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(54) Title: ARTIFICIAL ESOPHAGEAL SPHINCTER

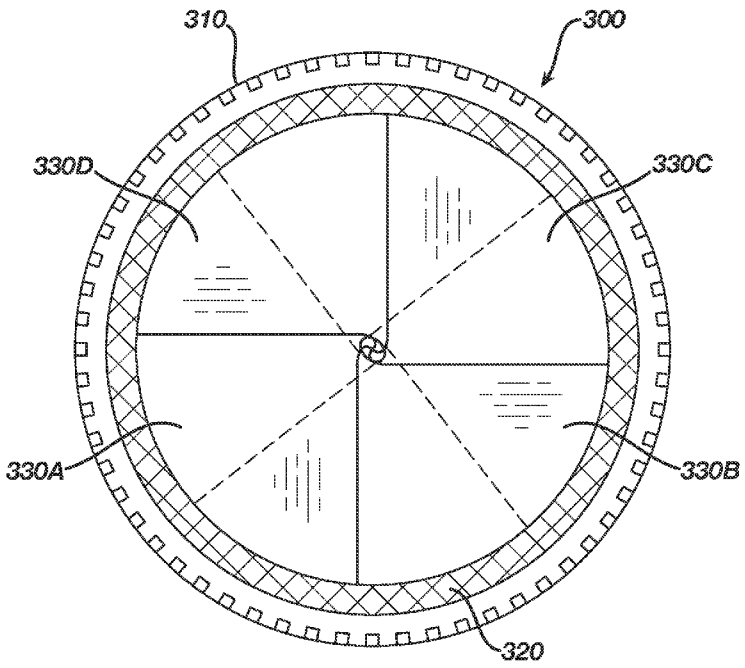


FIG. 3

(57) Abstract: A surgical implant (300) and delivery apparatus into a biological lumen. The implant has an outer ring (310) having an outer wall and an inner wall the outer ring disposed about a central axis. The implant further has an inner ring (320) adjacent to the outer ring inner wall disposed about the central axis defining an annular opening. The implant has a valve (330) flexibly attached to the inner ring and disposed about the central axis, the valve substantially occluding the annular opening in a first state and elastically opening to provide a variably sized bore in a second state to permit passage of a substance through the lumen.

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ARTIFICIAL ESOPHAGEAL SPHINCTER

BACKGROUND

The present artificial sphincter relates in general to surgical devices and procedures, and more particularly to minimally invasive surgery.

Surgical procedures are often used to treat and cure a wide range of diseases, conditions, and injuries. Surgery often requires access to internal tissue through open surgical procedures or endoscopic surgical procedures. The term "endoscopic" refers to all types of minimally invasive surgical procedures including laparoscopic, arthroscopic, natural orifice intraluminal, and natural orifice transluminal procedures. Endoscopic surgery has numerous advantages compared to traditional open surgical procedures, including reduced trauma, faster recovery, reduced risk of infection, and reduced scarring. Some forms of endoscopic surgery are often performed with an insufflatory fluid present within the body cavity, such as carbon dioxide or saline, to provide adequate space to perform the intended surgical procedures. The insufflated cavity is generally under pressure and is sometimes referred to as being in a state of pneumoperitoneum. Surgical access devices are often used to facilitate surgical manipulation of internal tissue while maintaining pneumoperitoneum. For example, trocars are often used to provide a port through which endoscopic surgical instruments are passed. Trocars generally have an instrument seal, which prevents the insufflatory fluid from escaping while an instrument is positioned in the trocar. Endoscopic surgery may also be performed in the absence of insufflatory gas. For example, minimally invasive thoracic surgery may be performed in the absence of insufflatory gas, as the rib cage provides the structure necessary to create the operating environment.

The field of gastrointestinal endoscopy has for many years focused on diagnostic and therapeutic techniques to observe, modify and remove tissues located in the digestive tract. General endoscopic procedural techniques such as visualizing, dilating, cutting and manipulating tissue have been

accomplished using flexible devices such as endoscopes, balloons, snares and electrosurgical tools well known in the art.

The present disclosure concerns apparatus and methods for improving the function of biological passages. The ability of biological passages to expand and contract actively or passively to regulate the flow of solids, liquids, gases, or combinations thereof, may be compromised by defects or disease. One example of a condition associated with decreased functionality of a body passage is Gastro Esophageal Reflux Disease (hereinafter, "GERD"), which effects the esophagus. Other body passages that may be subject to dysfunction, defect, and disease include, but are not limited to, a fallopian tube, a urethra (for example, in the case of incontinence), and a blood vessel (for example, in the case of an aneurysm). GERD and esophageal dysfunction will be further described herein for the sake of illustration.

The normal healthy esophagus is a muscular tube that carries food from the mouth through the chest cavity and into the upper part of the stomach. A small-valved opening in the distal esophagus, called the lower esophageal sphincter (hereinafter, "LES"), regulates the passage of food into the stomach. When functioning properly, the LES muscle presents a barrier to the reflux of acid or food back into the esophagus. The LES also regulates the stomach intra-gastric pressures, regulating acidic gases from refluxing from the stomach back into the esophagus. The LES, when functioning properly, will open to allow gases to be vented from the stomach. A healthy LES at rest can resist pressure from stomach gases that are at least 10 mm Hg greater than normal intragastric pressure. This pressure difference can regulate the amount of acidic fluid that refluxes from the stomach into the esophagus. The LES is controlled largely by two components.

The primary component is intrinsic smooth muscle of the distal esophagus wall. The second component is the skeletal muscle of the crural diaphragm or esophageal hiatus. The diaphragm is a muscle separating the stomach from the chest. Studies have shown that the diaphragm may act as a

sphincter around the lower end of the esophagus. The esophageal hiatus is the opening in the diaphragm where the esophagus attaches to the stomach. If the LES relaxes, atrophies, or degrades for any reason, the contents of the stomach, which may be acidic, are allowed back into the esophagus resulting in reflux symptoms. The major mechanism for esophageal reflux, which may be associated with GERD, is the relaxation of one or both of the LES or hiatal diaphragm sphincter mechanisms. Normally occurring mechanisms that diminish or prevent GERD include peristaltic squeezing by the esophageal body, gravity (when a person is in an upright position), and neutralization by saliva.

Chronic or excessive acid reflux exposure may cause esophageal damage. Drugs may be required to manage symptoms of the damage and medical intervention, including surgical or endoscopic procedures, may be required to repair the damage.

The lining of the esophagus is called mucosa. Chronic exposure to stomach gases may cause the mucosa to become inflamed or ulcerated. Inflamed or ulcerated mucosa may lead to problems that may require medical intervention.

Hiatal hernias are often associated with GERD. If the esophageal hernia becomes enlarged (herniated), the LES function may be compromised and the risk of GERD increased. (A hiatal hernia occurs when the upper portion of the stomach moves up through an opening in the diaphragm.)

Barrett's Esophagus is a disease of the esophagus that may compromise esophageal function. This disease may occur when the tissue that ordinarily lines the esophagus migrates away from the lower part of the esophagus to avoid exposure to the acidic fluids against the sensitive mucosa. Barrett's Esophagus is often a precursor to esophageal cancer.

The most common symptom of GERD is dyspepsia (commonly known as "heartburn"). Dyspepsia may be defined as an acute burning sensation in the chest area typically, behind the sternum. Other symptoms of GERD may

include hemorrhage, pulmonary disorders, chronic cough, intermittent wheezing, ulcers, Barrett's esophagus, and esophageal cancer.

One conventional surgical treatment for GERD is fundoplication. In this procedure, normally performed endoscopically, the upper part of the stomach is mobilized and is subsequently wrapped around the lower part of the esophagus. This highly invasive procedure is often initially successful, but has a high risk of morbidity including esophageal tears, tears of the spleen, subphrenic abcess, dysphagia, inability to vomit or belch, epigastric distension and persistent esphagitis.

Another conventional treatment for GERD is surgical suturing of a pleat of tissue between the LES and stomach to make the lower esophagus tighter. Suturing may be performed endoscopically using a suturing device on the end of an endoscope inserted into the esophagus through the mouth. Endoscopic procedures are less invasive than open surgery, but still require surgical incisions and great skill.

Surgery, whether endoscopic or open (such as fundoplication) may provide a basic mechanical correction. Surgical procedures may relocate and affix existing tissue of the stomach, esophagus, or both to add support and structure to the LES. LES strength is increased by the added support, thus reducing the incidence of reflux.

BRIEF DESCRIPTION OF DRAWINGS

While the specification concludes with claims which particularly point out and distinctly claim the artificial sphincter, it is believed the artificial sphincter will be better understood from the following description taken in conjunction with the accompanying drawings illustrating some non-limiting examples of the artificial sphincter. Unless otherwise indicated, the figures are not necessarily drawn to scale, but rather to illustrate the principles of the artificial sphincter.

Fig. 1 depicts is a sectional view of an illustrative biological passage;

Fig. 2 is an illustrative view of a human esophago-gastric junction;

Fig. 3 is an cross-sectional view of an artificial sphincter implant;
Fig. 4 is a cross-sectional view of a petal from the Fig. 3 implant;
Fig. 5 is a partial cut-away view of the Fig. 3 sphincter;
Fig. 6 is an isometric view of one expression of an artificial sphincter implant;
Fig. 7A is an isometric view of an artificial sphincter implant loaded onto an endoscope;
Fig. 7B is a partial cross sectional view of the Fig. 7A implant on a deployment device;
Fig. 7C is a cross sectional view of an artificial sphincter implant deployment;
Fig. 7D is a cross sectional view of anchor deployment;
Fig. 7E is an isometric cut-away view of the Fig. 7A artificial sphincter implanted in a biological passage;
Fig. 8A is a close-up cross sectional view of implant placement before anchor deployment;
Fig. 8B is a close-up cross sectional view of anchor deployment;
Fig. 8C is a close-up cross sectional view of anchors deployed into a biological structure;
Fig. 9A is an isometric view of another expression of an artificial sphincter implant;
Fig. 9B is an isometric view of another expression of an artificial sphincter implant in an open state;
Fig. 9C depicts the Fig. 9B implant in a closed state;
Figs. 10A, 10B and 10C depict an artificial sphincter prior to implantation, after implantation with minor tissue in-growth and with full tissue ingrowth;
Figs. 11A, 11B and 11C depict a substance passing through one expression of an artificial sphincter; and
Figs. 12A and 12B depict a substance passing through another expression of an artificial sphincter.

DETAILED DESCRIPTION

The devices and methods disclosed herein relate to providing an artificial sphincter apparatus and method for placing the same in a body lumen. The device may be used in a variety of biological lumens, including, but not limited to, the alimentary canal, particularly the distal esophagus.

Some expressions of the artificial sphincter may include an annular body that defines a central axis. (The axis may follow an approximately central path through the body and in some expressions may not be a straight line.) The central axis may define an axial, or longitudinal, direction. A plane perpendicular to or nearly perpendicular to the central axis may be referred to herein as an axial plane.

At least one anchor may be coupled to the body. As used herein, anchor may refer to a single barb or quill or, anchor may refer to a plurality of barbs or quills as a collective anchor. The anchor may be configured to engage a portion of the passage, for example, a portion of a passage wall. The anchor may be configured to engage a portion of a passage inner wall. In some expressions, the body may include an elastic material. In some expressions, the body may include an inert material. In some expressions, the body may include a moldable material. As used herein, a material that is biocompatible and resistant to reaction with biochemical solids, liquids, and gases may be an inert material. Stainless steel, nickel titanium alloy, tantalum and other non-reactive metals may be inert. Polymers such as PTFE, polyurethane, polyamide, and those sold under the trademark PEBAX by Elf Atochem North America may be inert. Medical grade metals and polymers may be inert.

The anchor may extend radially away from the axis and in some expressions is oriented normal to an outer surface of the band portion of the artificial sphincter. The anchor may extend in a non-radial direction away from the axis. The anchor may extend in a curved path away from the axis. The anchor may be pushed radially outward into the inner wall. The anchor may be twisted or rotated about the axis to engage the inner wall.

