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Suddaby

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(54) **EXPANDABLE INTERVERTEBRAL FUSION IMPLANT AND APPLICATOR**

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(*) Notice: Under 35 U.S.C. 154(b), the term of this patent shall be extended for 0 days.

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Related U.S. Application Data

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(51) **Int. Cl.⁷** **A61F 2/44**

(52) **U.S. Cl.** **623/17.11**

(58) **Field of Search** 623/17, 16, 12, 623/17.11, 17.12, 17.13, 17.14, 17.15, 17.16

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,834,757	*	5/1989	Brantigan	623/17
4,863,476	*	9/1989	Shepperd	623/17
5,665,122	*	9/1997	Kambin	623/17
5,865,848	*	2/1999	Baker	623/17

* cited by examiner

Primary Examiner—David H. Willse

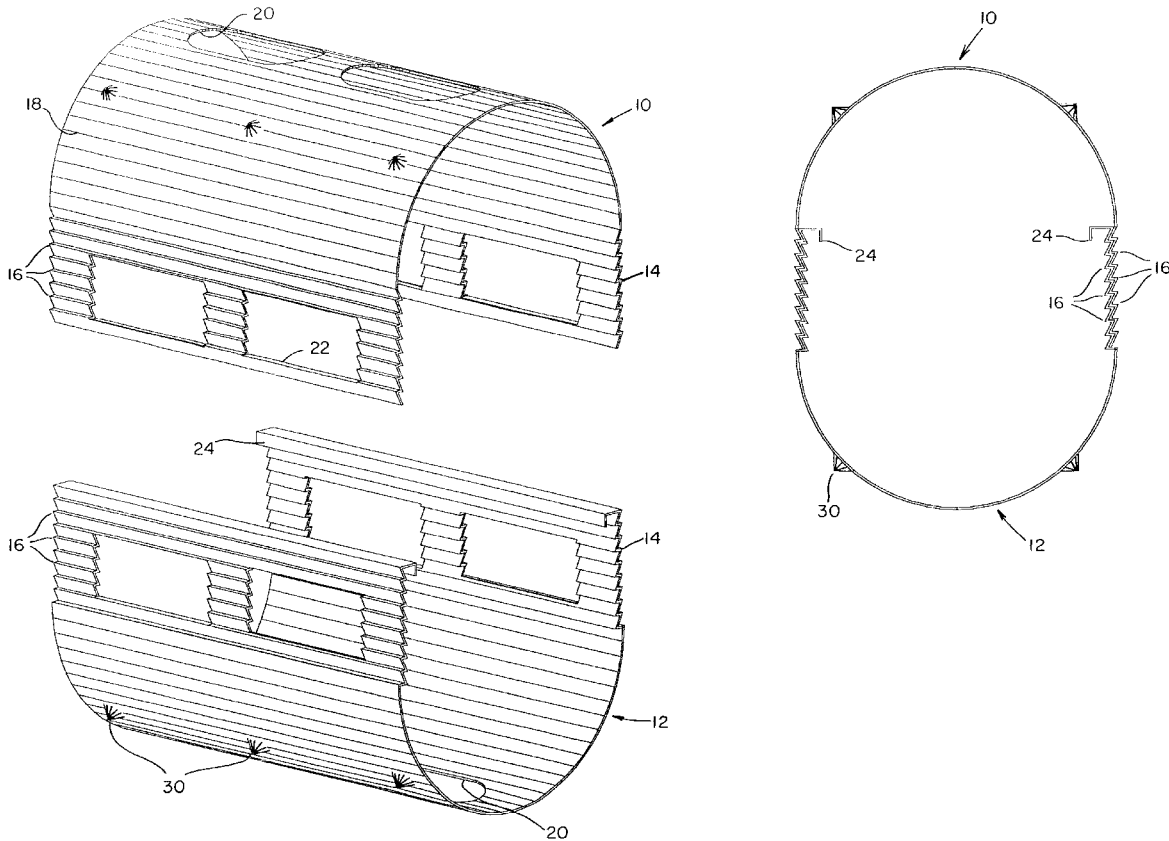
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(57) **ABSTRACT**

An expandable intervertebral implant includes two separate components having corrugated mating surfaces which resist compression and shifting when the parts are distracted by a special installation tool.

