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(54) SPINAL DISC NUCLEUS IMPLANT

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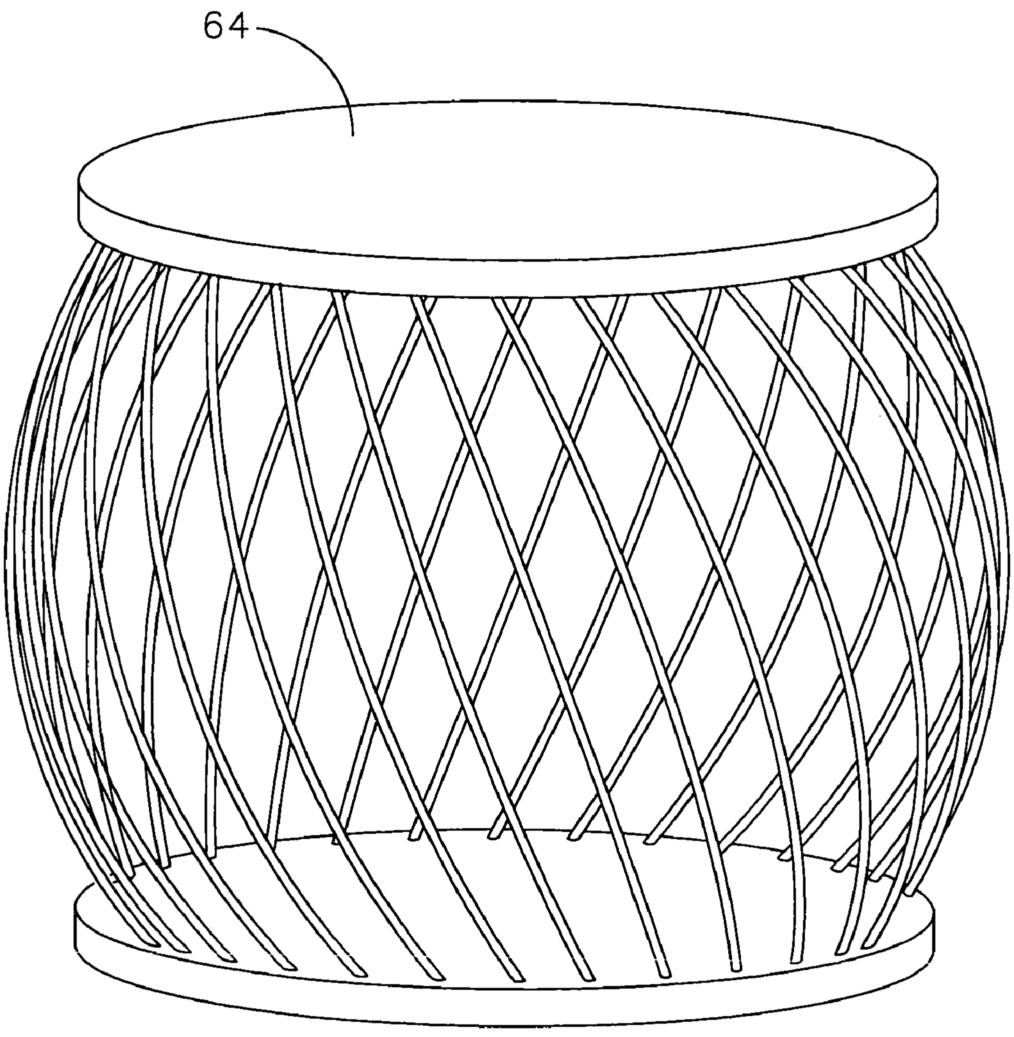
(52) U.S. Cl. **623/17.11**; 623/17.16; 606/86

(57) **ABSTRACT**

A device and method for repairing spinal discs in which the nucleus has been damaged. A central section of the nucleus is cored out using a device which ablates the tissue using RF energy. A nucleus implant comprising a shape memory material is placed in the central section of the disc through a cannula, which implant is activated by body heat to expand and fill the central section, such that the implant emulates the functions and strength of the disc's natural nucleus.



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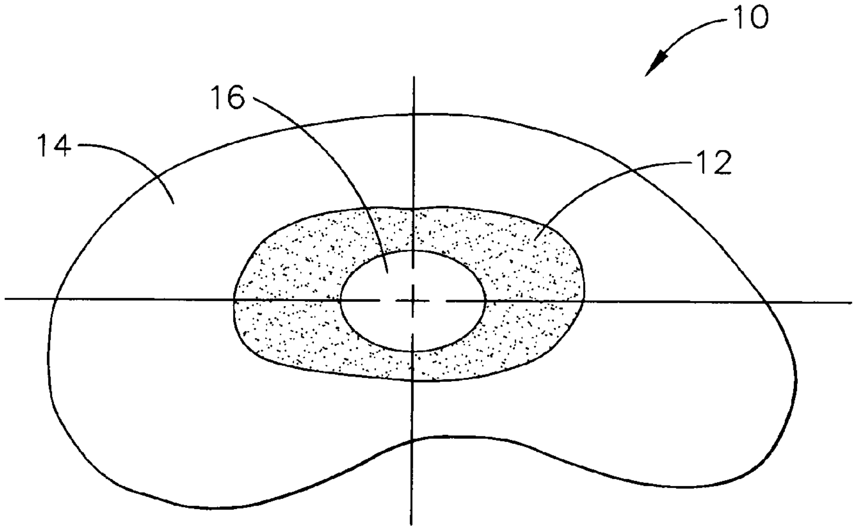

FIG. 1

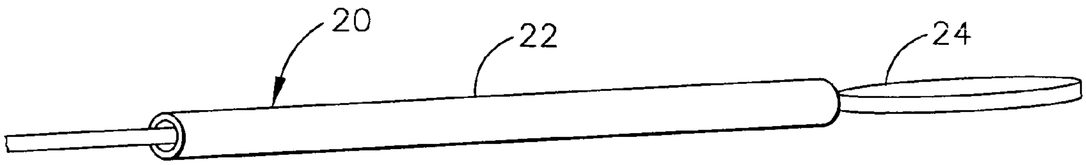

FIG. 2

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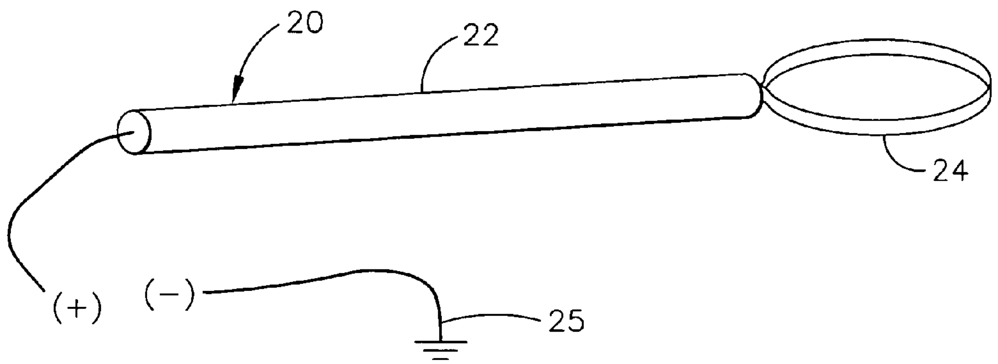

