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(54) **APPARATUS TO TREAT ESOPHAGEAL SPHINCTERS**

now Pat. No. 6,749,607, which is a continuation of application No. 09/036,092, filed on Mar. 6, 1998, now abandoned.

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**Publication Classification**

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(52) **U.S. Cl.** ..... **606/192**  
(57) **ABSTRACT**

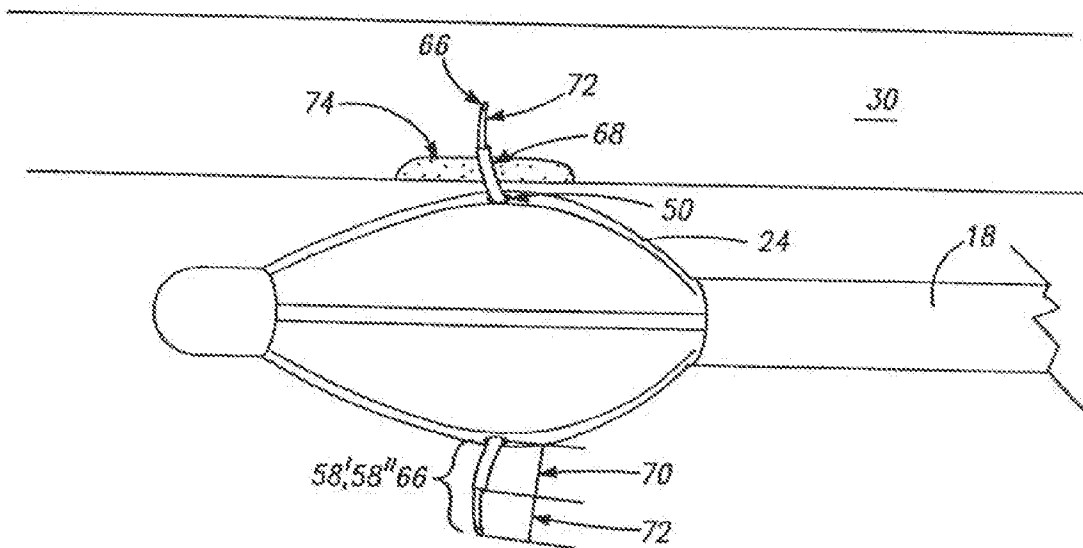
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(22) Filed: **Jan. 13, 2012**

**Related U.S. Application Data**

(60) Continuation of application No. 12/927,354, filed on Nov. 12, 2010, now abandoned, which is a division of application No. 11/638,952, filed on Dec. 14, 2006, now abandoned, which is a division of application No. 10/838,922, filed on May 4, 2004, which is a division of application No. 09/971,085, filed on Oct. 4, 2001,

A sphincter treatment apparatus has an introducer means including a distal portion means. An expandable device means includes a plurality of arm means. Each arm means of the plurality has a distal section means and a proximal section means. Each of distal sections means of the arm means are coupled and each of the proximal sections means of the arm means are coupled to the introducer means distal portion means. The expandable device means is configured to at least partially dilate a sphincter in a deployed state. An energy delivery device means is introduceable from the introducer means into a selected site of the sphincter. The energy delivery device means is configured to deliver sufficient energy to reduce a frequency of relaxation of the sphincter.