In some expressions, the anchor may include an elastic material. In some expressions, the anchor may include a metal. In some expressions, the anchor may include an alloy. In some expressions, the anchor may include a polymer. The anchor may include inert material. Some expressions may include one or more anchors having more than one of the foregoing features. The anchor may be any suitable type of anchor, including any of the anchors described herein. In some expressions of the artificial sphincter, the anchor may be comprised of an absorbable material (e.g. polyglycolic acid, polylactic acid, polydioxanone, PCL, organics – cellulose, collagen) and/or absorbable material that promotes tissue growth.

In some expressions of the artificial sphincter, one or more anchors may be present in or near an axial plane of the body. The axial plane may remain stationary or nearly stationary in the longitudinal direction when the body is deformed in the radial direction. This feature may reduce stress on the passage wall near an anchor if the body deforms in connection with deployment in the passage. The feature may reduce stress on the passage wall near the anchor if the body deforms in response to deformation of the biological passage. The biological passage may deform in response to muscular action, physiological processes, or any other processes. For example, the passage may deform in response to peristalsis, circulatory pumping, excretory processes, reproductive processes, or other physiological processes.

In some expressions of the artifical sphincter, the anchor may be shaped like a barb or quill. In some expressions, the anchor may be include a “catch”. As used herein, a catch is a feature of an anchor that may be used to resist the withdrawal of the anchor from tissue. In some expressions, a catch may be used to pinch or pin tissue. In some expressions, a catch may hook into tissue (for example, as does a barb). In some expressions, the anchor may include a staple. The staple may be C-shaped.

In some expressions, the artificial sphincter may include a sheath that may be drawn over the body to protect the inner wall of a biological lumen from the anchors, for example, when the body is being inserted into the biological

passage. The sheath may deflect the anchor away from a direction extending radially away from the body axis. The sheath may be removed to engage the anchor with the inner wall.

Some expressions of the artificial sphincter may include a coating. The coating may cover the entire surface of the body. The coating may cover a portion of the body. In some expressions, the coating may include an inert material.

Some expressions of the artificial sphincter may include a therapeutic substance. The substance may be present in or on the body. The substance may be present in the anchor, on the anchor, or both. The substance may be present in or on the lining. The substance may be embedded in a porous portion of the artificial sphincter. The substance may elute from a portion of the artificial sphincter into the tissue of the biological passage. The substance may include an agent configured to heal the tissue from a disease, defect, infection, inflammation, trauma, or any combination thereof. The substance may include an agent configured to physically protect the tissue from acidic compounds. For example, the substance may act to neutralize an acidic compound. The substance may be a drug. The substance may include a steroid. The substance may include an antibiotic.

Some expressions of the artificial sphincter may include anchor deployment means. The deployment means may be configured to apply force to the anchor to drive the anchor into the inner wall of the biological passage. In some of these expressions, the anchor may have prongs and be shaped like a staple, a “C”, a “U”, a barb or any other suitable form. The deployment means may be used to drive the barbs or bend the prongs to engage the biological passage. The deployment means may be used to secure the prongs to the biological passage.

In expressions of the artificial sphincter that include a moldable material, the anchor may be insert molded into a portion of the body. In some of these expressions, the anchor may be wholly or partially embedded in the polymer. The anchor may be made from a material that is less elastic than the polymer.

When the body is expanded away from the axis, the body portion housing the anchor may become thinner in the radial dimension. As the body portion thins, the anchor may protrude through and extend radially beyond the portion. This feature may permit the device to be inserted into the passage with the anchor in a retracted position. The feature may permit the anchor to be exposed or "activated" automatically as the body is expanded. In expressions having an anchor with a catch, this feature may permit the anchor to pinch a portion of the biological passage inner wall against the body when the body contracts. In some expressions, the body may include portions having different relative flexibilities. Some portions may have high flexibility. Some portions may have low flexibility. One or more anchors may be coupled to a low flexibility portion. One or more anchors may be coupled to a high flexibility portion. When the body expands, contracts, or otherwise deforms (for example, in response to peristalsis or other motion), the deformation may be concentrated in the portions having high relative flexibility. An anchor or anchors coupled to a low flexibility portion may be subject to less stress, less displacement, or both than if coupled to a relatively high flexibility portion.

High flexibility portions may be, for example, thin, long, elastic, extensible, rotatable, or otherwise compliant. Low flexibility portions may be, for example, thick, short, inelastic, fixed against rotation or shorter, or otherwise noncompliant.

In some expressions, the artificial sphincter may have annular outer body with barbs protruding normally from the outer surface of the body. The annular outer body and barbs may be coated with a short term adhesive to promote fixation such as cyanoacrylate, fibrin glue or oxidized regenerated cellulose. The inner artificial sphincter body may have magnetic petals or leaves attached to or integrally formed into the inner surface of the body. The magnetic petals or leaves open as the biological lumen peristalses as will be more fully described herein. The annular body may be comprised of flexible, biocompatible material adapted for placement in a biological lumen. The artificial sphincter may be entirely over molded in a biocompatible material

where that biocompatible material has nano-features to promote tissue in-growth.

In some expressions, the artificial sphincter may include a deployment apparatus (e.g. a catheter) for inserting the body into the biological passage. In some expressions, the body may be installed in the biological passage by placing the body in a portion of the passage, expanding the body, engaging the anchor or anchors with the passage inner wall, and allowing the body to relax. In some expressions, the body may be expanded and the anchor or anchors secured in the inner wall using a balloon. In some expressions, the body may be expanded sufficiently to partially engage the anchor or anchors with the wall. In some of these expressions, a deployment means may be used to complete the engagement of the anchor or anchors with the wall. In some expressions, the deployment means may be used to secure the anchor or anchors in the wall without previous partial engagement of the anchor or anchors.

In some expressions, the artificial sphincter may include a coating for a portion of the biological passage. Some of those expressions may include one or more anchors to secure the coating to the biological passage. The coating may include a first plurality of anchors, a second plurality of anchors, and a sleeve. The sleeve may extend from the first plurality of anchors to the second plurality of anchors. The sleeve may be configured to conform to the inner wall of the biological passage. The coating may include a polymer such as PTFE, polyurethane, polyamide, and PEBAX®. The coating may include any suitable medical polymer. The coating may include any suitable material that does not readily react with biological fluids such as stomach acid, biological waste, or other materials that may be present in a biological passage.

FIGS. 1 and 2 show esophageal anatomy. FIG. 1 shows healthy esophagus 2, including distal esophagus 3 connected to stomach 4. LES 6 is located at the junction of esophagus 2 and stomach 4 where esophagus 2 passes through hiatus 8 in hiatal diaphragm 10. Sling fibers 12 in LES 6 are

smooth muscle tissue that may regulate distal esophagus 3. Hiatus 8 may externally support and regulate LES 6. LES 6 is normally open at rest.

Referring now to FIG. 3, a plan view of an artificial sphincter implant 300 is depicted in a closed position. Implant 300 is annular in shape and is comprised of an outer retaining ring 310, an inner ring 320 and overlapping petals 330A-330D. Petals 330A-330D partially form an artificial valve. The rings 310 and 320 as well as the petals 330A-D may be arranged annularly around a central axis (not shown). Retaining ring 310 may be flexible in nature and may be comprised of any flexible polymer suitable for implant in a living body as is known and understood in the art. Petals 330A-330D may be comprised of flexible bio-compatible polymer having embedded magnets with poles oriented in such a manner that the petals flex distally to permit passage of a substance e.g. food and return to the closed position. The flexible petals provide for a variably-sized bore depending upon peristaltic force as well as the size and type of substance passing therethrough.

The petals 330A-330D may be comprised of a magnetic polymer where the magnet is formed from rare earth magnets NdFeB (Neodymium Iron Boron), AlNiCo (Aluminum Nickel Cobalt) SmCo (Samarium Cobalt), strontium ferrite and barium ferrite. Paramagnetism materials like: Cr(NH3)6]Br3, K3[Cr(CN)6], K3[MoCl6], K4[V(CN)6], [Mn(NH3)6]Cl2, (NH4)2[Mn(SO4)2]•6H2O, NH4[Fe(SO4)2]•12H2O. Paramagnetism is a form of magnetism whereby certain materials are attracted by an externally applied magnetic field. In contrast with this behavior, diamagnetic materials are repelled by magnetic fields. Paramagnetic materials include most chemical elements and some compounds; they have a relative magnetic permeability greater than or equal to 1 (i.e., a positive magnetic susceptibility) and hence are attracted to magnetic fields. Ferromagnets include iron, nickel, cobalt and manganese, or their compounds (FE, CO, Ni, Gd, Dy, CrO2, MnAs, MnBi, EuO, NiO/Fe, Y3Fe5O12, and others).

To make magnets biocompatible they may be coated with or encapsulated in a non-absorbable plastic like PEEK, Polypropylene, high

density polyethylene, and polycarbonate. They could also be plated or encapsulated in another non-magnetic material like Titanium. Alternatively that can be coated with a diamond-like carbon (DLC) coating or bioglass which is a commercially available family of bioactive glasses, composed of SiO2, Na2O, CaO and P2O5 in specific proportions. The proportions differ from the traditional soda-lime glasses in low amount of silica.

In order to allow elastic deformation or elastic bending of the magnet or magnets, expanded polypropylene (EPP) or high density polyethylene or an elastomer can be used e.g. isoprene or sanoprene. The coatings of DLC or bioglass can also be used for elastically deformable magnets.

In one expression of the implant 300, petals 330A-330D are comprised of flexible magnets. A flexible magnet may be composed of a high-coercivity ferromagnetic compound (usually ferric oxide) mixed with a plastic binder. This is extruded as a sheet and passes on a conveyor belt over a line of powerful cylindrical permanent magnets. These magnets are arranged in a stack with alternating magnetic poles facing up (N, S, N, S,...) on a freely rotating shaft. This impresses the plastic sheet with the magnetic poles in an alternating line format. No electromagnetism is used to generate the magnets. The pole-pole distance may be on the order of 5mm, but varies with manufacturer and application. The plastics can be PEEK, Polypropylene, high density polyethylene, polycarbonate or any other biocompatible polymer. The pole-pole distance can be varied to accommodate the need to stack the petals 330 and permit them to move axially.

Unlike most conventional magnets that have distinct north and south poles, flat flexible magnets are made from composite materials and can have either a traditional thru thickness N&S two poles in one or each side or an alternating north and south poles on the same surface of the plane as is known and understood in the art.

Figure 4 depicts a single petal 330C from implant 300. As is shown in FIG. 4, the petal 300C extends approximately 225° around an axis parallel to ring 310 centerline and normal to petals 330A-330D where the axis forms the

starting point of the radius of the ring 310. In one expression, the remaining rings are stacked on top of each other and spaced at 90°. The four petals, 330A-330D, overlap in a manner to completely occlude the area defined by outer ring 310 while permitting axial movement of a substance through the implant. The petals 330, in one expression, may have magnetic properties such that when interleaved or overlapped, the magnetic properties bias the artificial sphincter to a closed state.

FIG. 5 depicts another expression of implant 300. The FIG. 5 implant comprises petals 330A-330D where the lateral annular edge of each petal 330 is provided with an attachment means 540 that retain a filament 530. Attachment means 540 may be a raised cut-out defining an annulus or may be hole punched in the lateral edge of petals 330. Filament 530 is preferably flexible and is composed of bio-compatible material that maximizes flexibility and strength while minimizing the possibility of erosion through a biological structure e.g. stainless steel, nitinol, nylon, polyester, polypropylene. The filament 530 and petals 330 may be coated or extruded with a silicone coating to minimize the possibility of erosion through a biological structure. Once the filament 530 is attached to petals 330, an expandable, absorbable lattice structure 520 is bonded to filament 530. The lattice structure may be formed from PGA/PCL copolymer or PLA/PCL copolymer. Those copolymers balance absorption and strength for a time period sufficient to promote tissue ingrowth while providing sufficient strength. An absorbable retainer 515 is then bonded to the lattice 520 and filament 530.