FIG. 3

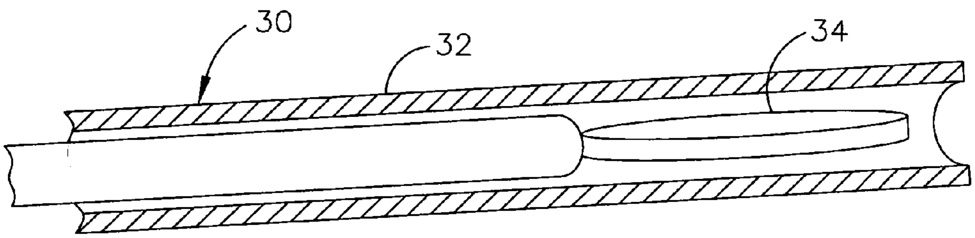

FIG. 4

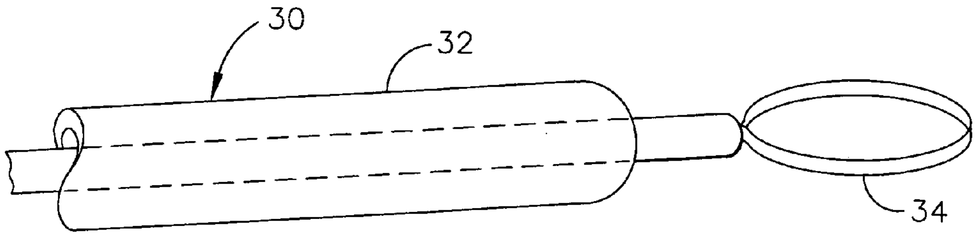

FIG. 5

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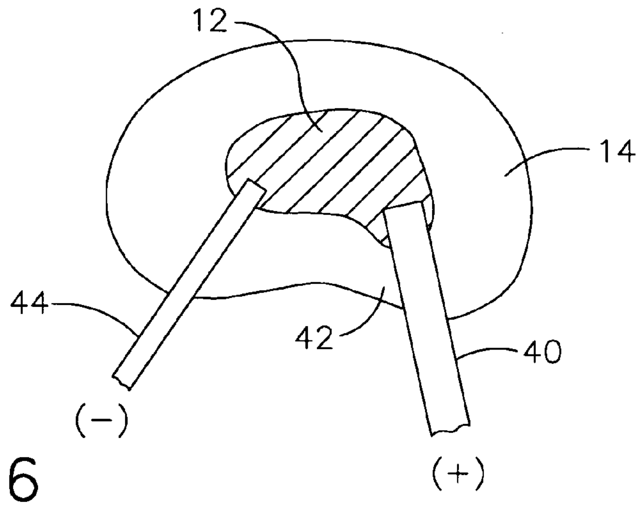

FIG. 6

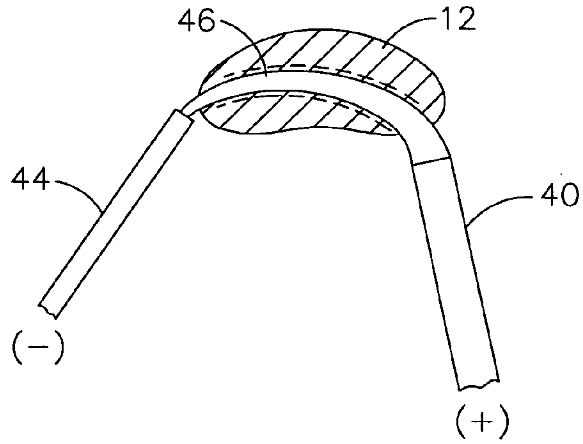

FIG. 7

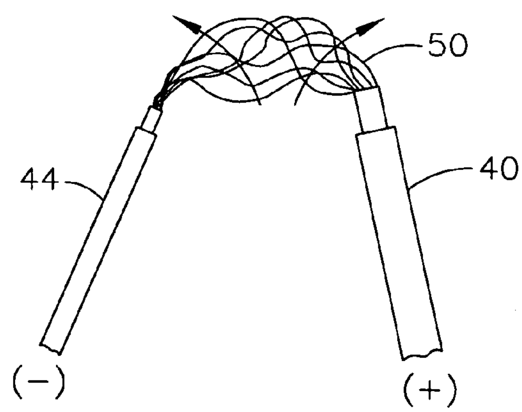

FIG. 8

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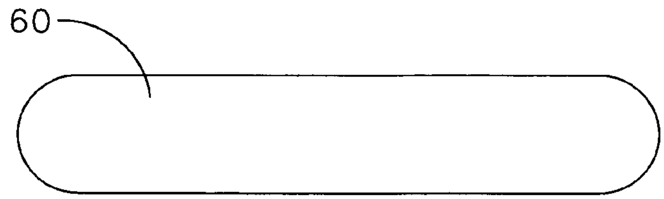

FIG. 9

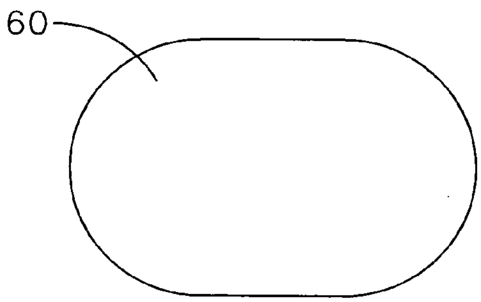

FIG. 10

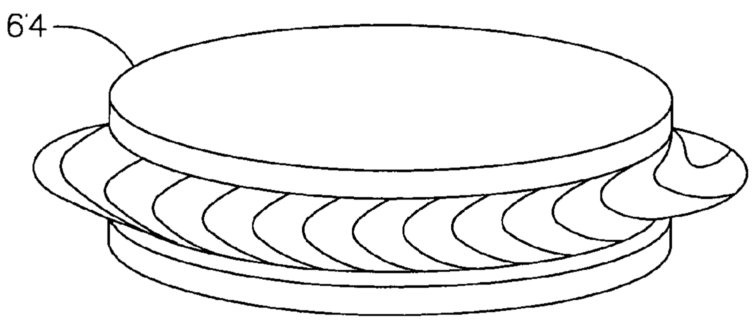

FIG. 11

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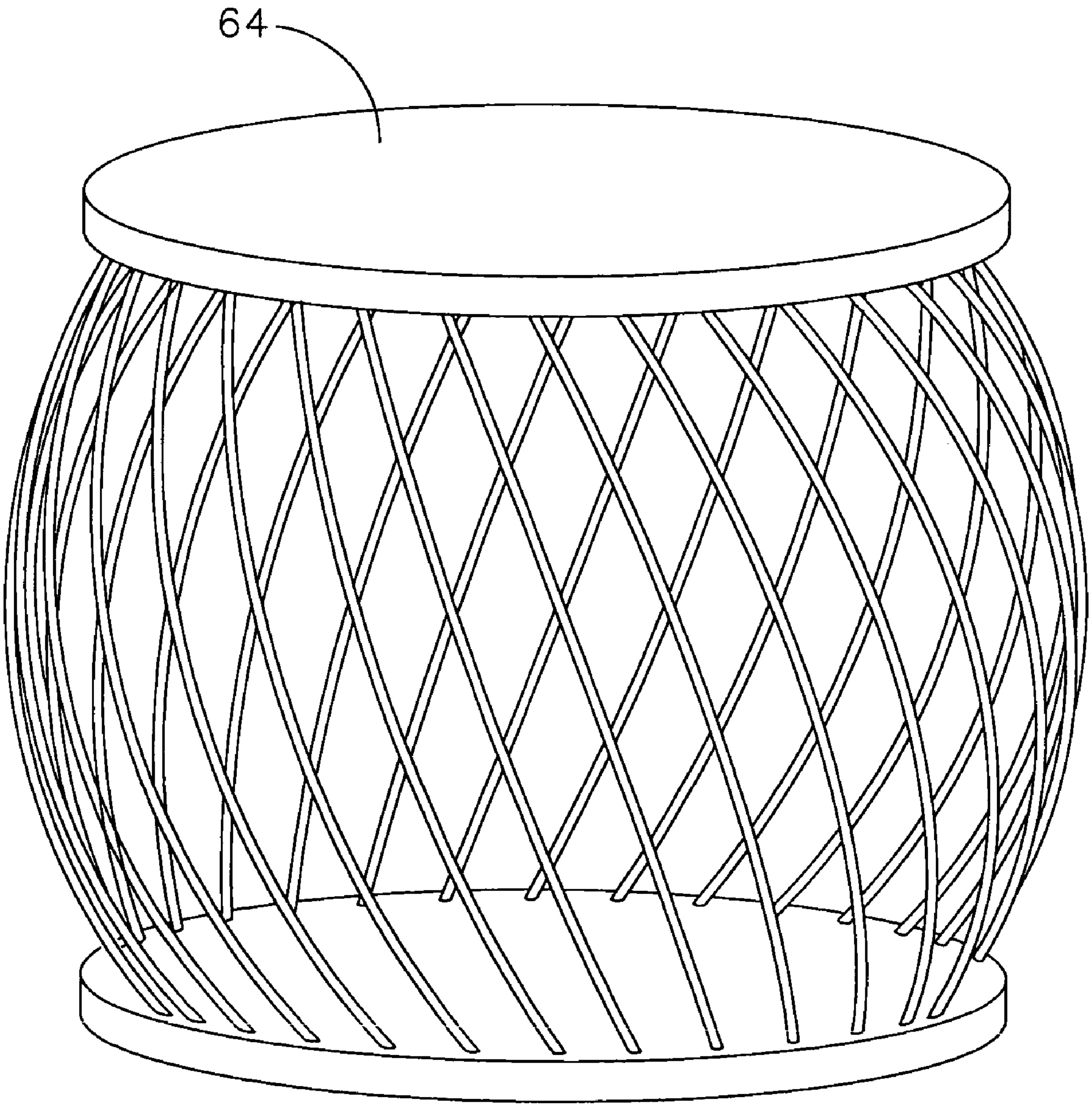

