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(54) **INSTRUMENTS FOR DELIVERY OF INTERVERTEBRAL DISC IMPLANTS**

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Related U.S. Application Data

(60) Division of application No. 09/943,441, filed on Aug. 30, 2001, which is a continuation-in-part of application No. 09/650,525, filed on Aug. 30, 2000, now Pat. No. 6,620,196.

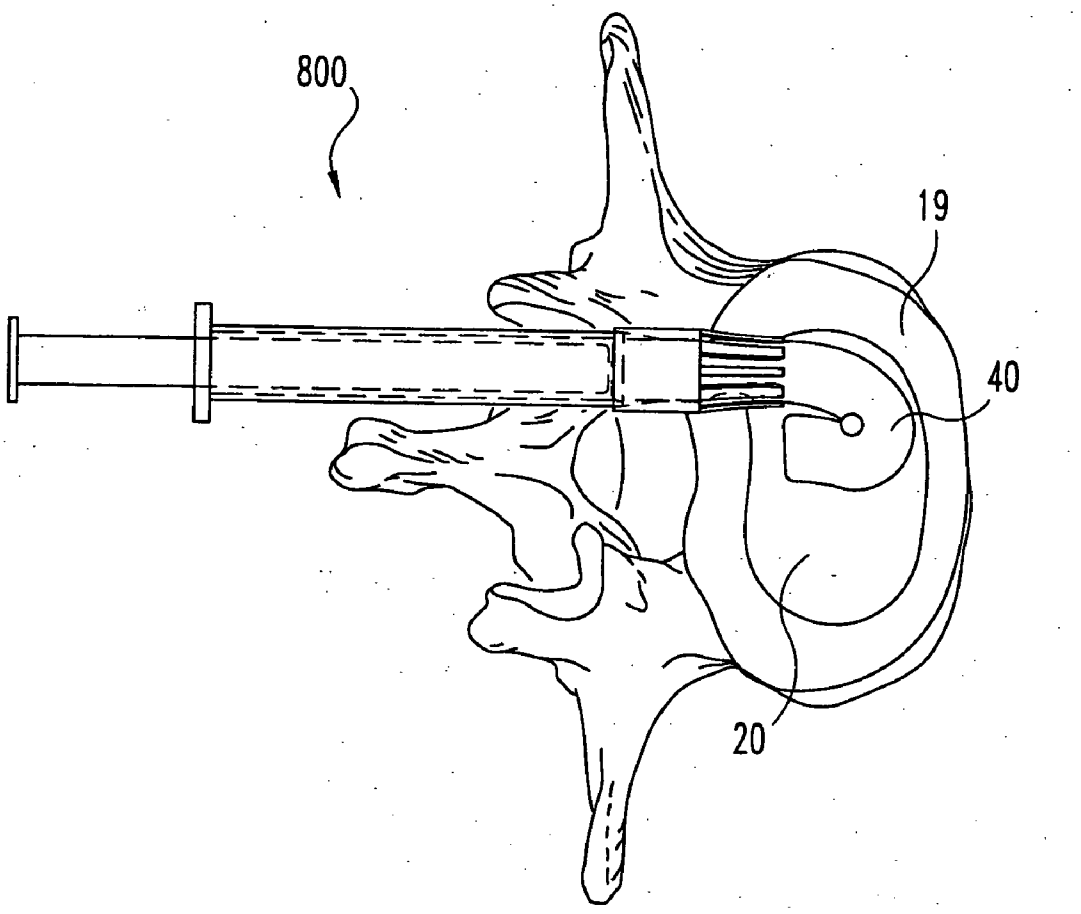
Publication Classification

(51) **Int. Cl.**[7] **A61B 17/58**; A61F 2/44

(52) **U.S. Cl.** **623/17.11**; 606/99

(57) **ABSTRACT**

Nucleus pulposus implants that are resistant to migration in and/or expulsion from an intervertebral disc space are provided. In one form of the invention, an implant includes a load bearing elastic body surrounded in s the disc space by an anchoring, preferably resorbable, outer shell. In certain forms of the invention, the elastic body is surrounded by a supporting member, such as a band or jacket, and the supporting member is surrounded by the outer shell. Kits for forming such implants are also provided. In another form of the invention, an implant is provided that has locking features and optional shape memory characteristics. In yet another aspect of the invention, nucleus pulposus implants are provided that have shape memory characteristics and are configured to allow short-term manual, or other deformation without permanent deformation, cracks, tears, breakage or other damage. Methods of forming and implanting the implants are also described, as are delivery devices and components thereof for delivering the implants.



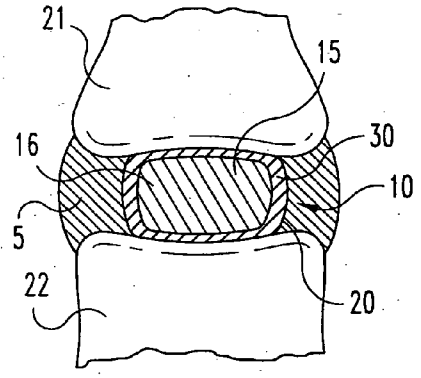


Fig. 1

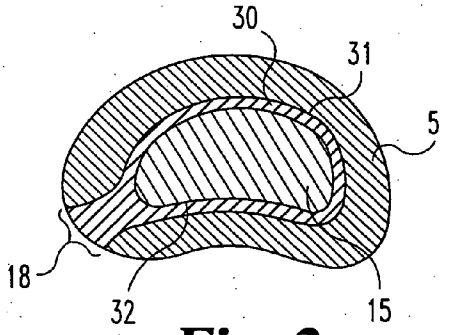


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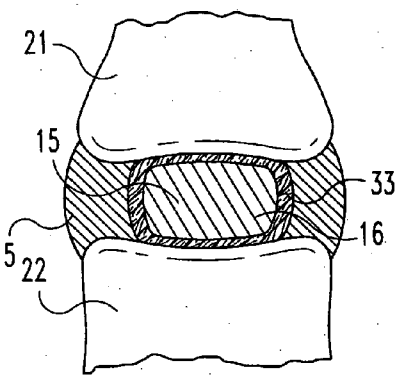


Fig. 3

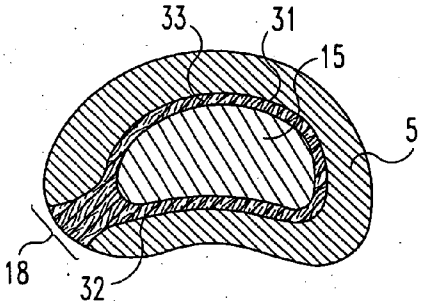


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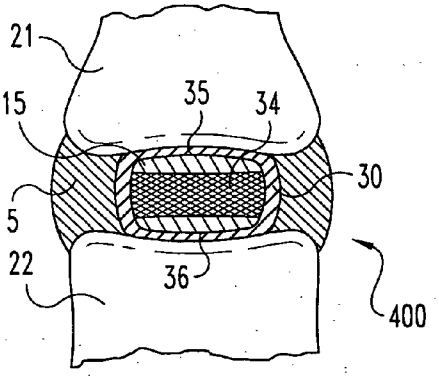


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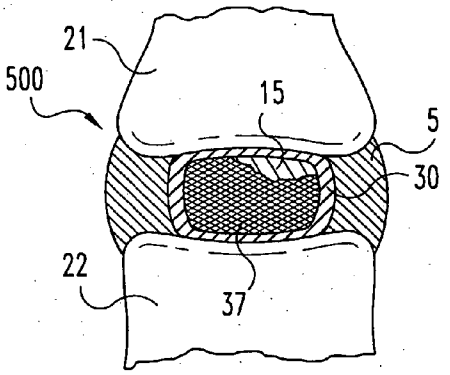


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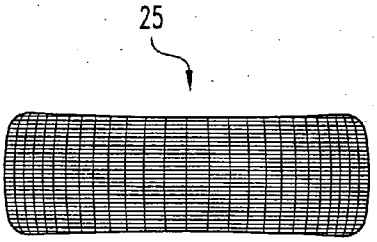


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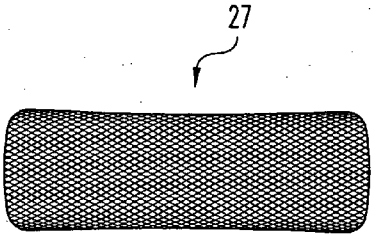


Fig. 7C

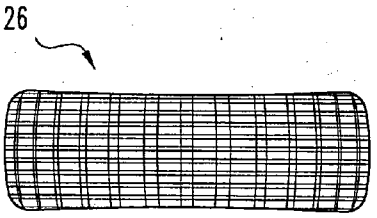


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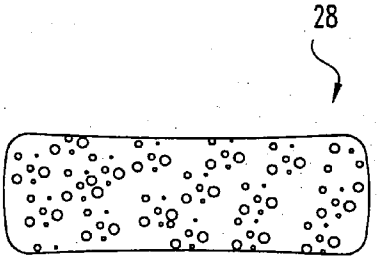


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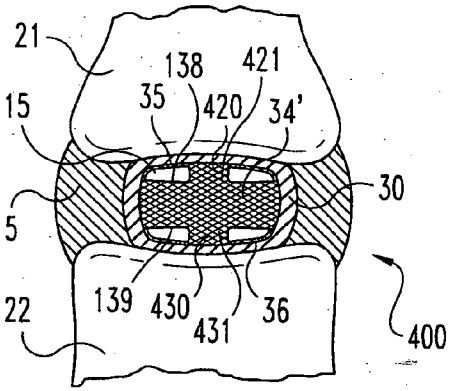


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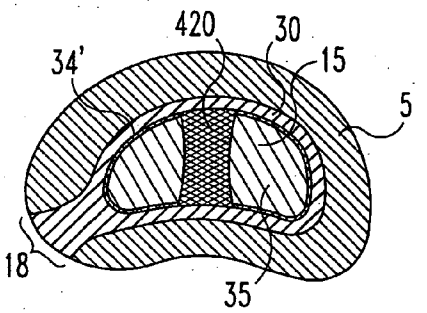


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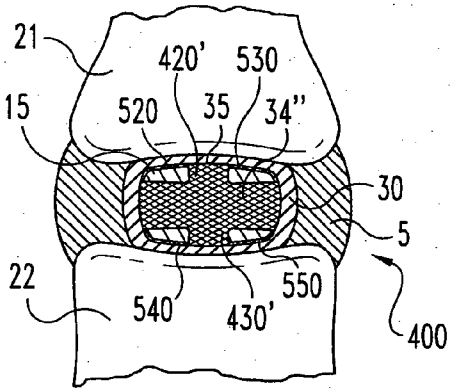


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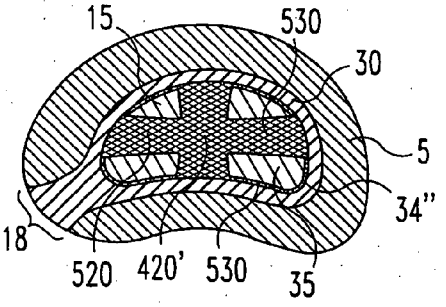


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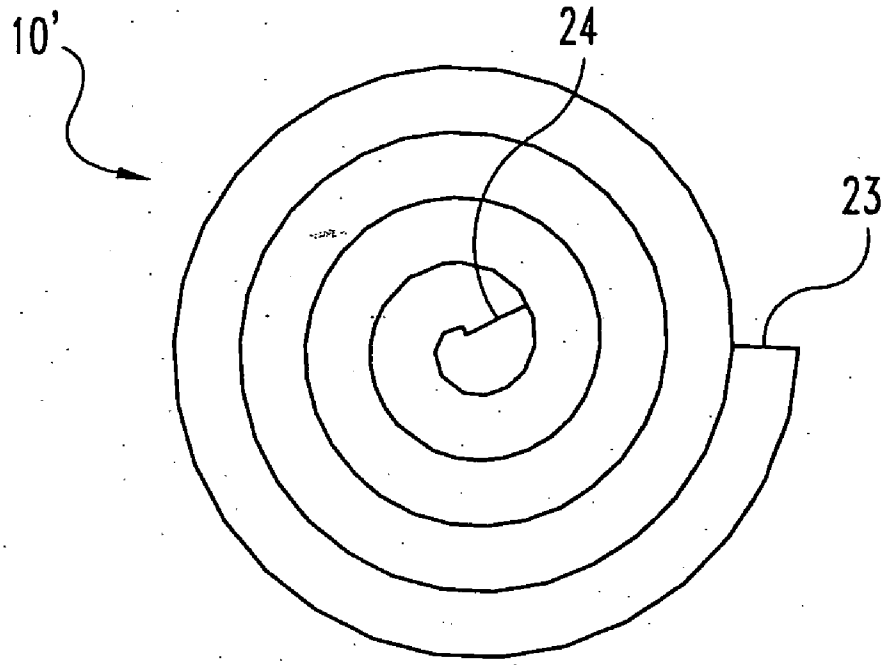


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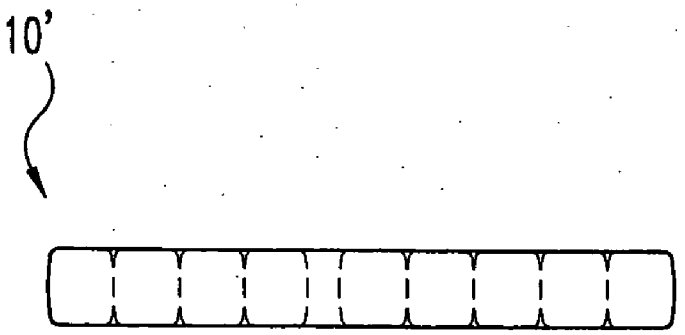


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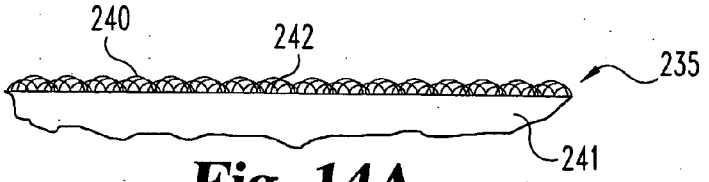


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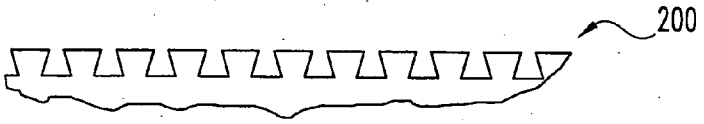


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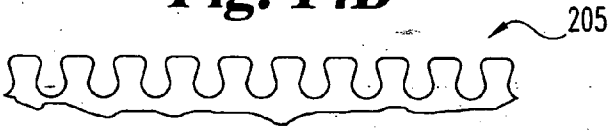


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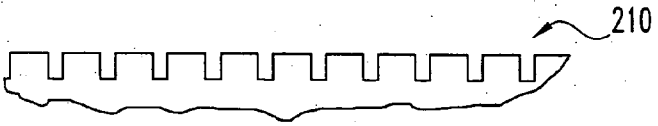


Fig. 14D

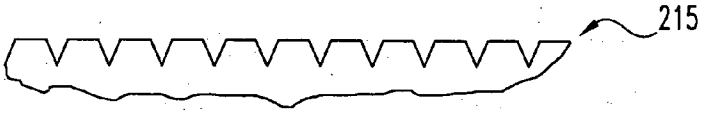


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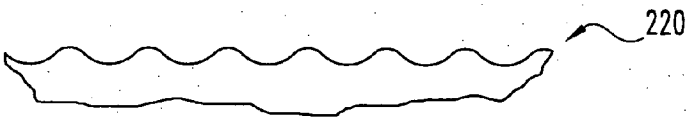


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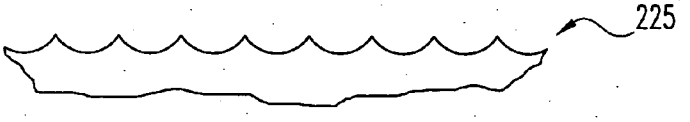


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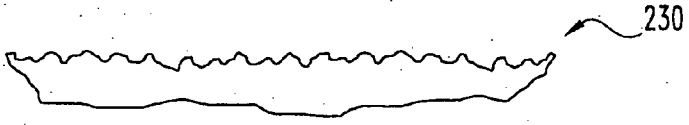


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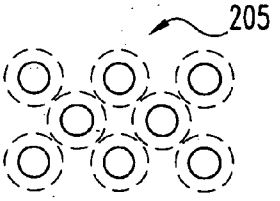


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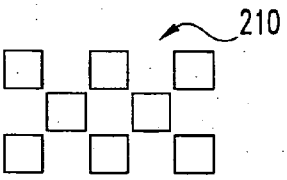


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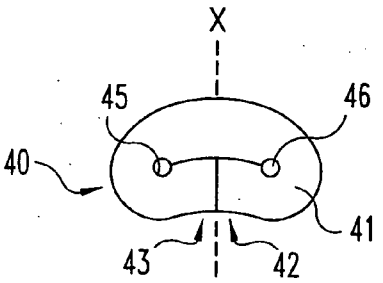


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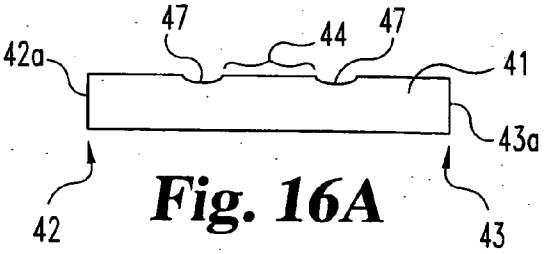


Fig. 16A

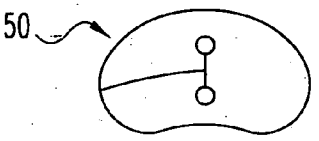


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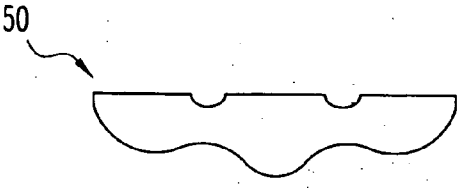


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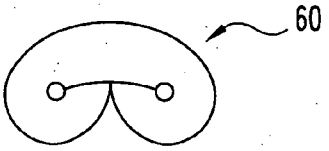


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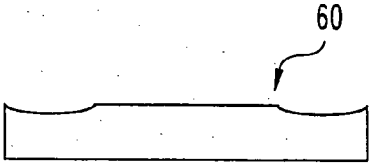


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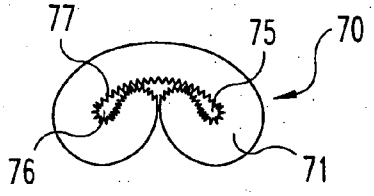


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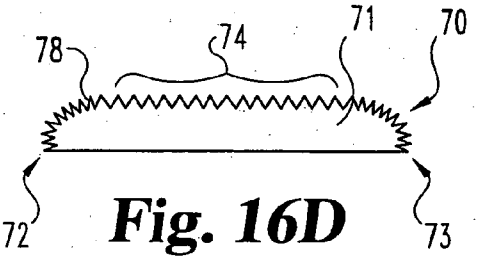


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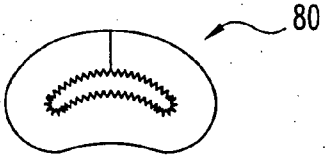


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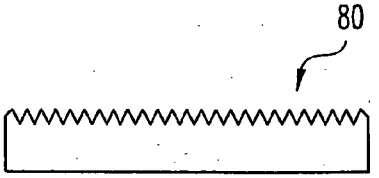