The absorbable lattice 520 may be comprised of polyglycolic acid, polylactic acid, polydioxanone or the like. Similarly, retainer 515 may be comprised of the same materials. Surface of retainer 515 may be treated with biologics that encourage tissue migration and over growth. Retainer 515 surface may further be provided with small cleats (approximately 100-250μm tall) to promote fixation and tissue in-growth. Retainer 515 is further provided with anchors 510 oriented normal to outer annular surface of retainer 515. Anchors 510 penetrate the mucosa and into the muscularis of the lumen (e.g.

the esophagus) to anchor the implant 300 into position during tissue in-growth. Barbs on anchor 510 prevent the anchor 510 from inadvertently backing out of the esophageal musculari. Anchor 510 and barbs are preferably comprised of absorbable material such as PGA/PCL copolymer or PLA/PCL copolymer or any other biocompatible absorbable material having appropriate flexibility and rigidity.

Implant 300 may have a variety of petal geometries. FIG. 6 depicts an implant 300 having a plurality of petals 630 that do not overlap. As shown, implant 300 is comprised of an outer retaining ring 615A. Like the FIG. 5 expression, retaining rings 615 may be absorbable. Ring 615 is configured with a non-absorbable band 660 that serves to retain and orient plurality of petals 630. Ring 615 is fixedly attached to band 660 and may be comprised of two rings 615A and 615B oriented above and below band 660 along a central axis 680. Or rings 615A and B and ring 660 may be one contiguous structure. Petals 630 may each be configured with internal magnets to fix the petals 630 in the closed position as shown in FIG. 6. The petals 630 may be a polymer having magnets disposed therein or may be a ferric oxide mixed with a polymer or plastic to impart magnetic properties to the petals 630. The magnetic properties and orientation of the poles of the petals 630 are such that the petals 630 are biased to remain in contact at a resting state. When all petals 330 are in contact, the implant is in a closed state. The FIG. 6 expression is further provided with anchors 610 that serve to fix implant 300 in a hollow biological structure. As shown, anchors 610 are comprised of quills oriented normal to the exterior surface of rings 615A and 615B. Rings 615A & B are configured with notches 685 to promote flexibility and permit rings 615A & B to be folded medially toward axis 680.

Referring now to FIGS. 7A – 7E, an implantation process utilizing implant 300 is shown. In FIG. 7A, implant 300 is oriented about deployment mechanism 700 in a retained state. As is shown in FIG. 7A, deployment mechanism is extending from a working channel of an endoscope 710. Deployment mechanism 700 is provided with an elongate shaft 705 of suitable

length to fit down an endoscope working channel. A sheath 715 is disposed about shaft 701. At the distal end of shaft 701, a plurality of arms 720 are flexibly attached to sheath 715 and arranged annularly about shaft 701. In the FIG. 7 expression, four arms 720 are provided but it is contemplated that as few as two and as many as 12 or more arms 720 may be provided. It is further contemplated that the arms 720 may be staggered such that alternating arms interact with upper 615A and lower 615B portions of ring 660.

As is shown, rings 615A and 615B are folded medially. Interior surface of rings 615A and 615B may be provided with annuli that mate with protrusions on deployment arms 720, FIG. 7B. When deployment arms 720 are extended as in FIG. 7C, implant 300 expands to contact the interior lumen walls of an anatomic structure e.g. the esophageal mucosa. Upon contact with the interior wall, a second deployment apparatus 730 is utilized to move rings 615A and 615B into contact with the interior wall. As depicted, small balloons 730 are utilized to move rings 615A and 615B into contact thereby deploying anchors 610 into the lumen interior walls. Once anchors 610 are deployed, deployment mechanism 700 is removed as is shown in FIG. 7E. Distal arms used to deploy ring 615B are pulled through petals 630. Due to magnetic orientation of petals 630, petals are biased back to a closed state as shown in FIG. 7E after removal of deployment mechanism 700. Although FIGS. 7A – 7E depict deployment of the FIG. 6 expression of implant 300, it is understood that deployer 700 may be used with the FIG. 3 expression as well.

Referring now to FIG. 8A, a close up view of rings 615A and 615B as well as anchors 610 is shown. In this view, rings 615A and 615B are shown folded medially about balloon 730. As stated above, medial surface of rings 615A and 615B may be provided with annuli (not shown) that mate with projections on balloons 730 (not shown) to retain rings 615A and 615B in the undeployed state. Alternatively, balloons 730 may be provided with a pressure sensitive adhesive that retains rings 615A and 615B in the undeployed state. As shown, anchors 610 are disposed about rings 615 in less than a normal orientation and may further rest against outer surface of rings 615 until rings 615 are

deployed. This anchor 610 orientation may aid in insertion into a biological lumen e.g. the esophagus. As shown in FIGS. 8A-8C, rings 615A and 615B and ring 660 are of unitary construction. As discussed above, rings 615 and 660 may be discrete components or a unitary ring as is known and understood in the art.

Once implant 300 is located in an appropriate deployment position in a biological lumen, arms 720 are deployed. Once arms 720 are deployed, implant 300 is biased against the lumen wall. Balloons 730 are then inflated as shown in FIG. 8B. As balloons 730 are filled with an appropriate substance e.g. saline via fill tubes 800, rings 615 move from a medial folded position to contact lumen wall 800. As rings 615 deploy, anchors 610 or quills 510 pierce the lumen wall sufficiently to retain implant in a fixed position relative to the lumen wall 810 as shown in FIG. 8C. As shown in FIG. 8C, quills or anchors 510, 610 may penetrate through the submucosa and into the muscularis 815.

Referring now to FIGS. 9A – 9C, another expression of implant 300 is depicted as implant 900. The FIG. 9 implant has an outer ring 915 that may have outer rings as set forth in FIGS. 5 and 6 along with anchors or quills disposed about ring 915's outer surface. In the FIG. 9 expression, a plurality of magnets 920 is oriented such that their poles are arranged end to end in an approximately annular arrangement about axis 950. As shown, magnets 920 are encased in highly flexible silicone sheath 925 which permits the magnets to move toward and away from each other thereby pursing sheath 925. Another plurality of magnets 930 may be arranged in the same manner as magnets 920 and are further enclosed in highly flexible silicone sheath 940 where the sheath permits the movement of magnets 930 toward each other but prevents magnets 930 from overlapping with magnets 920. This arrangement of magnets 920 and 930 allows silicone 925 and 940 to bunch or purse thereby occluding a lumen forming a valve. However, the magnetic force between magnets 920 and the force between 930 is not so sufficiently great that normal peristalsis cannot force a substance e.g. food or water through opening 960. As shown, opening

960 is in a partially opened state. At a resting state, silicone 940 would be occluded thereby preventing passage of food or water or any other substance. As shown in FIG. 9A, magnets 920 and 930 are arranged in an annular fashion about axis 950 where axis 950 defines a central lumen through implant 900. Magnets 920 and 930 may be organized in any fashion to accomplish the goal of permitting opening and closing of opening 960 through normal peristalsis as is known and understood in the art. In the FIG. 9A expression, plurality of outer ring magnets 920 are embedded in a flexible biocompatible material e.g. silicone forming an outer magnetic ring. A plurality of inner ring magnets 930 are embedded in flexible biocompatible material as well. Polarity of rings 920 and 930 are arranged in such a fashion that ring 920 repels ring 930 thereby biasing implant to a closed state. Ring 930 magnets are oriented with respect to each other such that they occlude opening 960. The relative repulsion between rings 920 and 930 and the magnetic strength of ring magnets 930 are such that normal peristalsis forces individual magnets in rings 920 and 930 to move away from each other such that opening 960 is created permitting passage of food.

Referring now to FIG. 9B, another expression of implant 900 is shown. In this expression, magnets 970 are generally spherical and are arranged about axis 950. Magnets 970 are spaced apart by spacers 975 and spacers 975 and magnets 970 are retained relative to one another by cord 980 where cord 980 passes through annuli in magnets 970 and spacers 975. Cord 980, magnets 970 and spacers 975 are provided in a highly flexible silicone bag 980 such that when magnets 970 and spacers 975 are in a relaxed state, bag 980 occludes opening 960 (see FIG. 9C). As in previous expressions, the FIG. 9B expression may be provided with rings 915 and anchors or quills as set forth above.

Referring now to FIGS. 10A – 10B, implant 300 is shown at various times after implantation. FIG. 10A depicts implant 300 just after implantation where implant fixation is reliant upon holding strength of anchors or quills 510, 610. FIG. 10B depicts ring 515, 615 beginning to break down thereby permitting

and stimulating tissue in growth 1005. Ring 515, 615 may be comprised of materials that promote tissue growth such as in one expression the, ring 515, 615 can include both hydrophilic portions and hydrophobic portions to form a hydrophilic-hydrophobic adjunct material. The resulting combination can advantageously have surfaces or portions that attract cells and encourage cell ingrowth (hydrophilic) and surfaces or portions that do not attract cells or otherwise encourage cell ingrowth (hydrophobic). In use, the hydrophobic portions can be placed in contact with the tissue, while the hydrophobic portions can be oriented away from the tissue surface.

In certain embodiments, synthetic polymers used to form adjunct materials can be hydrophobic, such as polycaprolactone (PCL) and polylactic acid (PLLA). It is noted that "polymers" as used herein can include copolymers. Synthetic adjunct materials, however, can be treated or otherwise produced to be hydrophilic, as will be discussed herein. To form the adjunct material, any method of creating a synthetic material having a hydrophilic portion and a hydrophobic portion can be used. In some embodiments, a surface of (or only half of) a hydrophobic adjunct material is treated with an acid or base which can cause the formation of pockets or pits in the surface. Alternatively, the adjunct material can be formed by bonding a hydrophilic layer to a hydrophobic layer. For example, an adjunct material can be treated such that the entire adjunct material becomes hydrophilic. Then this hydrophilic layer can be bound, such as by laminating, to a second hydrophobic adjunct material layer creating a material that is hydrophobic and hydrophilic. Various approaches can be used to create an adjunct material or matrix where a tissue contacting portion encourages cellular ingrowth while a non-tissue contacting portion discourages cellular ingrowth.

Referring now to FIG. 10C, anchors 510, 610 and rings 515, 615 have been fully absorbed. Mucosa 1010 is fully grown into scaffold 530, 635. After implanting, implant 300, as depicted in FIG. 11A, is situated in the esophagus 2 and is substantially located at the junction of the esophagus 2 and the stomach 4. Referring now to FIG. 11B, implant 300 and petals 630 are

depicted in an "open" state in response to esophageal peristalsis. A bolus of food is shown passing through the opening created by the expansion of implant 300 as well as the distal extension of petals 630. After the food passes through implant 300, petals 630 return to a closed state as shown in FIG. 11C.

Referring now to FIG. 12A, a cross-section of the FIG. 5 expression of implant 300 is shown in an implanted state. The overlapping nature of petals 330 is depicted. As lumen 2 expands through a peristaltic wave, implant 300 expands normal to axis 1200 (the direction of peristalsis and food movement) as shown in FIG. 12B. This normal expansion creates an opening about axis 1200 in petals 330 permitting passage of food past implant 300.

Having shown and described various expressions and examples of the present artificial sphincter, further adaptations of the methods and devices described herein can be accomplished by appropriate modifications by one of ordinary skill in the art without departing from the scope of the present artificial sphincter. Several of such potential modifications have been mentioned, and others will be apparent to those skilled in the art. For instance, the specific materials, dimensions, and the scale of drawings will be understood to be non-limiting examples. Accordingly, the scope of the present artificial sphincter should be considered in terms of the following claims and is understood not to be limited to the details of structure, materials, or acts shown and described in the specification and drawings.

CLAIMS

1. A surgical implant, comprising:
an outer ring having an outer wall and an inner wall, the outer ring disposed about a central axis;
an inner ring adjacent to the outer ring inner wall disposed about the central axis defining an annular opening;
a plurality of wedge-shaped petals flexibly attached to the inner ring disposed about the central axis, the petals substantially occluding the annular opening in a first state and flexibly opening to provide a variably sized bore in a second state.