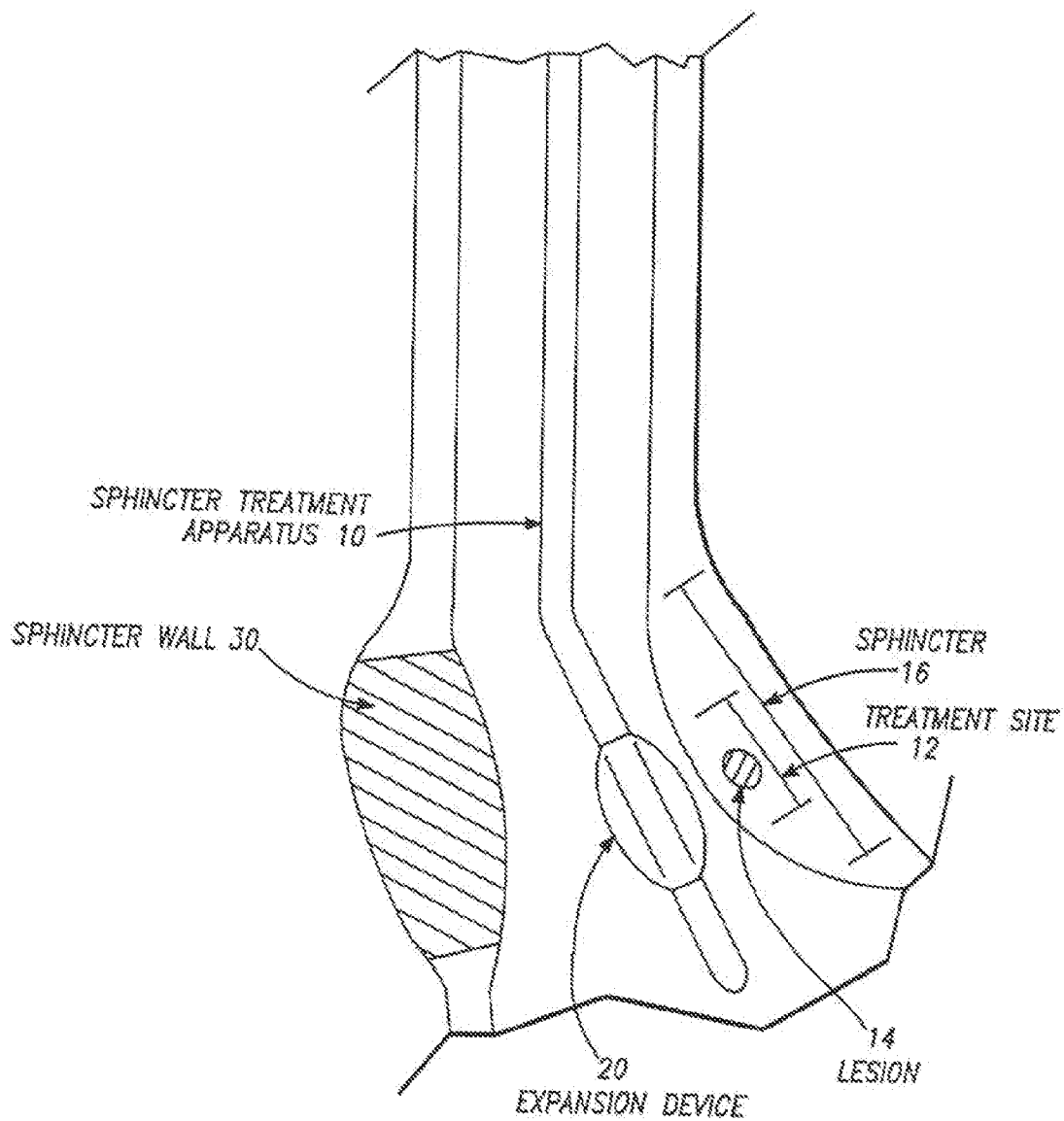


FIG. - 1

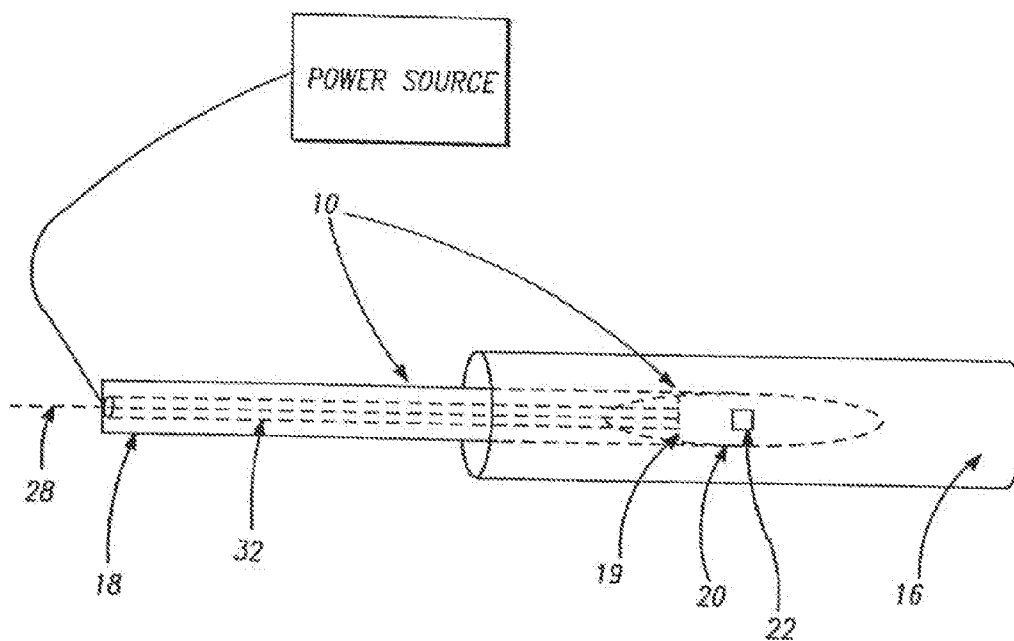


FIG. -2

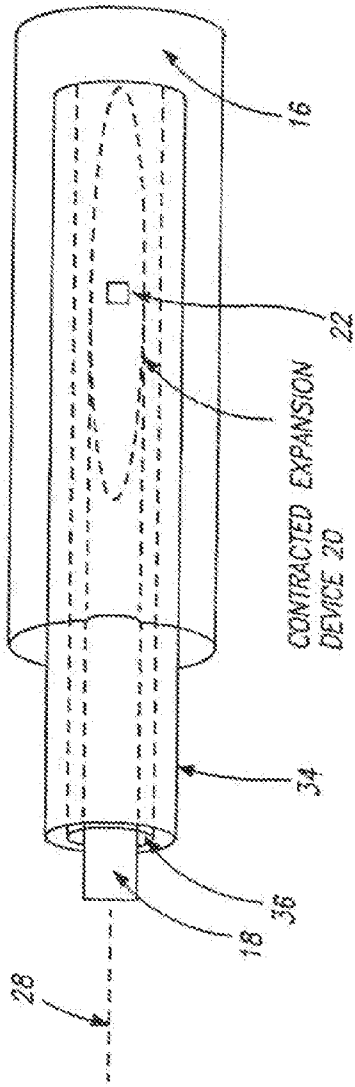


FIG. -3A