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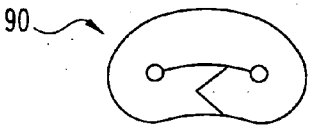


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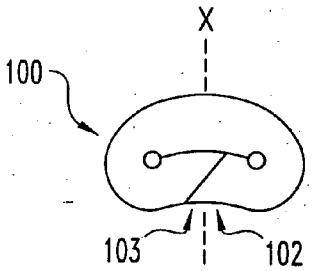


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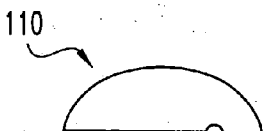


Fig. 15H

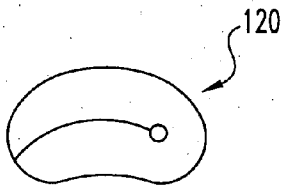


Fig. 15I

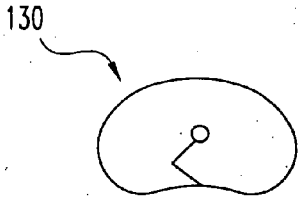


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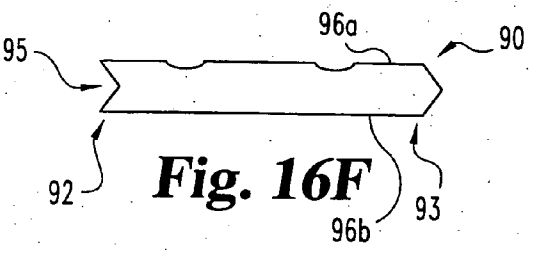


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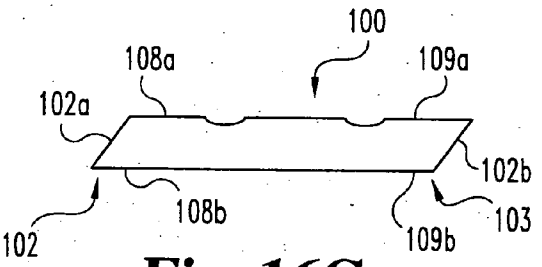


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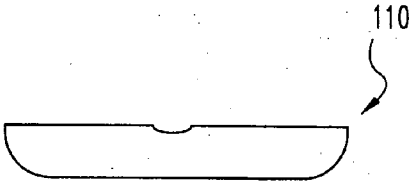


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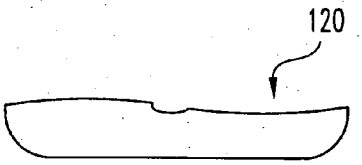


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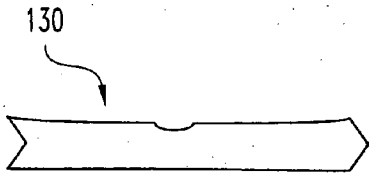


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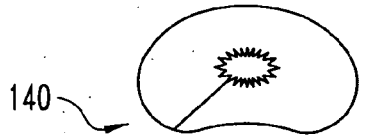


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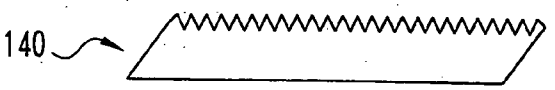


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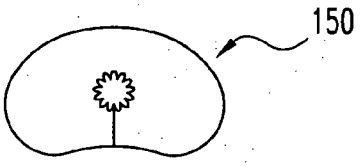


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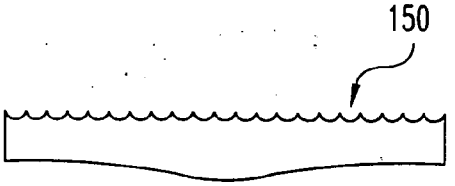


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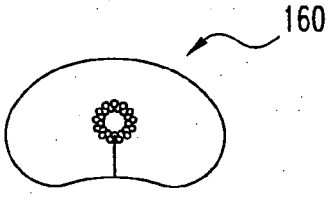


Fig. 15M

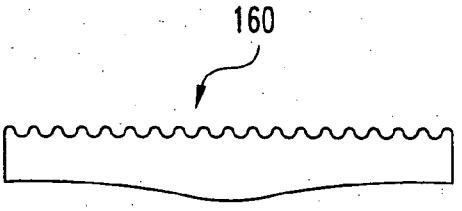


Fig. 16M

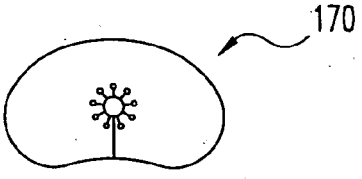


Fig. 15N

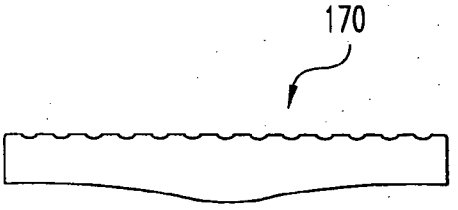


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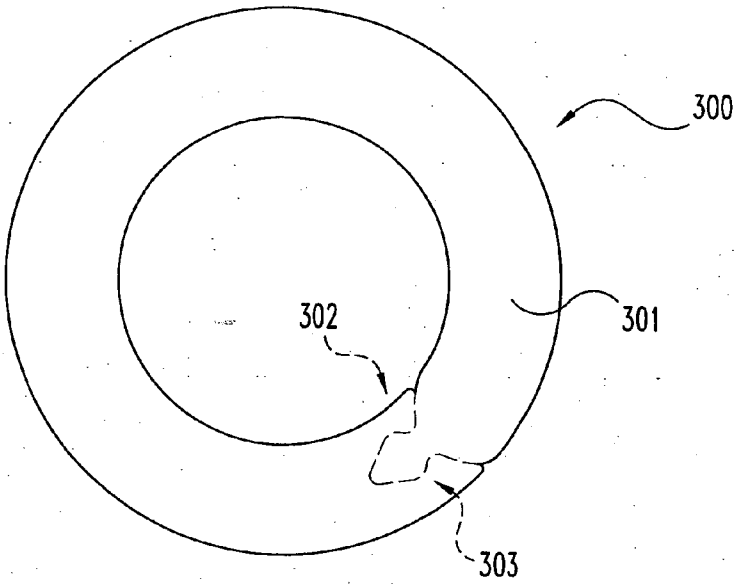


Fig. 17



Fig. 18

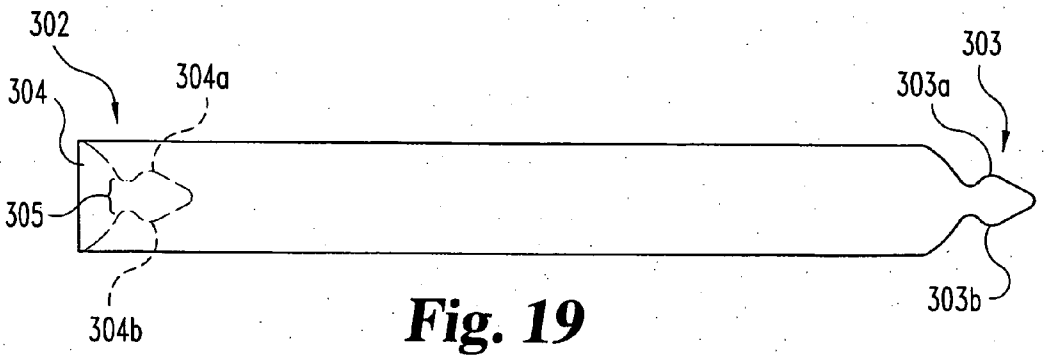


Fig. 19

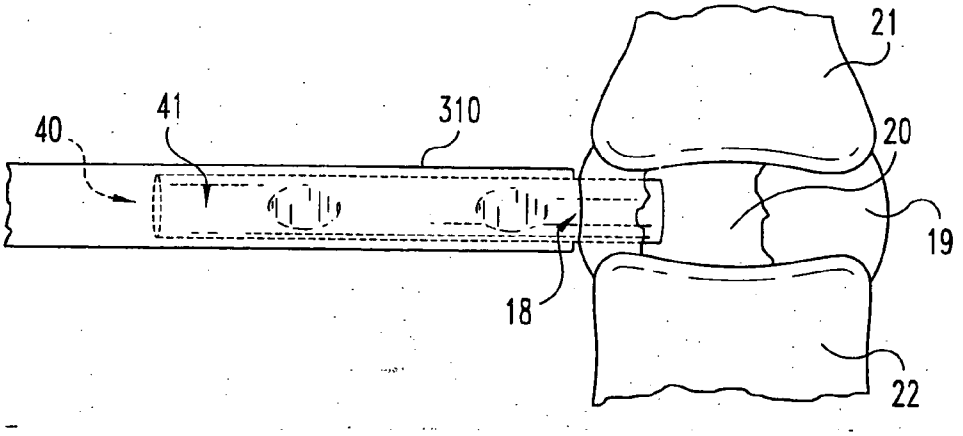


Fig. 20

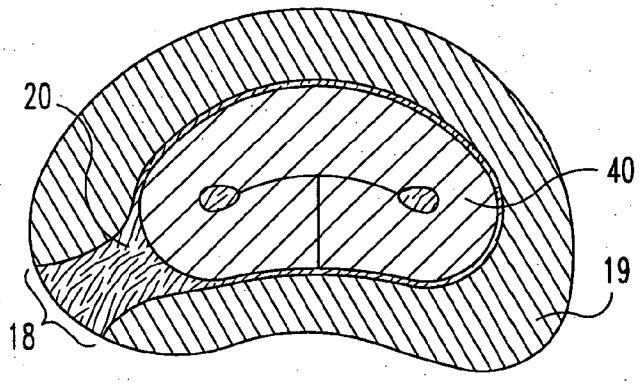


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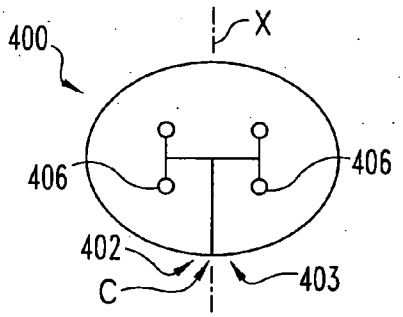


Fig. 22A

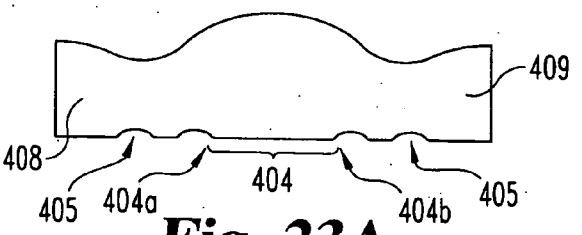


Fig. 23A

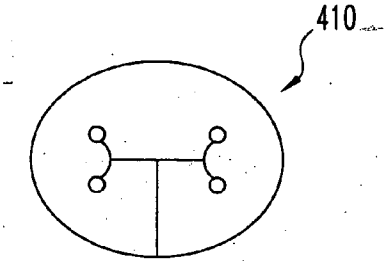


Fig. 22B

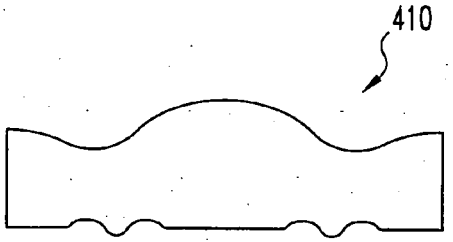


Fig. 23B

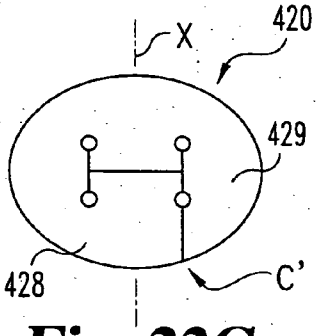


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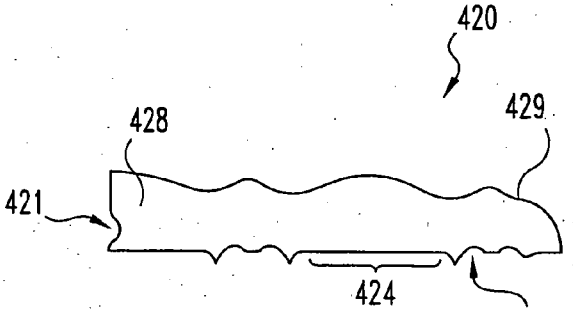


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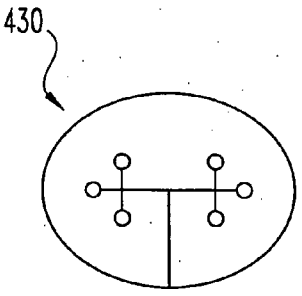


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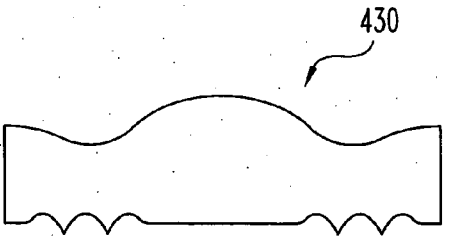


Fig. 23D

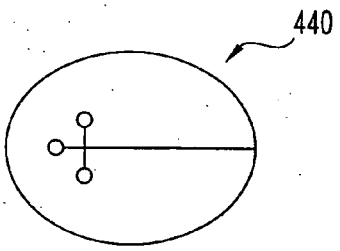


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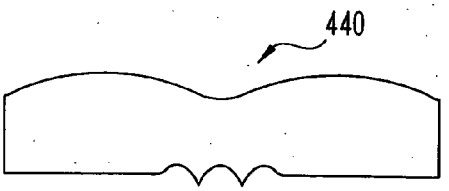


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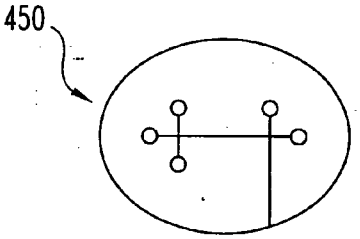


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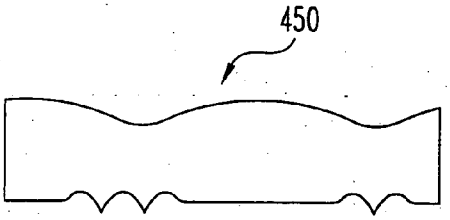


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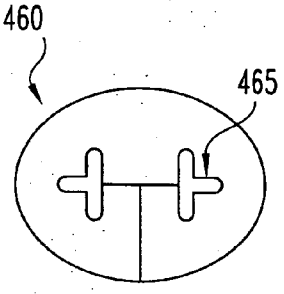


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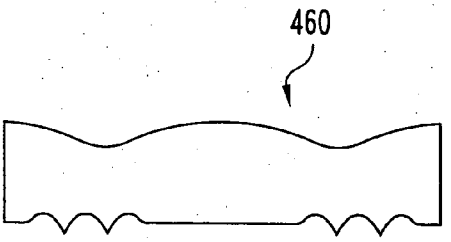


Fig. 23G

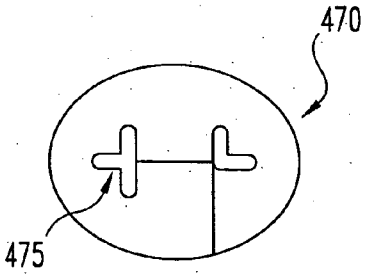


Fig. 22H

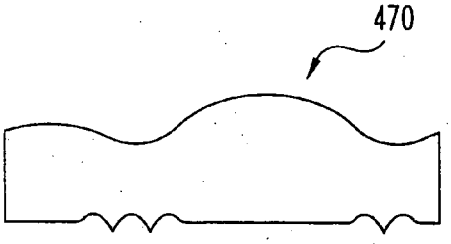


Fig. 23H

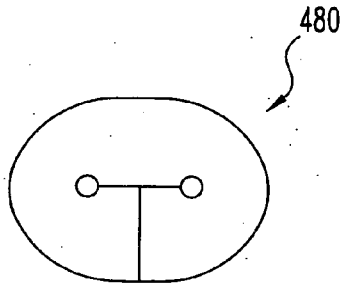


Fig. 22I

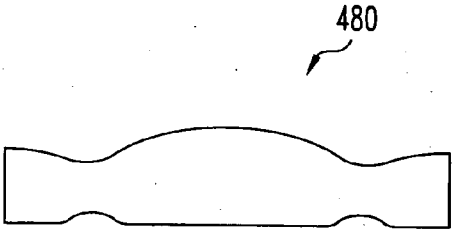


Fig. 23I

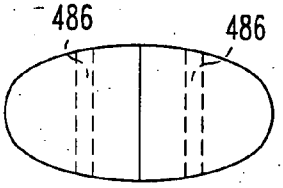


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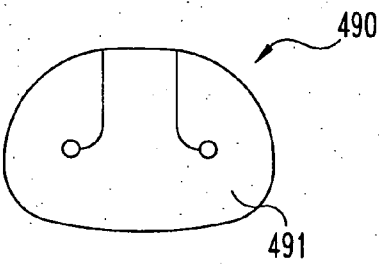


Fig. 22J

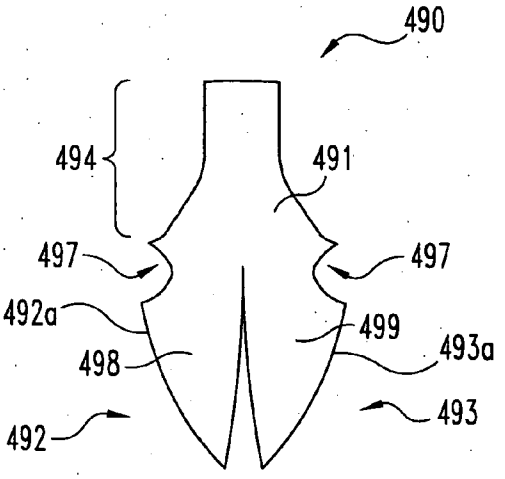


Fig. 23J

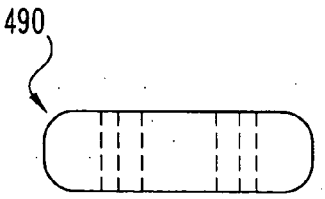


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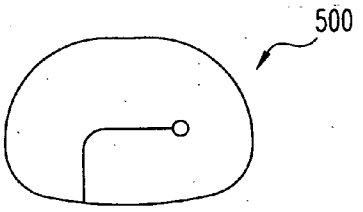