11 Claims, 6 Drawing Sheets



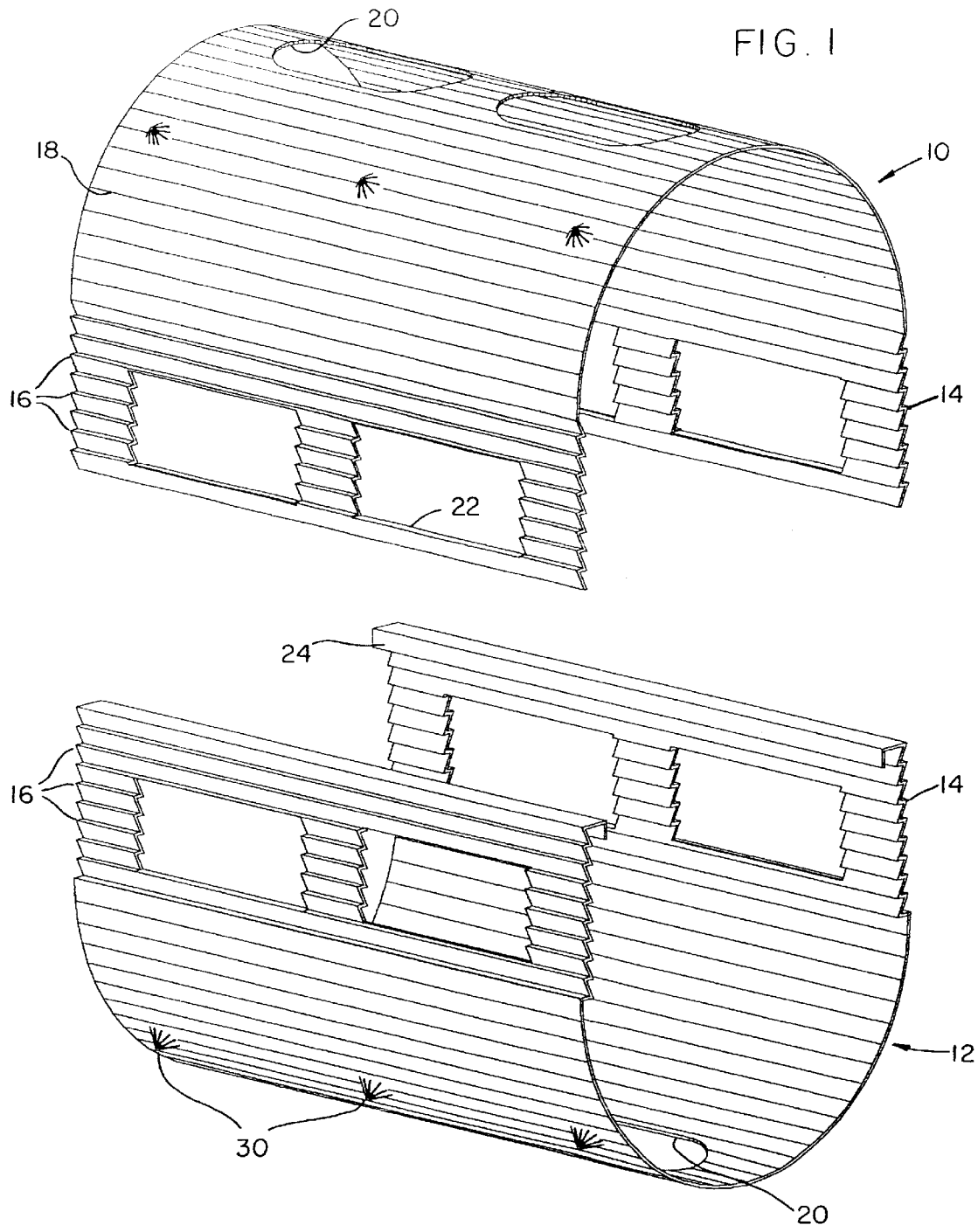


FIG. 2