2. The surgical implant of Claim 1, further comprising a plurality of anchors disposed about the outer ring outer wall.

3. The surgical implant of Claim 2 wherein the plurality of anchors are oriented substantially perpendicularly to the outer ring outer wall.

4. The surgical implant of Claim 3, wherein the anchors have a barb to promote fixation in tissue.

5. The surgical implant of Claim 4 wherein the outer ring and the anchors are comprised of a bio-absorbable material.

6. A surgical implant, comprising:
a bio-absorbable outer ring having an outer wall and an inner wall the outer ring disposed about a central axis;
an inner ring attached to the outer ring inner wall and disposed about the central axis defining an annular opening, the inner ring having a surface to promote tissue in-growth;
a plurality of wedge-shaped petals having an annularly-shaped distal end terminating in a point at a proximal end, the distal end flexibly attached to the inner ring disposed about the central axis, the petals substantially occluding the annular opening in a first state and elastically deformable to form a variably sized bore in a second state.

7. The surgical implant of Claim 6 wherein the plurality of petals have magnetic properties biasing the petals to the first state.

8. The surgical implant of Claim 7 wherein the plurality of petals comprises at least three wedge-shaped petals.

9. The surgical implant of Claim 8 wherein each petal does not overlap an adjacent petal.

10. The surgical implant of Claim 9 wherein the petals are attached to the inner ring with a non-absorbable filament.

11. A surgical implant, comprising:

an outer ring having an outer wall and an inner wall the outer ring disposed about a central axis wherein the outer wall has a first height and the inner wall has a second height;

an inner ring adjacent to the outer ring inner wall disposed about the central axis extending annularly from the inner wall towards the central axis; and

a plurality of non-overlapping wedge-shaped petals flexibly attached to the inner ring disposed about the central axis, the petals substantially occluding the annular opening in a first state and elastically opening to provide a variably sized bore in a second state, the petals having magnetic properties biasing them to the first state.

12. The surgical implant of Claim 11 wherein the inner ring has a height less than of the inner wall.

13. The surgical implant of Claim 12 wherein the outer ring and the inner ring are of unitary construction.

14. The surgical implant of Claim 13 wherein the inner ring and the outer ring are bio-absorbable.

15. The surgical implant of Claim 14 further comprising a lattice structure embedded within the outer ring.

16. The surgical implant of Claim 15 wherein the lattice structure is bio-absorbable.

17. The surgical implant of Claim 16 wherein the outer ring and inner ring absorb faster than the lattice structure.
18. The surgical implant of Claim 17 further comprising a plurality of anchors disposed about the outer ring outer wall.
19. The surgical implant of Claim 18 wherein the anchors hare bio-absorbable.
20. The surgical implant of Claim 18 wherein at least two of the anchors have barbs.