Fig. 22K



Fig. 23K

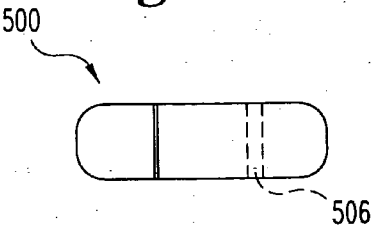


Fig. 26

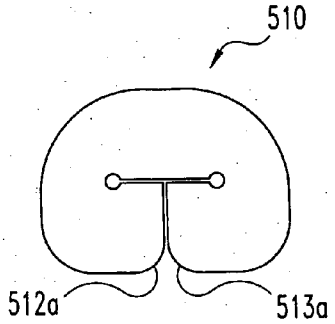


Fig. 22L

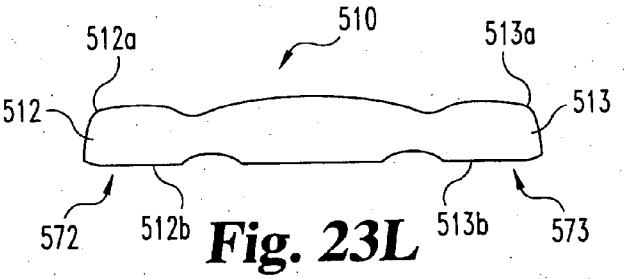


Fig. 23L

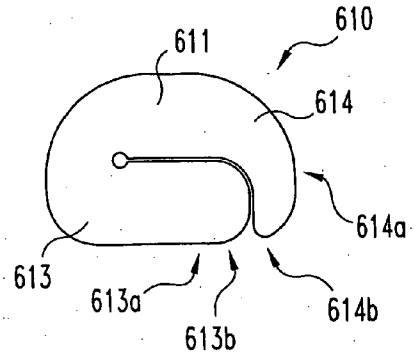


Fig. 22M

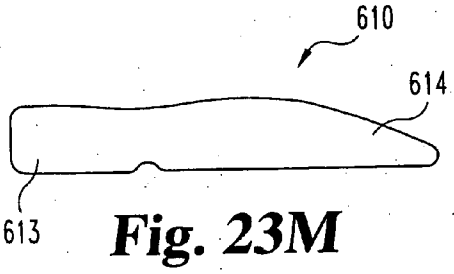


Fig. 23M

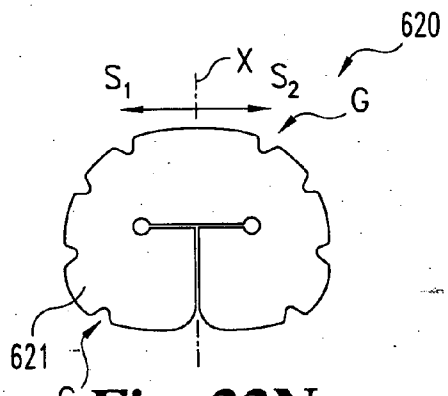


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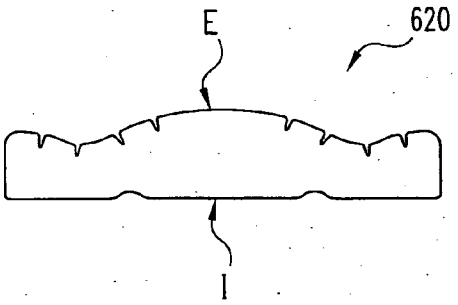


Fig. 23N

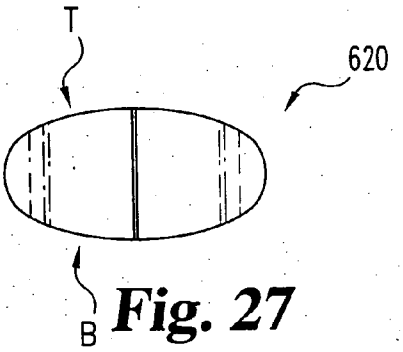


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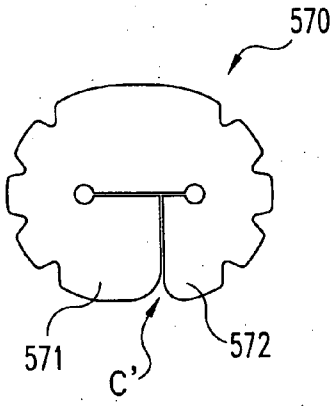