FIG. 12

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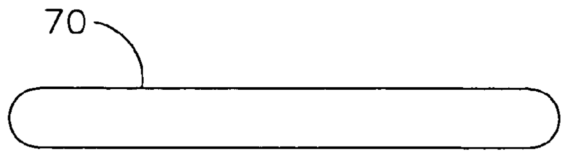

FIG. 13

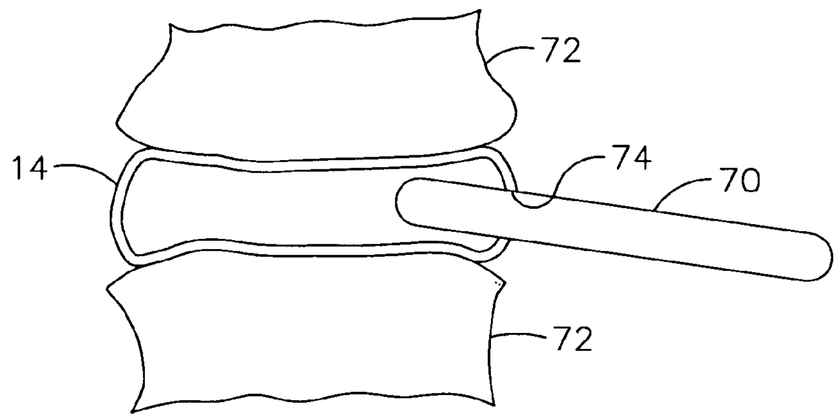

FIG. 14

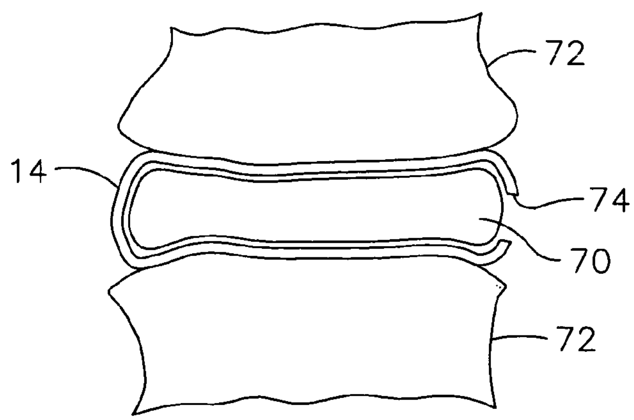

FIG. 15

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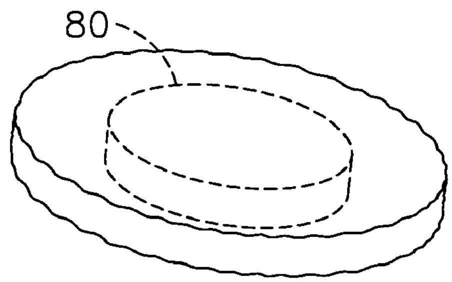

FIG. 16

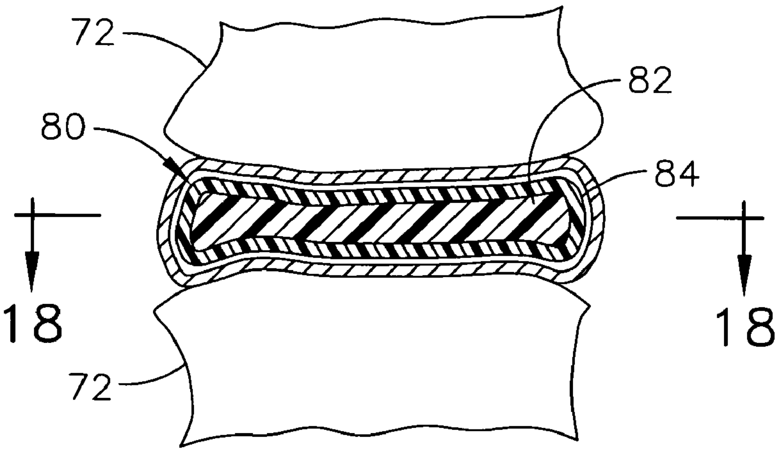

FIG. 17

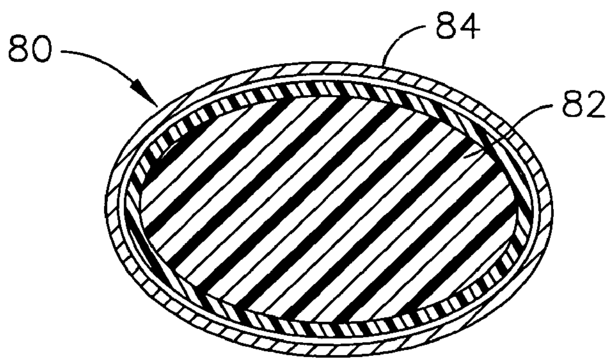

FIG. 18

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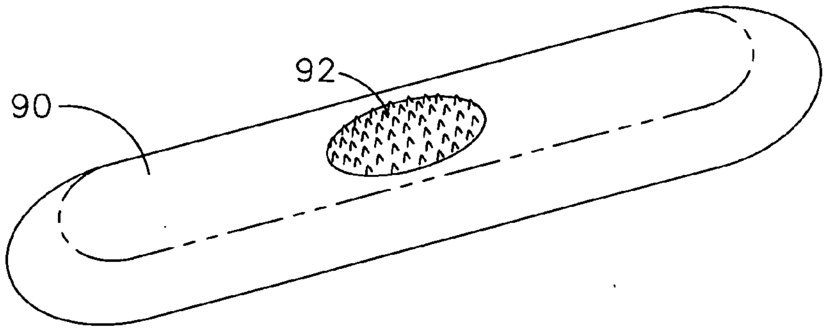

FIG. 19

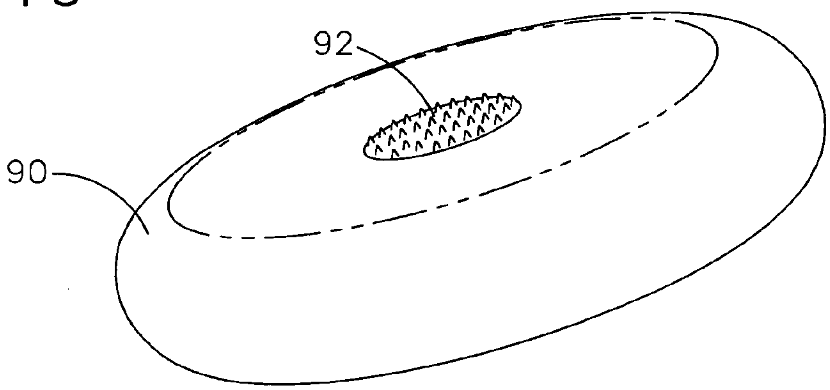

FIG. 20

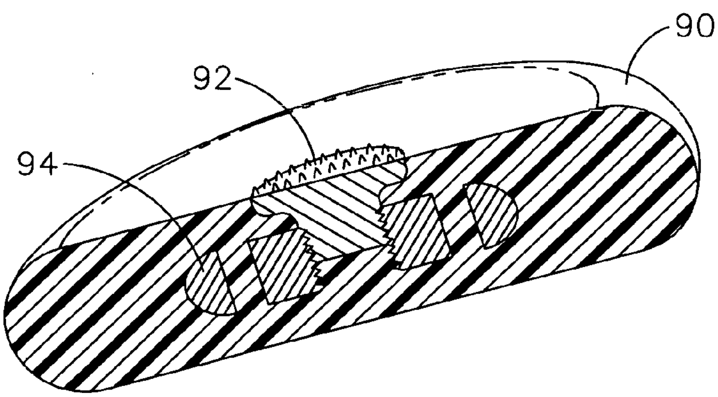

FIG. 21

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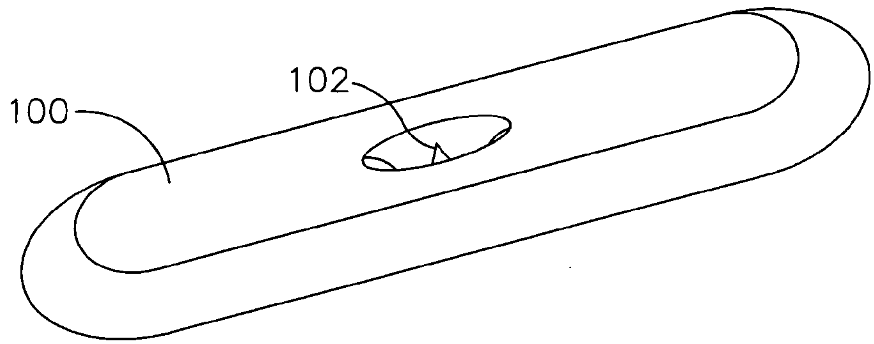