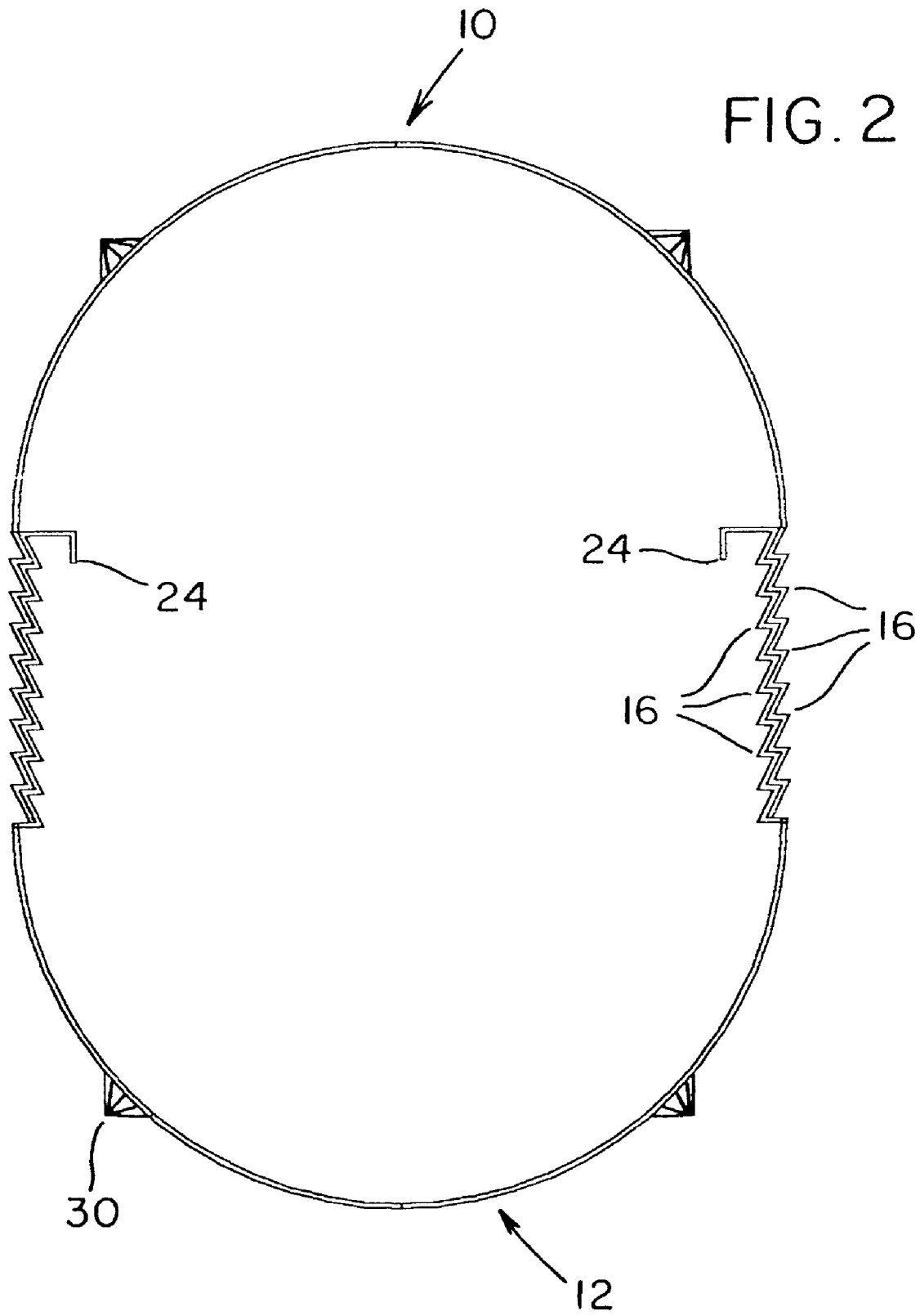
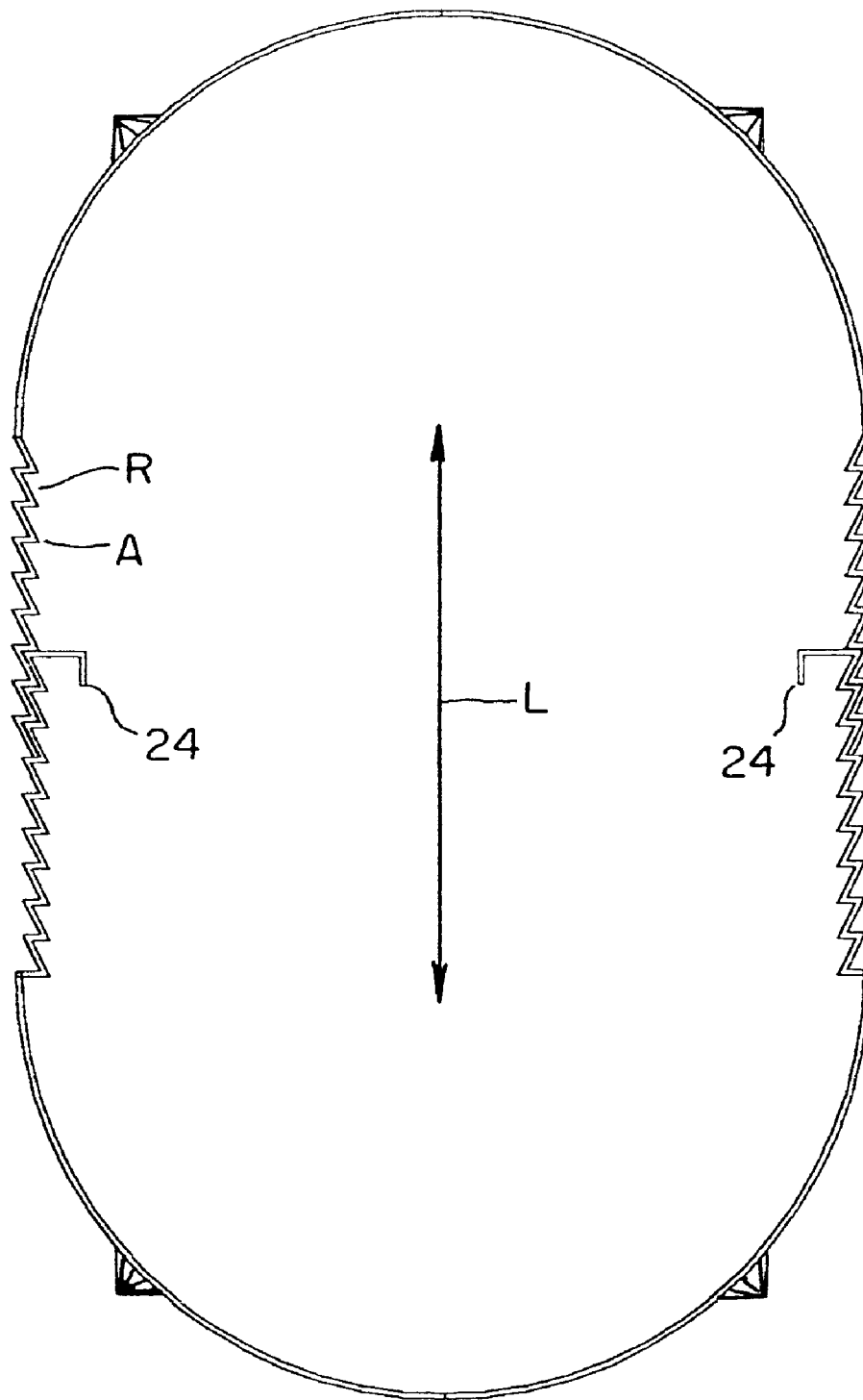