Fig. 22O

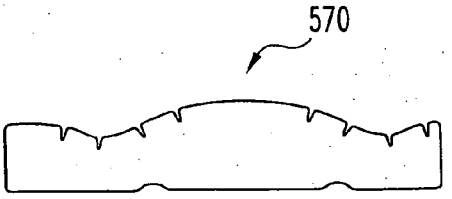


Fig. 23O

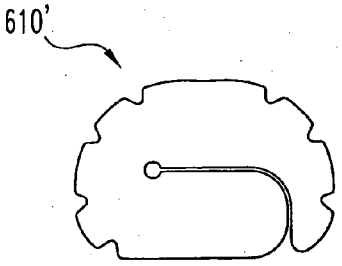


Fig. 22P

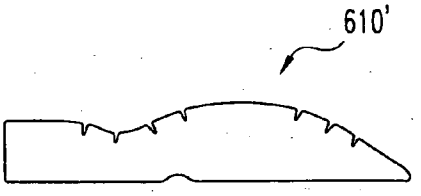


Fig. 23P

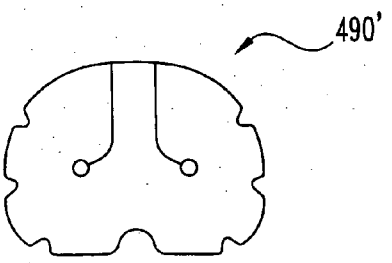


Fig. 22Q

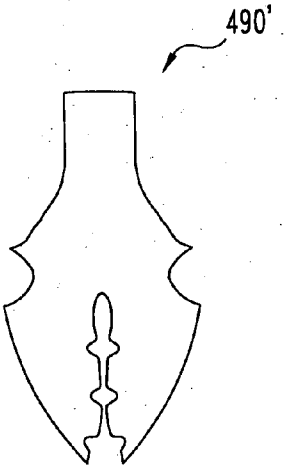


Fig. 23Q

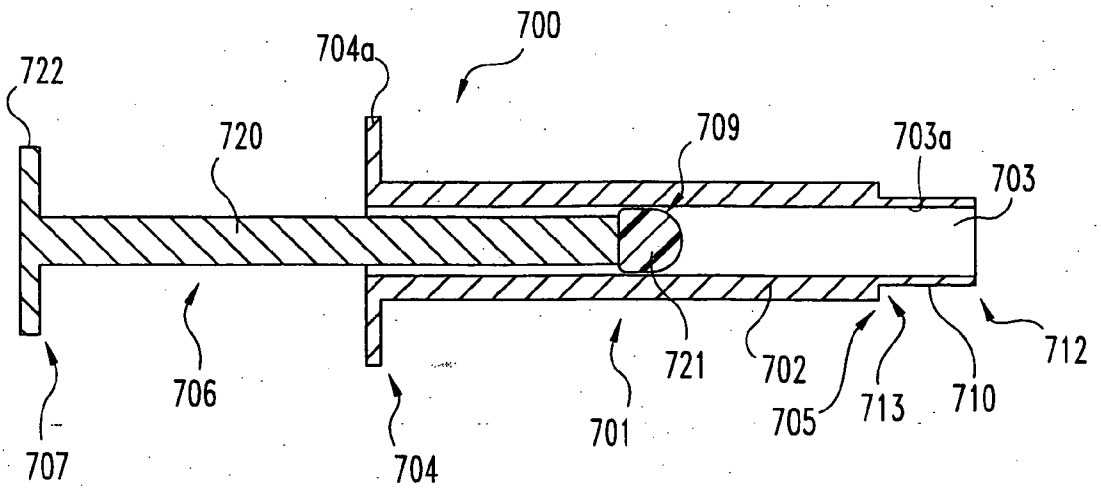

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Fig. 28

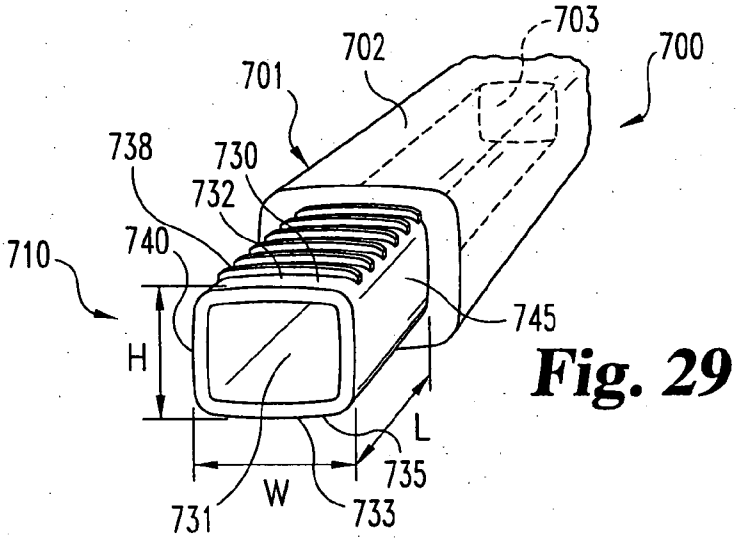

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Fig. 29

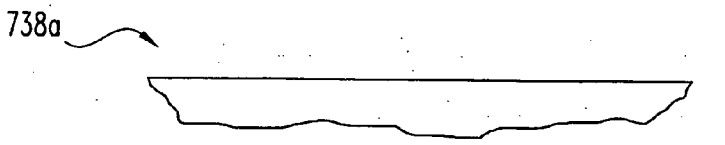


Fig. 30A

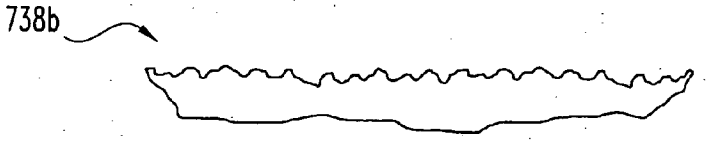


Fig. 30B

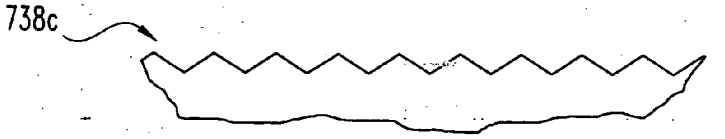


Fig. 30C

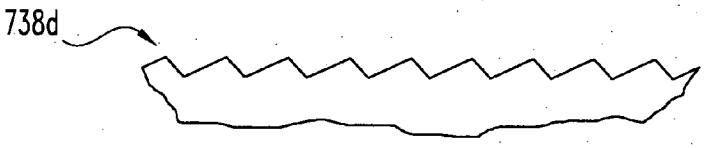


Fig. 30D

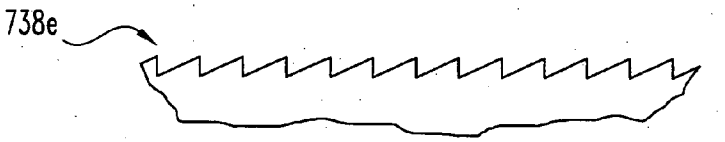


Fig. 30E

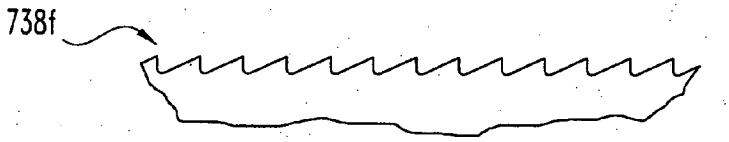


Fig. 30F

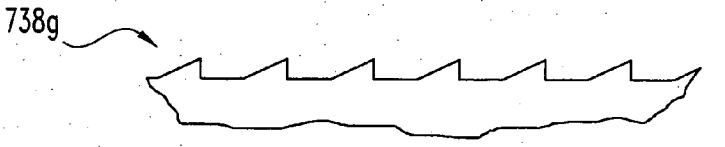


Fig. 30G

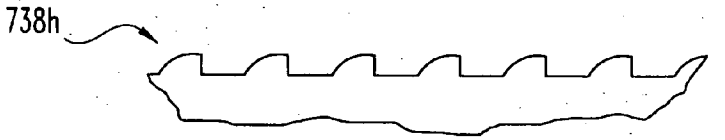


Fig. 30H

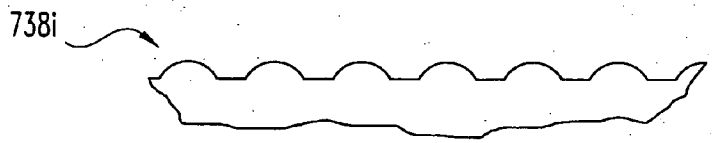


Fig. 30I

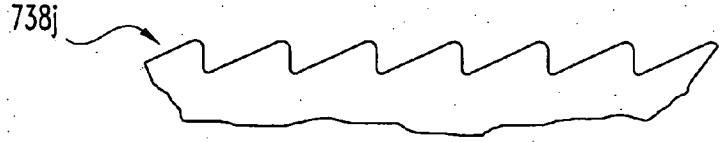


Fig. 30J

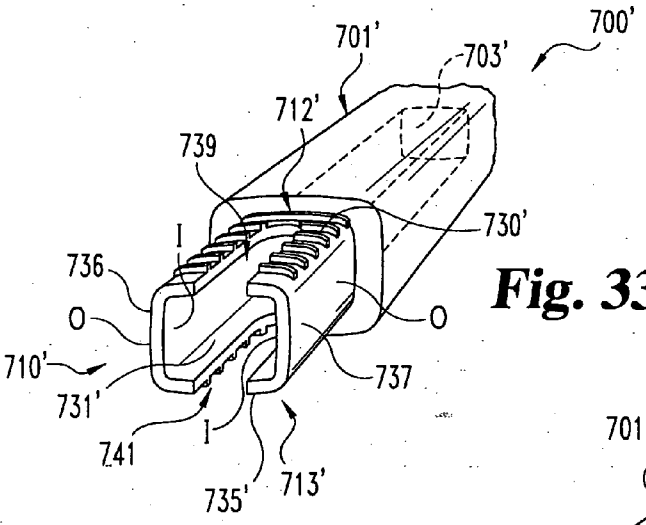


Fig. 33

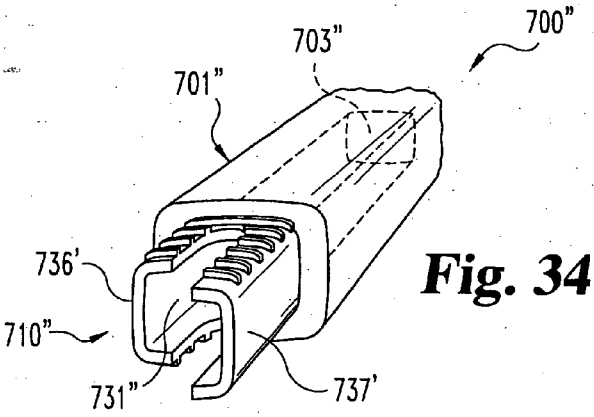


Fig. 34

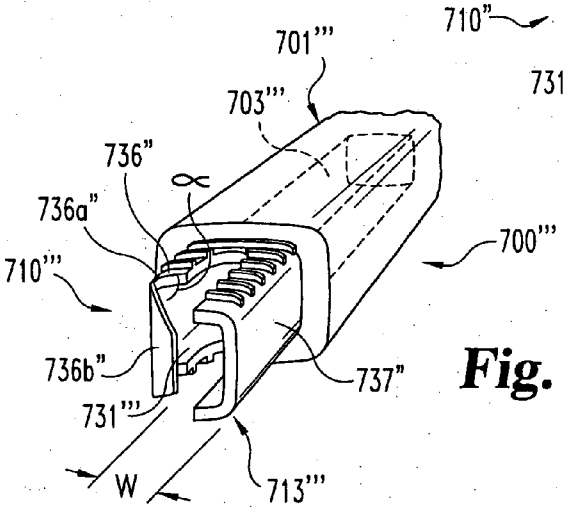


Fig. 35

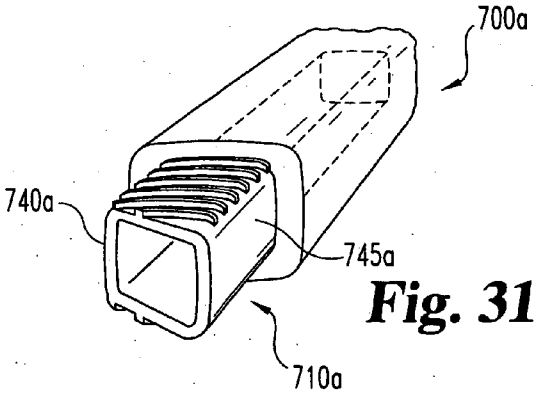


Fig. 31

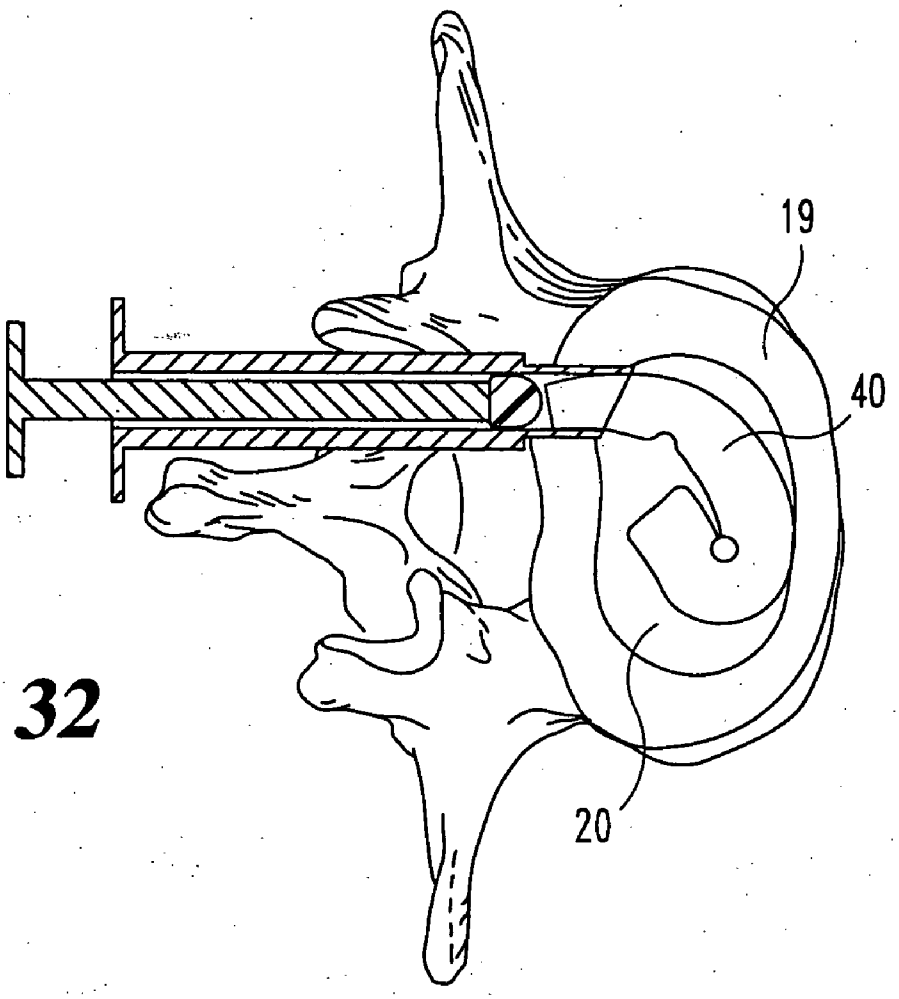


Fig. 32

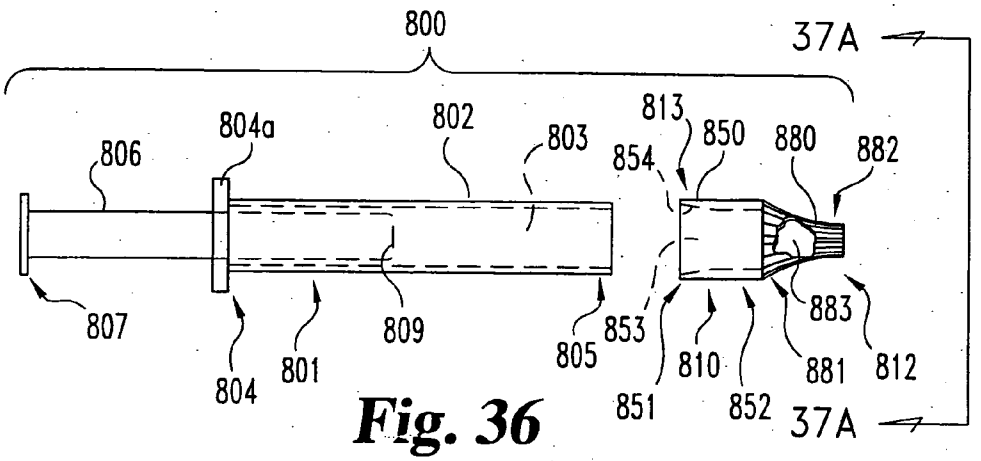


Fig. 36

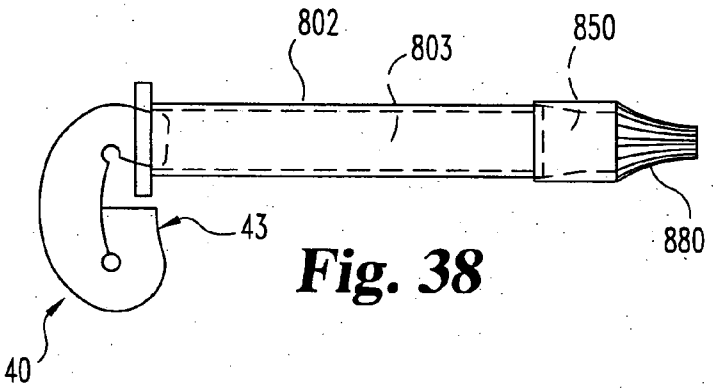


Fig. 38

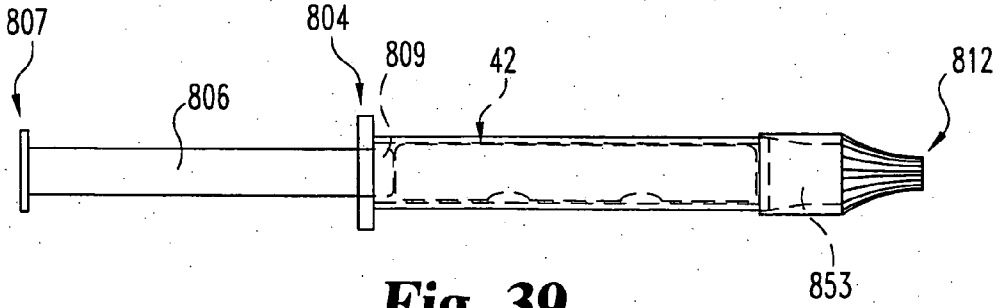


Fig. 39

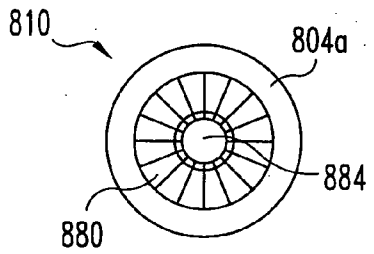


Fig. 37A

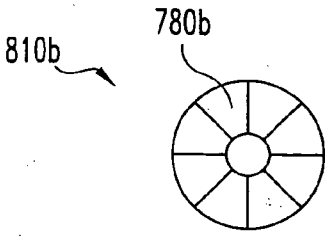


Fig. 37B

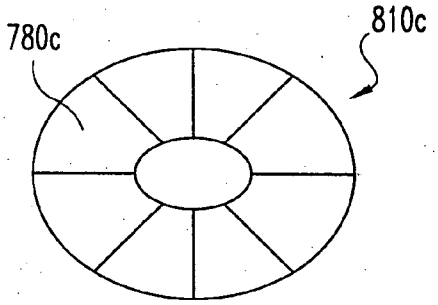


Fig. 37C

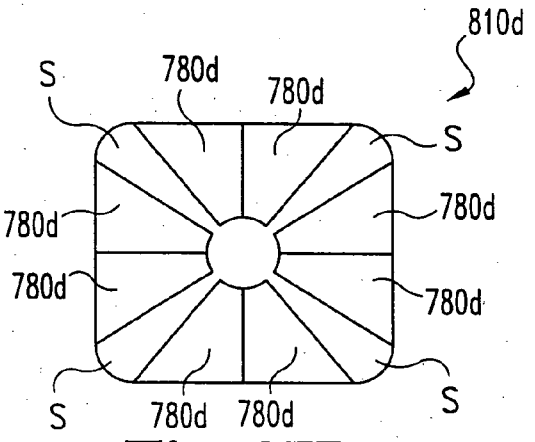


Fig. 37D

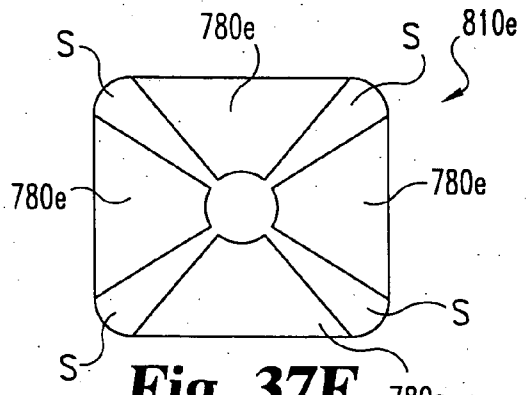


Fig. 37E

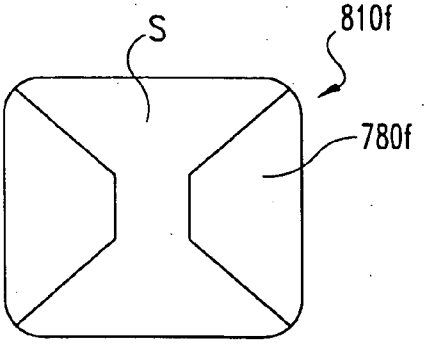


Fig. 37F

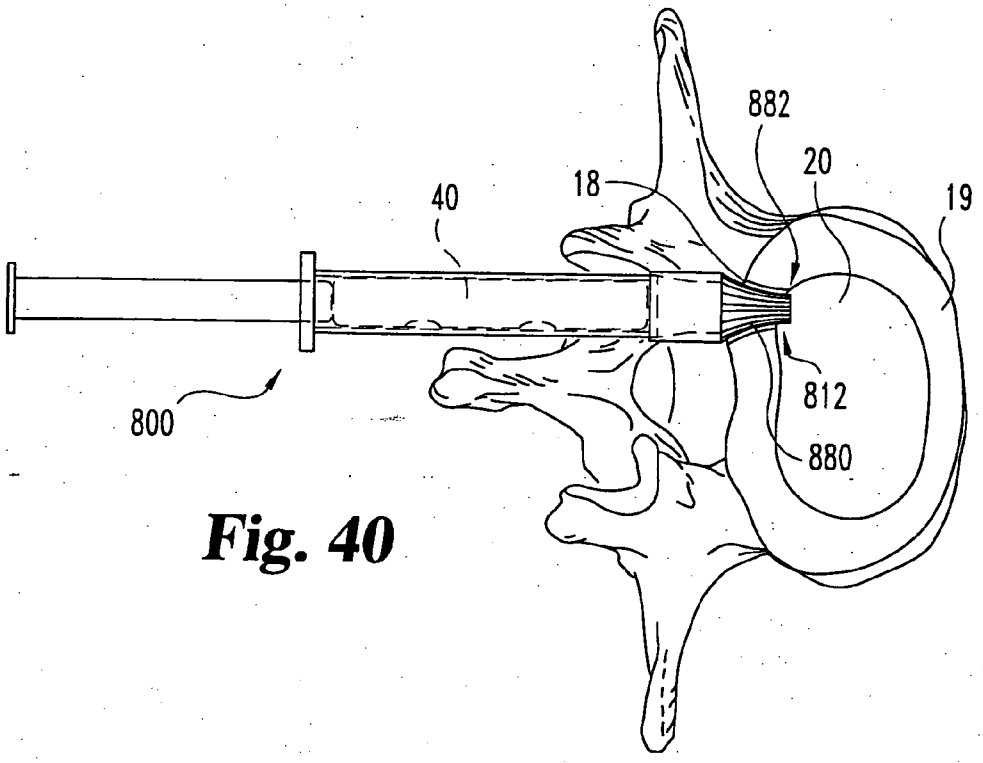


Fig. 40

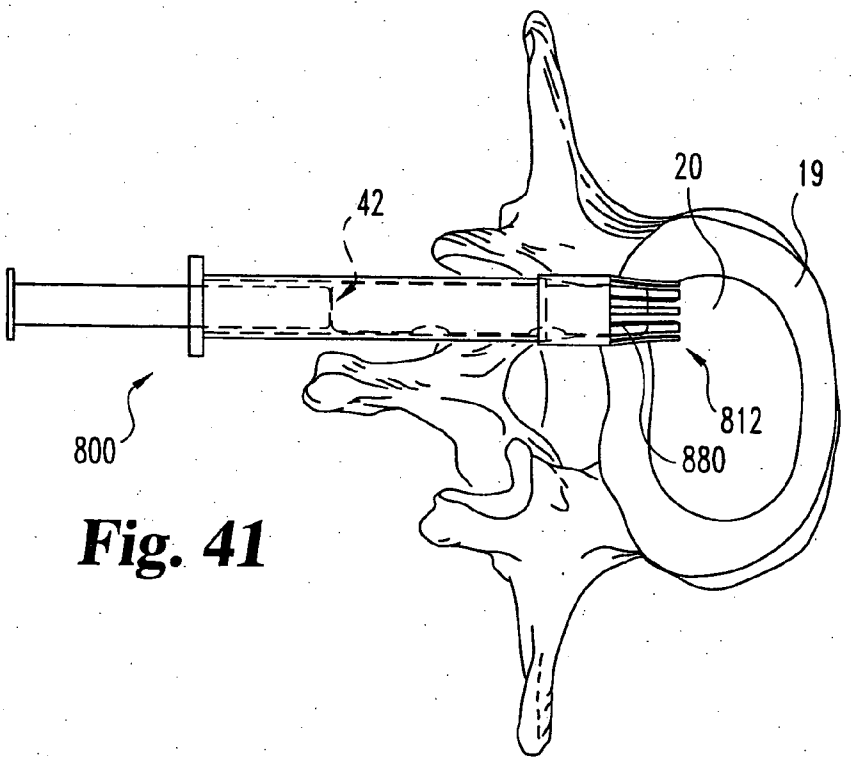


Fig. 41

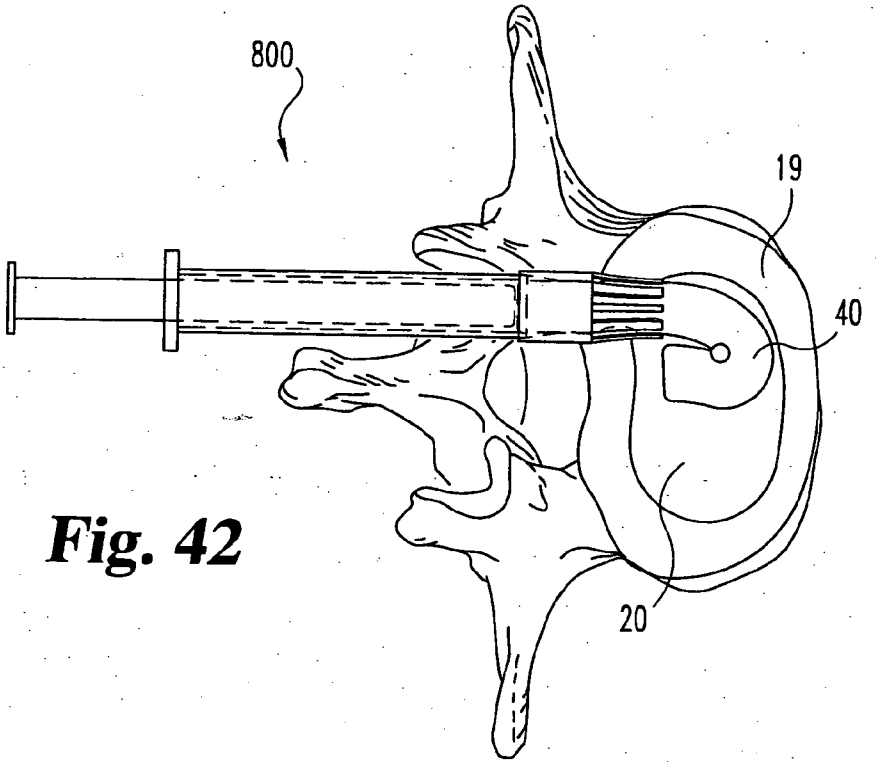


Fig. 42

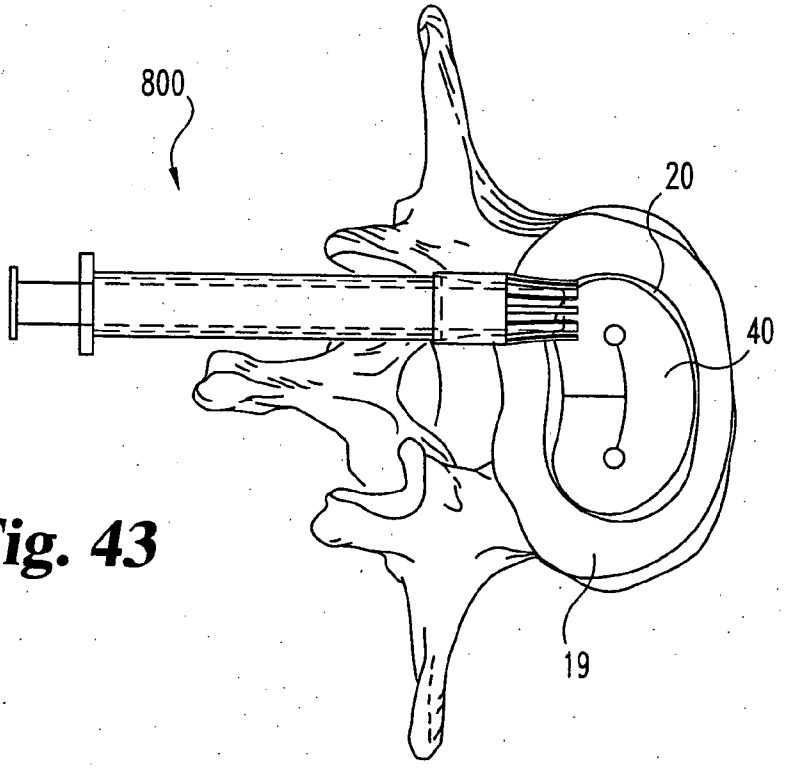


Fig. 43

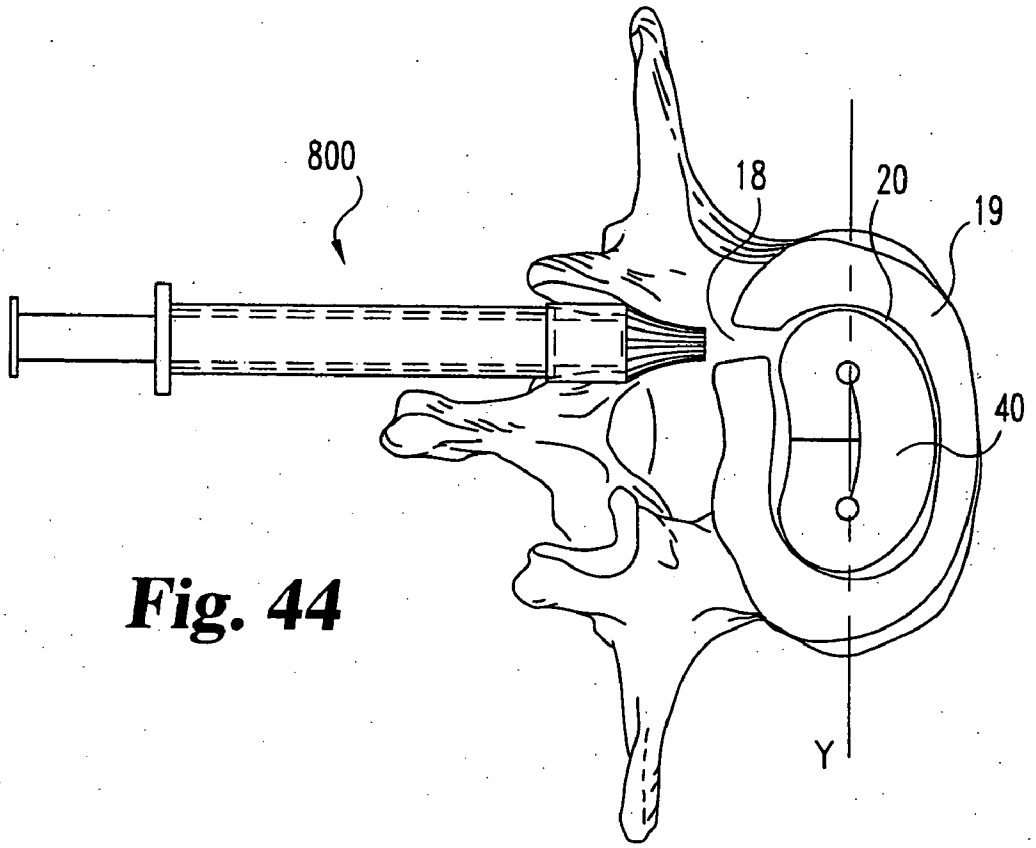


Fig. 44

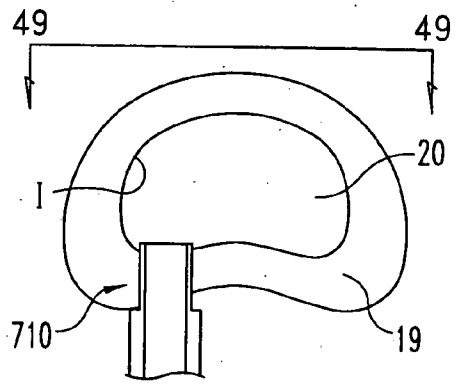


Fig. 45

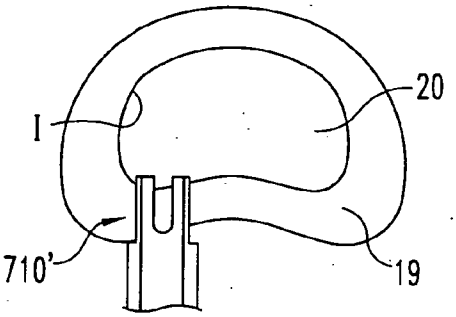


Fig. 46

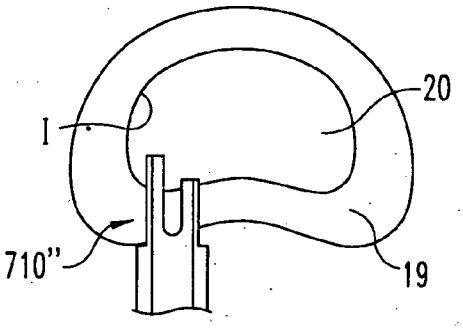


Fig. 47

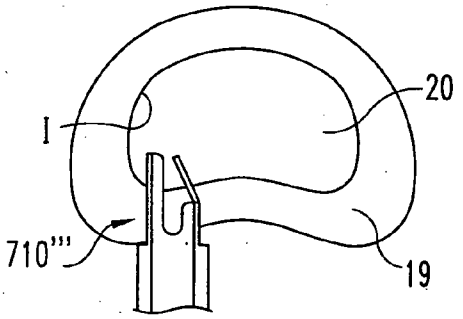


Fig. 48

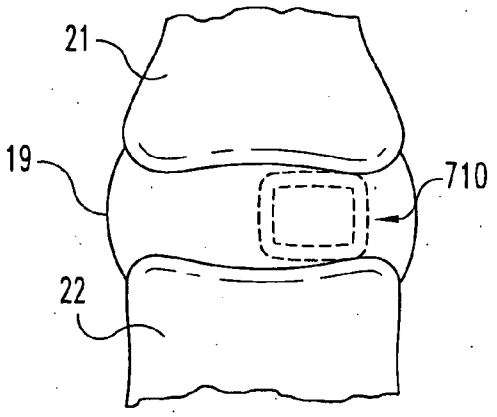


Fig. 49

INSTRUMENTS FOR DELIVERY OF INTERVERTEBRAL DISC IMPLANTS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part, and claims the benefit, of pending U.S. patent application Ser. No. 09/650,525, filed Aug. 30, 2000, which is hereby incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to nucleus pulposus implants and methods for their implantation.

