, wobei die vom Schneidkopf (1) spanabhebend abgetragenen Knochenspäne vom Schneidkopf (1) durch eine durchgehende Bohrung (10) im Schneidwerkzeug (16) förderbar sind, der Schaft (8) auf einem an den Schneidkopf (1) anschliessenden Teil (22) bezüglich Torsion und/oder Biegung um die Längsachse elastisch ist, die Vorrichtung zusätzlich einen unter Vakuum stehenden Behälter (17) umfassen kann und der Schaft (8) an seinem vom Schneidkopf (1) entfernten Ende (21) auch während der Spanabhebenden Gewinnung von Knochenspänen an den Behälter (17) anschliessbar ist.



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Description

Vorrichtung mit flexibler Welle zur Gewinnung von Knochenspänen

Die Erfindung bezieht sich auf eine Vorrichtung zur Gewinnung von Knochenspänen gemäss dem Oberbegriff des Patentanspruchs 1.

Das Implantieren von körpereigenem Knochenmaterial bleibt die effizienteste Behandlungsmethode bei Nichtheilen eines gebrochenen Knochens, Pseudoarthrosis und zur Optimierung der Erfolgsrate bei Arthrodesis. Die Verwendung von körpereigenem Knochenmaterial ist sicherer und wirksamer als die Verwendung künstlich hergestellter Hydroxyapatit-Materialien oder körperfremder Knochenspäne, bedingt jedoch einen zusätzlichen Eingriff am Körper des Patienten. Dies kann durch ein begrenztes Eindringen und durch den Gebrauch einer zylindrischen Nadel, wie sie zur Entfernung von Knochenmaterial für Diagnosezwecke verwendet wird, minimiert werden. Diese Technik ist jedoch kompliziert und gefährlich, da keine genaue Kontrolle gewährleistet ist. Meist wird deshalb die Spongiosa durch einen grösseren Hautschnitt und aus einer grossen Öffnung am Beckenkamm herausgemeisselt. Spezielle Knochenspan-Sammelinstrumente gestatten eine sichere und rasche Gewinnung von körpereigenen Knochenspänen durch einen kleinen Hauteinschnitt, was die Unannehmlichkeiten und Verletzungen des Patienten minimiert. Diese Vorrichtungen entfernen zuverlässig das Knochenmaterial und können mit einer Bohrmaschine angewendet werden, wodurch eine grössere Menge und eine bessere Kontrollmöglichkeit gewonnen werden sowie ein versehentliches Durchstossen durch die Kortikalis minimiert wird. Diese sichere und wirksame Technik ermöglicht, körpereigene Knochenspäne für Fusionen, Pseudoarthrosis und Knochenbrüche mit einer minimalen Verletzung des Spenders zu gewinnen. Die Entfernung der Knochenspäne am Körper des Patienten wird üblicherweise am Beckenknochen vorgenommen. Ebenfalls brauchbares Knochenmaterial lässt sich proximal an der Ulna oder distal am Radius gewinnen.

Eine solche Vorrichtung zur Gewinnung von Knochenmaterial ist beispielsweise aus der WO 97/39685 YUAN bekannt. Diese bekannte Vorrichtung umfasst einen starren hohlzylindrischen und durchsichtigen Schaft, worin die Knochenspäne

gesammelt werden und wegen der Durchsichtigkeit durch einen einzigen Blick die Menge der gesammelten Knochenspäne erkennbar ist, einen Schneidkopf am eine Ende und Mittel zur Aufnahme eines Drehmomentes am anderen Ende des Schaftes. Die Vorrichtung wird einfach in den Knochen eingedreht, wodurch mittels des Schneidkopfes der Knochen zerspant und abgetragen wird. Die Knochenspäne werden im Hohlraum im Schaft aufgenommen und gesammelt. Bei Gebrauch werden die gesammelten Knochenspäne mittels eines Kolbens, welcher vom dem Schneidkopf entgegengesetzten Ende des Schaftes in dessen Hohlraum eingeschoben wird, aus dem Schaft entnommen. Rotativ angetrieben werden kann die Vorrichtung von Hand oder maschinell.

Eine weitere solche Vorrichtung zur Gewinnung von Knochenmaterial ist aus der US 5,556,399 HUEBNER bekannt. Auch diese bekannte Vorrichtung umfasst einen Bohrkopf mit einem daran anschliessenden starren hohlzylindrischen Schaft, worin die Kochenspäne gesammelt werden und anschliessend durch einen vom Bohrkopf her einzuführenden handbedienten Kolben wieder aus dem Hohlraum entnommen werden.

