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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 :		(11) International Publication Number:
A61F 2/44	A1	WO 00/35389
		(43) International Publication Date: 22 June 2000 (22.06.00)

(21) International Application Number: PCT/US99/27940

(22) International Filing Date: 16 December 1999 (16.12.99)

(30) Priority Data:

09/212,288	16 December 1998 (16.12.98)	US
09/282,172	31 March 1999 (31.03.99)	US
09/365,223	30 July 1999 (30.07.99)	US

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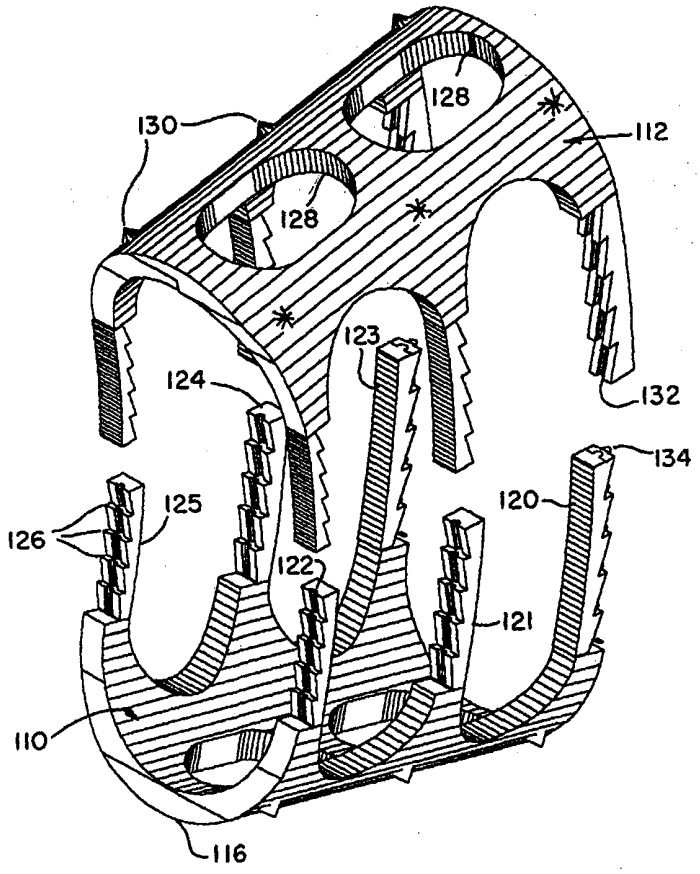
(81) Designated States: AU, CA, JP, NZ, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: EXPANDABLE INTERVERTEBRAL FUSION IMPLANT AND APPLICATOR

(57) Abstract

An expandable intervertebral fusion implant includes a pair of semi-cylindrical shells (110) (112) having mating surfaces which resist shifting when the parts are assembled. In one embodiment of the invention, the shells (110) (112) have pillars (120)-(125) provided with teeth (126) which permit the shells to be ratcheted outward after they have been placed between spinal elements. The pillars (120)-(125) may be curved, or non-perpendicular to the shells (110) (112), so that the resulting implant is tapered, to accommodate non-parallel spinal element, and plates, thus maintaining proper spinal curvature.



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Expandable Intervertebral Fusion Implant and Applicator

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. Patents 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 Patent 5,483,463 is hollow and tubular, with communicating windows in the top and bottom surfactes. External ribs, which may be serrated, stabilize the implant once it is inserted between the vertebrae. In Patent 5,665,122, an intervertebral cage is rendered expandable by a wedging mechanism. The degree of expansion is rather limited, however. Patents 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.

It is an 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, the invention provides a pair of semicylindrical shells which may be distracted inside an intervertebral space that has been appropriately prepared for fusion. An expansible installation tool is used to achieve optimal distraction and the shells are held apart by corrugations in their side walls, or by a separate spacer. The installation tool is thereafter disengaged, leaving the component parts as a stable assembly that can be packed with bone to promote osseous union.

The present invention 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 implant has the general form of a cylinder or tube 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 an expanding installation tool until optimal distraction of the

vertebral elements and appropriate tension on the ligamentous structures is achieved. Upon retraction of the tool, the two components seat against one another and lock together, and the tool may be 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.

In an alternative embodiment of the invention, one end of each shell is larger, and has larger corrugations relative to the smaller end. This embodiment therefore has the potential to expand to a greater height to address needs for greater kyphosis or lordosis at a single interspace. By varying the ratio of height of the larger corrugations to the smaller ones, varying degrees of angulation can be accommodated.

In the accompanying drawings,

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

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

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

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

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

Figure 8 is an exploded perspective view of a pair of shells forming an implant according to the invention;

Figure 9 is a side elevation, showing the shells assembled in a collapsed configuration;

Figure 10 is a view like Figure 9, showing the shells expanded between adjacent

vertebral elements;

Figure 11 is a view like Figure 9, showing an alternative embodiment of the invention;

Figure 12 is a perspective view of an anterior end cap shown in Figure 9; and

Figure 13 is a similar view of a posterior endcap.

Figure 14 is a perspective view, from the side, of another type of expandable intervertebral fusion implant embodying the invention;

Figure 15 is an exploded front elevation thereof, with a spacer added;

Figure 16 is an unexploded front elevation of the implant and spacer;

Figure 17 is a perspective view showing the spacer locked in place;

Figures 18a - 18c show alternative spacers having, respectively, neutral, lordotic and kyphotic tapers; and

Figure 19 shows the handle of the installation tool having been removed, and a spacer being installed over the tool's shaft.

An expandable intervertebral fusion implant embodying the invention appears in Figures 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 Figure 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. Together with compression forces from the spinal ligaments, the points prevent the shells from shifting lengthwise with respect to one another.

Figure 2 shows the shells assembled, as close together as possible, as is done prior to installation by the surgeon. Figure 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 (Figure 2) and placed over the jaws of the installation tool. Figure 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. Figure 5 shows the implant in its permanent, expanded configuration.

The installation tool 60 is shown in Figures 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.

An alternative embodiment of the invention appears in Figures 8 - 10. This implant comprises a pair of mating metal shells 110, 112. Each shell has a semicylindrical base 116 and an array of pillars 120 - 125 extending parallel to one another from the lateral edges 118 of the base.

In this embodiment, each of the pillars is curved, following the circumference of an imaginary cylinder having an axis "A" extending along the line of intersection between the planes forming the lateral edges of the two shells. Each pillar has a generally rectangular cross-section. Three sides of the pillar are smooth, while a fourth is serrated, having a plurality of triangular teeth 126 raked in one direction to as to permit only expansion of the shells after they have been assembled initially in a retracted position.

The teeth on the endmost pillars 120, 122, 123, 125 face in opposite longitudinal directions, so that when the shells are assembled, no relative longitudinal movement is possible, and the shells can move away from one another only when sufficient expanding force is applied to bend the pillars slightly, allowing the interfering teeth to pass over one another. During expansion, each time the tips of the teeth clear, the pillars snap back to their rest positions; this ratcheting action prevents the implant from collapsing, and also may provide useful tactile or audible feedback to the surgeon.

In the preferred form of this embodiment, the pitch (spacing) of the teeth on each pillar is proportional to its distance from the axis "A", that is, the more distant teeth have a greater pitch. This permits each incremental expansion of the shells to follow an arc about the axis "A", so that the taper angle of the implant grows as the implant is expanded.

Alternatively (Fig. 4), the pillars can be straight and parallel, with all the teeth having the same pitch, so that the relative movement of the shells during expansion is purely translational, and the taper angle of the implant remains constant, according to the angle at which the pillars extend from the longitudinal edges of the shell. Other geometries may prove useful as well. One could extend the principles of the invention to produce a device whose taper angle actually decreases during expansion, for example.