[0003] The intervertebral disc functions to stabilize the spine and to distribute forces between vertebral bodies. A normal disc includes a gelatinous nucleus pulposus, an annulus fibrosis and two vertebral end plates. The nucleus pulposus is surrounded and confined by the annulus fibrosis.

[0004] Intervertebral discs may be displaced or damaged due to trauma or disease. Disruption of the annulus fibrosis may allow the nucleus pulposus to protrude into the vertebral canal, a condition commonly referred to as a herniated or ruptured disc. The extruded nucleus pulposus may press on a spinal nerve, which may result in nerve damage, pain, numbness, muscle weakness and paralysis. Intervertebral discs may also deteriorate due to the normal aging process. As a disc dehydrates and hardens, the disc space height will be reduced, leading to instability of the spine, decreased mobility and pain.

[0005] One way to relieve the symptoms of these conditions is by surgical removal of a portion or all of the intervertebral disc. The removal of the damaged or unhealthy disc may allow the disc space to collapse, which would lead to instability of the spine, abnormal joint mechanics, nerve damage, as well as severe pain. Therefore, after removal of the disc, adjacent vertebrae are typically fused to preserve the disc space. Several devices exist to fill an intervertebral space following removal of all or part of the intervertebral disc in order to prevent disc space collapse and to promote fusion of adjacent vertebrae surrounding the disc space. Even though a certain degree of success with these devices has been achieved, full motion is typically never regained after such vertebral fusions. Attempts to overcome these problems have led to the development of disc replacements. Many of these devices are complicated, bulky and made of a combination of metallic and elastomeric components. Thus, such devices require invasive surgical procedures and typically never fully return the full range of motion desired.

[0006] More recently, efforts have been directed to replacing the nucleus pulposus of the disc with a similar gelatinous material, such as a hydrogel. However, there exists a possibility of tearing or otherwise damaging the hydrogel implant during implantation. Moreover, once positioned in the disc space, many hydrogel implants may migrate in the disc space and/or may be expelled from the disc space through an annular defect, or other annular opening. A need therefore exists for more durable implants, as well as implants that are resistant to migration and/or expulsion through an opening in the annulus fibrosis. The present invention addresses these needs.

SUMMARY OF THE INVENTION

[0007] Nucleus pulposus implants that are resistant to migration in and/or expulsion from an intervertebral disc space are provided. Accordingly, in one aspect of the invention, nucleus pulposus implants are provided that include a load bearing elastic body sized for introduction into an intervertebral disc space and surrounded by a resorbable shell that provides the initial fixation for the elastic body within the disc space. The implant may include various surface features on its outer surface, including surface configurations or chemical modifications, that enhance the bonding between the outer surface of the implants and the resorbable shell. Kits for forming such implants are also provided. In other forms of the invention, the elastic body may be surrounded by a supporting member wherein the supporting member is surrounded by the resorbable shell.

[0008] In yet another aspect of the invention, nucleus pulposus implants are provided that have shape memory and are configured to allow extensive short-term deformation without permanent deformation, cracks, tears or other breakage. In one form of the invention, an implant includes a load bearing elastic body sized for placement into an intervertebral disc space. The body includes a first end, a second end and a central portion wherein the first end and second end are positioned, in a folded, relaxed configuration, adjacent to the central portion to form at least one inner fold. The inner fold preferably defines an aperture. The elastic body is deformable into a second, straightened, non-relaxed, unfolded configuration for insertion through an opening in an intervertebral disc annulus fibrosis. The elastic body is deformable automatically back into a folded configuration after being placed in the intervertebral disc space. Advantageously, where the implant having shape memory is formed of a hydrogel material, or other hydrophilic material that may be dehydrated, the implant may be fully or partially dehydrated prior to insertion such that it may be inserted through a relatively small opening in the annulus fibrosis. The opening may, for example, be a pre-existing defect or may be made by making a small incision.

[0009] In still other aspects of the invention, nucleus pulposus implants having locking features and optionally having shape memory are provided. In one embodiment, an implant includes a load bearing elastic body having a first end and a second end that are configured for mating engagement with each other. The implant has a first, locked configuration wherein the first and second ends are matingly engaged to each other. The implant may be configured into a second, straightened configuration by application of external force for insertion through an opening in an intervertebral disc annulus fibrosis. When the implant includes shape memory characteristics, it may be automatically configured, or otherwise returned, back into its first, locked configuration after insertion through the opening in the annulus fibrosis and after any external force is removed, or may be placed into its locked configuration by application of external force.

[0010] In other aspects of the invention, methods of implanting the nucleus pulposus implants of the present invention are provided. In one mode of carrying out the invention, a method includes providing the appropriate implant, preparing the intervertebral disc space to receive the implant and then placing the implant into the interver-

tebral disc space. Where the implant includes a load bearing elastic body and an outer resorbable shell, a preferred method includes preparing the intervertebral disc space to receive the implant, introducing the elastic body forming the core of the implant into the disc space wherein the body is surrounded in the disc space by a resorbable outer shell. The material forming the resorbable shell may be placed in the disc space prior to, after, or at the same time as insertion of the elastic body. Alternatively, the elastic body may be surrounded by the outer shell prior to introduction of the elastic body into the intervertebral disc space.

[0011] In further aspects, a spinal disc implant delivery device is provided. In one form, the device includes a base member having a proximal end, a distal end and a lumen extending longitudinally therethrough; a plurality of movable members having a proximal end and a distal end; and an elongated member having a proximal end and a distal end and a lumen extending longitudinally therethrough. The proximal end of the movable members abut the distal end of the base member. The proximal end of the base member is matingly engaged to the distal end of the elongated member. Moreover, the movable members have a closed configuration that defines a cavity in communication with the lumen of the base member.

[0012] In further aspects of the invention, a spinal disc implant delivery device tip is provided that includes a base member and movable members as described above.

[0013] In other forms of the invention, a spinal disc implant delivery device includes an elongated housing member having a proximal end, a distal end and a lumen extending longitudinally therethrough and a tip member. The tip member advantageously has a top wall, a bottom wall, a first side wall, a second side wall, a proximal end, and a distal end. The walls of the tip member preferably define a lumen extending longitudinally therethrough. The proximal end of the tip member may be connected to the distal end of the elongated housing member. Additionally, the tip member is sized and configured for delivery of a spinal disc implant through an aperture in an annulus fibrosus. The lumen of the tip member is preferably in fluid communication with the lumen of the elongated housing member.

[0014] In other forms of the invention, the top wall and bottom wall include an opening therethrough that extends from the proximal end of the tip member to the distal end of the tip member.

[0015] It is an object of the invention to provide nucleus pulposus implants, and kits for their formation, that are resistant to migration in and/or explusion from an intervertebral disc space.

[0016] It is a further object of the invention to provide nucleus pulposus implants having shape memory that are configured to allow extensive short term manual, or other deformation without permanent deformation, cracks, tears, breakage or other damage.

[0017] It is yet another object of the present invention to provide nucleus pulposus implants having locking features.

[0018] It is a further object of the present invention to provide methods of forming and implanting the nucleus pulposus implants described herein, as well as spinal implant delivery devices or tools for implanting the implants.

[0019] These and other objects and advantages of the present invention will be apparent from the description herein.

BRIEF DESCRIPTION OF THE FIGURES

[0020] **FIG. 1** depicts a side view of a cross-section of a nucleus pulposus implant, including an elastic body **15** surrounded by an anchoring outer shell **30**, implanted in the intervertebral disc space of a disc.

[0021] **FIG. 2** depicts a top, cross-sectional view of the nucleus pulposus implant of **FIG. 1**.

[0022] **FIG. 3** depicts a side view of a cross-section of the nucleus pulposus implant of **FIG. 1** after outer shell **30** has been resorbed and replaced by fibrous scar tissue **33**.

[0023] **FIG. 4** shows a top, cross-sectional view of the nucleus pulposus implant of **FIG. 3**.

[0024] **FIG. 5** shows a side view of a cross-section of a nucleus pulposus implant, including an elastic body **15** surrounded by a supporting member **34**, in the form of a band, wherein the supporting member is surrounded by an anchoring outer shell **30**, implanted in the intervertebral disc space of a disc.

[0025] **FIG. 6** depicts a side view of a cross-section of a nucleus pulposus implant, including an elastic body **15** surrounded by a supporting member **37**, in the form of a jacket, wherein the supporting member is surrounded by an anchoring outer shell **30**, implanted in the intervertebral disc space of a disc.

[0026] **FIGS. 7A-7D** depict various patterns of a supporting member of the present invention.

[0027] **FIG. 8** depicts a side view of a cross-section of a nucleus pulposus implant including an elastic body **15** surrounded by a supporting member **34**, taking the form of a band, that is further reinforced, or otherwise supported, by straps **420** and **430**. The implant is surrounded by an anchoring outer shell **30** and is shown implanted in the intervertebral disc space of a disc.

[0028] **FIG. 9** shows a top, cross-sectional view of the nucleus pulposus implant of **FIG. 8**.

[0029] **FIG. 10** depicts a side view of an alternative embodiment of a nucleus pulposus implant of the present invention that includes peripheral supporting band **34**" and securing straps **520**, **530**, **540** and **550** and is surrounded by an anchoring outer shell **30** and implanted in the intervertebral disc space of a disc.

[0030] **FIG. 11** depicts a top, cross-sectional view of the nucleus pulposus implant of **FIG. 10**.

[0031] **FIG. 12** depicts a top view of an alternative embodiment of a nucleus pulposus implant having shape memory.

[0032] **FIG. 13** shows a side view of the implant shown in **FIG. 12**.

[0033] **FIGS. 14A-14J** depict portions of nucleus pulposus implants with surface modifications. **FIGS. 14A-14H** show side views of top portions of the implants, and **FIG. 14I** and **FIG. 14J** show top views of the views shown in **14**C and **14**D, respectively.

[0034] **FIGS. 15A-15N** show top views of alternative embodiments of nucleus pulposus implants having shape memory in folded, relaxed configurations.

[0035] **FIGS. 16A-16N** depict top views of the implants shown in **FIGS. 15A-15N**, respectively, in unfolded, non-relaxed configurations.

[0036] **FIG. 17** depicts a top view of an alternative embodiment of a nucleus pulposus implant of the present invention having a self-locking feature. The implant is shown in its locked, relaxed configuration.

[0037] **FIG. 18** depicts a side view of the implant of **FIG. 17**.

[0038] **FIG. 19** depicts a side view of the implant of **FIG. 18** in an unfolded, non-locked, non-relaxed configuration.

[0039] **FIG. 20** depicts one step in a method of implanting nucleus pulposus implant **40** into intervertebral disc space **20** between vertebrae **21** and **22** using a conventional implantation tool **310**.

[0040] **FIG. 21** depicts a top, cross-sectional view of a nucleus pulposus implant **10** in its folded, relaxed configuration positioned in intervertebral disc space **20**.

[0041] **FIGS. 22A-22Q** show top views of alternative embodiments of nucleus pulposus implants having shape memory in folded, relaxed configurations.

[0042] **FIGS. 23A-23Q** depict top views of the implants shown in **FIGS. 22A-22Q**, respectively, in unfolded, non-relaxed configurations.

[0043] **FIGS. 24, 25, 26** and **27** depict side views of the implants shown in **FIGS. 22I, 22J**, 22K and 22N, respectively.

[0044] **FIG. 28** depicts a side cross-sectional view of one embodiment of a spinal disc implant delivery tool configured to deliver the shape memory implants described herein.

[0045] **FIG. 29** depicts a view of another embodiment of a spinal disc implant delivery device showing features of the tip portion.

[0046] **FIGS. 30A-30J** depict side views of surface features that may be present on the surfaces of the tip portions of various spinal disc implant delivery devices described herein.

[0047] **FIG. 31** depicts a view of an alternative embodiment of a spinal disc implant delivery device showing features of the tip portion.

[0048] **FIG. 32** depicts how the spinal disc implant delivery device of **FIG. 31** may be used to aid placement of a spinal disc implant.

[0049] **FIG. 33** depicts a view of yet a further alternative embodiment of a spinal disc implant delivery device.

[0050] **FIG. 34** depicts a view of yet a further alternative embodiment of a spinal disc implant delivery device showing features of the tip portion.

[0051] **FIG. 35** shows a view of an alternative embodiment of a spinal disc implant delivery device showing features of the tip portion.

[0052] **FIG. 36** shows a side view of an alternative embodiment of a spinal implant delivery device.

[0053] **FIG. 37A** depicts an end view of the device of **FIG. 36**, taken along line **37A-37A**.

[0054] **FIGS. 37B-37F** depict end views of tip portions of the disc implant delivery devices described herein. The tip portions are of various shapes and have variously numbered movable members.

[0055] **FIG. 38** depicts a step in the method of implanting the shape memory implants described herein into an intervertebral disc space.

[0056] **FIGS. 39-44** depict further steps in the method of **FIG. 38**.

[0057] **FIGS. 45-48** show top views of how selected spinal disc implant delivery devices may be positioned in an intervertebral disc space for delivery of a spinal implant.

[0058] **FIG. 49** depicts an end view of the positioned spinal disc implant delivery device of **FIG. 45**, taken along line **49-49**.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0059] For the purposes of promoting an understanding of the principles of the invention, reference will now be made to preferred embodiments and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications of the invention, and such further applications of the principles of the invention as illustrated herein, being contemplated as would normally occur to one skilled in the art to which the invention relates.

[0060] The present invention provides prosthetic intervertebral disc nucleus pulposus implants that may fully or partially replace the natural, or native, nucleus pulposus in mammals, including humans and other animals. In one aspect of the invention, implants are provided that are configured to resist expulsion or other migration through a defect, or other opening, in the annulus fibrosis and to resist excessive migration within an intervertebral disc space. In certain forms, these implants combine the advantages of an injectable/in-situ curing implant with a pre-formed implant. For example, a nucleus pulposus implant may include a load bearing elastic body surrounded by an outer, preferably resorbable or otherwise temporary, shell. The outer shell advantageously anchors the elastic body within the intervertebral disc space. The surface of the elastic body may include various surface features, including various macro-surface patterns, and chemical or physical modifications as described herein to further enhance fixation of the implant to the outer resorbable shell. The surface features, such as the macro-surface patterns and physical modifications, for example, are also expected to enhance fixation of the elastic body to surrounding tissue such that, in certain forms of the invention, no outer shell may be needed.

[0061] In other aspects of the invention, nucleus pulposus implants having shape memory that are configured to allow extensive short-term manual or other deformation without permanent deformation, cracks, tears, breakage or other damage are provided. In preferred forms of the invention

wherein the implants are formed from a hydrogel or other hydrophilic material, the implants can not only pass through a relatively small incision in the annulus fibrosis, but can also substantially fill and conform to the intervertebral disc space. In one form of the invention, an implant includes a load bearing elastic body with shape memory having first and second ends that are positioned adjacent to a central portion to form at least one inner fold. The inner fold desirably defines an aperture or channel.

[0062] In other embodiments of the invention, the shape memory implants are configured to form a spiral or other annular shape in the disc space, and may also be configured to have ends that matingly engage each other for further securing the implant in the disc cavity. Methods of making and implanting the implants described herein are also provided.

[0063] As disclosed above, in a first aspect of the invention, a nucleus pulposus implant is provided that includes a load bearing elastic body sized for introduction into an intervertebral disc space and surrounded by an outer, preferably resorbable, shell. Referring now to **FIGS. 1 and 2**, prosthetic implant **10** includes a core load bearing elastic body **15** disposed in intervertebral disc space **20**, between vertebral body **21** and **22** and surrounded by an outer shell **30**. More specifically, elastic body **15** has an outer surface **16** in contact with, and preferably bonded to, an outer shell **30** that may advantageously be resorbable, or otherwise temporary. Outer surface **31** of outer shell **30** preferably conforms to the shape of the intervertebral disc space **20**, being in contact with annulus fibrosis **5**, and may completely surround elastic body **15** as seen in **FIGS. 1 and 2**, although outer shell **30** may only partially surround elastic body **15**. As an example, upper, lower and/or lateral voids surrounding elastic body **15** may be filled in by outer shell **30**, as long as the elastic body is in some way anchored, or otherwise fixed in place, by the outer shell so as to prevent its expulsion from, or excessive migration in, the disc cavity. Thus, outer shell **30** may be configured to fill the aforementioned voids. Additionally, inner surface **32** of outer shell **30** preferably conforms to the shape of elastic body **15**, and preferably bonds to outer surface **16** of elastic body **15** as discussed below. In preferred embodiments, the elastic core and the outer shell substantially fill the disc cavity as further discussed below.

[0064] Outer shell **30** not only provides for a properly fit implant **10** within intervertebral disc space **20** for maximum load-bearing, stress transfer, and bonding of the implant surface to the surrounding disc tissues for fixation against excessive migration, it also seals an annular defect **18** for further resistance to migration and/or expulsion of the implant. Such sealing of the annular defect may also provide additional physical and mechanical support to the disc. Furthermore, the injectable outer shell material may provide intra-operative flexibility in fitting the core elastic body of implant **10** within the disc space as it may compensate for the differences in geometry and size between the disc space and the pre-formed core.

[0065] Outer shell **30** is preferably resorbable and, in such form, is preferably replaced with tissue, such as fibrous tissue and including fibrous scar tissue, that may aid in permanently confining the load bearing elastic body within the disc space. Referring now to **FIGS. 3 and 4**, tissue **33** has replaced outer shell **30**, and thus surrounds elastic body **15**. Although elastic body **15** may be confined within the disc space with the aid of tissue **33**, body **15** is expected to have some mobility for normal biomechanics.

[0066] The dimensions of load bearing elastic body **15** may vary depending on the particular case, but elastic body **15** is typically sized for introduction into an intervertebral disc space. Moreover, elastic body **15** is preferably wide enough to support adjacent vertebrae and is of a height sufficient to separate the adjacent vertebrae. In order to provide long-term mechanical support to the intervertebral disc, the volume of elastic body **15** in the disc space should be at least about 50%, preferably at least about 70%, further preferably at least about 80% and more preferably at least about 90% of the volume of the entire disc space, the remaining volume occupied by outer shell **30**. However, the volume of elastic body **15** may be as large as about 99% of the volume of the intervertebral disc space, and thus about 99% of the volume of implant **10**. Accordingly, the volume of outer shell **30** may be at least about 1% of the volume of the implant, but may range from about 1% to about 50%. The appropriate size of implant **10** desired in a particular case may be determined by distracting the disc space to a desired level after the desired portion of the natural nucleus pulposus and any free disc fragments are removed, and measuring the volume of the distracted space with an injectable saline balloon. The disc volume can also be measured directly by first filling the disc space with a known amount of the outer shell precursor material.