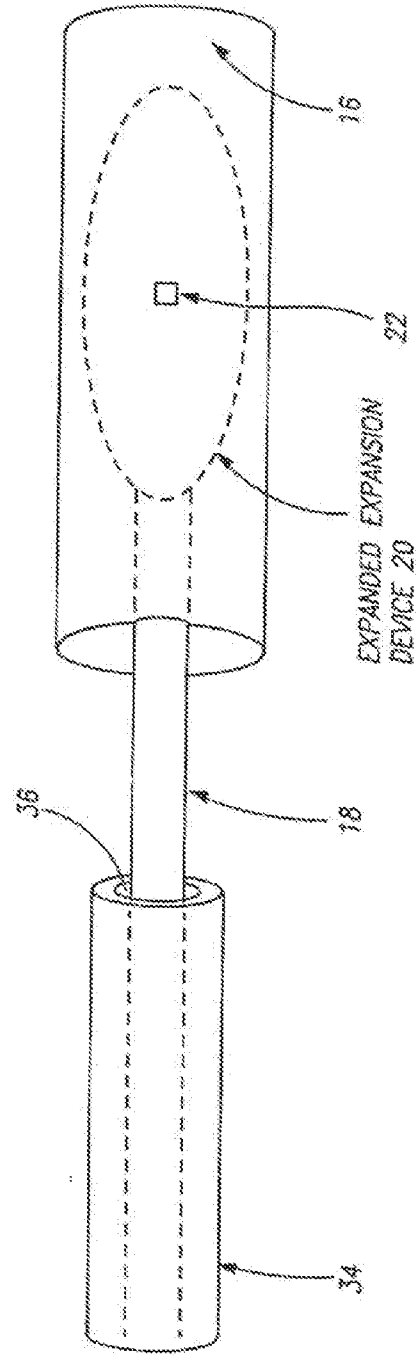


FIG. -3B

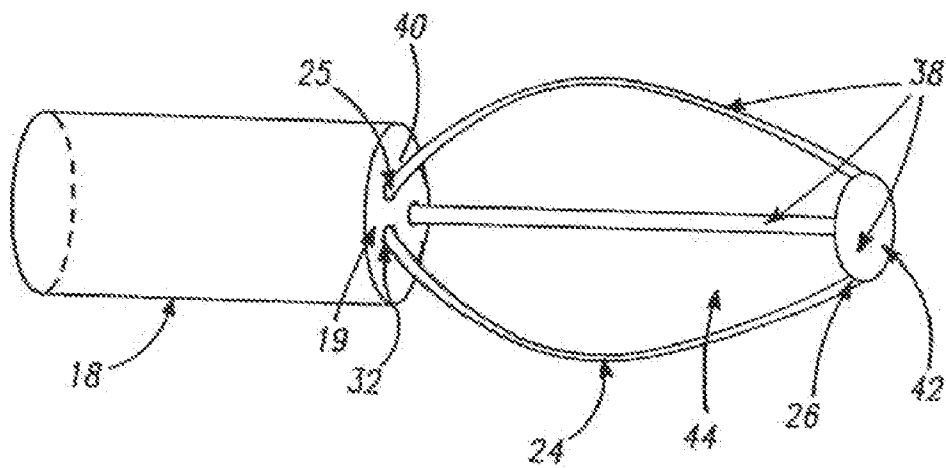


FIG. -4

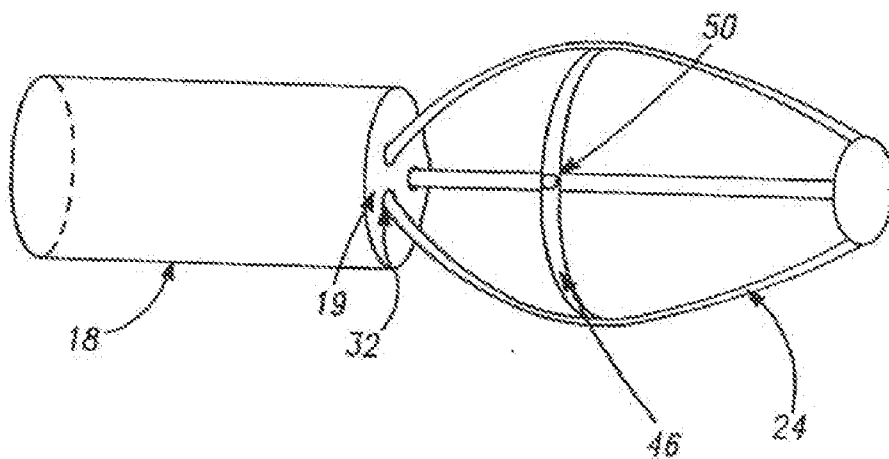


FIG. -5

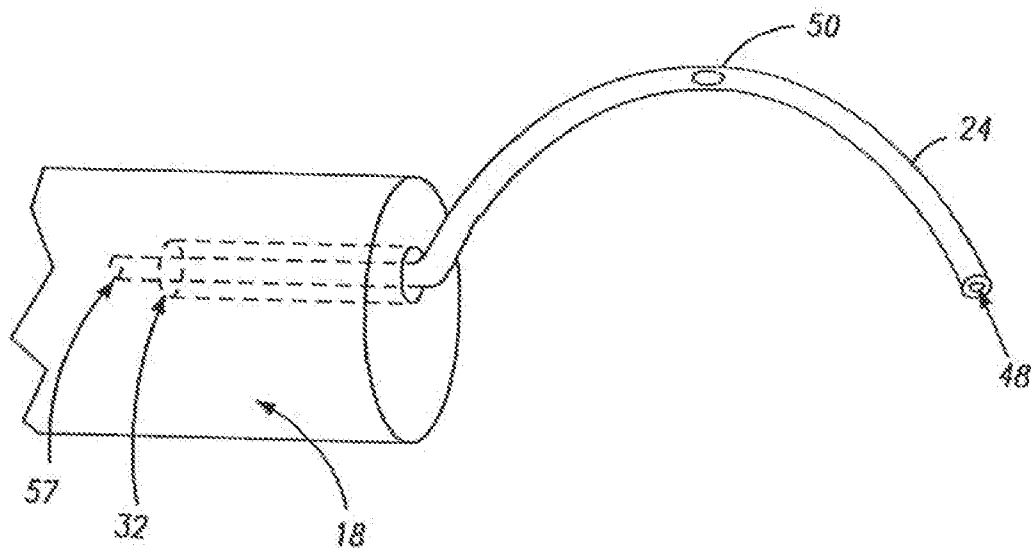