The shells form an open-ended structure. It may be desired to close one or both ends. If so, an end cap may be applied over an open end. Preferred end caps, include a oval plate 40 having slight outward concavity (Fig. 5) or convexity (Fig. 6) corresponding to the shapes of the ends of the implant. The cap is retained on the implant by a pair of arms 42,44, each of which has a hook 46 or the like at its free end, for engaging over the far end of the implant. Grooves or other structure, not shown, may be provided on the implant surfaces to retain the caps more securely.

The shells are provided with complementary structures such as detents 32 and ribs 34 on opposing teeth, to keep the shells from moving sideways once the spacer has been installed

It may be appreciated that changes in geometry and the like may be made to the elements of the invention while retaining their essential function. For example, the bases of the shells might be frustoconical, rather than cylindrical, and the number of pillars on either side of each shell could be any plural number.

In yet another form of this invention (Figs. 14 - 19), the implant comprises at least the pair of semicylindrical shells 210, 212, and, in most cases, a spacer 240 having angularity and height selected to provide the desired effective height and shape of the implant assembly. The shells have complementary mating surfaces, one having vee-profile ridges 214 and the other having vee-grooves 216 for preventing the parts from shifting laterally. One end of each half-shell is closed by an end wall 220 having a vee-shaped ridge 222 on its diametral edge 224. The other half-shell also has one end wall, this having a vee-groove 226 shaped to receive the beveled edge of its counterpart. When assembled, the nesting edges of the end walls prevent longitudinal shifting of the parts.

The longitudinal surfaces of the shells also are interrupted by complementary structures such as a detent 232 on one shell and a protrusion 234 on its mate, to keep the parts from moving lengthwise once the spacer has been installed and the nesting diametral edges of the end walls are no longer in contact to perform this function.

Figure 15 shows the two shells exploded away from another, exaggerating the distraction which is produced during installation. The spacer 240 between the shells has a profile like the capital Greek letter omega, featuring a cylindrical center portion 242 between two parallel side plates 244, 246. The free edges 248, 250 of the side plates have

complementary vee-profiles, to prevent lateral shifting of the parts, as described before. Figure 16 show the parts assembled, as seen from the front and the rear, respectively. The isometric view (Fig. 17) reveals a pair of windows 252, 254 in one side wall of the spacer, similar to those in the shells. The spacer, being symmetrical, has windows in its other wall as well.

The spacers shown in Figures 18a - 18c differ in their longitudinal taper. In 18a, there is no taper; in 18b, the taper is front-to-rear (lordotic), and in 18c, the taper is rear-to-front (kyphotic). The protrusions 256 and detents 258 mark the front of the spacer.

To install an implant, the shells are assembled and placed in the selected empty intervertebral space by means of the tool, with its jaws retracted, and aligned with the spine. Then the jaws are spread but 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.

Figure 8 shows the jaws still distended. The handle 266 has been removed as suggested by the arrow, one spacer 240 now being passed over the handle end of the tool. The spacer is down the shaft, toward the jaws, until it lies partially in between the shells. The handle is then reinstalled on the tool, and turned counterclockwise to retract the jaws. With the jaws retracted, the tool can be removed from the site, and finally the spacer is pushed fully between the shells until the protrusions and detents seat, locking the assembly together.

Patent Claims

1. An expandable intervertebral fusion implant comprising

a pair of shells which when joined form substantially a tube,

means for permitting unidirectional expansion of the tube from a retracted initial height to an expanded installed height.

2. The invention of claim 1, wherein the expansion means is a ratcheting mechanism including interengaging toothed structures.

3. The invention of claim 2, wherein the toothed structures are a pair of corrugated skirts on each of the shells.

4. The invention of claim 3, wherein each of the skirts on one shell is substantially aligned with a counterpart skirt on the other shell, so that the skirts interfere with one another and their corrugations interengage to provide ratcheting unidirectional expansion, but to prevent retraction after placement.

5. The invention of claim 3, wherein each shell has a thickness in the range of .25 to 2.5 mm.

6. The invention of claim 3, wherein each shell is made of a material comprising carbon fibers.

7. The invention of claim 3, 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.

8. The invention of claim 2, wherein each of the shells comprises a generally semicylindrical base having lateral edges and a plurality of pillars projecting from each of the lateral edges,

at least some of the pillars on one shell having ratchet teeth adapted to engage complementary ratchet teeth on the other shell,

the teeth preventing the shells from moving toward one another, but permitting the shells to move away from one another as the pillars deflect when the shells are driven apart with sufficient force.

9. The invention of claim 8, wherein the pillars are non-perpendicular to the axes of their bases, so that the implant when assembled tapers from one end to the other.

10. The invention of claim 8, wherein the pillars are curved about a remote axis and have teeth whose pitch varies proportionately with the distance of the teeth from said axis, so that the shells have arcuate relative motion as they are expanded, and the taper angle of the implant increases during expansion.

11. The invention of claim 1, further comprising a spacer for placement between the shells, once they have been positioned in an intervertebral space, so as to give the implant a predetermined total height appropriate for the intervertebral space.

12. The invention of claim 11, wherein the spacer has mating surfaces complementary to those of the shells.

13. The invention of claim 11, wherein each shell has a pair of parallel walls interconnected by an intermediate member having a longitudinal through hole.

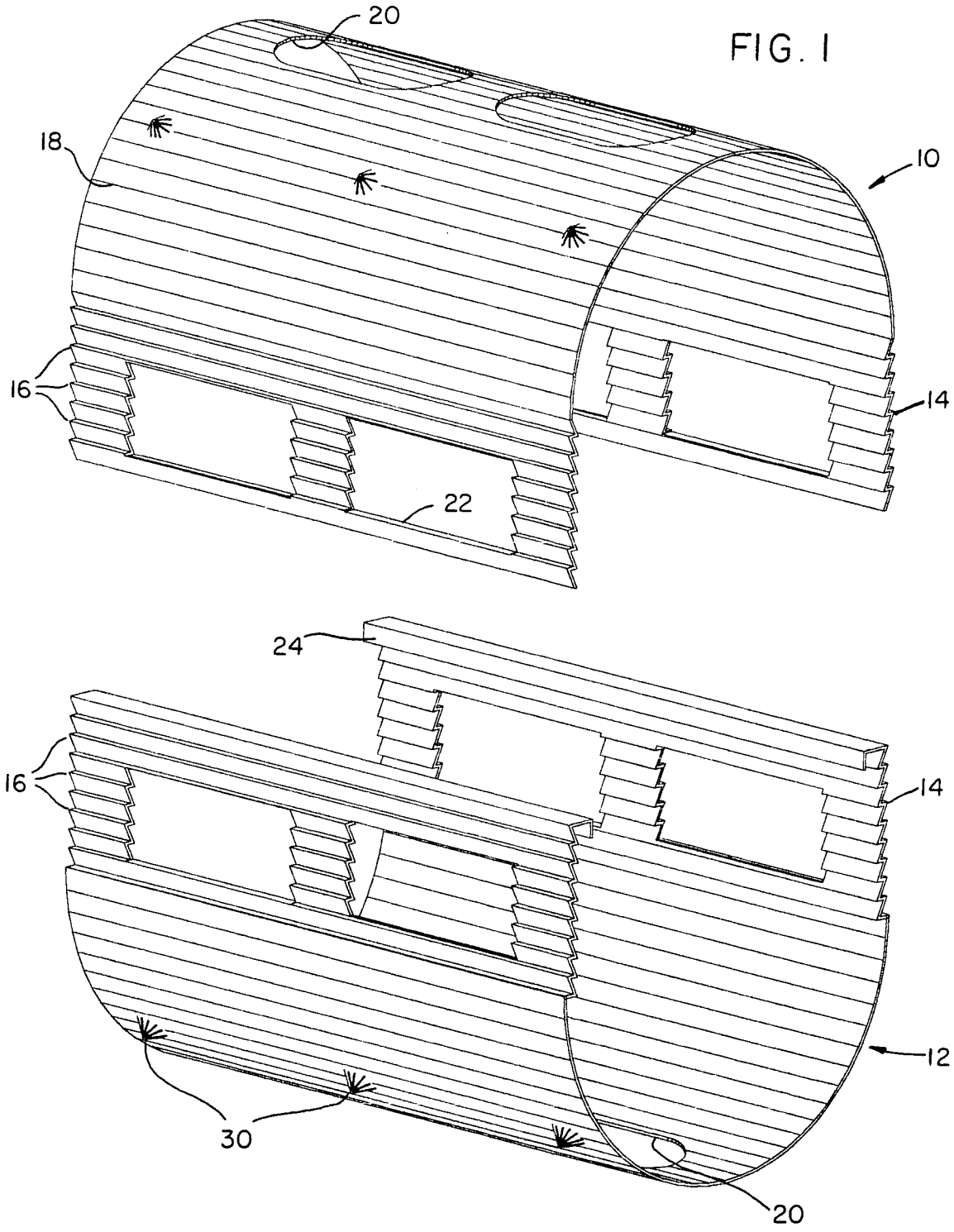
14. The invention of claim 11, wherein the longitudinal hole has an internal diameter substantially the same as that of said tube.

