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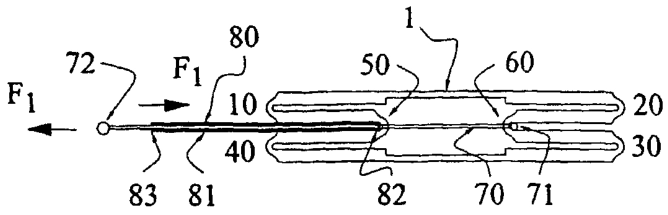
(54) Title: REINFORCED EXPANDABLE CAGE



(57) Abstract: This invention relates to a reinforced expandable cage (1) used for operations in a living body. The reinforced expandable cage (1) is especially important for operations on the spine, where the goal is to take over the supporting function of the inter-vertebra disc between two adjacent vertebra bodies (31, 32). By means of an endoscopic operation the damaged natural inter-vertebra disc is removed entirely or partly and than it is replaced by an expandable cage (1), that is applied through a delivery tube (90). Because of the high load on the spine, the required axial stability of the cage (1) must be very high. Therefore the cage (1) is reinforced by means of a strip (91) that is applied through the delivery tube (90) in an oblong shape and that rolls up in the cage (1) to transfer to a compact, relatively rigid body. The combination of cage (1) and rolled strip (90) results in a very compact and strong construction.

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REINFORCED EXPANDABLE CAGE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. provisional application Serial No. 60/142,252, filed July 2, 1999.

BACKGROUND OF THE INVENTION

This application relates to the field of producing an improved spinal cage that is used in surgical procedures for inter-vertebra replacement.

In conventional procedures,the area of the spine that has to be operated on is approached from the front side and normally rather large incisions have to be made for this operation. There are several options to achieve the fusion of two adjacent vertebra-bodies. In these procedures, it is necessary to maintain (or regain) the original distance between the vertebra bodies, because otherwise problems will occur with the nerves that run through this area.

Therefore it is important to pull or push the vertebra bodies apart during surgery and to place a support that is strong enough to withstand the axial compression forces during normal use that can be as high as 1000 N. An example of such a procedure is described in: "Subtotal and total vertebral body replacement and interbody fusion with porous Ti-Ni implants", by B.Silberstein in proceedings of SMST-97, Pacific Grove, California, USA on pages 617-621. In this procedure, a rigid porous metal implant is placed between the vertebra bodies, while a tension force is put onto the spine. This method requires a relatively large operation place around the area where the implant must be inserted.

Another method was developed by Krupp Medizintechnik in Essen, Germany , where an expandable ring was made of a NiTi shape memory alloy. This ring was applied in a compressed shape in the inter-vertebra gap and after placement it was heated to recover to the programmed height, which resulted in an expansion with a factor 2. After placement, this hollow ring was filled with bone particles and after several weeks total fusion was a fact. However, the initial stability of such a ring in combination with loose bone particles, was very restricted and the patient had to stay in bed for a long time. (See G.Bensmann et al. in Üntersuchungsberichte Krupp Forschungsinstitut, Band 42,1984, pages 25-38).

SUMMARY OF THE INVENTION

This invention relates to an improved method for a minimally invasive operation for spinal fusion. After a part or entire removal of the damaged inter-vertebra disc, the two adjacent vertebra bodies are brought to their normal distance by means of external tension force on the spine.

The implant that is used exists from at least one expandable cage, eventually reinforced by a filler strip that can take up high loads. The cage has the tendency of expansion in a direction parallel to the length axis of the spine, hereafter called the Z-axis. In this cage a series of elastic or plastic hinges enable a large expansion ratio and they also provide the cage with a well-defined final geometry after expansion. In one preferred embodiment the cage is made out of a single piece of shape memory material by means of cutting from a solid block. The cage has been heat-treated to give it the tendency to open up at body temperature by its superelastic properties, and therefore elastic energy will be stored in the cage as long as it is collapsed.

Through a delivery tube a collapsed cage is brought into place, but the delivery of a cage with a lot of stored energy would cause a very uncontrolled and sudden shape change. Therefore an additional restraining means is attached to keep the cage in its collapsed state, even after leaving the leading end of the delivery tube. Once it is found to be in the desired location, the restraining means is gradually released, thus enabling the full expansion of the cage. After placement of the cage the restraining means is removed through the delivery tube.

Eventually several small units can build up the cage. After placement of a first cage a second one can be placed in a different position or orientation to construct an assembled cage that provides more support to the vertebra bodies and gives stability along more directions.

The hinges in the expanding cage have such a shape, that upon full expansion these hinges arrive in a locked end position, thus giving the cage a predictable and stable end shape. As soon as the single or assembled cage is placed and the position is found to be correct, an additional reinforcement can be put into the hollow core of the cage. This reinforcement can have different shapes and can be made from several materials. Of course it is favorable if this reinforcement can be inserted through the same delivery tube.