[0067] Elastic body **15** may be fabricated in a wide variety of shapes as desired, as long as the body can withstand spinal loads and other spinal stresses. The non-degradable and preformed elastic body **15** may be shaped, for example, as a cylinder, or a rectangular block. The body may further be annular-shaped. For example, implant **10'** in **FIGS. 12 and 13** has a spiral, or otherwise coiled, shape. The implant includes a first end **23** and a second end **24**. Elastic body **15** may also be shaped to generally conform to the shape of the natural nucleus pulposus, or may be shaped as further described below. Although elastic body **15** is shown as one piece in, for example, **FIGS. 1-4**, it may be made from one or several pieces.

[0068] Elastic body **15** may be formed from a wide variety of biocompatible polymeric materials, including elastic materials, such as elastomeric materials, hydrogels or other hydrophilic polymers, or composites thereof. Suitable elastomers include silicone, polyurethane, copolymers of silicone and polyurethane, polyolefins, such as polyisobutylene and polyisoprene, neoprene, nitrile, vulcanized rubber and combinations thereof. The vulcanized rubber described herein may be produced, for example, by a vulcanization process utilizing a copolymer produced as described, for example, in U.S. Pat. No. 5,245,098 to Summers et al. from 1-hexene and 5-methyl-1,4-hexadiene. Suitable hydrogels include natural hydrogels, and those formed from polyvinyl alcohol, acrylamides such as polyacrylic acid and poly(acrylonitrile-acrylic acid), polyurethanes, polyethylene glycol, poly(N-vinyl-2-pyrrolidone), acrylates such as poly(2-hydroxy ethyl methacrylate) and copolymers of acrylates with N-vinyl pyrrolidone, N-vinyl lactams, acrylamide, polyurethanes and polyacrylonitrile, or may be other similar materials that form a hydrogel. The hydrogel materials may further be cross-linked to provide further strength to the

implant. Examples of polyurethanes include thermoplastic polyurethanes, aliphatic polyurethanes, segmented polyurethanes, hydrophilic polyurethanes, polyether-urethane, polycarbonate-urethane and silicone polyether-urethane. Other suitable hydrophilic polymers include naturally-occurring materials such as glucomannan gel, hyaluronic acid, polysaccharides, such as cross-linked carboxyl-containing polysaccharides, and combinations thereof. The nature of the materials employed to form the elastic body should be selected so the formed implants have sufficient load bearing capacity. In preferred embodiments, a compressive strength of at least about 0.1 Mpa is desired, although compressive strengths in the range of about 1 Mpa to about 20 Mpa are more preferred.

[**0069**] Outer shell **30** may be formed from a wide variety of biocompatible, preferably elastic, elastomeric or deformable natural or synthetic materials, especially materials that are compatible with elastic body **15**. The outer shell materials preferably remain in an uncured, deformable, or otherwise configurable state during positioning of the elastic body in the interverterbral disc space, and should preferably rapidly cure, become harder or preferably solidify after being introduced into the intervertebral disc space, or, in other embodiments, prior to positioning of the elastic body in the intervertebral disc space. In preferred embodiments, the outer shell materials may remain deformable after they harden or otherwise solidify. Suitable materials that may be used to form the outer shell include tissue sealants or adhesives made from natural or synthetic materials, including, for example, fibrin, albumin, collagen, elastin, silk and other proteins, polyethylene oxide, cyanoacrylate, polyarylate, polylactic acid, polyglycolic acid, polypropylene fumarate, tyrosine-based polycarbonate and combinations thereof. Other suitable materials include demineralized bone matrix. These precursor materials may be supplied in liquid, solution or solid form, including gel form.

[**0070**] Elastic body **15** may include a variety of surface features on outer surface **16**, including chemical modifications and surface configurations, to provide surface features that advantageously improve the bonding between outer surface **16** of the elastic body and inner surface **32** of outer shell **30**. In one form of the invention, outer surface **16** is chemically modified utilizing, for example, chemical groups that are compatible with the materials used to form outer shell **30**. Suitable chemical modifications include, for example, surface grafting of reactive functional groups, including hydroxyl, amino, carboxyl and organofunctional silane groups. The groups may be grafted by methods known to the skilled artisan. Other modifications include precoating with a primer, preferably one that is compatible with the outer shell material, such as a layer of adhesive, sealing or other materials used for forming the outer shell described above.

[**0071**] In yet another form of the invention, elastic body **15** may include a wide variety of surface configurations, such as macro-surface patterns, or protuberances, as seen in **FIGS. 14A-14J**, showing side views or top views of top portions of elastic bodies with various surface features. Referring now to **FIGS. 14A-14J**, the pattern may be a dove-tail pattern **200**, a circular pattern **205**, a square pattern **210**, a conical pattern **215**, various wave patterns **220** and **225** and random, irregular patterns **230**. In other embodiments, a fiber **240** may be disposed in elastic body **241** and may project from the surface **242** thereof to form a fibrous pattern **235**. Fiber **240** may be disposed as a loop projecting from the surface of the elastic body, its ends may project from the surface of the elastic body, or the fiber may have a wide variety of other appropriate configurations. The fiber may be a short, polymeric fiber, such as one that is cut to less than about one inch. The fiber may, alternatively, be a continuous polymeric fiber. The fiber may further be braided, and may be woven or non-woven. The macro-surface patterns are preferably formed during formation of elastic body **15**. However, outer surface **16** of elastic body **15** may also be physically modified after formation of elastic body **15** by, for example, laser drilling or thermal deformation. Physical modifications include, for example, a micro-texturized surface formed by bead-blasting, plasma etching or chemical etching. Procedures for modifying various surfaces in this manner are well known in the art.

[**0072**] In certain forms of the invention, the implant may include only elastic body **15** having one or more of the outer surface features as described above, without the outer resorbable shell. The surface features are expected to provide a certain level of fixation to the surrounding tissues for improved resistance to migration and/or expulsion.

[**0073**] In yet other forms of the invention, the implant may include an elastic body that is surrounded by a supporting, or otherwise constraining, member wherein the supporting member is surrounded by a resorbable shell as described herein. Referring now to **FIG. 5**, implant **400** includes a load bearing elastic body **15** that is surrounded by a supporting member **34**. In one form, supporting member **34** may be a preferably flexible, peripheral supporting band that is disposed circumferentially about elastic body **15** as seen in **FIG. 5**, leaving upper and lower surfaces **35** and **36**, respectively, of elastic body **15** free from the supporting band.

[**0074**] As seen in **FIG. 5**, portions of upper and lower surfaces **35** and **36**, respectively, of elastic body **15** are exposed to directly contact outer shell **30**. This exposure minimizes the amount of material needed to construct the supporting member, yet still effectively provides, for example, lateral support. Although the amount of the upper and lower surfaces of elastic body **15** that are exposed may vary, typically at least about 50%, preferably at least about 70%, more preferably at least about 80% and most preferably at least about 90% of the surfaces are exposed.

[**0075**] In yet another embodiment shown in **FIG. 6**, nucleus pulposus implant **500**, that includes elastic body **15** as described above, is reinforced with supporting member **37**, which takes the form of a jacket. The jacket preferably completely surrounds elastic body **15**.

[**0076**] Suitable supporting members, including reinforcing outer bands, covers, or other jackets, may be formed from a wide variety of biocompatible polymers, metallic materials, or combination of materials that form a strong but flexible support to prevent excessive deformation, including lateral (horizontal) deformation, of the core under increasing compressive loading. Suitable materials include non-woven, woven, braided, or fabric materials made from polymeric fibers including cellulose, polyethylene, polyester, polyvinyl alcohol, polyacrylonitrile, polyamide, polytetrafluorethylene, polyparaphenylene terephthalamide, and combinations thereof. Other suitable materials include non-reinforced or

fiber-reinforced elastomers such as silicone, polyurethane, copolymers of silicone and polyurethane, polyolefins, including polyisobutylene and polyisoprene, neoprene, nitrile, vulcanized rubber, and combinations thereof. In a preferred form of the invention, a combination, or blend, of silicone and polyurethane is used. Furthermore, the vulcanized rubber is preferably produced as described above for the nucleus pulposus implants. Supporting members **34** and **37** are advantageously made from a porous material, which, in the case of an elastic body made from a hydrogel, or other hydrophilic material, allows fluid circulation through the elastic core body to enhance pumping actions of the intervertebral disc. Supporting members may further be formed from carbon fiber yarns, ceramic fibers, metallic fibers or other similar fibers as described, for example, in U.S. Pat. No. 5,674,295.

[**0077**] **FIGS. 7A-7D** show supporting bands of various patterns, typically made from various braided materials (bands **25**, **26** and **27**), or porous materials (band **28**), as described above. It is also understood the jackets may also be formed of such patterns. It is realized that the braided materials may also be porous.

[**0078**] Supporting members **34** and **37** preferably decrease lateral deformation, compared to deformation of an implant without the supporting member, as desired. Supporting members **34** and/or **37** may, for example, decrease lateral deformation by at least about 20%, preferably at least about 40%, more preferably by at least about 60% and most preferably by at least about 80%. An implant, such as one that includes an elastic body, having such a supporting member will be flexible and otherwise resilient to allow the natural movements of the disc and provides shock absorption capability at low to moderate applied stress, but will resist excessive deformation for disc height maintenance under high loading conditions. As described herein in the case of a lumbar disc, for example, low applied stress includes a force of about 100 Newtons to about 250 Newtons moderate stress includes a force of about 250 Newtons to about 700 Newtons, and high loading conditions, or high stress, includes a force of above about 700 Newtons. In preferred forms of the invention, the supporting member is flexible, in that it may be folded, or otherwise deformed, but is substantially inelastic, so that the implant is more fully reinforced or otherwise supported.

[**0079**] The elastic body may be covered by the jacket supporting member, or the band supporting member may be wrapped around the circumference of the elastic body. In a form of the invention wherein the elastic body is formed from a hydrogel, or similar hydrophilic material, the hydrogel may be dehydrated a desired amount prior to being covered by the jacket, or prior to wrapping the band around the circumference of the hydrogel body.

[**0080**] The hydrogel elastic body may be exposed to saline outside of the body, or may be inserted into the disc space wherein it will be exposed to body fluids in situ, and the body will absorb water and swell. In reference to the peripheral band supporting member, the swelling or expansion of the hydrogel elastic body in the horizontal direction is controlled by the amount of slack designed in the band. After the limited allowable horizontal expansion is reached, the elastic body is forced to expand mostly in the vertical direction until reaching equilibrium swelling under the in vivo load. As the upper and lower surfaces of the elastic body are not substantially constrained, the vertical expansion is mainly controlled by the applied stress and the behavior of the hydrogel material.

[**0081**] In yet other forms of the invention, an implant reinforced with a peripheral supporting band as described above that is surrounded by a resorbable outer shell may be further reinforced with one or more straps. The straps may be advantageous in preventing the peripheral supporting band described herein from slipping, or otherwise sliding off the implant. Referring now to **FIGS. 8 and 9**, at least one strap **420** extends along upper surface **35** and at least one strap **430** extends along lower surface **36** of elastic body **15** of implant **400**. Ends **421** of strap **420** and ends **431** of strap **430** are each preferably connected, or otherwise attached, to peripheral supporting band **34'**. The point of attachment may be any location that will secure the strap, including at the upper margins **138** of the band, lower margins **139** of the band or any region between the upper and lower margins. Although two straps **420** and **430** are shown extending along upper surface **35** and lower surface **36**, respectively, in **FIGS. 8 and 9**, one continuous strap may be utilized that extends completely around the implant, or the strap utilized may be in one, two or multiple pieces, as long as the combination of straps are sufficient to prevent excessive slipping and or sliding of the supporting band. Furthermore, more than one strap may extend along upper surface **35** and more than one strap may extend along lower surface **36** of elastic body **15**, as seen, for example, in **FIGS. 10 and 11** of implant **500**, wherein straps **520**, **530**, **540** and **550** are shown attached, or otherwise connect to supporting member **34"**. It is realized that the straps may be present in one or more pieces. For example, straps **520** and **530** may form a single strap, as may straps **540** and **550**, or may all combine to form a single strap.

[**0082**] In other aspects of the invention, kits designed for forming the intervertebral disc nucleus pulposus implants that include the outer shell described above are provided. In one form, a kit may include a load bearing elastic body as described above, along with a container of material to form the outer, preferably resorbable, shell. The material may be selected from the materials as described above. Moreover, the container that houses the material that forms the shell may be made from a wide variety of materials that are compatible with the outer shell material, including glass and plastic. The kit may further include a supporting member, such as a supporting band, jacket or other outer cover as described above. Generally, the kits include sterile packaging which secures the kit components in spaced relation from one another sufficient to prevent damage of the components during handling of the kit. For example, one may utilize molded plastic articles known in the art having multiple compartments, or other areas for holding the kit components in spaced relation.

[**0083**] In a further aspect of the invention, nucleus pulposus implants are provided having shape memory that are configured to allow extensive short-term manual, or other, deformation without permanent deformation, cracks, tears, breakage or other damage, that may occur, for example, during placement of the implant into an intervertebral disc space. Referring now to **FIGS. 15A and 16A**, in one form of the invention, implant **40** includes a load bearing elastic body **41** with shape memory and having a first end **42** and

a second end **43** that are positioned adjacent to a central portion **44** to form at least one inner fold **45**. Inner fold **45** preferably defines at least one aperture **46** which is advantageously arcuate. The elastic body is deformable, or otherwise configurable, manually, for example, from this first folded, or otherwise relaxed configuration shown in **FIG. 15A** into a second, substantially straightened, or otherwise non-relaxed configuration shown in **FIG. 16A** for placement into the intervertebral disc space. As elastic body **41** has shape memory, it returns by itself, automatically, back into the first folded, relaxed configuration once manual or other force is no longer exerted on the body. These implants therefore provide improved handling and manipulation characteristics in that they may be deformed, configured and otherwise handled by an individual without resulting in any breakage or other damage to the implant.

[**0084**] Further describing the shape memory nucleus prosthesis implant **40**, implant **40** includes surface depressions **47**, or other surface irregularities as more fully described below, that form inner fold **45** when the implant is in its relaxed configuration. Ends **42** and **43** have end surfaces **42***a* and **43***a*, respectively, that are generally flat, and substantially parallel, or perpendicular in other forms, to an axis X passing through the width of the implant in its relaxed configuration, wherein the ends may abut each other as seen in **FIGS. 15A, 15B** and **15**E-**15**N. The ends of the implant may each alternatively abut the central portion of the implant, as shown for implants **60** and **70** in **FIGS. 15C and 15D**, respectively, to form a generally bi-lobed or binocular-shaped implant.

[**0085**] Alternatively, in other forms of the invention, one end of the implant may be tapered, or otherwise specifically shaped, and the other end may be shaped complementary to the tapered, or otherwise shaped, end. Moreover, either one or both sides **96***a* and **96***b* of the ends of the nucleus pulposus implant may be tapered. For example, and as seen in **FIGS. 15F and 16F**, both sides of end **93** of implant **90** are tapered to form a pointed end, such as a generally V-shaped end, that advantageously fits into a complementary-shaped (e.g., V-shaped) depression **95** defined by end **92**. An implant having only one inner fold that defines one aperture and ends that are similarly configured as ends **92** and **93** is shown in **FIGS. 15J and 16J**. As another example, one side of each of the ends of the implant may be oppositely tapered as seen in **FIGS. 15G and 16G**. That is, side **108***a* of end **102** of implant **100** and opposite side **109***b* of end **103** are tapered as seen in **FIG. 15G and 16G**. End surfaces **102***a* and **102***b* of implant **100** are transverse to axis X when the implant is in its relaxed configuration shown in **FIG. 15G**. In those embodiments where the ends of the implants are tapered, or otherwise shaped, it is preferred that, when the ends of the implants contact each other or the central or other portion of the implant, an implant is formed that is uniform along the length of the implant through the region of contact.

[**0086**] Although the implant may assume a wide variety of shapes, it is typically shaped, in its folded, relaxed configuration, to conform to the shape of the natural nucleus pulposus. Thus, the implants may be substantially elliptical when in their folded, relaxed, configurations in some forms of the invention. In yet further forms of the invention, the shape of the implants in their folded configurations may be generally annular-shaped or otherwise shaped as required to conform to the intervertebral disc cavity. Moreover, when the implants are in their unfolded, non-relaxed, configuration, such as their substantially straightened configuration, they may also assume a wide variety of shapes, but are most preferably generally elongated, and preferably generally cylindrical, or other shape as described herein.

[**0087**] In yet other forms of the invention, the folding implant may have a surface that includes surface projections that further aid in allowing short-term deformation of the implant without permanent deformation or other damage as described above. Referring now to **FIGS. 15D and 16D**, implant **70** includes a load bearing elastic body **71** having a first end **72**, a second end **73** and a central portion **74**. Inner fold **75** defines an aperture **76** and includes an inner fold surface **77** having wrinkles, or projections **78** thereon. Projections **78** of inner fold surface **77** extend into aperture **76**.

[**0088**] These wrinkles advantageously facilitate stretching of the implant without deformation, cracking, tearing, breakage, or other damage when the implant is straightened or elongated for insertion into the intervertebral disc space. In the embodiment shown in **FIGS. 15D and 16D**, the wrinkles, or surface projections, extend along the entire length of elastic body **71**, including central portion **74**. Other implants having wrinkled inner fold surfaces are seen in **FIGS. 15E and 16E** and other wrinkle configurations upon folding the implant are seen in **FIGS. 15K-15N** and **16**K-**16**N.

[**0089**] Other folding implants are shown in **FIGS. 22A-22Q**, **23**A-**23**Q and **24-27**. Referring to these figures, implants **400-620** are shown that have a plurality of inner folds, ranging from, for example, two to about six. Moreover, these implants, as well as the above-discussed folding implants, have first and second ends that are formed from first and second arms, respectively, of the implants. As seen in **FIGS. 22A and 23A**, for example, first end **402** of implant **400** is formed from a first arm **408** connected to, or otherwise associated with, one end **404***a* of central portion **404**. Second end **403** is formed from a second arm **409** connected to, or otherwise associated with, opposing end **404***b* of central portion **404**. Surface depressions **405** or other surface irregularities define inner folds **406** when the implant is in its relaxed configuration.

[**0090**] In certain forms of the invention, each of the arms connected to the central portions of the implant are the same length, as seen in **FIGS. 15A-15J**, **15**L-**15**N, **22**A-**22**B, **23**A-**23**B, **22**D-**22**E, **23**D-**23**E, **22**G and **23**G. In yet other forms of the invention, one of the arms is shorter than the other arm. For example, as seen in **FIG. 22C**, second arm **429** of implant **420** is shorter than first arm **428**, wherein each arm is connected to an end of central portion **424**. Stated alternatively, in certain forms of the invention, the ends of the implant abut each other along a plane extending along axis X and passing through the width of the implant, resulting in a center or central closure C of the implant as seen, for example, in **FIG. 22A**. In other forms of the invention, the ends of the implant abut each other along a plane extending parallel to a plane extending along axis X and passing through the width of the implant, resulting in an off-center closure C' of the implant as seen, for example, in **FIG. 22C**. The differential length of the arms of the implants can facilitate implantation and proper positioning of the implants in the disc space as more fully described below.