15. The invention of claim 1, wherein each of said shells has one end wall, said end walls having mating edges provided with complementary nesting profiles to prevent longitudinal shifting of said shells.

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

17. 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.

FIG. 1



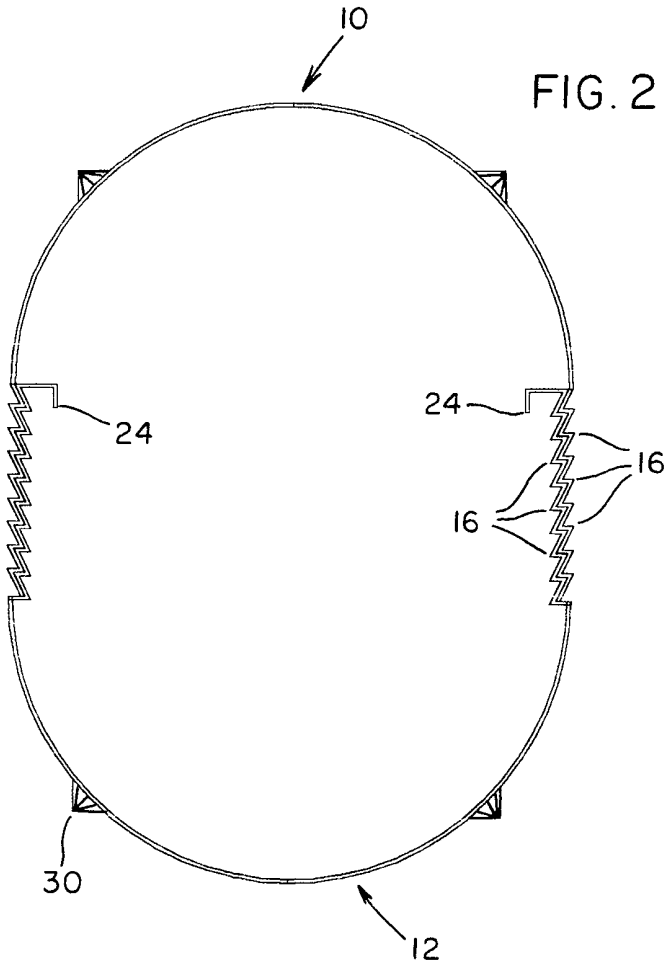
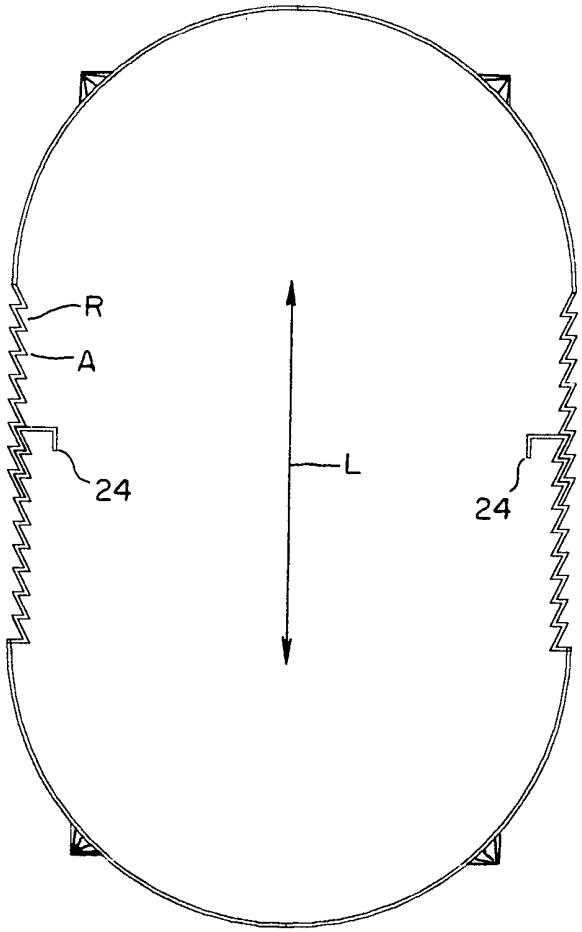