It is a part of this invention that the reinforcement has an oblong geometry that transforms into a compact body that fills the cage in such a way that the axial stability is increased considerably and that the overall geometry of the filled cage enables a permanent spinal fusion. The strip can be made of any material and form that give it the capability to be delivered in an oblong shape and to roll up in the cage. It can be made of a strip with a curved cross section, like in the well-known measuring band that easily rolls up in a cylindrical housing. Such a strip, e.g. made of surgical steel, can be moved into the cage with a very low axial force.

Further the strip can also be made from a shape memory material with superelastic or shape memory behavior. In the first case the shape memory strip will curl as soon as it leaves the restraining delivery tube and in the latter case it can be heated above its transformation temperature by means of a small heating source in the distal tip of the delivery tube. In the last option there is the advantage that the friction in the delivery tube is lower than in the option with the superelastic strip, where the tendency to curl has to be opposed by the inner wall of the delivery tube over the entire length of the strip.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1a shows a side view of a collapsed cage and the restraining tool;

Figure 1b shows the collapsed cage and restraining tool of fig.1a in a delivery tube;

Figure 1c shows a side view of two vertebra bodies and a cross section of the assembly of fig.1b;

Figure 2a shows a side view of an expanded cage and a released restraining tool;

Figure 2b shows the expanded cage and released restraining tool of fig.2a outside of the delivery tube;

Figure 2c shows a side view of two unloaded vertebra bodies and a cross section of the assembly of fig.2b;

Figure 3a shows a side view of an expanded cage and a removed restraining tool;

Figure 3b shows a loaded expanded cage with the hinges in locked position;

Figure 3c shows a side view of two loaded vertebra bodies and a cross section of the cage of fig.2b;

Figure 4a shows two expanded cages that can build an assembled cage;

Figure 4b shows a top view of a vertebra, a first cage and a delivery tube just after placement of the cage;

Figure 5a shows two expanded cages after they have been assembled;

Figure 5b shows a top view of the vertebra, the assembled cage and the delivery tube just after placement of the second cage;

Figure 6a shows a top view of a vertebra and the insertion from the delivery tube of the reinforcing strip into the unloaded assembled cage;

Figure 6b shows the final situation of an assembled cage in the loaded state where the cage has been filled with a large amount of helical loops of the strip and the hinges of the cage are in their final, stable position;

Figure 7a shows a loaded cage of a different type, which already has expanded into the Z-direction and has additional expansion capability by means of hinges in the X-Y-plane, but in this plane it is still unexpanded;

Figure 7b shows the cage of fig.7a after expansion in the X-Y-plane;

Figure 7c shows the cage of fig.7b after it has been filled with the reinforcing strip;

Figure 8a shows a loaded cage of still another different type, which already has expanded into the Z-direction and has additional expansion capability by means of bending in the X-Y-plane, but in this plane it is still unexpanded;

Figure 8b shows the cage of fig.8a after expansion in the X-Y-plane; and

Figure 8c shows the cage of fig.8b after it has been filled with the reinforcing strip.

DETAILED DESCRIPTION OF THE INVENTION

The advantages of the invention will become more apparent after reference to the following description, wherein some embodiments are elucidated.

There are several options to make an expandable cage. It may be clear that it is a great advantage when the amount of parts is as low as possible. Of course the use of hinges with separate parts is also an option, but this invention also includes the use of solid hinges. Preferential bending spots can be made by locally cutting, grinding or heat treating the material. Such hinges can further be made self-locking after expansion of the cage. This can easily be achieved by means of a mechanical stop in the hinge. In the description of the drawings the main principles of the invention will be disclosed.

Figure 1a shows a side view of a collapsed cage 1 with hinges 10,20,30 and 40 at the corners and hinges 50 and 60 in the middle of the left and right planes. The restraining tool 80 contains two components: a tension wire 70 with an end button or hook 71 that can be attached through a small hole near hinge 60 and an outer tube 81, that can be pushed against hinge 50 with its distal end 82. Hinges 50 and 60 can be pulled close towards each other, thus bringing and keeping the cage in its collapsed state. This constraint can be controlled at the proximal end of the constraining tool, by keeping tension on wire 70. The relative movement between proximal ends 72 of wire and 83 of the tube enables the operator to maintain the pull force F1 or release the cage.

Figure 1b shows the collapsed cage 1 and restraining tool 80 of fig.1a in a delivery tube 90, that has been drawn in a cut-open version for clarity.

Figure 1c shows a side view of two vertebra bodies 31 and 32 with the inter-vertebra disc·removed, thus creating a gap 32 that has to be filled. A tension force F2 on the spine maintains gap 33. Into this gap the cage 1 of fig. 1a, drawn in cross section, is inserted through insertion tube 90.

