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Masters

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(54) **SEALING DEVICE AND DELIVERY SYSTEM**

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See application file for complete search history.

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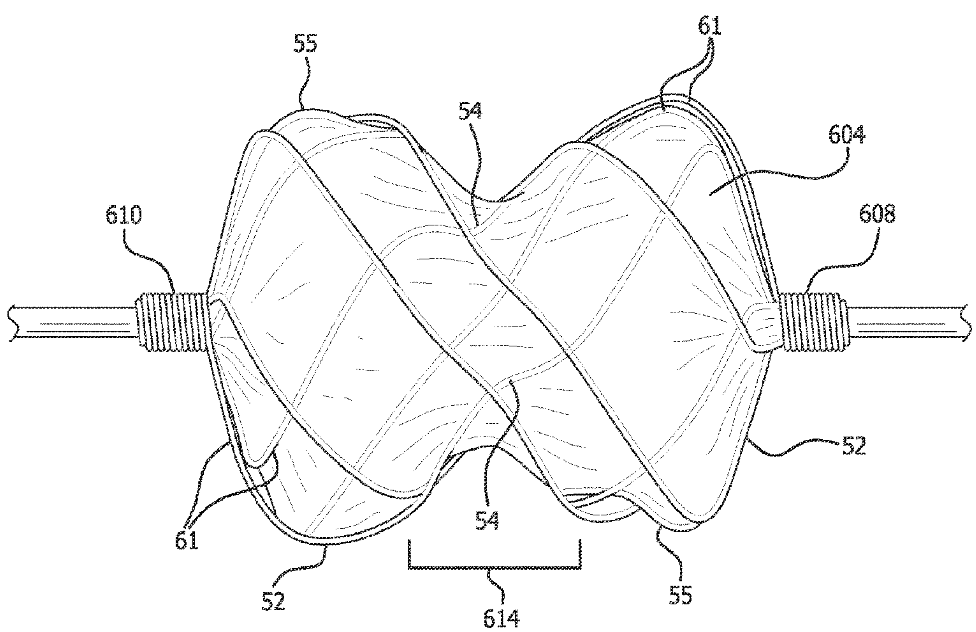
(57) **ABSTRACT**

The invention relates to a sealing device for repair of cardiac and vascular defects or tissue opening such as a patent foramen *ovale* (PFO) or shunt in the heart, the vascular system, etc. and particularly provides an occluder device and trans-catheter occluder delivery system. The sealing device would have improved conformity to heart anatomy and be easily deployed, repositioned, and retrieved at the opening site.

17 Claims, 36 Drawing Sheets



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continuation of application No. 13/165,673, filed on Jun. 21, 2011, now abandoned, which is a continuation-in-part of application No. 12/498,586, filed on Jul. 7, 2009, now Pat. No. 9,636,094.

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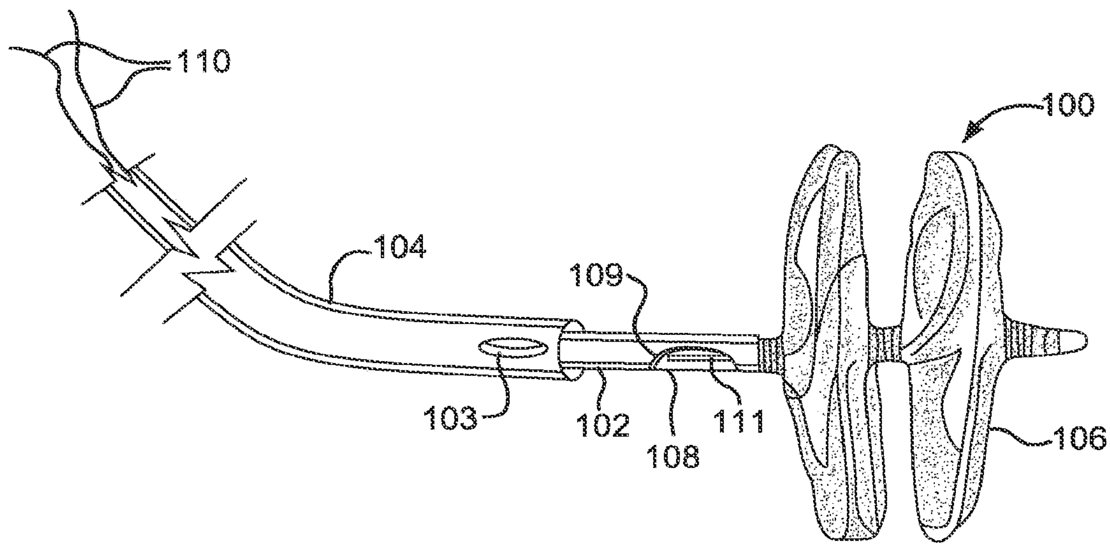

FIG. 1

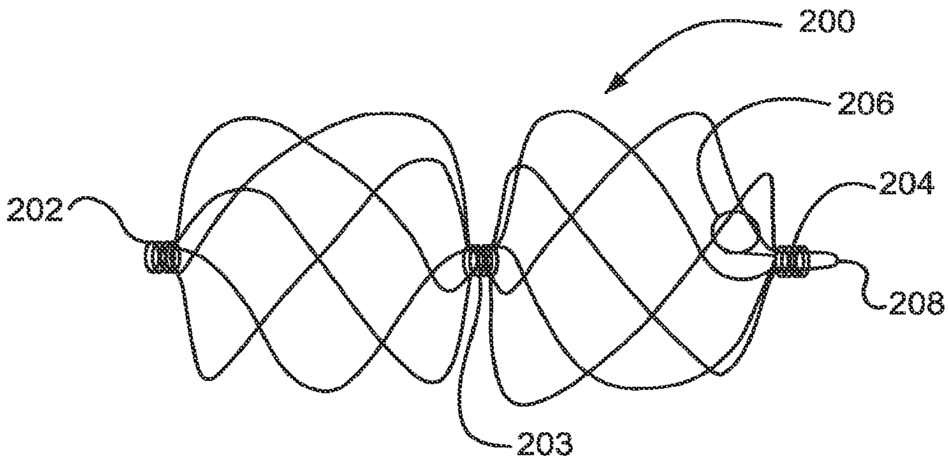

FIG. 2A

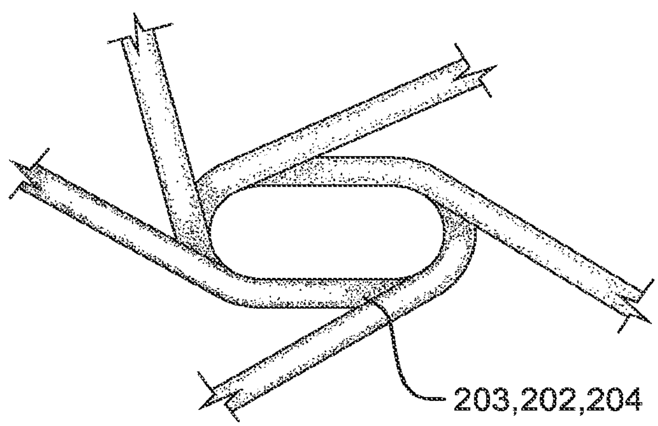

FIG. 2B

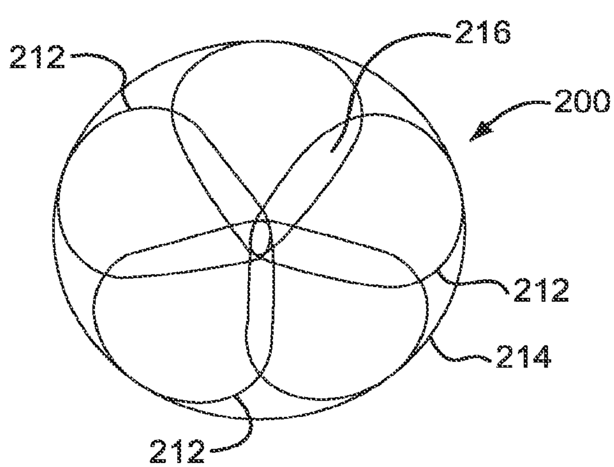

FIG. 2C

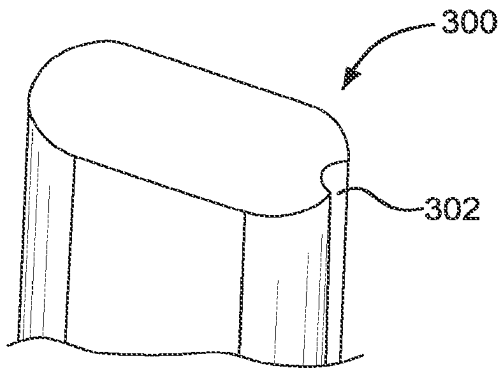

FIG. 3A

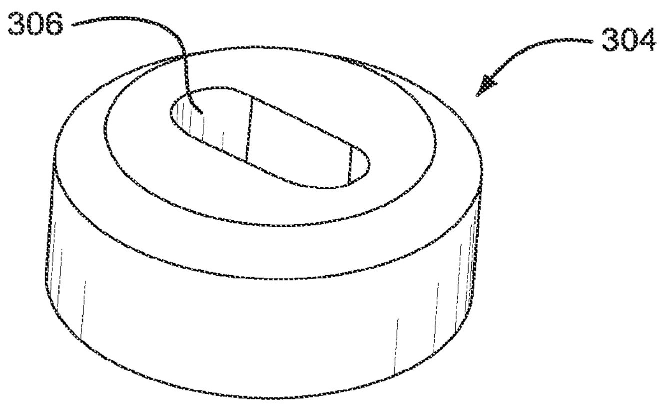

FIG. 3B

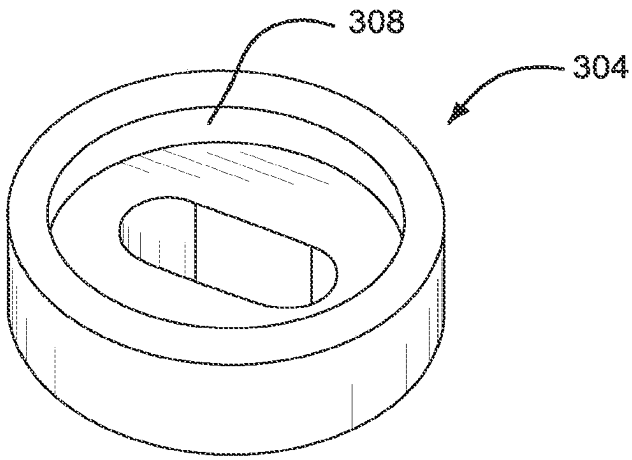

FIG. 3C

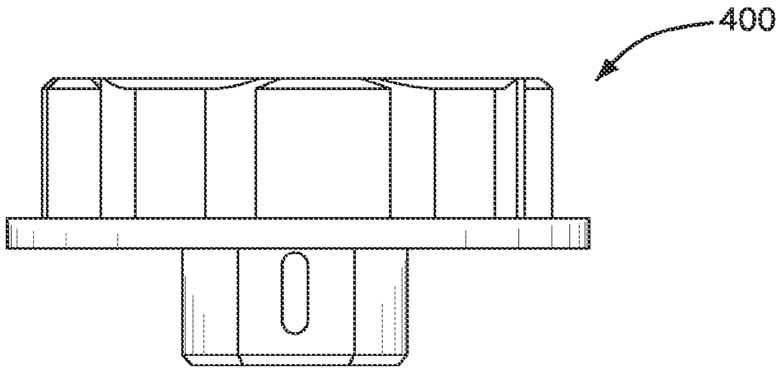

FIG. 4A

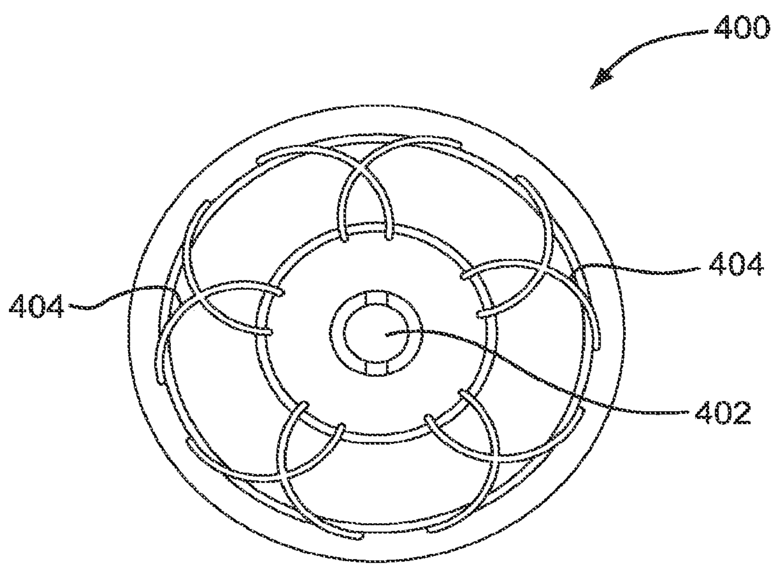

FIG. 4B

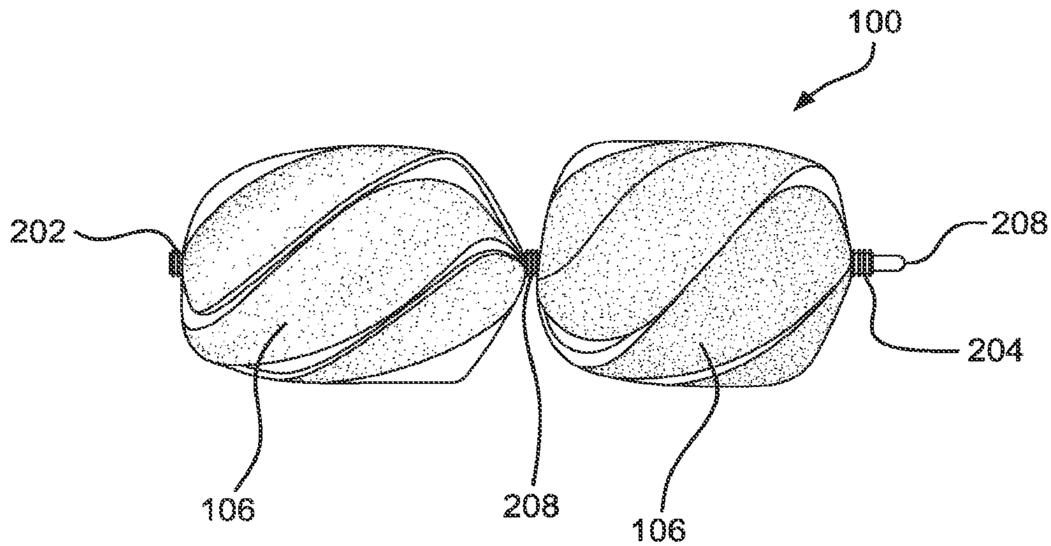

FIG. 5A

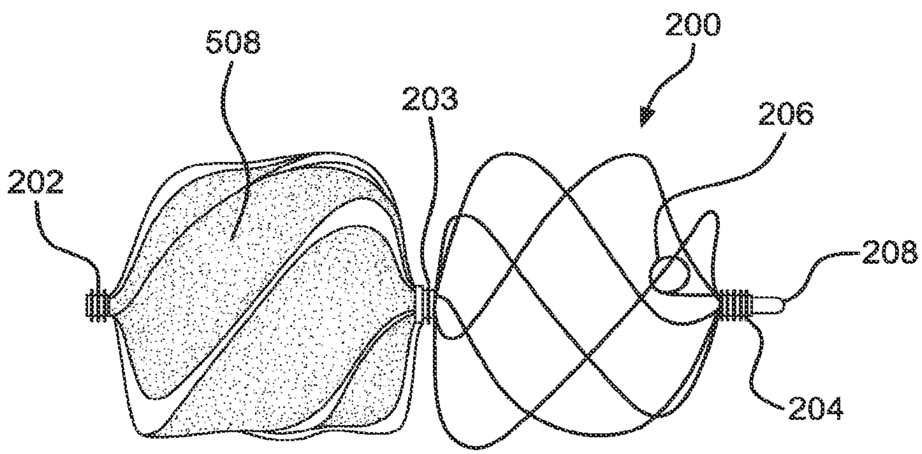

FIG. 5B

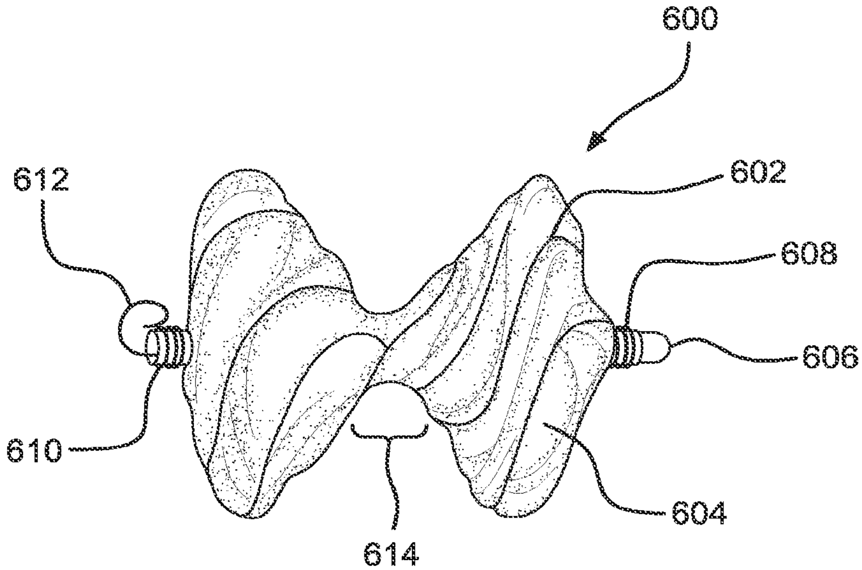

FIG. 6

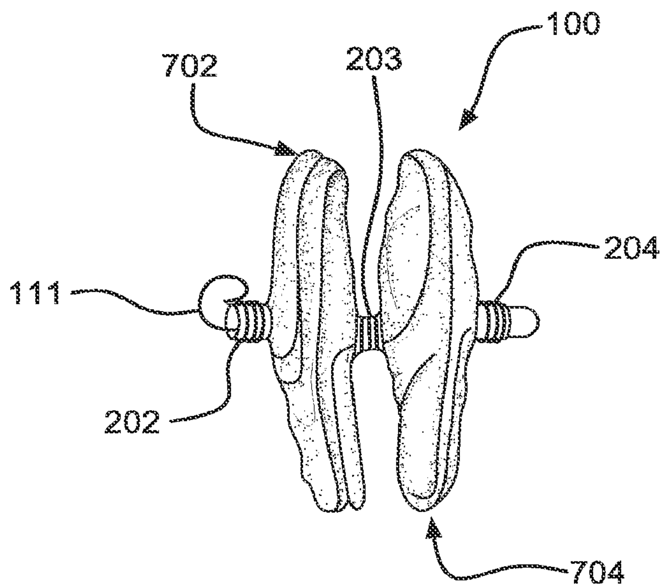

FIG. 7

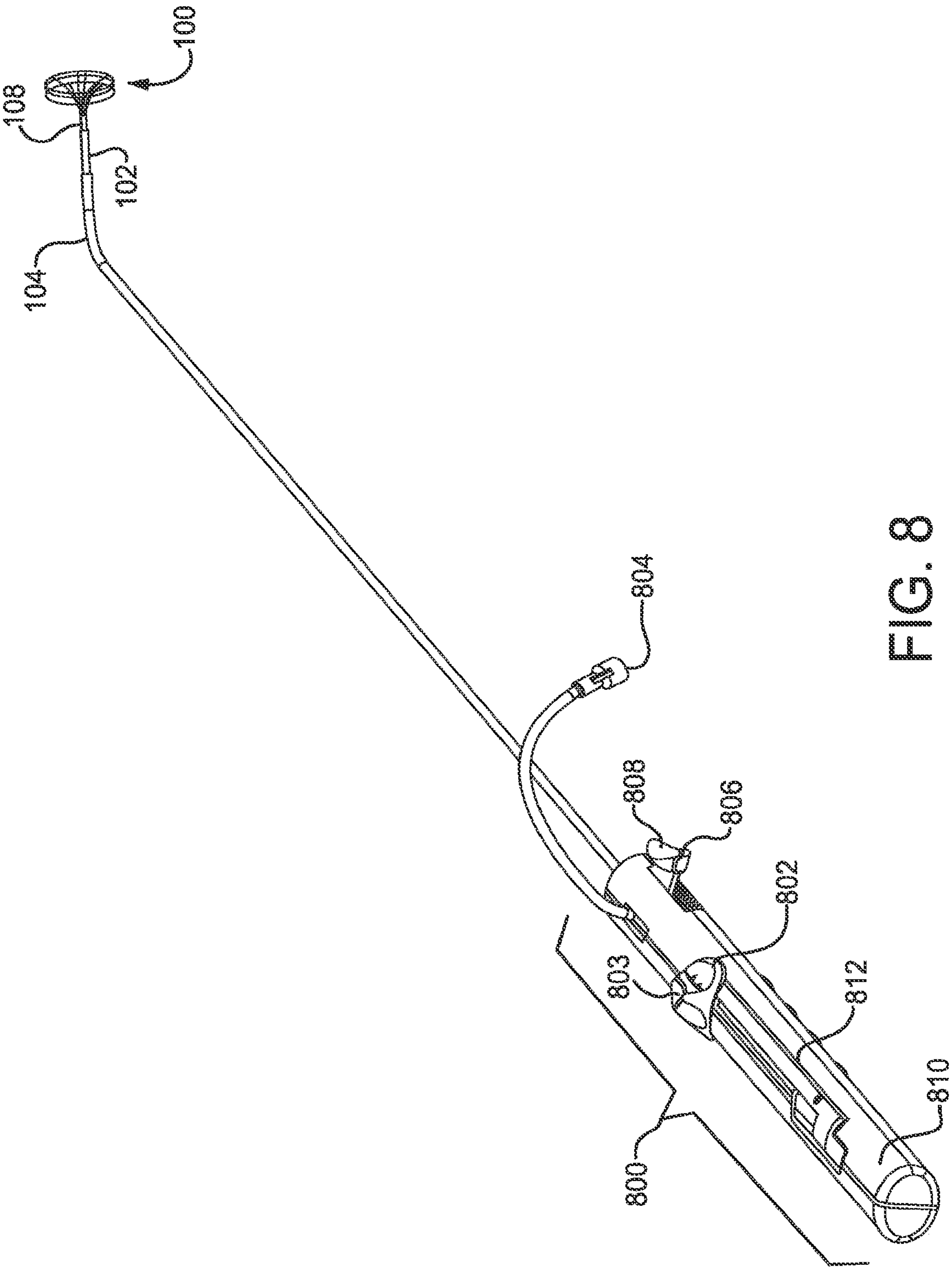

FIG. 8

Load the Device

	Clinician movement	Component movement
Step 1	Flush the delivery system with saline	Attach a saline filled syringe to the flushing port and push in saline until it comes out the distal end of the delivery system
Step 2	Move the first linear actuator to the right edge of the slot	The first linear actuator moves in slot to the right pressing on the spring The mandrel control lever rotates on slider rod to the right A first linear actuator is free of the distal notch in the sizing insert The second tube is prevented from moving
Step 3	Move the first linear actuator proximally	The first tube moves proximally The device proximal end moves proximally elongating the device
Step 4	Move the first linear actuator proximally until device is loaded in delivery catheter	The spring pushes the first linear actuator and mandrel control lever to the left into the proximal notch in the sizing insert The second tube is now free to move proximally with the device and the first tube The second tube, device and first tube slide into delivery catheter
Step 5	Flush the delivery system with saline	Attach a saline filled syringe to the flushing port and push in saline until it comes out the distal end of the delivery system