FIG. 2

FIG. 3



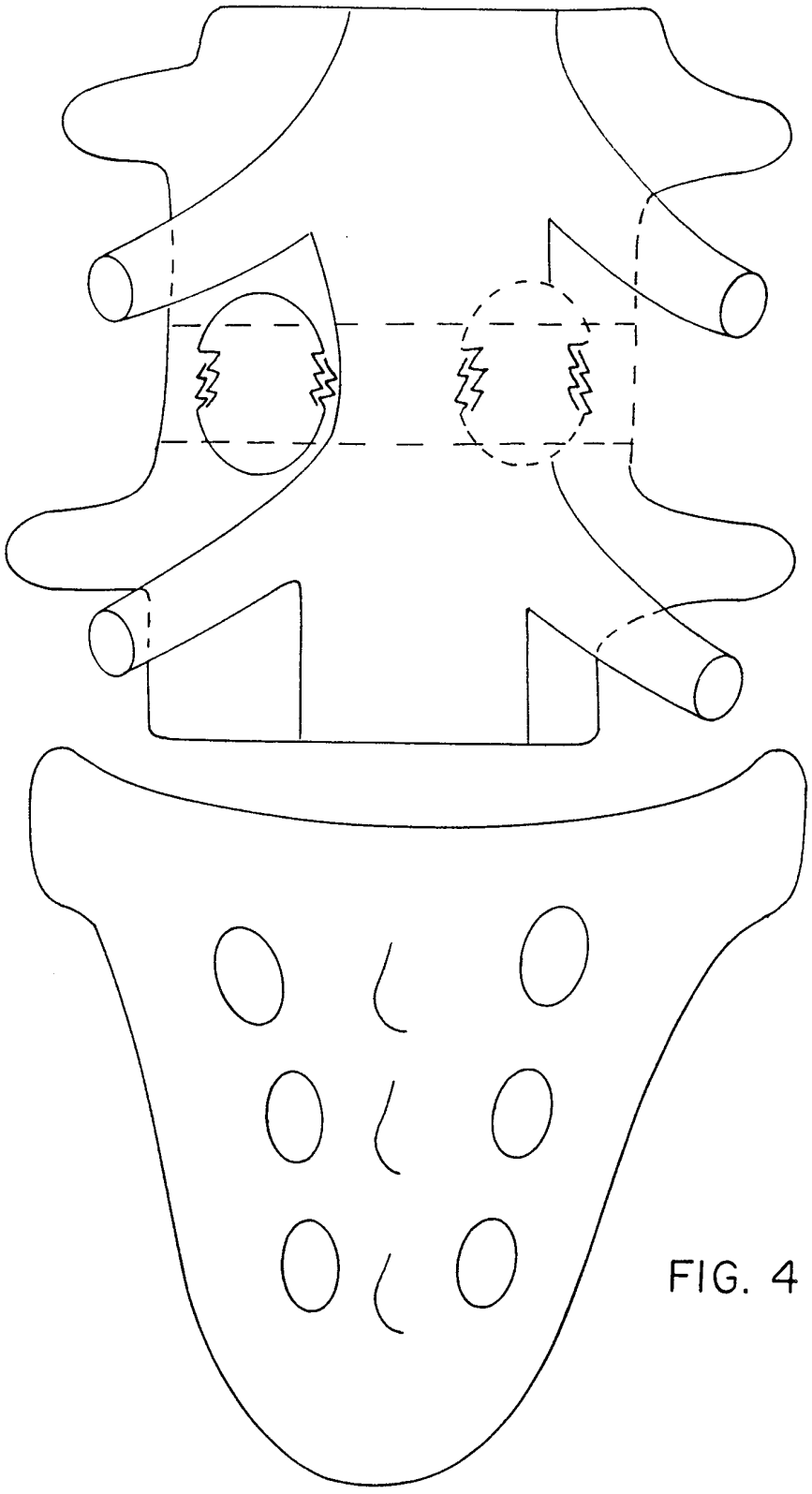


FIG. 4

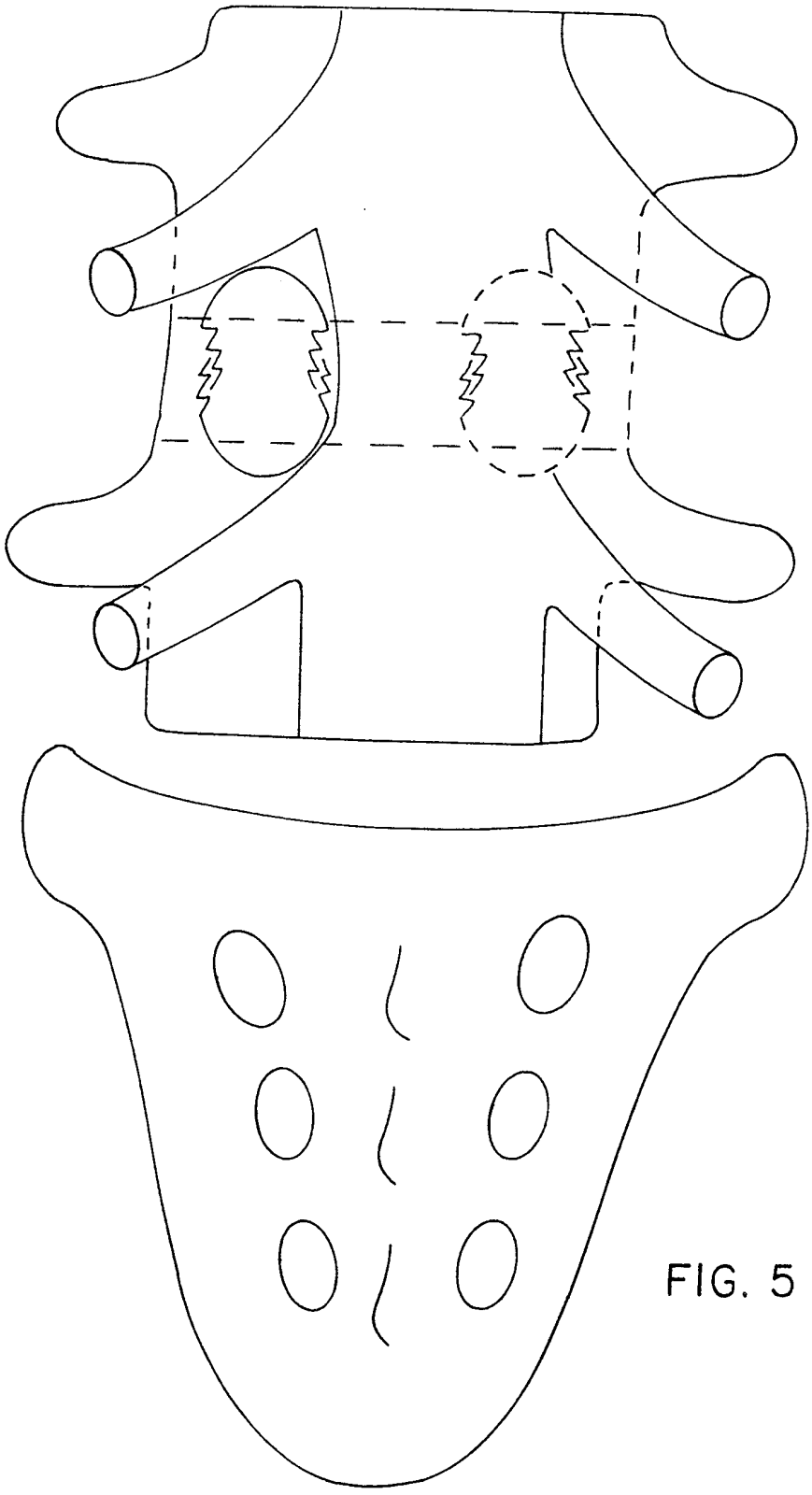


FIG. 5

FIG. 7

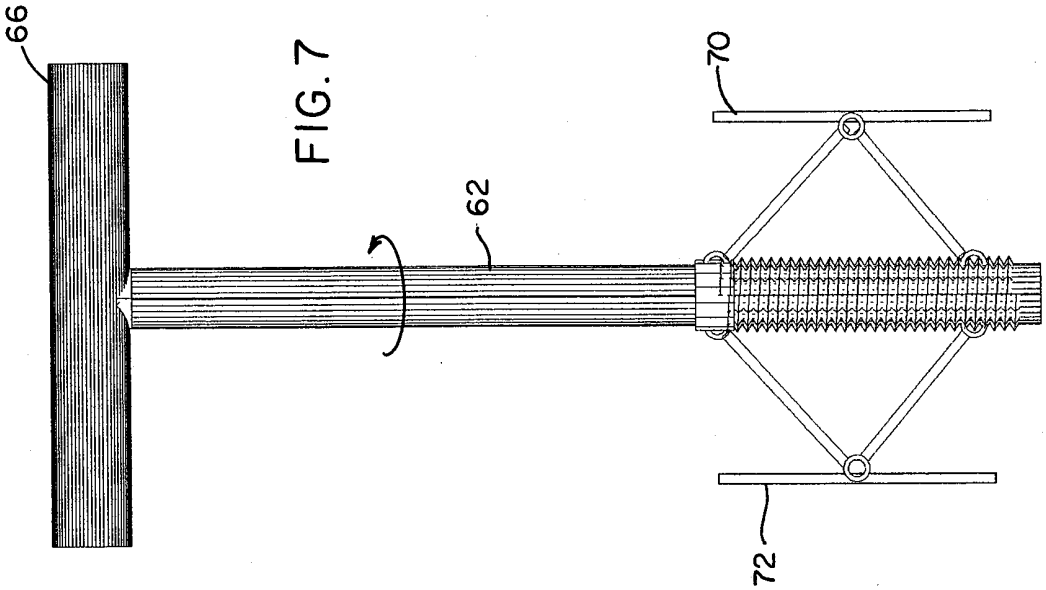
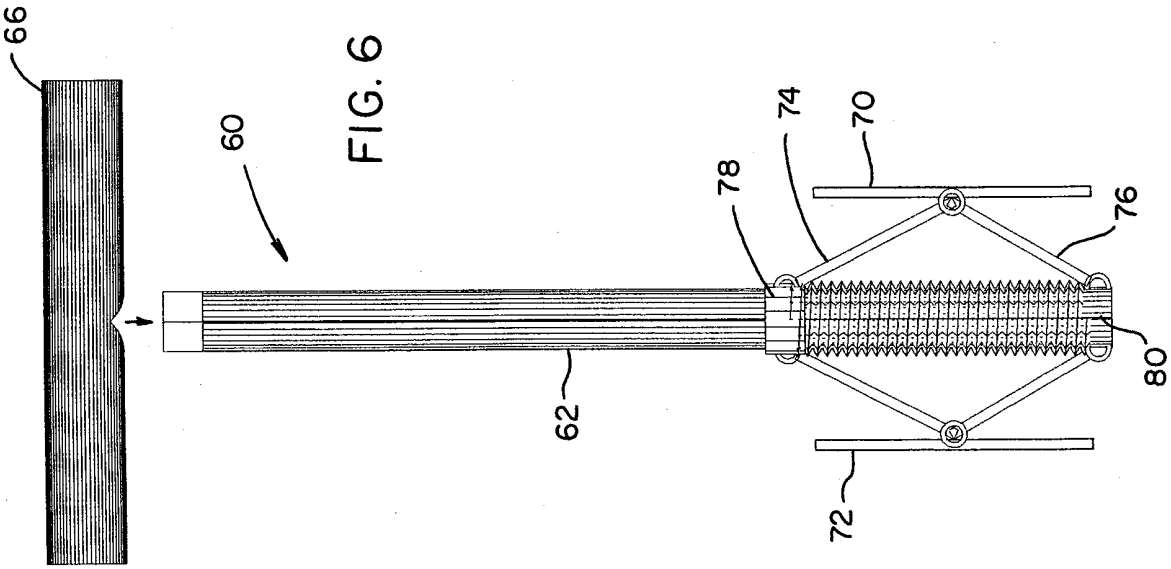