FIG. -6A

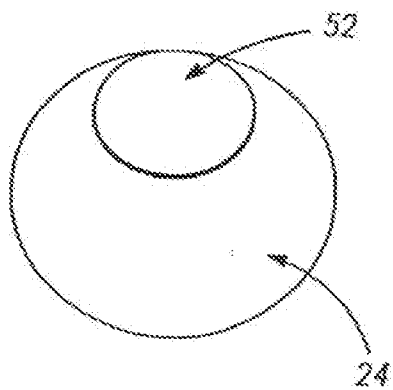


FIG. -6B

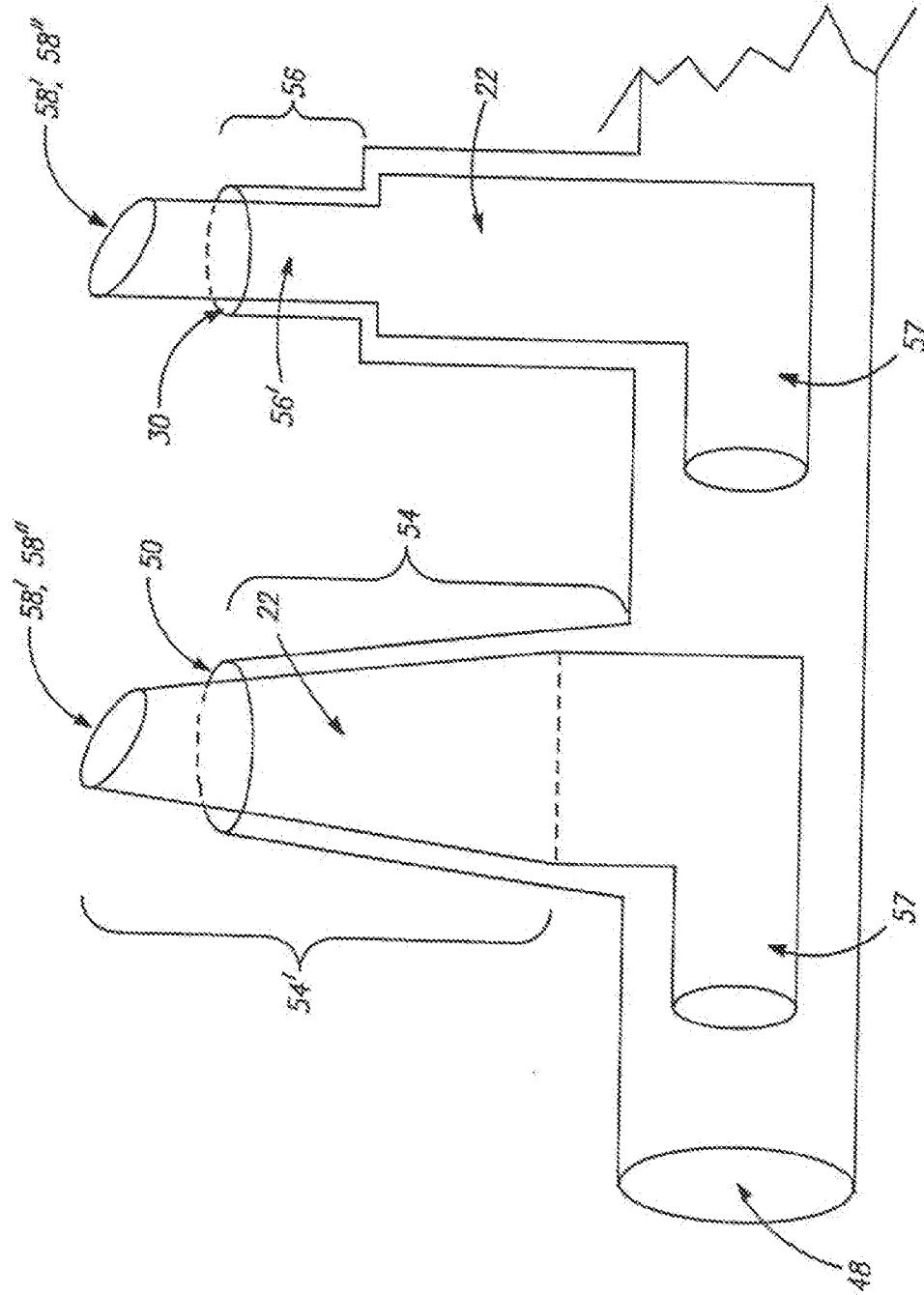


FIG. - 7A

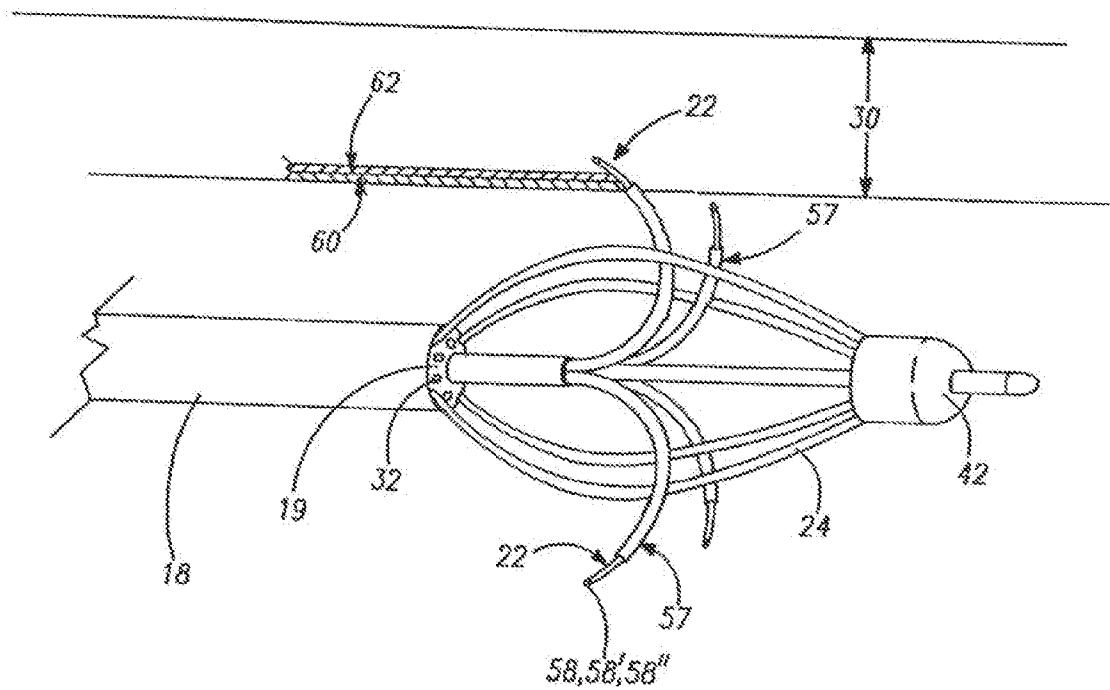