[0091] Moreover, some of the inner folds of the implants may be formed when the first end and the second end of the implant contact, or otherwise abut, each other, as seen, for example, in **FIG. 22C**. In such forms of the invention, each end of the implant may include a surface that has a surface depression, such as surface depression **421** or **422**, as seen in **FIG. 23C**, that forms a portion of the inner fold such that when the ends of the implant contact each other, an inner fold is formed from the combination of surface depressions. Additionally, the apertures defined by the inner folds may have a variety of cross-sectional shapes, including substantially annular or otherwise ring-shaped, substantially oval or otherwise elliptical-shaped, star-shaped or other various shapes known to the skilled artisan. The star-shaped pattern includes a plurality of finger-like or otherwise elongated projections **465** or **475** as seen, for example, in **FIGS. 22G and 22H**, respectively.

[0092] **FIGS. 221, 231, 24**, 22K, 23K and **26** show further details of implants of the present invention. For example, apertures, or channels, **486** and **506**, can be seen in **FIGS. 24 and 26**, respectively, showing implants **480** and **500**, respectively. Turning now to **FIGS. 22J, 23J** and **25**, implant **490** is shown that includes all of the features of the aforementioned implants, including a load bearing body **491**, a first arm **498** having a first end **492**, a second arm **499** having a second end **493**, and surface depressions **497**. Additionally, implant **490** includes a central portion **494** that extends along the full width of implant **490** from one end of the implant to an opposing edge of the implant. In such an embodiment, end surfaces **492***a* and **493***a* abut, and are otherwise in contact with, central portion **494** when implant **490** is in its folded configuration as seen in **FIG. 22J**.

[0093] In one form of the invention, at least one end of the implants may be curved, or otherwise arcuately-shaped or rounded. Referring to implant **510** in **FIGS. 22L and 23L**, first end **512** and second end **513** each have an inner edge **512***b* and **513***b*, and an outer edge, **512***a* and **513***a*, respectively. Outer edges **512***a* and **513***a* are shown as rounded and can facilitate implantation and proper positioning of the implants in the disc space as more fully described below.

[0094] For example, the rounded edges allow for better conformity of the implant to the disc space. Although not being limited by theory, it is believed that the dome-shaped, or otherwise concave-shaped, endplates may lead to increased stress concentrated at the edges of the implant. The rounded edges reduce such stress. In this manner, there is a smaller likelihood of the implant penetrating the endplate, and the durability of the implant is improved. Bone remodeling based on the shape of the implant is also reduced.

[0095] Referring to **FIGS. 22M and 23M**, implant **610** is shown wherein both ends of the implants have edges that are curved or otherwise rounded. Implant **610** includes body **611** having first arm **613** and second arm **614**. First arm **613** and second arm **614** include ends **613***a* and **614***a*, respectively, which both preferably have rounded edges **613***b* and **614***b*, respectively, although only one of the ends may have such a rounded, straight or other shaped edge. In this embodiment, end **614***a* of second arm **614** is tapered, or otherwise has a decreased diameter compared to end **613***a* of first arm **613**. Additionally, first arm **613** is shorter than second arm **614**.

[0096] Referring to **FIGS. 22N-22Q**, 23N-23Q and **FIG. 27**, alternative embodiments of the above-described folding implants are shown. As with all of the implants, the bodies forming the implants have a top surface T for contacting an upper vertebral endplate of an intervertebral disc and a bottom surface B for contacting a lower vertebral endplate of the intervertebral disc as seen, for example, in **FIG. 27**. Additionally, the implants have an external side surface E that includes at least one groove G extending along the side surface that advantageously further relieves the compressive force on the external side E of the implant when the implant is deformed into a substantially straightened, or otherwise unfolded configuration and thus further allows extensive short-term deformation without permanent deformation, cracks, tears or other breakage. For example, implant **620** shown in **FIGS. 22N, 23N** and **27** includes a load bearing body **621** that has a top surface T, a bottom surface B, an internal side surface I and an external side surface E. A plurality of grooves G are disposed along external side surface E that typically extend from the top surface to the bottom surface of the implant. When dividing the implant in half, thus more easily viewing a first side S_1 and a second side S_2, with a plane passing through the width of the implant along axis X, it can be seen in **FIG. 22N** that four grooves G are present on first side S_1 and four grooves G are present on second side S_2, although more or less may be present depending on the case. It is preferred that at least one groove is present on each side Si and S_2.

[0097] **FIGS. 220 and 230** depict implant **570**, which is similar to implant **620**, with the exception that implant **570** includes a second arm **572** that is smaller than first arm **571**, resulting in an off-center closure C' as more fully described above. **FIGS. 22P and 23P** depict implant **610'** and **FIGS. 22Q and 23Q** depict implant **490'**, which are identical to implants **610** and **490**, respectively, with the exception that implants **490'** and **600'** both include external side grooves G as described herein.

[0098] In yet other preferred forms of the invention, the top and bottom contact surfaces of the implants are configured to be complementary to the top and bottom endplates of an intervertebral disc, respectively. For example, the top and bottom contact surfaces of the implants may be convex, to conform to the respective concave intervertebral disc endplates. Additionally, although the implants are preferably one-piece implants, they may also be composed of one or more pieces. For example, an implant may be composed of a separate central portion and first and second arms, wherein the arms are associated or otherwise attached to the central portion as described herein.

[0099] In certain preferred forms of the invention, the apertures defined by the inner folds of the implants described above have a radius of at least about 1 mm. Moreover, in other preferred forms of the invention, a reinforcing material may be included at the inner fold surface to further improve the structural integrity of the implant. The reinforcing material may be a fabric that is either woven, or non-woven, and may be formed from braided fibers for further strength. The reinforcing material may be positioned on the inner fold surface, may project therefrom or may be entirely embedded under the inner fold surface. The implant may be formed as a single piece, or may be formed of more than one piece that is connected to the other pieces that form the assembled implant by fabric

that may be made from braided or other fibers, or may be connected by some other components or manner, such as by use of adhesives, or other methods of connecting such components together. Although these implants are designed to be used without an anchoring outer shell, they, as well as all of the implants described herein, may form the core elastic body of an implant that includes the outer shell described herein.

[0100] The implants may obtain their shape memory characteristics in a variety of ways. For example, the implants may be formed in a mold into a desired final shape, and, when deformed from this final shape by application of an external force, will return to the final shape upon release of the force.

[0101] In yet another embodiment of the invention, a nucleus pulposus implant is provided that has a locking feature, with optional shape memory characteristics, and thus may also resist being expelled from the disc cavity to some extent. In one form of the invention as seen in **FIGS. 17-19**, an implant **300** includes a load bearing elastic body **301** having a first end **302** and a second end **303**. The ends are typically configured for mating engagement with each other. Elastic body **301** has a first, locked configuration wherein first end **302** and second end **303** are matingly engaged to each other as seen more particularly in **FIG. 17**. When elastic body **301** has shape memory characteristics, elastic body **301** is deformable, manually, for example, into a second, substantially straightened, non-relaxed configuration for insertion into an intervertebral disc space, as seen in **FIG. 19**, and may automatically be configured or otherwise returned back into the first, locked, relaxed configuration after insertion due to its shape memory characteristics. In those cases where the elastic body does not have shape memory characteristics and the elastic body is configurable into a locked and/or straightened configuration, and in those cases where the elastic body has shape memory characteristics, the elastic body may also be placed into its locked configuration with the assistance of external force.

[0102] More particularly describing one form of the invention, end **302** defines an internal channel **304** as seen in **FIG. 19** whereas end **303** is configured to conform to the shape of internal channel **304**. The channel may take the form of a wide variety of shapes, as long as the ends of the elastic body may be matingly engaged to form a locked configuration. As seen in **FIG. 19**, the channel is somewhat hour-glass shaped. Manual, or other force, may be applied to end **303** so that it may be temporarily deformed, or configured, sufficiently to pass through narrowed passage **305** within internal channel **304**. Once properly positioned, end **303** will be secured within channel **304**, as end edges **303***a* and **303***b* are braced against channel edges **304***a* and **304***b*, respectively. Alternatively, one end of an implant with a locking feature may be friction-fit within the internal channel present in the other end of the implant. The friction-fit may arise as a result of the relative size differences between the inner diameter of the channel formed by one end and the outer diameter of the other end of the implant. Additionally, and/or alternatively, the outer surface of one end, and/or the inner surface of the channel defined by the other end, may include surface roughenings as described herein that aid in achieving the friction-fit. The implant may also be constructed from the biocompatible polymeric materials as described above.

[0103] When the implants are formed from an elastic material, such as a hydrogel, or other similar hydrophilic material, or include the resorbable outer shell, they may advantageously deliver desired pharmacological agents. The pharmacological agent may be a growth factor that may advantageously repair the endplates and/or the annulus fibrosis. For example, the growth factor may include a bone morphogenetic protein, transforming growth factorβ (TGF-β), insulin-like growth factor, platelet-derived growth factor, fibroblast growth factor or other similar growth factor or combination thereof having the ability to repair the endplates and/or the annulus fibrosis of an intervertebral disc.

[0104] The growth factors are typically included in the implants in therapeutically effective amounts. For example, the growth factors may be included in the implants in amounts effective in repairing an intervertebral disc, including repairing the endplates and the annulus fibrosis. Such amounts will depend on the specific case, and may thus be determined by the skilled artisan, but such amounts may typically include less than about 1% by weight of the growth factor. The growth factors may be purchased commercially or may be produced by methods known to the art. For example, the growth factors may be produced by recombinant DNA technology, and may preferably be derived from humans. As an example, recombinant human bone morphogenetic proteins (rhBMPs), including rhBMP 2-14, and especially rhBMP-2, rhBMP-7, rhBMP-12, rhBMP-13, and heterodimers thereof may be used. However, any bone morphogenetic protein is contemplated including bone morphogenetic proteins designated as BMP-1 through BMP-18.

[0105] BMPs are available from Genetics Institute, Inc., Cambridge, Mass. and may also be prepared by one skilled in the art as described in U.S. Pat. No. 5,187,076 to Wozney et al.; U.S. Pat. No. 5,366,875 to Wozney et al.; U.S. Pat. No. 4,877,864 to Wang et al.; U.S. Pat. No. 5,108,922 to Wang et al.; U.S. Pat. No. 5,116,738 to Wang et al.; U.S. Pat. No. 5,013,649 to Wang et al.; U.S. Pat. No. 5,106,748 to Wozney et al.; and PCT Patent Nos. WO93/00432 to Wozney et al.; WO94/26893 to Celeste et al.; and WO94/26892 to Celeste et al. All bone morphogenic proteins are contemplated whether obtained as above or isolated from bone. Methods for isolating bone morphogenetic protein from bone are described, for example, in U.S. Pat. No. 4,294,753 to Urist and Urist et al., 81 PNAS 371,1984.

[0106] In other forms of the invention, the pharmacological agent may be one used for treating various spinal conditions, including degenerative disc disease, spinal arthritis, spinal infection, spinal tumor and osteoporosis. Such agents include antibiotics, analgesics, anti-inflammatory drugs, including steroids, and combinations thereof. Other such agents are well known to the skilled artisan. These agents are also used in therapeutically effective amounts. Such amounts may be determined by the skilled artisan depending on the specific case.

[0107] The pharmacological agents are preferably dispersed within the hydrogel, or other hydrophilic, implant for in vivo release, and/or, with respect to the implants with the resorbable outer shell, may be dispersed in the outer shell. The hydrogel can be cross-linked chemically, physically, or by a combination thereof, in order to achieve the appropriate level of porosity to release the pharmacological agents at a desired rate. The agents may be released upon cyclic load-

ing, and, in the case of implants including a resorbable outer shell, upon resorption of the shell. The pharmacological agents may be dispersed in the implants by adding the agents to the solution used to form the implant, by soaking the formed implant in an appropriate solution containing the agent, or by other appropriate methods known to the skilled artisan. In other forms of the invention, the pharmacological agents may be chemically or otherwise associated with the implant. For example, the agents may be chemically attached to the outer surface of the implant.

[0108] The implants described herein may have embedded therein small metal beads or wire for x-ray identification.

[0109] Methods of forming and implanting the nucleus pulposus implants described herein are also provided. In one form of the invention, with respect to implant **10** described above having the anchorable outer shell **30**, implant **10** may be formed by first forming elastic body **15** and then forming the outer shell. Methods of forming elastic body **15** are well known in the art.

[0110] For example, if the elastic body is made of elastomeric materials, such as powdered elastomers including, for example, styrene-ethylene/butylene block copolymers, the powdered elastomer may be placed into an appropriate mold and may be compressed and heated to melt the powder. The mold is then cooled to room temperature. If the elastic body is made from a hydrogel, such as a polyvinyl alcohol, the polyvinyl alcohol powder may be mixed with a solvent, such as, for example, water or dimethylsulfoxide, or combinations thereof, and heated and shaken until a uniform solution is formed. The solution may then be poured into a mold, such as a rubber mold, and may be cooled at an appropriate temperature, such as about 0° C. to about −80° C., for several hours to allow for crystallization. After cooling, the hydrogel can be partially or completely hydrated by soaking and rinsing with water but, in certain preferred embodiments, may remain dehydrated so that it may be inserted through a smaller aperture in the annulus fibrosis.

[0111] Prior to positioning the implant in the intervertebral disc space, an incision may be made in the annulus fibrosis, or one may take advantage of a defect in the annulus, in order to remove the natural nucleus pulposus and any free disc fragments within the intervertebral disc space. The disc space is then distracted to a desired level by distractors or other devices known to the skilled artisan for such purposes. Once formed, and after preparing the disc space for receiving the implant, elastic body **15** may be implanted into the intervertebral disc space utilizing devices well known in the art and as described in U.S. Pat. Nos. 5,800,549 and 5,716,416. If the outer shell precursor material was already placed in the intervertebral disc space, excess precursor material may flow out of the disc space. This excess material should be promptly removed before it sets or otherwise cures. The outer shell material may be injected, or otherwise introduced, into the disc space utilizing devices that are well known in the art, such as syringes, sealant/caulk guns, automatic liquid injectors, and applicators that include, for example, two separate syringes which allow for simultaneous mixing of the components in a static mixer and delivery to the site, and may be injected either prior to or after introduction of the implant into the disc space. Whether the outer shell material is introduced prior to or after introduction of the implant into the disc space, the distractor is then removed, any excess precursor material seeping out of the disc space is removed and the precursor material within the disc space is cured to form the outer shell. It is noted that the elastic body may already be surrounded by the outer shell, which may be in a partially or fully hardened state but preferably remains deformable, prior to introducing the elastic body into the intervertebral disc space.

[0112] In further aspects of the invention, spinal disc implant delivery devices, or tools, are provided to be used in preferred methods of implanting the implants described herein, especially the shape memory implants. In one form, the device preferably includes an elongated member having a lumen extending longitudinally therethrough for loading of the desired implant, a tip portion for controlling passage of the implant out of the delivery tool and a plunger or other elongated member or other device for pushing the implant through the tool and into an intervertebral disc cavity. The tip portion preferably includes a movable member that may be moved from a first, closed position in which it blocks the passage of a spinal disc implant through the lumen, and out of the distal end, of the elongated member into which the spinal implant is loaded and otherwise housed. The tip portion may also preferably be moved to a second, open position, wherein egress of the spinal implant is allowed.

[0113] Referring to **FIG. 28**, device **700** includes an elongated member **701**, such as a syringe housing **702** or other elongated housing or barrel that defines a cavity, or lumen, **703** that extends along its length, and has a proximal end **704** and a distal end **705**. Proximal end **704** defines a flange **704***a*. Inner surface **703***a* of cavity, or lumen, **703** is preferably configured for passage of a spinal nucleus pulposus implant. For example, inner surface **703***a* is preferably smooth. Although elongated housing member **701** is shown in **FIG. 29** as having a square cross-sectional shape, the cross-sectional shape of housing member **701** may vary along its length and may be selected from a wide variety of geometric shapes, including elliptical, circular, rectangular, hexagonal or other multi-sided shape or a combination thereof. Device **700** further includes a plunger **706**, or elongated or other member. Plunger **706** includes an elongated member, or rod, **720** having proximal end **707** and distal end **709** that may be utilized to push a nucleus pulposus implant that may be disposed in cavity **703** through the housing and ultimately into an intervertebral disc space. Distal end **709** of plunger **706** may include a plunger tip **721** that is configured to contact an implant during extrusion. The cross-sectional shape of plunger tip **721** is preferably similar to that of elongated housing member **701**. Proximal end **707** of plunger **706** includes a plunger handle **722**. Plunger **706** may include one or more components that may facilitate extrusion of the implant by pneumatic, hydraulic or mechanical force, or by manual pushing or impacted force. For example, the plunger can be in the form of a pushing or impacted plunger, a syringe plunger, a caulk gun plunger, or a screw-driven plunger as known in the art.

[0114] Device **700** further includes component, or tip portion, **710** having a proximal end **713** and a distal end **712** wherein tip portion **710** may be integral or detachable. For example, proximal end **713** of tip portion **710** may be matingly engageable to, or is otherwise connected or associated with, distal end **705** of housing **702** of member **701**. In one form of the invention depicted in **FIG. 29**, tip portion

710 may include a top wall **730**, a bottom wall **735**, a side wall **740** and an opposing side wall **745**. Tip portion **710** defines a cavity, or lumen, **731** extending longitudinally therethrough wherein lumen **731** is continuous, and otherwise in fluid communication, with lumen **703** of elongated housing member **701**.

[**0115**] The dimensions of tip portion **710**, such as height H and width W, may be configured to accommodate a spinal disc implant to be delivered. Height H of tip portion **710** may have a height similar to or larger than the disc space height depending on whether disc space distraction is required. Additionally, length L of the tip portion may be chosen so that tip portion **710** will preferably not substantially extend past the inner wall of the annulus fibrosus as described more fully below. Different dimensions of the tip portion may be determined by the skilled artisan.

[**0116**] Tip portion **710** is preferably configured to enter an aperture in an annulus fibrosus for delivery of a spinal nucleus pulposus implant or other spinal implant. Although tip portion **710** is shown as a rectangular tube in **FIG. 29**, it may have a wide variety of shapes, including cylindrical, square, hexagonal or other multi-sided shape. Surface **732** of top wall **730** and surface **733** of bottom wall **735** contact the endplates during delivery of the implant, and may have surface features **738** that help anchor, engage or otherwise secure the tip to the opposing endplates. Examples of such surface features, such as surface roughenings, are shown in **FIGS. 30A-30J** and include teeth **738***c*-**738***g*, in the form of serrations or spikes **(FIGS. 30C-30H)**, ridges **738***i* and **738***j* **(FIGS. 30I and 30J)** a textured surface **738***b* **(FIG. 30B)** or a non-textured surface **738***a* **(FIG. 30A)**. The teeth or ridges may be directional and may restrict movement in a single direction, as seen in **FIGS. 30D, 30E**, **30**F, and **30**G for example.

[**0117**] In yet another form of the invention, one side wall may be shorter than the other to aid delivery and placement of the spinal disc implants described herein. Referring to **FIG. 31**, delivery device **700***a* includes tip portion **710***a* having side wall **740***a* that is shorter than side wall **745***a*. **FIG. 32** shows one way in which delivery of an implant **40** is aided. For example, as implant **40** exits the device, it veers to the shorter side wall and will subsequently fold up in the disc space.