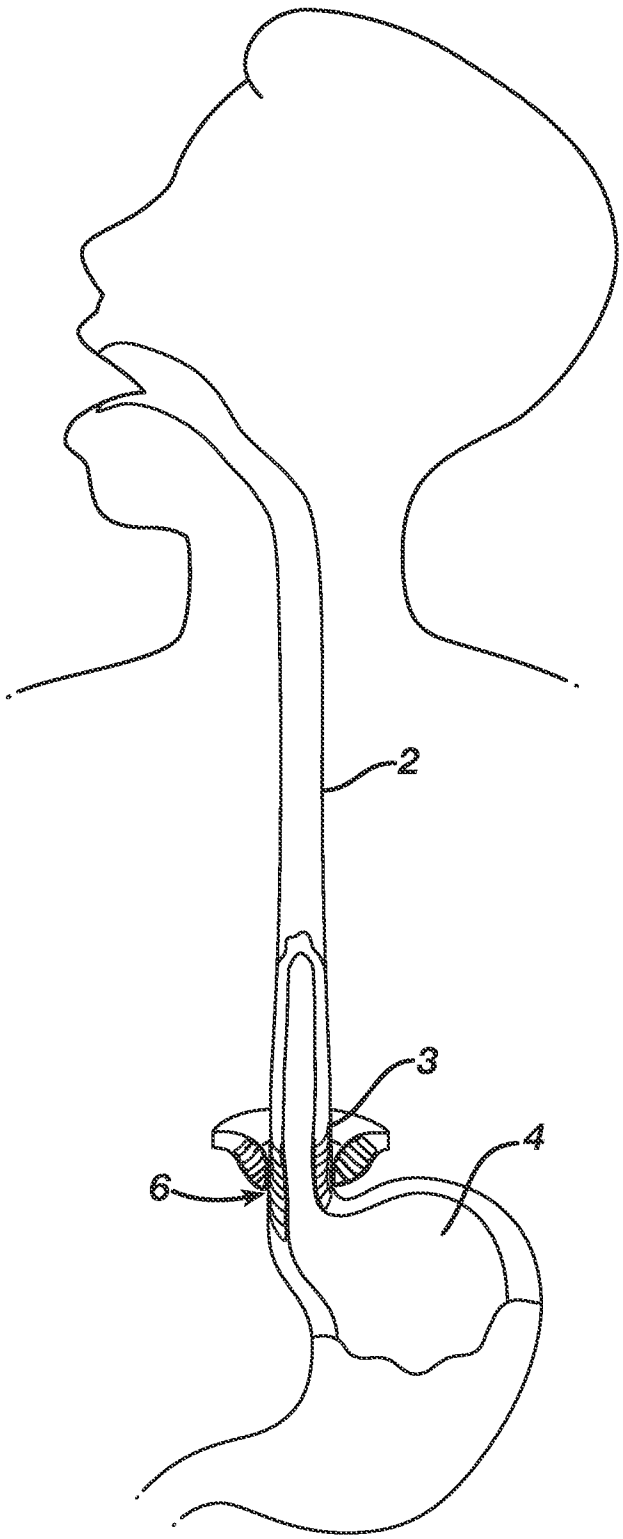


FIG. 1

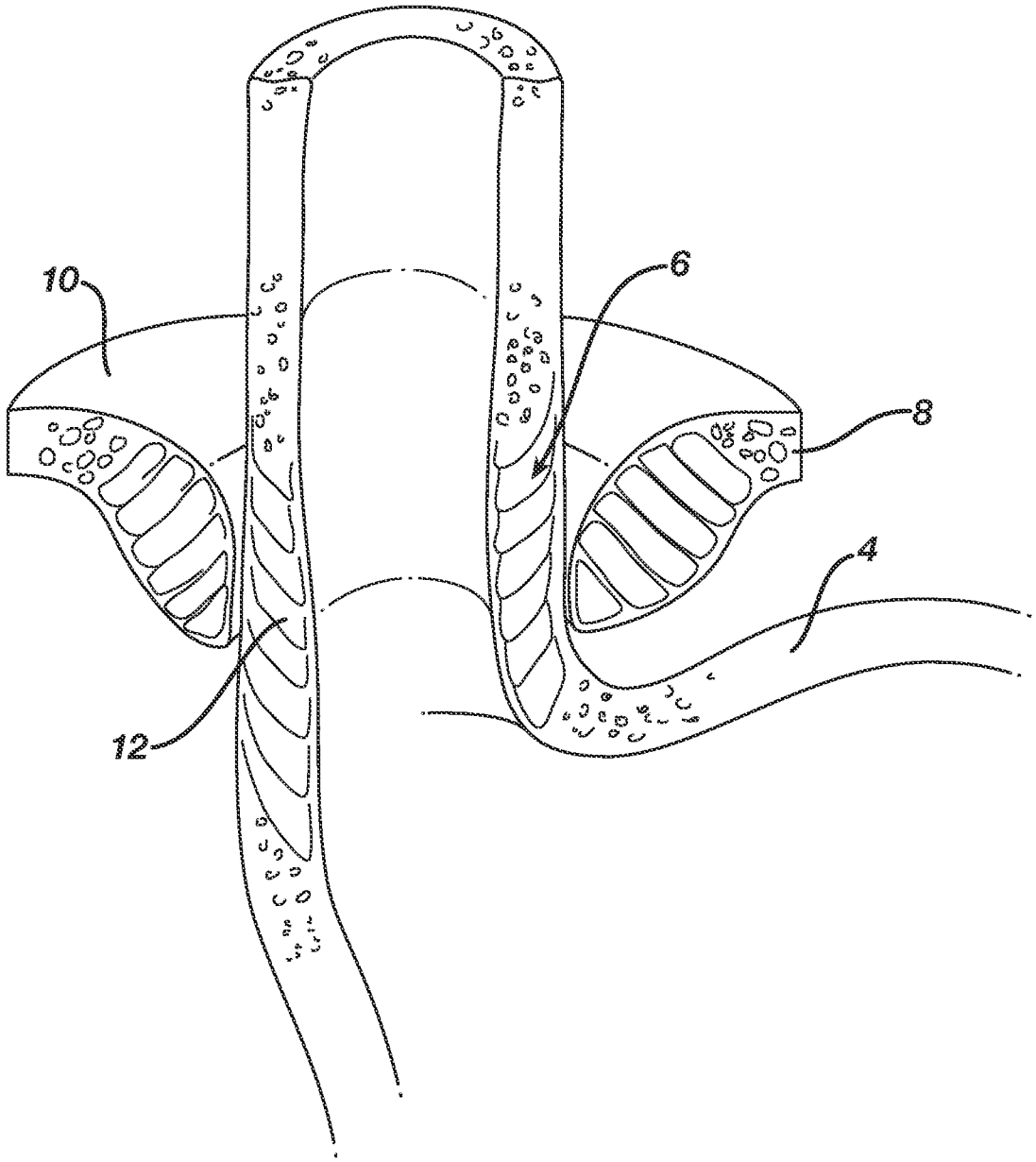


FIG. 2

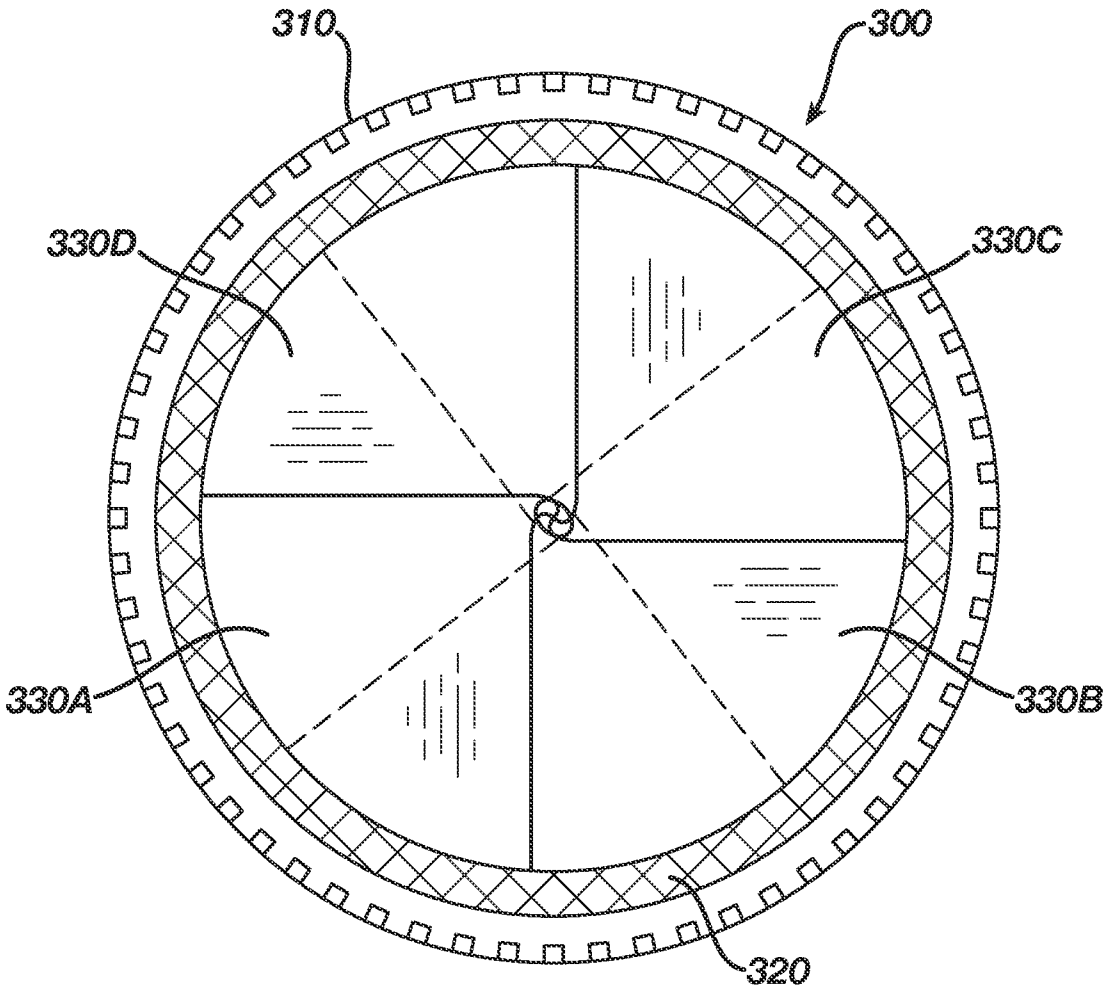


FIG. 3

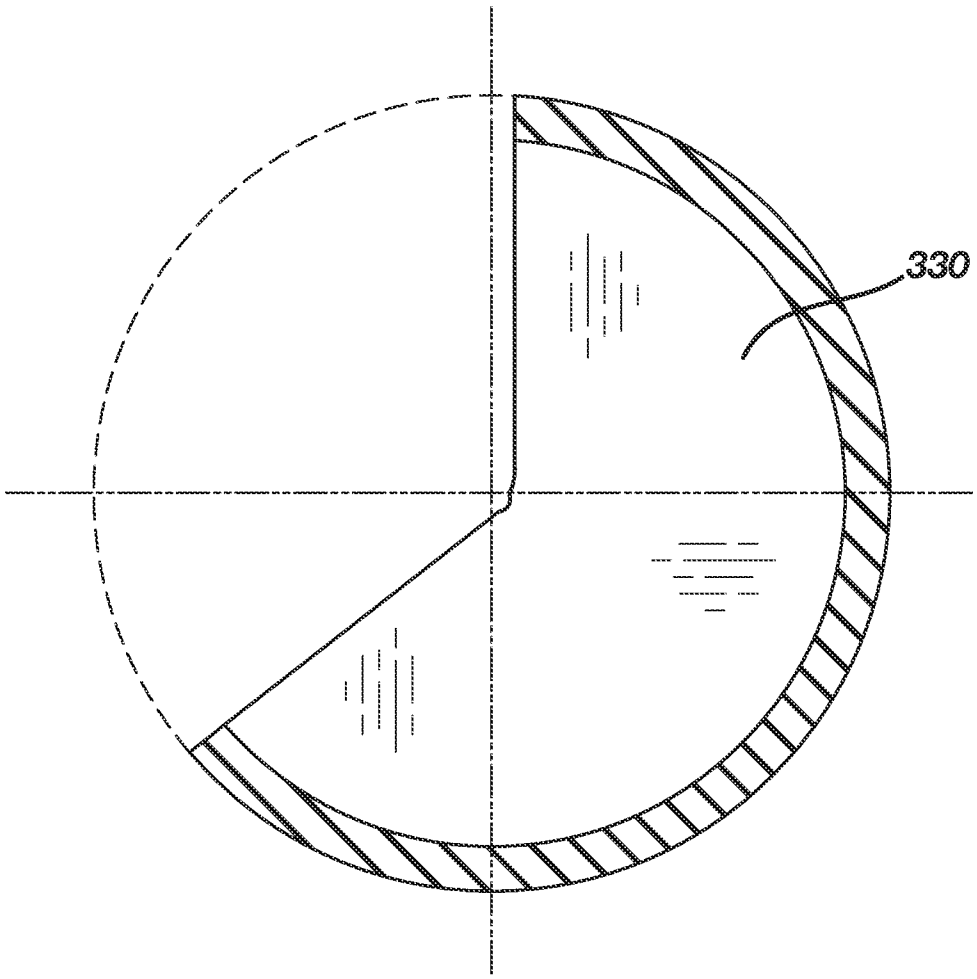


FIG. 4

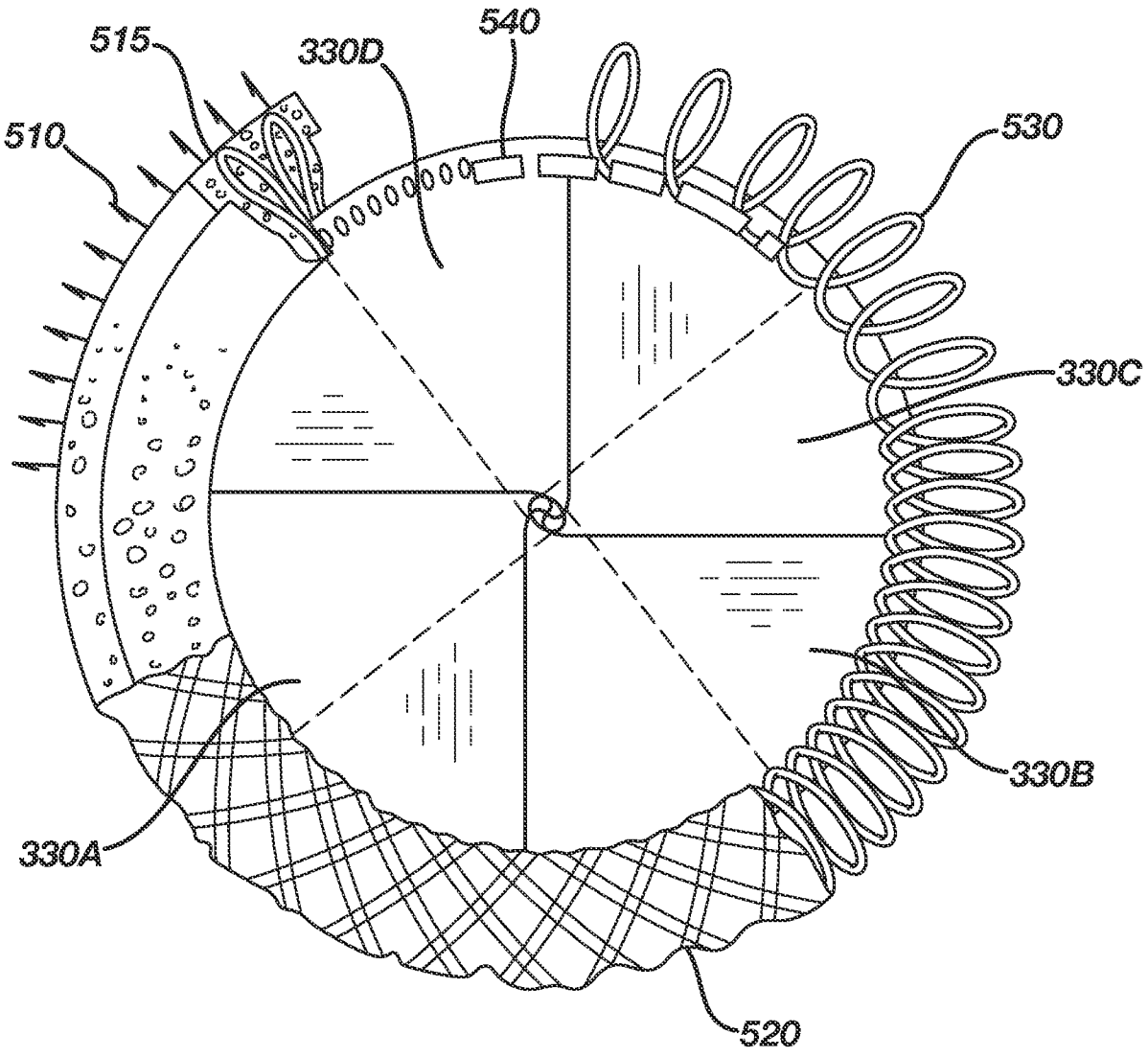


FIG. 5

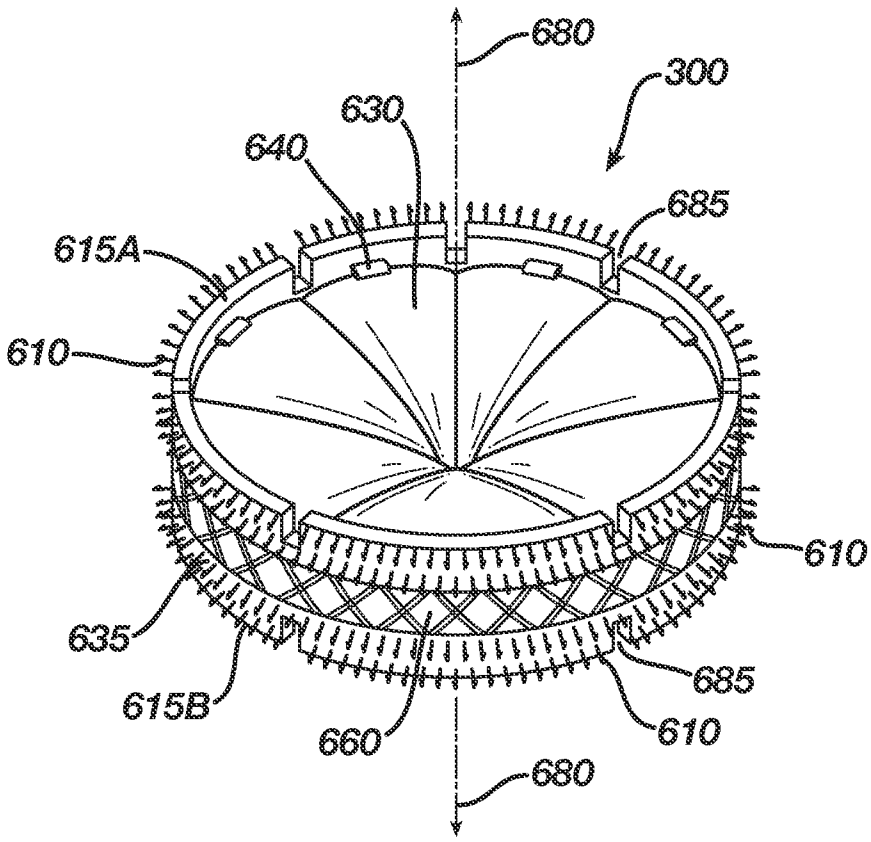


FIG. 6

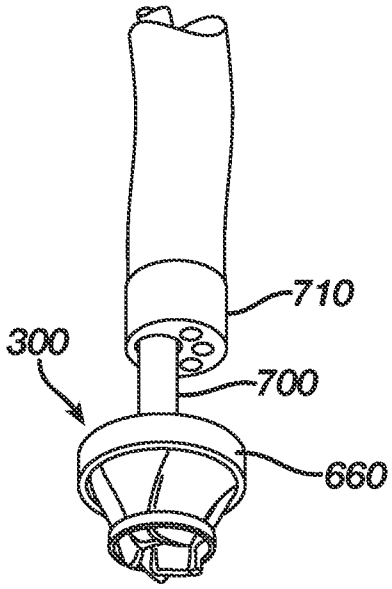


FIG. 7A

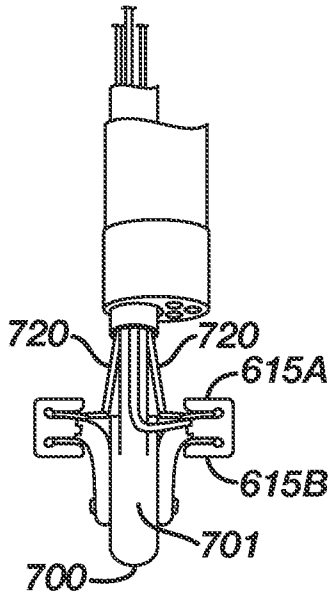


FIG. 7B

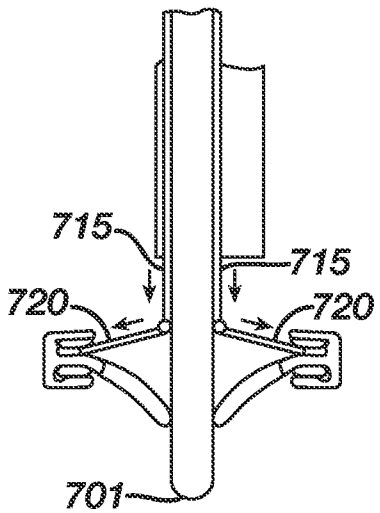


FIG. 7C

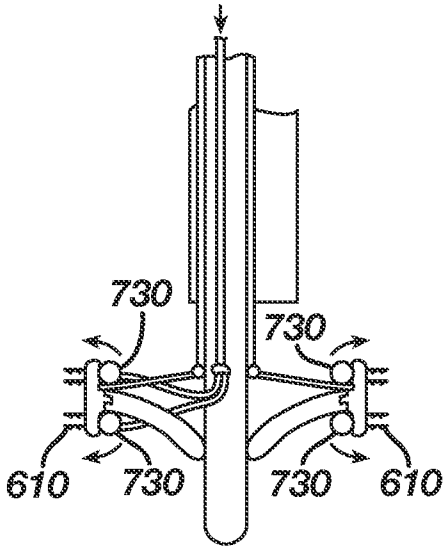


FIG. 7D

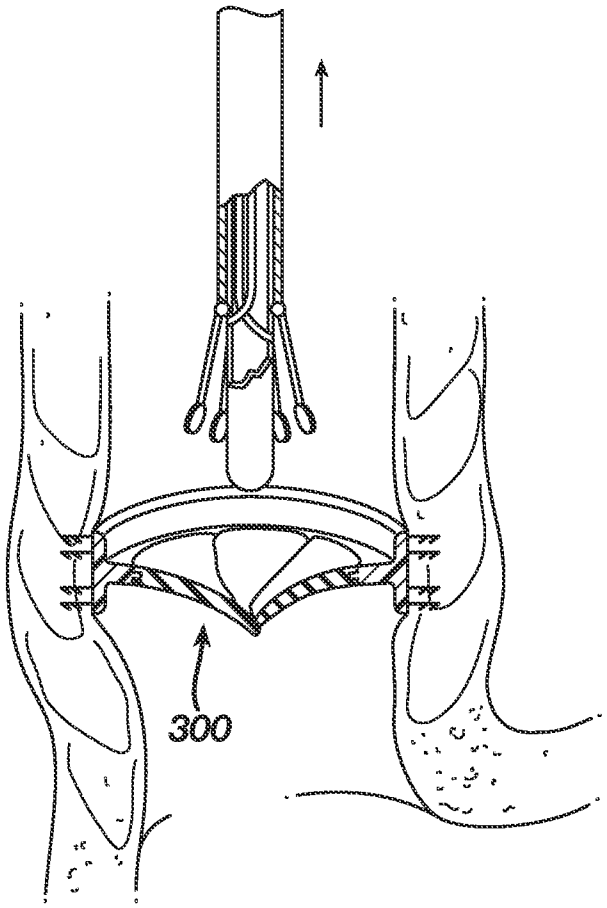


FIG. 7E