Figure 2a shows a side view of an expanded cage and a released restraining tool. The hinges have returned to their released position, because the operator has allowed the relative movement between hinges 50 and 60. This was made possible by a relative displacement of distal end 71 of wire 70 and distal end 82 of tube 81. The geometry of the distal end 71 and hole 61 in hinge 60 is chosen in such a way, that wire end 71 can easily be detached from the hinge. It can for example automatically release by the shape change of hole 61, caused by the elastic deformation of hinge 60.
Of course the geometry of the opposing hinge, surrounding hole 51, has to allow the removal of distal end 71 of the wire, but it also has take up the pressure force F1 of tube 81.

Figure 2b shows the expanded cage and released restraining tool of fig.2a outside of the delivery tube. The function of tube 81 is double: it is used as a restraining tool but also to push the cage out of delivery tube 90.

Figure 2c shows a side view of two unloaded vertebra bodies and a cross section of the assembly of fig.2b. The cage has just been pushed out of the delivery tube and the restraining tool has been released. As long as force F1 in the restraining tool is maintained, it is very easy to push the cage out of tube 90, while the friction is negligible than. Repositioning of the cage is very easy and precise in this way.

Figure 3a shows a side view of an expanded cage and a removed restraining tool. By compression force F2 the cage slightly deforms, until the hinges reach their locked position. For hinges 10,20,30 and 40 the respective gaps 12,22,32 and 42 close at the outside, while for hinges 50 and 60 the gaps 52 and 62 close at the inside.

Figure 3b shows a perspective view of a loaded expanded cage with the hinges in locked position. The holes 51 and 61 can also be seen.

Figure 3c shows a side view of two loaded vertebra bodies and a cross section of the cage of fig.2b. The removal of tension force F2 at the spine has lead to the loading of the cage.

Figure 4a shows two expanded cages 4 and 5, which can build an assembled cage. If cage 4 is already expanded, cage 5 must first be collapsed and then it can be inserted perpendicular to the direction of delivery of cage 4. Cage 4 has special surfaces 45 and 46 and cage 5 has surfaces 55 and 56. The geometry of these surfaces is made so, that the two cages fit tightly together by the interaction between grooves 45 with 55 and 46 with 56 respectively.

Figure 4b shows a top view of vertebra 32, a first cage 4 and a delivery tube just after placement of the first cage.

Figure 5a shows two expanded cages 4 and 5 after they have been assembled.

Figure 5b shows a top view of the vertebra, the assembled cage and the delivery tube just after placement of the second cage. The position of the delivery tube is different than for placement of the first cage.

Figure 6a shows a top view of a vertebra and the insertion from the delivery tube of the reinforcing strip 91 into the unloaded assembled cage. The distal end of strip 91 starts to roll up in the cavity of the cage and the rest of the strip can be pushed forward until the whole strip is brought into the cage. As long as the internal height of the cage is slightly larger than the width of the strip, it can easily be moved. However, after placement of the strip and removal of extraction force F2 from the spine, the inner surface of the cage will rest on the cylindrical strip body and even very high loads can be applied without plastic deformation of the reinforced cage. The strip can be made of any material and form that give it the capability to be delivered in an oblong shape and to roll up in the cage. It can be made of a strip with a curved cross section, like in the well-known measuring band that easily rolls up in a cylindrical housing. Such a strip, e.g. made of surgical steel, can be moved into the cage with a very low axial force.

Further, the strip can also be made from a shape memory material with superelastic or shape memory behavior. In the first case the shape memory strip will curl as soon as it leaves the restraining delivery tube and in the latter case it can be heated above its transformation temperature by means of a small heating source in the distal tip of the delivery tube. In the last option there is the advantage that the friction in the delivery tube is lower than in the option with the superelastic strip, where the tendency to curl has to be opposed by the inner wall of the delivery tube over the entire length of the strip. The heating source can be of any type, comprising radiation,warm liquid, a Peltier element and resistance heating.

Figure 6b shows the final situation of an assembled cage in the loaded state. The cage has been filled with a large amount of spiral loops of the strip. The hinges of the cage are in their final, stable position. In this position the axial load on the reinforced cage can be much higher than for an empty cage. The inner surface of the cage will be pressed against the top and bottom of the cylindrical strip body 93, so all parts will stay in place.

Figure 7a shows a cage 7 of a different type, which already has expanded into the Z-direction. It has additional expansion capability by means of hinges in the X-Y-plane, but in this plane it is still unexpanded. The top surface of this cage has two hinges 73 and 74,that are deformed to a closed position, while hinges 75 and 76 are deformed to an open position.

However, upon release from the delivery tube, the separate parts 77 and 78 of the top surface will move apart to relieve elastic energy. The shape of the hinges 73 to 76 enables a rotation of non-deforming surface sections 77 and 78.