FIG. 3



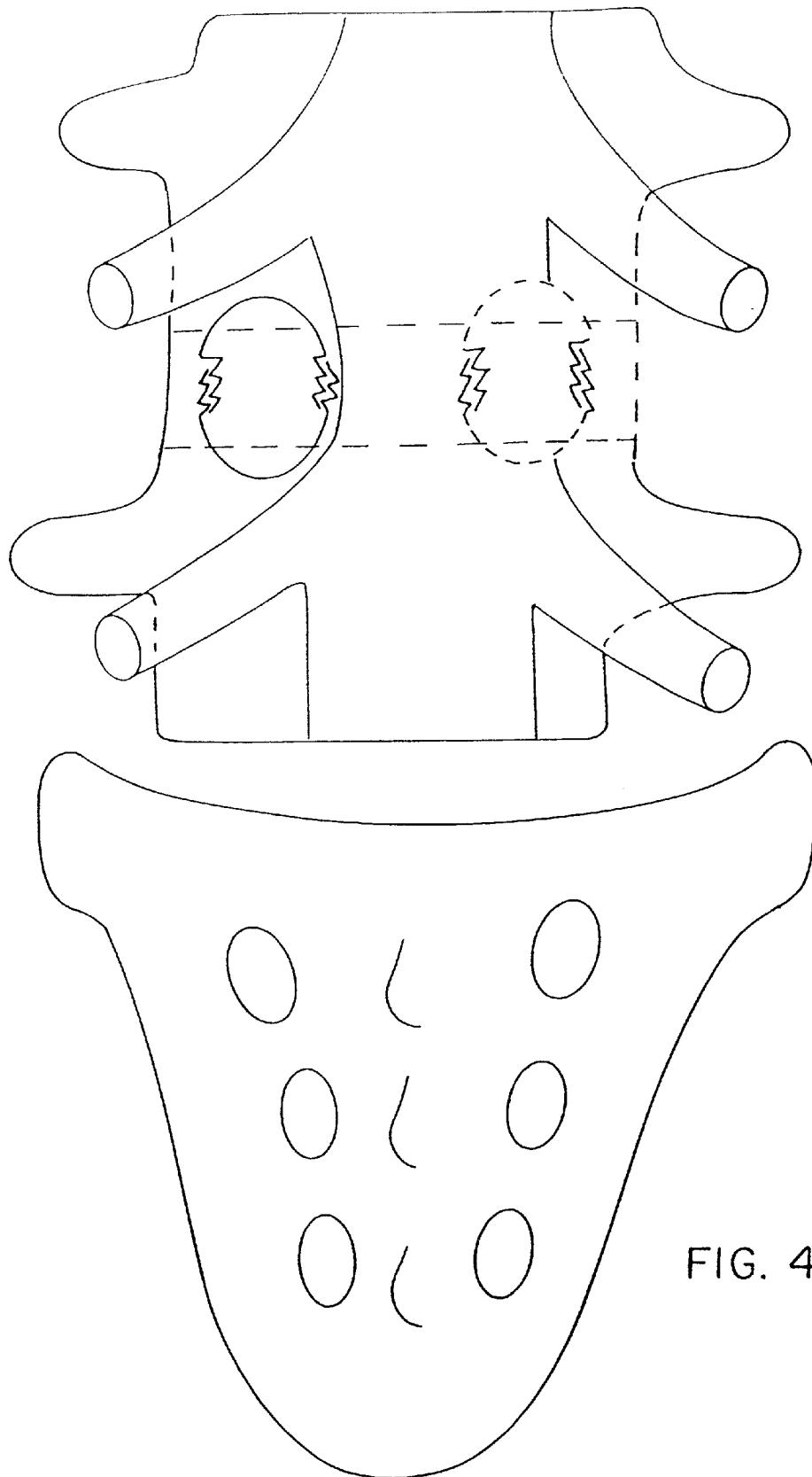


FIG. 4

