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(54) **ANNULOTOMY CLOSURE DEVICE AND RELATED METHODS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 713 days.

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Related U.S. Application Data

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(51) **Int. Cl.**

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A61B 17/70	(2006.01)
A61F 2/44	(2006.01)

(52) **U.S. Cl.** **606/213**; 623/17.12; 623/17.16

(58) **Field of Classification Search** 606/213, 606/61, 74, 246, 247, 248, 249; 623/17.12, 623/17.15, 17.16; 128/898

See application file for complete search history.

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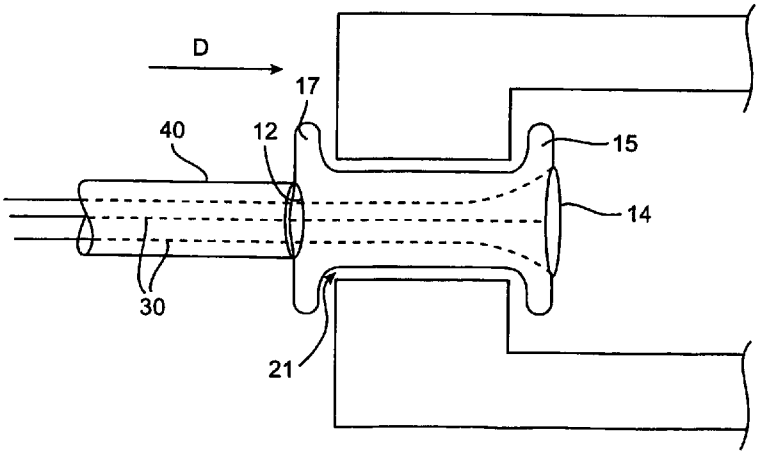
(57) **ABSTRACT**

A system for sealing a hole in a body, comprising a generally cylindrical mesh formed from a plurality of helical strands which is inserted into the hole, with at least one end of the cylindrical mesh being moved least partially through an interior portion of the cylindrical shaped mesh such that the mesh expands radially outwards against sides of the hole.

49 Claims, 13 Drawing Sheets



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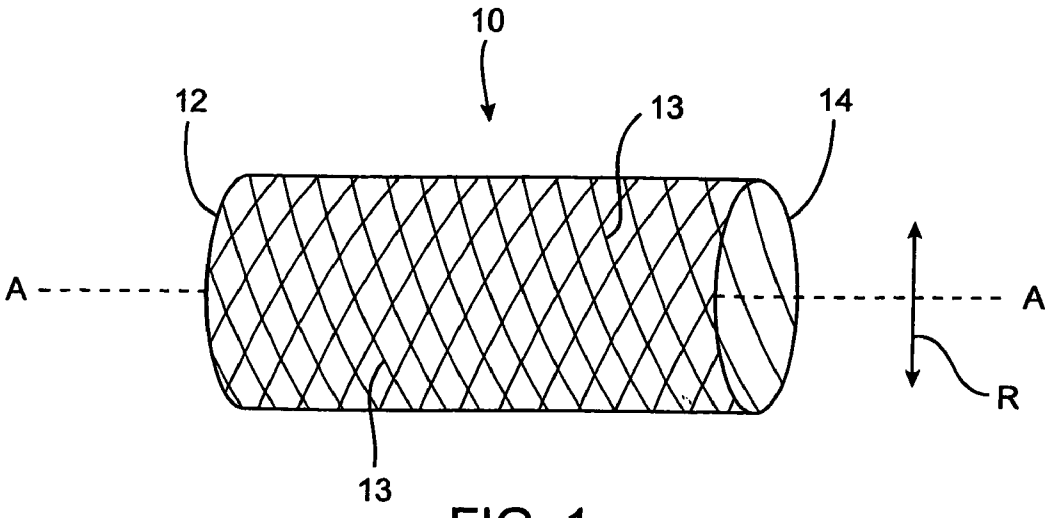

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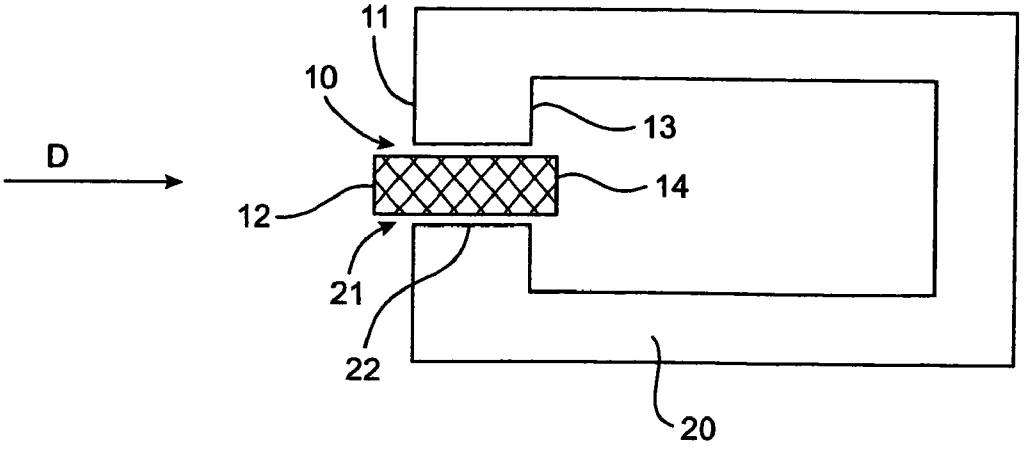
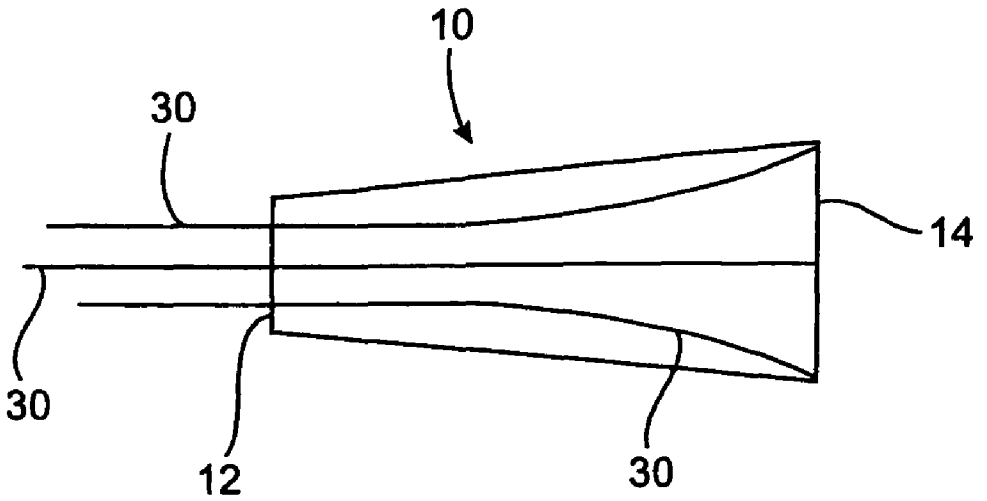


FIG. 2



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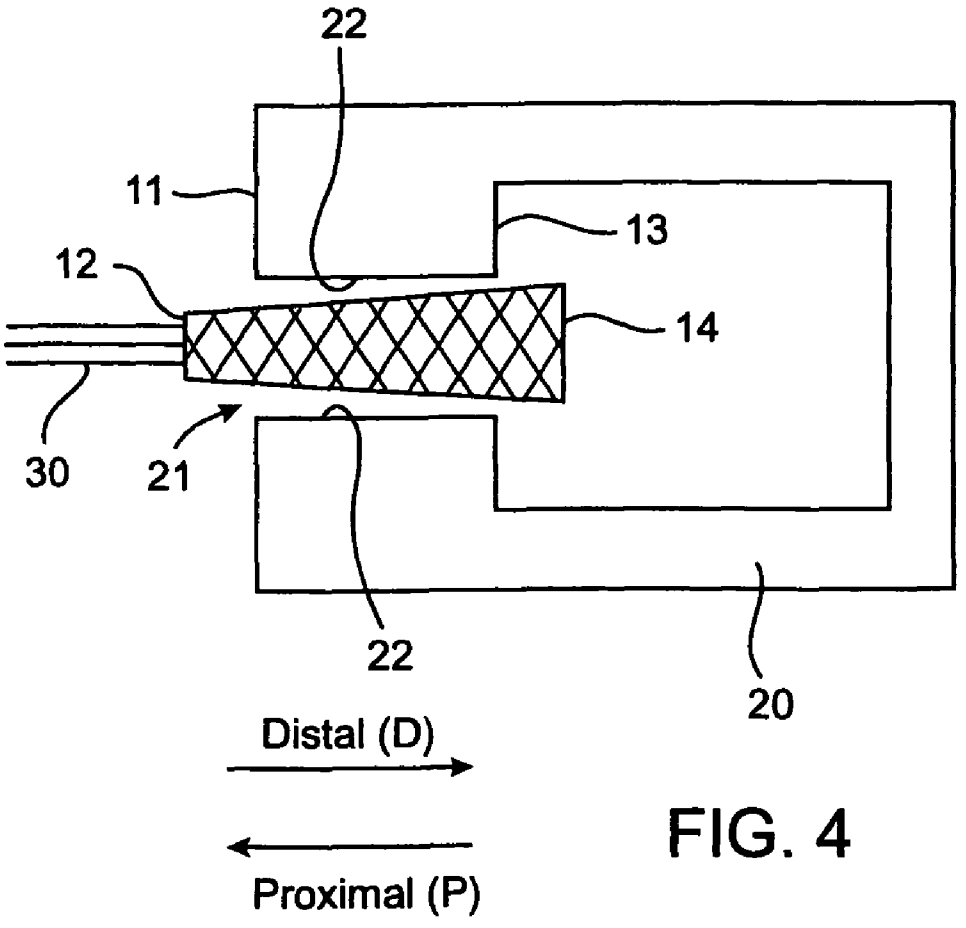