FIG. 22

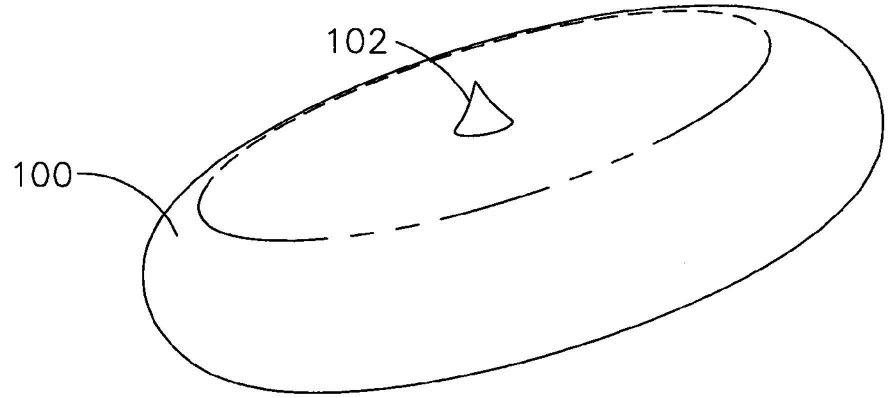

FIG. 23

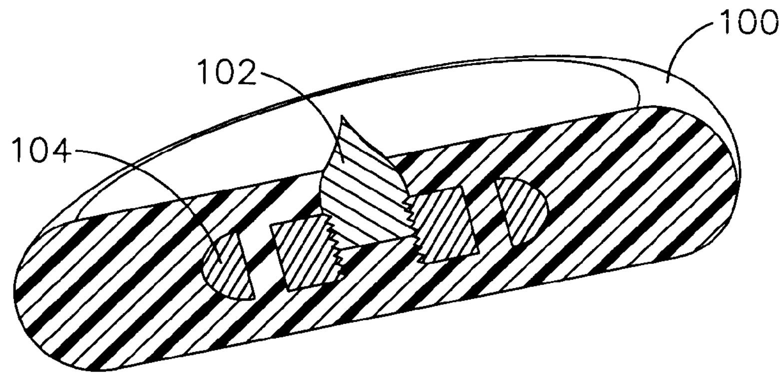

FIG. 24

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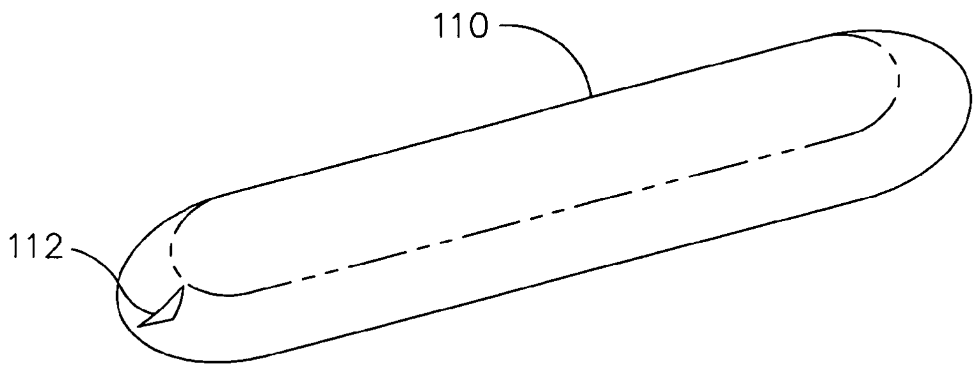

FIG. 25

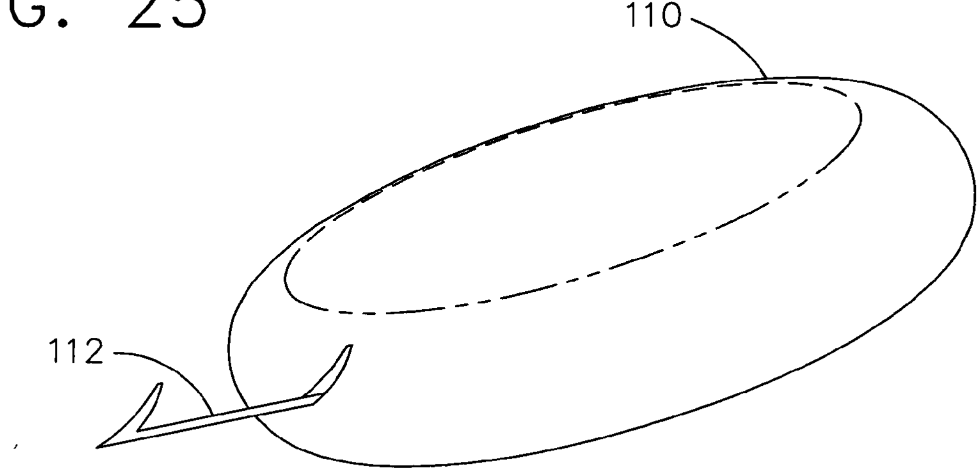

FIG. 26

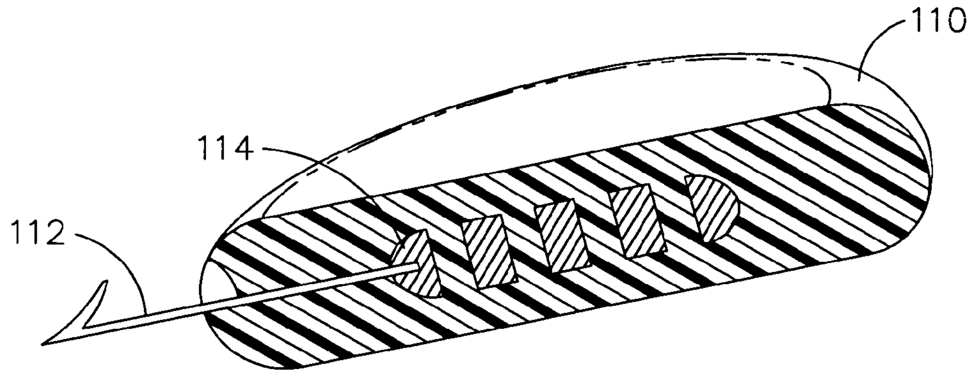

FIG. 27

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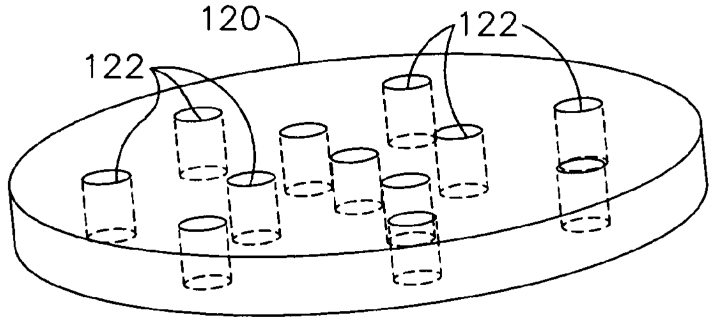