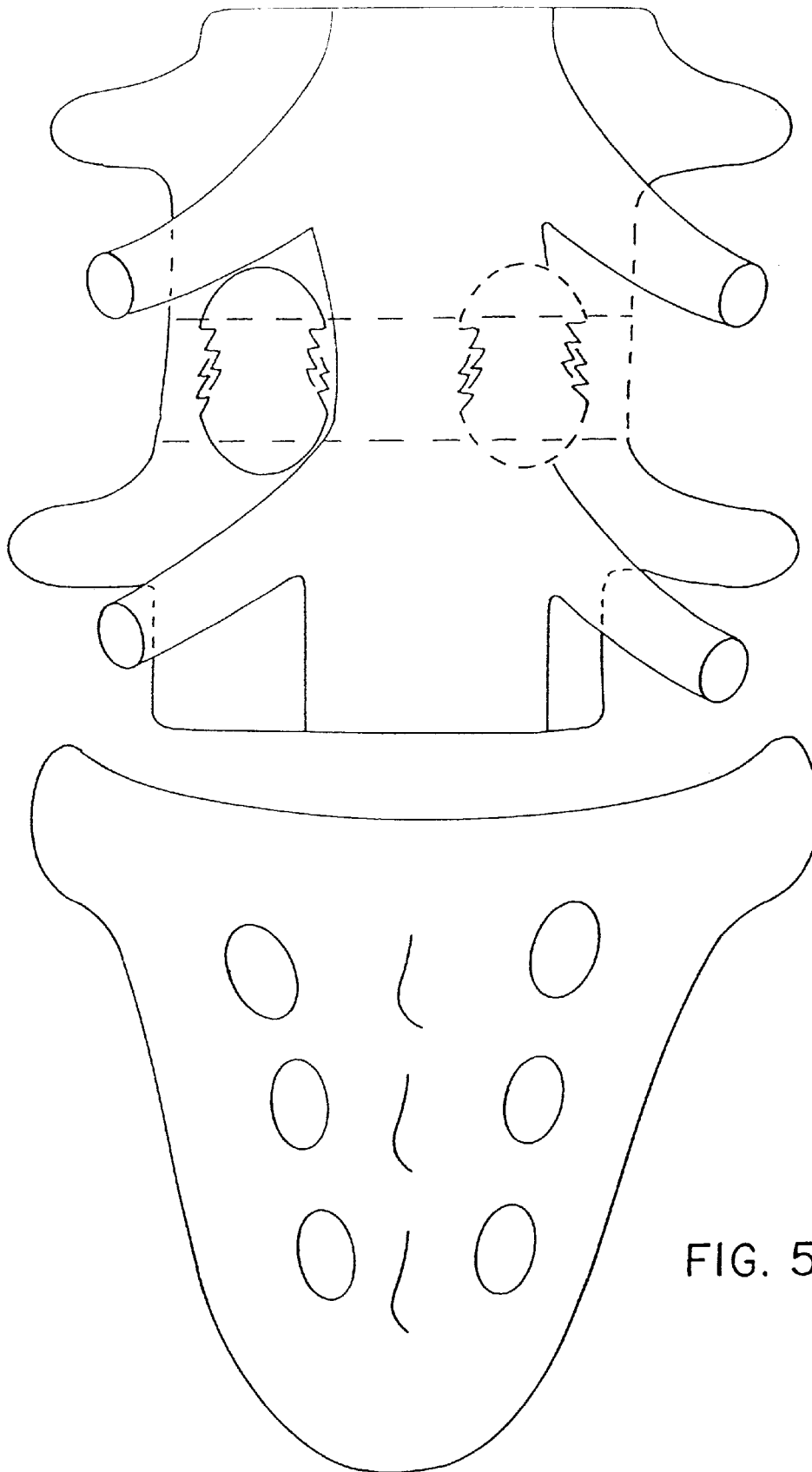
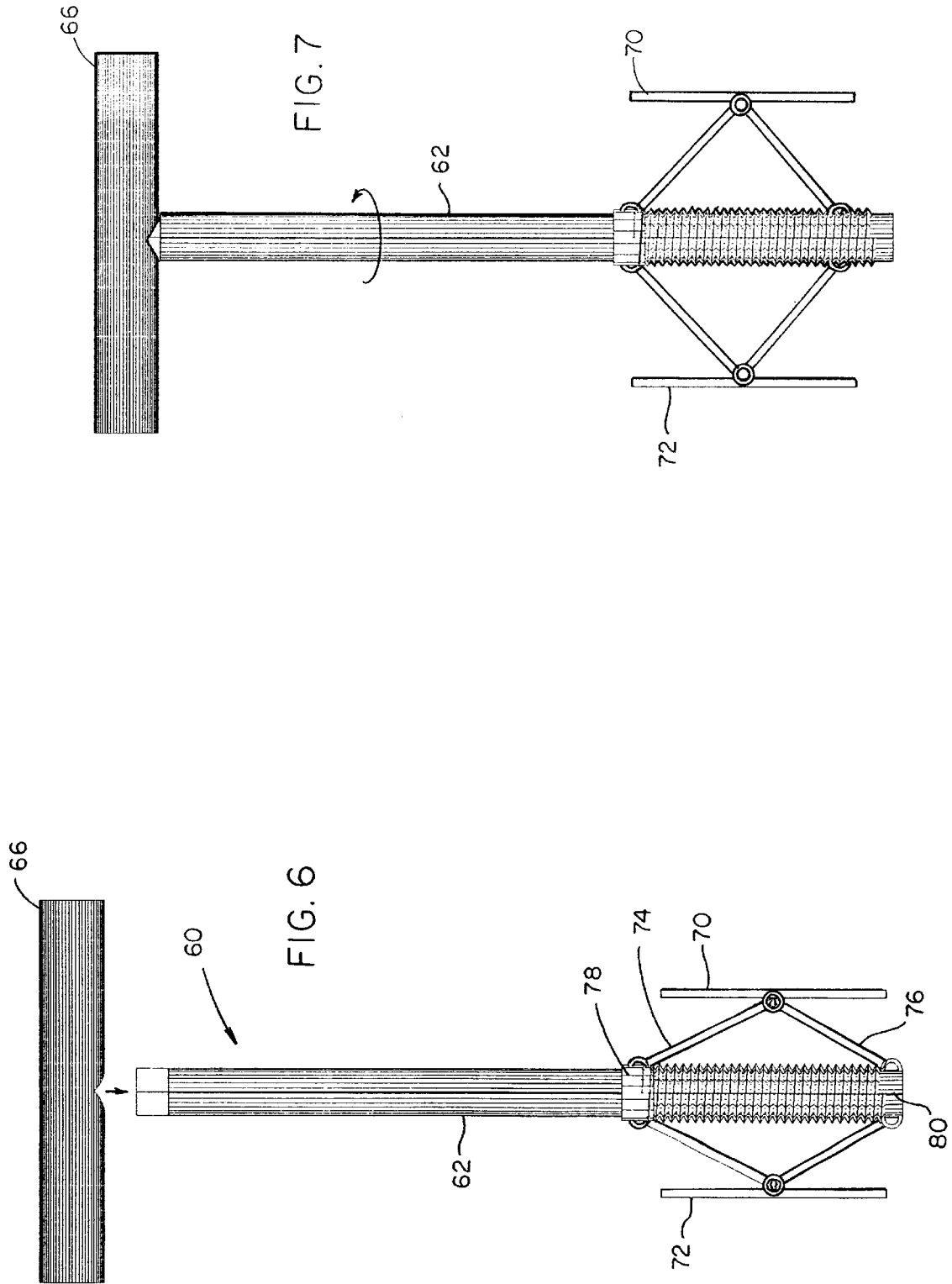


