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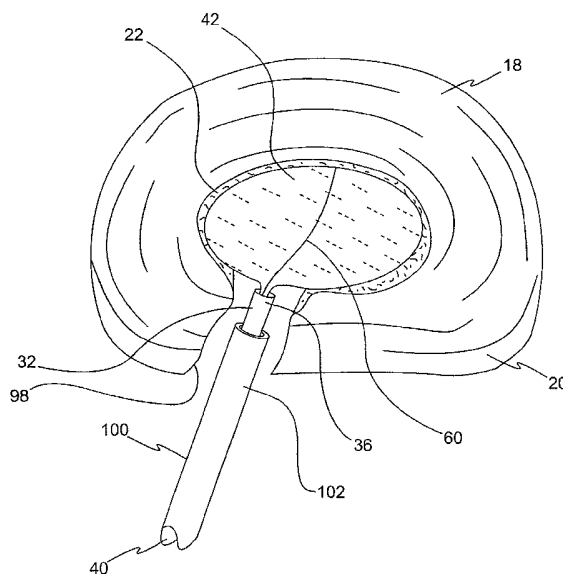
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- (71) Applicant: **MEDICINELODGE, INC.** [US/US]; 180 South 600 West, Logan, UT 84321 (US).
- (72) Inventors: **SMITH, Stephen, A.**; PO Box 25729, Fresno, CA 93729-5729 (US). **FALLIN, Wade, T.**; 210 East 200 South, Hyde Park, UT 84318 (US).
- (74) Agents: **TANGREN, Dana, L.** et al.; Workman, Nydegger & Seeley, 1000 Eagle Gate Tower, 60 East South Temple, Salt Lake City, UT 84111 (US).
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(54) Title: APPARATUS AND METHOD FOR THE *IN-SITU* FORMATION OF A STRUCTURAL PROSTHESIS



(57) Abstract: An apparatus for *in-situ* formation of a structural prosthesis (30) includes a tubular member (32) having a proximal end (34) and an opposing distal end (36). A balloon (42) having a compartment (50) is disposed on the tubular member (32) such that a curable biomaterial can be selectively delivered to the compartment (50) of the balloon (42) through the tubular member (32). A line (60) is disposed on or in the wall of the balloon (42) to facilitate at least partial severing of the wall of the balloon (42) after the biomaterial has at least partially cured therein such that the balloon (42) can be selectively removed from around the at least partially cured biomaterial, thereby forming a structural prosthesis (30).

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APPARATUS AND METHOD FOR THE IN-SITU FORMATION OF A STRUCTURAL PROSTHESIS

BACKGROUND OF THE INVENTION

5 1. The Field of the Invention

The present invention relates generally to apparatus and methods for the in-situ formation of structural prostheses and particularly for in-situ formation of structural prostheses for the spine.

2. The Relevant Technology

10 Depicted in Figure 1 is a section of a spinal column 10. Spinal column 10 comprises a plurality of stacked vertebrae 12. In general, each vertebrae 12 is comprised of a substantially cylindrical vertebral body 14 having a spinous process 16 projecting therefrom. Spinal column 10 further comprises an intervertebral disc 18 located between each adjacent vertebrae 12. As depicted in Figure 2, intervertebral
15 disc 18 generally consists of an outer ring structure called the annulus fibrosus 20. Annulus Fibrosus 20 encircles a gelatinous central core called the nucleus pulposus 22. Intervertebral disc 18 is comprised of collagen with annulus fibrosus 20 being significantly stiffer than the gelatinous nucleus pulposus 22. In this regard, annulus fibrosus 20 functions in part as a wall that retains nucleus pulposus 22. Intervertebral
20 disc 18 together with the two adjacent vertebrae 12 form a joint motion segment that serves to provide limited motion in forward bending, lateral bending, and rotation.

Degenerative discs 18 can cause debilitating back pain. Discs 18 progressively degenerate during aging, characterized by dehydration and hardening of the nucleus pulposus 22 and the annulus fibrosus 20. The annulus fibrosus 20 may
25 weaken and bulge, or may develop fissures that allow the nucleus pulposus 22 to extrude, commonly referred to as disc herniation. This bulging or extrusion often results in a decrease in disc height, thereby putting pressure on nerve roots and/or the spinal cord.

Various prefabricated prostheses have been developed to repair or replace a
30 damaged intervertebral disc 18, including: prostheses for the replacement of the nucleus pulposus, commonly referred to as nucleus replacements; prostheses for the concurrent replacement of the annulus fibrosis, commonly referred to as a total disc replacement; and prostheses in the form of cages filled with osteogenic materials, commonly referred to as interbody fusion devices. These prefabricated prostheses are
35 commercially offered in a limited number of sizes, limiting the surgeon's ability to

precisely restore the disc height for individual patients. Furthermore, most of these prostheses require the creation of a surgical incision at least large enough to pass the implant to the site of repair. Surgical incisions cause disruptions and damage to various skin, muscle, tendon and ligament structures that extend the time of recover
5 and rehabilitation for patients and that compromise the function of the violated anatomical structures.

More recently, disc replacements have been developed that use flowable biomaterials that harden in-situ to form a replacement nucleus pulposus. Forming a prosthesis in-situ from a flowable biomaterial potentially facilitates a minimally
10 invasive approach (*i.e.*, no resection of tissue) to the repair site, thereby minimizing the damage to anatomical structures and enabling much quicker patient recoveries to full function. However, nucleus replacements formed from flowable biomaterials either require an implantable mold, such as that disclosed by U.S. Patent Nos. 3,875,595 to Froning and 5,549,679 to Kuslich and U.S. Patent Application
15 Publication No. 2001/004710 to Felt et al., or utilize the existing annulus fibrosus as the mold as disclosed in U.S. Patent Application Publication No.'s US 2002/0049498 to Yussel et al. and US 2002/0045942 to Ham, and US Patent No. 6,183,518 to Ross et al.

Several disadvantages exist with both the implantable mold and the use of the
20 existing annulus fibrosus as the mold. An implantable mold cavity creates an additional interface between the mold and the flowable biomaterial which may be subject to interfacial shear stresses producing interfacial motions that create wear debris and compromise the structural integrity of both the mold and core formed from the flowable biomaterial. Using the existing annulus fibrosus as the mold is also
25 problematic in that the annulus fibrosus is often degenerated so as to have one or more fissures extending therethrough. Such fissures allow the injected flowable biomaterial to escape.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the present invention will now be discussed with
30 reference to the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope.

Figure 1 is an elevated side view of a section of a spinal column;

Figure 2 is a top plan view of an intervertebral disc;

Figure 3 is an elevated side view of an in-situ prosthesis formation apparatus;

Figure 4 is an enlarged cross sectional side view of the distal end of the apparatus shown in Figure 3;

Figure 5 is an enlarged cross sectional side view of an alternative embodiment
5 of the distal end of the apparatus shown in Figure 3;

Figure 6 is an enlarged cross sectional side view of another alternative embodiment of the distal end of the apparatus shown in Figure 3;

Figure 7 is an enlarged cross sectional side view of still another alternative embodiment of the distal end of the apparatus shown in Figure 3;

10 Figure 8 is a perspective view of a working cannula being positioned at a degenerated intervertebral disc shown in Figure 2 having a portion of the nucleus pulposus retracted;

Figure 9 is a perspective view of the apparatus shown in Figure 3 inserted through the working cannula shown in Figure 8 so that a balloon of the apparatus
15 resides within the site of the retracted nucleus pulposus;

Figure 10 is a perspective view of the balloon of Figure 9 being filled with a curable biomaterial within the site of the retracted nucleus pulposus;

Figure 11 is a perspective view of the balloon of Figure 10 being severed for removal around the biomaterial therein;

20 Figure 12 is a perspective view of the biomaterial of Figure 11 forming a structural prosthesis within the site of the retracted nucleus pulposus; and

Figure 13 is a partially cut away side view of the balloon of the apparatus shown in Figure 3 inserted within a vertebral body so as to form a structural prosthesis therein.

25 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention relates to apparatus and methods for the in-situ formation of structural prosthesis. In the embodiments depicted, such prosthesis are formed so as to replace all or a portion of an intervertebral disc or are formed within a vertebral body so as to reinforce the vertebral body or to restore the height of a
30 compressed vertebral body. In general, the apparatus and methods use a balloon as a mold. The balloon is surgically positioned at the location for the structural prosthesis. Once positioned, the balloon is filled to a predetermined extent with a curable biomaterial. The amount of biomaterial material used corresponds to the desired size

for the structural prosthesis. Once the biomaterial has at least partially cured, the balloon is removed leaving the biomaterial to fully cure into the structural prosthesis.

Depicted in Figures 3 and 4 is one embodiment of an in-situ prosthesis formation apparatus 30 incorporating features of the present invention. Apparatus 30
5 comprises an elongated tubular member 32 having a proximal end 34 and an opposing distal end 36. Tubular member 32 has an interior surface 38 bounding a passageway 40 (Figure 4) longitudinally extending therethrough. Tubular member 32 can be rigid or flexible and can be made from plastic, metal, or any other material capable sterilization for medical use. For example, tubular member 32 can comprise a flexible
10 catheter or a rigid cannula.