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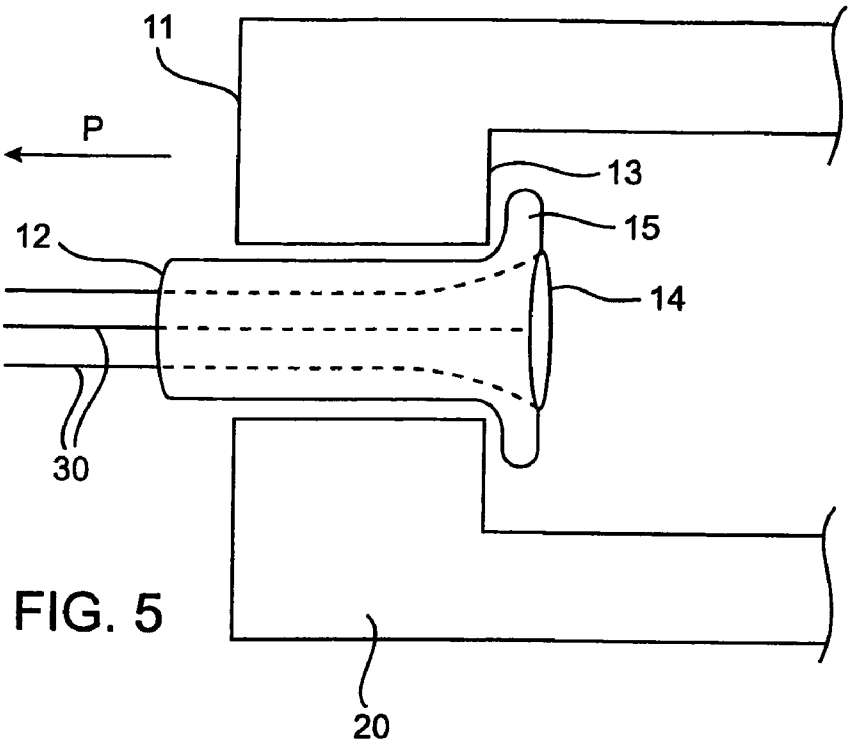

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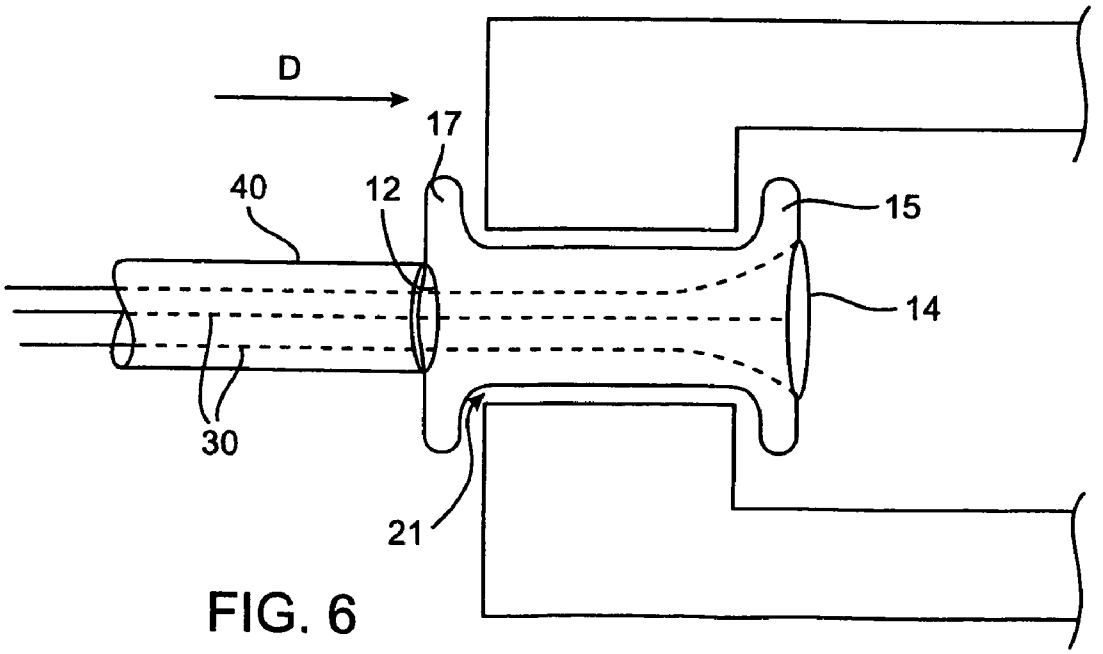

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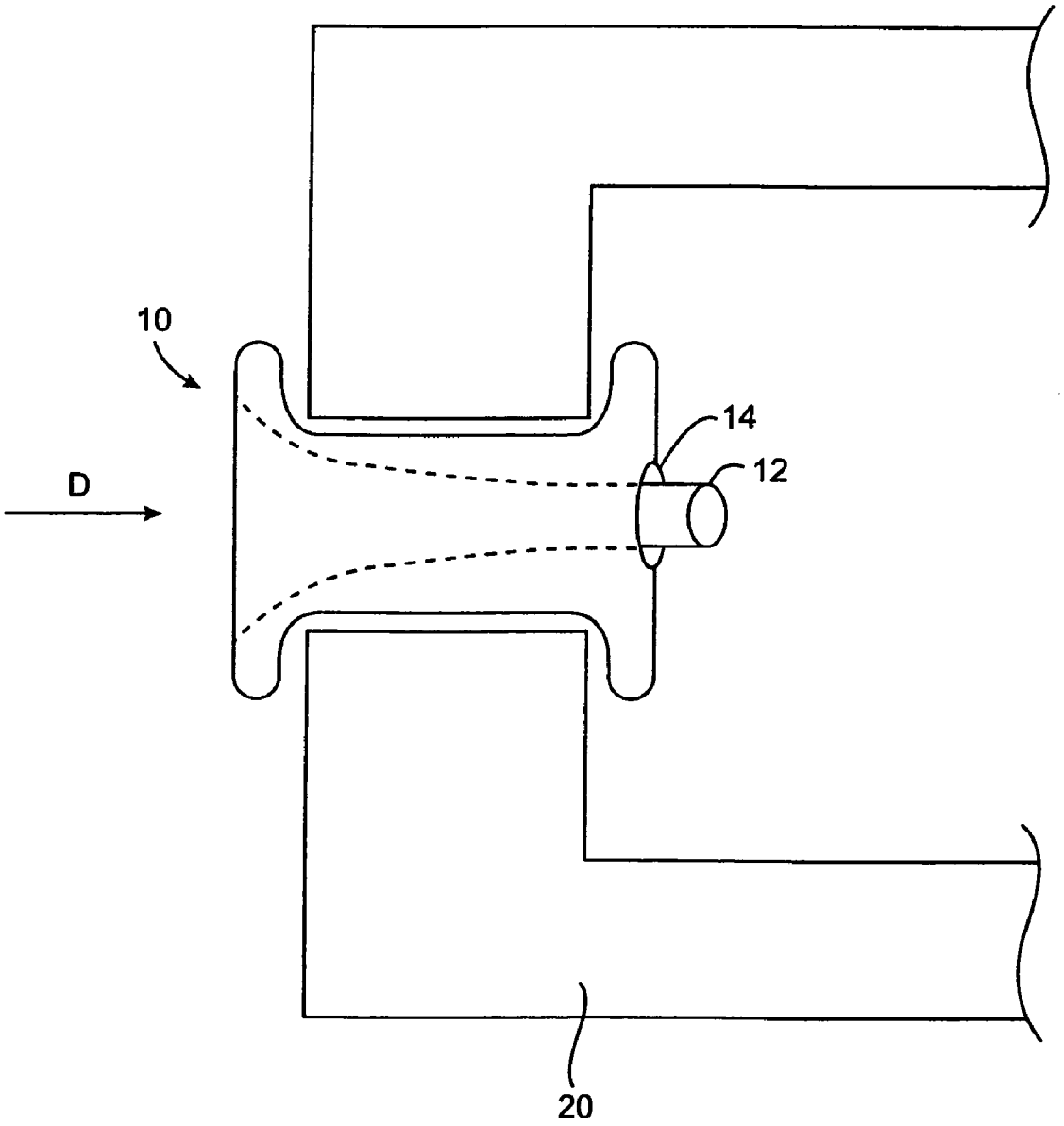
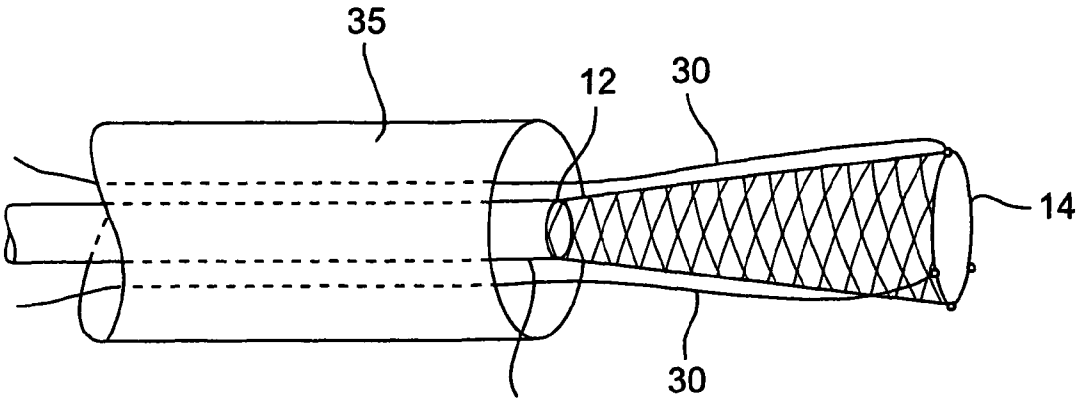