FIG. 28

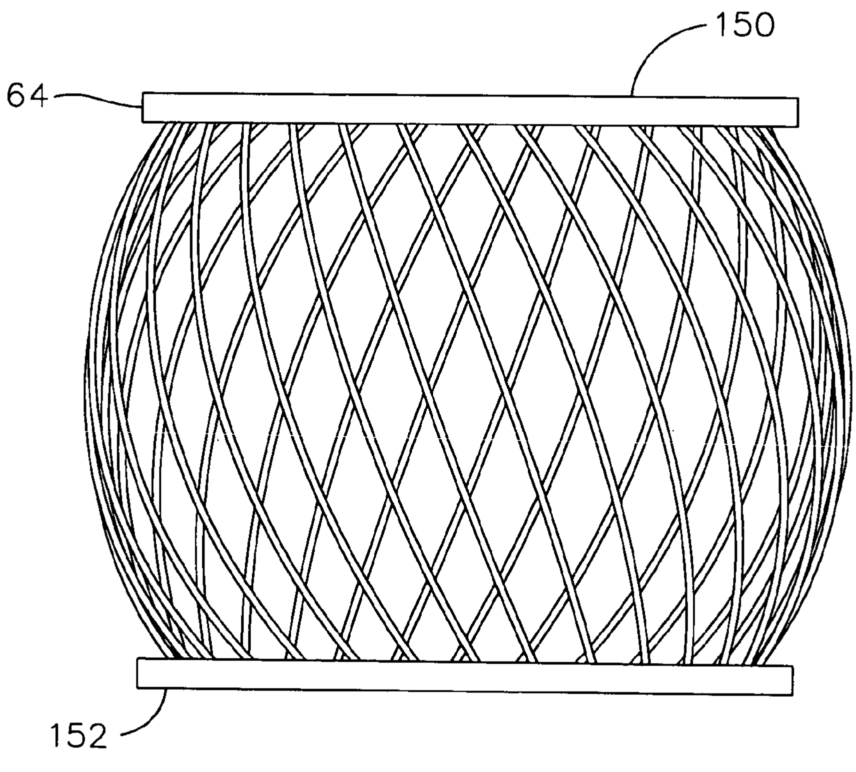

FIG. 29

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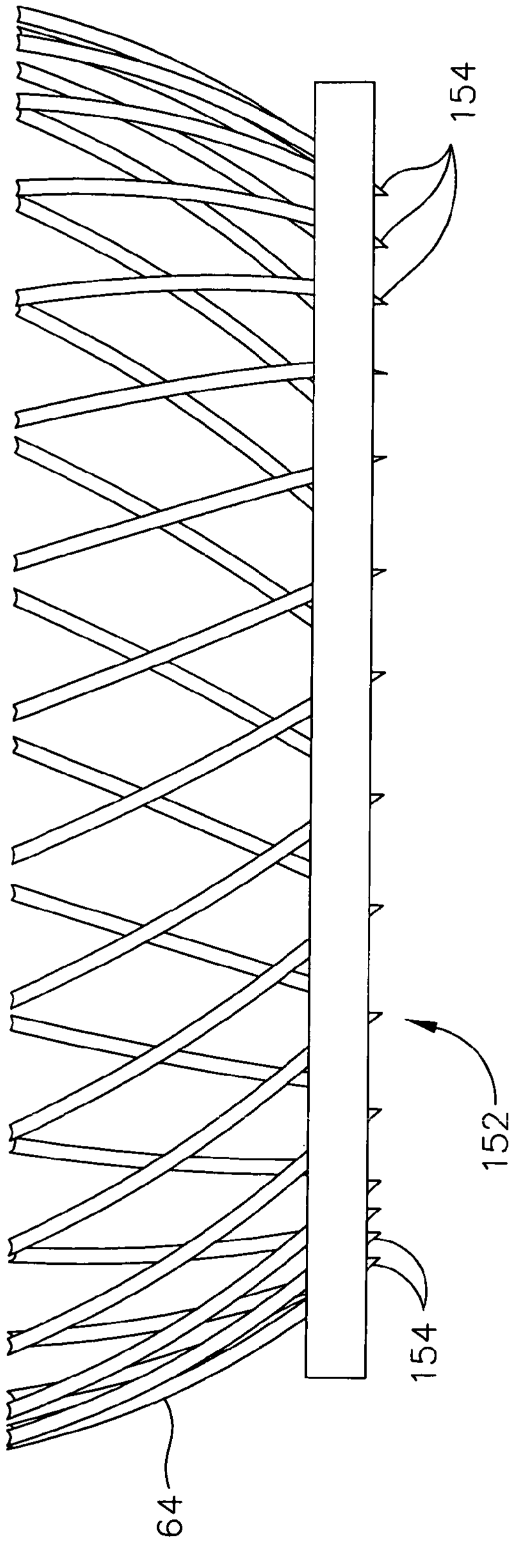

FIG. 30

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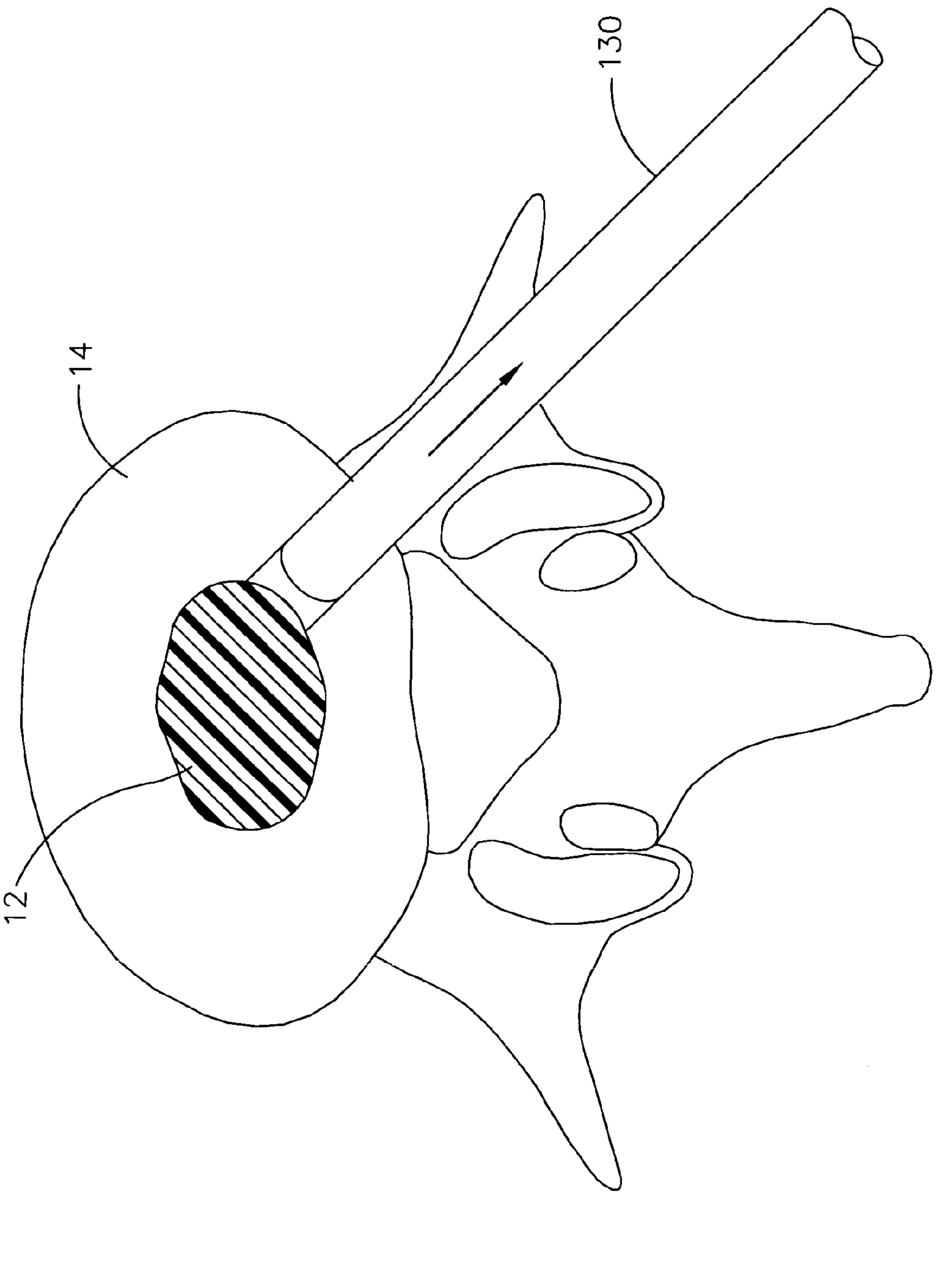