FIG. 5



EXPANDABLE INTERVERTEBRAL FUSION IMPLANT AND APPLICATOR

This application is a continuation-in-part of copending application Ser. No. 09/212,288 filed on Dec. 16, 1998.

BACKGROUND OF THE INVENTION

This invention relates to an expandable intervertebral fusion implant and applicator. The class of implements to which this invention pertains serve to stabilize adjacent vertebral elements, thereby facilitating the development of a bony union between them and thus long term spinal stability.

Of all animals possessing a backbone, human beings are the only creatures who remain upright for significant periods of time. From an evolutionary standpoint, this erect posture has conferred a number of strategic benefits, not the least of which is freeing the upper limbs for purposes other than locomotion. From an anthropologic standpoint, it is also evident that this unique evolutionary adaptation is a relatively recent change, and as such has not benefitted from natural selection as much as have backbones held in a horizontal attitude. As a result, the stresses acting upon the human backbone (or "vertebral column"), are unique in many senses, and result in a variety of problems or disease states that are peculiar to the human species.

The human vertebral column is essentially a tower of bones held upright by fibrous bands called ligaments and contractile elements called muscles. There are seven bones in the neck or cervical region, twelve in the chest or thoracic region, and five in the low back or lumbar region. There are also five bones in the pelvic or sacral region which are normally fused together and form the back part of the pelvis. This column of bones is critical for protecting the delicate spinal cord and nerves, and for providing structural support for the entire body.

Between the vertebral bones themselves exist soft tissue structures—discs—composed of fibrous tissue and cartilage which are compressible and act as shock absorbers for sudden downward forces on the upright column. The discs allow the bones to move independently of each other, as well. The repetitive forces which act on these intervertebral discs during repetitive day-to-day activities of bending, lifting and twisting cause them to break down or degenerate over time.

Presumably because of humans' upright posture, their intervertebral discs have a high propensity to degenerate. Overt trauma, or covert trauma occurring in the course of repetitive activities disproportionately affect the more highly mobile areas of the spine. Disruption of a disc's internal architecture leads to bulging, herniation or protrusion of pieces of the disc and eventual disc space collapse. Resulting mechanical and even chemical irritation of surrounding neural elements (spinal cord and nerves) cause pain, attended by varying degrees of disability. In addition, loss of disc space height relaxes tension on the longitudinal spinal ligaments, thereby contributing to varying degrees of spinal instability such as spinal curvature.

The time-honored method of addressing the issues of neural irritation and instability resulting from severe disc damage have largely focused on removal of the damaged disc and fusing the adjacent vertebral elements together. Removal of the disc relieves the mechanical and chemical irritation of neural elements, while osseous union (bone knitting) solves the problem of instability.