FIG. 9A

Deploy Device

	Clinician movement	Component movement
Step 1	Move the first linear actuator distally until it stops	The first tube and second tube move distally in the third tube
Step 2	Move the first linear actuator to the right	The first linear actuator moves in the slot to the right, pressing on the spring The mandrel control lever rotates on the slider rod to the right The first linear actuator is free of the proximal notch in the sizing insert
Step 3	Move the first linear actuator distally	The first tube moves distally The proximal eyelet of the device moves distally The distal end of device is stopped in place The first tube guides the device out of the third tube to deploy
Step 4	Move the first linear actuator to the distal most point in slot	The device is free of the third tube The first linear actuator is at a distal most point in slot The mandrel control lever is pushed to the left of the slot by the spring The first linear actuator is in the forward notch in the sizing insert

FIG. 9B

Lock the device

	Clinician movement	Component movement
Step 1	Flip up the retrieval cord lock in the first linear actuator	The retrieval cord lock flips up
Step 2	Grasp the second linear actuator and press it	The second linear actuator becomes free of the corrugations in slot The third tube is attached to the second linear actuator
Step 3	Move the second linear actuator proximally	The third tube moves proximally The mandrel control lever moves proximally The sizing insert moves proximally The second tube moves proximally from between the eyelets of the device
Step 4	Twist the retrieval cord lock then pull on the retrieval cord lock until the retrieval cord comes out of the handle	The retrieval cord is attached to the retrieval cord lock at one end Pulling removes the cord from the device through a lumen of the first tube The device is permanently deployed

FIG. 9C

Device Retrieval

	Clinician movement	Component movement
Step 1	Flip the retrieval lock lever down	The retrieval cord is locked
Step 3	Unscrew the retrieval luer	The delivery catheter is separated from the handle
Step 4	Hold the delivery catheter and pull the entire handle assembly proximally	The handle, first tube and second tube move proximally The device proximal end moves proximally elongating the device The device is withdrawn proximally into the delivery catheter