FIG. 7



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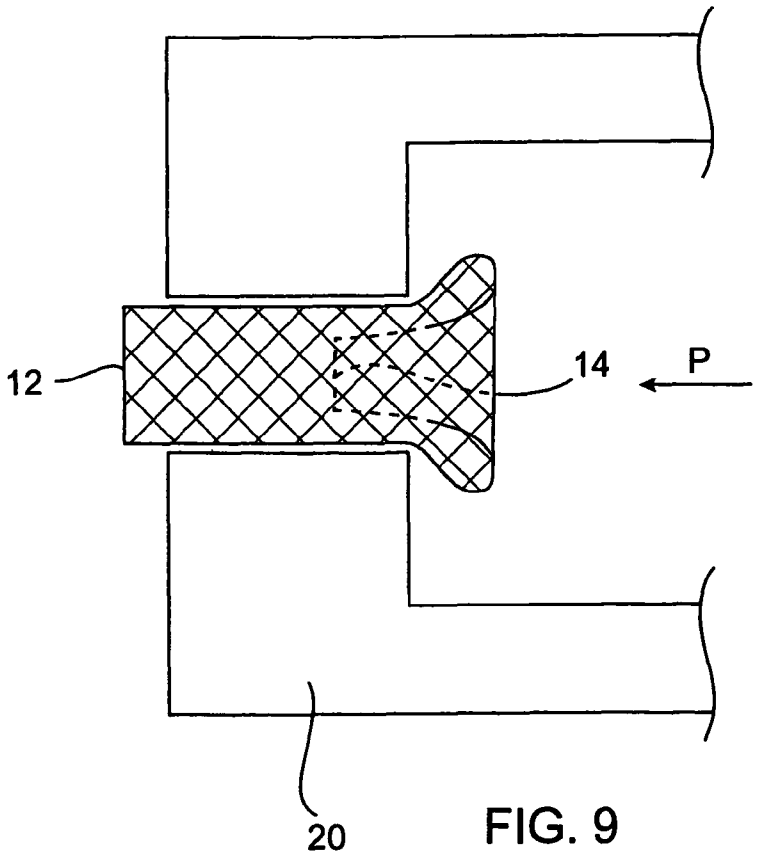


FIG. 9

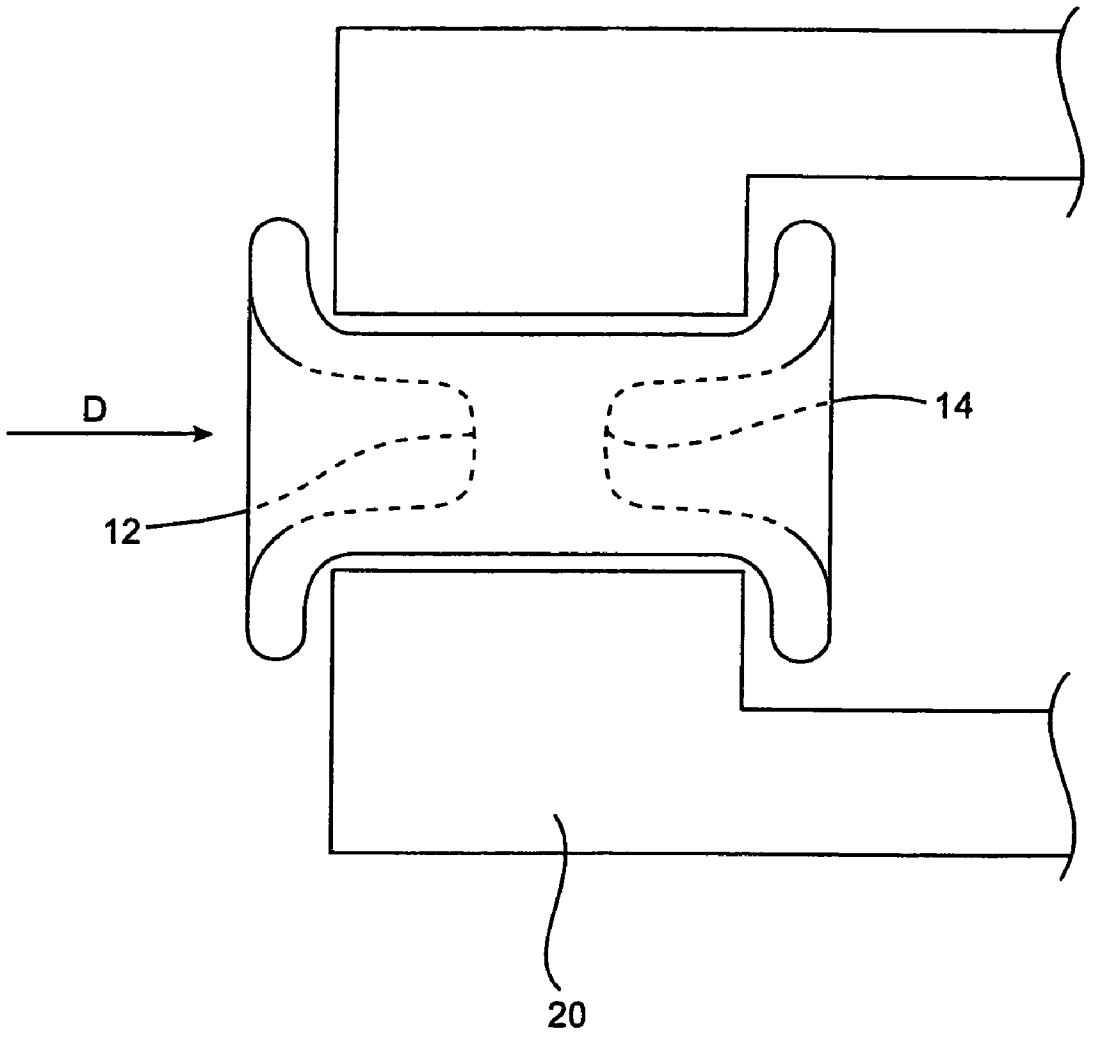


FIG. 10

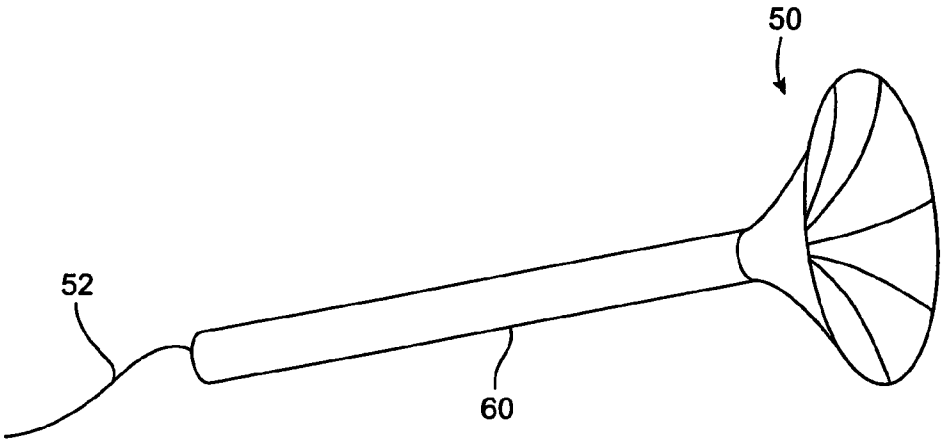
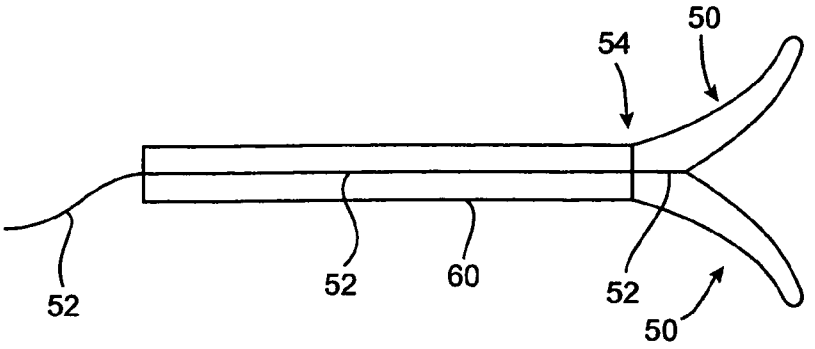


FIG. 11



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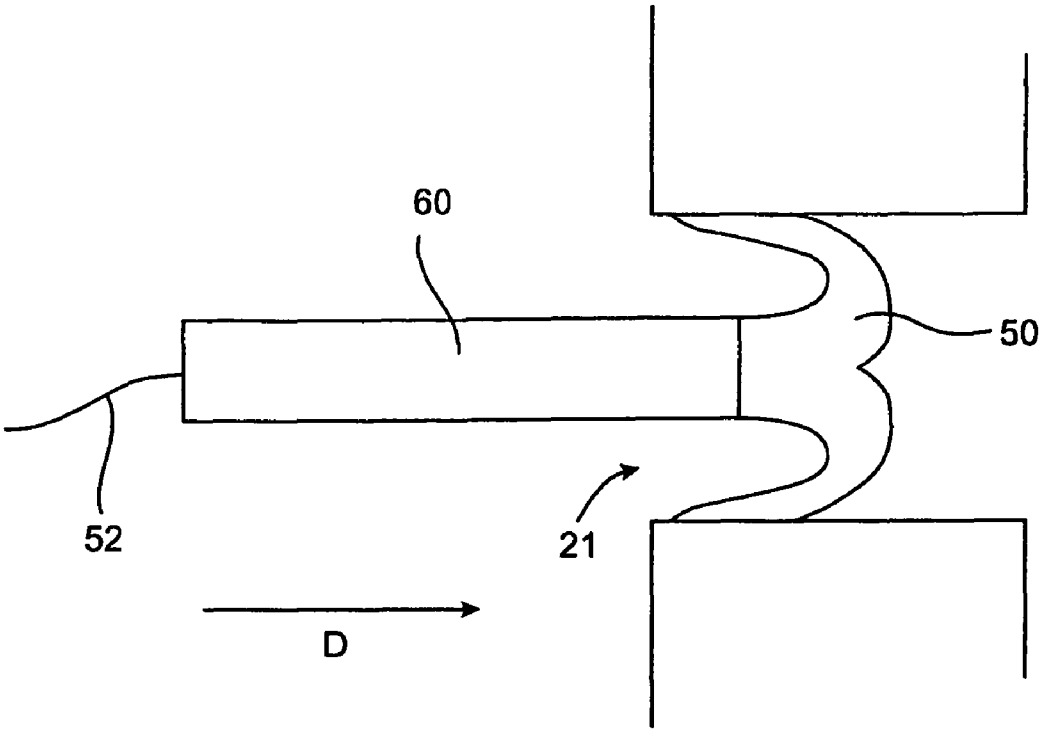