Mounted at distal end 36 of tubular member 32 is a balloon 42. Balloon 42 has a proximal end 44 and terminates at an opposing distal end 46. Balloon 42 is comprised of a boundary wall 48 having an exterior surface 51 and an interior surface 49. Interior surface 49 bounds a chamber 50. An annular mouth 52 is formed at
15 proximal end 44 of balloon 42 and provides fluid communication with chamber 50. Mouth 52 is coupled in sealed engagement with distal end 36 of tubular member 32 so that passageway 40 of tubular member 32 is in fluid communication with chamber 50 of balloon 42. For example, mouth 52 can be coupled with tubular member 32 by welding, adhesive, clamp, or other conventional fastening techniques. Balloon 42 can
20 also be integrally molded with tubular member 32 so that they form a one-piece member.

In one embodiment, balloon 42 is made of a resiliently expandable material. Accordingly, as balloon 42 is filled, it initially inflates to a non-stretched configuration. As balloon 42 is further filled, boundary wall 48 resiliently stretches
25 so as to allow balloon 42 to expand to a larger configuration. In an alternative embodiment, balloon 42 can be made of a flexible static material. For example, balloon 42 can be comprised of one or two or more sheets of polymeric material that are seamed together. In this embodiment, balloon 42 inflates to a predefined configuration but cannot significantly expand beyond that configuration. By using
30 seamed sheets of static material, balloon 42 can be more easily configured to inflate into any desired configuration.

Balloon 42 is typically made of materials commonly known in the art, such as those used in balloon catheters, balloon angioplasty devices, inflatable cuffs used in endotracheal devices, and balloons used as bone tamps for vertebral body

augmentation procedures. Examples of suitable materials for balloon 42 are natural materials or synthetic materials, such as polyurethane, polyolefin, polycarbonate, polyethylene, polyethylene terephthalate, tetrafluoroethylene, or copolymers thereof. The material for balloon 42 can also be reinforced with fibers or other additives to
5 adjust the strength, flexibility, elasticity, and/or other properties of balloon 42. The additives can also be used to provide desired shape constraints. Suitable materials for fiber reinforcement include: carbon fibers, glass fibers, nylon fibers, polyethylene fibers, polyester fibers, and the like. Depending on its intended use, balloon 42 can be configured to expand into any desired configuration.

10 As will be discussed below in greater detail, during use balloon 42 is surgically positioned at a location for the structural prosthesis. Once positioned, balloon 42 is selectively filled with a flowable, curable biomaterial. The biomaterial is injected into balloon 42 by way of tubular member 32. By way of example and not by limitation, the biomaterial can comprise curable hydrogel, polyurethane, calcium
15 phosphate, calcium sulfate, acrylic, carbonate, or any other suitable material that is biocompatible. In one embodiment, the biomaterial has a cure time of less than about 30 minutes and preferably less than about 5 minutes.

In one embodiment of the present invention, means are provided for at least partially severing boundary wall 48 of balloon 42 after the biomaterial has at least
20 partially cured therein such that balloon 42 can be selectively removed from around the at least partially cured biomaterial. By way of example and not by limitation, depicted in Figure 4 is a line 60 having a proximal end 62 (Figure 3) and an opposing distal end 64. Depending on the desired embodiment, line 60 or other lines disclosed herein can be comprised of a metal wire, suture, plastic line, small diameter cord or
25 cable, optical cable, or any other small diameter line.

In the embodiment depicted, line 60 extends through passageway 40 of tubular member 32 such that at least a portion of proximal end 62 of line 60 freely projects proximal of tubular member 32. Furthermore, at least a portion of distal end 64 of line 60 is disposed within balloon 42. More specifically, distal end 64 of line 60 is
30 embedded within boundary wall 48 of balloon 42 so as to follow a substantially semi-circular path extending from proximal end 44 of balloon 42, to distal end 46, and then back toward proximal end 44 on the opposing side of balloon 42. Line 60 is configured such that when proximal end 62 is pulled, line 60 is pulled out of balloon 42 so as to at least partially sever boundary wall 48 along the track of line 60. Once

boundary wall 48 is at least partially severed, tubular member 32 is retracted from its surgical placement. As tubular member 32 is retracted, balloon 42 opens along the at least partially severed track of line 60 so that balloon 42 retracts from around the at least partially set biomaterial disposed therein. Balloon 42 is then fully removed with
5 tubular member 32, leaving the biomaterial implanted so as to fully cure into the structural prosthesis.

Line 60 can be configured in a variety of different ways to facilitate severing of boundary wall 48. For example, line 60 can be embedded within boundary wall 48 such that by simply removing line 60, boundary wall 48 is sufficiently weakened so
10 that when balloon 42 is pulled on by tubular member 32, balloon 42 completely severs. Alternatively, line 60 can be embedded within boundary wall 48 such that line 60 tears boundary wall 48 as line 60 is removed. In yet another embodiment, line 60 can be made with a sharpened edge, a roughened surface, or sufficiently thin so that
15 line 60 cuts through boundary wall 48 as line 60 is removed. In still other embodiments, a sharpened tooth, hook, spike or other structure can be placed at one or more locations along line 60 so as to cut boundary wall 48 as line 60 is removed. In this embodiment, line 60 can be configured to efficiently cut both outward and inward.

In all of the embodiments discussed herein, it is appreciated that line 60 can
20 either sever completely through boundary wall 48 or sever a portion of boundary wall 48 sufficiently to weaken it so that boundary wall 48 completely severs as balloon 42 is retracted. Although line 60 is shown extending through passageway 40 of tubular member 32 and embedded within boundary wall 48, in other embodiments, line 60 can extend on the exterior of tubular member 32. Likewise line 60 can be positioned
25 on exterior surface 51 or interior surface 49 of balloon 42. Furthermore, in contrast to having a single line 60 that substantially bisects balloon 42, two or more lines 60 can be used to sever boundary wall 48 at different orientations. For example, two lines can extending on opposing sides of balloon 42 and intersect at distal end 46.

Depicted in Figure 5, in contrast to line 60 being embedded with boundary
30 wall 42, a support layer 70 is applied over line 60 so as to secure line 60 against interior surface 49 of balloon 42. Support layer 70 can be applied over all of interior surface 49 or only over the segment along line 60. Similarly, support layer 70 can be applied over exterior surface 51 of balloon 42 so as to secure line 60 against exterior surface 51. Support layer 70 can be comprised of an adhesive, tape, or any of the

materials of which boundary wall 48 is comprised. Again, as discussed above, multiple lines 60 can be used. Furthermore, any of the different techniques discussed herein can be used for line 60 to facilitate severing of boundary wall 48.

Depicted in Figure 6 is yet another alternative embodiment of the means for at least partially severing boundary wall 48 of balloon 42. As depicted therein, a line 76 is provided having a proximal end 78 and an opposing distal end 80. Proximal end 78 extends out through tubular member 32 while distal end 80 is secured to interior surface 38 of tubular member 32. Starting at the location where distal end 80 is secured to interior surface 38, line 76 extends into boundary wall 48 at proximal end 44 of balloon 42 and runs therein to distal end 46 of balloon 42. At distal end 46, line 76 extends out of boundary wall 48 and then freely passes out through tubular member 32. In this configuration, as proximal end 78 of line 42 is pulled proximally, line 42 cuts through the inwardly disposed portion of boundary wall 48. In modifications to this embodiment, distal end 46 can also extend out through passageway 40 where it is manually retained. Furthermore, two or more lines 76 can be used extending from opposing sides of balloon 42. In addition, line 76 can extend on exterior surface 51 of balloon 42 so as to completely cut through boundary wall 48 when line 76 is removed.

Depicted in Figure 7 is yet another alternative embodiment of the means for at least partially severing boundary wall 48 of balloon 42. In this embodiment, a looped line 86 has a proximal end 88 and an opposing distal end 90. Starting from proximal end 88, line 86 extends through passageway 40 and into boundary wall 48 of balloon 42 at proximal end 44 thereof. Line 86 extends embedded with boundary wall 48 to distal end 46 and then back to tubular member 32. Line 86 then continues out through passageway 40. Insulation 92 covers lines 86 within passageway 40. During operation, an electrical current is passed through lines 86 so that the non-insulated portion of line 86 embedded within boundary wall 48 functions as a filament that heats up and melts the contacting boundary wall 48. Again, multiple lines 86 can be used to sever balloon 42 along different paths. In contrast to applying an electrical current to line 86, line 86 can be a conductor of radiofrequency or ultrasound energy, creating localized heating and melting of boundary wall 48. In still yet another embodiment, wire 86 can comprise a side firing laser that produces localized heating and melting of balloon 42.

In view of the foregoing, there are a variety of different line configurations that can be used to partially or completely sever boundary wall 48 of balloon 42 by techniques such as cutting, tearing, melting, and the like. It is appreciated that features and placements of the above described embodiments can be mixed and
5 matched to form still other embodiments.