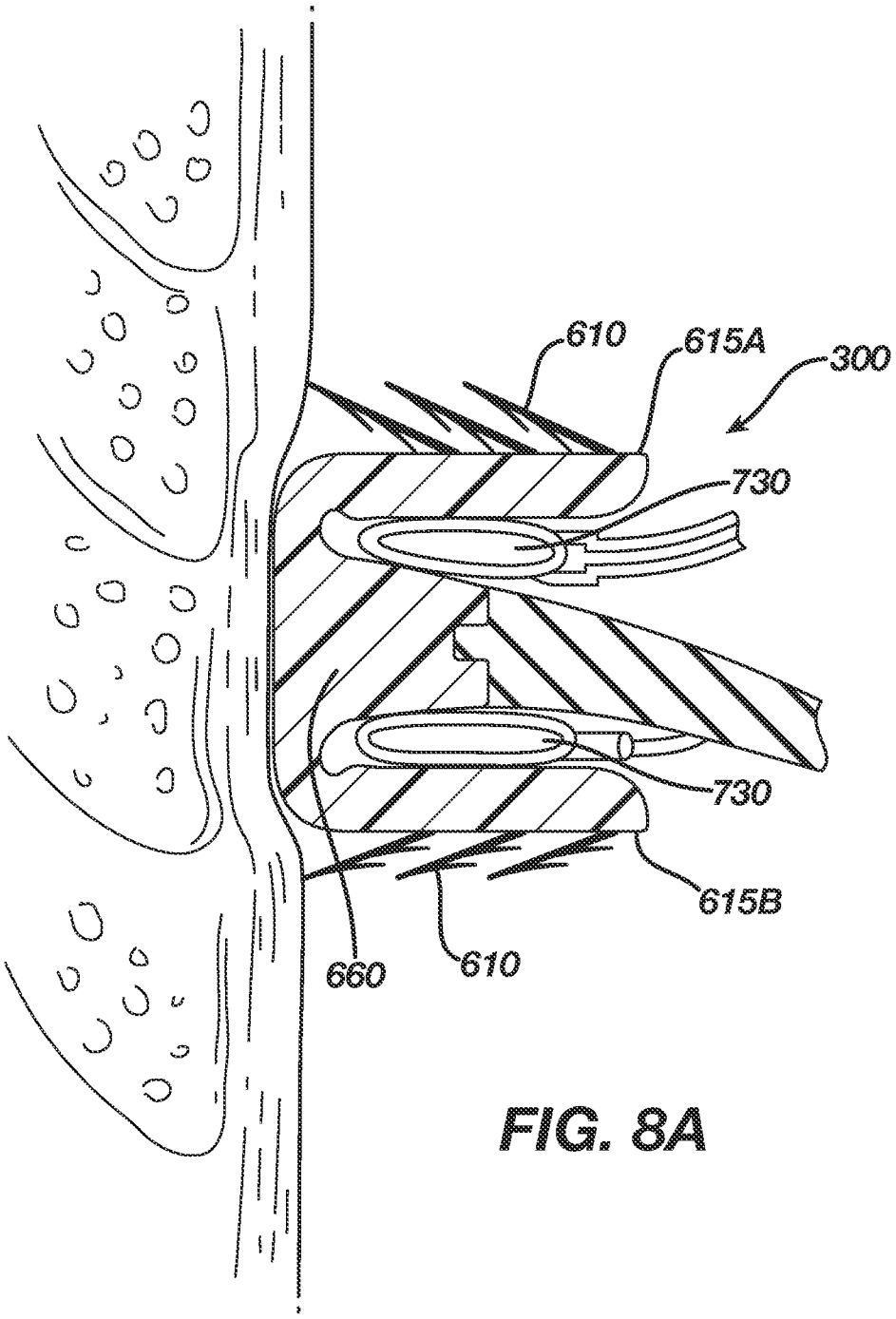


FIG. 8A

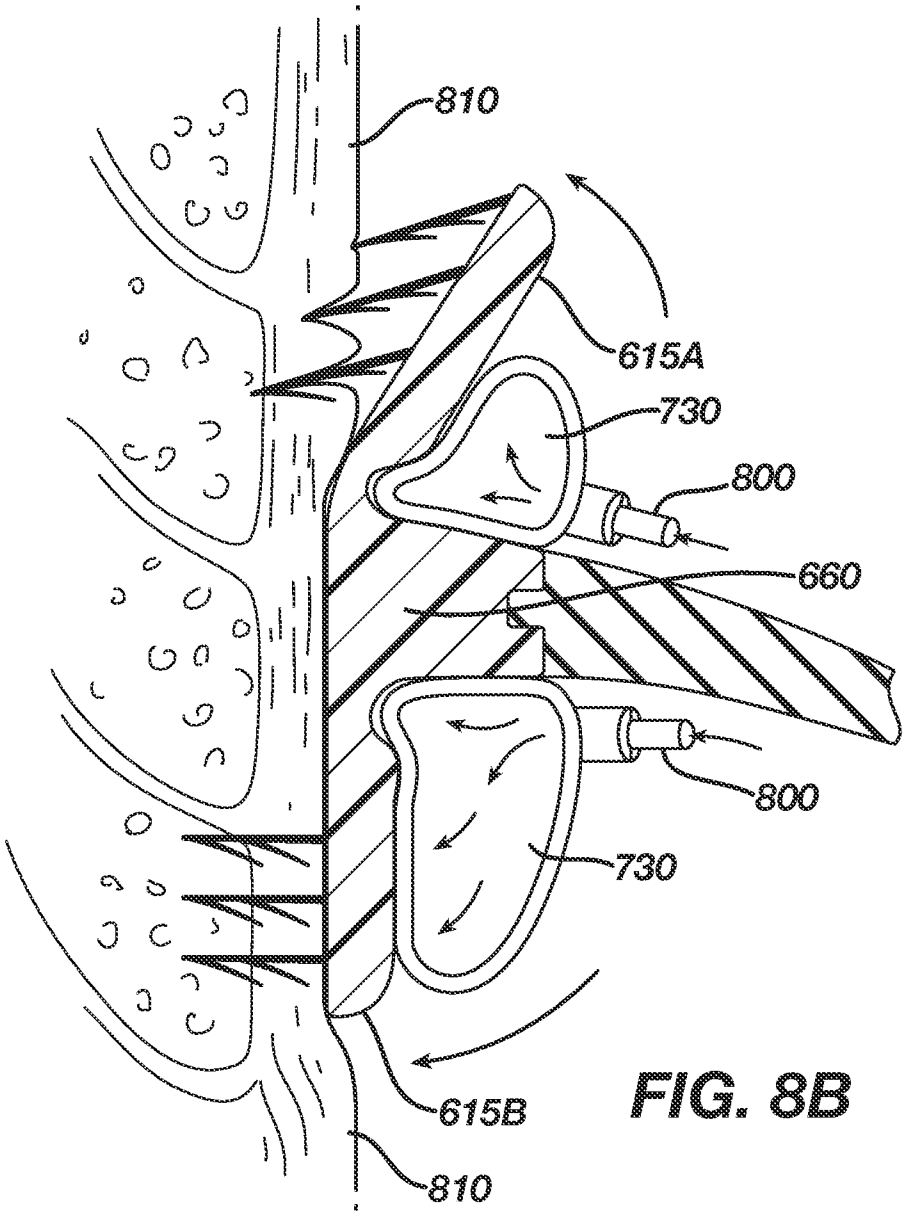


FIG. 8B

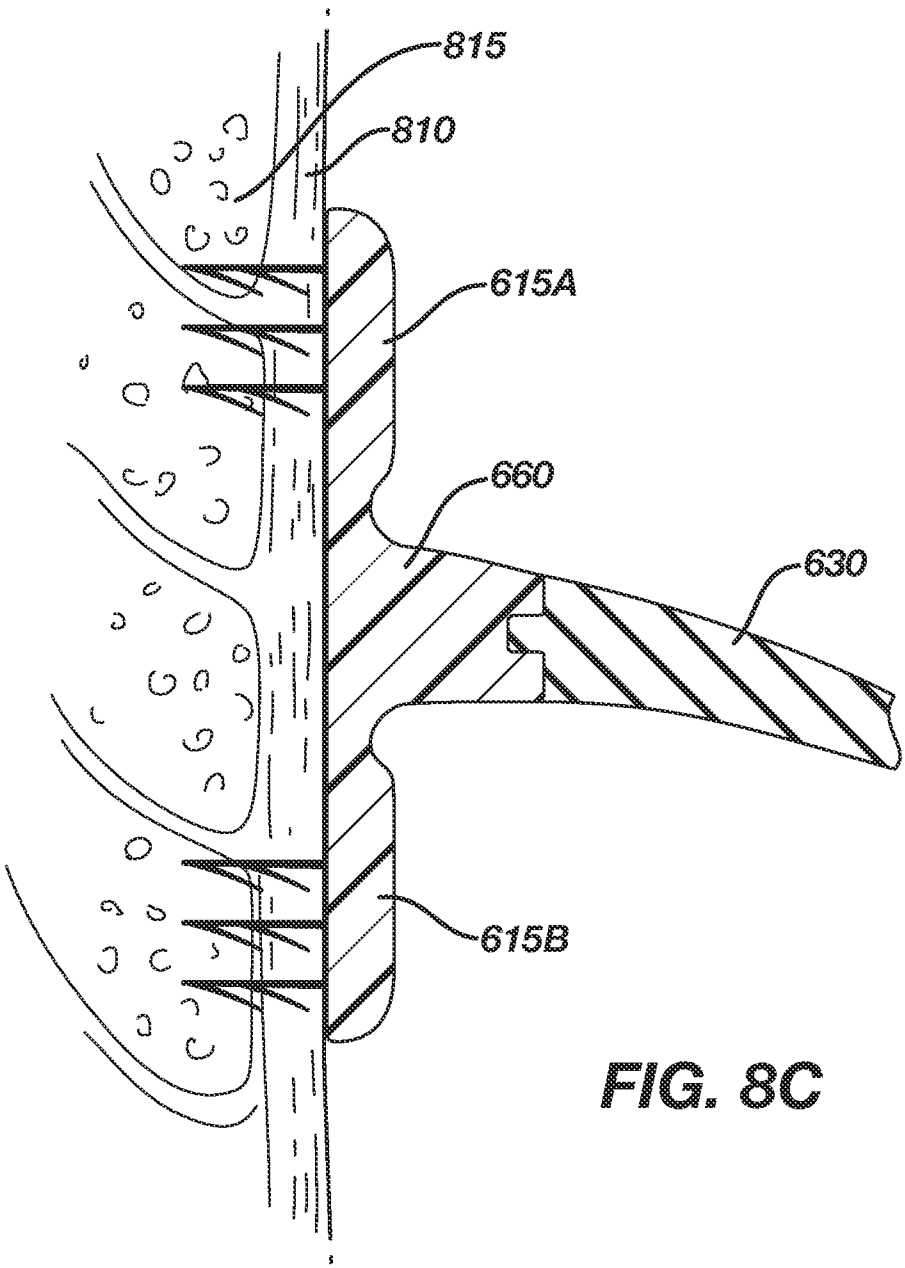


FIG. 8C

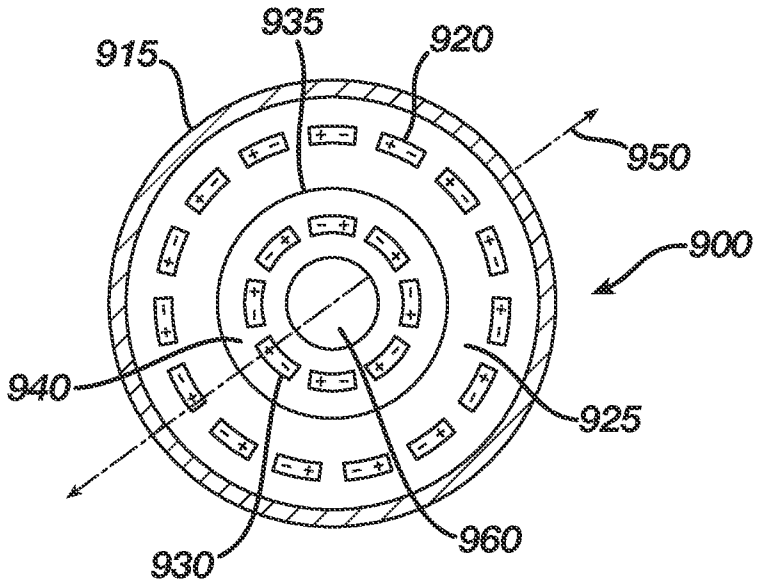


FIG. 9A

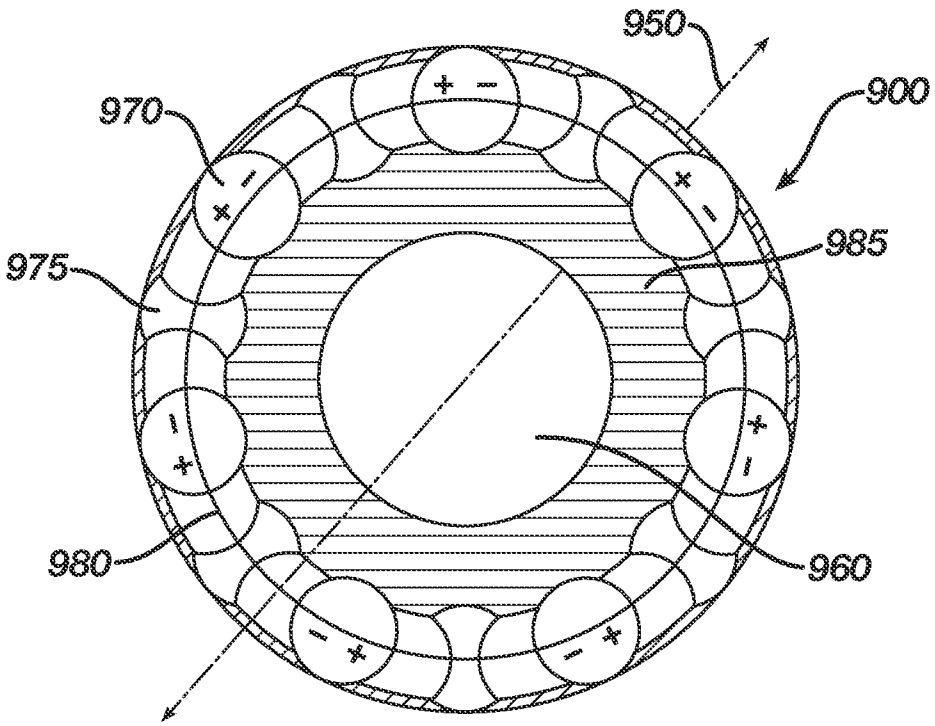


FIG. 9B

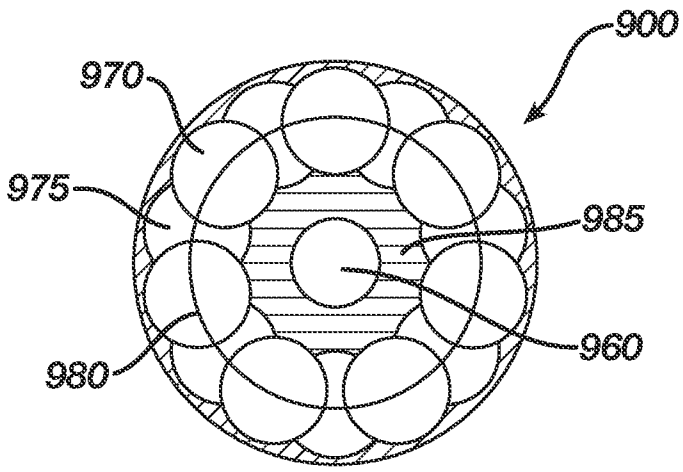


FIG. 9C

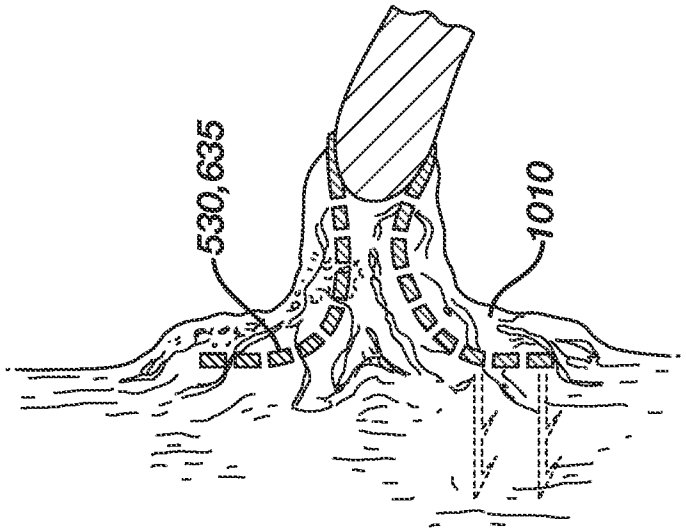


FIG. 10C

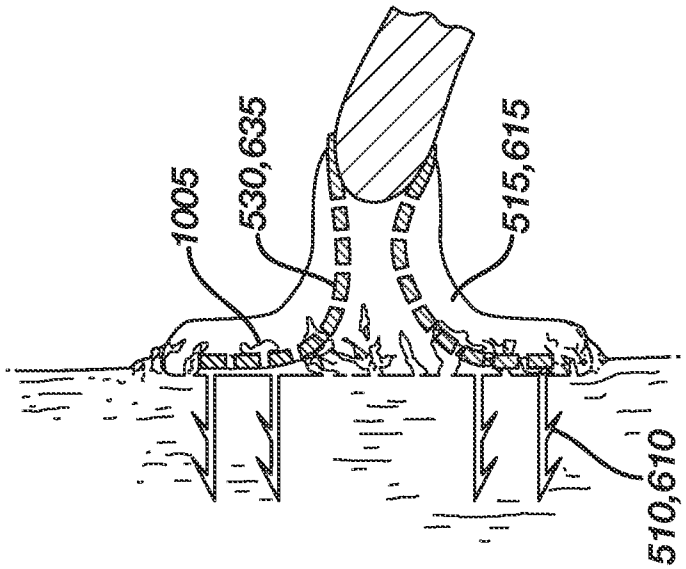


FIG. 10B

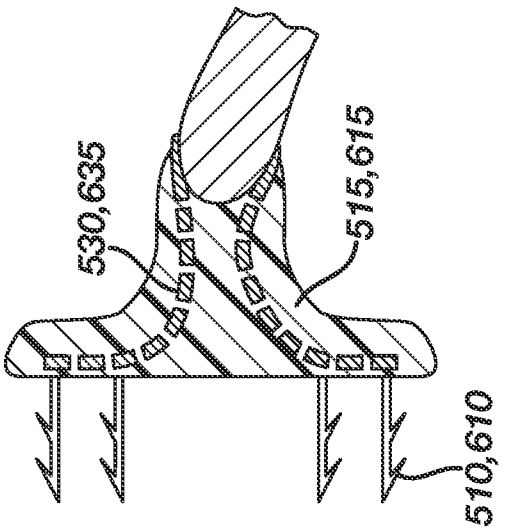


FIG. 10A

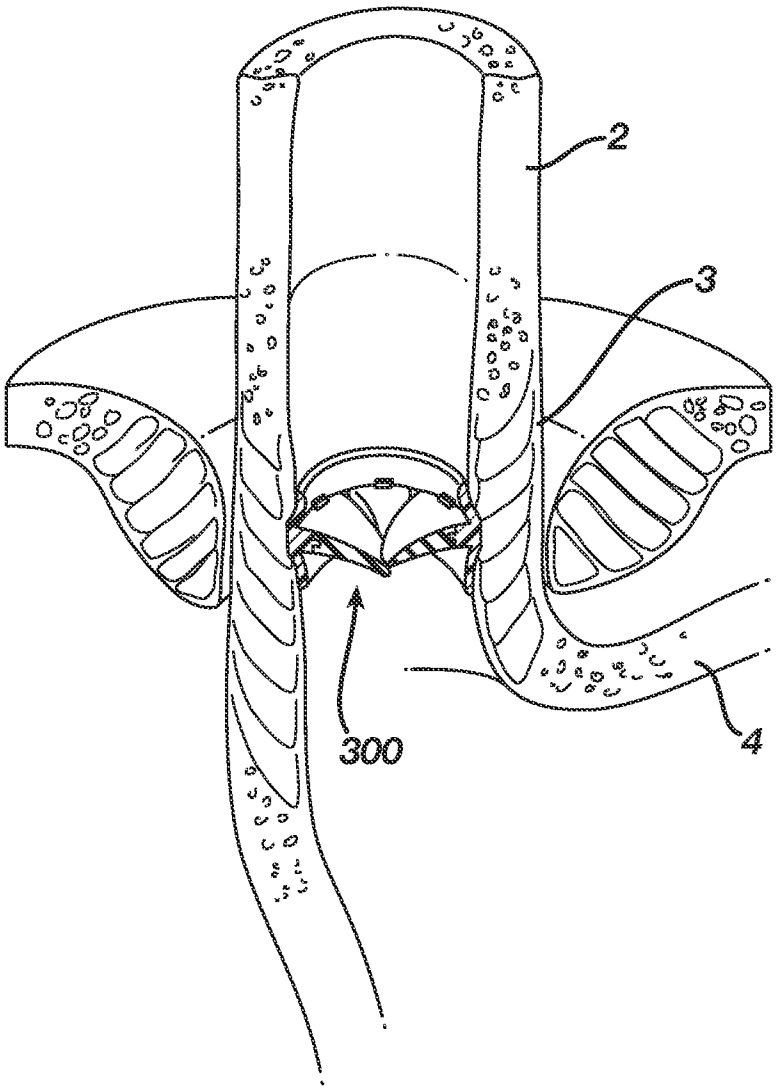


FIG. 11A

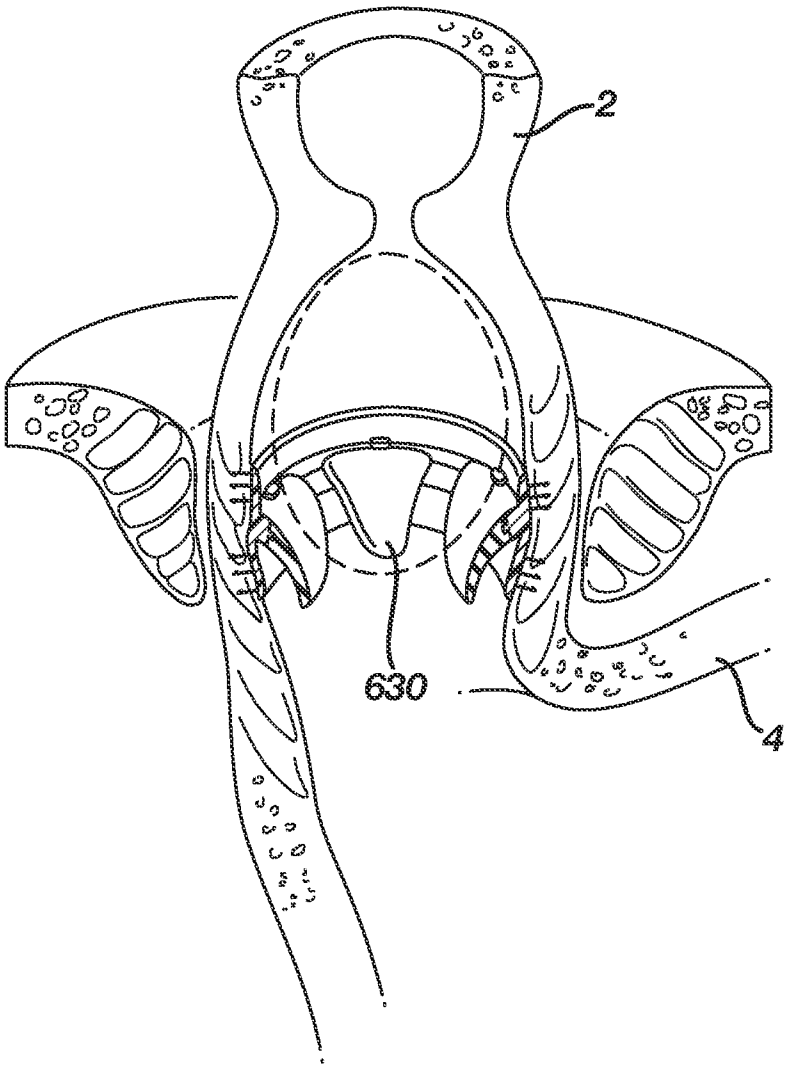