FIG. 31

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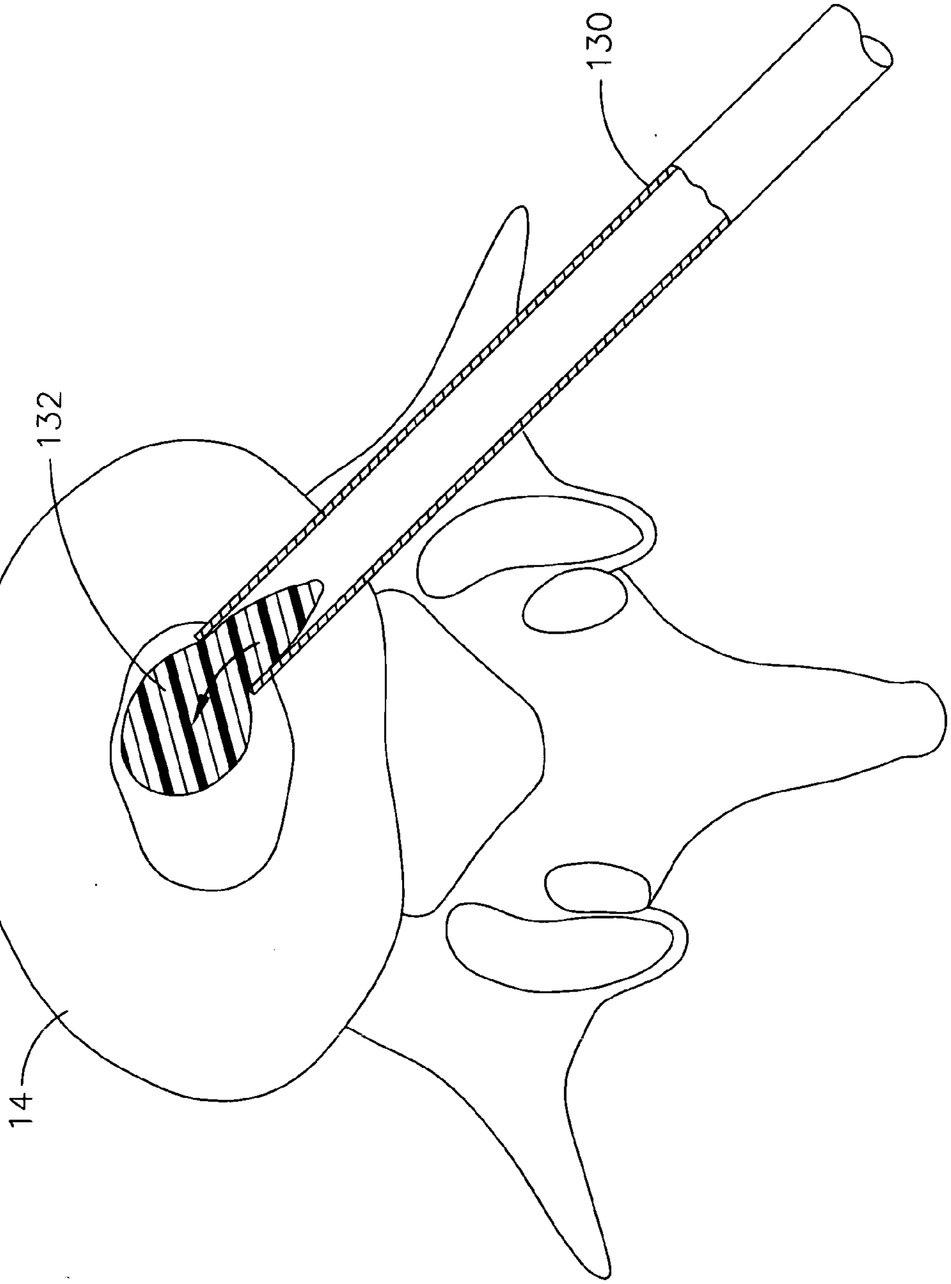

FIG. 32

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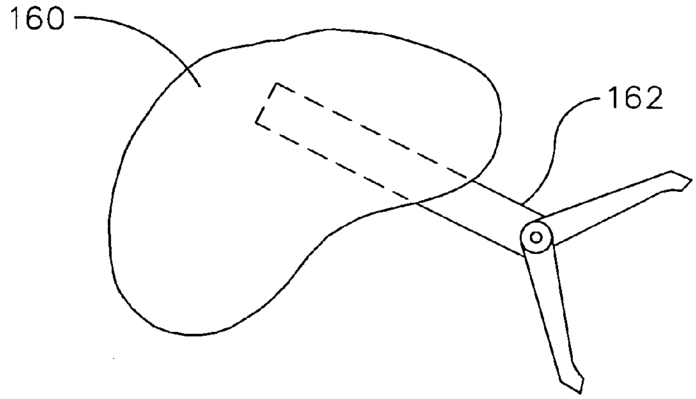

FIG. 33

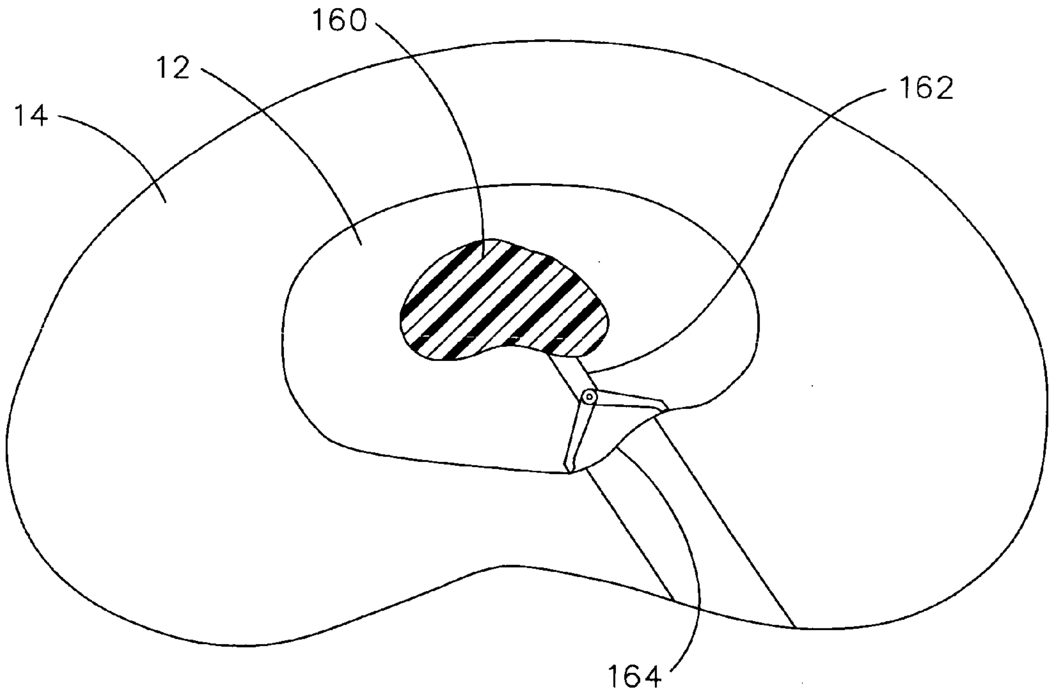

FIG. 34

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SPINAL DISC NUCLEUS IMPLANT

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims benefit from U.S. Provisional Application Ser. No. 60/484,091, filed Jul. 1, 2004, which application is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates generally to spinal implants, and, in particular, to devices and methods for repairing discs in which the nucleus has been damaged.

[0004] 2. Description of the Prior Art

[0005] Due to strain or degenerative disease, the nucleus of a spinal disc often herniates or erupts through the annulus of the disc. This action weakens the disc, as well as creating tremendous pain to the patient as the hernia "bulge" creates pressure on the spinal nerve bundles.

[0006] There are currently two common practices that are employed by surgeons to correct this situation:

[0007] 1) remove the hernial bulge by nibbling or coring away the tissue which is pressing on the nerve bundles. While this procedure is minimally invasive, the disc is weakened and compressed due to loss of nucleus tissue, and it also leaves a path for future disc herniation problems;

[0008] 2) fusing the spine by the application of spine screws and securing rods to the surrounding vertebrae to extrapolate the damaged disc. While this procedure provides rigid support for the spine at the damaged disc area, it is very invasive, and limits the patient's range of motion. In addition, it is limited to repairs on the lumbar vertebrae.

[0009] There have been many attempts in recent years to replace the damaged nucleus of a spinal disc. U.S. Patent Application Publication No. US2002/0183848A is directed to a spinal disc nucleus having a hydrogel core surrounded by a constraining jacket. The hydrogel core is configured to expand from a dehydrated state to a hydrated state. The dehydrated core is implanted through an annulus opening and then hydrated to fill the constraining jacket.

[0010] U.S. Patent Application Publication No. 2002/004800A is directed to a prosthetic pulposus for replacing the natural nucleus pulposus of an intervertebral disc. The prosthetic device comprises a partially collapsed sealed envelope formed from material permeable to extracellular body fluid. The envelope is implanted in the hollowed out interior of the disc and is allowed to absorb fluid, whereby expanding the envelope.

[0011] U.S. Patent Application Publication No. 2003/0199984A is directed to nucleus pulposus implants that are resistant to migration from an intervertebral disc space. The implants include a load bearing elastic body surrounded in the disc space by an anchoring, preferably resorbable, outer shell.

[0012] U.S. Patent Application Publication No. 2004/0030392A is directed to a system for minimally invasive disc augmentation having an annulus augmentation component and a nucleus augmentation component. The nucleus augmentation component restores disc height and/or replaces missing nucleus pulposus. This may be supported by inserting a flexible biocompatible material into the disc space.