FIG. 9D

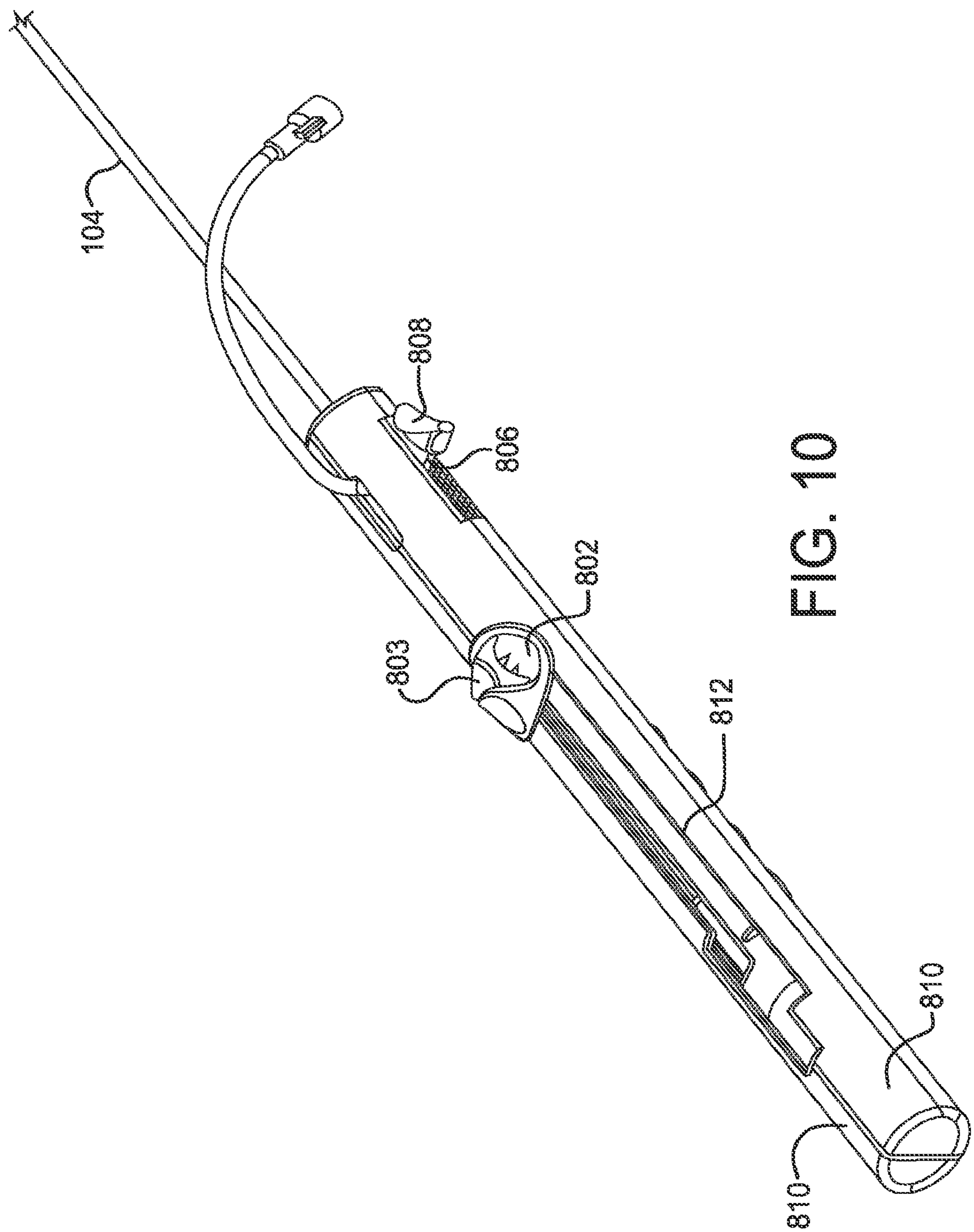

FIG. 10

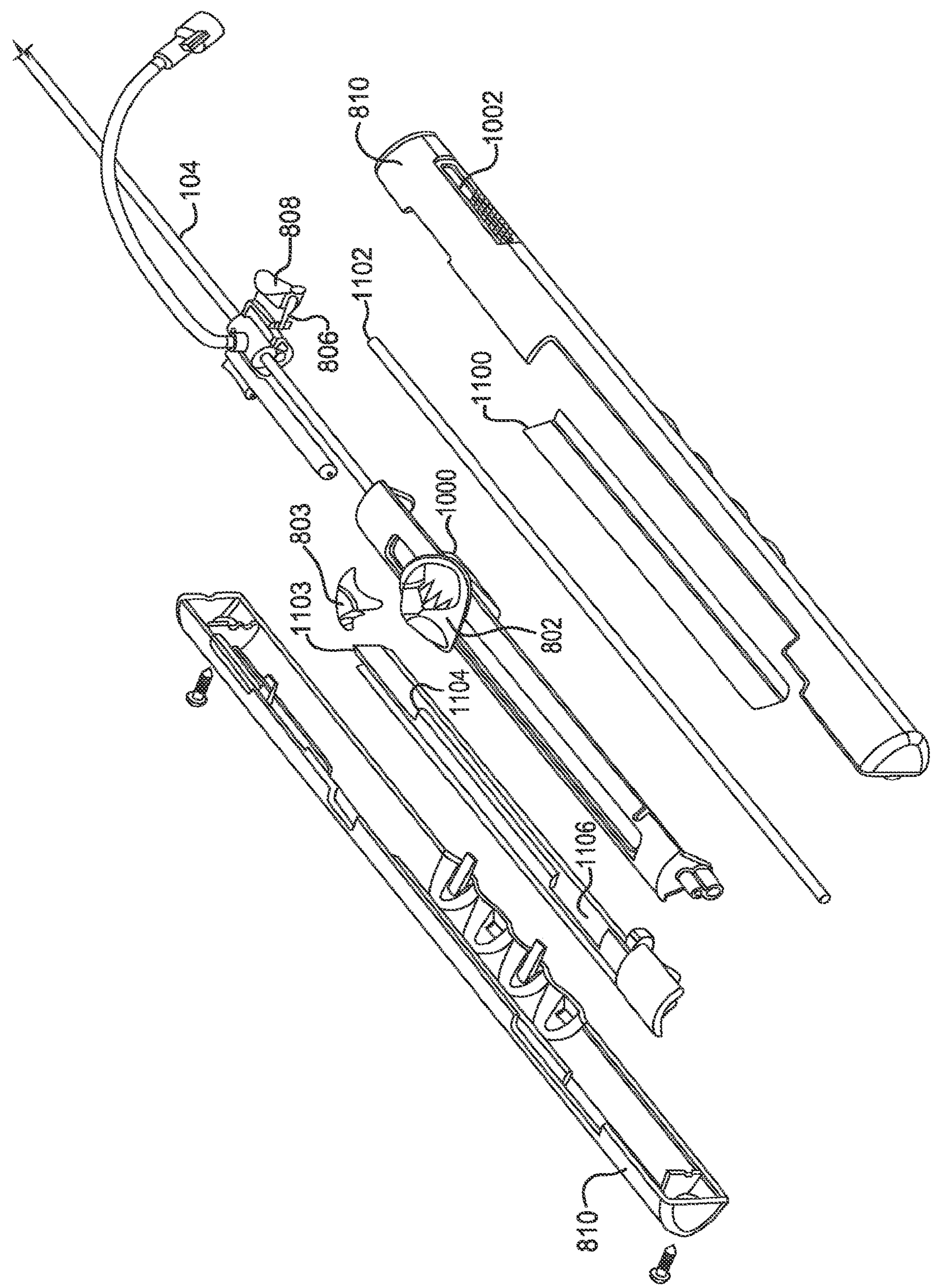

FIG. 11

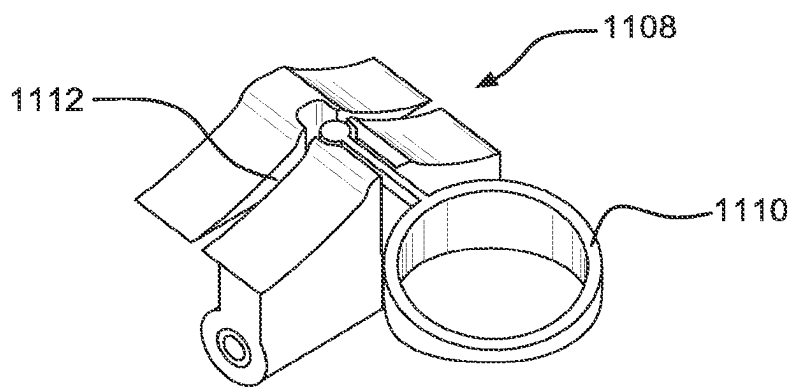

FIG. 12A

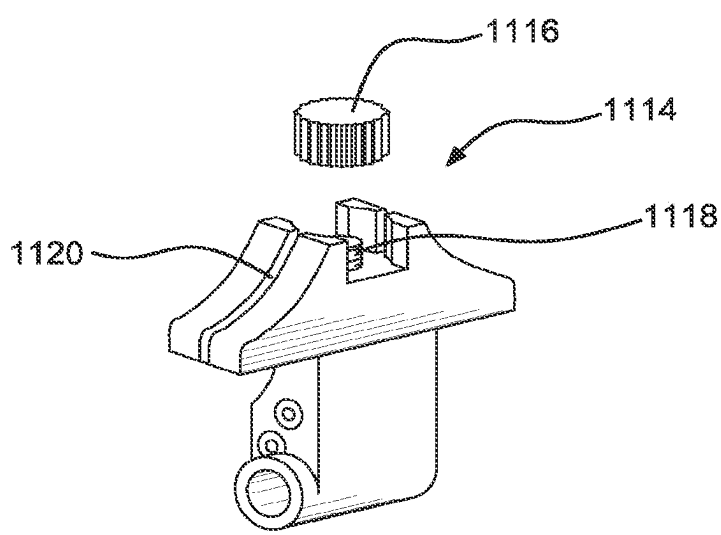

FIG. 12B

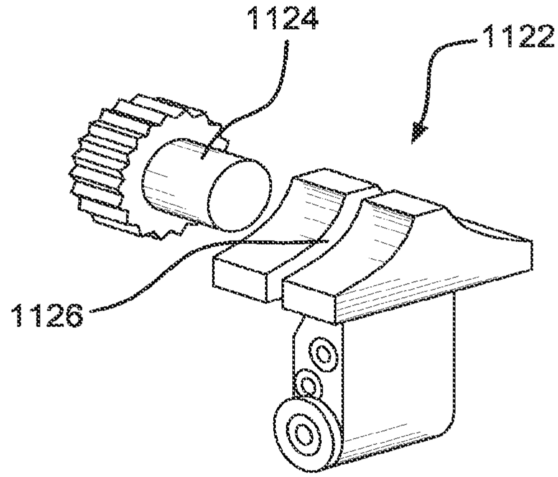

FIG. 12C

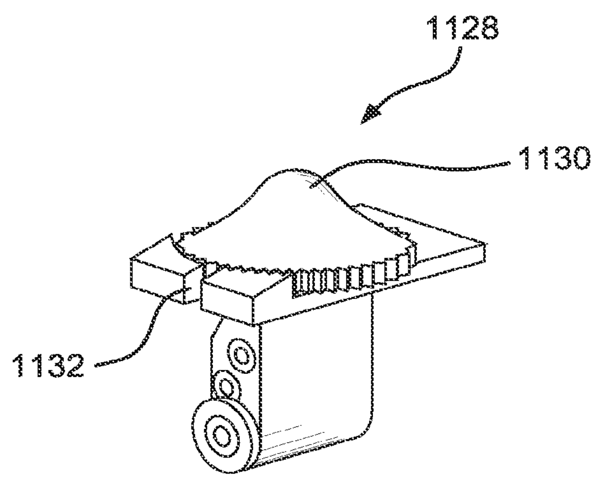

FIG. 12D

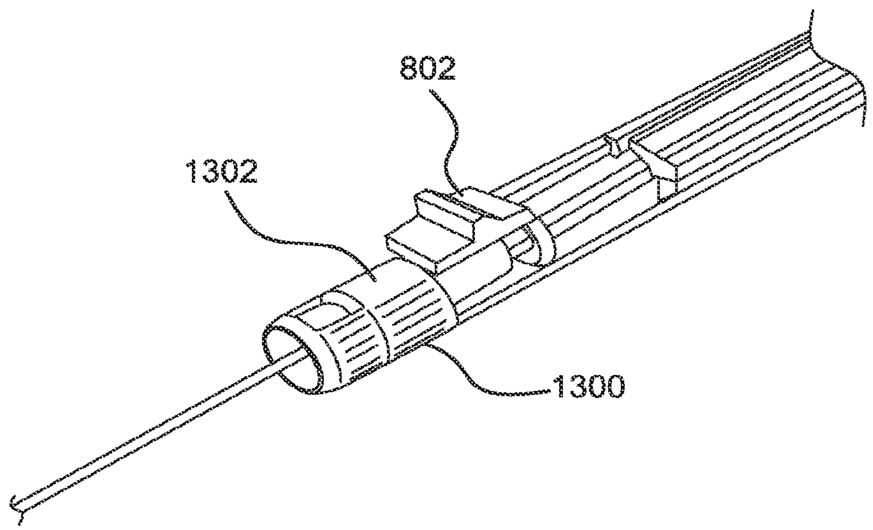

FIG. 13A

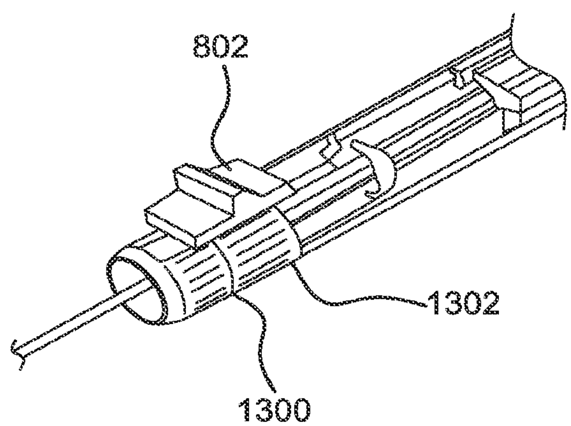

FIG. 13B

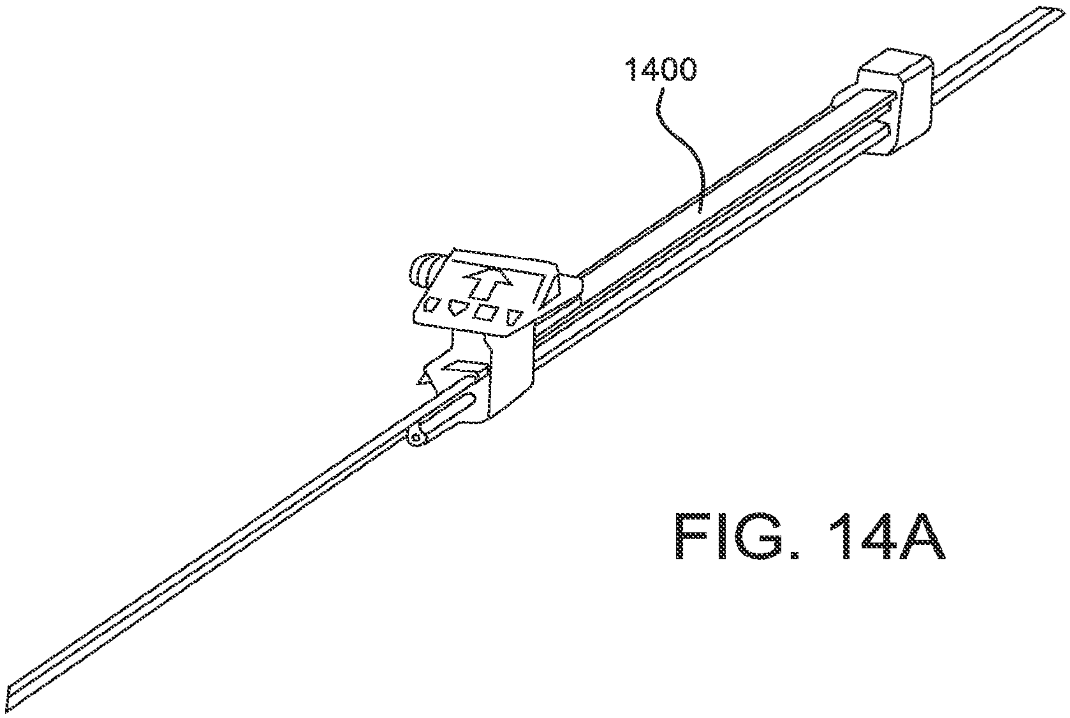

FIG. 14A

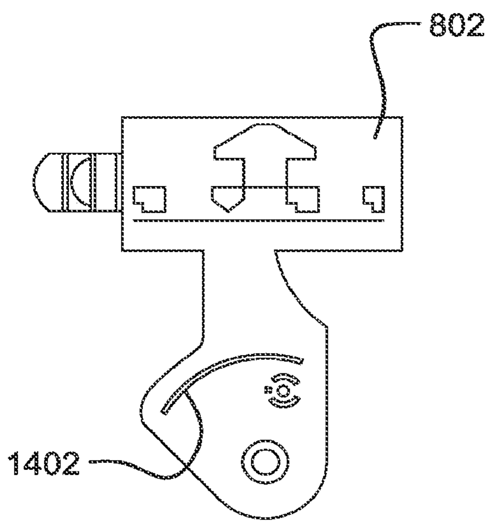

FIG. 14B

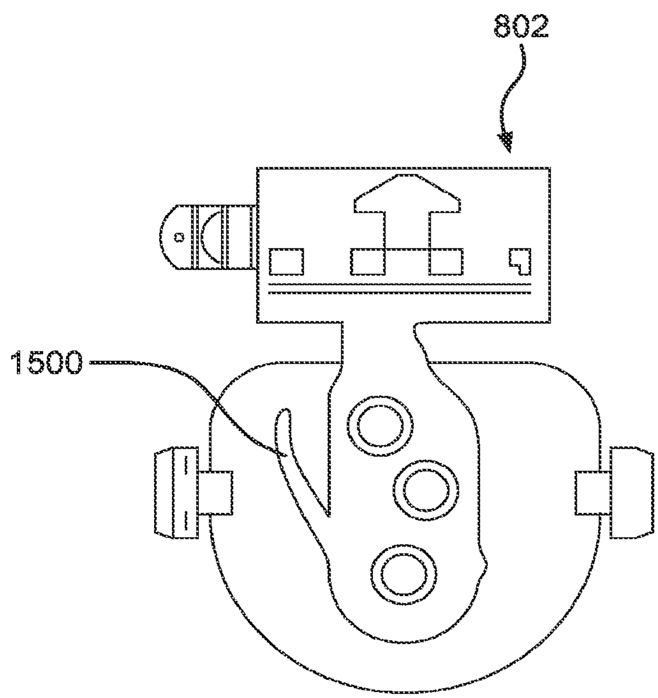

FIG. 15

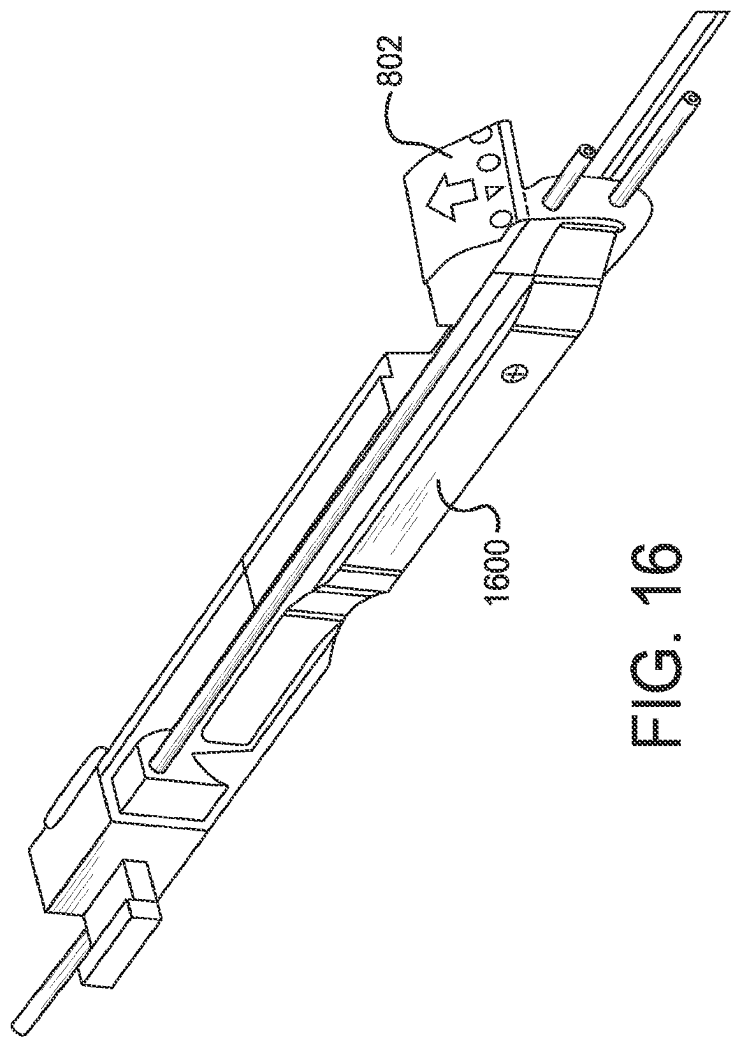

FIG. 16

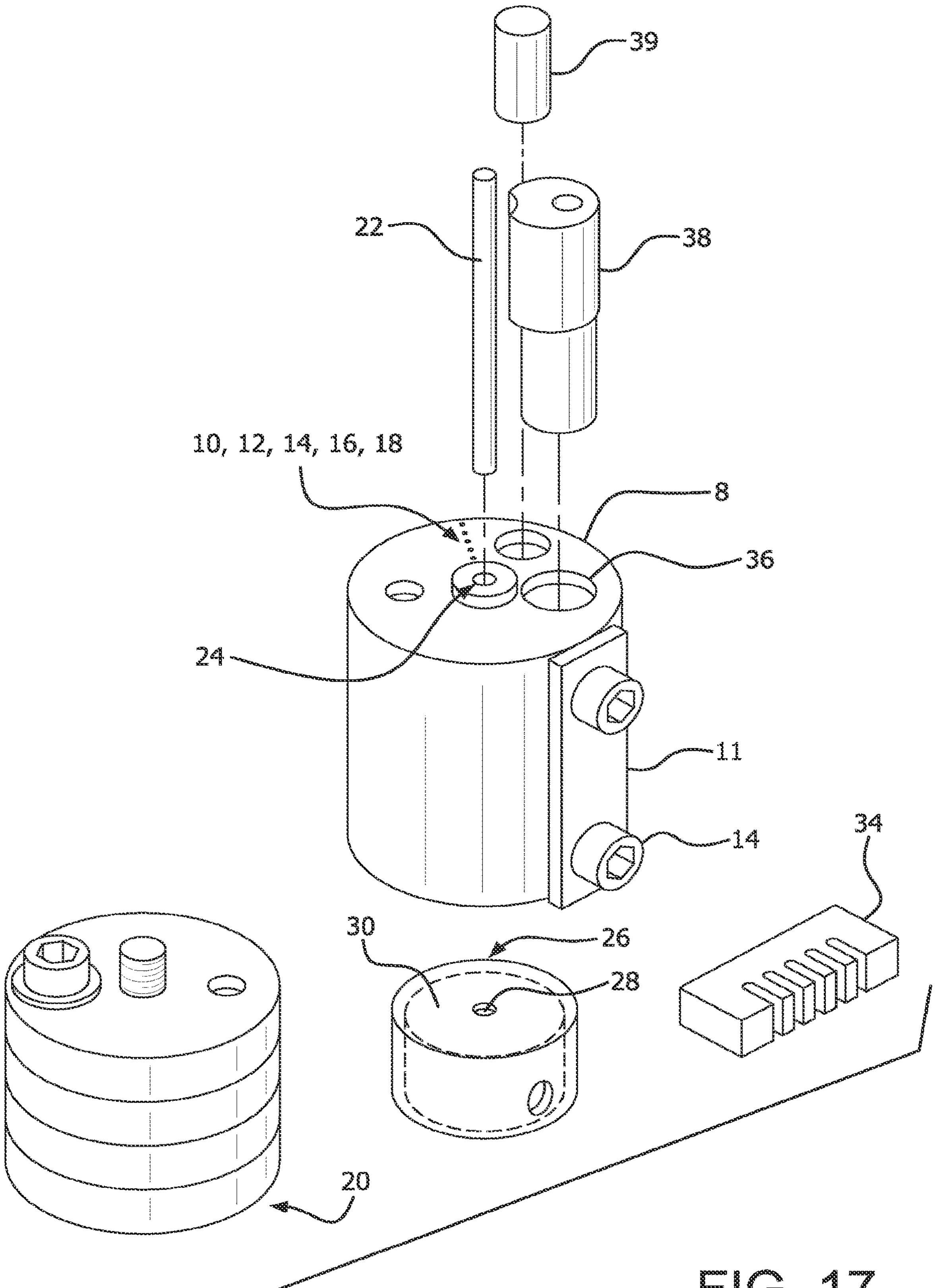

FIG. 17

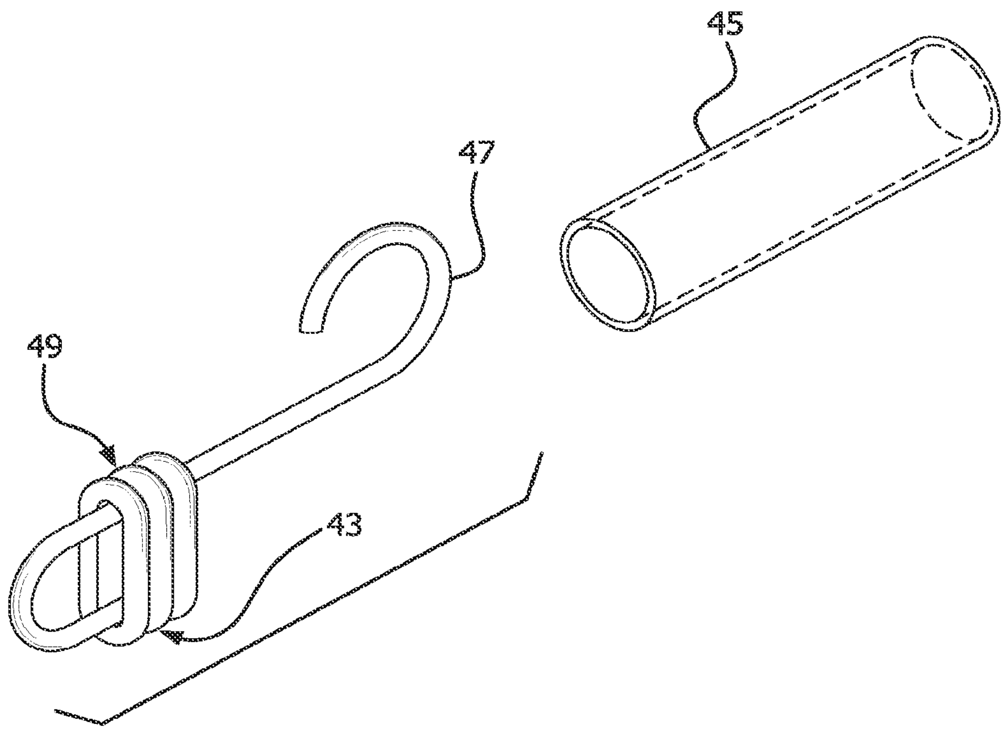

FIG. 18A

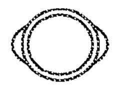

FIG. 18B

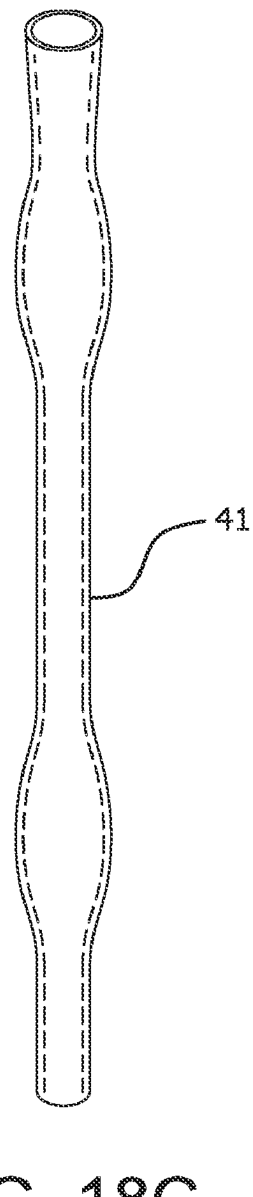

FIG. 18C

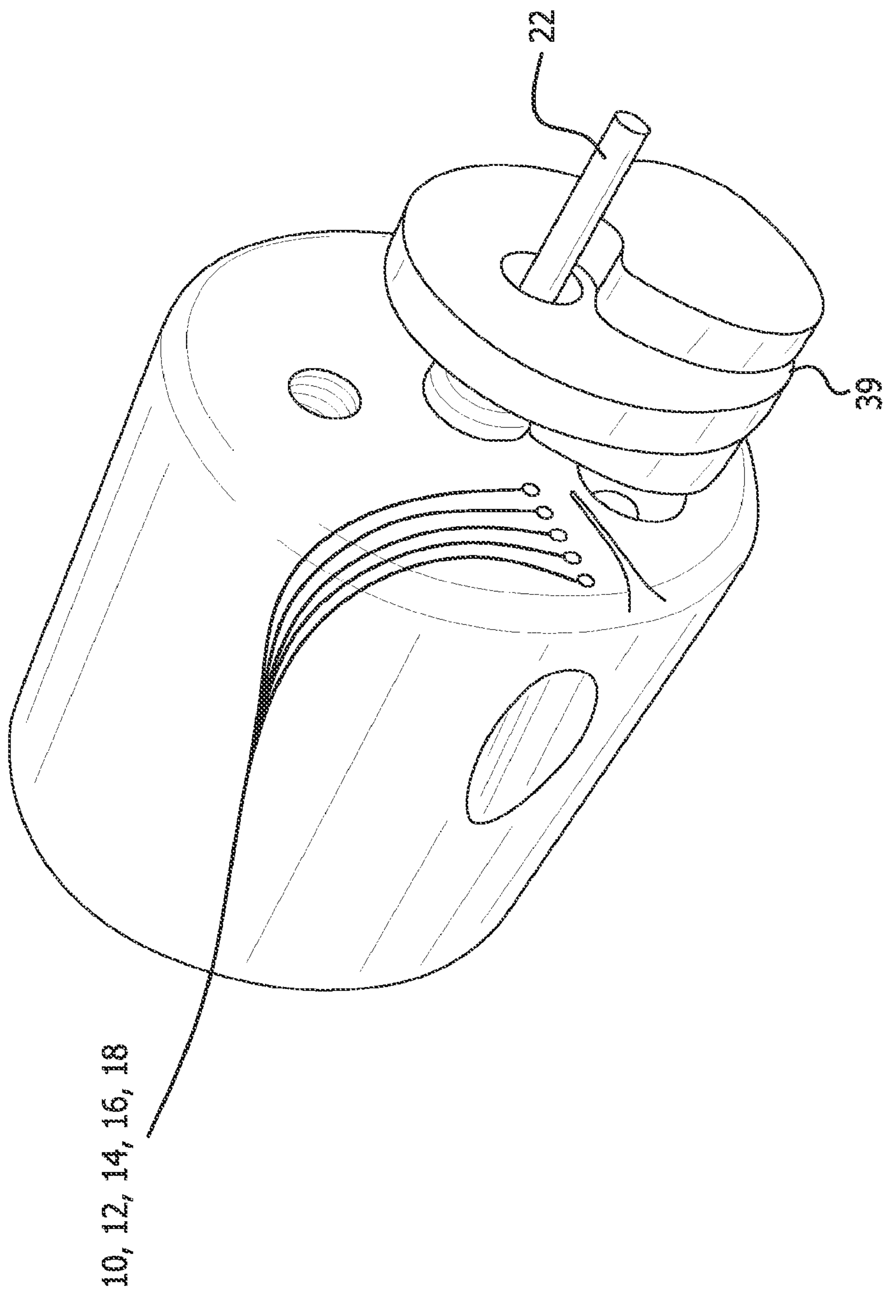

FIG. 19

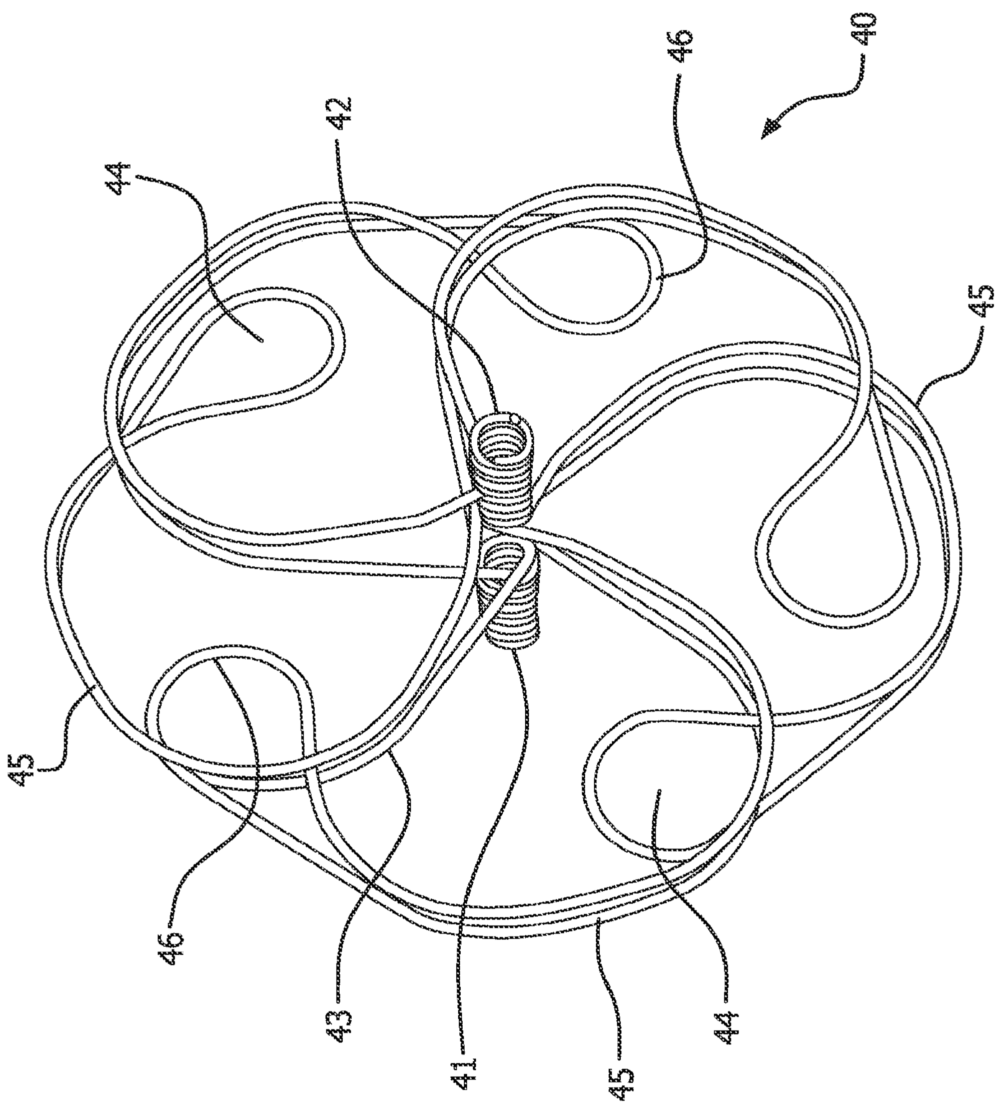

FIG. 20A

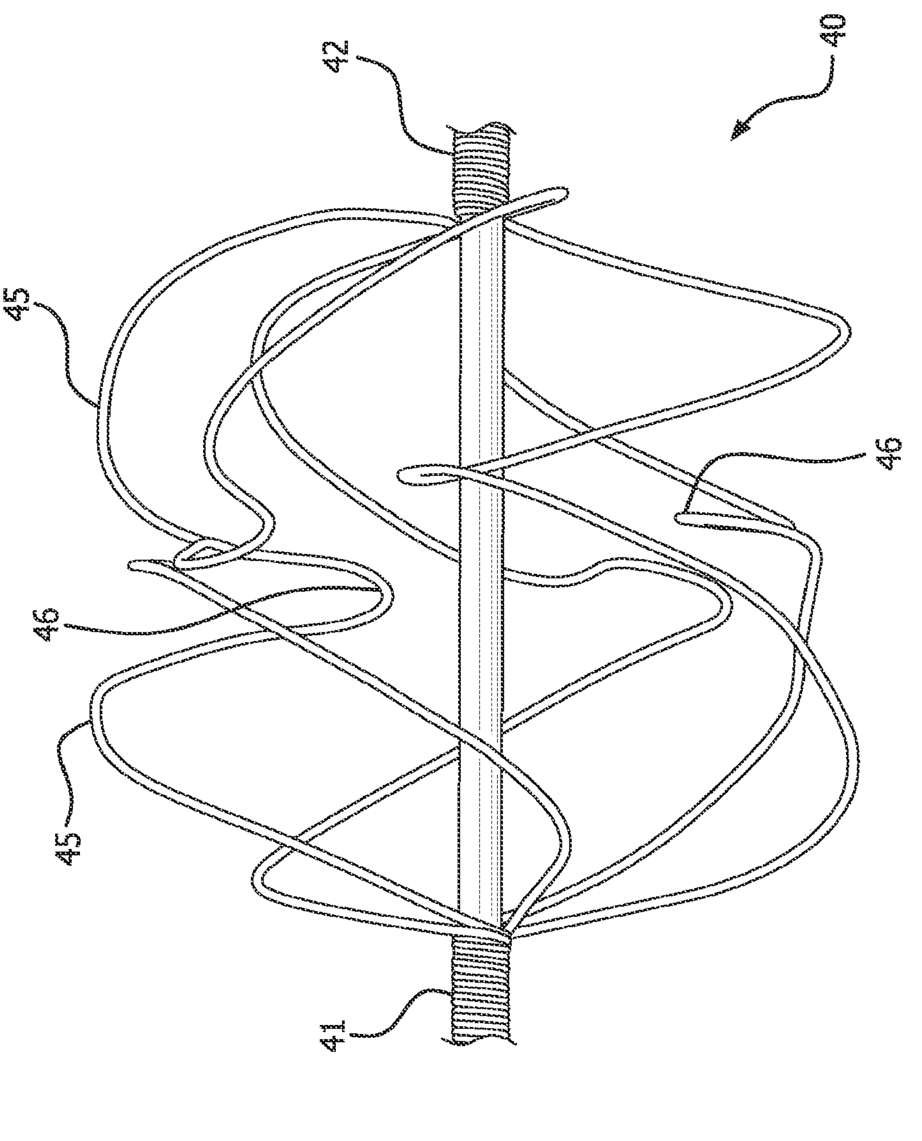

FIG. 20B

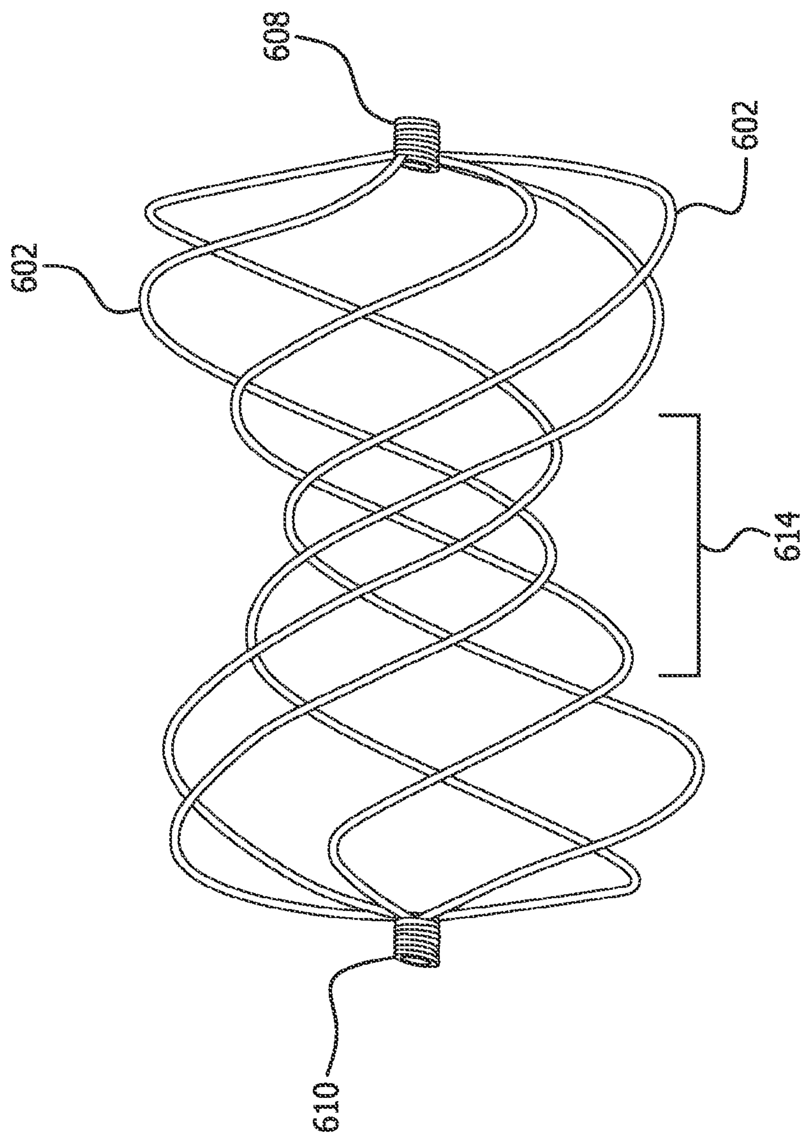

FIG. 21

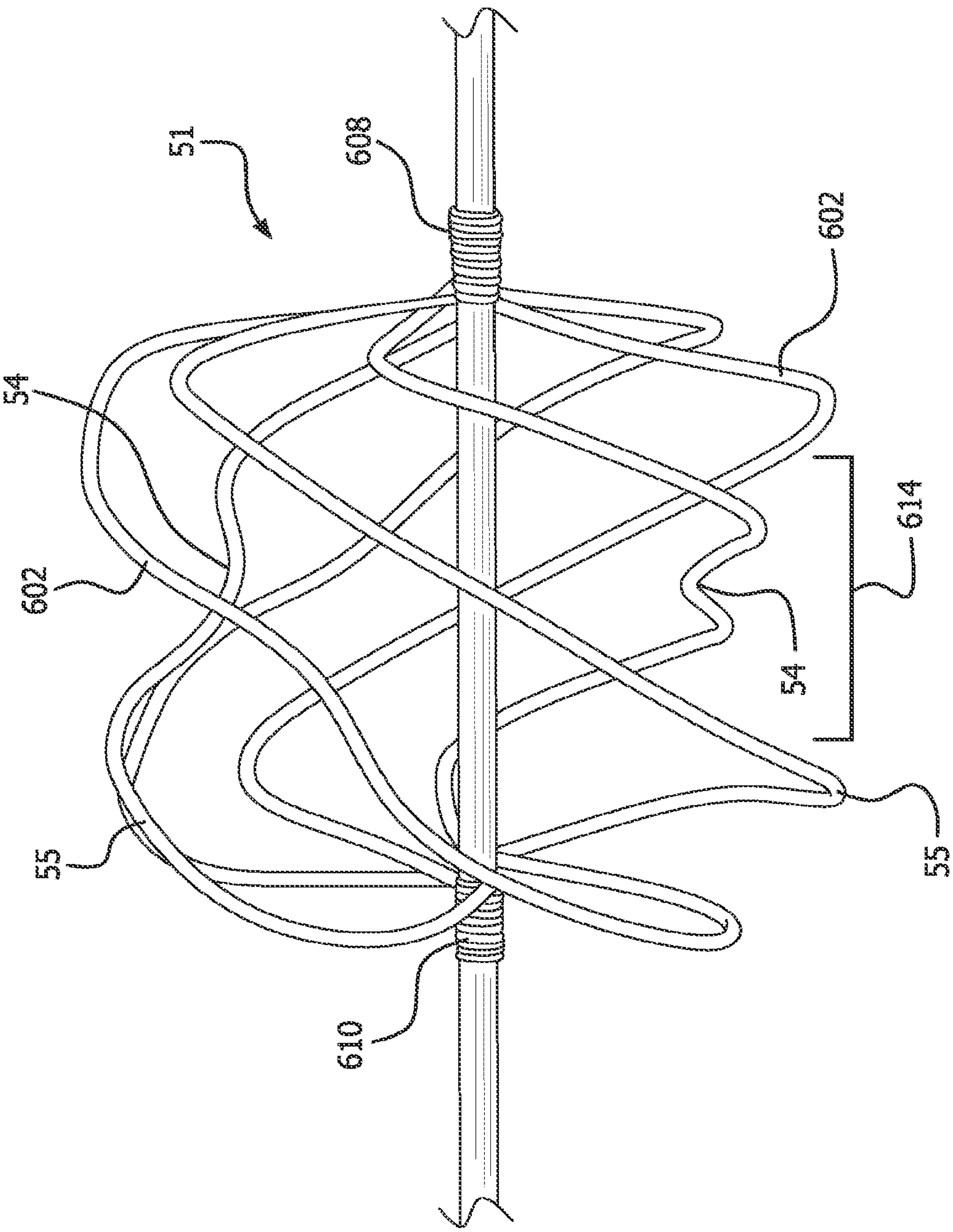

FIG. 22A

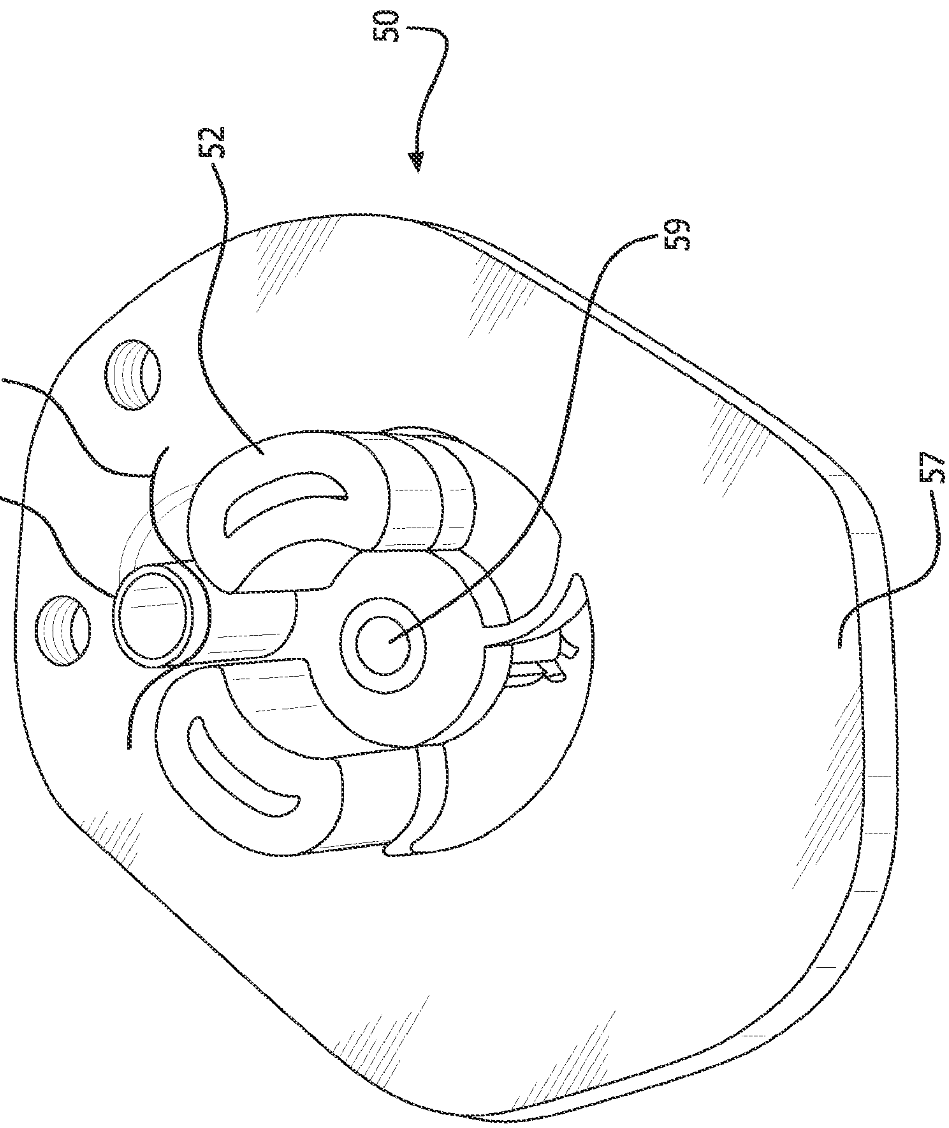

FIG. 22B

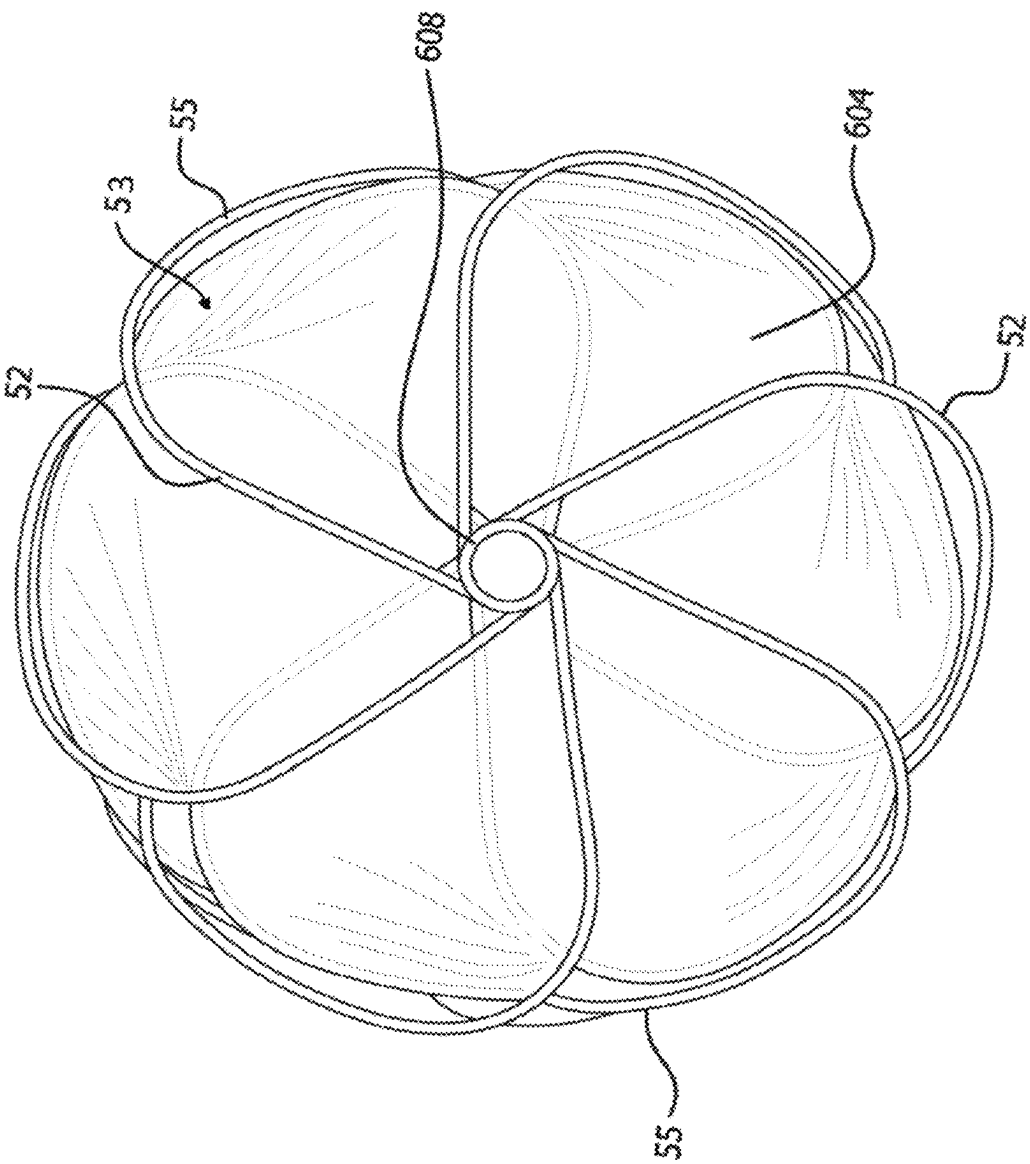

FIG. 23A

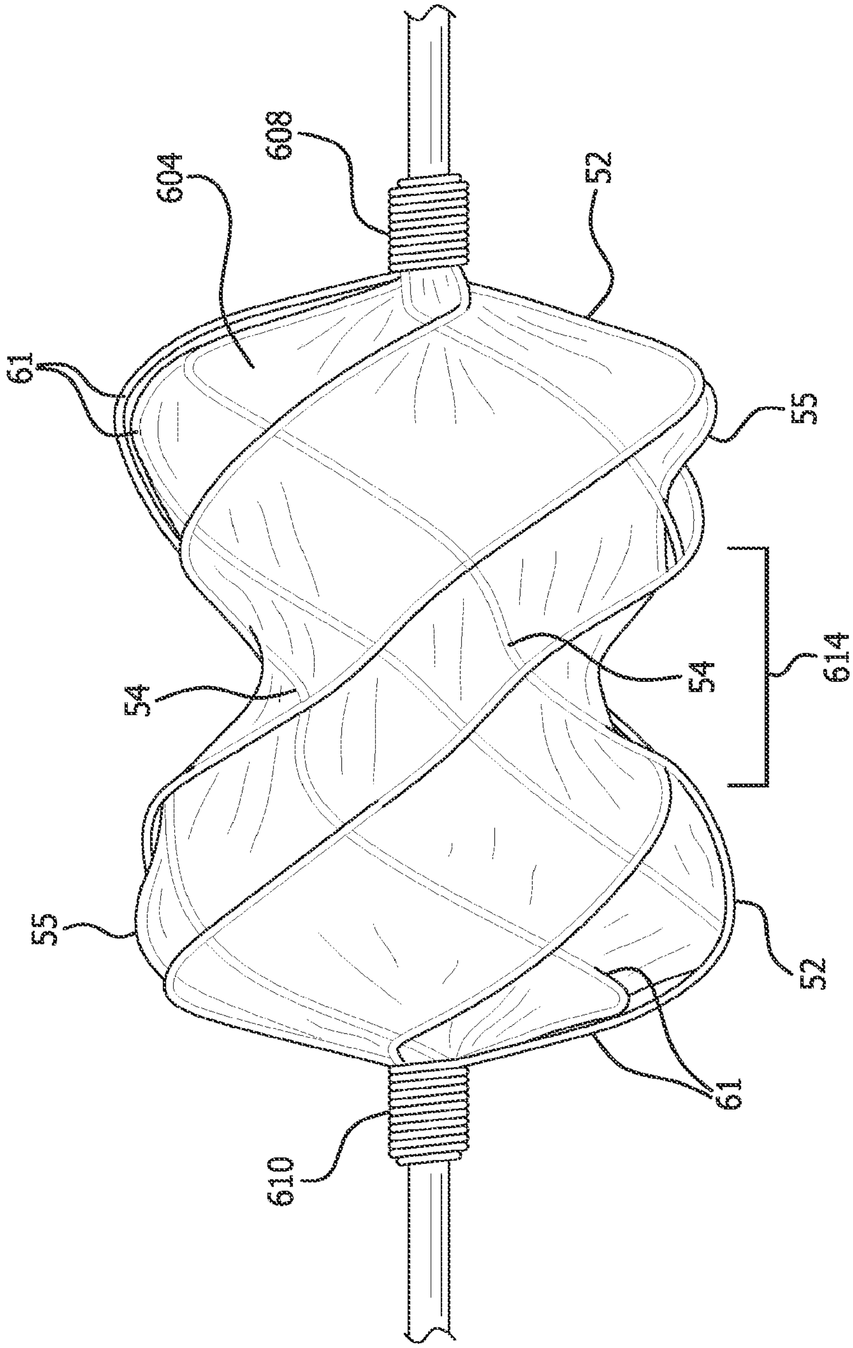

FIG. 23B

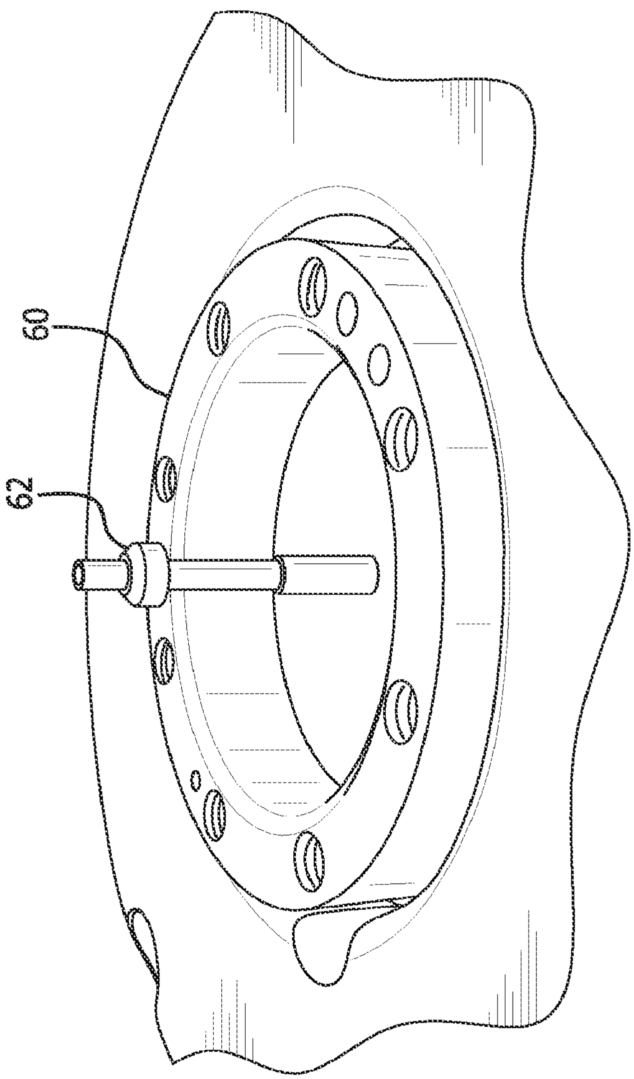

FIG. 24A

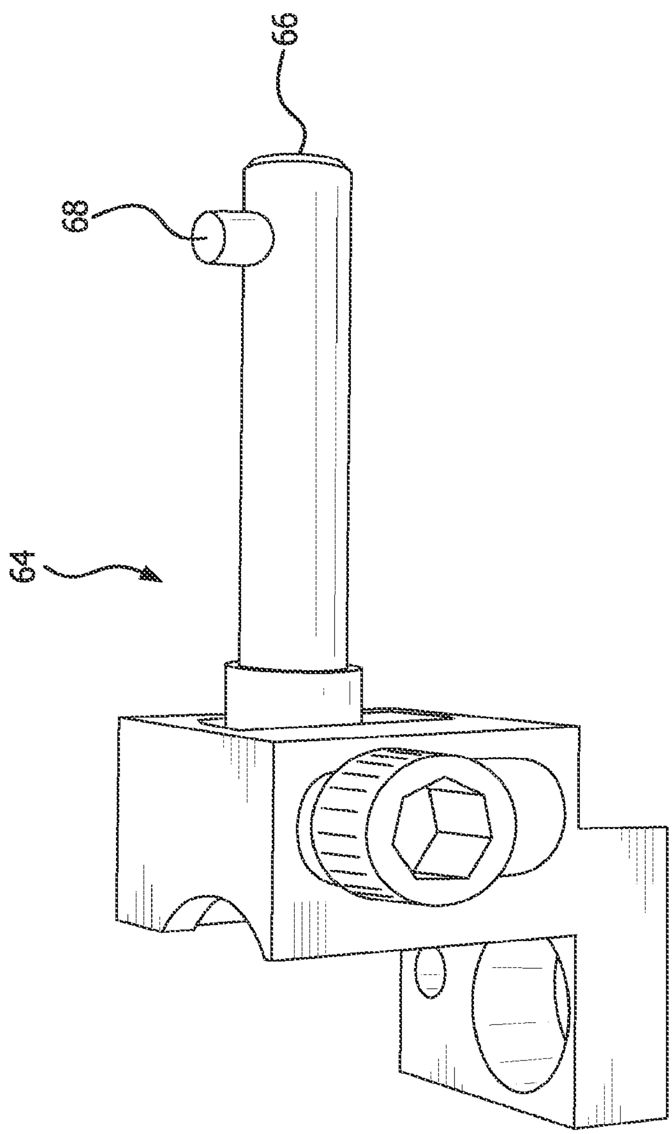

FIG. 24B

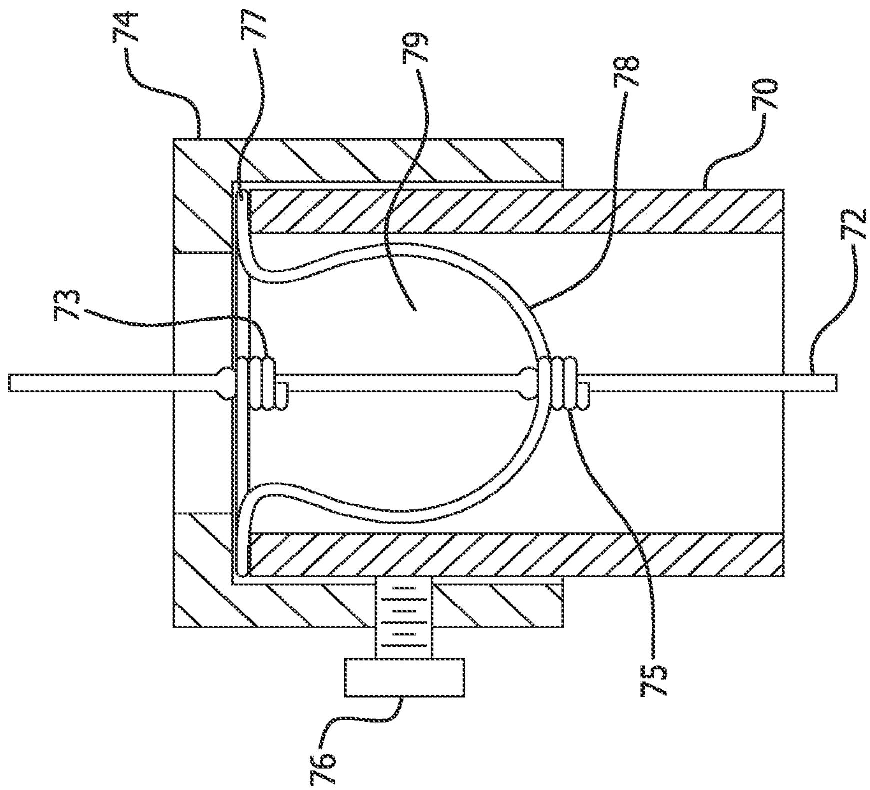

FIG. 25B

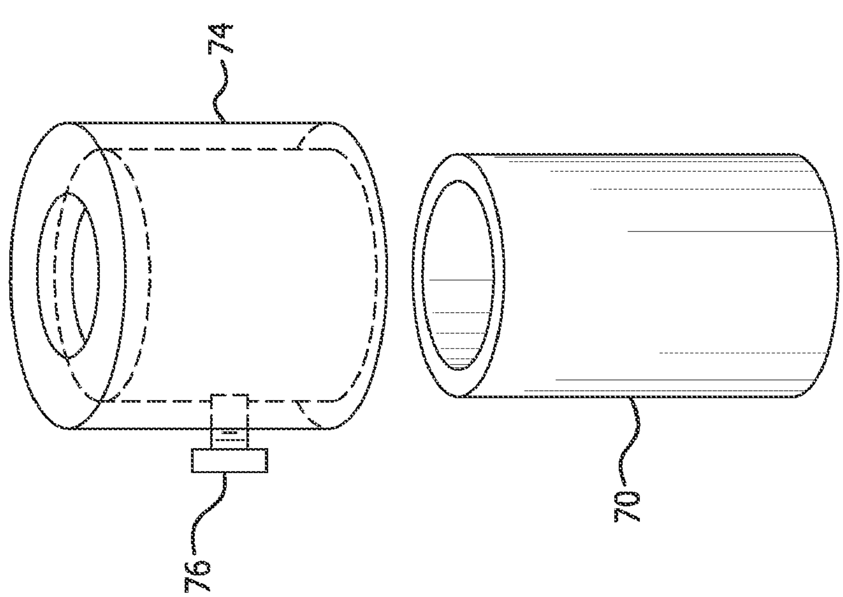

FIG. 25A

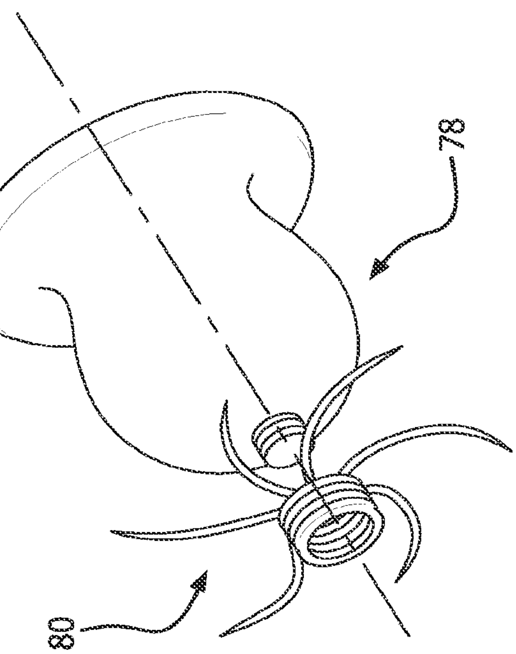

FIG. 26C

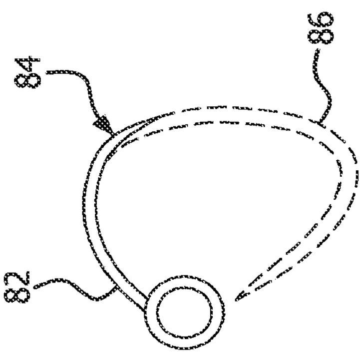

FIG. 26B

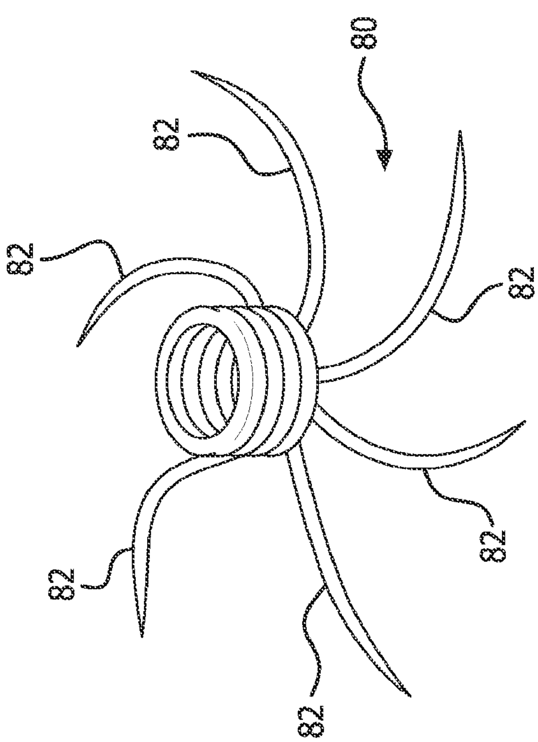

FIG. 26A

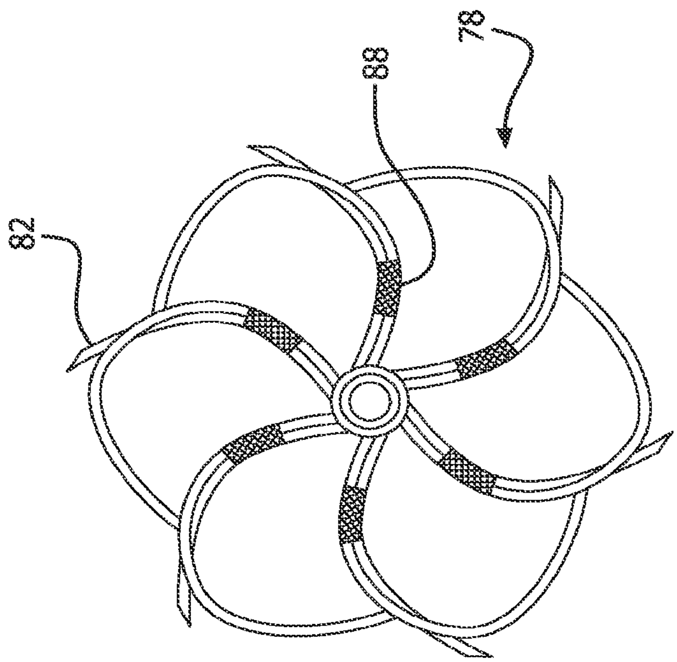

FIG. 27

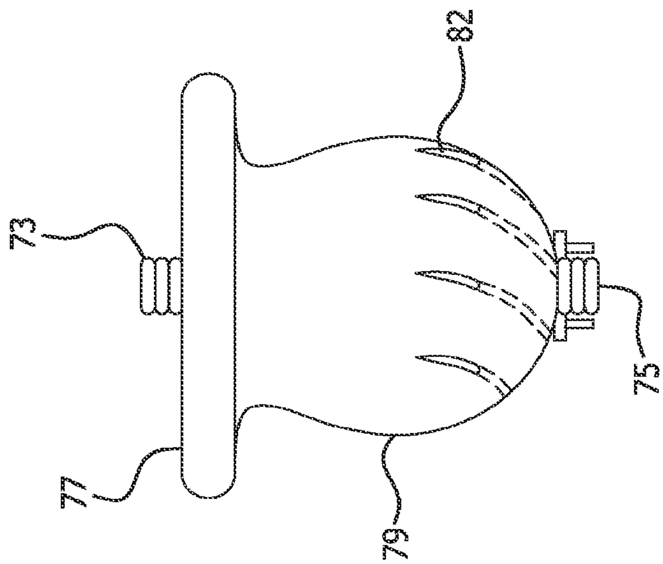

FIG. 28

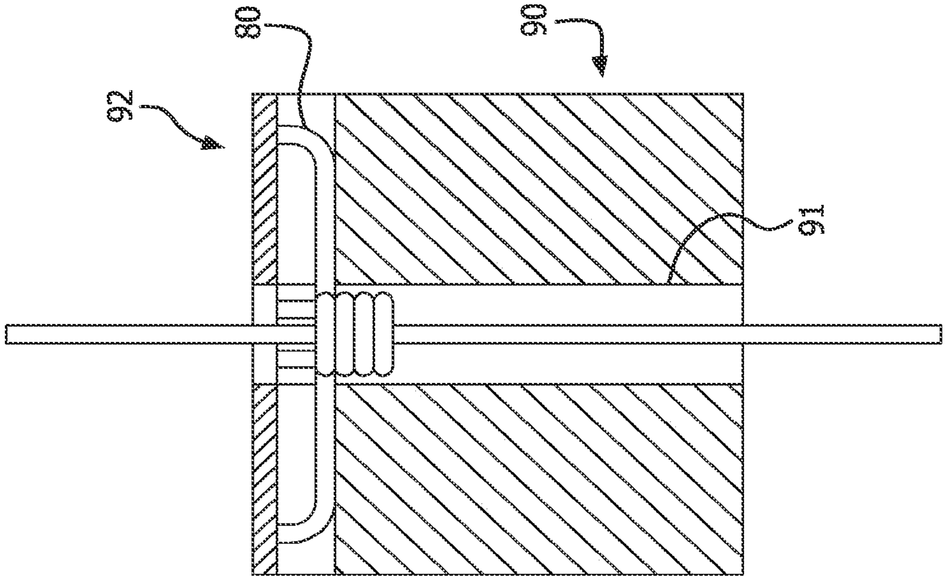

FIG. 29C

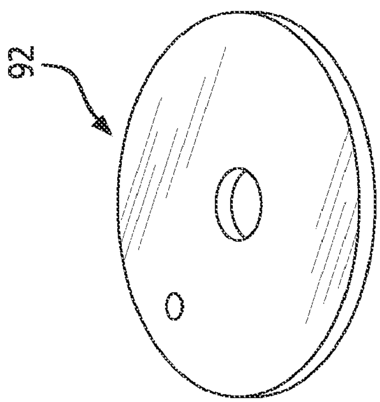

FIG. 29B

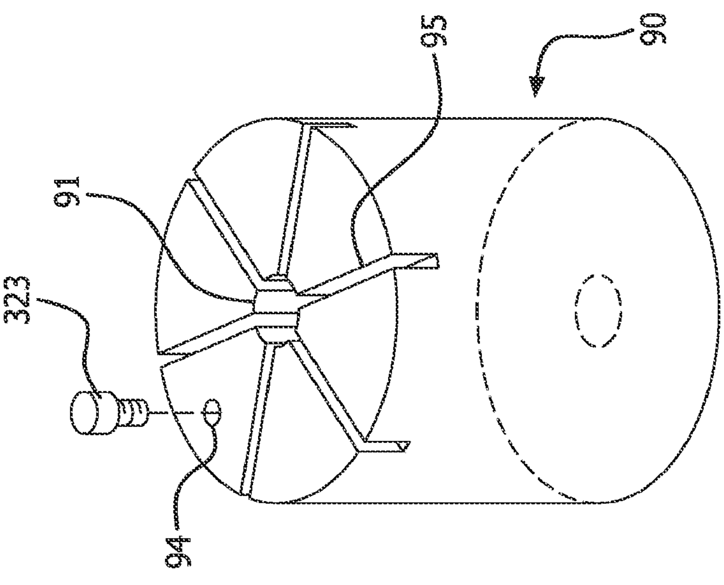

FIG. 29A

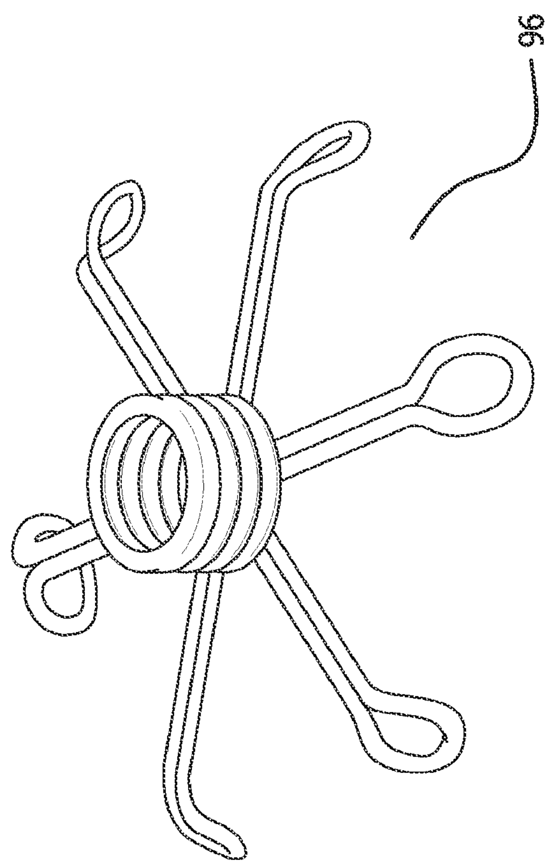

FIG. 30

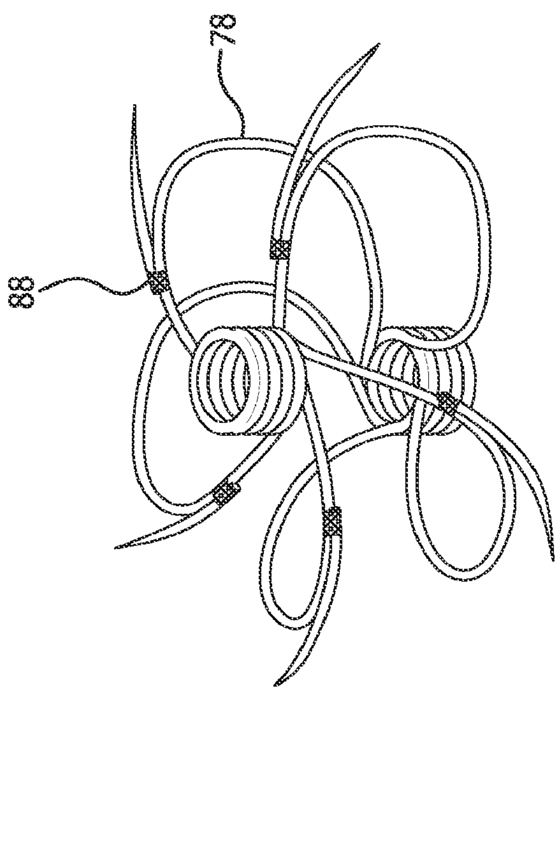

FIG. 31

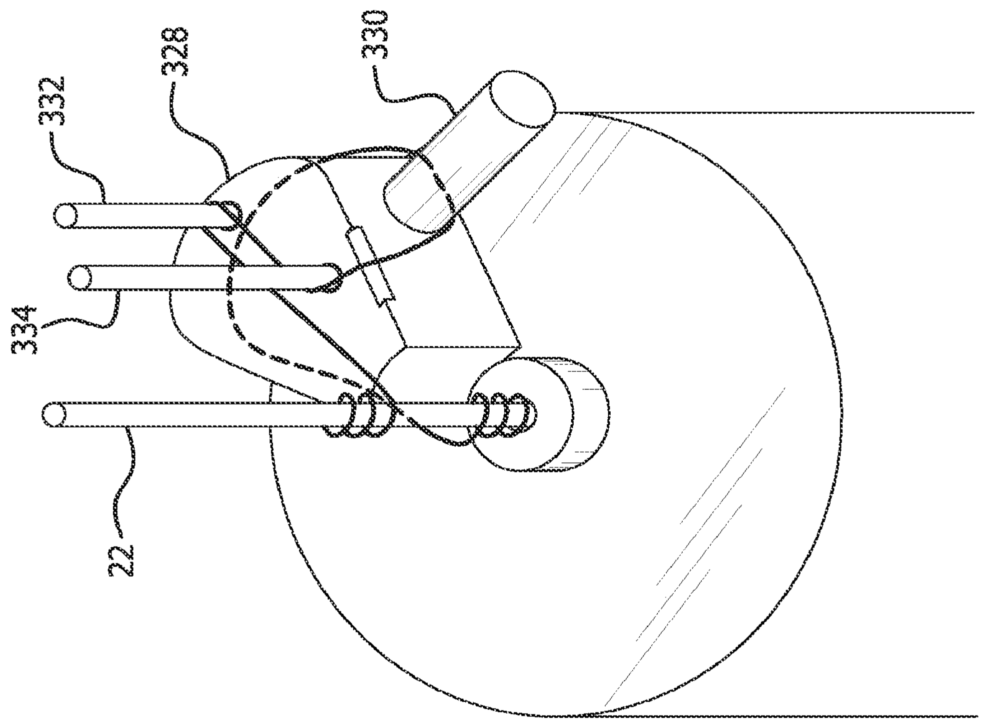

FIG. 32

SEALING DEVICE AND DELIVERY SYSTEM

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. patent application Ser. No. 13/745,671, filed Jan. 18, 2013, which is a continuation of U.S. patent application Ser. No. 13/165,673, filed Jun. 21, 2011, which is a Continuation in Part of U.S. patent application Ser. No. 12/498,586, filed Jul. 7, 2009, now U.S. Pat. No. 9,636,094, issued May 2, 2017, which claims priority to Provisional Application No. 61/219,120, filed Jun. 22, 2009.

FIELD OF THE INVENTION

The invention relates to a sealing device for repair of cardiac and vascular defects or tissue opening such as a patent foramen *ovale* (PFO) or shunt in the heart, the vascular system, etc. and particularly provides an occluder device and trans-catheter occluder delivery system.

BACKGROUND OF THE INVENTION

Sealing devices may be utilized for the occlusion of many types of tissue openings, such as septal defects, PFO, and the like.

Tissue openings have traditionally been corrected by open-heart surgery. In order to avoid the trauma and complications associated with open-heart surgery, a variety of trans-catheter closure techniques have been implemented. In such techniques, an occluding device is delivered through a catheter to the site of the opening or defect. A device is placed into the defect and permanently deployed.

A variety of trans-catheter delivered devices are known. These include devices that require assembly at the site of the tissue opening or require threading or "buttoning" of the discrete device elements. Other devices include self-expanding devices. These self-expanding devices tend to be difficult to visualize, cumbersome to load, difficult to position at the site of a tissue opening, and reposition. Most self-expanding devices do not conform to heart anatomy leading to tissue erosion.

An example of a self-expanding device includes an occlusion bag, a third tube, a guide catheter, a super elastic wire, a release mechanism and a delivery sheath. The super elastic wire is attached to the release mechanism and the wire, release mechanism, occlusion bag, guide catheter and third tube are inserted into a delivery sheath for transport to the aperture. After delivery, the occlusion bag is placed within the aperture and the wire is deployed within the bag. The bag and wire are repositioned if necessary, and the release mechanism is activated to release the wire.

Another example of a self-expanding device includes a shape set tubular metal fabric device and optionally, an occluding fiber included in the hollow portions of the device. The metal fabric defines a medical device shaped like a bell, which can be collapsed for passage through a catheter for deployment in a channel of a patient's body.

While these and other self-expanding devices are designed for trans-catheter delivery, they require assembly either prior to use or during use. They are also difficult to reposition or retrieve once deployed and provide poor conformity to heart anatomy. For these reasons, it would be desirable to provide an improved sealing device for use in trans-catheter techniques. Such sealing devices would preferably have improved conformity to heart anatomy and be easily deployed, repositioned, and retrieved at the opening site.

Trans-catheter self-expanding sealing devices may be delivered and deployed by a variety of means. Most trans-catheter delivery devices choose one of two basic systems for deploying the device: pulling back an outer catheter to release the device or pushing the device free of the catheter with a push rod. Each of these systems utilizes a handle to actuate the mechanism used to deploy the device. An example of such a system includes a flexible urging member for urging the sealing device through a catheter and a remotely located control means for advancing the urging member. In this example, the control means includes a threaded, tubular shaft connected to the urging member and a manually rotatable threaded rotor mounted on the shaft. The threads on the rotor mate with the threads on the shaft so that the rotation of the rotor through a known angle will advance the shaft and the urging member a known distance.

An example of a system that utilizes a pull back outer shaft or catheter includes a handle that may selectively hold the delivery system components at any configuration during deployment and positioning of the device. The outer catheter of such a system would be pulled back to release the device by actuating a sliding lever and a rotating finger ring on the delivery system handle.