As set forth below, the above apparatus and the alternatives thereto can be used in a variety of methods for forming in-situ structural prosthesis. By way of example, depicted in Figure 8 is an intervertebral disc 18, as previously discussed above with regard to Figures 1-2, in which it is desired to replace the degenerated
10 nucleus pulposus 22 with a structural prosthesis. A minimally invasive surgical approach is used to establish a percutaneous tract to the operative site with a guide wire 104. A working cannula 100 is then slid over guide wire 104 following which guide wire 104 is removed. Microsurgical techniques are then performed through
15 cannula 100 using endoscopic visualization techniques to form an incision 98 through annulus fibrosus 20 and then substantially remove the degenerated nucleus pulposus 22 therethrough. In an alternative embodiment, a rupture in annulus fibrosus 20 may have already resulted in a substantial loss of nucleus pulposus 22 therethrough.

Turning to Figure 9, with distal end 102 of a cannula 100 in communication with incision 98, distal end 36 of tubular member 32 is advanced down through
20 cannula 100 so as to position deflated balloon 42 within the site of the resected nucleus pulposus 22. During insertion of tubular member 32, it is appreciated that balloon 42 can either freely extend distally of tubular member 32 or can be drawn into passageway 40 of tubular member 32. If balloon 42 is retained within passageway 40, a push rod or other structure can be used to push balloon 42 out of passageway and
25 into the site of the resected nucleus pulposus 22. Alternatively, balloon 42 can be pushed out of tubular member 32 by the injection of biomaterial into tubular member 32 as discussed below.

Turning to Figure 10, once balloon 42 is properly positioned, the flowable, curable biomaterial 108 (Figure 11) is passed down through tubular member 32 and
30 into chamber 50 of balloon 42. Biomaterial 108 is injected until balloon 42 inflates and/or expands to the size corresponding to the original nucleus pulposus 22. In this embodiment, annulus fibrosus 20 functions as a wall that at least partially bounds the expansion of balloon 42 so that the proper amount of biomaterial 108 is injected.

Unlike the prior art, however, balloon 42 helps to ensure that biomaterial 108 does not leak out through incision 98 or fissures in annulus fibrosus 20.

As depicted in Figure 11, once biomaterial 108 has at least partially cured within balloon 42, line 60 (Figure 10), or other alternatives thereto as discussed
5 above, is used to at least partially sever balloon 42. Tubular member 32 is then retracted causing balloon 42 to completely sever, if not previously completely severed, as shown by split 110. Balloon 42 is then fully retracted out with tubular member 32 so that severed balloon 42 passes around biomaterial 108, thereby leaving biomaterial 108 at the site of resected nucleus pulposus 22.

10 In turn, as depicted in Figure 12, the remaining biomaterial finishes curing so as to form a structural prosthesis 112. In an alternative embodiment, it is noted that biomaterial 108 can be allowed to completely cure prior to use of line 60 or removal of balloon 42. Furthermore, it is also noted that prior to retraction of tubular member 32 and balloon 42, tubular member 32 is typically bent or otherwise manipulated so as
15 to break the connection of the biomaterial within tubular member 32 to the biomaterial within the site of resected nucleus pulposus 22.

In contrast to the above discussed replacement of nucleus pulposus 22, the present apparatus and methods can also be used for a total or substantially total intervertebral disc replacement or for fusing together adjacent vertebrae. That is,
20 microsurgical techniques are performed through cannula 100 to remove nucleus pulposus 22 and either all or a portion of annulus fibrosus 20. Using the same process as described above, balloon 42 is then placed at the site of the resected intervertebral disc. Balloon 42 is injected with the biomaterial until it extends to the size of the natural intervertebral disc or portion thereof resected. Once the biomaterial at least
25 partially cures, the line is used to at least partially sever balloon 42. Tubular member 32 and balloon 42 are then retracted leaving the biomaterial to cure into the final structural prosthesis.

For the nucleus replacement and total disc replacement, materials with greater flexibility and compressibility are preferred, such as a hydrogel or polyurethane. For
30 the interbody fusion device and the vertebral augmentation device, as discussed below, materials with greater stiffness and rigidity are preferred, such as calcium phosphate, calcium sulfate, acrylic, and carbonate.

The present apparatus and methods can also be used to repair a collapsed or degenerative vertebral body. For example, depicted in Figure 13 cannula 100 is

passed through an incision into a vertebral body 14. Again, tubular member 32 is passed through cannula 100 so that balloon 42 is disposed within vertebral body 14. Balloon 42 is then filled with the biomaterial so that the balloon 42 compress the bone material therein and fills all voids. If vertebral body 14 is collapsed, balloon 42 is filled to the extent necessary to raise vertebral body 14 to its original height. Once balloon 42 is filled to the proper size and the biomaterial is at least partially cured, the line is used to at least partially sever balloon 42. Tubular member 32 and balloon 42 are then retracted as discussed above leaving the biomaterial to cure into the final structural prosthesis within vertebral body 14.

10 It is clear from the foregoing that the inventive apparatus and methods have a number of benefits. For example, unlike the prior art prefabricated prostheses which require relative large incisions, balloons 42 and the curable biomaterial can be implanted through minimally invasive incisions, thereby reducing the risk of infection and decreasing patient recovery time. Furthermore, unlike some prior art which requires the use of a degenerative annulus fibrosus 20 as a mold, by using the biomaterial in conjunction with balloon 42, an entire intervertebral disc 18 or portion thereof can be replaced without the required use of annulus fibrosus 20 or the risk of loss of biomaterial by seepage through fissures. Although the present invention is depicted herein for use with a spinal column, it is also appreciated that the present invention can be used in other surgical and non-surgical procedures where it is desired to position in-situ a structural member.

20 The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS

What is claimed is:

1. An apparatus for in-situ formation of a structural prosthesis, the apparatus comprising:
 - 5 a tubular member having a proximal end and an opposing distal end;
 - a balloon comprising a wall bounding a compartment, the balloon being disposed on the tubular member such that a curable biomaterial can be selectively delivered to the compartment of the balloon through the tubular member; and
 - 10 means for severing at least a portion of the wall of the balloon after the biomaterial has at least partially cured therein such that the balloon can be selectively removed from around the at least partially cured biomaterial.
2. An apparatus as recited in claim 1, wherein the tubular member comprises a catheter.
- 15 3. An apparatus as recited in any one of the preceding claims, wherein the tubular member comprises a rigid tubular shaft.
4. An apparatus as recited in any one of the preceding claims, wherein the balloon is integrally formed with or is connected to the tubular member.
5. An apparatus as recited in any one of the preceding claims, wherein
20 the means for at least partially severing the wall of the balloon comprises a line disposed on the wall of the balloon such that pulling on the line causes the line to at least partially sever the wall of the balloon.
6. An apparatus as recited in any one of claims 1-4, wherein the means for at least partially severing the wall of the balloon comprises a line disposed on the
25 wall of the balloon such that heating or vibrating the line causes the line to at least partially sever the wall of the balloon.
7. An apparatus for in-situ formation of a structural prosthesis, the apparatus comprising:
 - 30 a tubular member having a proximal end and an opposing distal end;
 - a balloon comprising a wall bounding a compartment, the balloon being disposed on the tubular member such that a curable biomaterial can be selectively delivered to the compartment of the balloon through the tubular member; and

a line mounted on the wall of the balloon, the line being adapted to facilitate at least partial severing of the wall of the balloon.

8. An apparatus as recited in any one of claims 7 and 8, wherein at least a portion of the line is embedded within the wall of the balloon.

5 9. An apparatus as recited in any one of claims 7-9, wherein at least a portion of the line is secured against the wall of the balloon.

10. An apparatus as recited in any one of claims 7-9, wherein the line is a wire comprised of metal.

10 11. An apparatus as recited in any one of claims 7-9, wherein the line is comprised of a polymer.

12. An apparatus as recited in any one of claims 7-11, wherein the line has a cutting edge formed thereon.

13. An apparatus as recited in any one of claims 7-12, wherein the tubular member comprises a catheter.

15 14. An apparatus as recited in any one of claims 7-12, wherein the tubular member comprises a rigid tubular shaft.

15. An apparatus as recited in any one of claims 7-14, wherein the balloon is integrally formed with or is connected to the tubular member.

20 16. A method for forming a structural prosthesis within an intervertebral disc, the method comprising:

inserting at least a portion of a balloon within a site of an intervertebral disc;

at least partially filling the balloon within the site of the intervertebral disc with a biomaterial;

25 allowing the biomaterial to at least partially cure; and

removing the balloon from around the at least partially cured biomaterial within the site of the intervertebral disc.

17. A method as recited in claim 16, further comprising resecting at least a portion of the nucleus pulposus of the intervertebral disc prior to inserting the balloon.

30 18. A method as recited in claim 17, further comprising resecting at least a portion of the annulus fibrosus of the intervertebral disc prior to inserting the balloon.

19. A method as recited in claim 16, wherein the act of at least partially filling the balloon with a biomaterial comprises at least partially filling the balloon with a hydrogel or polyurethane.