FIG. 6



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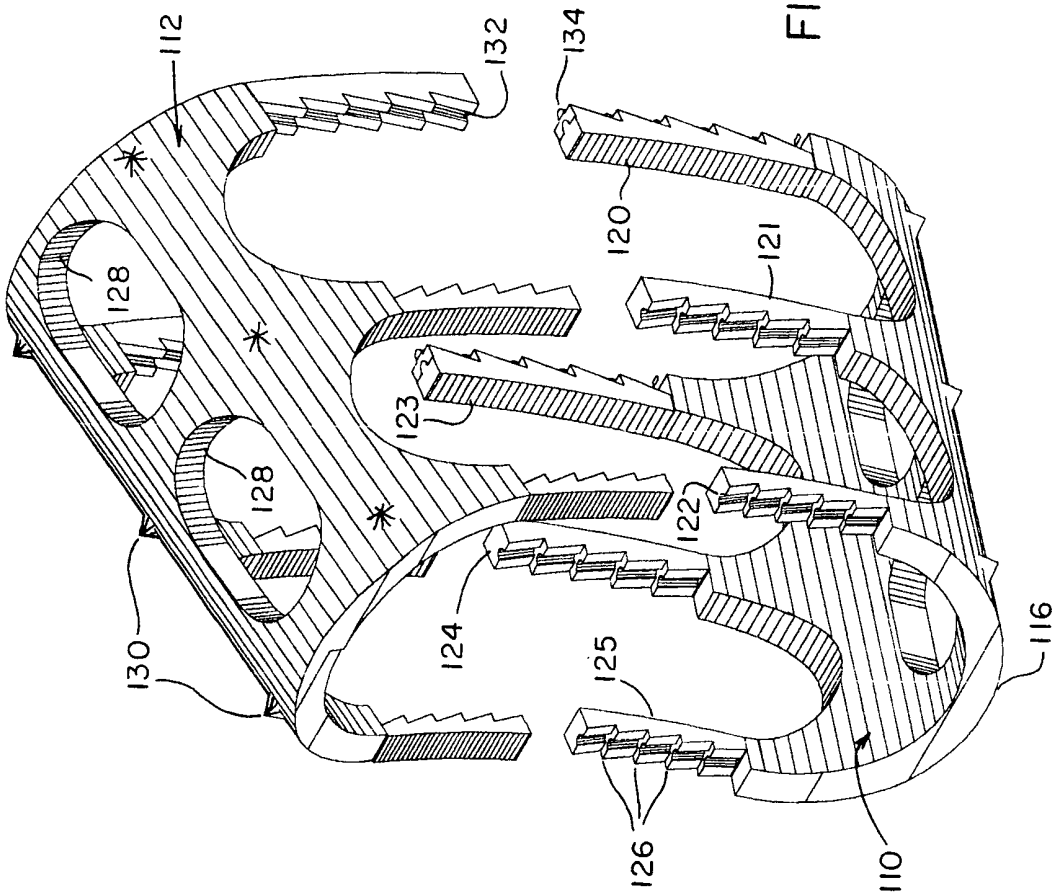