While these and other device delivery systems are designed for trans-catheter device deployment, they require the use of a threaded rotor, which can become difficult to rotate or they require large forces to pull back the outer catheter to expose the entire length of the constrained device. Most deployment systems are either not reversible or very difficult to reverse once the deployment procedure has taken place. For these reasons, it would be desirable to provide an improved delivery system for a sealing device. Such delivery system would preferably have a handle able to be operated simply with a single hand and would be able to execute multiple manipulations with minimal force or hand movement.

SUMMARY OF THE INVENTION

A first embodiment provides a sealing device having an expandable frame formed from a plurality of wires extending from a proximal end to a distal end of the frame with the wires forming a proximal and distal eyelet with a sealing member at least partially encapsulating the expandable wire frame.

A further embodiment provides a handle for deploying a sealing device having a housing having a slot and a length with a linear actuator located within the slot and the linear actuator capable of independently advancing and retracting at least three separate components by advancing and retracting the actuator along the slot length.

An additional embodiment provides an apparatus comprising a handle having a housing having a slot with a length and a linear actuator located within the slot the linear actuator capable of independently advancing and retracting at least three separate components by advancing and retracting the actuator along the slot length. The apparatus also comprising a sealing device having an expandable frame formed from a plurality of wires extending from a proximal end to a distal end of the frame with the wires forming a proximal and distal eyelet with a sealing member at least partially encapsulating the expandable wire frame.

Additional features and advantages of the invention will be set forth in the description or may be learned by practice of the invention. These features and other advantages of the invention will be realized and attained by the structure particularly pointed out in the written description and claims hereof as well as the appended drawings.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory and are intended to provide further explanation of the invention as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings are included to provide a further understanding of the invention and are incorporated in and constitute a part of this specification, illustrate embodiments of the invention, and together with the description serve to explain the principles of the invention.

In the drawings:

FIG. **1** is a perspective view of a deployed sealing device attached to the distal end of a delivery system.

FIG. **2**A is a view of an expanded frame of a sealing device.

FIG. **2**B is an end on view of an eyelet of a sealing device.

FIG. **2**C is an end on view of a frame of a sealing device.

FIGS. **3**A-C are views of components of a winding jig.

FIG. **4**A is a side view of a winding jig.

FIG. **4**B is a top view of a winding jig.

FIG. **5**A is a side view of an expanded covered sealing device.

FIG. **5**B is a side view of an expanded partially covered sealing device.

FIG. **6** is a side view of a self-centering embodiment of a sealing device.

FIG. **7** is a side view of a deployed sealing device.

FIG. **8** is a perspective view of a delivery system including a deployment handle and attached sealing device.

FIG. **9**A-D are flow charts describing the operation of the delivery system.

FIG. **10** is a perspective view of a sealing device deployment handle.

FIG. **11** is a perspective view of an assembly of a sealing device deployment handle.

FIG. **12**A is a top down view of an embodiment of a first linear actuator.

FIG. **12**B is a side view of an embodiment of a first linear actuator.

FIG. **12**C is a side view of an embodiment of a first linear actuator.

FIG. **12**D is a side view of an embodiment of a first linear actuator.

FIG. **13**A is a perspective view of an embodiment of a lock release actuator.

FIG. **13**B is a perspective view of an embodiment of a lock release actuator in the activated position.

FIG. **14**A is a perspective view of an embodiment of a spring.

FIG. **14**B is an end on view of an embodiment of a first linear actuator.

FIG. **15** is an end on view of an embodiment of a first linear actuator with molded spring component.

FIG. **16** is a perspective view of a spring component.

FIG. **17** is a schematic of a base jig assembly including winding jig, wire weight and wire guide.

FIGS. **18**A, **18**B and **18**C are schematics of a manufacturing mandrel and an embodiment of a lock loop.

FIG. **19** is a perspective view of a base jig with a self centering petal jig attached.

FIG. **20**A is a perspective view of a wire frame of a sealing device in a deployed configuration.

FIG. **20**B is a side view of a wire frame of a sealing device shown elongated along a mandrel.

FIG. **21** is a view of a wire frame of a sealing device.

FIG. **22**A is a side view of a wire frame of a sealing device shown elongated along a mandrel.

FIG. **22**B is an illustration of an embodiment of a base jig.

FIG. **23**A is an end on view of a sealing device.

FIG. **23**B is a side view of the sealing device of FIG. **23**A in an elongated configuration on a mandrel.

FIG. **24**A is a perspective view of a base jig.

FIG. **24**B is a side view of a lock loop forming tool.

FIGS. **25**A and **25**B show elements of a wire frame forming device and a wire frame of a sealing device.

FIGS. **26**A-C illustrate an anchor component and method of attaching anchor component to a sealing device.

FIG. **27** is an end view of a sealing device wire frame with an anchor component attached.

FIG. **28** is a side view of a covered sealing device with anchor component attached.

FIGS. **29**A-C are illustrations of anchor component forming tools.

FIG. **30** is a perspective view of an anchor component.

FIG. **31** is a perspective view of a wire frame with anchor components attached.

FIG. **32** is a perspective view of a winding path and jig for winding a sealing device with elongated waist area.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

A first embodiment provides a sealing device having an expandable frame formed from a plurality of wires extending from a proximal end to a distal end of the frame with the wires forming a proximal and distal eyelet with a sealing member at least partially encapsulating the expandable wire frame.