[0013] U.S. Patent Application Publication No. 2004/0054413A is directed to a spinal implant for replacing the natural nucleus of the disc made from a polymer such as hydrogel having a radiopaque material located within the polymer. The material may be in the form of a powder dispersed throughout the polymer or dispersed in layers within the polymer.

[0014] U.S. Patent Application Publication No. 2004/0091540A is directed to a minimally invasive method for restoring a damaged or degenerated intervertebral disc at an early stage. An injectable in situ setting formulation in the nucleus pulposus combines with nucleus matter and host cells to gel within the annulus fibrosis of the disc for increasing the thickness and volume of the damaged disc.

[0015] U.S. Patent Application Publication No. 2004/0117019A is directed to a method of implanting a prosthetic spinal disc nucleus by providing an instrument having a dilator for dilating an opening in the disc annulus and passing the prosthetic disc nucleus into the disc through the dilator in one configuration and allowing the disc to assume another configuration when implanted within the annulus.

[0016] In the replacement of the nucleus of a spinal disc, it is imperative that the implant be precisely centered within the nucleus to accept the natural movement and forces that are generated by normal patient activity, and must be retained in this location such that it is centered on the line of force to prevent the implant from placing undue forces on the annulus.

SUMMARY OF THE INVENTION

[0017] It is therefore an object of the present invention to provide a method for accurately removing the nucleus of a spinal disc which is minimally invasive.

[0018] It is a further object of the present invention to provide a spinal disc nucleus implant which emulates the functions and strengths of the spinal disc's natural nucleus.

[0019] It is a still further object of the present invention to provide a device for implanting the replacement nucleus into the proper location within the cored-out disc easily and safely.

[0020] These and other objects of the present invention will be more readily apparent from the description and drawings which follow.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] **FIG. 1** is a top view of the typical spinal disc showing a central core within the nucleus;

[0022] **FIG. 2** is a perspective view of a device for creating a core within the nucleus of a spinal disc;

[0023] **FIG. 3** is a perspective view of the device of **FIG. 2** with the electrode inflated;

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[0024] **FIG. 4** is a perspective view of another embodiment similar to the device of **FIG. 2**;

[0025] **FIG. 5** is a perspective view of the device of **FIG. 4** with the electrode expanded;

[0026] **FIG. 6** is a top view of another embodiment of a device according to the present invention;

[0027] **FIG. 7** is a top view of another embodiment of a device similar to the device of **FIG. 6**;

[0028] **FIG. 8** is a top view of another embodiment of a device similar to the device of **FIG. 6**;

[0029] **FIG. 9** is a plan view of a nucleus implant in its pre-insertion state;

[0030] **FIG. 10** is a plan view of the implant of **FIG. 9** in its implanted state;

[0031] **FIG. 11** is a perspective view of another embodiment of the present invention in its pre-insertion state;

[0032] **FIG. 12** is a perspective view of the implant of **FIG. 11** in its implanted state;

[0033] **FIG. 13** is a perspective view of another embodiment of the present invention in its pre-insertion state;

[0034] **FIG. 14** is a perspective view of the insertion of the implant of **FIG. 13**;

[0035] **FIG. 15** is a plan view of the implant of **FIG. 13** installed between two vertebrae;

[0036] **FIG. 16** is a perspective view of another embodiment of the present invention shown in its implanted state;

[0037] **FIG. 17** is a sectional view of the device of **FIG. 16** shown in its installed position;

[0038] **FIG. 18** is a cross-sectional view taken along line **18-18** in **FIG. 17**;

[0039] **FIG. 19** is a perspective view of another embodiment of the present invention shown in its uninstalled state;

[0040] **FIG. 20** is a perspective view of the device of **FIG. 19** shown in its implanted state;

[0041] **FIG. 21** is a perspective view of **FIG. 20** showing its cross section;

[0042] **FIG. 22** is a perspective view of another embodiment of the present invention shown in its uninstalled state;

[0043] **FIG. 23** is a perspective view of the device of **FIG. 22** shown in its implanted state;

[0044] **FIG. 24** is a perspective view of **FIG. 23** showing its cross section;

[0045] **FIG. 25** is a perspective view of another embodiment of the present invention shown in its uninstalled state;

[0046] **FIG. 26** is a perspective view of the device of **FIG. 25** shown in its implanted state;

[0047] **FIG. 27** is a perspective view of **FIG. 26** showing its cross section;

[0048] **FIG. 28** is a perspective view of a shape memory material core suitable for use in the present invention;

[0049] **FIG. 29** is a plan view of basket suitable for use in the present invention;

[0050] **FIG. 30** is a fragmentary view of an alternate end for use in the device of **FIG. 29**;

[0051] **FIG. 31** is top view, partly in cross-section, of a device for use in performing a procedure according to the present invention;

[0052] **FIG. 32** is a top view, partly in cross section, of the device shown in **FIG. 31** used for installing a device of the present invention;

[0053] **FIG. 33** is a plan view of another embodiment of the present invention; and

[0054] **FIG. 34** is a plan view of the device of **FIG. 33** shown in its implanted state.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0055] Referring now to **FIG. 1**, there is shown a representative spinal disc, generally indicated at **10**. Disc **10** contains a nucleus **12** and an annulus **14**. Within nucleus **12** is a centrally located cored out section **16**. Section **16** is created to precisely locate an artificial nucleus implant which would accept a standard shape. Section **16**, which houses the implant, should ideally be centered in the nucleus to accept the natural movement and forces that are generated by normal patient activity.

[0056] To define a standard core section **16** shape, an instrument must be developed which can consistently core out this area within nucleus **12**. The instrument should be small in size such that the procedure can be performed as minimally invasive. It is important that the nucleus implant remains centered on the line of force, preventing it from placing undue forces on annulus **14**. One method for accomplishing these objectives is to leave annulus **14** in place and some of the tissue of nucleus **12** but to locate an exact cavity **16** into which the implant is fitted.

[0057] One method for removing the tissue within nucleus **12** is by ablation. RF energy may be used to power an electrode that is the size and shape of the cavity desired. **FIGS. 2 and 3** show an instrument **20** suitable for use in forming core section **16** within nucleus **12**. Instrument **20** consists of a probe **22** having a collapsed electrode **24** at its tip. Instrument **20** can be inserted endoscopically into the disc until electrode **24** is at its desired location. Electrode **24**, which is a balloon in this embodiment, is slowly inflated using a gas or liquid, ablating the tissue as it grows. Electrode **24** acts as the positive electrode while the ground electrode is connected to the patient. Irrigation or evacuation could be used to remove gases generated during ablation.

[0058] **FIGS. 4 and 5** show another embodiment for an ablating instrument for use in the present invention. Instrument **30** contains a hollow shaft **32** within which a collapsed electrode **34** is stored. When the tip of instrument **30** reaches the desired destination, electrode **34**, which may consist of spring band, is expanded, ablating the nucleus tissue.

[0059] The aforementioned techniques and instruments would need to be centered in the disc. This may be accomplished by measuring the center line or by interoperative imaging. Additionally, hooked or straight probes may be employed to find the extremes of the disc and then measured to the center. Guidance and imaging will be critical to

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centrically locate core section **16** within the disc to insure that the nucleus implant performs optimally.

[**0060**] Another technique for creating a cored out section within the nucleus is shown in **FIGS. 6, 7**, and **8**. Referring now to **FIG. 6**, there is shown a first cannula **40** inserted through a herniated area **42** within annulus **14** into nucleus **12**. A second smaller cannula **44** may be inserted through a healthy section of annulus **14** into nucleus **12**. Cannulae **40** and **44** may act as positive and negative electrodes for an RF device, and cannula **44** helps to find the proper location.

[**0061**] An RF device **46** is deployed out of cannula **40** and the distal end inserted or retracted into cannula **44**. Device **46** may be a balloon-like catheter with a conductive coating or flexible wires that could be energized to ablate the nucleus tissue. Cannulae **40**, **44** may also have a vacuum port to remove gases and/or tissue. Device **46** may also consist of a series of wires **50**, as shown in **FIG. 8**, or a woven basket, that could be energized and rotated to core out tissue. As wires **50** are energized with RF energy, the woven basket would be slowly rotated.

[**0062**] The major goal of the aforementioned devices and procedures is to core out a standard shape centrically within the disc nucleus and insert an implant that will support and give full motion, emulating the spinal disc's natural nucleus.