Eine Methode und eine Vorrichtung zur Gewinnung von Gewebe ist aus der US 5,403,317 BONUTTI bekannt. Diese bekannte Erfindung umfasst eine Vorrichtung zur perkutanen Gewebegewinnung und besteht aus einem bezüglich Biegung flexiblen Bohrerschaft und Mitteln zum Antrieb des Schaftes. Zum Herausschneiden von Gewebefragmenten aus dem Gewebe ist vorne am Schaft eine Schneidspitze angebracht. Die Gewebefragmente werden während des Schneidvorganges mittels eines Unterdruckes durch den Schaft zu einem Ort ausserhalb des Körpers gesaugt.

Nachteilig bei allen diesen bekannten Vorrichtungen ist die Gefahr, dass mit den bekannten Vorrichtungen wegen der Starrheit des Schaftes bezüglich Torsion beim Ausräumen der Spongiosa zwischen der Kortikalis die härtere Kortikalis geschnitten oder durchbrochen wird.

Hier will die Erfindung Abhilfe schaffen. Der Erfindung liegt die Aufgabe zugrunde, eine Vorrichtung zu entwickeln, welche es in einfacher Weise gestattet, die

Spongiosa zwischen der Kortikalis auszuräumen, ohne dadurch die härtere Kortikalis zu schneiden oder durch diese hindurchzubrechen.

Die Erfindung löst die gestellte Aufgabe mit einer Vorrichtung zur Gewinnung von Knochenspänen, welche die Merkmale des Anspruchs 1 aufweist.

Weitere vorteilhafte Ausgestaltungen der Erfindung sind in den abhängigen Ansprüchen gekennzeichnet.

Die durch die Erfindung erreichten Vorteile sind im wesentlichen darin zu sehen, dass die elastische Verformbarkeit des Schaftes und ein nicht zu scharfkantig ausgebildeter Schneidkopf gestatten, die Spongiosa zwischen der Kortikalis auszuräumen, ohne dadurch die härtere Kortikalis zu schneiden oder durch diese hindurchzubrechen.

Die erfindungsgemässe Vorrichtung umfasst ein hohlzylindrisches Schneidwerkzeug mit einem hohlzylindrischen Schneidkopf, welcher verschieden gestaltete Bohrspitzen und Schneidkanten aufweisen kann, einem hohlzylindrischen Schaft mit Mitteln zum Einspannen des Schaftes in eine Antriebsvorrichtung, und eine Antriebsvorrichtung, welche beispielsweise aus einer Universalbohrmaschine bestehen kann. Die hohlzylindrische Ausgestaltung des Schneidkopfes und des Schaftes ermöglicht eine Aufnahme der vom Schneidkopf abgetragenen Knochenspäne aus der Spongiosa in der Bohrung im Innern der Hohlzylinder. Der an den Schneidkopf anschliessende Schaft ist bezüglich Torsion und/oder Biegung elastisch verformbar.

Diese Verformbarkeit lässt sich durch eine Ausführung des Schaftes als spiralförmig gewickeltes Metallblechband, als mit einer Drahtarmierung verstärkter Kunststoff- oder Gummischlauch oder auch als Metallrohr mit balgartiger Seitenwand herstellen.

Die Bohrspitze des Schneidkopfes ist vorzugsweise als Sektor einer Kugelkalotte mit einer Schneidkante ausgeführt. Die durch diese Ausgestaltung des Schneidkopfes erreichten Vorteile sind darin zu sehen, dass ein nicht zu scharfkantig

oder mit scharfen Ecken ausgebildeter Schneidkopf gestattet, die Spongiosa zwischen der Kortikalis auszuräumen, ohne dadurch die härtere Kortikalis zu schneiden oder durch diese hindurchzubrechen.

Eine spezielle Ausführungsform des Schneidkopfes besteht darin, dass die Bohrspitze des Schneidkopfes kugelkalottenförmig mit mindestens zwei koaxial und radial zur Längsachse sich in den Hohlraum erstreckenden Durchgangsöffnungen ausgebildet ist, wobei an den Kanten der Durchgangsöffnungen Schneidkanten zum Abtragen von Knochenspänen angebracht sind und die abgetragenen Knochenspäne durch die Durchgangsöffnungen in den Hohlraum des Schneidkopfes förderbar sind.

Andere Ausführungsformen der Bohrspitze sind als Kegelsektoren mit Schneidkanten oder als hohlzylindrische Fräser mit stirnseitigen Schneidezähnen denkbar.

Die Verbindung zwischen Schneidkopf und Schaft ist als lösbare oder feste Verbindung denkbar, wobei eine lösbare Verbindung einen kleineren Werkzeugsatz ermöglicht. Als lösbare Verbindung sind Schraubverbindungen, radiale Stiftschrauben oder radiale Stiftverbindungen möglich.