FIG. 12B

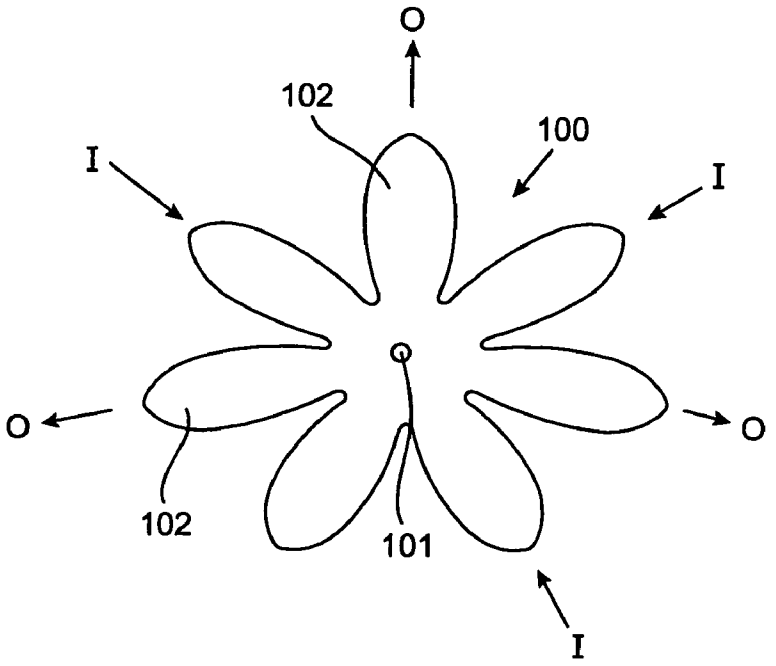
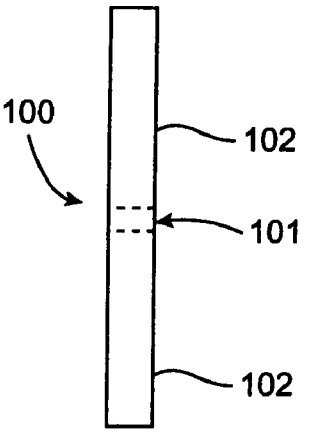


FIG. 13A



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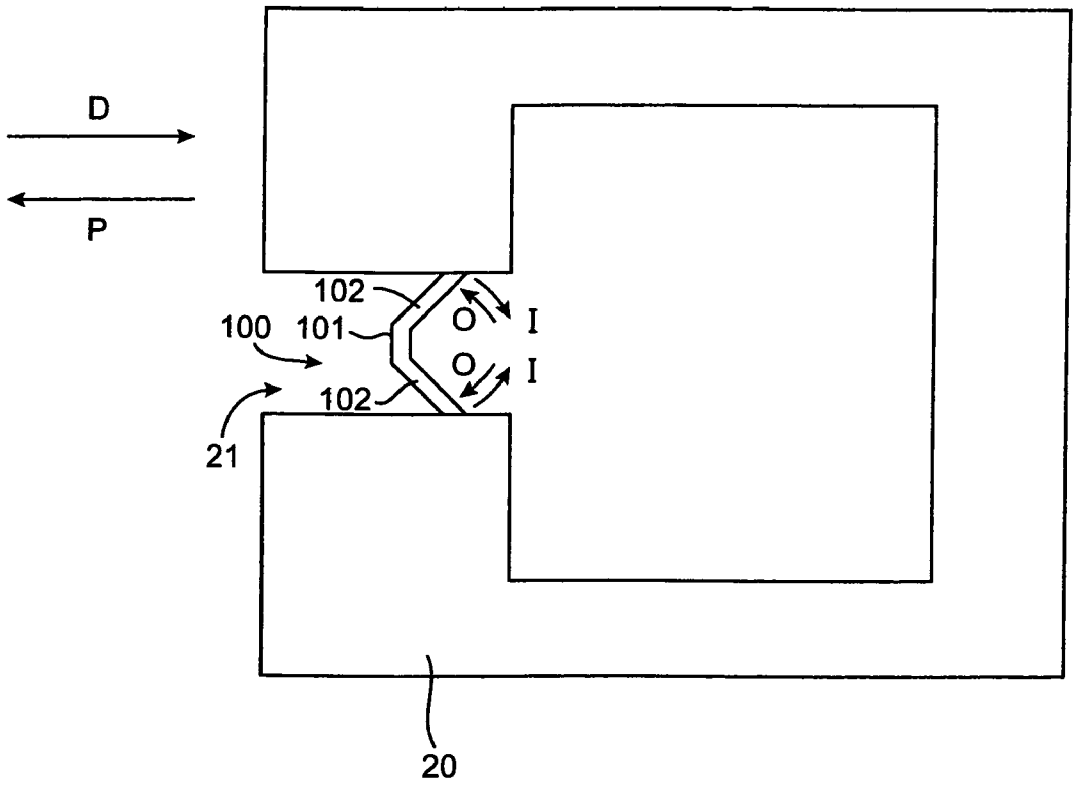

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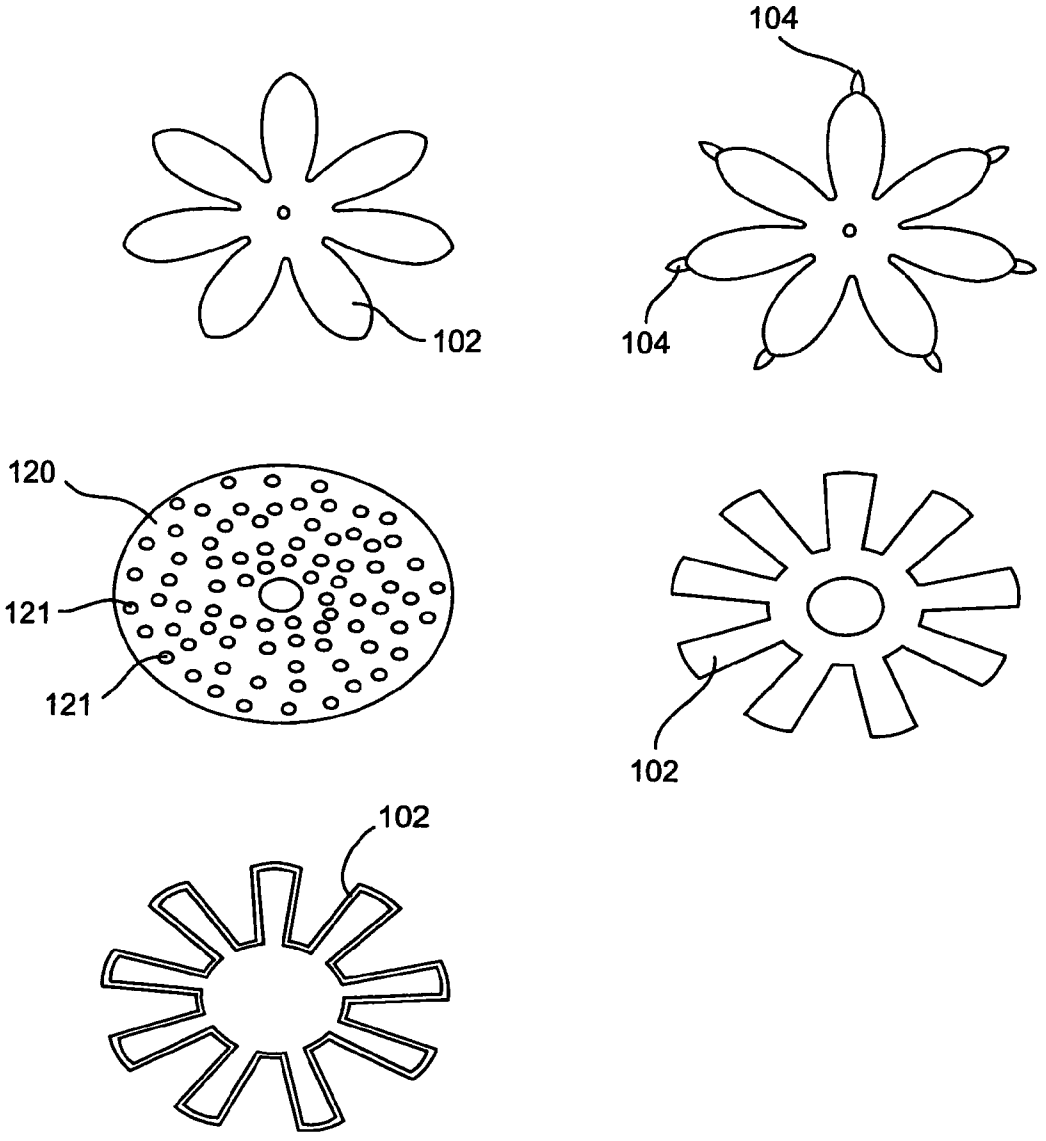
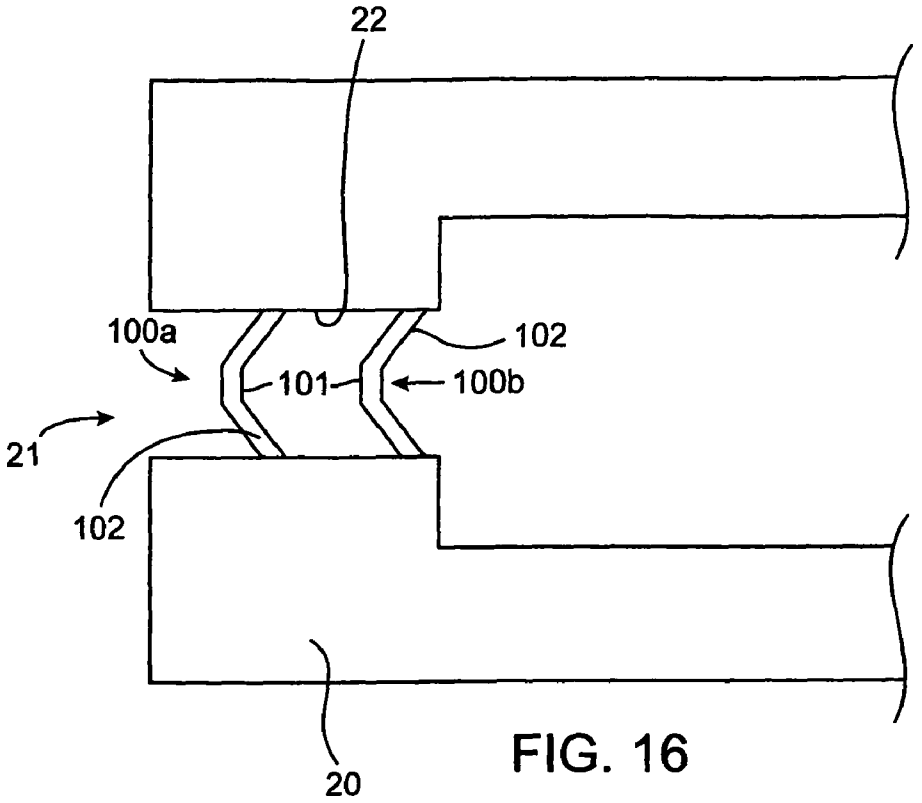