FIG. 11B

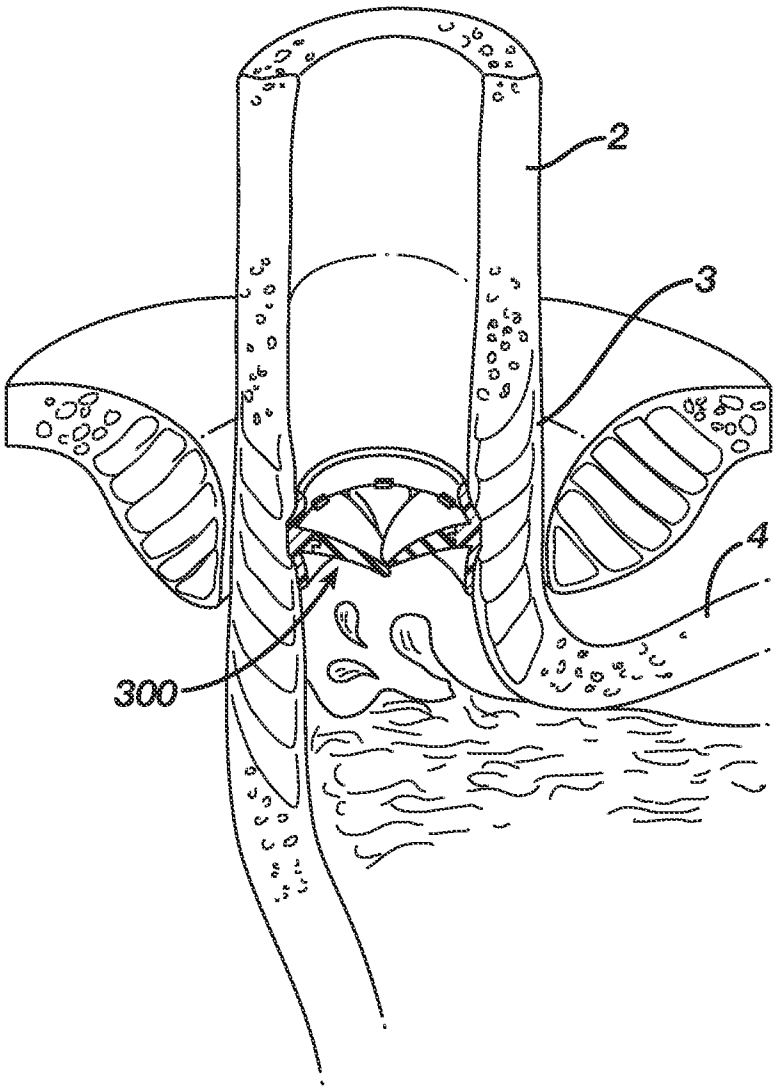


FIG. 11C

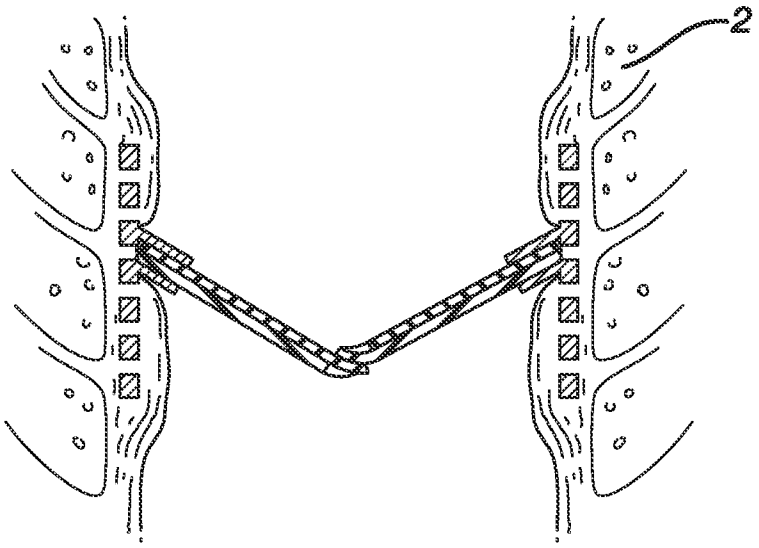


FIG. 12A

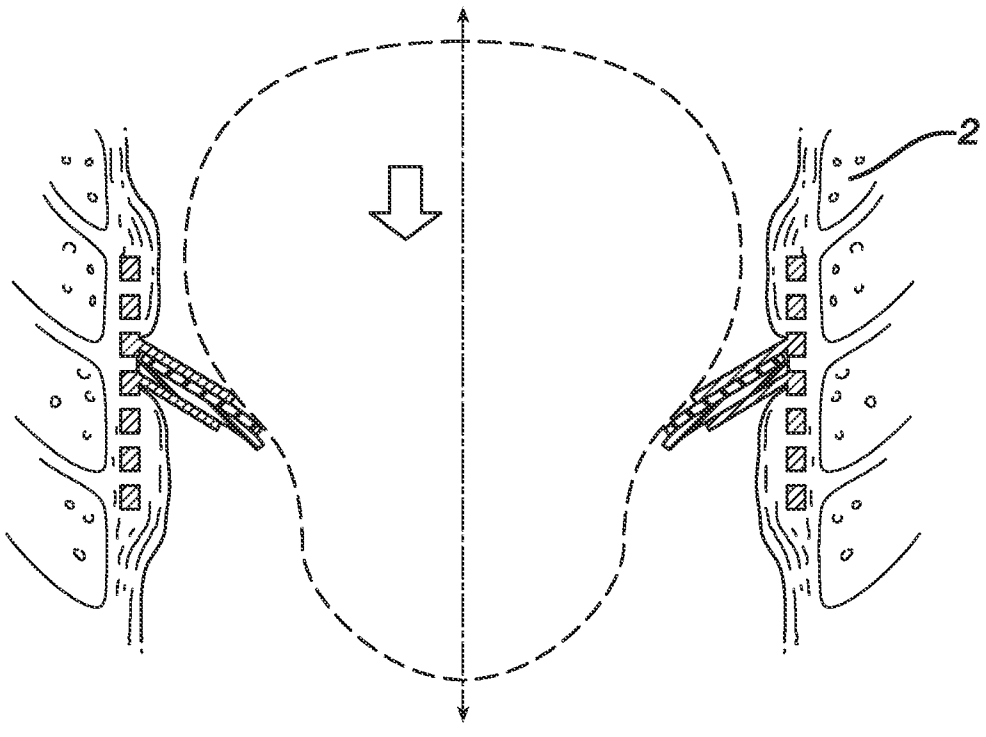


FIG. 12B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/031293

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/04 A61F5/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/031951 A1 (COSTELLO KIERAN [IE] ET AL) 30 January 2014 (2014-01-30) paragraph [0069]; figures 1-2d,5c	1-20
X	WO 2009/100313 A1 (UNIV PENNSYLVANIA [US]; FRIEDBERG JOSEPH [US]) 13 August 2009 (2009-08-13) page 8, line 1 - line 6; figure 3	1,6,11
X	US 2014/039641 A1 (TRAINOR CHRISTOPHER V [US] ET AL) 6 February 2014 (2014-02-06)	1,11
A	figures 1a,3a-3c,11a-11c	6

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 July 2015	06/08/2015

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Franz, Volker

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2015/031293

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2014031951 A1	30-01-2014	NONE	
WO 2009100313 A1	13-08-2009	NONE	
US 2014039641 A1	06-02-2014	US 2014039641 A1	06-02-2014
		WO 2014022500 A1	06-02-2014