In einer weiteren Ausführungsform der erfindungsgemässen Vorrichtung ist an der Antriebsvorrichtung ein mit einem Vakuum beaufschlagter Behälter so angebracht, dass das hohlzylindrische Schneidwerkzeug mit seinem vom Schneidkopf entfernten Ende in den Behälter mündet, wodurch die Knochenspäne mittels des Vakuums auf einfache Weise durch das hohlzylindrische Schneidwerkzeug in den Behälter förderbar sind und im Behälter gesammelt werden können. Zum Absaugen der Knochenspäne ist am Behälter ein Stutzen für den Anschluss eines Vakuumschlauches angebracht. Durch das so angelegte Vakuum werden die Knochenspäne durch eine oder mehrere Durchgangsöffnungen im Schneidkopf in die Bohrung im Schaft gesaugt und von dort durch das gesamte Schneidwerkzeug hindurch in den Behälter gefördert. Damit die Knochenspäne nicht in den Vakuumschlauch geraten, ist im Behälter eine Abscheidevorrichtung zum Abscheiden der Knochenspäne aus dem Luftstrom angebracht. Dieser Abscheider kann als Filter, Sieb, Prallplatte oder Zyklon ausgeführt sein.

Diese Ausgestaltung der erfindungsgemässen Vorrichtung gestattet, dass die Knochenspäne ohne Entfernung des Bohrwerkzeuges aus dem Bohrloch von der Bohrspitze durch den Schaft hindurch wegförderbar sind und in einem direkt an das Bohrwerkzeug anschliessenden Behälter gesammelt werden können. Der Behälter kann von der Vorrichtung demontiert werden und bei Bedarf sind die Knochenspäne einfach aus dem Behälter entnehmbar.

Das am Behälter angelegte Vakuum umfasst einen Druckbereich von 0 bar bis 1 bar, vorzugsweise jedoch einen Druckbereich von 0,2 bar bis 0,8 bar.

Zur Abdichtung der unter Vakuum stehenden Bohrung im Schaft des Schneidwerkzeuges wird vorzugsweise in diese Bohrung ein Gummi- oder Kunststoffschlauch eingezogen.

Die Erfindung und Weiterbildungen der Erfindung werden im folgenden anhand der teilweise schematischen Darstellungen mehrerer Ausführungsbeispiele noch näher erläutert.

Es zeigen:

Fig. 1 eine Ansicht des Schneidwerkzeuges mit dem flexiblen Schaft gemäss einer Ausführungsform der erfindungsgemässen Vorrichtung;

Fig. 2 eine perspektivische Darstellung des Schneidkopfes mit dem flexiblen Schaft einer Ausführungsform der erfindungsgemässen Vorrichtung;

Fig. 3 eine schematische Darstellung einer Ausführungsform der erfindungsgemässen Vorrichtung; und

Fig. 4 eine schematische Darstellung einer weiteren Ausführungsform der erfindungsgemässen Vorrichtung.

In Fig. 1 ist das Schneidwerkzeug 16 mit Schneidkopf 1 und Schaft 8 dargestellt. Der Schaft 8 umfasst einen bezüglich Torsion und/oder Biegung elastisch

verformbaren Teil 22 und einen mit Mitteln 13 zur Aufnahme eines Drehmomentes versehenen, vom Schneidkopf 1 entfernten Teil 11. Die Mittel 13 bestehen aus einem Abschnitt 25 mit Aussensechskant und einem daran anschliessenden zylindrischen Abschnitt 27 mit einer Nute 26. Die beiden Abschnitte 25 und 27 lassen sich in entsprechende Einspannmittel 15 (Fig. 3) an einem Antriebsmittel 14 (Fig. 3) einspannen, wobei der Schaft 8 mittels der Nute 26 axial und durch den Aussensechskant rotativ im Einspannmittel 15 (Fig. 3) lösbar fixierbar ist. Die Bohrung 10 im hohlzylindrischen Schaft 8 durchdringt den Schaft 8 in Richtung der Längsachse 2 vom Schneidkopf 1 bis zu dem vom Schneidkopf 1 entfernten Ende 21 des Schaftes 8, so dass die vom Schneidkopf 1 abgetragenen Knochenspäne entlang der Längsachse 2 durch das ganze Schneidwerkzeug 16 förderbar sind. Zur Fixation des Schneidkopfes 1 am Schaft 8 sind Feststellschrauben oder beispielsweise auch Federstifte zwischen Schaft 8 und Schneidkopf 1 denkbar. Der elastisch verformbare Teil 22 des Schaftes 8 ist aus einem spiralförmig gewickelten Metallstreifen gefertigt, wobei in der Bohrung 10 ein Gummi- oder Kunststoffschlauch 36 (Fig. 4) eingelegt ist, welcher gegenüber der Umgebung einen luftdichten Abschluss in der Bohrung im Schlauch 36 gewährleistet.