FIG. - 8A



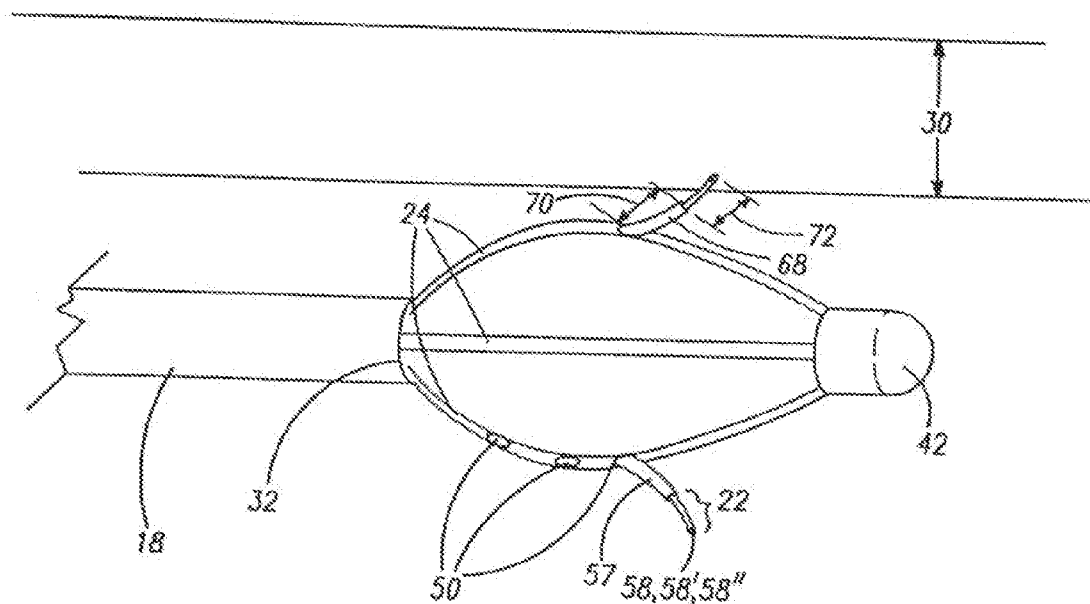


FIG. -8B

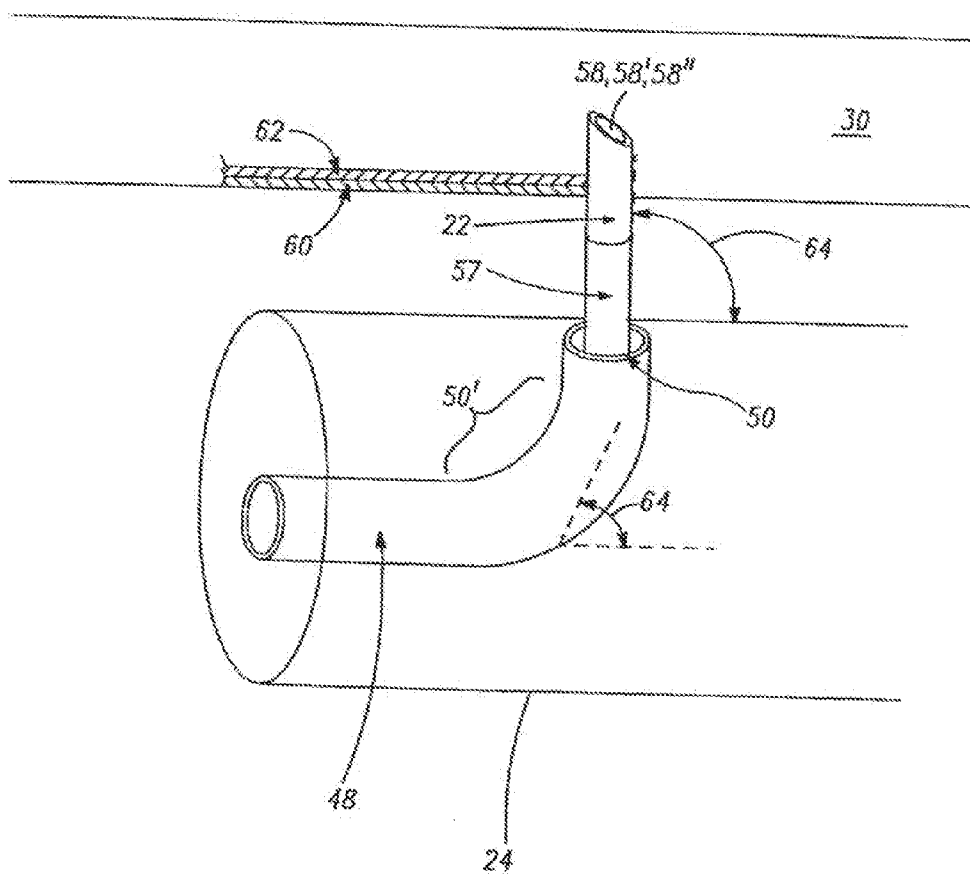


FIG. - 9

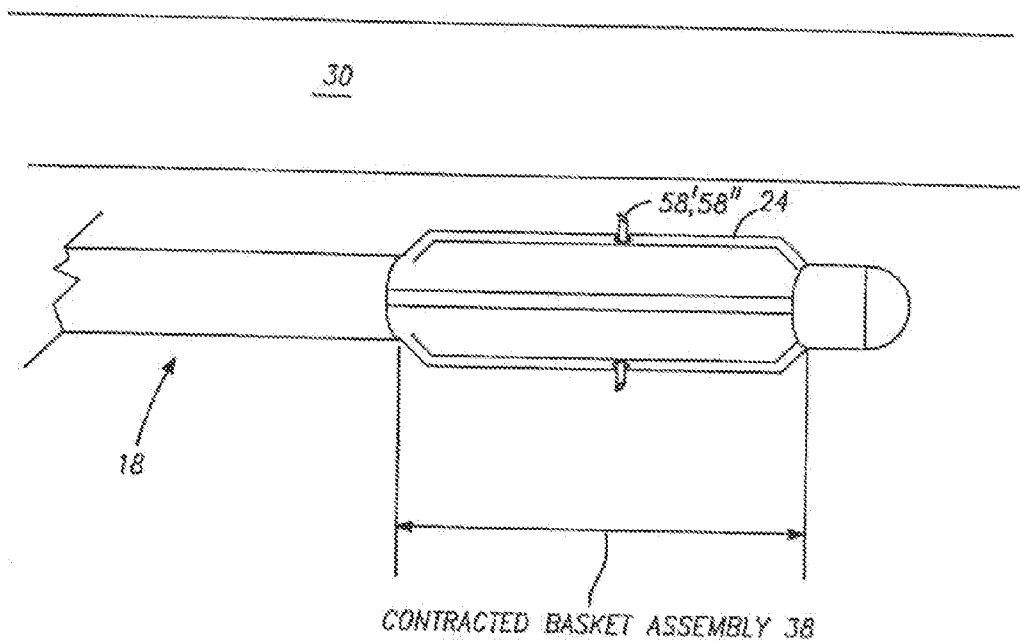