FIG. **1** shows one embodiment of sealing device **100**. Sealing device **100** will be discussed in detail in a later section. Sealing device **100** may housed within third tube **104**. Third tube **104** contains sealing device **100**, first tube **102**, second tube **108**, retrieval cord **110** and locking loop **111**. Third tube **104** may be manufactured of Pebax® or any other material with suitable biocompatible and mechanical properties. A material choice with radiopacity may also be an option. The third tube **104** may be manufactured with or without a reinforcing braid to provide appropriate kink resistance and strength for the chosen application. Third tube **104** may also be designed with or without a radiopaque marker band. The design and materials of third tube **104** may be chosen for other properties such as torqueability, steerability and vascular trauma reduction. One skilled in the art will appreciate that there are a wide variety of potential materials that may be used to facilitate the present invention. The third tube **104** may be of any size but is preferably 10fr. with an inner diameter of about 0.048 mm and an outer diameter of about 0.33 mm. Third tube **104** may be used with or without a guidewire and may include a rapid exchange port **103**. The tip of first tube **104** is preferably curved to aid in navigation and delivery of sealing device **100** from the access site to the defect with or without a guidewire.

Also shown in FIG. **1** is first tube **102**. As previously stated, first tube **102** may be housed within third tube **104**. The first tube **102** may be of any outer diameter size but is preferably sized to fit within the lumen of the third tube **104**.

First tube **102** may be manufactured of Pebax® or any other material with suitable biocompatible and mechanical properties. First tube **102** is preferably a triple lumen catheter. The lumens may be of any geometric shape but are preferably round or oval or a combination of both. First tube **102** may be used to position and aid in the deployment of sealing device **100**. First tube **102** may be utilized in conjunction with second tube **108** to cause sealing device **100** to protrude from the distal tip of third tube **104** once sealing device **100** has reached the defect site. The first tube **102** may also have the function of retaining sealing device **100** onto the delivery system until final device deployment. First tube **102** has an opening **109** in the distal most end to allow the locking loop **111** to protrude during device deployment. The opening **109** and protruding locking loop **111** provide attachment to the device delivery system. Locking loop **111** is shown in its extended position prior to retaining its pre-set shape. The first tube **102** may be surface treated or coated to enhance the material's biocompatibility or alter or enhance the surface friction.

First tube **102** may house the second tube **108**. The second tube **108** is essentially tubular with an oval cross section and can have an outer diameter suitable to fit inside first tube **102**. A preferred outer diameter range would be from about 1.27×0.68 mm and would be flared at the distal end. The second tube **108** may be fabricated from any suitable biocompatible material including polymers or metals. A preferable material would be PEEK (polyetheretherketone). Second tube **108** can be used to aid in the delivery and deployment of sealing device **100** to a defect site. Second tube **108** is threaded through the eyelets of sealing device **100** to hold sealing device **100** on the delivery system and to provide stability while deploying the sealing device **100**. Sealing device eyelets will be discussed further.

Retrieval cord **110** is looped through two of the smaller lumens of the first tube **102** and through the proximal eyelet of the sealing device **100** to provide attachment to the delivery system and a method of retrieval once the sealing device has been deployed. Retrieval cord **110** extends through the length of first tube **102** with the ends terminating at the handle used for deploying sealing device **100**. Retrieval cord **110** may be manufactured of any biocompatible material of sufficient strength and size. A preferable material is ePTFE (expanded polytetrafluoroethylene).

As shown in FIG. **2**A sealing device **100** is formed of a wire frame **200**. When situated for delivery, wire frame **200** is at an extended position on second tube **108** and within third tube **104**. Wire frame **200** may be of any size appropriate for an application but is preferably sized with finished outer diameters of 15, 20, 25, or 30 mm. The wire frame **200** is formed of continuous wires. Any number of wires may be used to construct the wire frame **200**. A preferable number of wires is five. The wire frame **200** can be constructed of wires that have elastic properties that allow for wire frame **200** to be collapsed for catheter based delivery or thoracoscopic delivery, and self-expand to a "memory" induced configuration once positioned in a defect. The elastic wire may be a spring wire, or a shape memory NiTi (nitinol) alloy wire or a super-elastic NiTi alloy wire. The elastic wire may also be of a drawn-filled type of NiTi containing a different metal at the core. Preferably, wire frame **200** would be constructed of a drawn-filled type of NiTi wire containing a radiopaque metal at the center. Upon deployment, the wire structure resumes its deployed shape without permanent deformation.

Wire frame **200** and other wire frames shown are formed from elastic wire materials that have outer diameters between 0.12 and 0.4 mm. In a preferable embodiment, wire outer diameter size would be about 0.3 mm. When formed, wire frame **200** comprises a distal bumper **208**, distal eyelet **204**, locking loop **206**, an optional center eyelet **203**, and proximal eyelet **202**. FIG. **2**B shows the position of elastic wires during the formation of eyelets **202**, **203** and **204** of wire frame **200**. In certain instances, the proximal eyelet **202** may be defined by proximal end portions of each of the plurality of wires **52** are wrapped around a longitudinal axis of the device and converging from different locations of about a circumference of the proximal eyelet **202** to form a wound eyelet and the distal eyelet **204** may be defined by distal end portions of each of the plurality of wires **52** that are wrapped around the longitudinal axis of the device converging from different locations of about a circumference of the distal eyelet **204** to form a wound eyelet.