Fig. 2 zeigt eine Ausführungsform des Schneidkopfes 1. Der Schneidkopf 1 ist als Hohlzylinder mit einer Längsachse 2 und einer Bohrspitze 20 ausgeführt und umfasst einen vorderen an die Bohrspitze 20 anschliessenden Abschnitt 4 und einen hinteren von der Bohrspitze 20 entfernten Abschnitt 5. Der vordere Abschnitt 4 besteht aus einem Hohlzylinder mit einer als Kugelkalottensektor ausgebildeten Bohrspitze 20, wobei die im Querschnitt rechtwinklig zur Längsachse 2 betrachtete Seitenwand des vorderen Abschnitts 4 nur einen Kreisringsektor einschliesst, so dass eine radial zum hohlzylindrischen Teil und axial zur Bohrspitze 20 verlaufende Durchgangsöffnung 7 entsteht. Die Seitenwand des vorderen Abschnittes 4 ist von der Bohrspitze 20 bis zum hinteren Abschnitt 5 gegen die Durchgangsöffnung 7 hin als Schneidkante 3 ausgebildet. Wird der rotierende Schneidkopf 1 in den Knochen gebohrt, so werden durch die Schneidkanten 3 Knochenspäne abgetragen und gelangen durch die Durchgangsöffnung 7 in den Hohlraum 9 des Schneidkopfes 1 und werden von dort durch die Bohrung 10 im Schaft 8 gefördert.

In Fig. 3 ist eine bevorzugte Ausführungsform der erfindungsgemässen Vorrichtung dargestellt. Das Schneidwerkzeug 16, welches zur Gewinnung der Knochenspäne dient, besteht aus einem Schneidkopf 1 mit einem sich entlang einer Längsachse 2 erstreckenden hohlzylindrischen Schaft 8. Dieser Schaft 8 ist in Einspannmitteln 15 einer als Antriebsmittel 14 dienenden Universalbohrmaschine 30 axial und rotativ fixiert. Durch die Antriebsmittel 14 wird dem Schaft 8 mit dem Schneidkopf 1 eine Rotationsbewegung um die Längsachse 2 aufgeprägt, wodurch sich der Schneidkopf 1 in den Knochen bohrt und die zu sammelnden Knochenspäne abträgt. Der Schaft 8 ist vom Schneidkopf 1 bis zu seinem vom Schneidkopf 1 entfernten Ende 21 hohlzylindrisch ausgeführt, so dass die Knochenspäne entlang der gesamten Länge des Schneidwerkzeuges 16 förderbar sind. Ebenfalls an den Antriebsmitteln 14 angebracht ist ein als Behälter 17 für die Knochenspäne dienendes Gefäss. Der Behälter 17 ist koaxial zur Längsachse 2 mit seinem vorderen Ende 24 so an den Antriebsmitteln 14 lösbar befestigt, dass das vom Schneidkopf 1 entfernte Ende 21 des Schneidwerkzeuges 16 gegenüber der Umgebung luftdicht in den Behälter 17 mündet. An seinem vom Schaft 8 entfernten Ende 23 ist der Behälter 17 mit einem Stutzen 18 versehen, woran sich ein Vakuumschlauch (nicht gezeichnet) anschliessen lässt. Durch das Vakuum im Schlauch wird der Behälter 17 ebenfalls evakuiert, wodurch im Innern des hohlzylindrischen Schneidwerkzeuges 16 ein Unterdruck entsteht und somit die vom Schneidkopf 1 abgetragenen Knochenspäne durch das Innere des Schaftes 8 gesaugt werden und in den Behälter 17 gelangen, wo sie dann in der Folge gesammelt werden können. Damit die Knochenspäne nicht durch das Vakuum mit in den Vakuumschlauch gerissen werden, ist im Behälter 17 eine Abscheidevorrichtung 19, welche in der bevorzugten Ausführungsform als Filter ausgestaltet ist, so angebracht, dass die Knochenspäne nicht durch den Stutzen 18 austreten können.

In Fig. 4 ist eine weitere bevorzugte Ausführungsform der erfindungsgemässen Vorrichtung dargestellt. Diese hier dargestellte Ausführungsform der erfindungsgemässen Vorrichtung unterscheidet sich von der in Fig. 3 dargestellten Ausführungsform nur darin, dass das Schneidwerkzeug 16 durch den koaxial zur Längsachse 2 angeordneten Behälter 17 durchgeht und die Mittel 13 zur Aufnahme eines durch die Universalbohrmaschine 30 abgegebenen Drehmomentes

im Bereich des vom Schneidkopf 1 entfernten Behälterbodens 33 mit der Universalbohrmaschine 30 lösbar verbunden sind. Der Behälter 17 ist mit seinem Behälterboden 33 an der Universalbohrmaschine 30 lösbar befestigt. Anstelle eines Behälterdeckels ist ein Lagergehäuse 34 im Behälter 17 angebracht, worin das Schneidwerkzeug 16 bezüglich seiner Rotationsbewegung um die Längsachse 2 beispielsweise mittels Kugellager 35 gelagert und mittels einer ringförmigen Dichtung (37) der Behälter (17) gegenüber der Umgebung abgedichtet ist. Zudem ist der Stutzen 18 für den Anschluss eines Vakuumschlauches an der Seitenwand des Behälters 17 angebracht. Zur Abdichtung des flexiblen Schaftes 8 ist in dessen Bohrung 10 ein Gummi- oder Kunststoffschlauch 36 entlang der Längsachse 2 eingeführt.