[**0063**] The second element of the present invention is the implant. The size and shape of the implant is determined by the core shape formed with the aforementioned instruments. **FIGS. 9 and 10** show a nucleus implant constructed according to the present invention. **FIG. 9** shows an implant **60** in its pre-insertion state. Implant **60** is composed of a material having shape memory properties which will be activated by external means such as thermal mans, light means, RF means, or chemical means. Acceptable shape memory materials are available from the Polymer Technolgy Group of Berkeley, Calif. and mnemoScience GmbH of Aachen, Germany. Before the material is activated, it will be small in size for ease of insertion into the created core. Upon activation, implant **60** will change shape to fit within the cored out area of the disc, as seen in **FIG. 10**. As can be seen in the FIGS., before material **60** is activated, it will be small in size for ease of insertion into the created core **16** in disc **10**, and then activated by swelling or expanding to populate core **16**.

[**0064**] Another embodiment of an implant for use in the spinal disc is shown in **FIGS. 11 and 12**. Referring now to **FIG. 11**, there is shown a shell or stent-like basket **64** created using a metallic material which contains a shape memory material within the basket. After insertion into core **16** of disc **10**, the shape memory material within basket **64** expands to fill core **16**.

[**0065**] The use of an implant constructed from shape memory material within the spine is shown in **FIGS. 13, 14**, and **15**. Implant **70** is shown in **FIG. 13** in a shape, prior to insertion, at room temperature or below. In **FIG. 14**, implant **70** is inserted between two vertebrae **72**, which are L4 and L5 in this embodiment. Implant **70** is inserted through a hole **74** in annulus **14** of the damaged disc. As implant **70** warms to body temperature, the shape memory polymer expands to fill the space cored out within the disc. After implant **70** expands, it will not be able to extrude through hole **74** in annulus **14**.

[**0066**] **FIGS. 16, 17**, and **18** show an implant **80** according to the present invention in position within a disc **10** between vertebrae. **FIG. 16** shows implant **80** in its expanded shape at body temperature. **FIG. 17** shows implant **80** located between vertebrae **72** surrounded by annulus **14**. In this embodiment, shape memory material **82** is encapsulated within a shell **84**.

[**0067**] When the implant is molded in its cold or inactivated state, stabilizing elements can be included such that when the material assumes its activated state, these elements assist in anchoring the implant in its proper place. Examples of these elements can be seen in **FIGS. 19-27**.

[**0068**] **FIGS. 19, 20**, and **21** show a nucleus disc implant **90** in which a stabilizing plate **92** is incorporated into the shape memory material. **FIG. 19** shows implant **90** in its constrained state, while **FIGS. 20 and 21** show implant **90** in its implanted state. Plate **92**, which is attached to an anchor **94** molded within implant **90**, contacts the lower surface of the vertebra above it to assist in holding implant **90** in its proper location.

[**0069**] **FIGS. 22, 23**, and **24** show a disc implant **100** having a central prong **102** which serves to affix implant **100** in its proper location in its implanted state. Prong **102** which extends upwardly in its implanted state **(FIG. 24)**, is attached to an anchor **104** molded within implant **100**. Prong **102** extends upwardly to affix implant **100** in its proper position by contacting the vertebra directly above it.

[**0070**] **FIGS. 25, 26**, and **27** show a disc implant **110** having a central prong **112** which extends laterally from the implant to affix implant **110** in its proper position. Prong **112** is attached to an anchor **114** which is molded into implant **110**.

[**0071**] **FIG. 28** shows a core **120** which, when molded into shape memory material, will assure mechanical bonding within a thin shell elastomer as shown in **FIGS. 16, 17**, and **18**. Core **120** contains a series of circular channels **122** into which the shape memory material will flow to insure a secure fit within the implant.

[**0072**] **FIGS. 31 and 32** show a delivery device for installing the nucleus implant into its proper location. A cannula device **130** is shown in **FIG. 31** removing the cored out section of nucleus **12**. The same device **130** can be used to introduce implant **132** into nucleus **12**. Device **130** would hold implant **132** in a constrained state and act as a delivery cannula to the cored out cavity **16**. Device **130** may also act as the activator of the shape memory material used for implant **132**. For example, device **130** could deliver saline at the desired temperature to activate the shape memory material. This technique would allow the material to have a higher temperature, in the active state, such that it is hard and stable when cooled to body temperature. The walls of device **130** can be insulated such that only implant **132** is subjected to the temperature within device **130**. Device **130** may have the ability to heat, cool, or transfer other energy to stimulate the material.

[**0073**] The basket concept of **FIGS. 11 and 12** can also be adapted to assist in secure positioning of the implant of the present invention. Referring now to **FIGS. 29 and 30**, basket **64** contains a polished surface **150** at one end and a rough surface **152** at its other end. Basket **64** is filled with shape memory material when collapsed, and basket **64** is then inserted into hollowed out core **16** of the nucleus of a disc. When the material is activated, basket **64** expands, and

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rough surface **152** is captured in place on the adjacent vertebra. Surface **152** may also be fitted with a series of prongs **154** to prevent slippage.

[0074] Shape memory material may also be used in combination with other features to improve the stability of a nucleus implant. **FIG. 33** shows a combination shape memory polymer **160** into which a metal spring loaded molly **162** has been molded. When the implant is positioned within hollow core section **16** within nucleus **12**, molly **162**, which may manufactured from stainless steel or nitinol, expands across hernia path **164** in annulus **14**, accurately positioning the implant within nucleus **12** and preventing it from leaking out through hernia path **164** in annulus **14**.

[0075] In summary, some of advantages of the devices and methods of the present invention include: a minimally invasive procedure, meaning less time for incision healing; restores full strength to the spinal disc; allow almost immediate motion and minimal therapy; applications within the spinal disc between the cervical, thoracic, and lumbar vertebrae; and prevents future disc nucleus hernias of the impacted disc.

[0076] While the invention has been shown and described in terms of preferred embodiments, it will be understood that this invention is not limited to these particular embodiments and that many changes and modifications may be made without departing from the true spirit and scope of the invention as defined in the appended claims.

What is claimed is:

1. An intervertebral replacement disc nucleus implant for implantation within the annulus of a spinal disc, comprising:

a shape memory material element having a first shape for easily inserting said element through an opening in the annulus, and a second shape wider than said first shape, which will not pass through said opening in the annulus, wherein said element transforms from said first shape to said second shape by exposure to external energy acting upon said element.

2. The implant of claim 1, wherein said external energy is provided by body heat.

3. The implant of claim 1, wherein said external energy comprises light energy.

4. The implant of claim 1, wherein said external energy comprises thermal energy.

5. The implant of claim 1, wherein said external energy comprises RF energy.

6. The implant of claim 1, wherein said shape memory material comprises a polymer.

7. A method of implanting a disc nucleus replacement device comprised of a shape memory material capable of having a first shape and a second wider shape into a spinal disc of a patient, comprising the steps of:

creating a space within the disc by removing all or a portion of the nucleus tissue;

inserting a cannula into the created space;

transporting the replacement device in the first shape through the cannula into the created space;

and applying external energy to said device to cause the device to transform into said second shape, filling the space created within the disc.

8. The method of claim 7, wherein said external energy is applied by the body of the patient.

9. The method of claim 7, wherein the space creating step is accomplished by ablating the nucleus tissue.

10. The method of claim 9, wherein the nucleus tissue is ablated using RF energy.

11. The method of claim 7, wherein external energy is applied to said device through the cannula.

12. The method of claim 11, wherein said external energy comprises heat energy.

13. The method of claim 11, wherein said external energy comprises light energy.

14. A device for removing tissue from the nucleus of a spinal disc, comprising:

a hollow tube which can be inserted into the nucleus of the disc;

an energy delivering element which can be inserted through said tube into the nucleus;

an RF energy source, coupled to said energy delivering element;

such that when RF energy is applied to said energy delivering element when it is contacting the nucleus tissue, said tissue is ablated, creating an open space within said nucleus.

15. The device of claim 14, wherein said energy delivering element comprises a conductive balloon.

16. The device of claim 14, wherein said energy delivering element comprises a conductive expandable ribbon.

17. A method for removing tissue from the nucleus of a spinal disc, for the purpose of implanting a nucleus implant, comprising the steps of:

inserting a hollow tube into the nucleus of a spinal disc;

inserting an expandable energy delivering element through said tube to contact said nucleus tissue;

applying RF energy to said energy delivering element;

slowly expanding said energy delivering element while RF energy is applied;

and ablating nucleus tissue to create a space within the disc to permit insertion of a nucleus implant.

18. The method of claim 17, wherein said energy delivering element comprises a balloon.

19. The method of claim 17, wherein said energy delivering element comprises an expandable ribbon.

20. The device of claim 1, further comprising securing means, molded into said shape memory material element, such that it is completely enclosed within said element when in said first shape, and extends from said element in said second shape.

21. The device of claim 20, wherein said securing means comprises a prong.

22. The device of claim 21, wherein said prong extends laterally from said shape memory material element.

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