FIG. **2**C shows a disk formed when wire frame **200** is deployed. The elastic wires that form wire frame **200** form petals **212** during deployment. The pre-set elastic wire configuration of wire frame **200** allows the frame to twist during deployment. This twist forms petals **212**. Deployed petals **212** form the outer diameter **214** of the wire frame **200**. Deployed petals **212**, when covered with sealing member **106**, form proximal and distal disks, to be discussed further. Petals **212** are optimally formed to have overlapping zones **216** to improve sealing qualities. The radius of petals **212** may be maximized to minimize sharp bend angles in the elastic wire and to minimize unsupported sections of petals **212** that improve sealing qualities of the device, reduce bending fatigue in the wire and aid in reducing device loading forces. Deployed petals **212** form a disk on either side of the center eyelet **203**. The deployed configuration will be discussed further.

Construction of wire frame **200** may be accomplished by a variety of means including machine winding with automatic wire tensioning or by hand winding with weights suspended from each wire during construction. Shown in FIGS. **3**A-C are keyed center pin **300** and button **304**, which may be used to aid in the construction of wire frame **200**. One commonly skilled in the art would recognize that there are many materials suitable for use as a manufacturing aid or tooling. A preferable material for use in forming a center pin **300** would be cobalt high strength steel. A preferable material for use in forming a button **304** and winding jig would be corrosion resistant tool steel. The winding jig will be discussed further. Shown in detail in FIG. **3**A, keyed center pin **300** may have groove **302**, which can be used to secure an elastic wire during device construction. Keyed center pin **300** can be used to guide an elastic wire through opening **306** in button **304**, the features of which are illustrated in FIGS. **3**B-C. Button **304** is preferably formed with an indention **308** in the bottom to fit securely in a winding jig. An elastic wire held in groove **302** and inserted through opening **306** in button **304** can form a bumper **208** and locking loop **206**. Keyed center pin **300** is also used in the formation of eyelets **202**, **203** and **204**. During device construction, after the formation of bumper **208**, elastic wires can be wound around keyed center pin **300** to form a distal eyelet **202**. Other eyelets, **203** and **204** can be formed in a similar manner. Once keyed center pin **300** is inserted in button **304** an elastic wire may be inserted into grooves in a winding jig.

A winding jig may be used to secure and form the elastic wires during construction and processing of the sealing device **100**. A typical winding jig may be constructed as commonly known in the arts. Materials used for construction of such a winding jig have been discussed previously.

A preferable winding jig is shown in FIGS. **4**A and **4**B. FIG. **4**A illustrates a side view of the winding jig **400**. FIG. **4**B shows a view of the top of a preferable winding jig **400**. Winding jig **400** contains an aperture **402** that may be shaped and sized to hold keyed center pin **300** and button **304** during device construction. Grooves **404** in the jig surface are used to secure and form the elastic wires into petals **212**. Grooves **404** may be of any diameter but are preferably sized to accommodate an outer diameter of elastic wire. In one embodiment shown in FIG. **5**A, the winding jig assembly may be used to form a center eyelet **203**, a petal assembly and proximal eyelet **204**. The shaped wire may be constrained in the winding jig assembly, heated and processed to shape set as commonly known in the arts.

FIG. **5**A shows an embodiment of sealing device **100** which is a composite assembly of wire frame **200** and sealing member **106**. Sealing member **106** may be attached to wire frame **200** by a bonding agent. Wire frame **200** may be coated with a bonding agent, for example fluorinated ethylene propylene (FEP) or other suitable adhesive. The adhesive may be applied through contact coating, powder coating, dip coating, spray coating, or any other appropriate means. In a preferred embodiment, the FEP adhesive is applied by electrostatic powder coating. Sealing member **106** may be constructed of a variety of materials, such as DACRON®, polyester, polyethylene, polypropylene, fluoropolymers, polyurethane, foamed films, silicone, nylon, silk, thin sheets of super-elastic materials, woven materials, polyethylene terephthalate (PET), collagen, pericardium tissue or any other biocompatible material. In one embodiment, sealing member **106** can be formed of a thin porous ePTFE (expanded polytetrafluoroethylene) substrate. Sealing member **106** is designed to enhance the defect closure characteristics of sealing device **100** by providing defect blockage and a medium for cellular in growth.

Also shown in FIG. **5**A are proximal, distal and center eyelets (**202**, **203** and **204**) respectively covered with sealing member **106** and wrapped with a film. The eyelets **202**, **203** and **204** may be wrapped with a film to encourage adhesion of sealing member **106** to the device. The film used to wrap eyelets **202**, **203**, and **204** may be any biocompatible thin material but is a material preferably comprised of multiple layers of thin porous ePTFE that may be laminated with one or more layers of non-porous FEP.

FIG. **5**B illustrates an embodiment of sealing device **100** that includes a sealing member **508** that partially covers wire frame **200**. A partially covered device may have either the distal or proximal bulb covered in part or in entirely with a sealing member **508**.

Another embodiment of the device is a self centering device **600**. Shown in FIG. **6**, self centering device **600** comprises a wire frame **602** similar to that of wire frame **200**. Self centering device **600** is a composite assembly of wire frame **602** and sealing member **604**. Wire frame **602** may be constructed with the same techniques and a material as wire frame **200** but has no center eyelet. Wire frame **602** comprises distal bumper **606**, covered distal eyelet **608**, covered proximal eyelet **610**, and locking loop **612**. The pre-set elastic wire configuration of wire frame **602** allows the frame to twist upon deployment and create a centering region **614** of the device **600** during deployment. During deployment, region **614** may center itself in the defect forming a disk comprised of petals on either side of region **614** and the defect.

FIG. **7** shows a sealing device **100** fully deployed. During deployment, the constraint of the third tube **104** is removed from device **100** and the device returns to its pre-set shape. During deployment and locking, lock loop **111** is released from the constraint of first tube **102** and returns to its pre-set shape, curling from the proximal eyelet **202**. In this manner, the device is locked in a deployed state. FIG. **7** also illustrates the position of the proximal and distal disks, elements **702** and **704**, in relation to the proximal, center, and distal eyelets **202**, **203**, and **204** respectively.

FIG. **19** shows a base jig and other manufacturing aids used to manufacture an embodiment shown in FIGS. **20**A and **20**B and described in Example 4. As shown in FIGS. **20**A and **20**B sealing device **40** is formed of wires **43**. Wire frame **40** may be of any size appropriate for an application but is may be sized with outer peripheral edge diameters of 15, 20, 25, or 30 mm. The wire frame **40** is formed of continuous wires. Any number of wires may be used to construct the wire frame **40**. FIGS. **20**A and **20**B show a device formed from 5 continuous wires. FIG. **20**A shows a device in a deployed configuration while **20**B shows a device in an extended configuration. The wire frame **40** may be constructed of wires that have elastic properties that allow for wire frame **40** to be collapsed for catheter based delivery or thoracoscopic delivery, and self-expand to a "memory" induced configuration once positioned in a defect. The elastic wire may be a spring wire, or a shape memory NiTi (nitinol) alloy wire or a super-elastic NiTi alloy wire. The elastic wire may also be of a drawn-filled type of NiTi containing a different metal at the core. Wire frame **40** may be constructed of a drawn-filled type of NiTi wire containing a radiopaque metal at the center. Upon deployment, the wire structure resumes its deployed shape without permanent deformation.

Wire frame **40** and other wire frames shown are formed from elastic wire materials that have outer diameters between 0.12 and 0.4 mm. When formed, wire frame **40** comprises a first eyelet **41**, a second eyelet **42**, a plurality of wires **43**, a closed teardrop shape with an internal area **44** and inner peripheral edge **46** and an outer peripheral edge **45**. In an end view of a deployed device, the outer peripheral edge **45** is shown as the outermost edge of the wire frame **40**. The inner peripheral edge **46** of wire frame **40** is illustrated by the inner most edge of the internal area **44** of the closed teardrop shape. In the deployed configuration a wire and closed teardrop shape will nest or interleaf itself between the wire form of the next wire of the device. In a deployed configuration, the inner peripheral edge **46** will at least in part center itself within a cardiac defect or other tissue gap.

The wire frame **40** may be covered with a sealing member as previously described.

FIG. **21** illustrates an embodiment of the wire frame described in example 5. The embodiment comprises a proximal **610** and distal eyelet **608** with at least five wires **602**, and a self centering waist portion **614** similar to that describe previously in relation to FIG. **6**. Such an embodiment may be manufactured of similar materials and methods as described previously.

An alternate embodiment of a sealing device may be made by procuring two sealing device frames and seating one inside the other. Then covering the resulting frame as previously described. Such a device is described in example 6. An embodiment such as this may be manufactured with similar materials and methods as described previously and subsequently described. This technique may be used with any of the wire frames described herein.

An embodiment is illustrated in FIG. **22**A and described in example 8. FIG. **22**A illustrates a wire frame **51** of a sealing device. The embodiment of FIG. **22**A comprises a proximal **608** and distal eyelet **610**, a plurality of wires **602**, wires forming a wire frame **51**, a self centering waist portion **614**, a reniform shape with an open internal area **53** (not shown) with an inner peripheral edge **54** and an outer peripheral edge **55**. The self centering waist portion **614** of this embodiment forms a reniform with an open internal area **53** when in the deployed configuration. In an end view of a deployed device, the outer peripheral edge **55** is shown as the outermost edge of the wire frame **51**. The inner peripheral edge **54** of wire frame **51** is illustrated by the inner most edge of the open internal area **53** of the reniform shape. In a deployed configuration, the inner peripheral edge **54** will at least in part center itself within a cardiac defect or other tissue gap.

The wire frame **51**, as illustrated in FIG. **22**A, has a relatively short extended length prior to deployment. A delivery configuration length to deployed radius ratio is about 2.5. Such a device may be formed of similar materials as described previously and may be covered with a sealing member also described previously.

A lock loop **43** (illustrated in FIG. **18**) may be manufactured separately from the wire frame of the sealing device. The lock loop **43** may be formed of any material suitable for forming a sealing device wire frame. The lock loop **43** may be made of a different material or have a different wire diameter than that of the sealing device wire frame. Lock loop component **43** is manufactured with an eyelet **49** similar to the eyelets of the sealing devices described herein. Lock loop **43** may be attached to any sealing device wire frame prior to or post sealing member attachment. Any suitable method of attaching the separate lock loop component to the sealing device may be used. A method of manufacture of a lock loop component is described further in example 9.

FIGS. **23**A and B illustrates an embodiment comprising a proximal **608** and distal eyelet **610**, a plurality of wires **52**, wires forming a wire frame **61**, a self centering waist portion **614**, a reniform shape with an open internal area **53** (not shown) with an inner peripheral edge **54** and an outer peripheral edge **55** and a sealing member **604**. The self centering waist portion **614** of this embodiment forms a reniform with an open internal area **53** when in the deployed configuration. In an end view of a deployed device, the outer peripheral edge **55** is shown as the outermost edge of the wire frame **51**. The inner peripheral edge **54** of wire frame **51** is illustrated by the inner most edge of the open internal area **53** of the reniform shape. In a deployed configuration, the inner peripheral edge **54** will at least in part center itself within a cardiac defect or other tissue gap. This embodiment may be constructed with two frames previously described. This embodiment may be constructed of two frames wound in opposite directions or with two frames wound in the same direction. This and the other described wire frames may be constructed with the eyelets configured either as shown or with the eyelets turning toward the center area of the frame along the inner diameter of the device. Materials suitable for use as a sealing member **604** have been discussed previously. Sealing member may be attached to the frame in this and other described embodiments as discussed previously. Sealing member in this and other embodiments may be attached to the interior or inner surface of the wire frame and alternately to the exterior of the frame. The sealing member may be attached at only portions of the wire frame leaving certain portions of the wire frame more degrees of freedom of movement. Sealing member might also be attached to cover one side, portions or the entire wire frame. In certain instances, adjacent petals of the proximal disk overlap one another to create overlapping zones of the sealing member **604** with a portion of the sealing member **604** on a proximal disk side and another portion of the sealing member **604** on a distal disk side in the deployed configuration adjacent petals of the distal disk overlap one another with one another to create overlapping zones of the sealing member **604** with a portion of the sealing member on the distal disk side and another portion of the sealing member **604** on the proximal disk side in the deployed configuration. In addition, the waist portion **614** may have a diameter greater than a diameter of at least one of the proximal eyelet **202** and the distal eyelet **204** in an elongated configuration.

Another embodiment is shown in FIG. **25**B. This embodiment may be constructed with similar materials as those described previously. The embodiment comprises a wire frame **78**, first and second eyelets (**73** and **75** respectively), a sealing disc **77**, a plug region **79** and optionally a sealing member **604** (not shown). The embodiment may be constructed of any of the previously described wire frames. The sealing disc portion **77** of the embodiment is adapted to cover a wide range of opening sizes while the plug region **79** is adapted to conform to the anatomy into which it is inserted over its entire length. Sealing disc portion **77** has minimal deformation under radial pressure changes or radial pressure exerted upon the plug region **79**. Sealing disc **77** and plug region **79** have substantial directional independence due to the flexibility of waist portion **614**: that is, the longitudinal axis of the first eyelet **73** may be at significant offset with respect to the longitudinal axis of the second eyelet **75**.

Anchor components or fixation devices may be attached to any of the embodiments. Examples of anchor complements (**80** and **96**) are shown in FIGS. **26**A and **30**. FIG. **26**A illustrates an anchor component **80** with fixation elements configured to pierce, puncture or protrude into tissue adjacent to the device during or after deployment. Anchor component **96** in FIG. **30** illustrates fixation elements configured with blunt ends designed to grasp or engage the adjacent tissue without substantially protruding into the tissue. Other anchor components may be envisioned including anchor components configured to possess both piercing and grasping capabilities. Such an anchor component may be similar to that shown in FIG. **30** but instead of having looped wire arm, have a single wire arm with a looped end the end of which may be crimped or positioned to either be in the same plane as the single wire arm or to protrude from the plane thereby being available to pierce or puncture tissue. Anchor components may be attached at any eyelet of the device. Anchor components may be configured to bend in any direction. Single or multiple anchor components may be affixed to any device or wire frame in any combination. Said anchors can be designed to release the tissue for repositioning and/or retrieval. Further, when the sealing device is in a delivery configuration, the barbs may be collapsed to avoid catching on the catheter components during retrieval of the device.

FIG. **8** shows a perspective view of sealing device **100** attached to a delivery system including first tube **102**, third tube **104**, and a handle for deploying a sealing device **100**. FIG. **8** further illustrates a first linear actuator **802**, a flushing port **804**, the second linear actuator **806**, lock release actuator **808**, a housing **810** and a slot with a length in the housing **812**. First linear actuator **802** may have a variety of configurations which will be discussed further.

FIGS. **9**A-D are flow charts which describe the movements of the various components of the delivery system and attached sealing device **100** during use. Loading sealing device **100** into the delivery system prior to use is described in FIG. **9**A. Components of the delivery system handle are shown in FIGS. **8**, **10** and **11**. A clinician may flush the delivery system by attaching a syringe or other suitable implement onto flushing port **804** and filling the system with saline or any other appropriate flushing material. The first linear actuator **802** may then be moved in slot **812** in housing **810** against a spring **1100**. Spring **1100** may be configured as shown or may be formed as a leaf spring, stepped spring or any form commonly known in the arts. This action rotates the mandrel control lever **1000**, shown in FIG. **11**, about a slider rod **1102** to the side of housing **810**. This same motion moves the first linear actuator **802** free of distal notch **1104** in the sizing insert **1103** and prevents the second tube **108** from translating either proximally or distally. Sizing insert **1103** may be of any material with suitable mechanical properties.

Typical handles, handle components, tools or catheters used to deliver medical devices can comprise commonly known materials such as Amorphous Commodity Thermoplastics that include Polymethyl Methacrylate (PMMA or Acrylic), Polystyrene (PS), Acrylonitrile Butadiene Styrene (ABS), Polyvinyl Chloride (PVC), Modified Polyethylene Terephthalate Glycol (PETG), Cellulose Acetate Butyrate (CAB); Semi-Crystalline Commodity Plastics that include Polyethylene (PE), High Density Polyethylene (HDPE), Low Density Polyethylene (LDPE or LLDPE), Polypropylene (PP), Polymethylpentene (PMP); Amorphous Engineering Thermoplastics that include Polycarbonate (PC), Polyphenylene Oxide (PPO), Modified Polyphenylene Oxide (Mod PPO), Polyphenelyne Ether (PPE), Modified Polyphenelyne Ether (Mod PPE), Thermoplastic Polyurethane (TPU); Semi-Crystalline Engineering Thermoplastics that include Polyamide (PA or Nylon), Polyoxymethylene (POM or Acetal), Polyethylene Terephthalate (PET, Thermoplastic Polyester), Polybutylene Terephthalate (PBT, Thermoplastic Polyester), Ultra High Molecular Weight Polyethylene (UHMW-PE); High Performance Thermoplastics that include Polyimide (PI, Imidized Plastic), Polyamide Imide (PAI, Imidized Plastic), Polybenzimidazole (PBI, Imidized Plastic); Amorphous High Performance Thermoplastics that include Polysulfone (PSU), Polyetherimide (PEI), Polyether Sulfone (PES), Polyaryl Sulfone (PAS); Semi-Crystalline High Performance Thermoplastics that include Polyphenylene Sulfide (PPS), Polyetheretherketone (PEEK); and Semi-Crystalline High Performance Thermoplastics, Fluoropolymers that include Fluorinated Ethylene Propylene (FEP), Ethylene Chlorotrifluroethylene (ECTFE), Ethylene, Ethylene Tetrafluoroethylene (ETFE), Polychlortrifluoroethylene (PCTFE), Polytetrafluoroethylene (PTFE), Polyvinylidene Fluoride (PVDF), Perfluoroalkoxy (PFA). Other commonly known medical grade materials include elastomeric organosilicon polymers, polyether block amide or thermoplastic copolyether (PEBAX) and metals such as stainless steel and nickel/titanium alloys.

A distal notch **1104** and proximal notch **1106** in sizing insert **1103** may be used to aid in the positioning of the first linear actuator **802** in housing slot **812**. The distance between the two notches, **1104** and **1106** respectively, may be the length of sealing device **100** when it is elongated over second tube **108** prior to loading onto the delivery system. Sizing insert **1103** may be sized to accommodate a variety of device lengths and is preferably from about 22.28 cm long with a distance between the proximal end of distal notch **1104** and proximal end of proximal notch **1106** from about 6.25-13.32 cm. Notches **1104** and **1106** may be of any shape but are preferably rectangular.

The first linear actuator **802** is then moved to a mid point in slot **812** toward the proximal end of the housing **810**. This action causes the first tube **102** to move proximally and the sealing device **100** proximal end to move proximally, thus elongating sealing device **100**. First linear actuator **802** may be any shape (lever, ball) but is preferably shaped to accommodate a clinician's thumb. First linear actuator **802** may be constructed of any material with suitable mechanical properties but is preferably a material similar to that of sizing insert **1103**. A feature of the first linear actuator **802** are recessed teeth formed in the top portion of the first linear actuator **802** for securing retrieval cord **110**. This feature is preferred but optional. The teeth could be made into any tortuous path or have any shape desired to create resistance for retrieval cord **110** during loading, deployment, or retrieval of sealing device **100**. Corresponding protruding teeth (not shown) may be formed in the bottom surface of retrieval cord lock **803**. These teeth may fit together and hold the retrieval cord firmly. Other methods commonly known in the art for securing a small diameter cord may also be used and will be discussed in detail in a following section.

The first linear actuator **802** is then moved further proximally until the device is loaded in third tube **104**. During this action, spring **1100** pushes the first linear actuator **802** and the mandrel control lever **1000** to the left of slot **812** and into the proximal notch **1106** in sizing insert **1103**. The second tube **108** is free to move proximally with sealing device **100** and first tube **102**. As the first linear actuator **802** is moved proximally, the second tube **108**, sealing device **100** and first tube **102** slide or translate into the third tube **104**. After the first linear actuator **802** is in its proximal most position, the system may again be flushed with saline in the manner described above.

Alternate embodiments of first linear actuator **802** are shown in FIGS. **12**A-D. FIG. **12**A shows a perspective view of the alternate linear actuator **1108** in the locked retrieval cord position. Linear actuator **1108** is similar in construction to linear actuator **802** but features a retrieval cord locking ring **1110** and retrieval cord groove **1112**. FIG. **12**B depicts alternate embodiment **1114**, which is configured with a thumb wheel **1116** that extends beyond the sides of the linear actuator to facilitate easy manipulation. Thumb wheel **1116** is screwed onto a threaded post **1118** around which the retrieval cord is wound. Embodiment **1114** also contains a retrieval cord groove **1120** through which the retrieval cord is guided prior to securing it around threaded post **1118**. FIG. **12**C illustrates yet another embodiment **1122** that utilizes a side fitted threaded thumb wheel **1124** around which the retrieval cord is wound and secured to the actuator **1122** by the act of inserting the threaded post **1124** into a threaded aperture (not shown) in the side of the actuator **1122**. Prior to threading the retrieval cord around the threaded post **1124**, the retrieval cord is inserted through the retrieval cord groove **1126**. Yet another embodiment **1128** is shown in FIG. **12**D. Embodiment **1128** shows a linear actuator with molded thumb wheel **1130**. The thumb wheel **1130** extends slightly beyond the edges of the linear actuator facilitating manipulation of the linear actuator. The retrieval cord is inserted through cord groove **1132** and wound around a threaded post (not shown). The molded thumb wheel **1130** is then secured on the threaded post securing the retrieval cord.

Deploying sealing device **100** into a defect is described in FIG. **9**B. The first linear actuator **802** is moved distally until a stop is reached. This movement causes the first tube **102** and second tube **108** to move distally within the third tube **104**. The linear actuator **802** must then be moved to the right in slot **812**, against spring **1100**. When the linear actuator **802** is moved to the right, mandrel control lever **1000** rotates on slider rod **1102**. This action causes the linear actuator **802** to be free of the proximal notch **1106** in sizing insert **1103**. After this action, the linear actuator **802** is further translated distally. This causes the first tube **102** and proximal eyelet **202** of sealing device **100** to move distally. Also affected by this action is the distal end of sealing device **100** which is prevented from moving. The first tube **102** guides the device out of the third tube **104** to deploy the device in a defect. Moving linear actuator **802** distally to the end of slot **812** results in the entire sealing device being deployed. One skilled in the art would recognize that the steps described above could be halted and reversed at certain points to allow optimal positioning of sealing device **100**.

Locking the device is described in the flowchart illustrated in FIG. **9**C. The retrieval cord lock **803** would be unsnapped from the first linear actuator **802**. A clinician would grasp the second linear actuator **806** by gripping attached lock release actuator **808** and press it toward the middle of housing **810**. The second linear actuator **806** may be of any size or shape but is preferably sized to fit within a slot **1002** in the longitudinal surface of housing **810**. Linear actuator **806** is fitted with lock release actuator **808** by means of a snap fitting. Any means of attachment would suffice to fasten lock release actuator **808** to linear actuator **806** such as glue or construction as a molded part. Materials appropriate for both the second linear actuator **806** and lock release actuator **808** may be any material of suitable mechanical properties but are preferably similar to that of the previously mentioned handle components. Lock release actuator **808** is designed to enable a user to grip the device securely. Gripping may be aided by protrusions on the lateral sides of the lock release actuator **808**. These protrusions may be made of a similar material as that of the lock release actuator **808** or may be made of a material with a high coefficient of friction or of a material more compliant than that of lock release actuator **808**. These protrusions may also be made with grating, a roughening, a raised design, or striations in the surface in conjunction with the material listed above to further aid in the gripping of the device. These features on the surface of lock release actuator **808** may also be used to aid in gripping without the use of gripping protrusions and may be applied directly to the lateral surface of the second linear actuator **806**. Slot **1002** may be configured to have a stop to hold the second linear actuator **806** in a distal most position until lock release of the sealing device. A preferred stop is shown in FIGS. **10** and **11** in the form of a corrugated area but may also be any manner of mechanical stop. Slot **1002** may be of any length but preferably has a length sufficient to translate motion proximally about the width of the second linear actuator **806** plus about 3.18 cm. Slot **1002** may be any shape that would accommodate the second linear actuator **806**.