Claims

Patentansprüche

1. Vorrichtung zur Gewinnung von Knochenspänen, welche
A) ein rotierbares Schneidwerkzeug (16) mit einer Längsachse (2), einem Schneidkopf (1) und einem an den Schneidkopf (1) anschliessenden, konzentrisch zur Längsachse (2) angeordneten longitudinalen Schaft (8); und
B) Antriebsmittel (14), welche dem Schneidwerkzeug (16) mit dem Schneidkopf (1) eine Rotationsbewegung um die Längsachse (2) aufprägen, umfasst; wobei
C) das Schneidwerkzeug (16) eine in Richtung der Längsachse (2) durchgehende Bohrung (10) aufweist und der Schneidkopf (1) mit mindestens einer Durchgangsöffnung (7) versehen ist, so dass die vom Schneidkopf (1) spanabhebend abgetragenen Knochenspäne durch die Bohrung (10) förderbar sind, dadurch gekennzeichnet, dass
D) der Schaft (8) mindestens auf einem Teil seiner Länge bezüglich Torsion und/oder Biegung um die Längsachse (2) elastisch ist.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass der Schaft (8) aus einem spiralförmig gewickelten Metallband gefertigt ist.

3. Vorrichtung nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass in der Bohrung (10) des Schneidwerkzeuges (16) entlang der Längsachse (2) zusätzlich ein Kunststoff- oder Gummischlauch eingeführt ist.

4. Vorrichtung nach Anspruch 1 oder 3, dadurch gekennzeichnet, dass der Schaft (8) aus einem Metallrohr mit balgartiger Wand besteht.

5. Vorrichtung nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass der Schneidkopf (1) hohlzylindrisch gestaltet ist und einen sich entlang der Längsachse erstreckenden Hohlraum (9), einen mit einer Bohrspitze (20) und mit mindestens einer Schneidkante (3) versehenen vorderen Abschnitt (4), einen hohlzylindrischen hinteren Abschnitt (5) und mindestens eine im vorderen Abschnitt (4) die Aussenwand (29) des Schneidkopfes (1) radial durchdringende Durchgangsöffnung (7) zur Förderung der durch die mindestens eine Schneidkante (3) abgetragenen Knochenspäne in den Hohlraum (9) des Schneidkopfes (1) umfasst.

6. Vorrichtung nach Anspruch 5, dadurch gekennzeichnet, dass die Bohrspitze (20) des Schneidkopfes (1) als Kugelkalottensektor ausgebildet ist.

7. Vorrichtung nach Anspruch 5, dadurch gekennzeichnet, dass die Bohrspitze (20) des Schneidkopfes (1) kugelkalottenförmig mit mindestens zwei koaxial und radial zur Längsachse (2) sich in den Hohlraum (9) erstreckenden Durchgangsöffnungen (7) ausgebildet ist, wobei an den Kanten der Durchgangsöffnungen (7) Schneidkanten (3) zum Abtragen von Knochenspänen angebracht sind und die abgetragenen Knochenspäne durch die Durchgangsöffnungen (7) in den Hohlraum (9) des Schneidkopfes (1) förderbar sind.

8. Vorrichtung nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, dass die Antriebsmittel (14) aus einer Universalbohrmaschine (30) bestehen.

9. Vorrichtung nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, dass das Schneidwerkzeug (16) durchgehend hohlzylindrisch ausgeführt ist, Mittel (13) zur Aufnahme eines Drehmomentes, welches eine Rotation des Schaftes (8) um die Längsachse (2) verursacht, aufweist und an seinem am Schneidkopf (1) anschliessbaren Ende (12) so an den hinteren Abschnitt (5) anschliessbar ist, dass die Bohrung (10) des hohlzylindrischen Schaftes (8) mit dem Hohlraum (9) fluchtend ausrichtbar ist und vom Schaft (8) das Drehmoment auf den Schneidkopf (1) übertragbar ist.

10. Vorrichtung nach Anspruch 9, dadurch gekennzeichnet, dass die Antriebsmittel (14) Einspannmittel (15) zur rotativen und axialen Fixierung der Mittel (13) am Schneidwerkzeug (16) umfassen.

11. Vorrichtung nach einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, dass die Vorrichtung einen unter Vakuum stehenden Behälter (17) umfasst und das Schneidwerkzeug (16) an seinem vom Schneidkopf (1) entfernten Ende (21) auch während der spanabhebenden Gewinnung von Knochenspänen an den Behälter (17) anschliessbar ist.