FIG. 8

FIG. 9

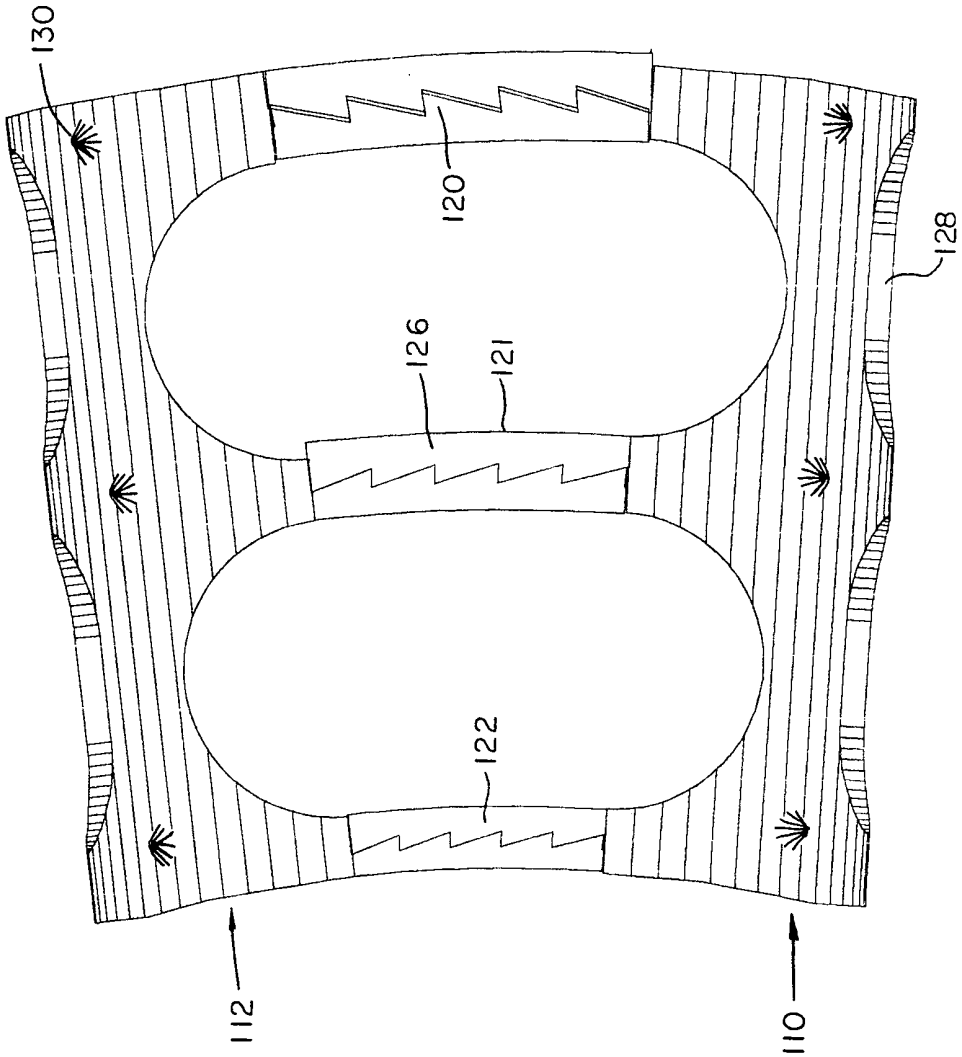


FIG. 10

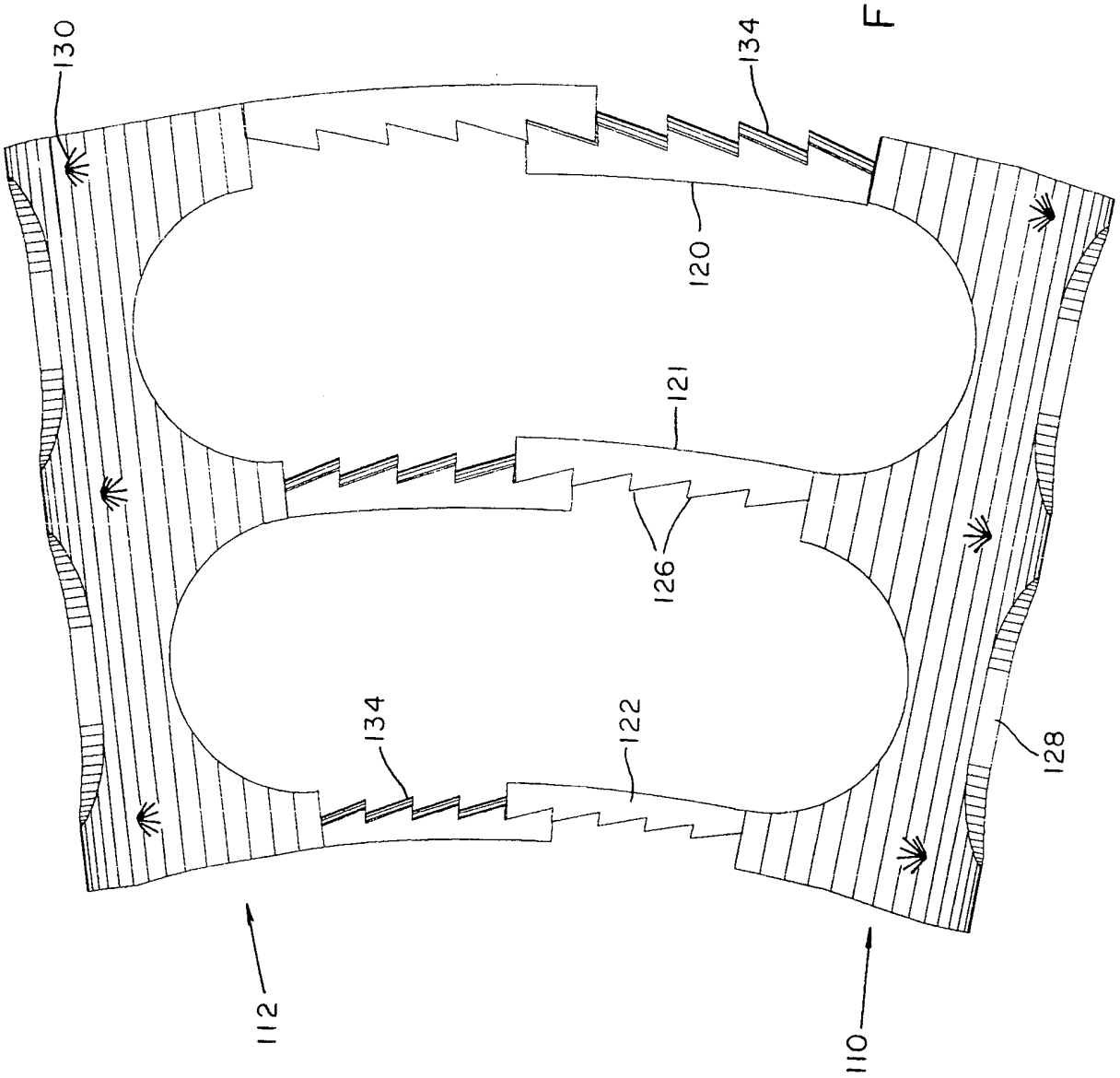
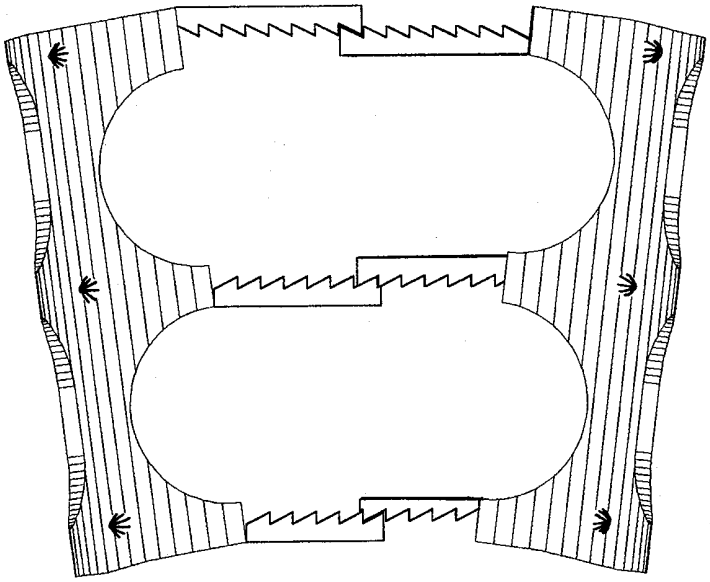