[**0118**] In a further form of the invention, the top and bottom walls of the tip portion may be partially open to alleviate any possible constriction of the implant as it exits the device and is delivered into a disc space. For example, referring to **FIG. 33**, tip portion **710'** of device **700'** may include a top wall **730'** having an opening **739** and a bottom wall **735'** having an opening **741**, wherein both openings may extend from a proximal end **712'** to a distal end **713'** of tip portion **710'**. In such a fashion, tip portion **710'** forms opposing arms **736** and **737**, each having an inner surface I and an outer surface O. Inner surfaces I are preferably concave and preferably accommodate a spinal disc implant.

[**0119**] Although both arms **736** and **737** of tip portion **710'** are shown in **FIG. 33** as having the same. length, one of the arms may be shorter than the other to, for example, aid placement of the folding implants described herein. For example, as seen in **FIG. 34**, arm **736'** of tip portion **710"** of device **700"** is shorter than arm **737'**.

[**0120**] In yet another embodiment of a spinal disc implant delivery device, one of the arms of the tip portion may be movable and the other non-movable or otherwise stationary. As seen in **FIG. 35**, for example, arm **737"** of tip portion **710'"** of device **700'"** is similar in configuration as arm **737'** and is preferably non-movable and further preferably otherwise rigid. Arm **736"** may also be non-movable or otherwise rigid, but it may include both a non-movable portion **736***a"* and a movable, flexible or otherwise elastic portion **736***b"* so that arm **736"** may move, or be bent, and form a closed configuration. For example, by appropriately positioning arm portion **736***b"*, arm **736"** may be bent, preferably at an angle α of greater than about 30°, further preferably between about 45° to about 90°, and typically about 60°. It is preferred, especially when the tip portion also functions as a distractor, that the movable portion of the arm has a height that is less than the height of a disc space, and/or the height of the arm at its distal end is shorter than at its proximal end, so that it may move freely. In the closed configuration, the width W of distal end **713'"** of tip portion **710'"** is narrow, such as about 2 mm to about 10 mm, which makes it easier to guide the tip portion into a small annular opening. Additionally, the implant for delivery ill be blocked from exiting the delivery device by arm **736"** in its closed configuration.

[**0121**] After the tip portion is inserted into the disc space, movable arm **736"** may be moved, radially, for example, to form an open configuration, such as the configuration of arm **736** of device **700'** of **FIG. 33**, under extrusion pressure to expand the annular opening and to allow the implant to exit the device and enter the disc space as described below. After the implant is delivered to the disc space, the movable arm retracts, bends or otherwise moves back to its closed configuration in order to decrease the expansion of the annular opening. It is realized that both arms may also be rigid, flexible or otherwise elastic as desired. Other tip portions that have such open and closed configurations are described below. In preferred embodiments of the spinal disc implant delivery devices described herein, the tip portion has wall support for the top, bottom and side surfaces of the spinal disc implants to be delivered. It is further noted that lumens **703'**, **703"**, **703'"** of elongated members **701'**, **701"** and **701'"**, respectively, are continuous, and in fluid communication, with cavity **731'**, **731"**, **731'"**, respectively.

[**0122**] In yet another form of the invention, and referring to **FIG. 36**, a spinal disc implant delivery device **800** includes an elongated member **801**, such as a syringe housing **802** that defines a cavity **803**, and has a proximal end **804** with a flange portion **804***a* and a distal end **805**. Device **800** further includes a plunger **806**, or elongated or other member, having proximal end **807** and distal end **809** that may be utilized to push a nucleus pulposus implant that may be disposed in cavity **803** through the housing, out of the distal end of the housing and ultimately into an intervertebral disc space.

[**0123**] Device **800** further includes component, or tip portion, **810** having a proximal end **813** and a distal end **812**, wherein proximal end **813** is matingly engageable to, or is otherwise connected or associated with, distal end **805** of housing **802** of member **801** which is also seen in **FIG. 36**. Tip portion **810** preferably includes a base member **850** which has a proximal end **851**, a distal end **852**, and a lumen **853** extending longitudinally therethrough. Tip portion **810** further preferably includes at least one movable member that may form a closed configuration as described herein. In

preferred forms of the invention, tip portion **810** includes a plurality of movable members **880**. Proximal end **881** of movable members **880** abut, or are connected to or are otherwise associated with, distal end **852** of base member **850**.

[**0124**] Movable members **880** have a first, closed configuration wherein they define a channel or cavity **883**. The members may further have a closed configuration which includes a narrowed distal end. Lumen **853** of base member **850** and cavity **883** are preferably in fluid communication. Lumen **853** of base member **850** and cavity **803** of housing **802** are also preferably in fluid communication when distal end **805** of housing **802** and proximal end **851** of base member **850** are matingly engaged. In their closed configuration, movable members **880** preferably further define an aperture **884**, or other opening, at their distal end as best seen in **FIG. 37A**. Aperture **884** is preferably sized and/or configured for ease of insertion of the tip into an annular opening, preferably an undersized or relatively small annular opening. For example, the diameter of aperture **884** of movable members **880** may range from about 2 mm to about 10 mm in its closed configuration.

[**0125**] Movable members **880** are preferably movable, flexible, or otherwise elastic, but in certain forms of the invention may be otherwise rigid, and further have an open configuration wherein movable members **880** are moved, flexed or otherwise bent sufficiently to enable passage of a spinal implant, such as a nucleus pulposus implant described herein, through lumen **853** of base member **850** and through an area circumscribed by the movable members in their open configuration so that the spinal implant may exit the delivery tool and may be inserted into or otherwise positioned in an intervertebral disc space. Movable members **880** are preferably placed in their open configuration when, for example, a spinal implant is positioned in housing **802** of syringe **801** and plunger **806**, or other elongated or similar member, transmits a force sufficient for translation of the spinal implant through cavity **803** of housing **802**, lumen **853** of base member **850** and cavity **884** defined by movable members **880**. Contact of the inner surfaces of movable members **880** with, and continued translation of, a spinal implant toward distal end **812** of device **800** forces the radial flexing, bending or movement of movable members **880** as more fully described below.

[**0126**] Movable members **880** and base member **850** may be engaged, connected or otherwise associated with each other in a variety of ways, including use of an adhesive. Moreover, movable members **880** and base member **850** may be integral. Base member **850** may also be integral with syringe housing **802**, or may be attached by adhesive or other manner of attachment described herein and/or known to the skilled artisan. For example, base member **850** may have an inner surface **854** defining lumen **853** that is tapered as desired to varying degrees so that base member **850** may be associated with syringe housing **802** by friction fit. Other mechanical interlocking methods known to the art may also be utilized to couple proximal end **851** of base member **850** to distal end **805** of housing **802** of syringe **801**.

[**0127**] Tip portion **810** may include a plurality of movable members and may assume a wide variety of shapes. As seen in **FIG. 37A**, tip portion **810** is round and includes **16** movable members **880**, although more or less may be present as desired. For example, the tip portion may include **8** movable members **780***b*, **780***c* and **780***d* (tip portion **810***b*-**810***d*, respectively) as seen in **FIGS. 37B-37D**, 4 movable members **780***e* (tip portion **810***e*) as seen in **FIG. 37E** or 2 movable members **780***f* (tip portion **810***f*) as seen in **FIG. 37F**. Additionally, the movable members may contact a neighboring movable member or may be variously spaced apart. For example, **FIGS. 37D, 37E** and **37**F show movable members, some of which are spaced apart by space S. Furthermore, the tip portions may assume a wide variety of cross-sectional shapes, including circular, elliptical, square, rectangular or other multi-sided or geometric shape.

[**0128**] The housing members, plunger members and base members described herein may be made from a variety of materials, including metals known to the art, such as stainless steel and titanium alloys, polymers known to the art, including polyethylene, polypropylene, polyetheretherketone and polyacetal. Movable members, such as movable members **880**, may also be made from a variety of materials, preferably those which are flexible or otherwise elastic, and allow for flexing, bending or pivoting. Movable members **880** may be made from the same materials as the housing members, plunger members and base members described herein.

[**0129**] In yet another form of the invention, a method for implanting a prosthetic intervertebral disc having shape memory is provided. In one embodiment, an implant including a load bearing elastic body having a first end and a second end positioned adjacent to a central portion to form at least one inner fold as described above is provided. As mentioned previously herein, the disc space may be distracted if necessary and all or a portion of the nucleus pulposus may be removed. The implant **40**, for example, may be deformed by, for example, manual force into a substantially straightened, non-relaxed configuration for insertion through an aperture formed in the annular fibrosis as indicated in **FIG. 20**, and as best seen in **FIG. 21**. The aperture may be formed through deterioration or other injury to the annulus fibrosis, or may be made by purposely incising the annulus. The implant may then be. positioned in a delivery tool **310** known in the art, such as that described in U.S. Pat. No. 5,716,416, and inserted through aperture **18** in annulus **19**, although utilization of the delivery devices or tools described more fully herein is preferred. As the implant enters the intervertebral space **20** and is no longer subject to manual force, it deforms back into its relaxed, folded configuration as seen in **FIG. 21**. A portion, or substantially all, of the natural nucleus pulposus may be removed from the intervertebral disc space, depending on the circumstances, prior to introduction of the implant into the intervertebral disc space. When implanting an implant that includes a locking feature, or other implant with shape memory as described herein, a similar protocol is followed. Additionally, with respect to an implant with a locking feature, the implant may be placed into the locked configuration with external force, imposed by, for example, medical personnel. It is noted that, due to the symmetrical features of a variety of the implants described herein, the implant may be inserted into the disc space by a wide variety of approaches, including anterior and posterior approaches.

[**0130**] In preferred forms of the invention, a method for implanting a prosthetic intervertebral disc having shape memory is practiced with the spinal disc implant delivery

devices described herein. As an example, the method may be practiced with device **800** as depicted in **FIGS. 38-44**. After implant **40** is deformed by, for example, manual force into a substantially straightened, non-relaxed, unfolded, configuration for insertion through an aperture formed in the annular fibrosis, it is loaded, or otherwise positioned in cavity **803** of syringe housing **802**. Alternatively, as seen in **FIG. 38**, implant **40** may be straightened as it is inserted into cavity **803** at proximal end **804** of housing **802**. Distal end **809** of plunger **806** may then be inserted into cavity **803** from proximal end **804** of housing **802**. Device **800**, loaded with implant **40**, may then be positioned adjacent aperture **18** in annulus **19** as seen in **FIG. 40**. Distal end **882** of movable members **880** are preferably positioned through aperture **18** in annulus **19** and preferably extend into intervertebral disc space **20** surrounded by annulus **19**, as seen in **FIG. 40**. Force is applied to plunger **806**, preferably at its proximal end **807**, to contact end **42** of implant **40** for translation of the implant towards distal end **812** of delivery tool **800**. The force preferably will allow contact of distal end **809** of plunger **806** with an adjacent end of the implant and may be provided manually, with a mechanical pressurization device, including a caulk gun, or by other devices and methods known to the skilled artisan, including the force generator described in U.S. Pat. No. 5,800,849, as well as other hydraulic, pneumatic, manual or power-assisted hydraulic force generators. It is noted that, when utilizing device **700**, **700'**, **700"** or **700'"**, the tip portion of these devices may act as a distractor to distract the disc space, although a distractor may also be used depending on the circumstances and preference of the surgeon.

[0131] As implant **40** enters cavity **883** (cavity **883** being seen in **FIG. 36**) defined by movable members **880** in their closed configuration, movable members **880** begin to move radially, or otherwise flex or bend radially, as seen in **FIG. 41**. Radial movement of movable members **880** allows the movable members to contact the surrounding annular tissue and press or otherwise push the tissue such that the annular defect, or other opening such as aperture **18**, is dilated. This allows implant **40** to exit distal end **812** of delivery device **800** and enter intervertebral disc space **20** as seen in **FIGS. 41-43**, wherein movable members **880** are seen in their open configuration.

[0132] As mentioned above, implants described herein having arms of differential length can facilitate implantation and proper positioning of the implants in the intervertebral disc space. For example, such an implant having an off-center closure may prevent possible excessive rolling of the implant during insertion so that the implant will be positioned such that the length of the implant extends substantially parallel to the coronal plane of a patient's body.

[0133] It is noted here that distal end **809** of plunger **806** may retain movable members **880** in their open configuration as end **42** of implant **40** approaches distal end **812** of delivery device **800** prior to completely exiting the device. After the plunger is translated a sufficient amount distally to allow implant **40** to exit the device, if necessary, the plunger is retracted, or translated in a proximal direction to ensure the deforming members are in their closed configuration as seen in **FIG. 44**. Delivery device **800** is then removed. As seen in **FIG. 44**, implant **40** is properly positioned in intervertebral disc space **20**.

[0134] Referring now to **FIGS. 45-48**, placement of the spinal implant delivery devices having tip portions **710**, **710'**, **710"** and **710'"**, respectively, in an intervertebral disc cavity **20**, is shown. As can be seen in the figures, the distal ends of the tip portions preferably extend slightly, e.g., about 1 mm to about 10 mm, past the inner face, or wall, I of annulus fibrosus **19**. **FIG. 49** is a view along line **49-49** of **FIG. 45** showing placement of tip portion **710**.

[0135] The preferred delivery instrument, or device, and methods described herein are compatible with Medtronic Sofamor Danek's MetRX™ microdiscectomy system and surgical procedures.

[0136] While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected. In addition, all references cited herein are indicative of the level of skill in the art and are hereby incorporated by reference in their entirety.

1-32. (canceled)

33. A spinal disc implant delivery device tip, comprising:

(a) a base member having a proximal end, a distal end and a lumen extending longitudinally therethrough, wherein said lumen has a diameter sized to receive a nucleus pulposus implant; and

(b) a plurality of movable members, said movable members having a proximal end and a distal end, said proximal end of said movable members abutting said distal end of said base member, said movable members having a closed configuration defining a cavity in communication with said lumen of said base member, wherein said cavity has a diameter smaller than the diameter of said lumen, and wherein said movable members are sized and configured for passage into an aperture in an annulus fibrosus when said movable members are in their closed configuration, said movable members further being openable to an open configuration wherein the distal ends of said movable members define a passageway having a diameter at least as large as the diameter of said lumen to allow passage of a nucleus pulposus implant therethrough.

34-35. (canceled)

36. A spinal disc implant delivery device, comprising:

(a) a base member having a proximal end, a distal end and a lumen extending longitudinally therethrough, wherein said lumen has a diameter sized to receive a nucleus pulposus implant;

(b) a plurality of movable members, said movable members having a proximal end and a distal end, said proximal end of said movable members abutting said distal end of said base member, said movable members having a closed configuration defining a cavity in communication with said lumen of said base member, wherein said cavity has a diameter smaller than the diameter of said lumen, and wherein said movable members are sized and configured for passage through an aperture in an annulus fibrosus when said movable members are in their closed configuration, said mov-

able members further being openable to an open configuration wherein the distal ends of said movable members define a passageway having a diameter at least as large as the diameter of said lumen to allow Passage of a nucleus pulposus implant therethrough; and

(c) an elongated housing member having a proximal end, a distal end and a lumen extending longitudinally therethrough, said proximal end of said base member matingly engaged to said distal end of said elongated housing member.

37-38. (canceled)

39. The device of claim 36, said device further comprising a plunger member, said plunger member disposed in said lumen of said elongated housing member.

40. A spinal disc implant delivery device, comprising:

(a) an elongated housing member having a proximal end, a distal end and a lumen extending longitudinally therethrough, wherein said lumen has a diameter sized to receive a nucleus pulposus implant;

(b) a tip member, said tip member having a top wall, a bottom wall, a first side wall, a second side wall, a proximal end, and a distal end, said walls defining a lumen extending longitudinally therethrough, wherein said lumen has a diameter sized to receive a nucleus pulposus implant, said proximal end of said tip member connected to said distal end of said elongated housing member, said tip member sized and configured for delivery of a spinal disc implant through an aperture in an annulus fibrosus, said lumen of said tip member in communication with said lumen of said elongated housing member.

41. The device of claim 40, said device further comprising a plunger member, said plunger member disposed in said lumen of said elongated housing member.

42. The device of claim 40, wherein said top wall and said bottom wall both include an opening therethrough that extends from said proximal end of said tip member to said distal end of said tip member.

43. The device of claim 42, wherein at least one of said top wall and said bottom wall has a surface that includes a surface roughening.

44. The device of claim 43, wherein said surface roughening comprises teeth, ridges, indentations, or projections.

45. The device of claim 42, wherein one of said side walls has a length greater than the other of said side walls.

46. The device of claim 40, wherein at least one of said top wall and said bottom wall has a surface that includes a surface roughening.

47. The device of claim 40, wherein one of said side walls has a length greater than the other of said side walls.

48. The device of claim 40, wherein said teeth, ridges, indentations, or projections are directional.

49. The device of claim 40 wherein said tip member has a height that is greater than the height of a disc space.

50. A spinal disc implant delivery device, comprising:

(a) an elongated member having a proximal end, a distal end, and a lumen extending longitudinally therethrough, wherein said lumen has a diameter sized to receive a nucleus pulposus implant; and

(b) a plurality of opening members positioned at the distal end of said elongated member, each of said opening members having a proximal end and a distal end, each of said proximal ends of said opening members abutting said distal end of said elongated member, at least one of said opening members being a movable member, said opening members having a closed configuration defining a cavity in communication with said lumen of said elongated member, wherein said cavity has a proximal end and a distal end, wherein the distal end of said cavity has a diameter smaller than the diameter of said lumen, wherein said opening members are sized and configured such that their distal ends may be inserted in an aperture in an annulus fibrosis when said opening members are in their closed configuration, said opening members further being openable to an open configuration by moving at least one movable member to an open configuration, wherein the distal ends of said opening members define a passageway having a diameter at least as large as the diameter of said lumen when said opening members are in their open configuration to allow passage of a nucleus pulposus implant therethrough;

51. The device of claim 50 wherein said plurality of opening members includes at least two movable members.

52. The device of claim 51 wherein said plurality of opening members includes at least four movable members.

53. The device of claim 50 wherein at least some of said opening members are rigid.

54. The device of claim 50 wherein at least some of said opening members are flexible.

55. The device of claim 50 wherein said elongated member has a cross sectional shape selected from the group consisting of elliptical, circular, rectangular, hexagonal, and other multi-sided shapes, and combinations thereof.

56. The device of claim 50 and further including a component to facilitate extrusion of an implant from the device by pneumatic, hydraulic, or mechanical force.

57. The device of claim 56 wherein said component to facilitate extrusion of an implant comprises a plunger effective for contacting an implant to extrude the implant from the device.

58. The device of claim 57 wherein said plunger is a pushing or impacting plunger, or a syringe plunger, or a caulk gun plunger, or a screw-driven plunger.

59. The device of claim 50 wherein said movable members define a tip having an outer diameter of between 2 mm and 10 mm when said movable members are in their closed configuration.

60. The device of claim 50 wherein said movable members are openable to their open configuration by passage of a nucleus pulposus implant therethrough.

61. The device of claim 50 wherein said elongated member is made of at least one material selected from the group consisting of stainless steel, titanium, stainless steel alloys, titanium alloys, polyethylene, polypropylene, polyetheretherketone and polyacetal.

62. The device of claim 50 wherein said movable members are made of at least one material selected from the group consisting of stainless steel, titanium, stainless steel alloys, titanium alloys, polyethylene, polypropylene, polyetheretherketone and polyacetal.

63. The device of claim 50 wherein said movable members flex, bend, or pivot.

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