FIG. 15



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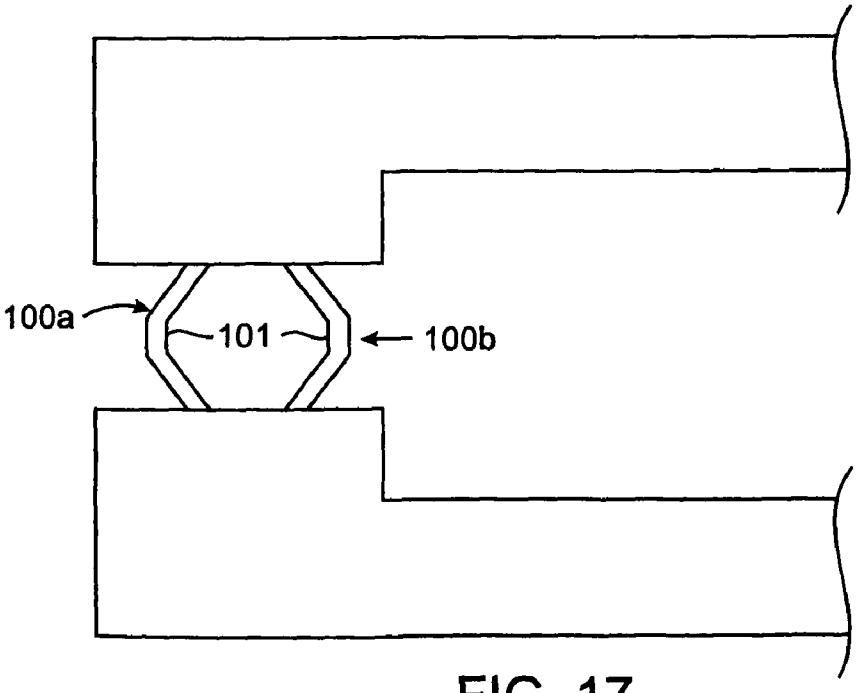

FIG. 17

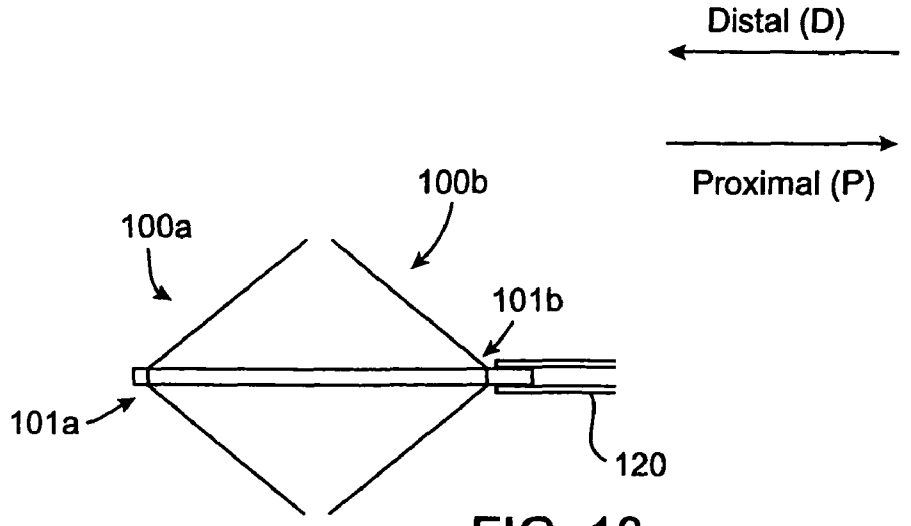

FIG. 18

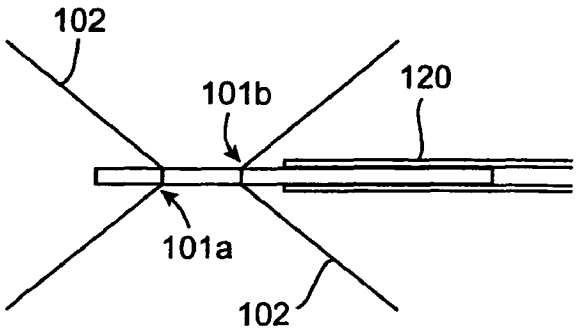

FIG. 19

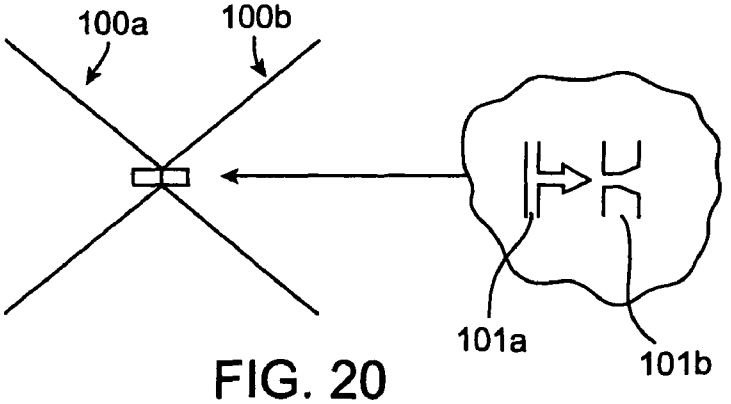

FIG. 20

ANNULOTOMY CLOSURE DEVICE AND RELATED METHODS

CROSS REFERENCES TO RELATED APPLICATIONS

The present application is a divisional of commonly owned and U.S. patent application Ser. No. 09/663,250 filed Sep. 15, 2000, now U.S. Pat. No. 6,964,674 the complete disclosure of which is hereby incorporated herein by reference in its entirety for all purposes. Additionally, the present application claims benefit under 35 U.S.C. §119(e) from U.S. Provisional Application Ser. No. 60/154,969, filed on Sep. 20, 1999, the entire contents of which are hereby expressly incorporated by reference into this disclosure as if set forth fully herein.

BACKGROUND OF THE INVENTION

I. Field of the Invention

The present invention relates to systems for sealing holes in body parts and to sealing surgically formed holes in a bony structure in general and in particular to systems for providing closure of a surgical access hole in an intervertebral disc following an annulotomy.

II. Description of the Related Art

Each intervertebral disc has a firm outer layer, called the annulus fibrosus, and a gelatinous interior called the nucleus pulposus. The annulus fibrosus acts as a semi-rigid elastic pressure vessel to contain the nucleus pulposus, therefore creating a compliant interface between the relatively rigid vertebrae above and below each disc. Adjacent to each disc, a pair of nerve roots pass from the spinal canal through apertures called intervertebral foramen on each side of the spine. Due to the location of the nerve roots, they are vulnerable to pressure from a herniated disc. In certain instances, the herniated section of the annulus fibrosus may become thinner through the transverse plane of the disc.

When a partial intervertebral discectomy is performed, the offending portion of the herniated disc is excised. In this procedure, the surgeon must first make an appropriate incision through the skin and other tissue layers, and then typically create an access hole into the herniated annulus (an annulotomy) to treat the offending tissue. Such access holes are created with a variety of surgical instruments including scalpels, probes, trephines, etc., and the access hole may range in size from 3 to 6 mm in diameter. Furthermore, as instruments are passed through the circular hole, the hole may become enlarged or elongated in nature upon completion of the procedure. Upon entry to the interior annular space, the offending tissue is then manipulated and/or removed by the surgeon. In current practice, the surgeon closes the outer wounds created by the procedure, but leaves the access hole open. Due to the semi-rigid nature of the annular tissue, closure by means of traditional tissue approximation techniques, such as suturing, is nearly impossible. Closure is further complicated by the proximity of nerves and the depth of the access hole below the surface of the skin. As a complication of disc excision surgery, such annular defects can represent a potential liability with respect to subsequent recurrent disc herniations. This is due to the fact that the annular defect between the interior space of the annulus and the area adjacent to the annulotomy allows for possible future passage of nucleus pulposus tissue therethrough. During the course of normal movement by the patient during the post operative healing phase, (which may last up to several weeks), relatively high fluidic pressures can be generated within the annular space. These high pressures can cause the nucleus pulposus to be extruded through the open hole and impinge upon nearby nerves, thus causing a reoccurrence of the original symptoms that the surgeon intended to treat.