20. A method as recited in claim 16, wherein the act of at least partially filling the balloon with a biomaterial comprises at least partially filling the balloon with calcium phosphate, calcium sulfate, acrylic, carbonate, or combinations thereof.

21. A method as recited in claim 16, wherein the act removing the balloon
5 comprises at least partially severing a wall of the balloon.

22. A method as recited in claim 21, wherein the act of at least partially severing the wall of the balloon comprises cutting or tearing a portion of the wall of the balloon.

23. A method as recited in claim 21, wherein the act of at least partially
10 severing the wall of the balloon comprises melting a portion of the wall of the balloon.

24. A method comprising:
inserting at least a portion of a balloon within a vertebral body;
at least partially filling the balloon within the vertebral body with a
15 biomaterial;
allowing the biomaterial to at least partially cure; and
removing the balloon from around the at least partially cured
biomaterial within the vertebral body.

25. A method as recited in claim 24, wherein the act of at least partially
20 filling the balloon with a biomaterial comprises at least partially filling the balloon with calcium phosphate, calcium sulfate, acrylic, carbonate, or combinations thereof.

26. A method as recited in claim 24, wherein the act removing the balloon comprises at least partially severing a wall of the balloon.

27. A method as recited in claim 26, wherein the act of at least partially
25 severing the wall of the balloon comprises cutting or tearing the wall of the balloon.

28. A method as recited in claim 26, wherein the act of at least partially severing the wall of the balloon comprises melting a portion of the wall of the balloon.