FIG. - 10A

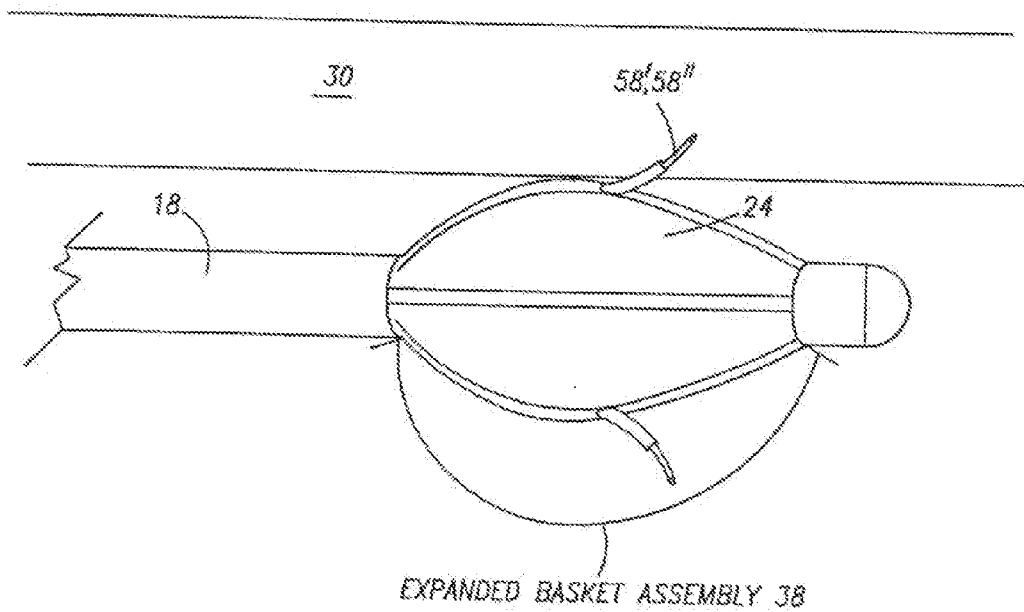


FIG. - 10B

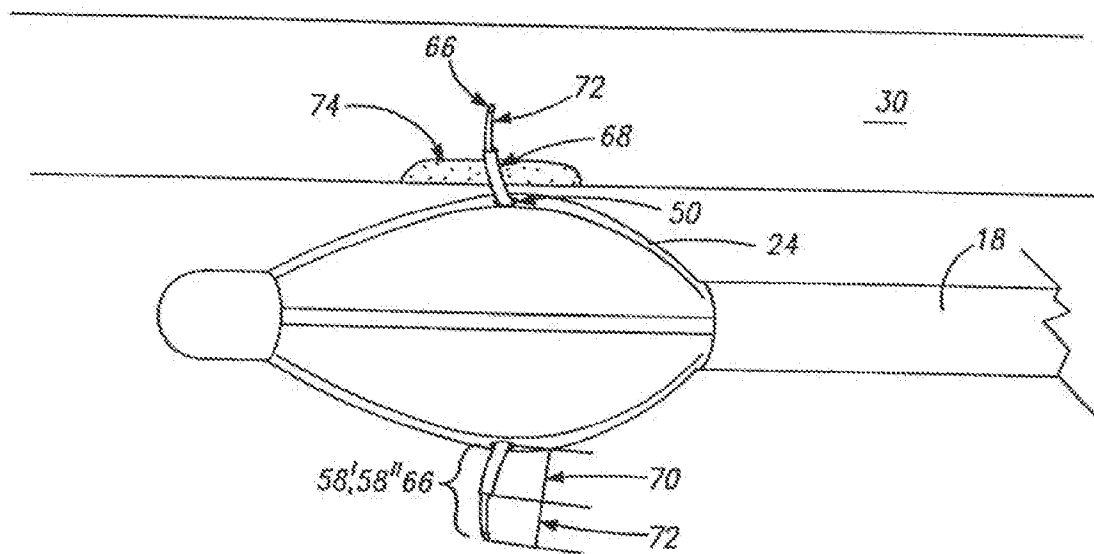


FIG. -11

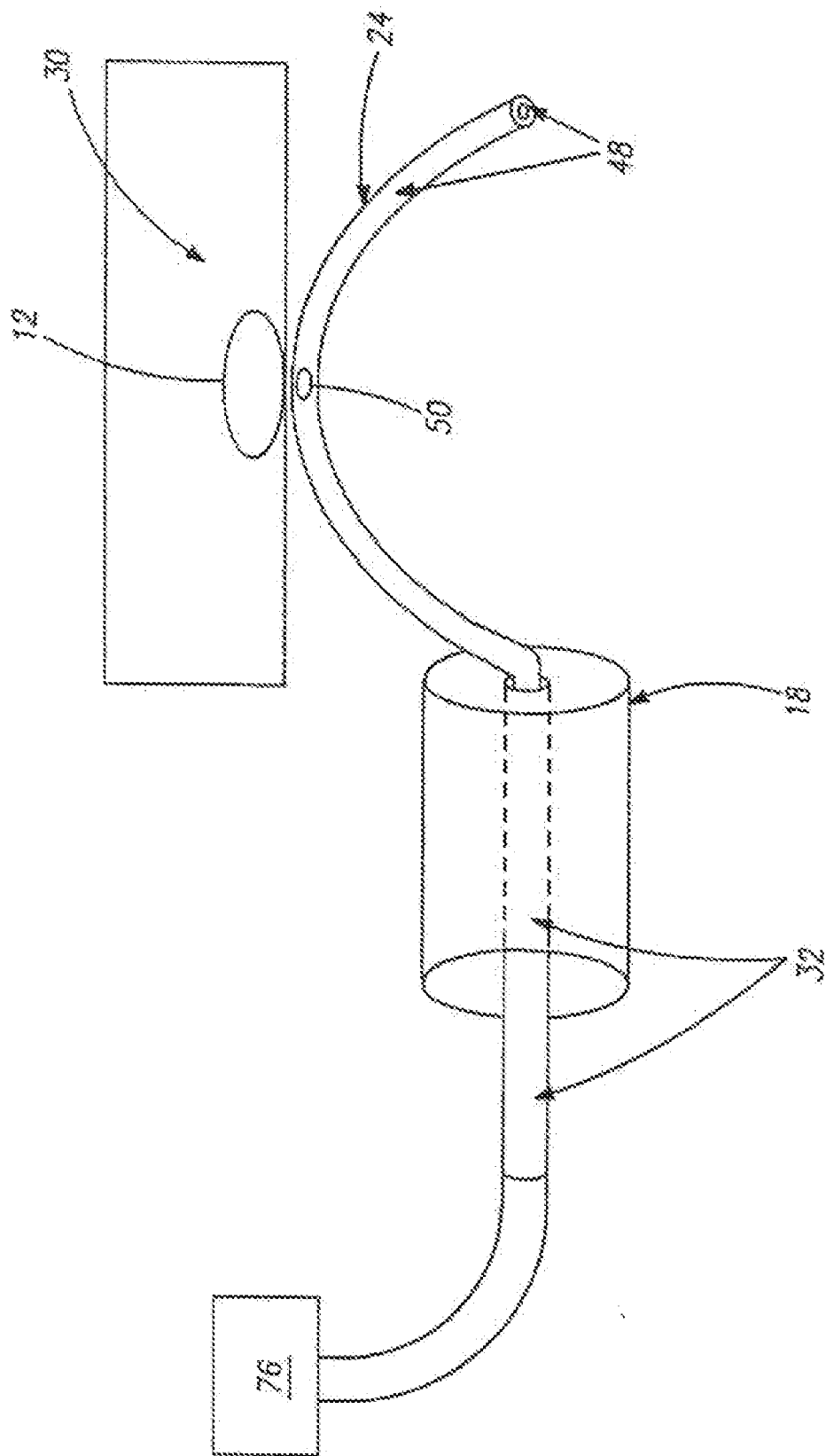