While cancellous bone appears ideal to provide the biologic components necessary for osseous union to occur, it

does not initially have the strength to resist the tremendous forces that may occur in the intervertebral disc space, nor does it have the capacity to adequately stabilize the spine until long term bony union occurs. For these reasons, many spinal surgeons have found that interbody fusion using bone alone has an unacceptably high rate of bone graft migration or even expulsion or nonunion due to structural failure of the bone or residual degrees of motion that retard or prohibit bony union. Intervertebral prostheses in various forms have therefore been used to provide immediate stability and to protect and preserve an environment that fosters growth of grafted bone such that a structurally significant bony fusion can occur.

U.S. Pat. No. 5,505,732, No. 5,653,762, No. 5,665,122, and No. 5,683,463 describe different prior spinal implants. The implant shown in U.S. Pat. No. 5,483,463 is hollow and tubular, with communicating windows in the top and bottom surfaces. External ribs, which may be serrated, stabilize the implant once it is inserted between the vertebrae. In U.S. Pat. No. 5,665,122, an intervertebral cage is rendered expandable by a wedging mechanism. The degree of expansion is rather limited, however. U.S. Pat. Nos. 5,653,762 and 5,505,732 show shaft-type tools used for installing implants. The prior devices do not enable one to achieve great ranges of implant height.

Limitations of most present-day intervertebral implants are significant and revolve largely around the marked variation in disc space shape and height that results from either biologic variability or pathologic change. For example, if a disc space is 20 mm in height, a circular implant bridging this gap requires a minimum diameter of 20 mm just to contact the end plate of the vertebral bone. Generally, end plate disruption must occur to allow a generous bony union, meaning that an additional 2–3 mm must be added on either end, resulting in a final implant size of 24–26 mm. During implantation from an anterior approach (from the front of the body), excessive retraction (pulling) is often required on the great blood vessels which greatly enhances the risk of devastating complications such as vascular tears or thrombosis. On the other hand, during a posterior approach, large implant diameters may require excessive traction on neural elements for adequate placement, even if all posterior bony elements are removed. In some instances, an adequate implant size cannot be inserted posteriorly, particularly if there is a significant degree of ligamentous laxity requiring higher degrees of distraction to obtain stability by tautening the annular ligamentous tension band. Compromising on implant size risks sub-optimal stability or a loose implant, which has a greater chance for migration within or expulsion from the disc space. The alternative of excessively retracting neural elements to facilitate a posterior implant application results in a neuropraxia at best and permanent neural damage at worst.

SUMMARY OF THE INVENTION

It is the object of this invention to provide an expandable intervertebral fusion implant that is both simple to manufacture and simple to use in daily clinical surgical practice while remaining versatile enough to address the complex biologic and pathologic variability of the human spine.

It is also intended that this device be applicable to all generally accepted surgical approaches to the spine, including microsurgical and endoscopic applications.

To achieve these objectives, a pair of semicylindrical shells are distracted inside an intervertebral space that has been appropriately prepared for fusion. An expansible instal-

lation tool is used to achieve optimal distraction and the shells are held apart by corrugations in their side walls. The installation tool is then unscrewed and disengaged, leaving the component parts as a stable assembly that can be packed with bone to promote osseous union.

The present invention not only provides an expandable intervertebral fusion implant, but also lends itself readily to use in anterior, lateral and posterior approaches. In addition, one can insert devices of different sizes in a single intervertebral space to address lateral differences in disc space height to account for degrees of scoliosis, or lateral spinal curvature

The cylindrical implant is split horizontally so that the cranial (upper) and caudal (lower) shells that contact the vertebral bones above and below can be distracted, or spread apart, by a screw-type installation tool until optimal distraction of the vertebral elements and appropriate tension on the ligamentous structures is achieved. The installation tool is then retracted, allowing the two components to seat against one another and lock together, and the tool is then removed. The implant assembly is now packed with allograft or auto graft bone to allow long term bony union to develop between the vertebral elements.

The advantages provided by this invention include (1) the fact that both the tool and the implant components are of simple manufacture, and (2), because of its expandable nature, this implant has the potential for use in microsurgical laminotomy, where only a small opening is made in the spine, resulting in minimal retraction of neural structures and maximizing preservation of posterior bony and ligaments spinal elements. Most existing posterior interbody approaches require extensive bone removal to achieve spinal fusion whether or not an implant is used.

BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings,

FIG. 1 is an exploded front elevation of an intervertebral fusion implant embodying the invention;

FIGS. 2 and 3 are front elevations of the implant, shown in retracted and expanded configurations, respectively;

FIG. 4 is an anterior view of a pair of implants installed between two vertebrae, without expansion;

FIG. 5 is a similar view, showing implants which have been expanded between the vertebrae;

FIGS. 6 and 7 are retracted and expanded views, respectively, of an installation tool.

DESCRIPTION OF THE PREFERRED EMBODIMENT

An expandable intervertebral fusion implant embodying the invention appears in FIGS. 1-5. The implant in every case comprises a pair of semicylindrical shells 10, 12 which when assembled form a generally tubular implant assembly.