Figure 7b shows the cage of fig.7a after expansion in the X-Y-plane. As can be seen the shape of hinges 73 to 76 has changed and the new geometry of the cage gives it more stability against loads along the X- and Y-axes.

Figure 7c shows the cage of fig.7b after it has been filled with the reinforcing strip. It may be clear that such a single-piece cage can be inserted through only one incision, while for the assembled cage of figs. 4,5 and 6 more incisions are used. The placement of cage 7 may also have some drawbacks. The construction of a restraining tool that keeps the cage under constraint in three main directions is more complicated than for the cage that only expands in Z-direction.

Figure 8a shows a cage 8 of still another different type, which already has expanded into the Z-direction. It has additional expansion capability by means of bending in the X-Y-plane, but in this plane it is still unexpanded. Sections 87 and 88 of the top surface are still parallel, but without restraint they have the tendency to bend in the X-Y-surface. In contrary to cage 7 the parts 87 and 88 deform, where in cage 7 the hinges take up the strain.

Figure 8b shows the cage of fig.8a after expansion in the X-Y-plane, in the fully released state.

Figure 8c shows the cage of fig.8b after it has been filled with the reinforcing strip. Of course it is also possible to make combinations of some of the described principles. A cage, like cage 8 of fig. 8c can also have some hinges like the cage of fig. 7 has, so the strains can be divided between bending sections like 87 and 88 and hinges like 74 to 76.

It is an object of the invention that the cage can be made of any material and form that give it the capability to be delivered in an collapsed shape and to expand when it is in place. It can be made from any metal, but preferably of shape memory material with superelastic or shape memory behavior. This is because of the high strains that these materials can take up without failure. In the first case the superelastic shape memory cage will expand as soon as it is released.

In the latter case it can be heated above its transformation temperature by means of body heat or any additional heating source. By use of a shape memory cage a restraining tool may not be necessary.

It is a part of this invention that the reinforcement has an oblong geometry that transforms into a compact body that fills the cage in such a way that the axial stability is increased considerably and that the overall geometry of the filled cage enables a permanent spinal fusion.

Of course it is also an object of the invention that the material of the cage can deform pure elastically or also partly plastically.

Another object of the invention is that the reinforcing strip is not necessary for special cases, by a proper dimensioning of the hinges and the cage-wall or by stronger materials for the cage.

It is further another object of the invention that the cage not only works with locking hinges, but also without the end stops.

It will be obvious to those skilled in the art having regard to this disclosure that other modifications of this invention beyond these embodiments specifically described here may be made without departing from the spirit of the invention. Accordingly, such modifications are considered within the scope of the invention as limited solely by the appended claims.

CLAIMS

1. An expandable intervertebral prosthesis for replacement of the nucleus of an intervertebral disc, the prosthesis comprising at least one cage made from a relatively thin walled material, which after placement and expansion at its final location, is reinforced with an element that rolls up from an oblong geometry into the form of at least one plane spiral in the force-free state to transform to a compact body that at least partly fills a hollow space in the cage in such a way that the axial stability of the reinforced cage in a direction parallel at the length axis of the spine is increased considerably and that the overall geometry of said reinforced cage enables a permanent spinal fusion.

2. The prosthesis in accordance with claim 1, wherein said cage is configured so that it can be brought into the patient's body in a collapsed state and then caused to change shape to the final, expanded shape.

3. The prosthesis in accordance with claim 2, wherein said collapsed cage is configured so that it can be brought into the patient's body by pushing it through a delivery tube with an elongated instrument.

4. The prosthesis in accordance with claim 3, wherein said collapsed cage is configured so that the elongated instrument can hold the collapsed cage in a collapsed state by an additional restraining means, until said collapsed cage is brought from the distal end of the delivery tube into the final location where it is caused to expand.

5. The prosthesis in accordance with claim 4, wherein said collapsed cage is configured so that the elongated instrument which has a pulling unit and a pusher unit, enables the release of the cage from its collapsed state to its expanded state by the relative movement between said pusher unit and pulling unit.

6. The prosthesis in accordance with claim 1, wherein several cages are assembled in the patient's body to create said hollow space.

7. The prosthesis in accordance with claim 1, wherein said cage has preferential bending spots that act as hinges.

8. The prosthesis in accordance with claim 7, wherein said preferential bending spots are created by locally cutting, grinding, heat treating the material of the cage, or by the use of an additional hinge pin.

9. The prosthesis in accordance with claim 7, wherein at least some of said hinges have a well defined end position, acting as a mechanical stop to lock the cage into a stable end position after expansion.

10. The prosthesis in accordance with claim 1, wherein said cage has an expansion possibility in said axial direction, parallel to the length axis of the spine, and in a direction perpendicular to this axial direction.

11. The prosthesis in accordance with claim 1, wherein said reinforcing element has the shape of an elongated strip with a flat or slightly curved cross section.