FIG. 11



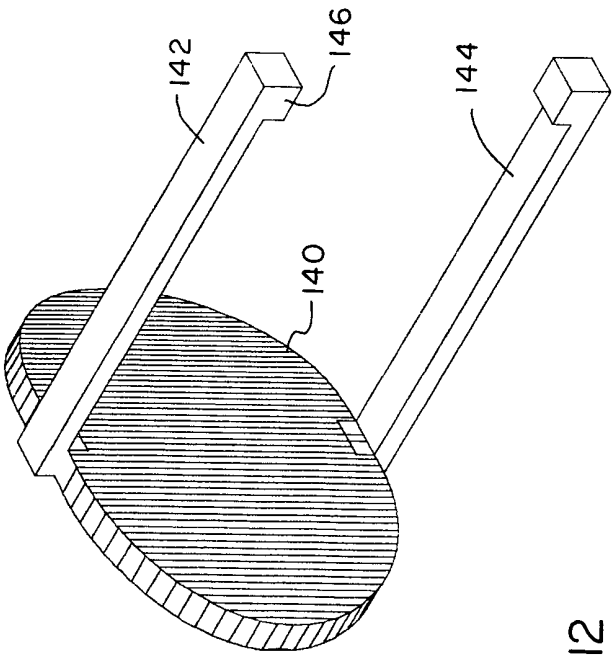


FIG. 12

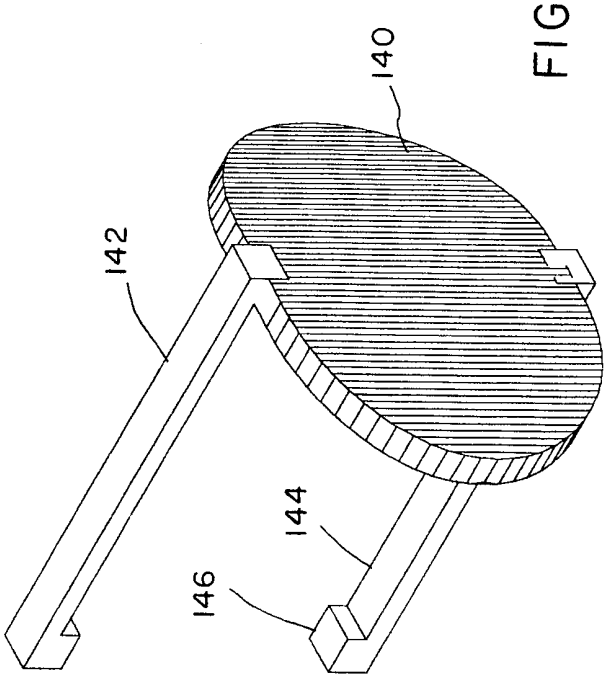


FIG. 13

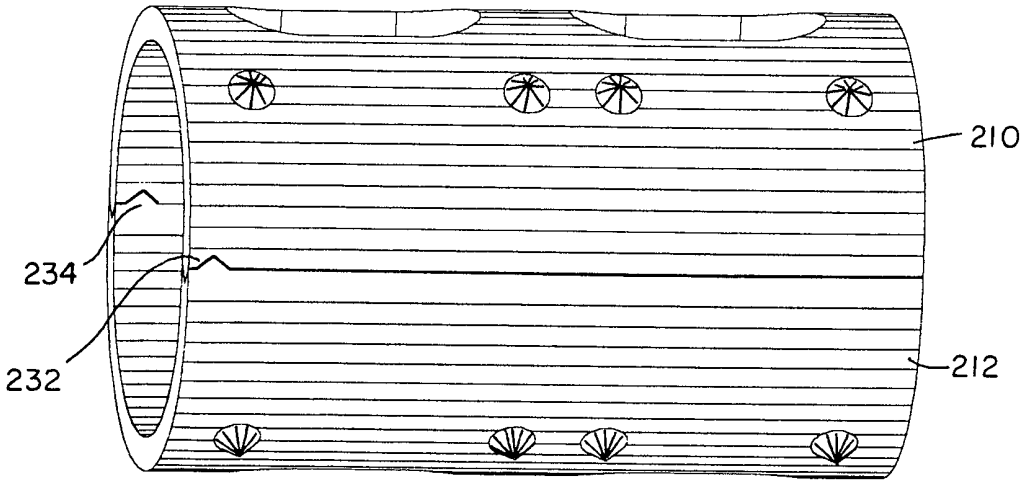


FIG. 14

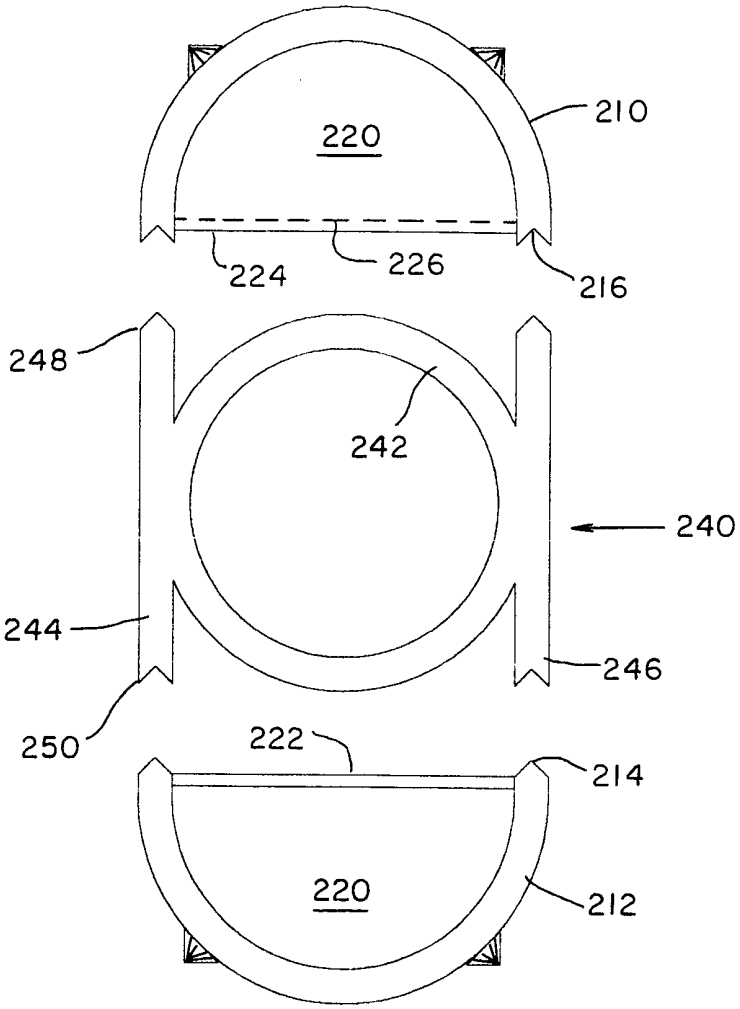


FIG. 15

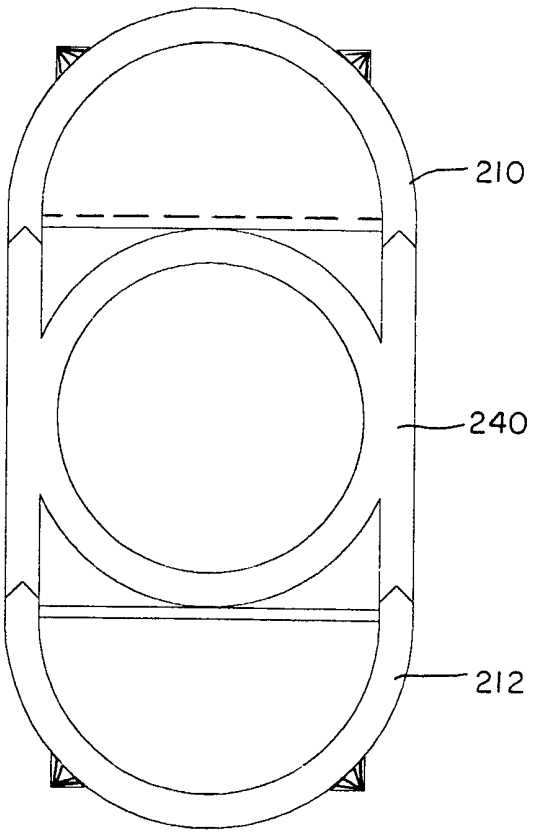


FIG. 16

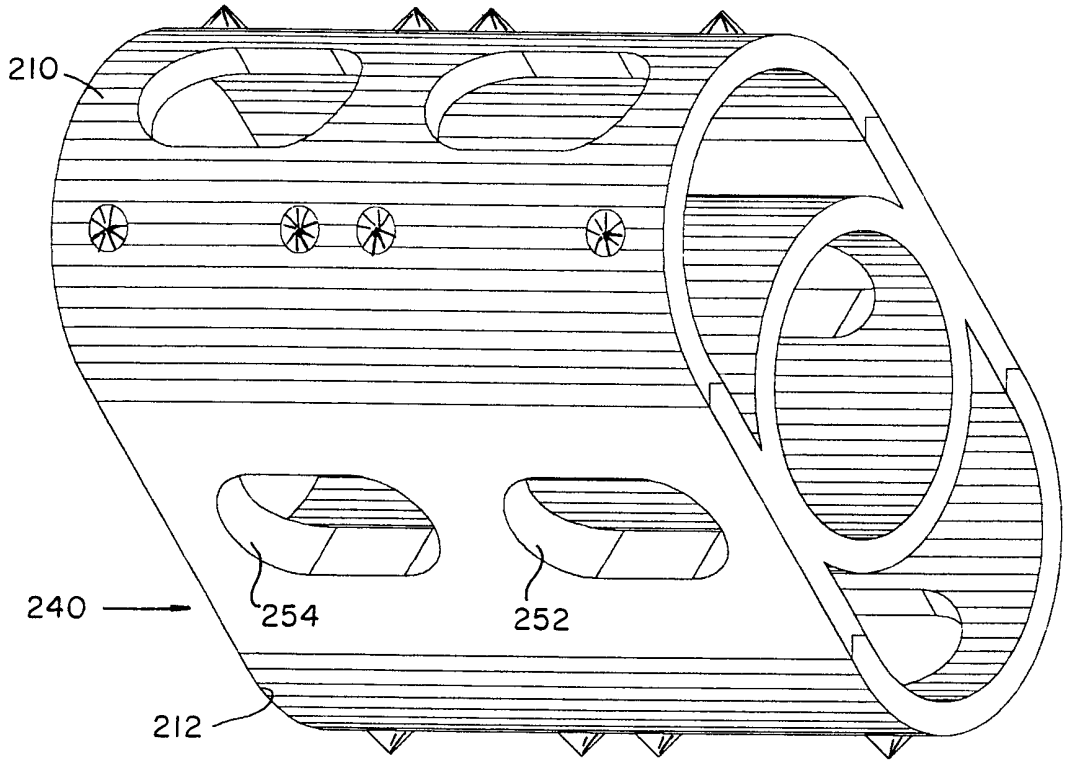


FIG. 17

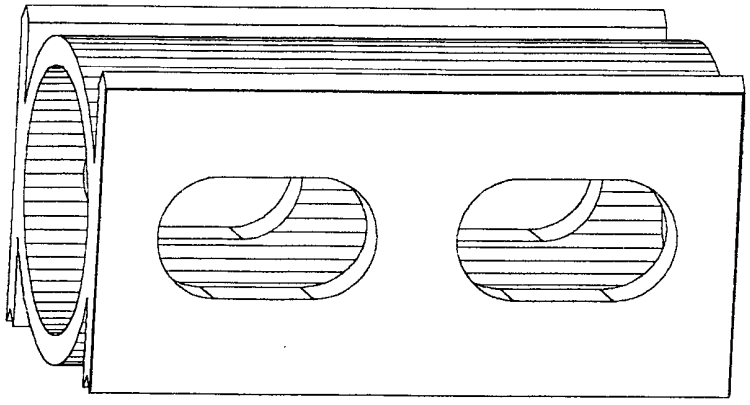


FIG. 18a

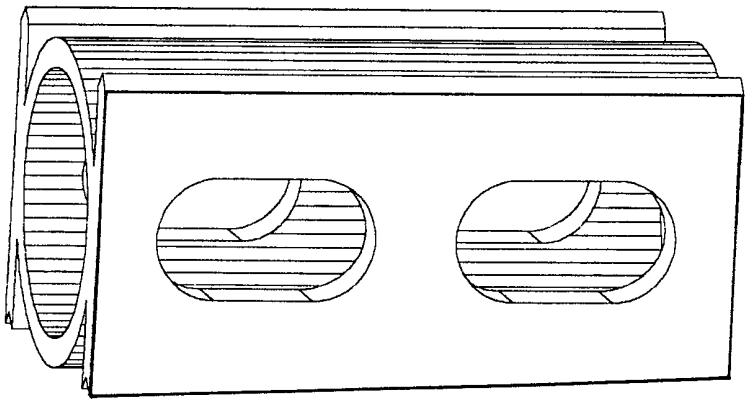


FIG. 18b

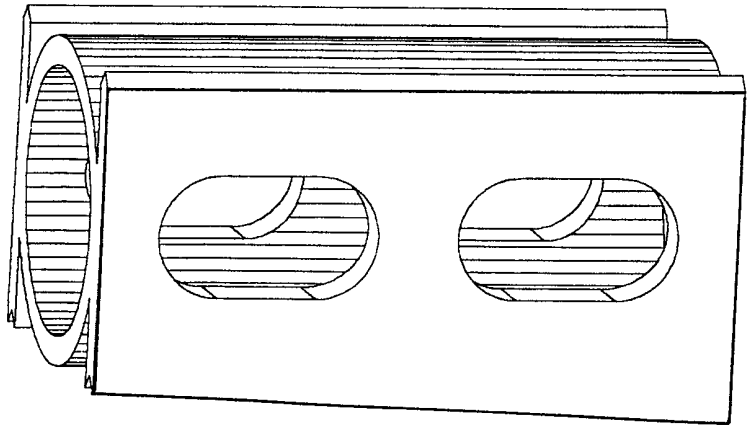


FIG. 18c

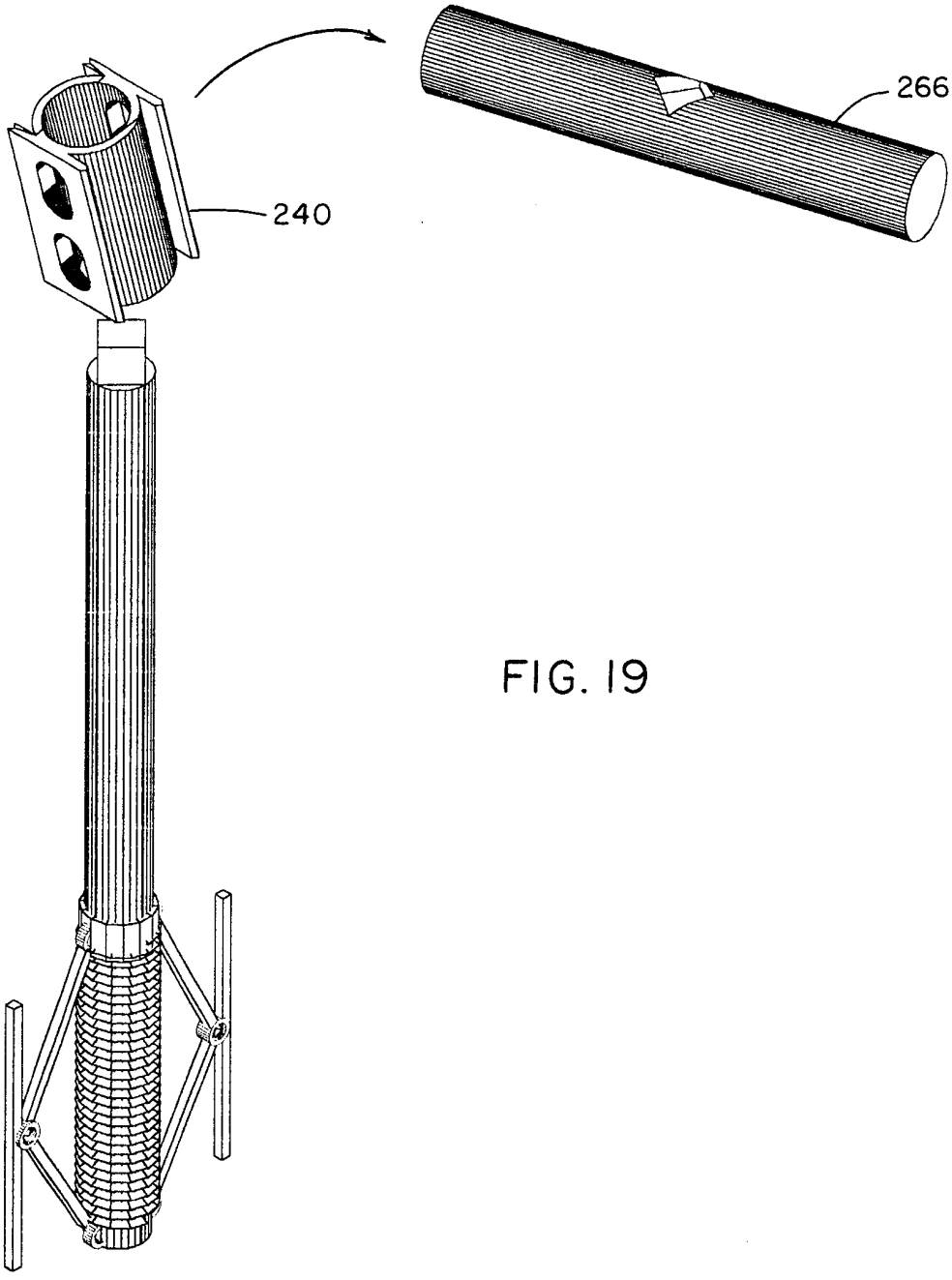


FIG. 19

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/27940

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 2/44
US CL : 623/17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST, WEST
Search Terms: vertebrae, ratchet, disengage$

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	US 5,865,848 A (BAKER) 02 February 1999, Fig 6A, and col. 6 lines 61-67	1-4, 16, 17
Y,P		5, 6
X	US 5,665,122 A (KAMBIN) 09 September 1997, Figs. 5-9.	1, 11-12, 15
Y	US 4,834,757 A (BRANTIGAN) 30 May 1989, col. 4 lines 1-7	6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"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
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 22 FEBRUARY 2000	Date of mailing of the international search report 11 APR 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer ALVIN STEWART Telephone No. (703) 305-0277

Form PCT/ISA/210 (second sheet)(July 1992)*