SUMMARY OF THE INVENTION

The present invention provides methods and apparatus for the closure of holes, including surgical access holes formed in a rigid or semi-rigid body, and is particularly useful in closing a surgical access hole in an intervertebral disc. As such, the present invention provides systems of annulotomy closure which reduce the risks of reherniation.

In a first aspect of the invention, a system comprising a generally cylindrical-shaped mesh is used to seal a hole which may be a surgical access hole. The mesh itself may preferably comprise a braid of separate strands with each strand following a helical path around a central longitudinal axis such that the mesh comprises a flexible tube of interwoven springs. In various optional aspects, at least one of the proximal (i.e.: outer surface) and distal (i.e.: deep) ends of the cylindrical-shaped mesh may optionally be covered by an end-cap which may be made of the mesh material.

In this first aspect of the invention, the mesh cylinder may first be inserted into the hole in the annulus and positioned such that both the proximal and distal ends of the mesh extend somewhat out of the respective proximal and distal ends of the hole. Thereafter, the proximal end of the mesh can be pushed longitudinally in a distal direction through the "interior" of the mesh (i.e.: through the central tube defined by the cylindrically-shaped mesh body) to a distance such that the proximal end may pass fully through the interior of the mesh, and extend in a distal direction at least partially past the distal end of the mesh. This causes the mesh cylinder to become folded over upon itself, with one end of the mesh being folded into the center of the mesh.

In further aspects, the distal end of the cylindrical-shaped mesh may be pulled in a proximal direction such that a region of the mesh adjacent the distal end expands radially outwards, bulging around the inner (distal) perimeter of the distal end of the hole. Furthermore, the proximal end of the cylindrical mesh can be pushed in a distal direction such that a portion of the mesh adjacent the proximal end of the hole expands radially outwards, bulging around the outer (proximal) perimeter of the hole.

The present invention also provides a method of sealing a hole in a body part, comprising introducing a generally cylindrical shaped mesh into the hole and then moving at least one end of the cylindrical shaped mesh at least partially through an interior portion of the cylindrical shaped mesh such that the mesh expands radially outwards against sides of the hole.

The pushing of the proximal end in a distal direction and/or the pulling of the distal end in proximal direction will preferably tend to cause the cylindrical shaped mesh to expand radially outwards, thereby firmly anchoring the mesh against the walls of the hole in the annulus.

In further preferred aspects, the proximal and distal ends of the cylindrical mesh can be formed to be of a fixed diameter such as by the attachment or formation of a non-expandable ring thereon.

A plurality of suture/tethers may optionally be attached to the distal end of the mesh to pull it in a proximal direction. Tubular inserters for positioning the cylindrical mesh within the bore of the hole may also be provided.

In various aspects, the diameter of one end of the mesh is constructed to be smaller than that of the other end of the mesh such that a first end can easily be pulled through a

second end of the mesh. In specific preferred aspects, the diameter of the proximal end will be smaller than that of the distal end.

In an alternate method of employing the present invention, each of the proximal and distal ends of the cylindrical mesh may be pulled partially into the center of the cylindrical mesh (ie: pulled partially through the interior tube defined by the mesh body) such that the proximal end is moved distally and the distal en if moved proximally, towards, or optionally passing through, one another.

In a second aspect of the invention, various systems for sealing a surgically cut hole in the disc are provided comprising a generally planar sheet-like material which is cut or formed into a circular pattern having a plurality of radially extending "flower petal"-type extensions. These petals are first bent radially inwards giving the structure a generally conical shape. The petals will then tend to flex radially outwards when released after the device has been place into the hole in the annulus, thereby sealing the hole. Specifically, the resultant conical structure of the second aspect of the invention is inserted longitudinally into the hole in the annulus and is then released such that the petals will tend to flex radially outwards, thereby anchoring the structure in position in the hole. In this aspect of the invention, the spaces cut between successive radially extending petals may be adapted to permit some fluid movement therethrough. In various designs of this aspect of the invention, a plurality of such sheet-like "flower petal" structures are bent into a conical shape and are inserted in succession into the hole.

Advantages of both aspects of the present invention include its encouragement of rapid healing by providing a lattice structure to enhance tissue growth. Moreover, the present annulotomy closure systems are also able to accommodate the various sizes and geometries of annular holes that may be encountered by the surgeon. Furthermore, the present annulotomy closure systems all provide compensation for normal movement during patient healing since the system itself remains transversely flexible but is positionally stable along its longitudinal axis. A further advantage of the present system is that should any portion of the mesh remain on the outside of the hole on the annulus, this would be atraumatic to adjacent nerves in close proximity to the device due to the soft and flexible nature of the mesh material.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a cylindrical shaped mesh.

FIG. **2** is a sectional side elevation view of the cylindrical mesh of FIG. **1** positioned in a hole in the annulus of an intervertebral disc.

FIG. **3** is a sectional side elevation view of a tubular shaped mesh.

FIG. **4** is a sectional side elevation view of the mesh of FIG. **3** received through a hole in an intervertebral disc.

FIG. **5** is the system of FIG. **4** after the distal end of the mesh has been pulled in a proximal direction, causing a portion of the mesh to expand around the inner surface of the hole.

FIG. **6** shows the system of FIG. **4** after the proximal end of the mesh has been pushed in a distal direction, causing a portion of the mesh to expand around the outer surface of the hole.

FIG. **7** shows the system of FIG. **6** after the proximal end of the mesh has been pushed distally through the distal end of the mesh.

FIG. **8** is a perspective view of a system for delivering the tubular mesh illustrated in FIGS. **3** to **7**.

FIG. **9** is a sectional side elevation view of the mesh of FIG. **1** in a first position.

FIG. **10** is a sectional side elevation view of the mesh of FIG. **1** in a second position.

FIG. **11** is a perspective view of an alternate aspect of the first embodiment of the present invention.

FIG. **12**A is a sectional side elevation view of the system of FIG. **11** positioned in the annular hole.

FIG. **12**B is a side elevation view corresponding to FIG. **12**A, but with the system distally advanced into the hole.

FIG. **13**A is a front elevation view of a second aspect of the present invention.

FIG. **13**B is a side elevation view of the device of FIG. **13**A.

FIG. **14** is a side elevation view of the system of FIGS. **13**A and **13**B deformed into a conical shape and inserted into a surgical access hole in an intervertebral disc.

FIG. **15** is a front view of different designs for the second aspect of the present invention shown in FIGS. **13**A and **13**B.

FIG. **16** is a side elevation view of a plurality of devices as illustrated in FIG. **13**A, **13**B or **15** deformed into conical shapes and inserted into a surgical access hole in an intervertebral disc.

FIG. **17** corresponds to FIG. **16** but illustrates the apexes of the conical shapes pointing in opposite directions.

FIG. **18** is a side elevation view of a pair of systems as illustrated in FIG. **13**A, **13**B or **15** for insertion into a surgical access hole in oppositely facing directions.

FIG. **19** shows a side view of the system arrangement of FIG. **18**, but with the conical shaped structures deformed into an inverted position.

FIG. **20** shows a side view and an enlarged close-up view of the conical shaped structures of FIGS. **18** and **19** interlocked together.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides methods and apparatus for sealing holes in various bony structures. In a preferred aspect, the present invention provides methods and apparatus for sealing a surgical hole drilled in a patient's annulus. As such, the present invention is ideally suited to seal a hole drilled in an intervertebral disc such that nucleus pulposus on the inside of the disc is compressed during normal movement. The present system is not limited only to sealing holes which have been drilled in an annulus, but may also be used to seal naturally occurring holes as well. Moreover, the present invention is not limited to sealing holes in the annulus alone but may be used to seal any hole, thereby inhibiting the passage of soft tissue therethrough.

FIG. **1** shows a generally cylindrical tubular mesh which is comprised of a multiplicity of monofilament or multifilliar strands **13** of suture-type material, each following a helical path about central longitudinal axis A. Mesh **10** has a proximal end **12** and a distal end **14**. An advantageous property of mesh **10** is that as proximal end **12** and distal end **14** are moved closer together with respect to one another, mesh **10** will tend to expand radially outwards, widening in its diameter D.

In a preferred design, the mesh diameter D is approximately 1 to 8, millimeters, and more preferably about 3 millimeters when mesh **10** is in its relaxed state, (i.e.: when ends **12** and **14** are not being pushed together). When ends **12** and **14** are pushed together, however, diameter D of mesh **10** may reach 9 millimeters. In preferred designs, strands **13** may each be made of 0.15 millimeter polypropylene sutures. Other

materials having suitable dimensions, bioabsorption, strength, spring rate or radiopacity may also be used.

In an optional aspect, proximal end **12** may be sealed, for example with a mesh closure positioned thereover. In another optional aspect of the invention, as will be explained, ends **12** and **14** may be formed to be non-expandable such that their diameters do not change as ends **12** and **14** of mesh **10** are pushed together relative to one another. For example, a solid ring may be formed at, or attached to, one or both of ends **12** and **14**.

FIG. **2** illustrates a preferred method of operating the present invention, as follows. Mesh **10** is inserted longitudinally in distal direction D into surgically cut hole **21** in disc **20** such that proximal end **12** and distal end **14** extend out of hole **21** past outer surface **11** and inner surface **13** of hole **21** in disc **20** as defined by walls **22** as shown.