12. The prosthesis in accordance with claim 11, wherein said reinforcing element is selected from a material consisting of a polymer, a composite, a metal, a shape memory material with superelastic behavior, a shape memory material with shape memory behavior, and combinations thereof.

13. The prosthesis of claim 11, wherein said reinforcing element has the tendency to roll up from the oblong geometry to a spiral, caused by the elastic energy in the element.

14. The prosthesis of claim 11, wherein said reinforcing element has the tendency to roll up from the oblong geometry to a spiral, caused by a stored shape memory effect that is triggered by temperature change at the distal tip of a delivery tube.

15. The prosthesis of claim 14, wherein said temperature change is caused by a heating method comprising resistance heating, radiation, a warm liquid, a Peltier element and combinations thereof.

16. The prosthesis according to claim 1, said cage made from a material selected from the group consisting of a polymer, a metal, a shape memory material with superelastic behavior, a shape memory material with shape memory behavior, and combinations thereof.

17. The prosthesis according to claim 1, wherein the deformation of the material of said cage or reinforcing element is selected from the group of deformations comprising plastic deformation, elastic deformation, superelastic deformation, deformation by shape memory behavior and combinations thereof.

18. An expandable intervertebral prosthesis with increased axial stability in a direction parallel at the length axis of the spine for replacement of the nucleus of an intervertebral disc, the prosthesis comprising:

a) a first cage that can be placed into the final position in the spine in a collapsed state and can be caused to expand to an expanded state;

b) a second collapsed cage that can be placed inside the first expanded cage and then be caused to expand to create an assembled cage together with said first cage; and

c) a reinforcing element that rolls up from an oblong geometry into the form of at least one plane spiral in the force-free state to transform to a compact body that at least partly fills a hollow space in the cage.

19. The prosthesis of claim 18, wherein said reinforcing element forms a form-fitted spiral without intervening spaces in the force-free state.

20. The prosthesis of claim 18, wherein said spiral has surfaces at the base and top that have a geometry corresponding with the inner surfaces of the cage to be able to take up high axial loads.

21. The prosthesis of claim 18, wherein said assembled combination of at least one cage and a spiral consists of sterilizable material whose deformation properties correspond essentially to those of an intervertebral disc to be replaced.