The shells have complementary corrugated skirts 14, which provide a ratcheting size adjustment and prevent the parts from shifting laterally. On each shell, the corrugations or teeth 16 are angled (raked) in the direction of the central curved portion 18, so that the shells can be spread apart by an installation tool after the parts are assembled, but reverse, inward, movement cannot occur once the implant has been installed. One can see that, for each tooth, there is a ramping surface "R", which is oblique to the line of relative movement "L" (FIG. 3) of the shells, meeting an abutment surface "A" which is substantially perpendicular to the line of relative movement.

As shown in the exploded view of FIG. 1, each shell preferably has several windows to encourage interlocking bone growth. The preferred arrangement is a pair of oval central windows 20 in the curved central portion 18 of each shell, and a pair of rectangular windows 22 in each skirt 14.

The skirts on the lower shell lie between those of the upper shell, when the device is oriented as in the drawings, so the inner skirts are those on the lower shell. Each of these inner skirts is provided with a protruding element, specifically a hooked flange 24, so that, if it becomes desired to removed the implant, the surgeon can grasp the flanges and draw them together to release the teeth from engagement and allow the implant to retract.

The points 30 adjacent the windows dig into the surfaces of the bones between which the implant is installed, and, together with compression forces from the spinal ligaments, prevent the shells from shifting lengthwise with respect to one another.

FIG. 2 shows the shells assembled, as close together as possible, as is done prior to installation by the surgeon. FIG. 3 shows the shell in an exemplary expanded configuration, as following the installation described below.

The shells may be made of the same material, or different materials. Suitable materials include stainless steel, titanium, ceramic, graphite, carbon fiber material, and various plastics and composites of the foregoing. The selection of material may affect the dimensions or proportions of the parts somewhat, but is generally a matter of design choice.

To install an implant, the shells are assembled (FIG. 2) and placed over the jaws of the installation tool. FIG. 4 shows a pair of implants, unexpanded, situated between a pair of vertebrae. Then the jaws are spread by turning the handle clockwise, forcing the shells outward into contact with the bones above and below. The points on the shells dig into the bony material somewhat to resist accidental dislodgement of the implant subsequently. Once the implant has been adequately expanded, the surgeon manipulates the tool to retract the jaws, and then removes it from within the implant. FIG. 5 shows the implants in their permanent, expanded configuration.

The installation tool 60 is shown in FIGS. 6 and 7. It includes a shaft 62 having one non-circular end 64 for receiving a removable handle 66. The other end has a radially expandable structure 68, preferably in the form of two jaws 70, 72, each of which is connected at its midpoint to the outer ends of a pair of pivoting arms 74, 76. The inner ends of these arms are hinged to respective collars 78, 80 or the like at the ends of a screw thread 82 on the shaft. The screw mechanism changes the spacing between the collars as the handle is rotated, thus driving the jaws in (FIG. 6) or out (FIG. 7).

The tool may be conveniently used not only to expand the implant in situ, but also to place the implant prior to expansion. The assembled implant (FIG. 2) is placed over the jaws prior to placement. The surgeon can then, using the tools as a manipulator, position the implant in its intended location between vertebrae. Then the handle is turned to expand the implant to its desired final height, and finally the jaws are retracted, so that the tool can be removed from the site.

Since the invention is subject to modifications and variations, it is intended that the foregoing description and the accompanying drawings shall be interpreted as only illustrative of the invention defined by the following claims.

I claim:

1. An expandable intervertebral fusion implant comprising a pair of shells which when joined form substantially a

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hollow tube, each of said shells having a pair of corrugated skirts forming interengaging toothed structures for permitting unidirectional expansion of the tube from a retracted initial height to an expanded installed height.

2. The invention of claim 1, wherein each shell is a single piece.

3. The invention of claim 2, wherein each shell is made of sheet metal.

4. The invention of claim 3, wherein the metal is stainless steel.

5. The invention of claim 3, wherein the metal is a titanium alloy.

6. The invention of claim 3, wherein the metal has a thickness in the range of 0.01 to 0.1 inches.

7. The invention of claim 2, wherein each shell is made of a material comprising carbon fibers.

8. The invention of claim 1, wherein the skirts of one of said shells nest within those of the other of said shells, and the inner skirts each have an inwardly protruding element, whereby the inner skirts may be grasped and pulled toward one another in order to disengage the skirts when it is desired to remove the implant.

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9. The invention of claim 1, wherein each shell has a plurality of windows through which bone may grow.

10. The invention of claim 1, wherein each shell has a plurality of outwardly directed points for digging into bones between which the implant is placed, to resist longitudinal movement of the implant.

11. A method of inserting an implant between vertebral elements to maintain spacing between the elements while promoting osseous union between them, said method comprising steps of

assembling a pair of semicylindrical shells having ratcheting means thereon to form an implant having unidirectional adjustable height,

placing the implant on an expansible portion of an installation tool,

inserting the implant between said vertebral elements, expanding the expansible portion of the installation tool, to expand the implant to a desired final height, and removing the installation tool.

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