As is shown in FIG. **3**, mesh **10** may optionally be fitted with a plurality of sutures/tethers **30** which are tied to the distal end **14** of mesh **10** and extend through the central chamber of mesh **10** as shown.

As shown in FIG. **4**, mesh **10** is inserted in a distal direction D such that it is positioned in hole **21** with its distal end **14** extending past inner surface **13** of disc **20**, and with its proximal end **12** extending past outer surface **11** of disc **20**. The placement of distal end **14** at an appropriate distal depth such that a portion of mesh **10** extends in a proximal direction from outer surface **11** of hole **21** can be enhanced through various visualization techniques such as shaft depth markers or endoscopic, radiographic or ultrasound methods.

For clarity of illustration, to show both the side walls of hole **21** and mesh **10**, the following Figs. show a small clearance between the walls of the mesh and the walls of the hole when the mesh has been expanded into position, (for example, by pushing proximal end **12** and distal end **14** together, or through the central longitudinally extending chamber of the mesh). It is to be understood that such clearance would not exist as mesh **10** becomes anchored against walls **22** when positioned.

Following the step shown in FIG. **4**, suture tethers **30** are preferably pulled in proximal direction P while proximal end **12** is held in a fixed position relative to hole **21**, (as shown in FIG. **5**). When pulled by suture/tethers **30**, distal end **14** will tend to move in proximal direction P such that mesh **10** will expand radially in diameter in the region of the mesh pushing outwardly against the inner surface of hole **21**, and forming a bulge **15** at mesh distal end **14** against inner surface **13**.

Thereafter, as is shown in FIG. **6**, a rod **40**, (which can be used to hold proximal end **12** in position relative to hole **21** while pulling on suture tethers **30** as illustrated in FIG. **5**), can be used to push proximal end **12** in distal direction D such that the region of mesh **10** between proximal end **12** and outer surface **11** will tend to expand around the proximal end of hole **21**, forming a bulge **17** against outer surface **11**, as shown. In this aspect of the invention, proximal end **12** may optionally be formed to be non-expandable, for example by attachment to a fixed diameter ring therearound.

The effect of mesh **10** being deformed to form respective bulges **17** and **15** at the outer surface **11** and inner surface **13** of disc **20** will be to hold mesh **10** at a fixed longitudinal position relative to hole **21** (such that it doesn't move in either a proximal or distal direction).

Thereafter, as is shown in FIG. **7**, proximal end **12** may optionally be pushed longitudinally in distal direction D such that is passes through the center of the mesh such that it extends out through distal end **14**. In this aspect of the invention, proximal end **12** may be formed to be non-expandable and have a slightly larger diameter than that of distal end **14** such that distal end **12** can pass through distal end **14** and be snap-fit through the opening of proximal end **14**.

FIG. **8** is a perspective view of a system for delivering and positioning mesh **10** into hole **21** of the disc **20** as illustrated in FIGS. **1** to **7**. Rod **40** may be used to support proximal end **12** at a fixed position relative to hole **21** when suture/tethers **30** are used to pull distal end **14** in a proximal direction. In addition, rod **40** can be used to push proximal end **12** through distal end **14**, as was shown in FIG. **7**. Suture/tethers **30** which may preferably comprise three tethers anchored to distal end **14** at locations which are spaced radially 120° apart may be received over push rod **40** as shown. A tubular inserter **35** is then received thereover. Inserter **35** may be used for pushing mesh **10** against the proximal end of hole **21** as is shown in FIG. **6** so as to create bulge **17**. Suture tethers **30** may preferably be cut or removed after insertion.

In another aspect of the invention, as illustrated in FIGS. **9** and **10**, each of the proximal and distal ends of the cylindrical mesh may be pulled inwardly towards the longitudinal center of the cylindrical mesh such that the proximal end is moved distally and the distal end is moved proximally, as follows.

FIG. **9** shows a sectional elevation view of the mesh of FIG. **1** in a first position wherein distal end **14** has been pulled partially through the center of the cylindrical mesh **10** such that distal end **14** is received within the central body portion of mesh **10**. Thereafter, as shown in FIG. **10**, proximal end **12** is then pushed partially through the center of the cylindrical mesh **10** such that proximal end **12** is also received within the central body portion of mesh **10**.

In the aspect of the invention shown in FIGS. **9** and **10**, mesh **10** will especially tend to expand radially at outer surface **11** and inner surface **13** close to ends **12** and **14** as shown. Expansion of mesh **10** in these regions will cause formation of bulges immediately outside of the distal and proximal ends of hole **21** as shown. Such bulges will tend to anchor the mesh such that it does not move longitudinally in hole **21**. In the aspect of the invention shown in FIGS. **9** and **10**, both proximal end **12** and distal end **14** may optionally be covered by mesh or end caps since these ends need not pass through one another.

In this and the above discussed aspects of the invention, outward radial forces of the portions of the mesh which are curled within the main body of the mesh will preferably act against the outside walls of the outer tube creating frictional loads along the longitudinal axis that far exceed the unfolding tendency of the mesh.

A further advantage of the present invention is that it may be adapted to compensate for both thick or thin annular walls. For example, should the length of hole **21** be slightly longer than the length of mesh **10**, ends **12** and **14** will still be fully engaged within hole **21**. Another advantage of the present invention is that the exposed portions of the mesh projecting out of hole **21** (e.g.: bulges **15** and **17**) will be atraumatic, minimizing any potential irritation due to tissue contact due to the soft and flexible nature of the mesh.

An alternate aspect of the first embodiment of the present invention is shown in FIGS. **11** to **12**B, as follows. A mesh **50**, (similar in characteristics to mesh **10** as described above), is provided. As seen in the cross sectional view of FIG. **12**A, a suture/tether **52** runs from distal end **54** through the center of installation tube **60**. As mesh **50** is advanced distally into hole **21**, as shown in FIG. **12**B, it will form a "reversing funnel" shape with the outer edges of mesh **50** wrapping over the body of the mesh inserted therethrough.

FIGS. **13**A and **13**B show respective front and side views of a second design of the present invention in which device **100** comprises a generally planar sheet of material which is cut or

formed in a circular shape, having a plurality of radially extending "flower petal" extensions **102**. These devices allow pressure equalization through the venting of lower viscosity fluids but retain higher viscosity fluids and solids.

When inserted into a surgical access hole, petals **102** are first flexed radially inward in direction I. Accordingly, sheet **100** assumes a generally conical shape when inserted into hole **21** in intervertebral disc **20**, as is shown in FIG. **14**. After device **100** has been positioned in hole **21**, (for example with a rod), petals **102** are released. Accordingly, petals **102** will tend to "spring back", moving radially outwards in direction O such that petals **102** will press against the outer surfaces **22** of hole **21** thereby anchoring device **100** in position in hole **21**. As such, petals **102** act as cantilever leaf springs anchoring device **100** in position in hole **21**, thereby resisting outward (i.e. proximal) loading due to extruding nucleus pulposus.

As is shown in FIG. **15**, optional barbs **104** may also be provided at the distal ends of petals **102** to assist in anchoring petals **102** of device **100** against walls **22** of hole **21**. FIG. **15** shows a variety of alternate designs with differently shaped petals **102**. FIG. **15** also shows an optional design for a sheet **120** which does not have petals. Rather, such a sheet is preferably crimped into a conical shape such that it can be positioned in hole **21**. Thereafter sheet **102** will expand (ie: flatten itself) to seal hole **21** with holes **121** allowing for fluid movement similar to the movement permitted between adjacent petals **102** as shown in other aspects of the invention.

Device **100** may preferably by formed to accommodate hole **21** having an inner diameter ranging from one-half to three quarters of the disc diameter in its free and flattened state. Device **100** can be formed from wire or molded from plastic.

In preferred aspects, a plurality of devices **100** can be inserted into hole **21** in sequence as shown in FIG. **16**. Such an arrangement has the advantage of further restricting the movement of nucleus pulposus out of the center of disc **20**. FIG. **17** corresponds to FIG. **16** but with the apexes **101** of devices **100***a* and **100***b* pointing in opposite directions.

FIGS. **18**, **19** and **20** show successive steps in a method of inserting oppositely facing interlocking devices **100**. Referring to FIG. **18**, discs **100***a* and **100***b* are first introduced into hole **21** (not shown) in an orientation such that their apexes **101***a* and **101***b* are pointing in opposite directions. A positioning rod **120** is used to push devices **100***a* and **100***b* together such that devices **100***a* and **100***b* become inverted such that their apexes **101***a* and **101***b* will be pushed together. As is seen in FIG. **20**, apexes **101***a* and **101***b* can comprise interlocking features such that they can be assembled to interlock together thereby forming a solid structure which tends to reduce radial movement of the respective apexes.

Experimentally Developed Embodiments

The Applicants of the present invention have succeeded in constructing various experimental embodiments of the present invention, as follows. These experimental embodiments are meant to illustrate various exemplary systems in accordance with the present invention. The present invention is not limited to the experimental embodiments described herebelow. Rather, any suitable system for achieving the structures and methods of the present invention as claimed is considered within the scope of the present invention.

Mesh **10** of the present invention was experimentally constructed as a braided tube approximately 3 mm in diameter when in the relaxed state, and at least 9 mm in diameter when expanded. This tube was be braided from 24 individual strands of 0.15 mm polypropylene suture. Alternatively, however, various numbers of strands may employed in the braiding of the tube.