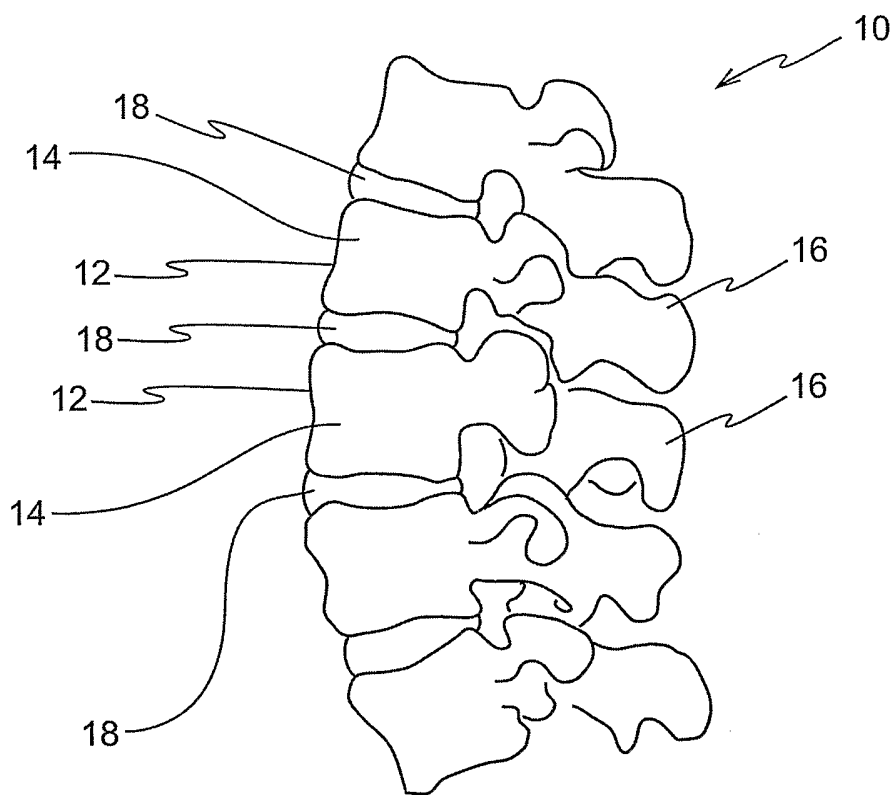


FIG. 1

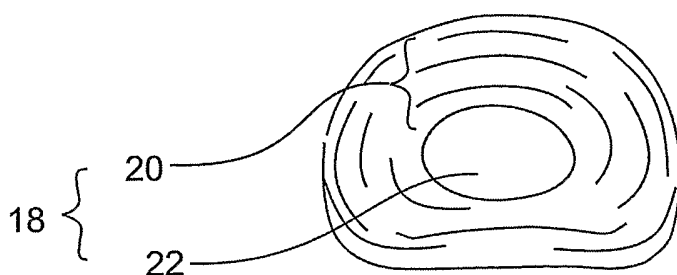


FIG. 2

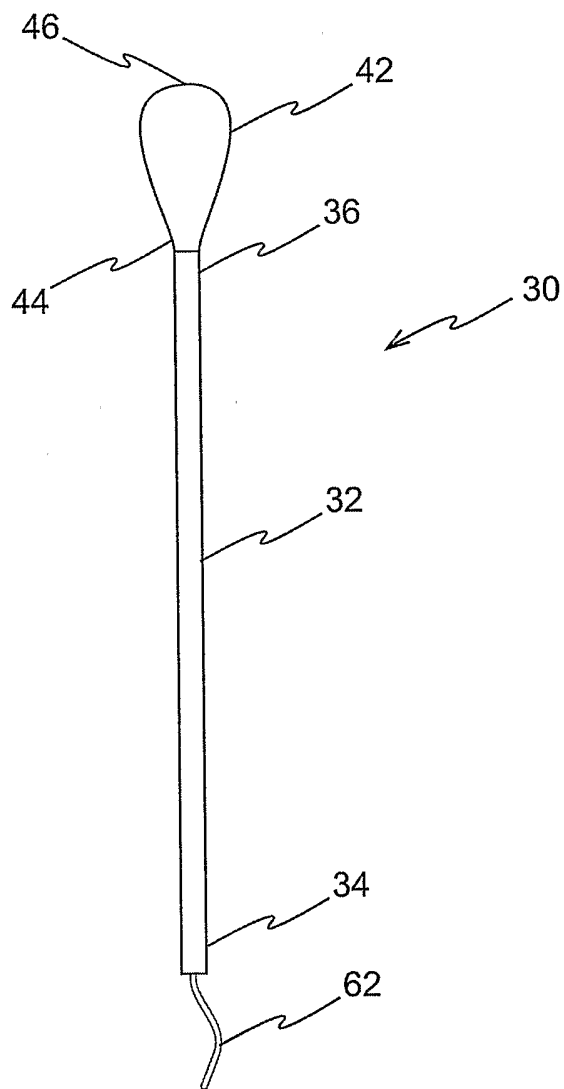


FIG. 3

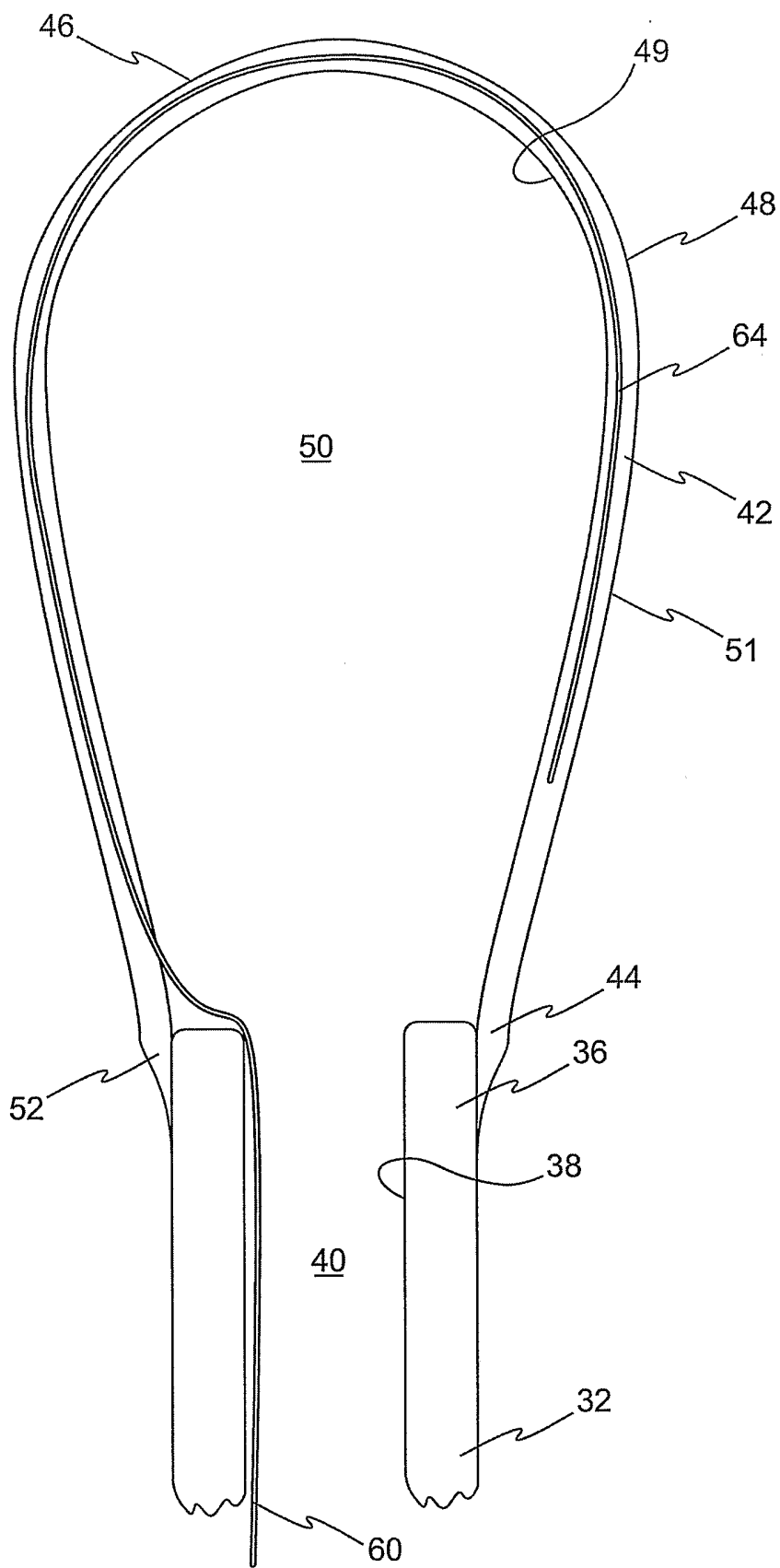


FIG. 4

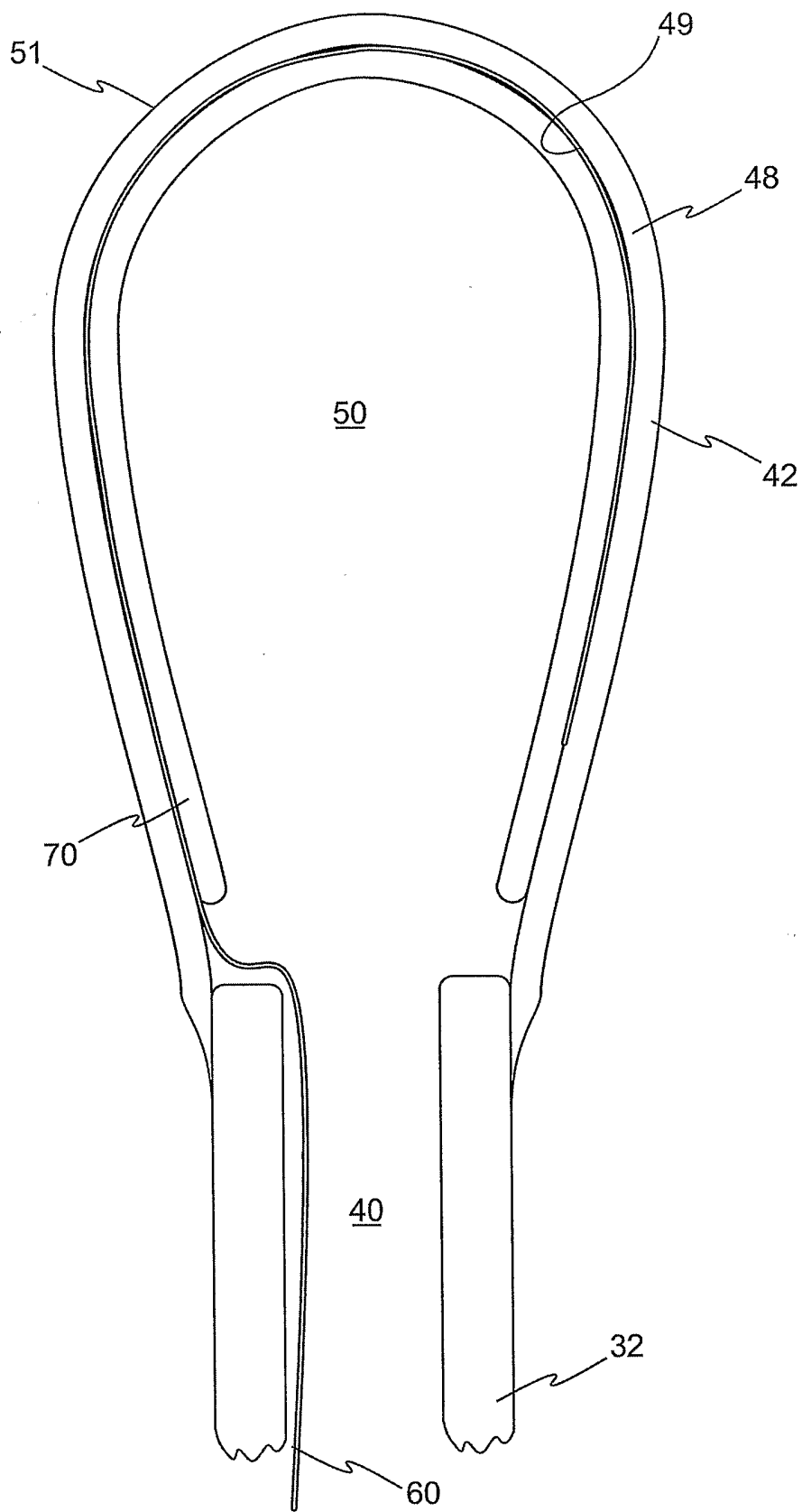


FIG. 5

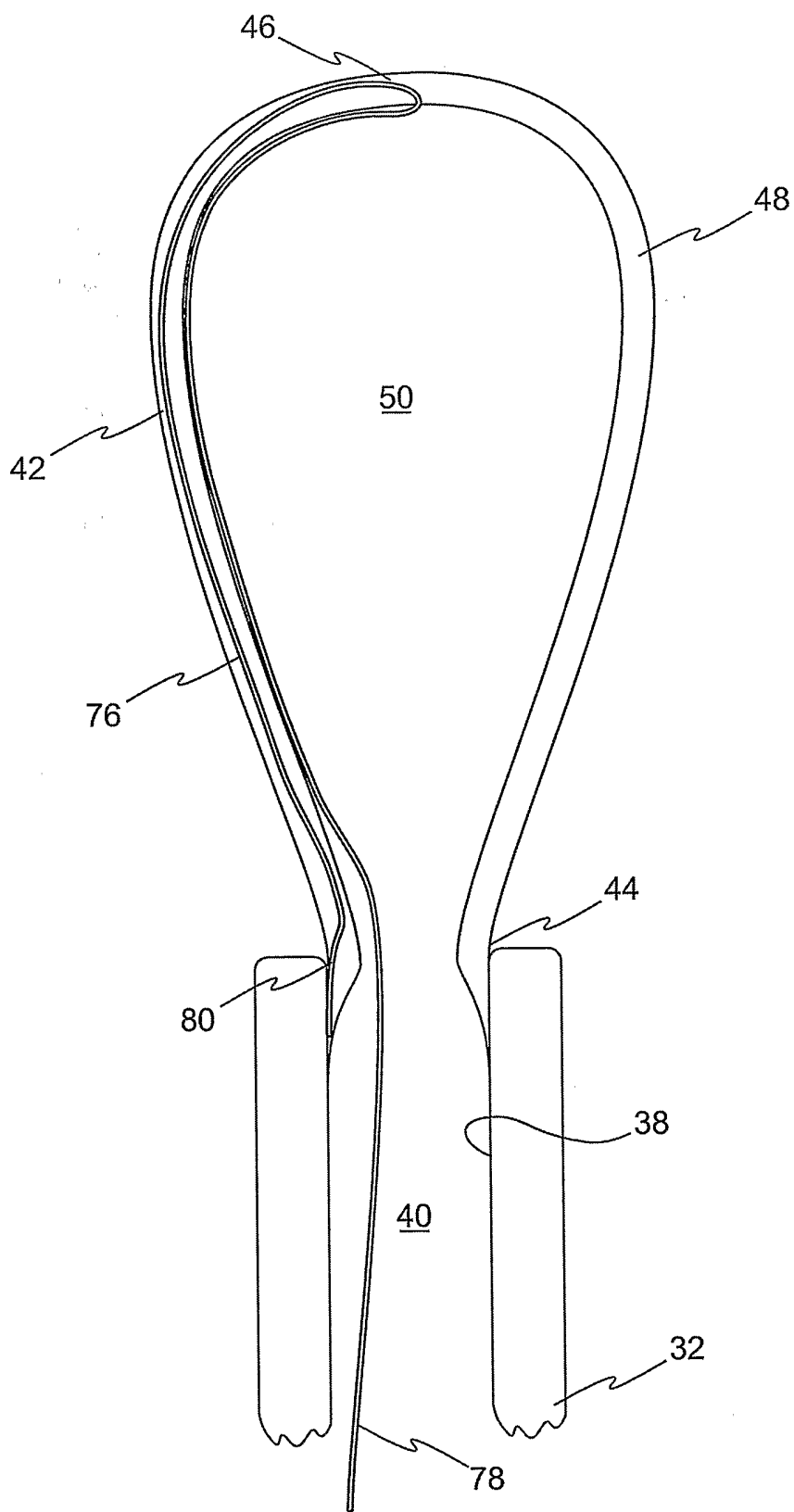


FIG. 6

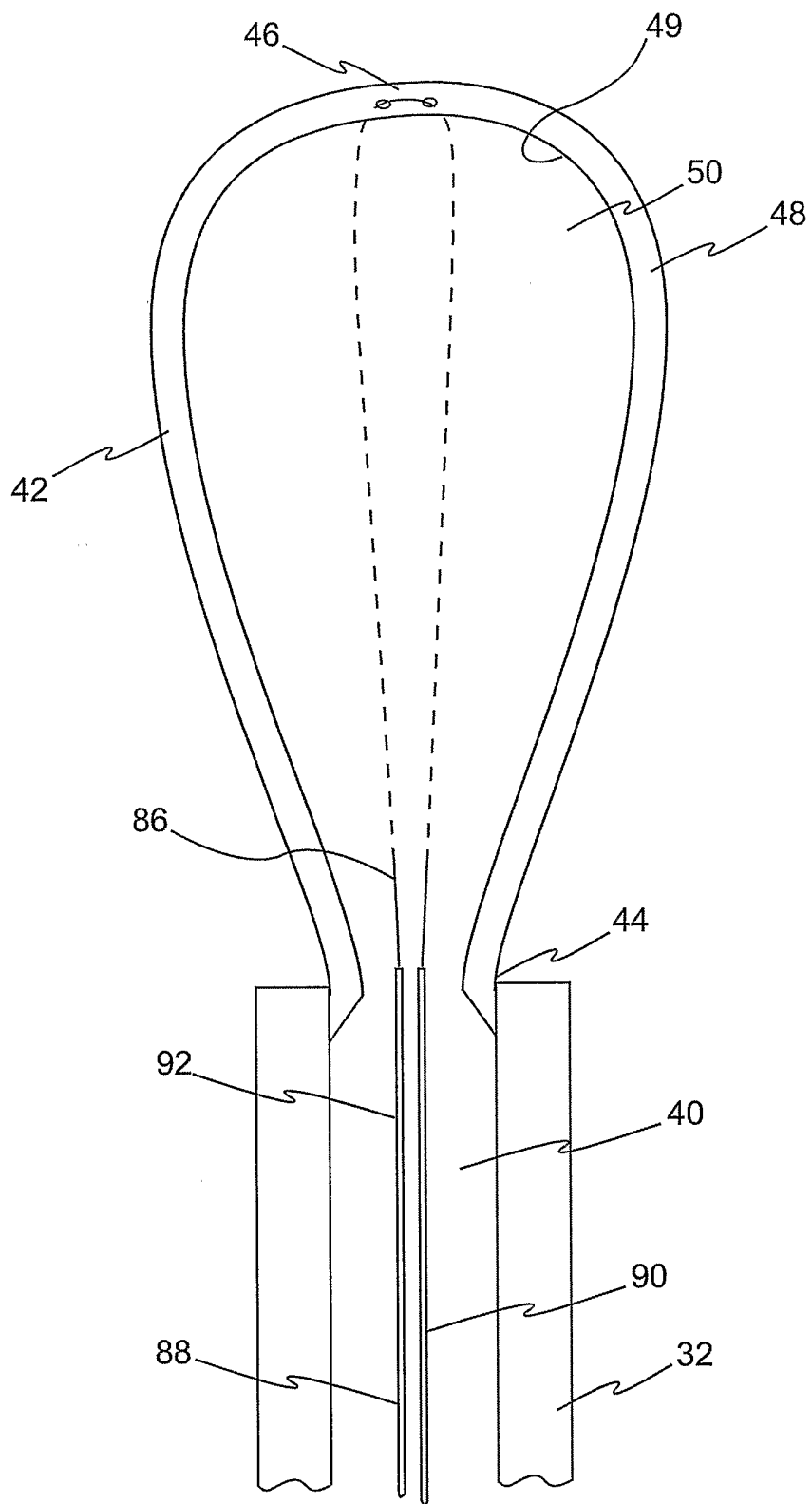


FIG. 7

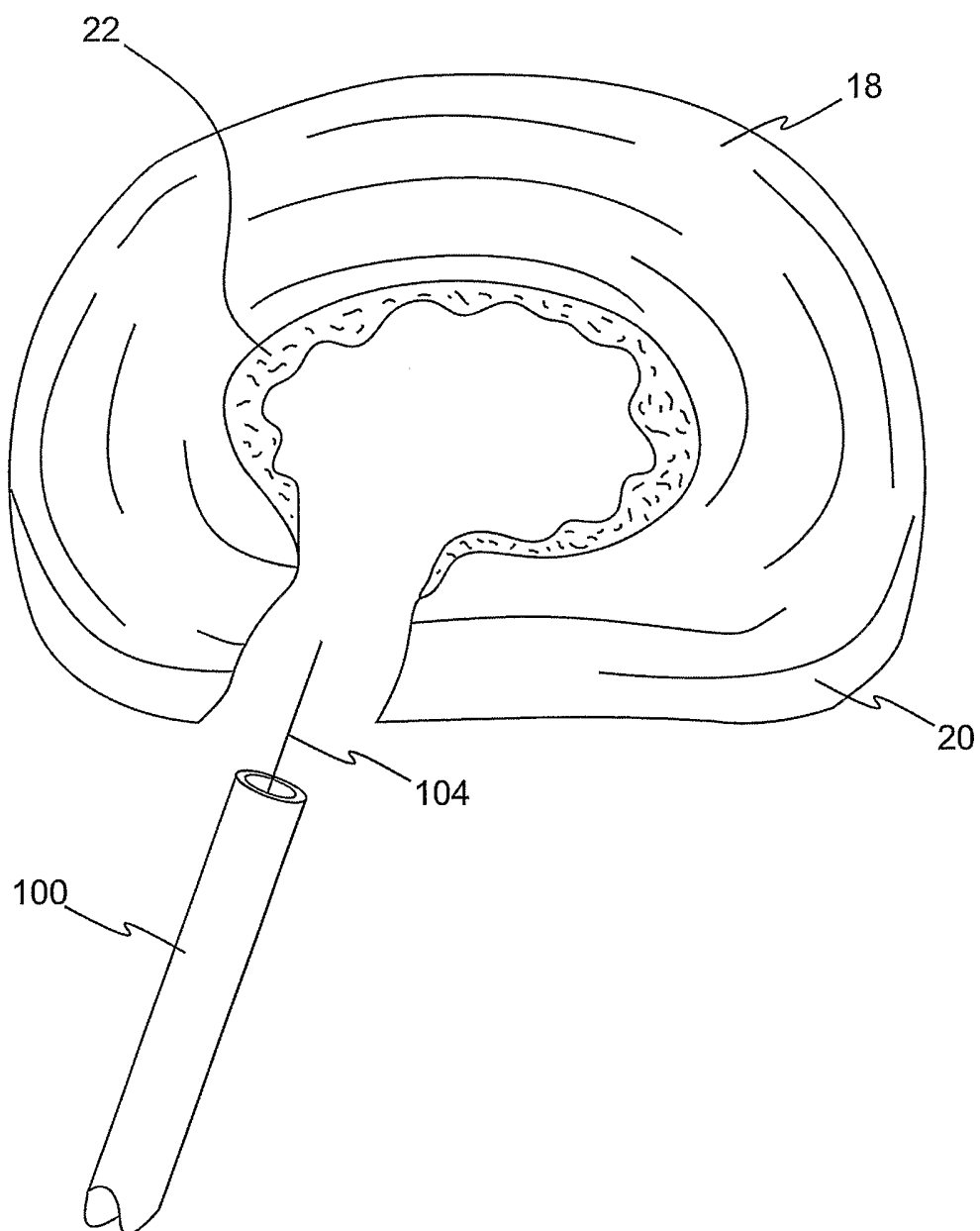


FIG. 8

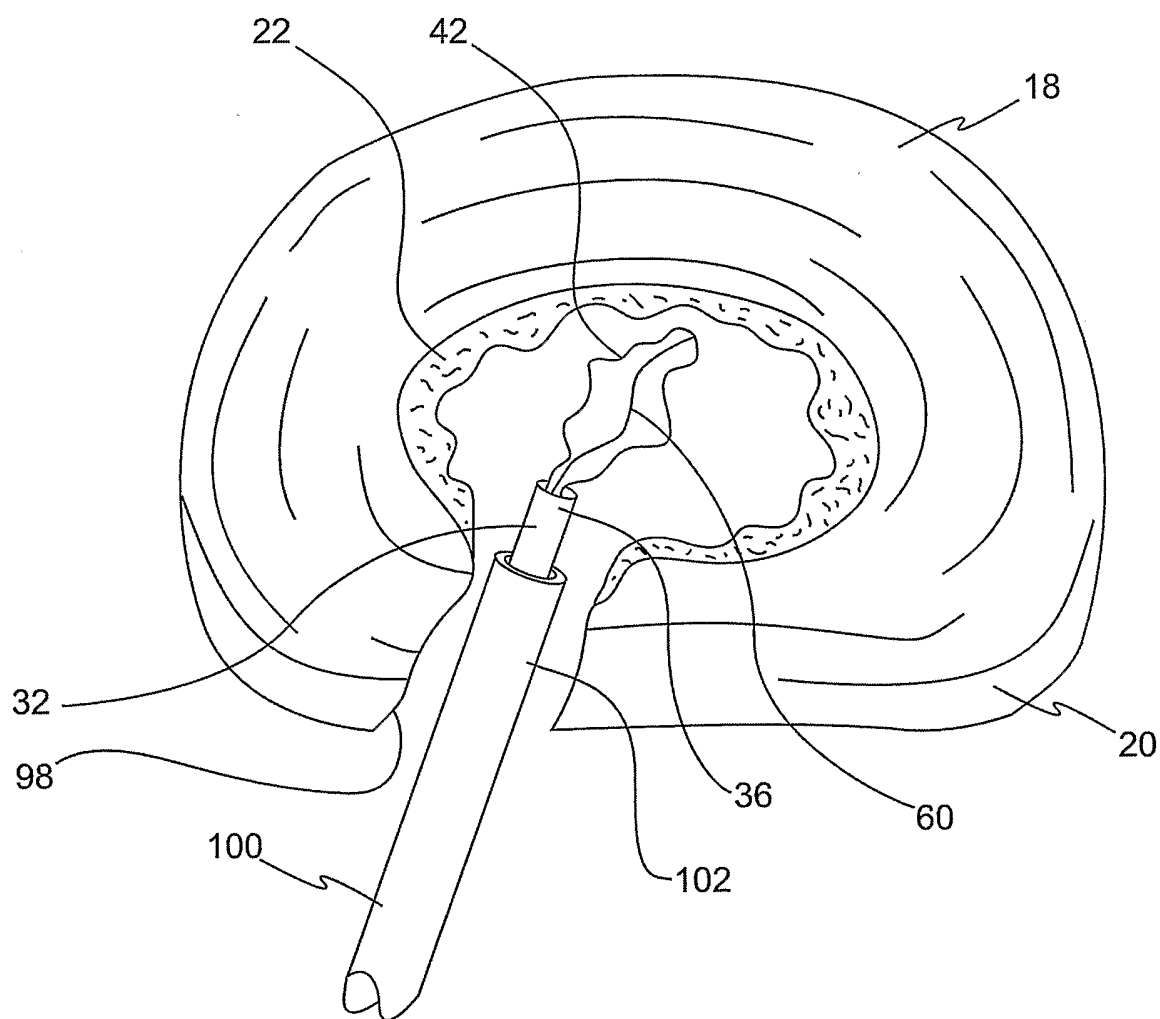


FIG. 9

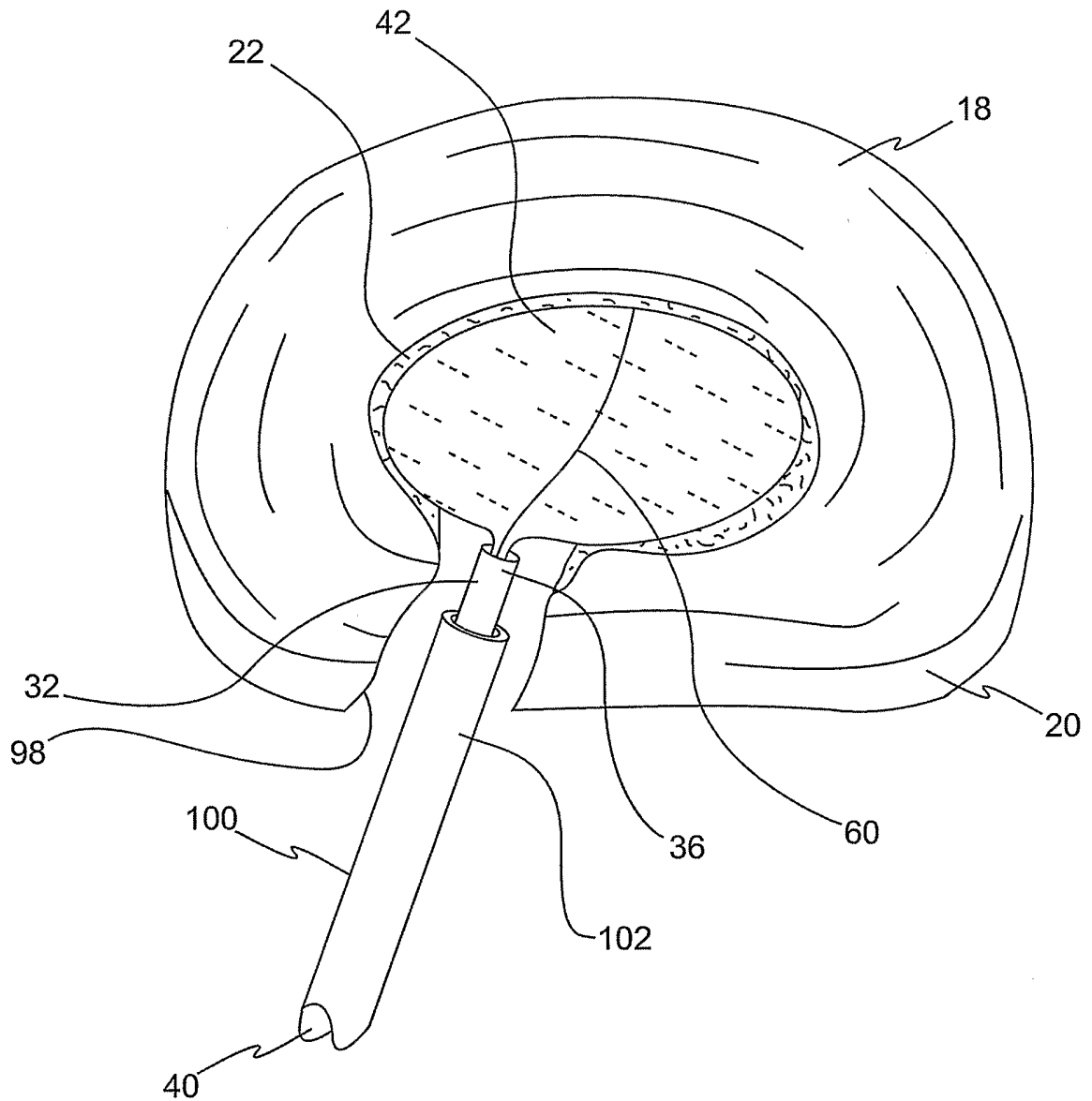


FIG. 10

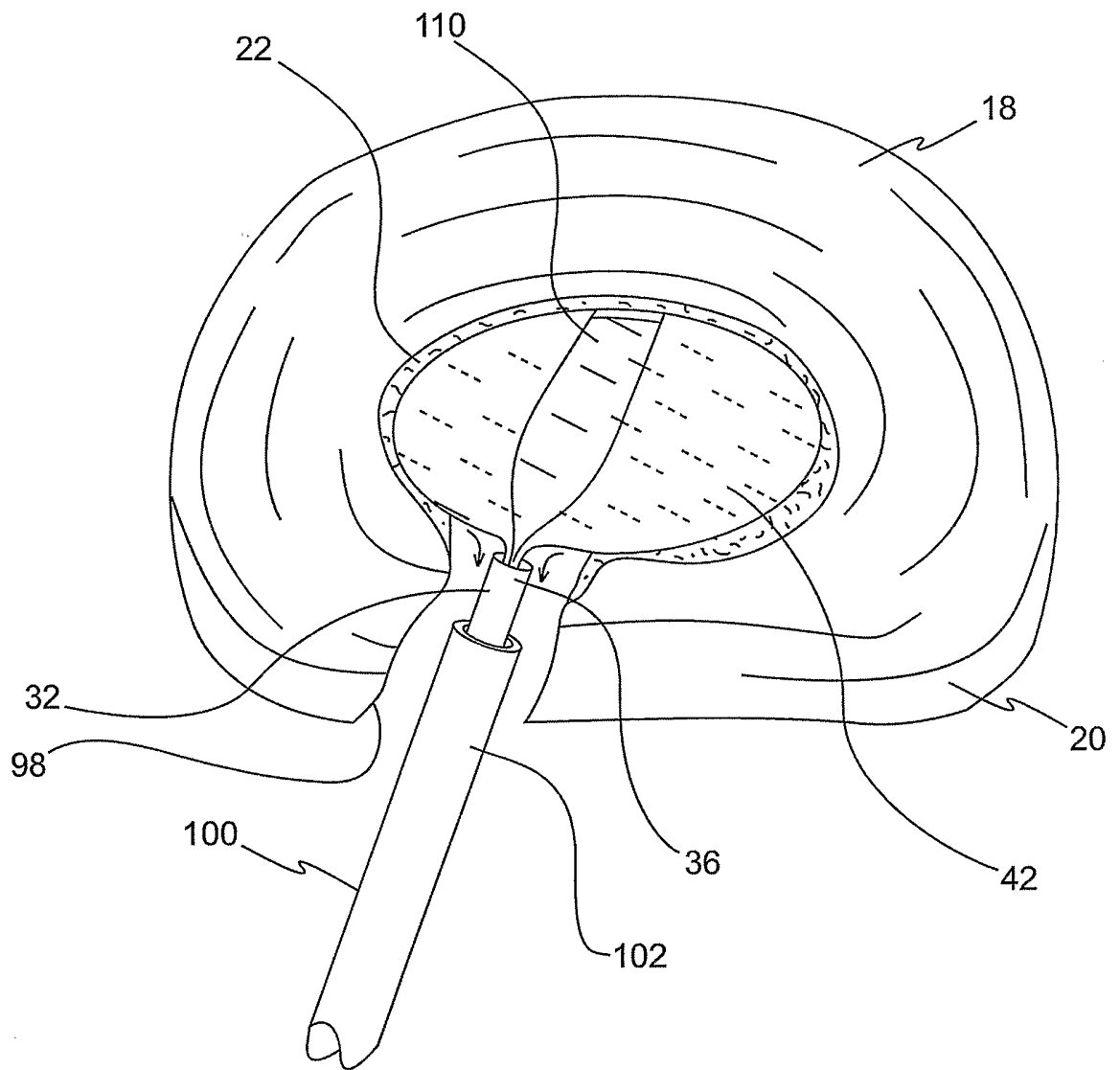