An alternate embodiment of second linear actuator **806** is shown in FIGS. **13**A and **13**B. Instead of gripping lock release actuator **808** and activating second linear actuator **806** a rotatable lock release actuator **1300** is gripped and rotated to affect lock release. The rotatable lock release actuator **1300** may contain a window **1302** which would prevent forward movement of the first linear actuator **802**. When rotated, lock release actuator **1300** allows the same actions as lock release actuator **806** shown in FIG. **10**.

Once the second linear actuator **808** is gripped, a clinician may move the second linear actuator **806** proximally. This action results in proximal movement of third tube **104**, mandrel control lever **1000**, sizing insert **1103** and second tube **108**. Second tube **108** moves proximally from between eyelets of the device. An alternate method of achieving this action would be to provide a twist mechanism to the distal end of the handle instead of a second linear actuator **806**. This twist mechanism would be provided with a slot that allows for the same movement of the third tube **104**, mandrel control lever **1000**, sizing insert **1103** and second tube **108** as the second linear actuator **806**.

Once lock release has been achieved, the retrieval cord lock **803** is then twisted to remove it from the first linear actuator **802** and pulled until the retrieval cord **110** is free of the delivery system. Retrieval cord **110** is attached to the retrieval cord lock **803** at one end. Retrieval cord **110** may be constructed of any material with suitable mechanical properties such as Kevlar®, flexible metal wire, polymers and the like. A preferably material for retrieval cord **110** is an ePTFE fiber. Retrieval cord lock **803** may be configured in a variety of shapes and sizes. Possible retrieval cord locks may be designed to provide a slot in the linear actuator **802** through which the retrieval passes. In one configuration, the retrieval cord is secured by passing the cord through a slot or hole in the axis of the thumb wheel disposed in the linear actuator **802** and tightened by twisting the thumb wheel. An alternate configuration would provide a slide lock that binds the retrieval cord between the lock and the linear actuator **802** using friction. A preferred design would be to secure the retrieval cord between teeth formed in the retrieval cord lock as shown in FIG. **11**.

Materials suitable for constructing retrieval cord lock **803** are similar to that used to construct housing **810** and other handle components. As mentioned previously, retrieval cord lock **803** preferably has teeth or protrusions that correspond to indentations in linear actuator **802** for the purpose of gripping retrieval cord **110**. Retrieval cord lock **803** may be configured in a variety of shapes to enable retrieval cord **110** to be secured. A preferred configuration would include apertures through the retrieval cord lock **803** to allow retrieval cord **110** to be threaded therethrough and knotted. After twisting the retrieval cord lock **803**, it is pulled until the retrieval cord **110** is removed from the delivery system.

Prior to the step four described in FIG. **9**C, the sealing device **100** may be retrieved as described in the flowchart illustrated in FIG. **9**D. The retrieval cord lock **803** may be snapped into the first linear actuator **802**. This serves to lock the retrieval cord **110** in place. The clinician then moves the first linear actuator **802** to the right edge of slot **812**. The first linear actuator **802** moves in slot **812** to the right pressing on spring **1100** while the mandrel control lever **1000** rotates on the slider rod **1102** to the right of the handle. Slider rod **1102** is preferably of a round cross-section but one skilled in the art would recognize that a variety of cross-sectional shapes (e.g. square or triangular) would be acceptable. Slider rod **1102** could also be configured in the shape of a crown spring **1400** as shown in FIGS. **14**A and B. The spring could be inserted in a slot **1402** through the linear actuator to allow fore and aft translation of the linear actuator. An alternate embodiment of spring **1100** may be a spring molded as an integral part **1500** of first linear actuator **802** as illustrated by FIG. **15**. Another embodiment of spring **1100** is shown in FIG. **16**. In this configuration, a spring **1600** is attached to housing **810** and pushes on the first linear actuator **802** in key positions. As stated above, one skilled in the art would recognize the appropriate materials for use as a spring or molded part. The first linear actuator **802** is free of distal notch **1104** and the second tube **108** is prevented from moving. The first linear actuator is moved proximally by the clinician causing first tube **102** to move proximally. This motion translates the proximal end of sealing device **100** proximally elongating the device **100** and allowing it to be pulled into the third tube **104**.

EXAMPLES

Without intending to limit the scope of the invention, the following examples illustrate how various embodiments of the invention may be made and/or used.

Example 1

A sealing device similar to FIG. **1** was manufactured using the following components and assembly process.

An expanded polytetrafluoroethylene material was obtained with the following properties:

Methanol bubble point of 1 psi

Mass/area of 2.2 grams/square meter

Longitudinal maximum load of 1.6 kg/inch

Thickness of 0.0003 inch

Longitudinal matrix tensile strength of 92000 psi

The following test methods and equipment were used to determine the above-mentioned properties: Methanol bubble point was measured using a custom built machine with a 1 inch diameter foot, a ramp rate of 0.2 psi/second and a liquid media of methanol. Length and width of the material were measured using a metal ruler. Mass/area was measured using a balance (Model GF-400 Top Loader Balance, ANG, San Jose Calif.) with a 36×5 inch sample. Longitudinal maximum load was measured using a materials test machine (Model 5564, Instron, Grove City, Pa.) equipped with a 10 kg load cell. The gauge length was 1 inch and the cross head speed was 25 mm/minute. Sample width was 1 inch. Longitudinal tensile test measurements were taken in the length direction of the material. Thickness was measured using a thickness gauge (Mitutoyo Digital Indicator 547-400) with a foot diameter of ¼ inch. The longitudinal matrix tensile strengths (MTS) were calculated using the following equation: Density was calculated using the formula, density=mass/volume.

$$\text{Matrix Tensile Strength} = \frac{(\sigma_{sample}) * (\rho_{PTFE})}{(\rho_{sample})}$$

where:

ρ_{PTFE} = 2.2 grams/cc

σ_{sample} = (Maximum Load/Width)/Thickness

ρ_{sample} = (Mass/Area)/Thickness

An expanded polytetrafluoroethylene with a thin layer of FEP (fluorinated ethylene propylene) material was obtained with the following properties:

Mass/area of 36.1 grams/square meter

Maximum Load, Longitudinal of 12.6 kg/inch

Maximum Load, Transverse of 0.3 kg/inch

Thickness of 0.0012 inch

The following test methods and equipment were used to determine the above-mentioned properties: Material was weighed using a precision analytical balance (Model GF-400 Top Loader Balance, ANG, San Jose Calif.) with a sample area of 36×1 inch sample. Length and width of the material were measured using a metal ruler. Material thickness was measured using a digital thickness gauge (Mitutoyo Digital Indicator 547-400) with a foot diameter of ¼ inch. Maximum transverse load was measured using a materials test machine (Model 5564, Instron, Grove City, Pa.) equipped with a 10 kg load cell. The sample width was 1 inch, the gauge length was 1 inch and the cross head speed was 25 mm/minute. Maximum longitudinal load was measured using a materials test machine (Model 5564, Instron, Grove City, Pa.) equipped with a 200 kg load cell. The sample width was 1 inch, the gauge length was 1 inch and the cross head speed was 25 mm/minute. Longitudinal tensile test measurements were taken in the length direction of the material and transverse tensile test measurements were taken in the direction orthogonal to the length direction.

A distal eyelet was formed by first obtaining a length of 10% platinum drawn filled nitinol wire (Fort Wayne Metals, Fort Wayne, IN.) with a diameter of about 0.23 mm. This wire was labeled "first wire". A free end of the first wire was doubled on itself to create an open-ended loop and the open-ended loop was inserted into the button. The button was then inserted onto the keyed center pin. The button was shaped to have an opening through the center to accommodate the keyed center pin and to have features that allow it to rest securely in the winding jig. The keyed center pin (major axis of about 0.51 mm and minor axis of about 0.25 mm and length of about 10.16 mm) was then inserted in the center of a winding jig. The keyed center pin was fabricated from high strength steel (Super Cobalt HSS Tool Bit, MSC#56424278, Seco Fagersta). The steel was tempered per manufacture's instructions at 1475° F. for one hour. The winding jig and button were fabricated in house from corrosion resistant tool steel.

A second length of the same type of drawn filled nitinol wire was obtained and labeled "fifth wire". The first, fifth and an additional three wires were tensioned by attaching weights to the wire ends. The first wire and the fifth wire were then wound around the free end of the first wire one full revolution. The three additional wires were introduced to the winding jig and all five wires were wound around the free end of the first wire to a height of about 1.98 mm.

A distal disk was then formed by separating the five wires and securing them in radial grooves around the circumferential edge of the winding jig. A radius was formed with the dimensions of 15 mm. Each wire formed one petal of the distal disk. The radius on the curvature of the petals was maximized in order to minimize sharp bend angles in the wire.

A center eyelet was formed by grouping the wires together and winding them around the free end of the first wire and the keyed center pin to a height of about 1.98 mm. The wires were then separated and secured in radial grooves around the circumferential edge of the winding jib creating a proximal disk with a radius of 15 mm.

A proximal eyelet was formed by again grouping the five wires and winding them around the free end of the first wire and the keyed center pin to a height of about 1.98 mm. The five wires were then separated and secured by placing a stainless steel plate on top of the wires and locking down the plate with screws. The free end of the first wire was then wound one revolution around a stainless steel pin with a diameter of about 3.18 mm and secured similarly to the other five wires.

The jig with sealing device was then removed from the stabilizing fixture and placed in an oven (BlueM SPX Electric Forced Air Convection Oven) and the wires were thermally shape set as commonly known in the arts. The device and jig were then water quenched. The secured wires were released from the securing plate and the device was chilled and removed from the jig and keyed center pin. The device was then placed on a piece of flattened PEEK (polyetherether ketone) and trimmed by hand to the outer diameter of the distal eyelet. The lock loop was trimmed by hand to a point just beyond one complete revolution and pulled through the proximal and center eyelets.

The device was pushed from the PEEK mandrel onto a keyed stainless steel process mandrel with an oval cross section. The mandrel was produced from flattened stainless steel wire (Ft. Wayne Metals, Fort Wayne, IN) with an oval cross-section to have a 45° clockwise twist between the proximal eyelet and the center eyelet and a second 45° clockwise twist between the center eyelet and the distal eyelet.

The process mandrel and device were then placed in a stabilizing fixture which was placed in a FEP powder coating machine (C-30, Electrostatic Technology, Inc., Bradford, CN) and processed until coated completely. Excess FEP powder was removed from the device. The FEP was vacuumed from the lock loop, process mandrel and bumper. The process mandrel and device were removed from the stabilizing fixture, placed into an oven and baked to set the FEP coating as commonly known in the arts.

A hollow core film mandrel (35.99 mm O.D. 76.2 cm long stainless steel) was obtained. Expanded polytetrafluoroethylene material with a slit width of 22.22 mm was obtained and loaded onto a spiral wrapping machine. The machine was manufactured in house to wrap PTFE (polytetrafluoroethylene) material at any desired angle, tension and rate. The mandrel was loaded onto the wrapping machine and the material was wrapped three times around the circumference of the hollow core mandrel. The material was then wrapped around the mandrel at an angle of about 8° for the length of the mandrel. The direction of wrapping was reversed and the material over wrapped at the same angle. The third and fourth layers were wrapped in the same manner with the seams offset. The mandrel was removed from the wrapping machine, inserted in an oven and baked at 370° C. for 45 minutes. The wrapped mandrel was removed from the oven and allowed to cool to room temperature. The resulting PTFE tube was removed from the mandrel.

The PTFE tube was then cut to about 140 mm and hand stretched to a desired length 155 mm. The PTFE tube was then pulled over the frame. The PTFE tube was then crimped onto the center eyelet and then crimped onto the distal and proximal eyelets.

An expanded polytetrafluoroethylene with a thin layer of FEP (fluorinated ethylene propylene) material was then wrapped four times around the eyelets starting with the center eyelet. The wrapped eyelets were tacked into place a soldering iron. The PTFE tube was then heat set for 3 minutes at 320° C. and trimmed to the outer most points of the proximal and distal eyelets. The device was removed from the mandrel.

Example 2

A sealing device similar to FIG. **6** was manufactured using the following components and assembly process.

Expanded polytetrafluoroethylene and expanded polytetrafluoroethylene with a thin layer of FEP (fluorinated ethylene propylene) materials similar to that described in Example 1 were obtained.

A distal eyelet was formed by first obtaining a length of 10% platinum drawn filled nitinol wire (Fort Wayne Metals, Fort Wayne, IN.) with a diameter of about 0.23 mm. This wire was labeled “first wire”. A free end of the first wire was doubled on itself to create an open-ended loop and the open-ended loop was inserted into the button. The button was then inserted onto the keyed center pin. The button was shaped to have an opening through the center to accommodate the keyed center pin and to have features that allow it to rest securely in the winding jig. The keyed center pin (major axis of about 5.79 mm and minor axis of about 0.25 mm and length of about 10.16 mm) was inserted in the center of a winding jig. The keyed center pin was fabricated from high strength steel (Super Cobalt HSS Tool Bit, MSC#56424278, Seco Fagersta). The winding jig and button were fabricated in house from corrosion resistant tool steel.

A second length of the same type of drawn filled nitinol wire was obtained and labeled “fifth wire”. The first, fifth and an additional three wires were tensioned by attaching weights to the wire ends. The first wire and the fifth wire were then wound around the free end of the first wire one full revolution. The three additional wires were introduced to the winding jig and all five wires were wound around the free end of the first wire to a height of about 1.98 mm.

A device was then formed by separating the five wires and securing them in radial grooves around the circumferential edge of the winding jig. A radius was formed with the dimensions of 15 mm. Each wire made an entire revolution around the winding jig.

A proximal eyelet was formed by grouping the five wires and winding them around the free end of the first wire and the keyed center pin to a height of about 1.981 mm. The five wires were then separated and secured by placing a stainless steel plate on top of the wires and locking down the plate with screws. The free end of the first wire was then wound one revolution around a stainless steel pin with a diameter of about 3.18 mm and secured similarly to the other five wires.

The jig with sealing device was removed from the stabilizing fixture and placed in an oven (Blue M SPX Electric Forced Air Convection Oven) where the wires were partially thermally shape set as commonly known in the arts. The device and jig were then water quenched. The secured wires were released from the securing plate and then the device was chilled and removed from the jig and keyed center pin. The lock loop was trimmed by hand to a point just beyond one complete revolution and pulled through the proximal and center eyelets.

The device was pushed from the PEEK mandrel onto a keyed stainless steel transfer mandrel with an oval cross section. The mandrel was produced from flattened stainless steel wire (Ft. Wayne Metals, Fort Wayne, IN) with an oval cross-section. The device was then partially removed from one end of the transfer mandrel. The removed device end was twisted approximately 180° clockwise and repositioned on the transfer mandrel. The device and transfer mandrel were placed in an oven (Blue M SPX Electric Forced Air Convection Oven) where the wires were thermally shape set as commonly known in the arts.

The transfer mandrel and device were then placed in a stabilizing fixture which was placed in a FEP powder coating machine (C-30, Electrostatic Technology, Inc., Bradford, CN) and processed until coated completely. Excess FEP powder was removed. FEP powder was vacuumed from the lock loop, process mandrel and bumper. The transfer mandrel and device were then removed from the stabilizing fixture, placed into an oven and baked to set the FEP coating as commonly known in the arts.

A hollow core film mandrel (35.99 mm O.D. 76.2 cm long stainless steel) was obtained. An ePTFE material with a slit width of 22.24 mm was obtained and loaded onto a spiral wrapping machine. The machine was manufactured in house to wrap ePTFE film at any desired angle, tension and rate. The mandrel was loaded onto the wrapping machine and the film was wrapped three times around the circumference of the hollow core mandrel. The ePTFE material was then wrapped around the mandrel at an angle of about 8° for the length of the mandrel. The direction of wrapping was reversed and the material over wrapped at the same angle. The third and fourth layers were wrapped in the same manner with the seams offset. The mandrel was removed from the wrapping machine, inserted in an oven and baked at 370° C. for 45 minutes. The wrapped mandrel was removed from the oven and allowed to cool to room temperature. The resulting ePTFE tube was removed from the mandrel.

The ePTFE tube was then cut to about 140 mm and hand stretched to a desired length 155 mm. The ePTFE tube was then pulled over the frame. The ePTFE tube was then crimped onto the distal and proximal eyelets. An ePTFE with a thin layer of FEP (fluorinated ethylene propylene) material was then wrapped four times around the eyelets. The wrapped eyelets were tacked into place a soldering iron. The ePTFE tube was then heat set for 3 minutes at 320° C. and trimmed to the outer most points of the proximal and distal eyelets. The device was then removed from the mandrel.

Example 3

A handle assembly similar to FIG. **8** was manufactured using the following components and assembly process.

Components for the handle assembly were fabricated using an injection molding process. The parts were fabricated by Contour Plastics (Baldwin, WI) using Lustran® 348. This material was suitable for use in medical devices and has an advertised tensile strength of 48.2 MPa and a tensile modulus of 2.62 GPa. Nine parts were fabricated using this injection process and Lustran® 348. The parts included the second linear actuator, flushing gasket retainer, a first linear actuator, retrieval cord lock, mandrel control lever, left body housing, sizing insert, right body housing, and a lock release actuator.

Other materials required for the assembly of the handle were purchased items. A catheter tube formed with a layup process commonly known in the arts was ordered (Teleflex Medical, Jaffrey, NH) with an I.D. of 0.048 mm and an O.D. of 0.33 mm and a platinum iridium marker band placed near the end of the distal tip. The main body of the catheter tube was Pebax® 7233 tube with PTFE liner and stainless steel braid (65 PPI) and the distal most 20.32 mm of the catheter tube was comprised of 6333 Pebax®(0.027 mm I.D. and an 0.033 mm O.D.) and a curve in the distal end (39.98 mm radius). A guidewire port formed by a laser was placed in the catheter tube proximal of the marker band. A flushing gasket or u-cup type gasket made of silicone (22.99 mm depth, I.D. tapered from 2.89 mm to 1.85 mm I.D. tapered from 6.71 mm to 7.75 mm) was procured from Apple Rubber of Lancaster, NY. A flushing port (Merit Medical, South Jordan, UT) having an about six inch flexible pvc (polyvinyl chloride) tube with a 3.18 mm O.D. female luer connector was obtained. A quick set cyanoacrylate adhesive was supplied from in-house stock. Stainless steel hypotubes were ordered from Small Parts, Inc. (1.45 mm O.D., 1.30 mm I.D., length of 30.48 cm.). Slider rods (PTFE coated stainless steel hypotubes, 3.18 mm O.D., 1.65 mm I.D., length of 33.02 cm) were procured from Applied Plastics. Control springs (PTFE-coated stainless steel leaf springs, thickness 0.10 mm, minor flange length 5.33 mm, major flange length 10.11 mm, overall length 15.88 mm) were ordered from Incodema of Ithaca, N.Y.

The remainder of the components were supplied from in house stock or manufactured in house. All triple lumen tubes were manufactured of Pebax® 7233 with 20% barium sulfate. Both triple lumen tubes had an O.D. (outer diameter) of 0.25 mm. One triple lumen tube had round lumens with two I.D.s (inner diameters) of 0.035 mm and one I.D. of 0.15 mm. One triple lumen tube had one lumen with an oval cross-section with two I.D.s of 0.036 mm and one I.D of 0.127×0.07 mm. Stainless steel PTFE coated (polytetrafluoroethylene) process mandrels were manufactured in house. One process mandrel had a cross-sectional shape that transitioned from round (O.D. of 0.16 mm) to oval (O.D. of 0.14×0.07 mm). PTFE covered stainless steel wire was procured from in house stock (O.D. 0.03 mm). Standard luer fittings were obtained from in house stock. A PEEK (polyetheretherketone) second tube extrusion was obtained from in house stock with an oval cross-section of 1.27×0.69 mm O.D.

A first tube was made in the following manner. One triple lumen extruded tube with round lumens was obtained. Another triple lumen extruded tube was obtained with one lumen having an oval cross-section. A stainless steel processing mandrel was also obtained having a cross-sectional shape, which transitions from round (O.D. of 1.52 mm), to oval (O.D. of 1.39×0.81 mm). Both extruded tubes were loaded onto the mandrel with the mandrel being inserted through the larger lumen on both tubes. Two small PTFE covered stainless steel wires were inserted through the smaller lumens of both extruded tubes. The mandrel and tubes were inserted into a RF (radio frequency) die (2.51 mm I.D., 4.45 mm length, fabricated from D**2** tool steel). The junction of the two catheters was positioned in the center of the RF die. The RF die and mandrel was placed in the middle of an RF coil on an RF welding machine (Hot Shot I, Ameritherm Inc., Scottsville, NY) and welded as commonly known in the art. When the components had reflowed, pressure was applied to each end of the extruded tubes to meld the junction of the tubes. The die was then sprayed with compressed air to cool the die and to set the Pebax®. The extruded tube and die were removed from the RF machine and the extruded tube was removed from the die. The process mandrel and wires were removed from the lumens of the extruded tube.

A lubricious coating may be applied to the second tube. A silicone mold release spray (Nix Stix X-9032A, Dwight Products, Inc., Lyndhurst NJ) may be sprayed onto about the distal 30 cm of the second tube and allowed to dry at ambient temperature under a fume hood.

A third tube sub-assembly was made in the following manner. A catheter tube was bisected with a straight razor at approximately 6.35 cm from the proximal end of the catheter tube. A male and female in-line luer connector (Qosina, Edgewood, N.Y.) was obtained and drilled to an I.D. of 3.45 mm. U.V. (ultra-violet) cured adhesive (Loctite **3041**) was applied to the bisected ends of the catheter tube and the drilled luer fittings were attached. The adhesive was cured per manufacture's instructions and the luer fittings were screwed together.

The second linear actuator sub-assembly was made in the following manner. The second linear actuator, flushing port, flushing gasket retainer and silicone flushing gasket were obtained. The flushing gasket was inserted into the back of the second linear actuator with the u portion of the flushing gasket facing distally. The flushing gasket retainer was fitted over the top inside the second linear actuator. Cyanoacrylate glue was applied around the gasket retainer to hold the gasket retainer in place. The flushing port was placed into an aperture in the second linear actuator and an U.V. cure adhesive was applied and cured according to manufactures instructions.

A first tube was obtained and cyanoacrylate was applied to the outside surface of the round I.D. section of the catheter in a 2.54 cm band from the end. The catheter was then inserted into the distal end of the control shuttle until the catheter became flush with the back of the control shuttle. The catheter was oriented so that the two small lumens were horizontal and on the top portion of the round lumen. The retrieval cord lock was snapped onto the control shuttle.

The second tube sub-assembly was manufactured in the following manner. A four inch piece of 0.033 mm diameter nitinol wire was inserted into the second tube extrusion. The second tube extrusion with wire insert was inserted into a hypotube. The distal end of the hypotube was crimped by hand three times.

The distal end of the first tube was threaded through the top of the mandrel control lever and through the top aperture on the distal end of the mandrel control lever. The distal end of the second tube was threaded into the proximal end of the control catheter. The second tube was pushed into the first tube until about 4 in. of hypotube were protruding from the end of the control catheter. A cyanoacrylate adhesive was applied to the proximal end of the hypotube over about a 12.7 mm section. This section was inserted into the top aperture in the proximal end of the mandrel control lever until flush with the back of the mandrel control lever. The distal end of the first tube was then threaded into the proximal end of the second linear actuator. The second linear actuator was moved to the back most position on the control catheter.