An experimental embodiment of mesh **10** was constructed from a 45 mm length of braid which is cut and then placed over a heat resistant mandrel that just fits inside of the braid. The mandrel may preferably be fabricated from a machineable ceramic. A 12 mm long stainless steel tube whose inside diameter just fits over the braid may be placed over the braid/mandrel assembly with approximately 1 mm of braid exposed over the mandrel. The braid/mandrel/tube assembly was then placed in a lathe chuck or other machine capable rotating the assembly about it's longitudinal axis in a controlled manner. The end of the braid was then radiantly heated to just past the melting point of the braid polymer. The braid end was reformed to create a semi -rigid ring with in inside diameter of approximately equal to the original inside diameter of the braid. By using this non-contact method of forming using radiant heat and the fluidic surface tension of the re-flowing polymer, a robust and smooth unitary ring was quickly formed. The whole assembly was then removed from the rotating machinery. The first mandrel was removed from the assembly and a second forming mandrel was inserted in it's place. The second forming mandrel was made of a machineable ceramic material, and one end of the mandrel being formed with a tapered bullet shaped tip. The bullet tip was placed even with the tapered tip at the end of the proximal end of the braid. The 12 mm long stainless steel tube was then placed over the braid/mandrel assembly with approximately 1 mm of braid exposed over the bullet tipped mandrel. The braid/mandrel/tube assembly was again placed in the rotating machinery and slowly rotated about it's longitudinal axis. The proximal end of the braid was then radiantly re-flowed to form a semi-rigid ring with an inside diameter of approximately one half to one quarter of the original braided diameter. The forming process described above can be accomplished in many different ways using a variety of equipment and techniques. Alternatively, rings of non native material may have instead been secondarily added to the braided tube. The braid was then removed from the forming tools. A long piece of suture was then transversely passed through at least one braid intersection located near the distal end of the device. The tag ends of the suture are then brought together to form a loop with the device near the approximate center of the suture. This loop forming procedure is repeated twice more to form a system of three equally spaced suture loops with a radial spacing of about 120° when viewed from the end. The braid/loop assembly was then placed at the distal end of a long rod or tube whose outside diameter will allow for the longitudinal urging of the proximal end of the device and still allow for diametral clearance of at least two wall thickness of the braid material. The loops of suture were placed along side the length of the urging rod and arranged in a manner to prevent tangling of the tag ends. A second long hollow tube with an outside diameter that allows for passage into the surgical defect and inside diameter that allows for a slight diametral compression of the braid/loop assembly, is passed over the braid/loop assembly until approximately 4 mm of braid is exposed. It is to be understood that appropriate handles, grips and controls may also be added to the installation tool to enhance placement of the device and ease of use.

While the present invention has been shown and described in terms of preferred embodiments thereof, it should be understood that this invention is not limited to any particular embodiment, and that changes and modifications may be made without departing from the true spirit and scope of the invention as defined in the appended claims.

What is claimed is:

1. A method for blocking a hole in a vertebral annulus, comprising:

introducing a blocking element situated on the end of an insertion rod through at least a portion of said hole such that a plurality of tethers attached to said blocking element extend proximally out of said hole along said insertion rod, said blocking element having a distal end and a proximal end, said insertion rod being disposed through an insertion tube and moveable relative to said insertion tube; and

moving said insertion rod and said insertion tube relative to each other to move at least one of said distal end and said proximal end in a direction towards the other end to radially expand at least a portion of said blocking element such that said expanded portion of said blocking element at least partially blocks said hole.

2. The method of claim 1, wherein said blocking element is generally cylindrical in shape.

3. The method of claim 1, wherein said blocking element is generally conical in shape.

4. The method of claim 1, wherein said blocking element is comprised of surgical mesh.

5. The method of claim 4, wherein said surgical mesh is comprised of one of braided monofilament strands and braided multifilliar strands of suture-type material.

6. The method of claim 5, wherein said suture-type material is a plastic.

7. The method of claim 1, wherein said proximal end is positioned exterior to said annulus and said radial expansion occurs outside said annulus to block said hole.

8. The method of claim 1, wherein said distal end is positioned within an interior annular space and said proximal end is positioned exterior to said annulus, and wherein said radial expansion occurs within said interior annular space and outside said annulus.

9. The method of claim 1, wherein said radial expansion occurs substantially within said hole.

10. The method of claim 1, wherein movement of said distal end towards said proximal end is further accomplished by pulling proximally on said plurality of tethers attached to said blocking element.

11. The method of claim 10, wherein said plurality of tethers are longer than said blocking element such that said tethers are pulled from a position proximal to said proximal end.

12. The method of claim 11, wherein said plurality of tethers are comprised of suture-type material.

13. The method of claim 12, wherein said plurality of tethers are spaced an equal distance apart radially.

14. The method of claim 13, wherein said plurality of tethers comprise three tethers spaced radially apart 120 degrees.

15. The method of claim 1, wherein said distal end is advanced beyond an inner surface of said annulus into an interior annular space and said radial expansion occurs within said interior annular space to block said hole.

16. A method for blocking a hole in a vertebral annulus, comprising:

introducing a blocking element situated on the end of an insertion rod and having distal and proximal ends through at least a portion of said hole, said insertion rod being disposed through an insertion tube and moveable relative to said insertion tube, wherein said distal end of said blocking element is advanced beyond an inner surface of said annulus into an interior annular space and a plurality of tethers attached to said blocking element extend proximally out of said hole along said insertion rod; and

moving said insertion rod and said insertion tube relative to each other to move said distal end toward said proximal end to radially expand at least a portion of said blocking element within said interior annular space to at least partially block said hole.

17. A method for blocking a hole within a vertebral annulus, comprising:

advancing a blocking element having a first end and second end through at least a portion of said hole and radially expanding at least a portion of said blocking element to at least partially block said hole, wherein said blocking element is advanced through at least a portion of said hole on an insertion rod and a plurality of tethers attached to said blocking element extend proximally out of said hole along said insertion rod, said insertion rod being disposed through an insertion tube and moveable relative to said insertion tube, said radial expansion occurring when at least one of said first end and said second end is moved toward the other end.

18. The method of claim 17, wherein said blocking element is generally cylindrical in shape.

19. The method of claim 17, wherein said blocking element is generally conical in shape.

20. The method of claim 17, wherein said blocking element is comprised of surgical mesh.

21. The method of claim 20, wherein said surgical mesh is comprised of one of braided monofilament strands and braided multifilliar strands of suture-type material.

22. The method of claim 21, wherein said suture-type material is a plastic.

23. The method of claim 17, wherein one of said first and second ends is advanced beyond an inner surface of said annulus into an interior annular space and said radial expansion occurs within said interior annular space to block said hole.

24. The method of claim 17, wherein one of said first and second ends is positioned exterior to said annulus and said radial expansion occurs outside said annulus to block said hole.

25. The method of claim 17, wherein said first end is positioned within an interior annular space and said second end is positioned exterior to said annulus, and wherein said radial expansion occurs within said interior annular space and outside said annulus.

26. The method of claim 17, wherein said radial expansion occurs substantially within said hole.

27. The device of claim 17, wherein movement of one of said first and second ends is accomplished by pulling proximally on said plurality of tethers attached to said blocking element.

28. The method of claim 27, wherein the end that moves is said distal end and said plurality of tethers are longer than said blocking element such that said plurality of tethers are pulled from a position proximal to said proximal end.

29. The method of claim 28, wherein said plurality of tethers are comprised of suture-type material.

30. The method of claim 29, wherein said plurality of tethers are spaced an equal distance apart radially.

31. The method of claim 30, wherein said plurality of tethers comprise three tethers spaced radially apart 120 degrees.

32. The method of claim 17, wherein said insertion rod and said insertion tube are moved relative to each other to move said at least one of said first end and said second end towards the other.

33. A method of blocking a hole in a vertebral annulus comprising:

advancing a blocking element having a distal end and a proximal end through said hole, said blocking element being positioned on an insertion rod; and

expanding at least a portion of said blocking element by shortening the distance between said distal end and said proximal end until said expanded portion at least substantially blocks said hole;

wherein said insertion rod is disposed through an insertion tube and moveable relative to said insertion tube to shorten the distance between said distal end and said proximal end and a plurality of tethers attached to said blocking element extend proximally out of said hole along said insertion rod.

34. The method of claim 33, wherein said blocking element is generally cylindrical in shape.

35. The method of claim 33, wherein said blocking element is generally conical in shape.

36. The method of claim 33, wherein said blocking element is comprised of surgical mesh.

37. The method of claim 36, wherein said surgical mesh is comprised of one of braided monofilament strands and braided multifilliar strands of suture-type material.

38. The method of claim 37, wherein said suture-type material is a plastic.

39. The method of claim 33, wherein said proximal end is positioned exterior to said annulus and said expansion occurs outside said annulus to block said hole.

40. The method of claim 33, wherein said distal end is positioned within an interior annular space and said proximal end is positioned exterior to said annulus, and wherein said expansion occurs within said interior annular space and outside said annulus.

41. The method of claim 33, wherein said expansion occurs substantially within said hole.

42. The method of claim 33, wherein shortening the distance between said distal end and said proximal end is further accomplished by pulling proximally on said plurality of tethers attached to said blocking element.

43. The method of claim 42, wherein said plurality of tethers are longer than said blocking element such that said tethers are pulled from a position proximal to said proximal end.

44. The method of claim 43, wherein said plurality of tethers are comprised of suture-type material.

45. The method of claim 44, wherein said plurality of tethers are spaced an equal distance apart radially.

46. The method of claim 45, wherein said plurality of tethers comprise three tethers spaced radially apart 120 degrees.

47. The method of claim 33, wherein said distal end is advanced beyond an inner surface of said annulus into an interior annular space and said expansion occurs within said interior annular space to block said hole.

48. A method of blocking a hole in a vertebral annulus comprising:

positioning in said hole a blocking element having a distal end and a proximal end, said blocking element being situated on an insertion rod that is disposed through an insertion tube and moveable relative to said insertion tube, said blocking element being positioned such that said distal end is advanced beyond an inner surface of said annulus into an interior annular space and a plurality of sutures attached to said blocking element extend out of said hole along said insertion rod; and

expanding at least a portion of said blocking element within said interior annular space by shortening the distance between said distal end and said proximal end until said expanded portion at least substantially blocks said hole.

49. The method of claim 48, wherein said insertion rod and said insertion tube are moved relative to each other to shorten the distance between said distal end and said proximal end.

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