FIG. 11

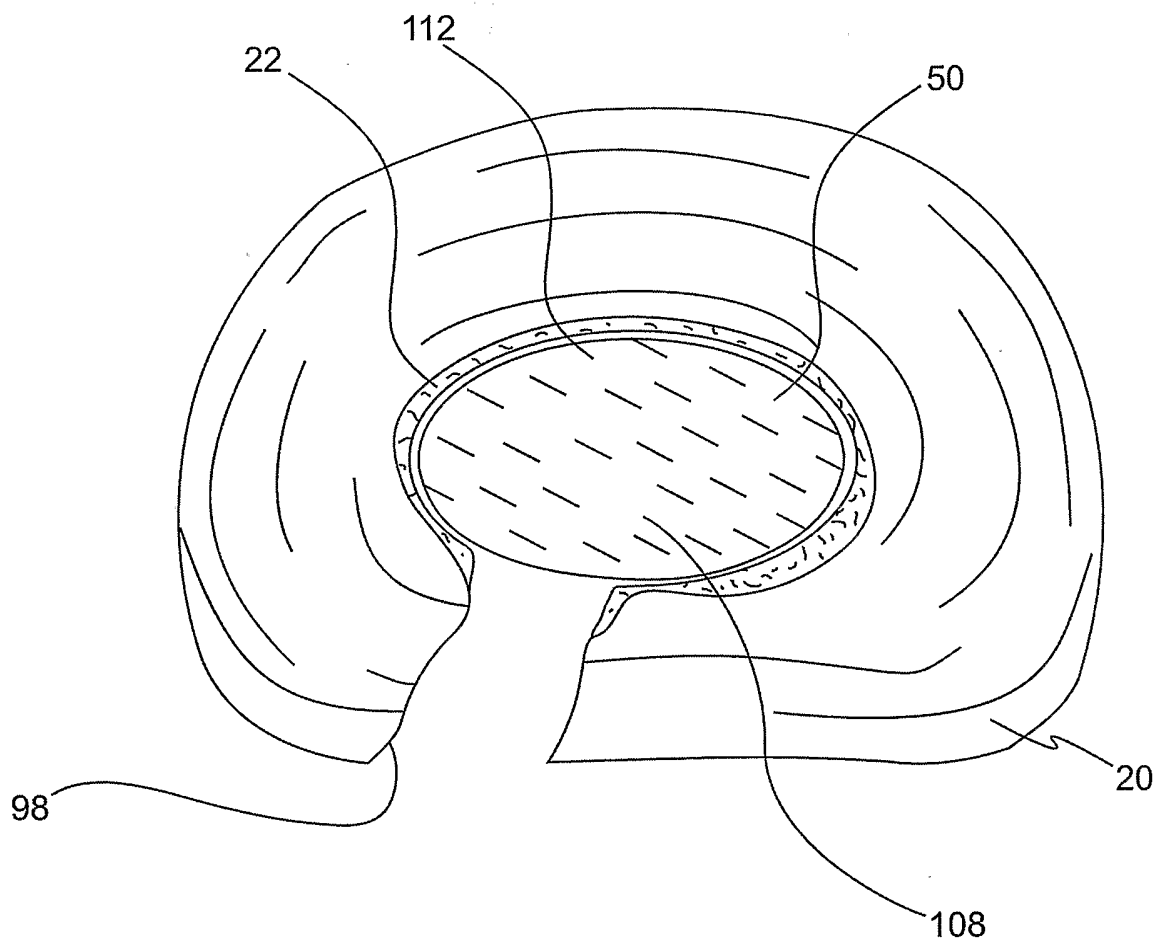


FIG. 12

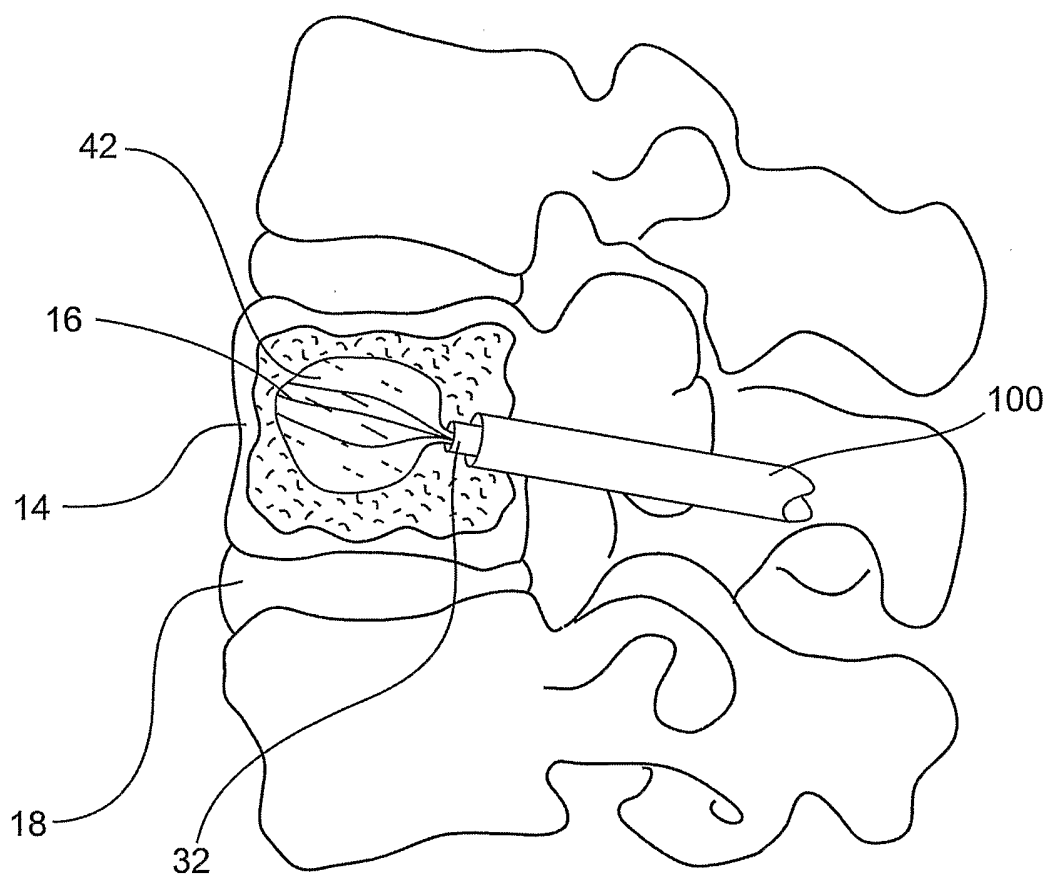


FIG. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/23966

A. CLASSIFICATION OF SUBJECT MATTER
 IPC(7) : A61F 2/44
 US CL : 623/17.11
 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. : 623/17.11,17.12,17.16; 606/86,87,88,92,93,94,61

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

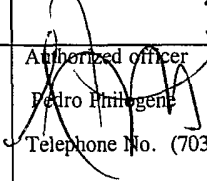
C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,443,988 B2 (Felt et al.) 03 September 2002 (03.09.2002) see entire document.	1-7, 16-28
A,P	US 6,582,446 B1 (Marchosky) 24 June 2003 (24.06.2003) see entire document	1-28
A	US 6,248,131 B1 (Felt et al.) 19 June 2001 (19.06.2001) see entire document	1-28
A	US 5,888,220 A (Felt et al.) 30 March 1999 (30.03.1999) see entire document	1-28
A	US 5,556,429 A (Felt) 17 September 1996 (17.09.1996), see entire document	1-28

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

<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"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</p> <p>"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</p> <p>"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</p> <p>"&" document member of the same patent family</p>
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Date of the actual completion of the international search 07 October 2003 (07.10.2003)	Date of mailing of the international search report 12 NOV 2003
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Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer  Pedro Rittiggen Telephone No. (703) 308-2252
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