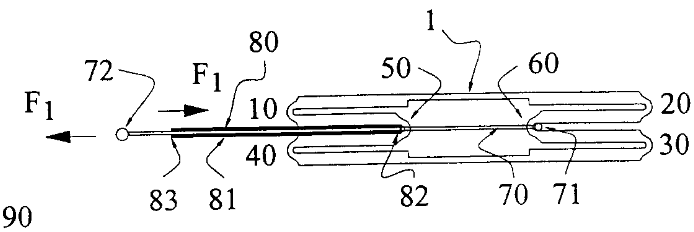


FIG. 1a

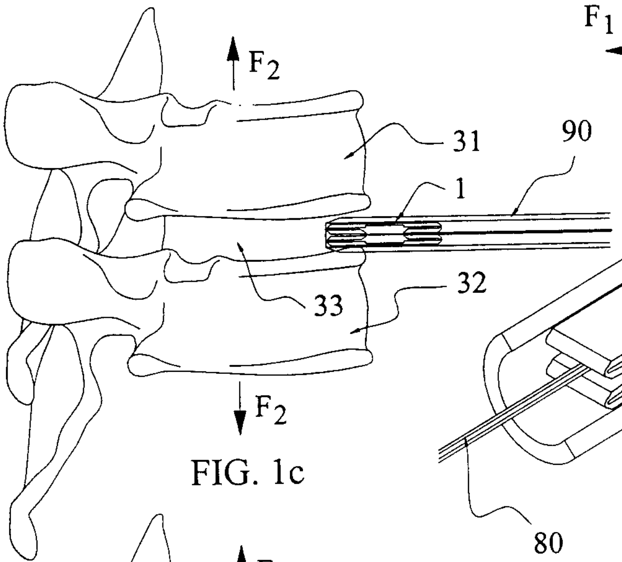


FIG. 1c

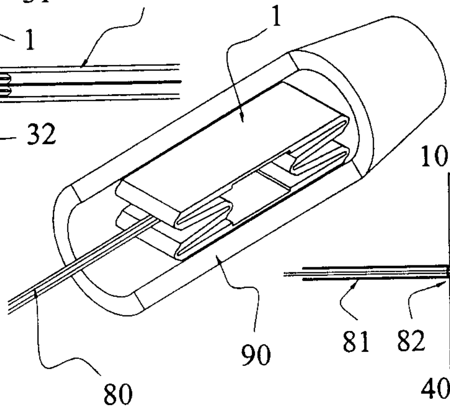


FIG. 1b

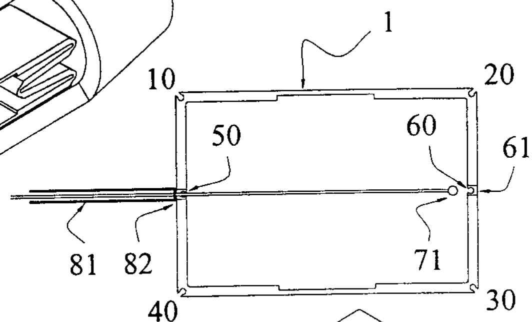


FIG. 2a

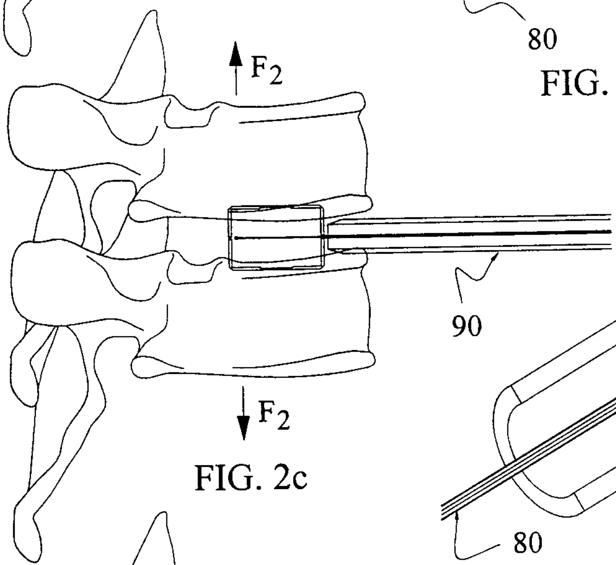
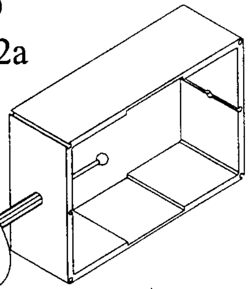