12. Vorrichtung nach Anspruch 11, dadurch gekennzeichnet, dass der Behälter (17) fluchtend zur Längsachse (2) am Antriebsmittel (14) lösbar angebracht ist, wobei der Behälter (17) relativ zur Längsachse (2) stillsteht und das vom Schneidkopf (1) entfernte Ende (21) des rotierenden hohlzylindrischen Schneidwerkzeuges (16) mittels einer ringförmigen Dichtung (37) abgedichtet in den Behälter (17) mündet, so dass der Übergang zwischen Schneidwerkzeug (16) und Behälter (17) gegenüber der Umgebung luftdicht abgeschlossen ist.

13. Vorrichtung nach Anspruch 11 oder 12, dadurch gekennzeichnet, dass am Behälter (17) ein Stutzen (18) für den Anschluss eines Vakuumschlauches angebracht ist.

14. Vorrichtung nach einem der Ansprüche 11 bis 13, dadurch gekennzeichnet, dass der Behälter (17) eine Abscheidevorrichtung (19) zur Abscheidung der Knochenspäne aus dem Luftstrom umfasst.

15. Vorrichtung nach Anspruch 14, dadurch gekennzeichnet, dass die Abscheidevorrichtung (19) aus einem Filter besteht.

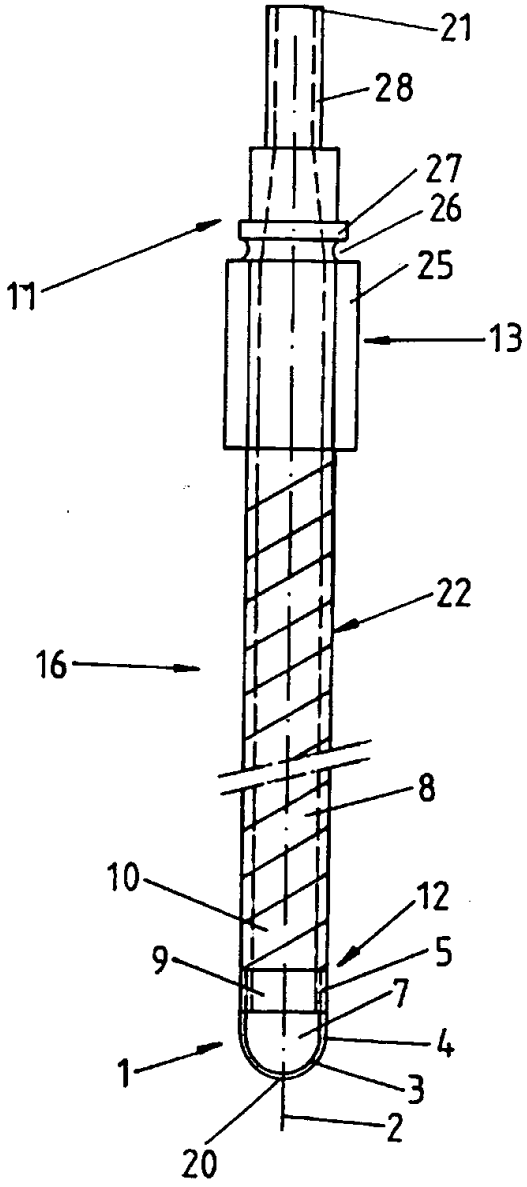

Fig.1

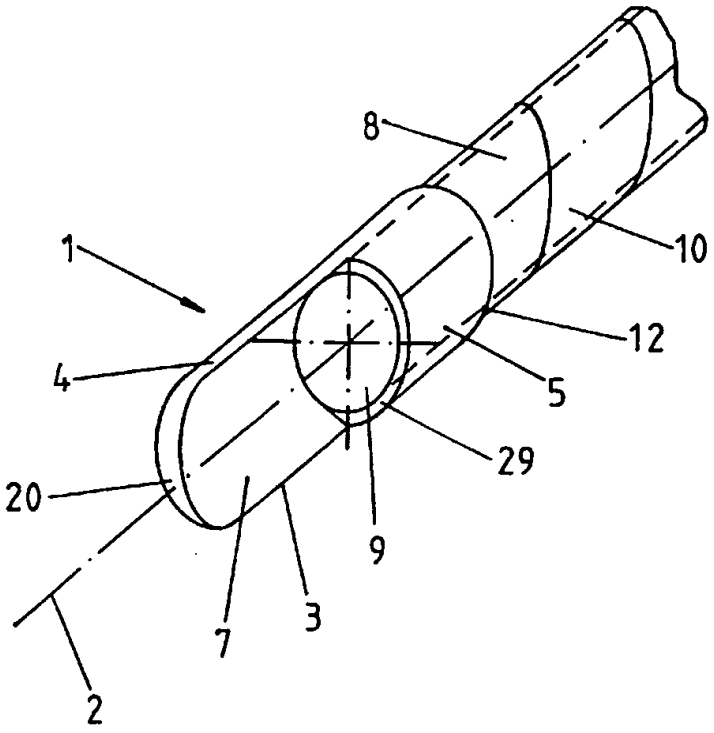

Fig. 2

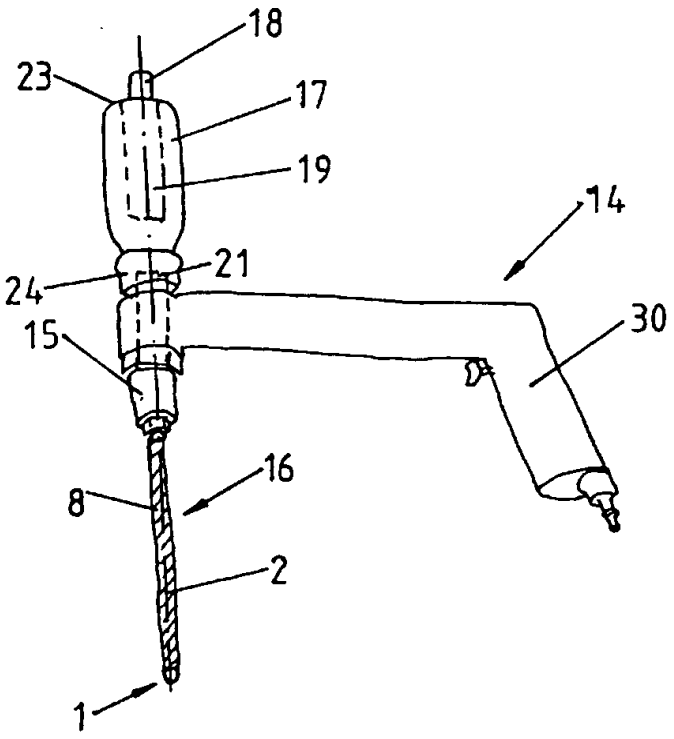

Fig.3

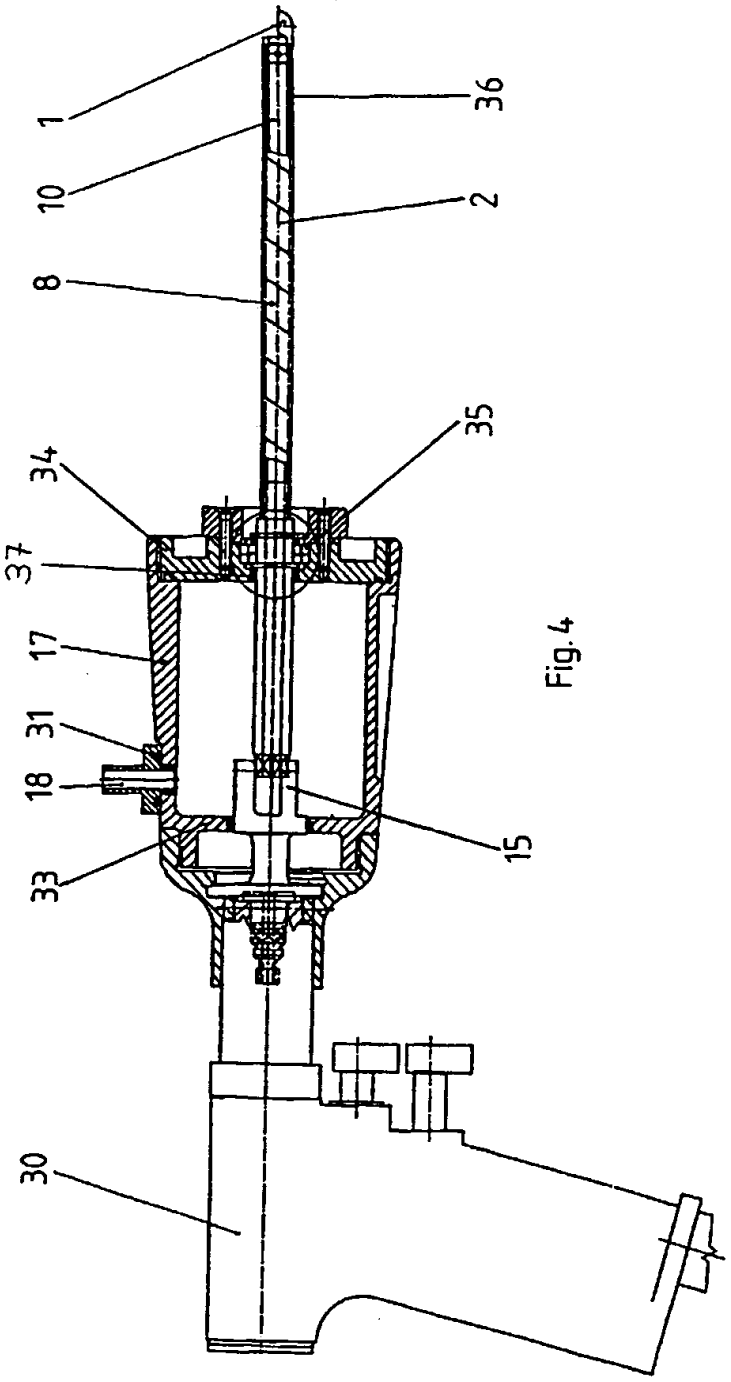

Fig.4

INTERNATIONAL SEARCH REPORT

Interna l Application No
PCT/CH 00/00047

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/16

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)