FIG. -12

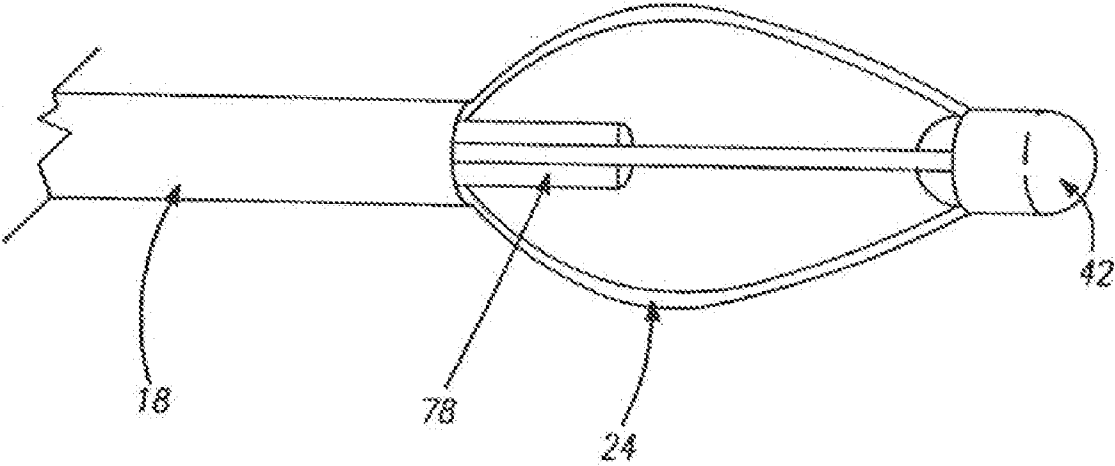


FIG. - 13

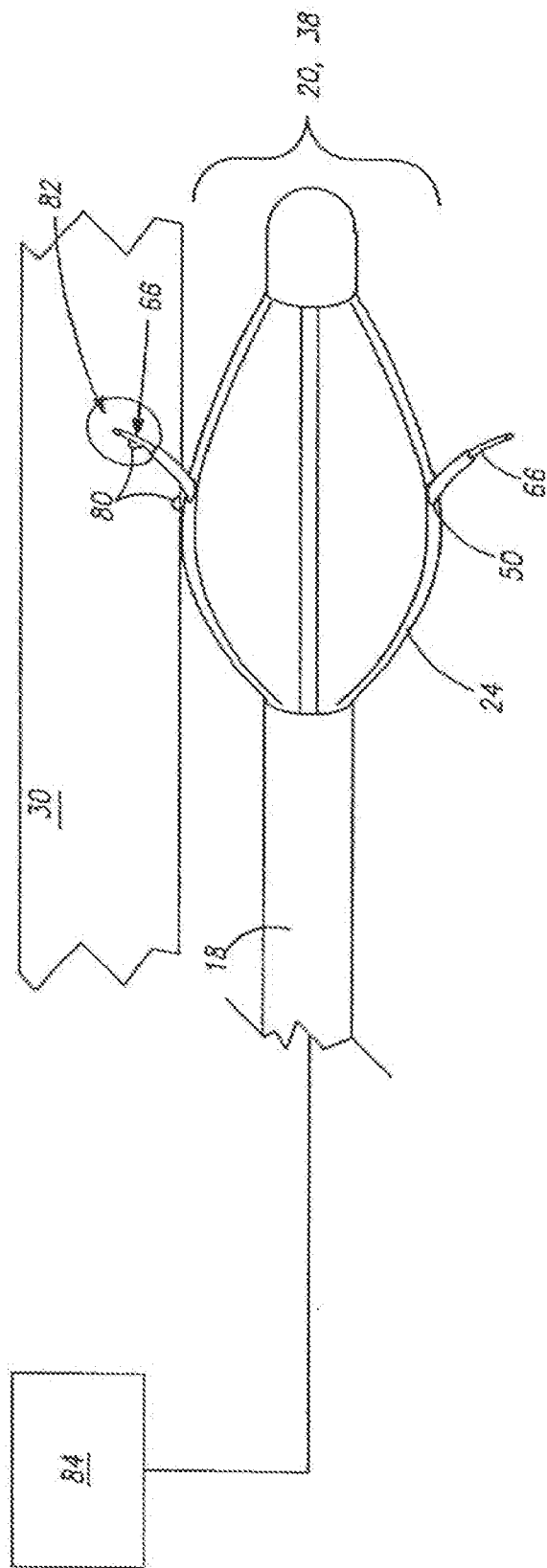


FIG. - 14

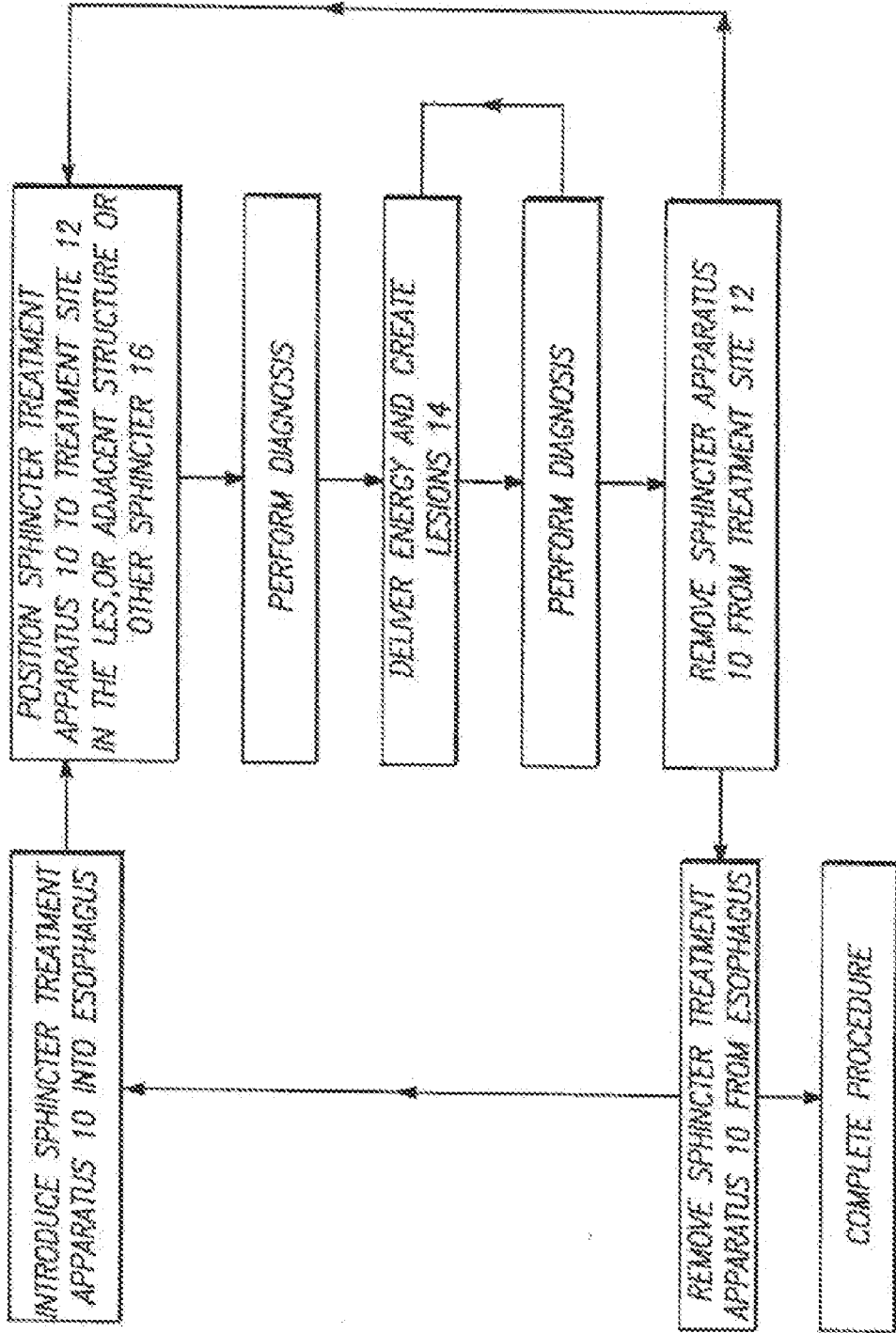


FIG. - 15