FIG. 2c



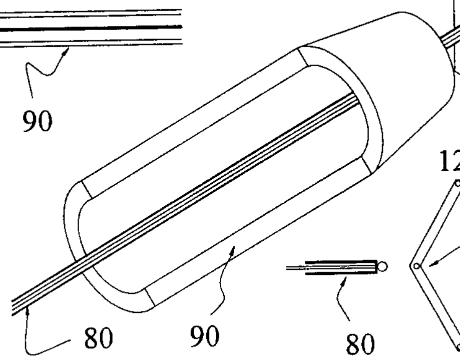


FIG. 2b

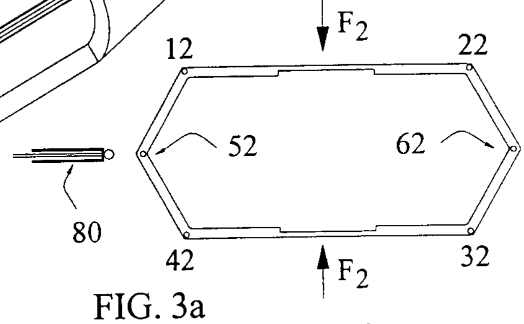


FIG. 3a

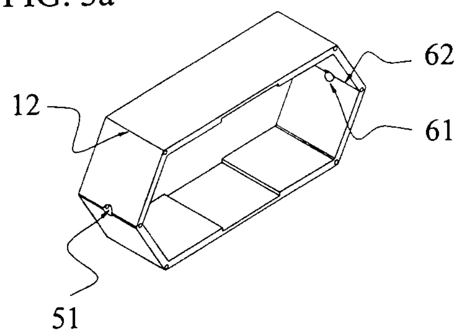


FIG. 3b

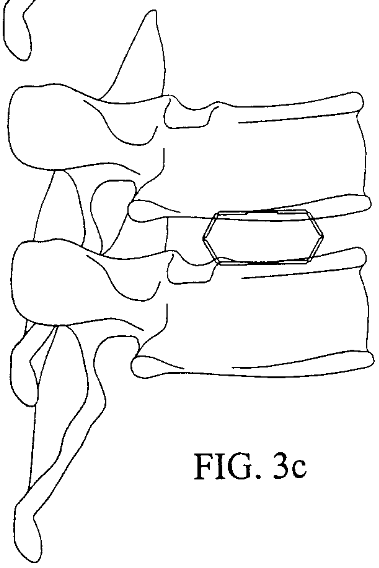


FIG. 3c

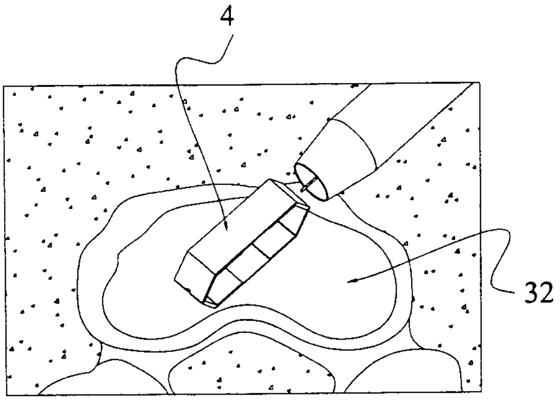


FIG. 4b

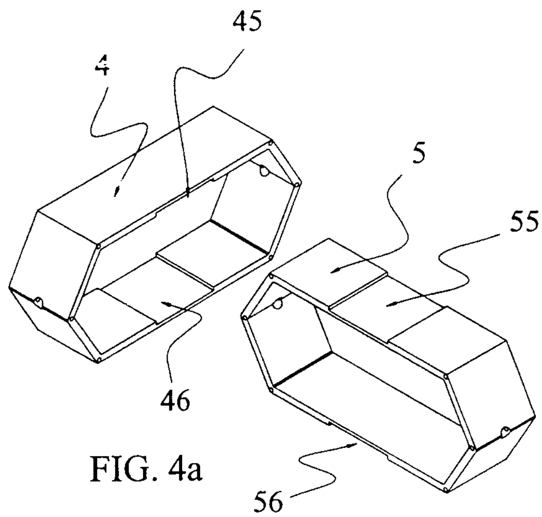


FIG. 4a

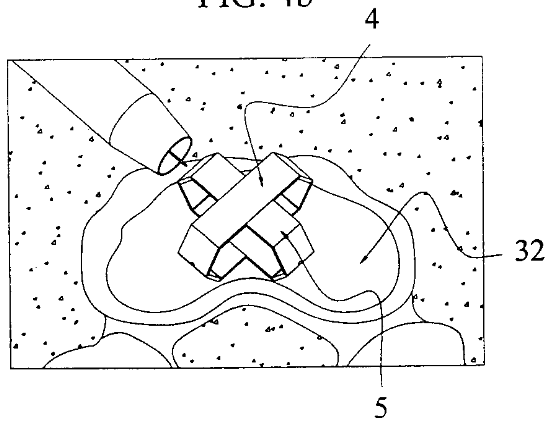


FIG. 5b

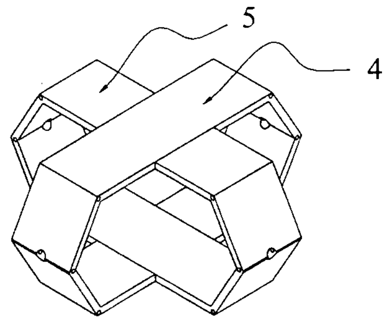


FIG. 5a

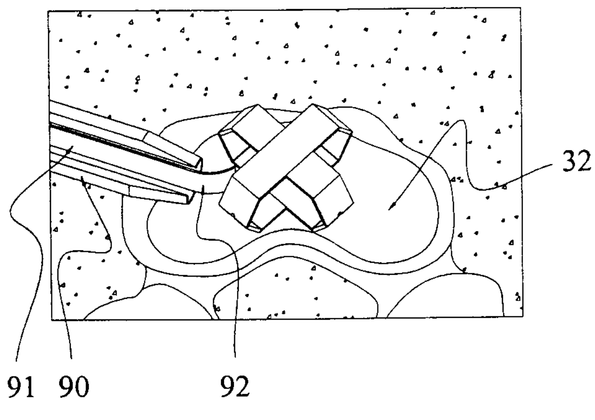


FIG. 6a

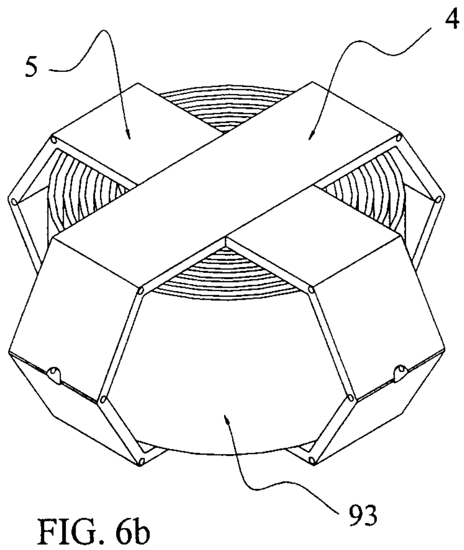


FIG. 6b

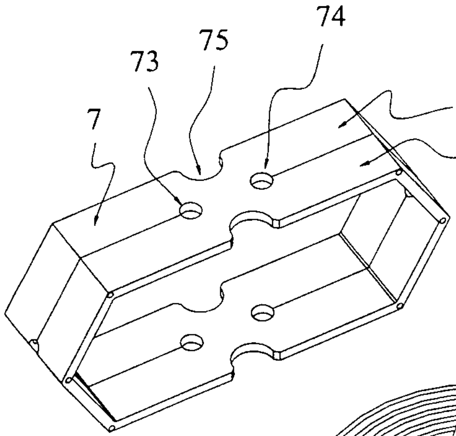


FIG. 7a

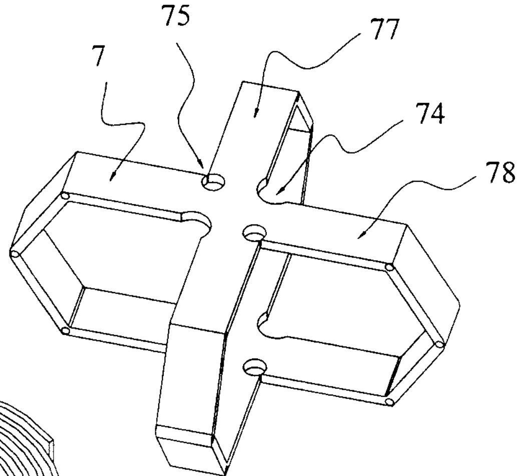


FIG. 7b

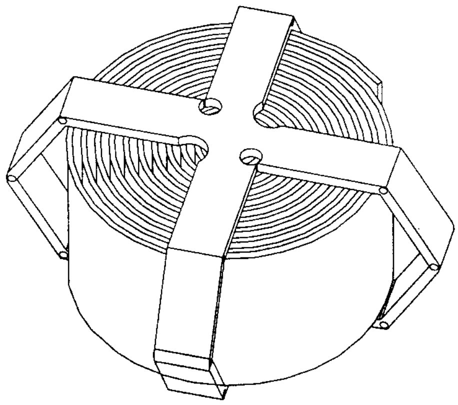
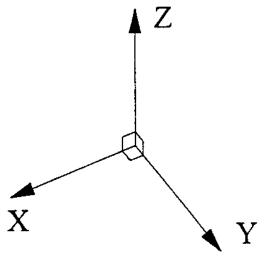


FIG. 7c



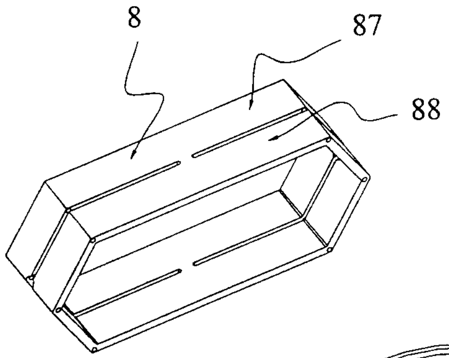


FIG. 8a

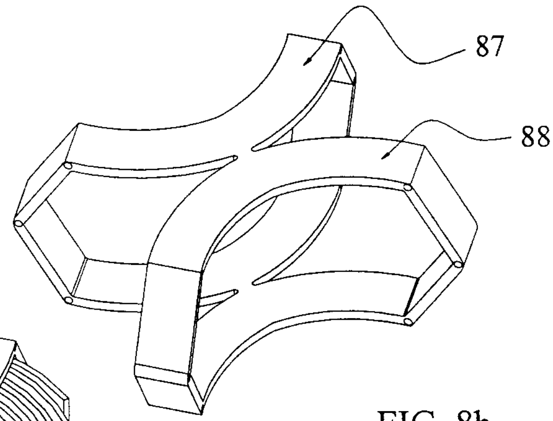


FIG. 8b

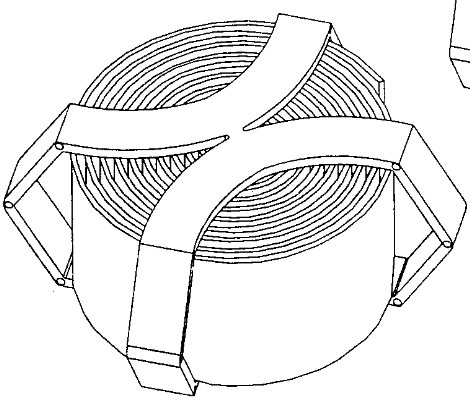


FIG. 8c

INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/IB 00/00971

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

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 A61F

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

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

EPO-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 14142 A (SURGICAL DYNAMICS INC) 9 April 1998 (1998-04-09) abstract; figures 1-6	1,18
A	EP 0 773 008 A (SULZER ORTHOPAEDIE AG) 14 May 1997 (1997-05-14) abstract column 6, line 40 - line 45; figures 1-3	1,18

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 November 2000	16/11/2000

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	Arjona Lopez, G

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IB 00/00971

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9814142 A	09-04-1998	US 5782832 A	21-07-1998
		AU 4598797 A	24-04-1998
		EP 1009336 A	21-06-2000
EP 0773008 A	14-05-1997	US 5919235 A	06-07-1999
		JP 9164156 A	24-06-1997