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 5 403 317 A (P.M.BONUTTI) 4 April 1995 (1995-04-04) cited in the application abstract; figures 1,3,12 column 3, line 6 - line 8 column 5, line 38 - line 62	1,4,5, 8-11, 13-15 6,7
X	US 4 646 738 A (A.F.TROTT) 3 March 1987 (1987-03-03) column 7, line 21 -column 8, line 2 column 8, line 36 - line 58; figures 3,9	1,2,5,9, 10
X A	WO 96 39956 A (AUST & TAYLOR MEDICAL) 19 December 1996 (1996-12-19) abstract page 7, line 1 - line 11 page 14, line 3 - line 6 page 20, line 12 - line 17	1,2 3

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[X] Further documents are listed in the continuation of box C. [X] Patent family members are listed in annex.

* Special categories of cited documents :

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

Date of the actual completion of the international search	Date of mailing of the international search report
19 April 2000	02/05/2000

Name and mailing address of the ISA	Authorized officer
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	Nice, P

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page 1 of 2

INTERNATIONAL SEARCH REPORT

Internat l Application No
PCT/CH 00/00047

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
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A	column 10, line 23 - line 32	3
Y	WO 97 38635 A (DISK WHISK) 23 October 1997 (1997-10-23)	6,7
A	page 4, line 5 - line 13 page 6, line 5 - line 16 page 7, line 26 - line 30 figures 3,18	5
A	WO 97 39685 A (SPINETECH) 30 October 1997 (1997-10-30) cited in the application figures 1,2	1,5-7
A	US 5 556 399 A (R.J.HUEBNER) 17 September 1996 (1996-09-17) cited in the application abstract; figure 1	1,5-8
A	US 5 569 284 A (W.P.YOUNG ET AL.) 29 October 1996 (1996-10-29) abstract; figures 1,7,9	12-15

3

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat l Application No
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		EP 0904014 A	31-03-1999
US 5556399 A	17-09-1996	NONE	
US 5569284 A	29-10-1996	NONE	

Form PCT/ISA/210 (patent family annex) (July 1992)

INTERNATIONALER RECHERCHENBERICHT

Interne des Aktenzeichen
PCT/CH 00/00047

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
IPK 7 A61B17/16

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
IPK 7 A61B

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X Y	US 5 403 317 A (P.M.BONUTTI) 4. April 1995 (1995-04-04) in der Anmeldung erwähnt Zusammenfassung; Abbildungen 1,3,12 Spalte 3, Zeile 6 - Zeile 8 Spalte 5, Zeile 38 - Zeile 62	1,4,5, 8-11, 13-15 6,7
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-/—

[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

[X] Siehe Anhang Patentfamilie

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"&" Veröffentlichung, die Mitglied derselben Patentfamilie ist

Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
19. April 2000	02/05/2000

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Nice, P

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INTERNATIONALER RECHERCHENBERICHT

Interne Aktenzeichen
PCT/CH 00/00047

C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	WO 96 39956 A (AUST & TAYLOR MEDICAL) 19. Dezember 1996 (1996-12-19)	1,2
A	Zusammenfassung Seite 7, Zeile 1 - Zeile 11 Seite 14, Zeile 3 - Zeile 6 Seite 20, Zeile 12 - Zeile 17	3
X	US 5 322 505 A (K.W.KRAUSE ET AL.) 21. Juni 1994 (1994-06-21) Spalte 10, Zeile 5 - Zeile 6; Abbildungen 2,3	1
A	Spalte 10, Zeile 23 - Zeile 32	3
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A	Seite 4, Zeile 5 - Zeile 13 Seite 6, Zeile 5 - Zeile 16 Seite 7, Zeile 26 - Zeile 30 Abbildungen 3,18	5
A	WO 97 39685 A (SPINETECH) 30. Oktober 1997 (1997-10-30) in der Anmeldung erwähnt Abbildungen 1,2	1,5-7
A	US 5 556 399 A (R.J.HUEBNER) 17. September 1996 (1996-09-17) in der Anmeldung erwähnt Zusammenfassung; Abbildung 1	1,5-8
A	US 5 569 284 A (W.P.YOUNG ET AL.) 29. Oktober 1996 (1996-10-29) Zusammenfassung; Abbildungen 1,7,9	12-15

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Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internat. ee Aktenzeichen
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			AU	2734697 A	12-11-1997
			EP	0904014 A	31-03-1999
US 5556399	A	17-09-1996	KEINE		
US 5569284	A	29-10-1996	KEINE		

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