A sizing insert was then fitted into a left body shell. The sizing insert was oriented so that the groove in the sizing insert fit over the ridge in the left shell. The catheter sub assembly was placed into the left body shell so that the mandrel control lever fit into the sizing insert and the second linear actuator fit into the slot in the distal end of the left body shell. A slider rod was inserted through the openings in the sizing insert, mandrel control lever, control shuttle and the second linear actuator. The slider rod was made to rest on two supports in the left body shell. The control spring was inserted into the right body shell so that it fit into the opposing teeth. The right body shell was then placed onto the left body shell and the two were snapped together. Two screws (#4-24×½ in. thread-forming Pan Head) were inserted into the available apertures on the left body shell and tightened. The lock release actuator was snapped into place on the right tab of the second linear actuator with a drop of cyanoacrylate adhesive to ensure that it remained attached.

The second linear actuator, control shuttle, and the mandrel control lever were moved to their forward most positions. The second linear actuator was pulled back and then returned to its forward position. The distal end of the first tube was trimmed by hand with a razor blade to 1.27 mm measured from the tip of the third tube. The sizing insert was pushed forward. The second tube was trimmed by hand using a razor blade to a length of about 0.76 mm measured from the distal most end of the control catheter. An about 4 inch long piece of nitinol wire (0.30 mm diameter) was obtained. A cyanoacrylate adhesive was applied into the tip of the second tube with an elongated applicator tip. The nitinol wire was inserted into the tip of the locking and another piece of wire was used to insert the nitinol wire about 2 mm into the second tube. The cyanoacrylate adhesive was allowed to cure.

The second linear actuator was pulled back and a slot was punched out of the control catheter. The slot had a width that was about the same width as the small axis of the oval lumen of the catheter. A razor was used to skive the slot to a final length of about 19.05 mm. The second linear actuator and the sizing insert were then moved to a forward position.

A retrieval cord approximately 3.05 m long (PTFE fiber with a 0.25 mm O.D.) and a 1.52 m (0.15 mm O.D.) nitinol wire were obtained. The nitinol wire was inserted into one of the 0.04 mm lumens in the first tube and pushed through until it came out into the handle. Tweezers were used to grasp the wire and pull it out of the slot in the handle. About 76.2 mm of wire were made to protrude from the distal end of the control catheter. A loop was formed in the wire by inserting the loose end into the same lumen at the distal end of the control catheter. About 76.2 mm of retrieval cord was then threaded through the resulting loop. The nitinol wire was pulled through the catheter until the retrieval cord protruded into the handle.

A sealing device was obtained. A needle of a type commonly used for sewing was threaded with the retrieval cord and the needle was inserted through the PTFE bag opposite the lock loop and through the lumen of the proximal eyelet of the sealing device. The nitinol wire was then threaded through the remaining unoccupied 0.04 mm lumen in the first tube with the loop end of the wire pointing distally. The needle was removed from the retrieval cord and the cord was threaded through the loop on the nitinol wire. The retrieval cord was then pulled through the catheter in the manner described previously.

The control shuttle was retracted approximately 12.7 mm. The second tube was then threaded through the eyelets of the device. Tweezers were used to grasp the retrieval cord and pull in to the outside of the handle. A loop was formed in a portion of small diameter nitinol wire. The loop was inserted through an aperture in the distal portion of the top of the control shuttle. The retrieval cord was threaded through this loop and pulled through the aperture in the distal portion of the control shuttle. The retrieval cord lock was removed from the control shuttle and one free end of the retrieval cord was inserted through the aperture in the retrieval cord lock from the bottom. Four over hand knots were tied in the cord. Excess cord was trimmed by hand and the retrieval cord lock was returned to the control shuttle.

The remaining free retrieval cord was pulled until all slack was gone. The remaining free end of the retrieval cord was inserted into an aperture in the front of the top of the control shuttle. The retrieval cord was pulled until taught and the retrieval cord lock was snapped closed. The cord was trimmed by hand to about 20.32 cm.

The second tube was flared by obtaining a soldering iron with a sharp tip and heating it to about 500° F. The tip of the iron was inserted into the second tube until a flare was created that was approximately 1.39 mm in diameter. The locking loop on the device was chilled.

Example 4 (Tear Drop):

A length of 0.23 mm diameter nitinol wire (Fort Wayne Metals, Fort Wayne, IN.) was obtained. The specific length of the wire was not measured, it is only necessary that the wire be long enough to double through the feed holes described in the following paragraph. The wire was obtained having been electro polished.

A base jig **8** as described in FIG. **17** was obtained. The base jig was secured in a chuck of a lathe and center pin **22** was inserted into center pin hole **24** far enough to securely seat it. A knot was tied into one end of one length of a length of nitinol wire and the unknotted end was fed through a wire feed hole **10**. Two additional lengths of nitinol wire were folded in half and the free ends were fed through the remaining four feed holes **12**, **14**, **16**, **18**. Weights **20** were attached to the free ends of the five wires to hold the wires taut and in place.

The other end of center pin **22** was located inside the center hole **28** of tail stock support **26** which was chucked into the tail stock, wherein the closed face **30** of the tail stock support **26** faced the base jig **8**. The base jig **8** and tail stock support **26** were positioned about 5 cm apart. A wire guide **34** was used to prevent the wires from crossing. The base jig **8** was positioned so that the wire feed holes **10**, **12**, **14**, **16**, **18** were oriented vertically above the center pin **22** and the wires were positioned on the trailing side of the center pin **22**. The wires were wrapped twice around the center pin **22** and left to hang parallel to the wire feed holes.

The petal jig hole **36** was rotated 720°. The petal jig **38** was inserted into the petal jig hole **36**. Without crossing the wires, the wires were wrapped counter clockwise around the petal jig **38** past the tear drop pin **39** and around the circumference of the tear drop pin **39**. The wires were wrapped around the outer circumference of the petal jig **38** to bring the wire between the petal jig **38** and the center pin **22**. They were then wrapped around the center pin **22** twice.

The wires were placed under anchor plate **11**. The anchor plate **11** was secured with Allen head screws **14**. The wires were cut on the weight **20** side of the anchor plate **11**.

With the weights **20**, the tail stock support **26**, and the wire guide **34** removed, the assembly was placed in a convection oven set to 475° C. for 14 minutes.

The assembly was removed from the oven and quenched in water. The jigs were disassembled and the article was removed.

The wire ends were trimmed to the eyelets and the petals were fanned in the same direction as the helical winding, such that each petal was oriented 72° relative to the adjacent petal.

The article was powder coated with FEP powder (obtained from in house stock) in the following manner. A 2 mm outer diameter steel hollow mandrel was obtained of sufficient length to hold the article and have remaining length to extend into the commercial blender. The mandrel was inserted into the center hole of the article. One end the mandrel was grounded. A commercial blender (Variable Speed Lab Blender, Waring, Torrington, Conn.) was obtained and a quantity of FEP powder was added, leaving the tip of the blender blades exposed. The article and mandrel were suspended in the center of the blender, the lid was replaced, and the blender was turned on to the highest setting for about 5 seconds. The article and mandrel were removed, the mandrel was tapped to achieve a more uniform powder coating, the powder coating was vacuumed from the madrel and the article and mandrel were then hung inside a convection oven set to 320° C. for 3 minutes. The article and mandrel were removed from the oven, allowed to cool, and excess FEP was removed from the article, the mandrel was removed.

In a separate process a lock loop **43** (illustrated in FIG. **18**A) was manufactured. The lock loop **43** was inserted through a hypotube **45** (smaller than the ID of the eyelets) with the looped end **47** of the lock loop **43** straightened. The hypotube **45** was inserted through the eyelets from the distal end until lock loop eyelet **49** is situated over the distal eyelet **608** of the device. The hypotube was removed.

A crimped mandrel **41** (shown in FIGS. **18**B and **18**C) was inserted into the article through the eyelets with the lock loop **43** along the outer length of the mandrel **41**. The article was extended in length on the mandrel by grasping the proximal and center eyelets with tweezers. The eyelets were fixed in place by positioning them beyond the crimps in the mandrel.

Next, a porous ePTFE film having the following properties was obtained:

Methanol bubble point of 0.7 psi
Mass/area of 2.43 grams/square meter
Longitudinal matrix tensile strength of 96000 psi
Matrix tensile strength in the orthogonal direction of 1433 psi
Longitudinal maximum load of 1.6 kg/inch
Thickness of 0.00889 mm

Methanol bubble point is measured using a custom built machine with a 1 inch diameter foot, a ramp rate of 0.2 psi/second and a liquid media of methanol. Length and width of the material are measured using a metal ruler. Mass/area is measured using a balance (Model GF-400 Top Loader Balance, ANG, San Jose Calif.) with a 36×5 inch sample. Longitudinal maximum load is measured using a materials test machine (Model 5564, Instron, Grove City, Pa.) equipped with a 10 kg load cell. The gauge length is 2.54 cm and the cross head speed is 25 mm/minute. Sample width is 2.54 cm. Longitudinal tensile test measurements are taken in the length direction of the material. Thickness is measured using a thickness gauge (Mitutoyo Digital Indicator 547-400) with a foot diameter of ¼ inch. The longitudinal matrix tensile strengths (MTS) are calculated using the following equation: Density is calculated using the formula, density=mass/volume as described in a previous example.

A 30 mm film tube is constructed from the ePTFE material in the following manner. For a 25 mm diameter device, a film with a slit width of about 1.905 cm is wound on a 30 mm OD mandrel. The amount of film overlap is not critical but no overlap of the edges is unacceptable. The film tube is then removed from the mandrel and stretched to make the ID of the tube to be about 25 mm. The film tube was slipped over the tensioned article and using ePTFE film, the ends of the tube were cinched around the center of the device then the eyelets.

Another porous ePTFE film, having a layer of FEP, was obtained having the following properties:

Mass/area of 36.1 grams/square meter
Maximum Load, Longitudinal of 12.6 kg/inch
Maximum Load, Transverse of 0.3 kg/inch
Thickness of 0.030 mm

Test methods for the above tests are described previously. The FEP thickness in the film is about 62.5%. FEP thickness (%) is calculated as ratio of the FEP thickness and the film thickness. The reported value represents the average measurements for five samples. FEP thickness and film thickness is measured from scanning electron microscope images of cross sections of the ePTFE/FEP laminate material in the following manner. The magnification is chosen to enable the viewing of the entire film thickness. Five lines perpendicular to the horizontal edge of the image are randomly drawn across the full thickness of the film. Thickness is determined by measuring the thickness of the FEP and the thickness of the film.

A 2 mm wide strip of this FEP-coated ePTFE film, with the FEP side down, was wrapped four times around the cinched portions and heated with a soldering iron to bond the film layers together.

The article and mandrel were placed inside a convection oven set to 320° C. for 3 minutes and then removed and allowed to cool. The excess ePTFE material was trimmed and the article removed from the mandrel.

Example 5 (Long **5** Wire):

An article was constructed in the same manner as example 1 with the following exceptions:

Instead of using petal jig **38**, self centering petal jig **39** (FIG. **19**) was used wherein jig **39** was placed over the center pin **22** and tail stock support **26** was introduced prior to wrapping the first eyelet. After wrapping the first eyelet self centering petal jig **39** was inserted into petal jig hole **36**. The wire was wrapped around the perimeter of petal jig **39** to form petals and wrapping was continued around center pin **22** to create a second eyelet. A fully extended final article of this example is shown in FIGS. **20**A and B.

Example 6 (Long **10** Wire):

An additional article **32** shown in FIG. **21** was constructed using two intermediate (i.e., not powder coated) articles (one inner and one outer) of example 5 wherein, the intermediate articles were wrapped in opposite directions. Additionally the inner intermediate article was manufactured such that the eyelets of the inner intermediate article would fit within the eyelets of the outer intermediate article. Prior to FEP coat, the inner and outer intermediate articles were nested using the following method:

In order to achieve nesting of the two intermediate articles, the distal eyelets and the proximal eyelets must be nested. Inner intermediate article was positioned at the end of a straight, circular mandrel. One eyelet of the outer intermediate article was positioned over an eyelet of the inner intermediate article and both intermediate articles were repositioned to the other end of the mandrel. The remaining eyelet of the outer intermediate article was positioned over the remaining eyelet of the inner intermediate article. They were arranged such that the overlapping wires were equally spaced (about 72° apart) thereby creating a frame. The frame was subsequently FEP coated and covered with an ePTFE bag in order to create the final article.

Example 7 (Short **6** Wire):

With the following exceptions, an article similar to that as described in example 1 was created: A similar jig **50** illustrated in FIG. **22**B as previously described in example 1 was obtained. The petal jigs **52** and waist jig **54** were positioned as shown in FIG. **22**B. The wire wrapping process is shown in the wire path **56** depicted in FIG. **22**B, wherein the wire starts at anchor points **57** and ends at eyelet pin **58** (not shown) that is inserted into eyelet pin hole **59**. The wire is wrapped 720° around the eyelet pin at the start of the device wrapping and at the finish of the device wrapping. The fully extended final article **51** of this example is shown in FIG. **22**A.

Example 8 (Short **12** Wire):

An additional article (FIGS. **23**A and **23**B) was constructed using two intermediate (i.e., not powder coated) articles (one inner and one outer) of example 7 wherein, the intermediate articles were wrapped in opposite directions. Additionally the inner intermediate article was manufactured such that the eyelets of the inner intermediate article would fit within the eyelets of the outer intermediate article.

Prior to FEP coat, the inner and outer intermediate articles were nested using the following method:

In order to achieve nesting of the two intermediate articles, the distal eyelets and the proximal eyelets must be nested. Inner intermediate article was positioned at the end of a straight, circular mandrel. One eyelet of the outer intermediate article was positioned over an eyelet of the inner intermediate article and both intermediate articles were repositioned to the other end of the mandrel. The remaining eyelet of the outer intermediate article was positioned over the remaining eyelet of the inner intermediate article. They were arranged such that the overlapping wires were equally spaced (about 72° apart) thereby creating a frame. The frame was subsequently FEP coated and covered with an ePTFE bag in order to create the final article.

Example 9 (Lock Loop Build):

Wire was obtained as described in the previous examples. A lock loop base jig **60** (FIG. **24**A) with center pin **22** was placed in custom stand as a manufacturing aid. A button component **62** configured such that the inner lumen is not round but is keyed to keep from rotating on center pin was obtained. The wire was formed into a loop and the loop was inserted through the lumen of the button **62**. The button with wire loop was threaded onto center pin **22** with loop toward the opposite side of center pin as the keyed portion of the inner lumen of the button component. The keyed portion of the button component **62** was situated to the right of the lock loop base jig **60**. A wire was chosen and bent toward the builder then wrapped 360° around the button component **62**, then wrapped around the center pin **22** for a minimum of four revolutions and tied off after the fourth revolution. The wire wraps should be spacing apart approximately 1 mm. Loop forming tool **64** (FIG. **24**B) was inserted in lock loop base jig **200** against the center pin **22**. The free wire was wound about 370° shaft **66** of loop forming tool **64** then wrapped around the pin **68** on the loop forming tool **64** and anchored onto the lock loop base jig **60**. The base jig **60** and loop forming tool **64** were removed from the stand and placed in an oven. The entire assembly was heated in an oven such as described previously for 14 min. at 475° C. The lock loop was removed from the jig **60** and loop forming tool **64** and the excess wire was trimmed.

Example 10 (Space Filling Device):

The following embodiments teach a heat set for the device described in Example 7 prior to the application of the cover, hereinafter called the frame of Example 7.

The frame of Example 7 was placed over about a 2 mm mandrel. The mandrel **72** was crimped on both sides if the article in order to secure it from moving. The frame was then placed on the tubular cylinder **70** described in FIG. **25**A such that the frame outer perimeter rested on the upper edge of cylinder **70**. Cap **74** was then placed over the frame and cylinder **70** as shown in FIG. **25**B and secured in place via set screw **76**. The entire assembly was then placed in a forced air oven set to 475° C. for 14 minutes. The assembly was removed from the oven and quenched in room temperature water. The frame **78** was subsequently FEP powder coated as described in Example 2.

Example 11 (Space Filling Anchors):

The following embodiments teach an anchor means for the device described Example 10.

(a) An anchor component **80** as shown in FIG. **26**A was created by the method as generally shown in FIG. **26**B. The wire **82** of each of the petals was cut at location **84** thereby eliminating the remainder **86** of the length of the loop, resulting in anchor **80**. Anchor component **80** was next affixed to frame **78** as generally shown in FIG. **26**C. The spokes **82** of anchor **80** were aligned with the wires of frame **78**. A tape made from ePTFE film with a thin layer of FEP was wrapped **88** around the wires **82** and the wires of frame **78** and then heated to bond the wires together as shown in FIG. **27**.

The article was powder coated with FEP powder as previously described. The frame **78** was covered as previously described, after which wires **82** were individually manipulated to protrude through the sealing member **106** as shown in FIG. **28**.

(b) In another embodiment, the anchor component **80** of Example 11 (a) was further modified as follows. Jig **90** and washer **92**, as shown in FIGS. **29**A and **29**B, respectively, were obtained. The anchor component **80** was inserted, eyelet down into jig **90**, such that eyelet of **80** was located inside hole **91** and the wires **82** were located inside grooves **95** of jig **90**. Washer **92** was placed on top of anchor component **80** to hold it in place and the washer **92** was secured with screw **323** in hole **94**, as shown in FIGS. **29**A-**29**C, which caused the points of the wire **82** to orient toward the face of the washer.

(c) In another embodiment, the anchor component **80** (shown in FIG. **30**) is manufactured as follows:

An about 1 meter length of 10% platinum drawn filled nitinol wire (Fort Wayne Metals, Fort Wayne, IN.) with a diameter of about 0.23 mm is obtained. The specific length of the wire is not measured, it is only necessary that the wire be long enough to complete the winding pattern as described in the following paragraph. The wire is obtained having been electropolished. Electropolishing nitinol wire imparts certain well known properties, such as spontaneously forming a titanium dioxide layer on the surface, selectively reducing the amount of nickel on the surface of the wire, and removing some of the stresses in the wire thus improving fatigue.

A base jig **8** as described in FIG. **17** is obtained. A knot is tied into one end of one length of an about 0.5 meter long wire and the unknotted end is fed through a wire feed hole **10**. Two additional lengths of wire (about 1 meter each) are folded in half and the free ends are fed through the remaining four feed holes **12**, **14**, **16**, **18**, with the wire entering the holes at funnel-shaped opening **19** (not shown) with the small feed holes at the bottom of opening **19**. The wires then exit through holes **10**, **12**, **14**, **16** and **18** at the flat end surface of jig **8**. Weights **20** are attached to the free ends of the five wires to hold the wires taut and in place. The base jig is secured in a chuck of a lathe and center pin **22** is inserted into center pin hole **24** far enough to securely seat it.

The other end of center pin **22** is located inside the center hole **28** of tail stock support **26** which is chucked into the tail stock, wherein the closed face **30** of the tail stock support **26** faces the base jig **8**. The base jig **8** and tail stock support **26** are positioned about 5 cm apart. A wire guide **34** is used to prevent the wires from crossing. The base jig **8** is positioned so that the wire feed holes **10**, **12**, **14**, **16**, **18** are oriented vertically above the center pin **22** and the wires are positioned on the trailing side of the center pin **22**.

The petal jig hole **36** is rotated 720°. The petal jig **38** is inserted into the petal jig hole **36**. Without crossing the wires, the wires are placed on top of the petal jig **38**. The base jig **8** is rotated 360° to create the petals of the device. The base jig **8** is rotated another 720° with the wires placed on top of the center pin **22**.

With the weights **20**, the tail stock support **26**, and the wire guide **34** removed, the assembly is placed in a convection oven set to 475° C. for 14 minutes. The assembly is removed from the oven and quenched in water. The jigs are disassembled and the article is removed. The wire ends are trimmed to the eyelets and the anchor loops are fanned in the same direction as the helical winding, such that each anchor loop is oriented 72° offset relative to the adjacent anchor loops. The anchor loops are crimped at the center by hand and heat set again as previously described.

(d) In another embodiment, anchor components are manufactured by clipping about 2 cm straight lengths of nitinol wire **71**. A tape made from ePTFE film with a thin layer of FEP is wrapped **88** around the wires **71** and the wires of frame **78** and then heated to bond the wires together as shown in FIG. **31**.

Example 12 (space filler with **2** planes of anchoring):

A device as previously described in Example 10 with anchors as described in example 11(d) is manufactured by attaching the anchors at multiple locations along the wires of frame **78**.

In addition to being directed to the teachings described above and claimed below, devices and/or methods having different combinations of the features described above and claimed below are contemplated. As such, the description is also directed to other devices and/or methods having any other possible combination of the dependent features claimed below.

Numerous characteristics and advantages have been set forth in the preceding description, including various alternatives together with details of the structure and function of the devices and/or methods. The disclosure is intended as illustrative only and as such is not intended to be exhaustive. It will be evident to those skilled in the art that various modifications may be made, especially in matters of structure, materials, elements, components, shape, size and arrangement of parts including combinations within the principles of the invention, to the full extent indicated by the broad, general meaning of the terms in which the appended claims are expressed. To the extent that these various modifications do not depart from the spirit and scope of the appended claims, they are intended to be encompassed therein.

What is claimed is:

1. A medical device for sealing a tissue opening, the medical device comprising:

a wound wire frame including a plurality of wires separate from each other and having free ends, the plurality of wires extending from a proximal end of the wound wire frame to a distal end of the wound wire frame, the plurality of wires forming:

a first occluding member adjacent a first eyelet;

a second occluding member adjacent a second eyelet, and

a waist portion disposed between the first occluding member and the second occluding member;

wherein the plurality of wires are shape set such that, when deployed, the wound wire frame provides the waist portion wherein each of the plurality of wires individually defines a reniform shape with an open internal area when deployed; and

a sealing member attached to the wound wire frame.

2. The device of claim **1**, wherein a portion of a curved segment of each of the plurality of wires defines an inner peripheral edge of the device, and wherein the inner peripheral edge is adapted to, at least in part, center itself within the tissue opening.

3. The device of claim **1**, wherein the device comprises an extended length in a delivery configuration and a radius in a deployed configuration, and wherein a ratio of the extended length of the device in the delivery configuration length to the radius of the device in the deployed configuration is about 2.5.

4. The device of claim **1**, further comprising a lock loop component attached to the wound wire frame.

5. The device of claim **1**, wherein the sealing member is attached to an exterior of the wound wire frame.

6. The device of claim **1**, wherein the sealing member is attached to an interior of the wound wire frame.

7. The device of claim **1**, wherein the sealing member substantially encapsulates the wound wire frame.

8. The device of claim **1**, wherein the sealing member partially encapsulates the wound wire frame.

9. The device of claim **1**, wherein the wire frame twists to provide the waist portion.

10. A medical device for sealing a tissue opening, the medical device comprising:

a wire frame that includes a plurality of wires each having a proximal free end and a distal free end, each of the plurality of wires extending from a proximal end of the wire frame to a distal end of the wire frame, the plurality of wires forming:

a first eyelet near the proximal end of the wire frame, the first eyelet defined by the proximal free ends of the plurality of wires,

a second eyelet near the distal end of the wire frame, the second eyelet defined by the distal free ends of the plurality of wires;

a first occluding member adjacent the first eyelet and a second occluding member adjacent the second eyelet, and

a waist portion disposed between the first occluding member and the second occluding member, the waist portion adapted to substantially fully occupy the tissue opening without appreciably enlarging the tissue opening; and

a sealing member that is attached to the wire frame,

wherein a first wire of the plurality of wires defines a reniform shape and includes a first end and a second end, the first end being wound in a first direction in the first eyelet and the second end being wound in the first direction in the second eyelet.

11. The device of claim **10**, wherein the wire frame includes six wires.

12. The device of claim **10**, wherein the sealing member is attached to an exterior of the wire frame.

13. The device of claim **10**, wherein the sealing member is attached to an interior of the wire frame.

14. The device of claim **10**, wherein the sealing member completely encapsulates the wire frame.

15. The device of claim **10**, wherein the sealing member partially encapsulates the wire frame.

16. The device of claim **10**, wherein a portion of the curved segment defines an inner peripheral edge of the device.

17. The device of claim **10**, wherein one or more wires of the plurality of wires forms a reniform shape when the device is in a deployed configuration.

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