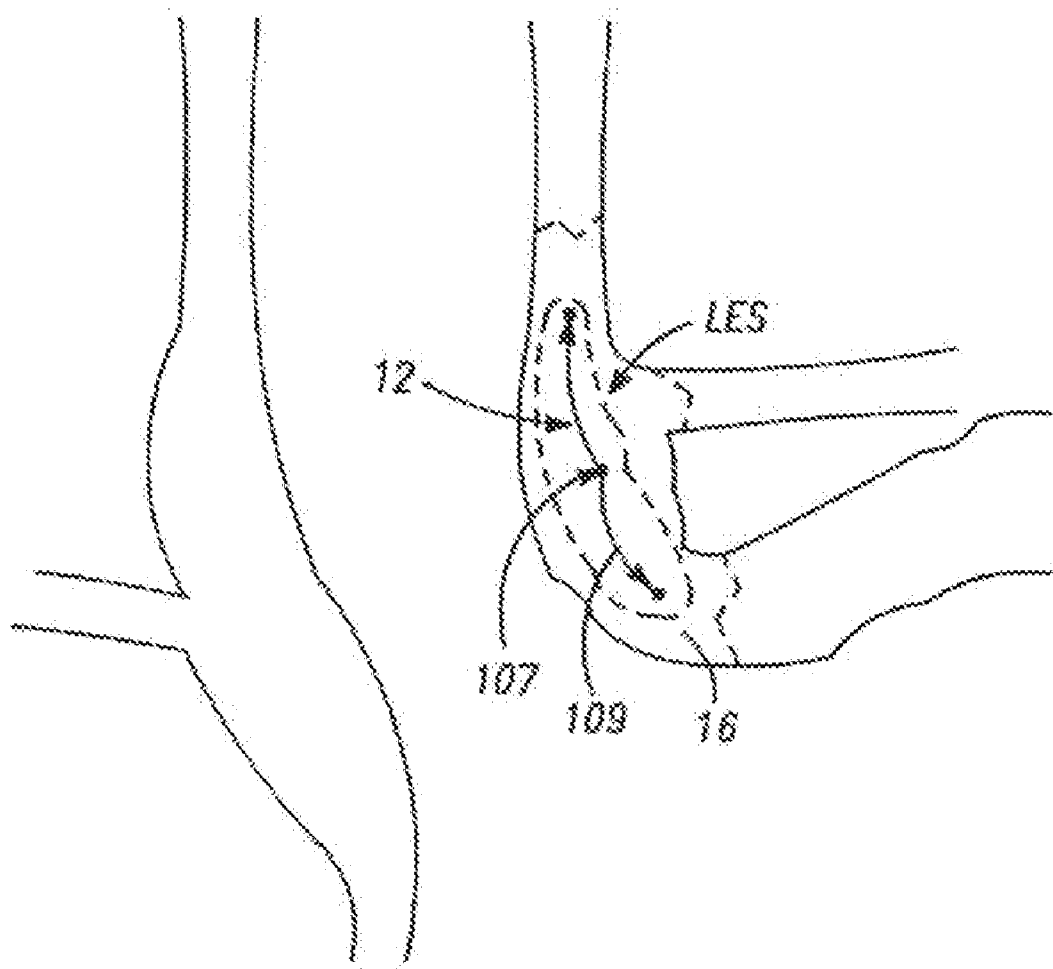


FIG. - 16

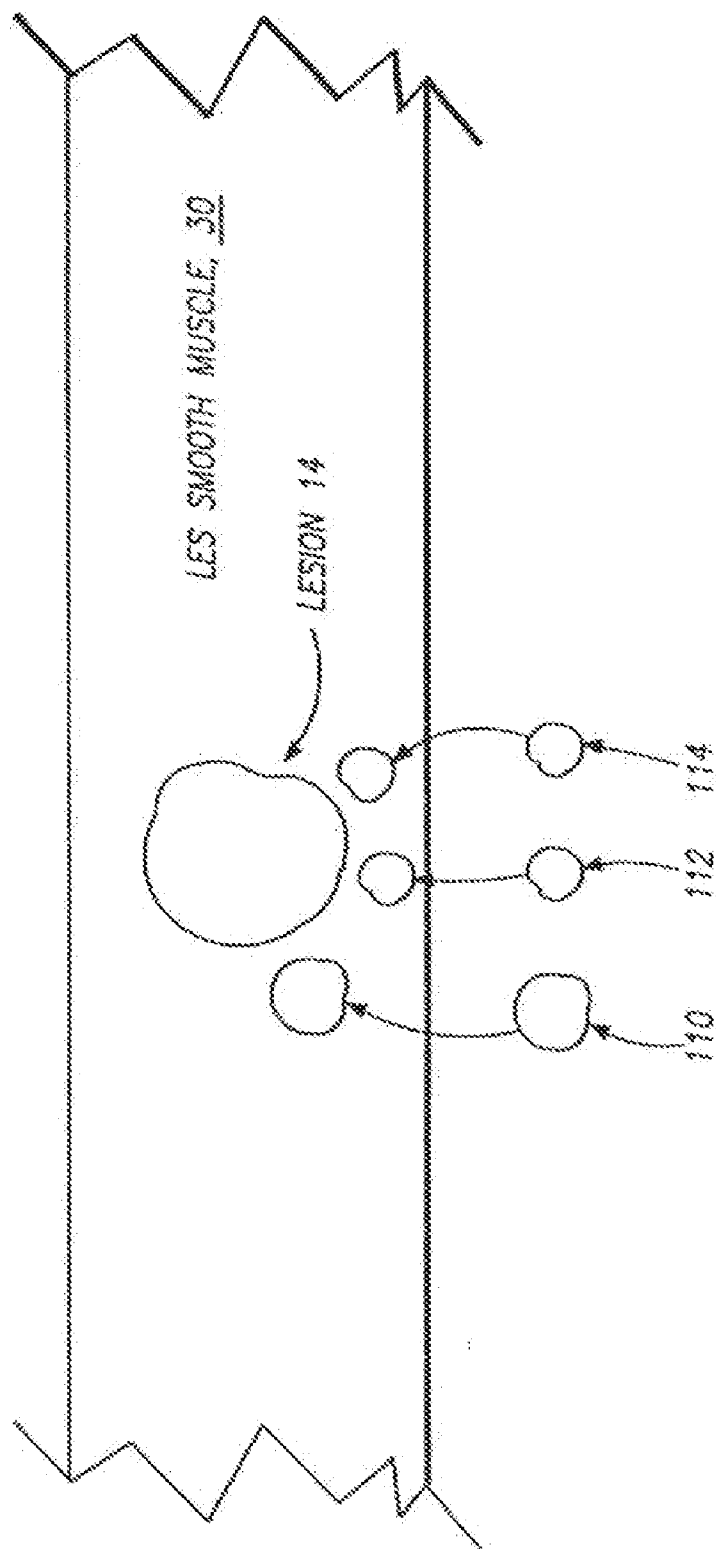


FIG. - 17

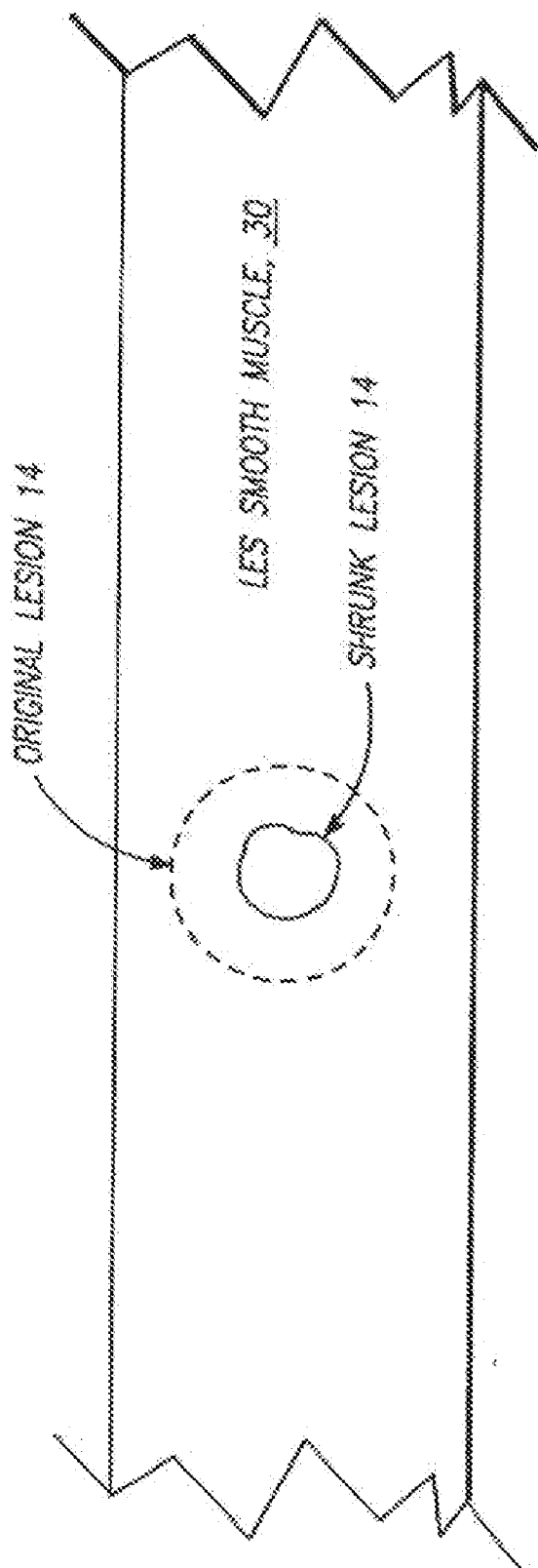


FIG. - 18

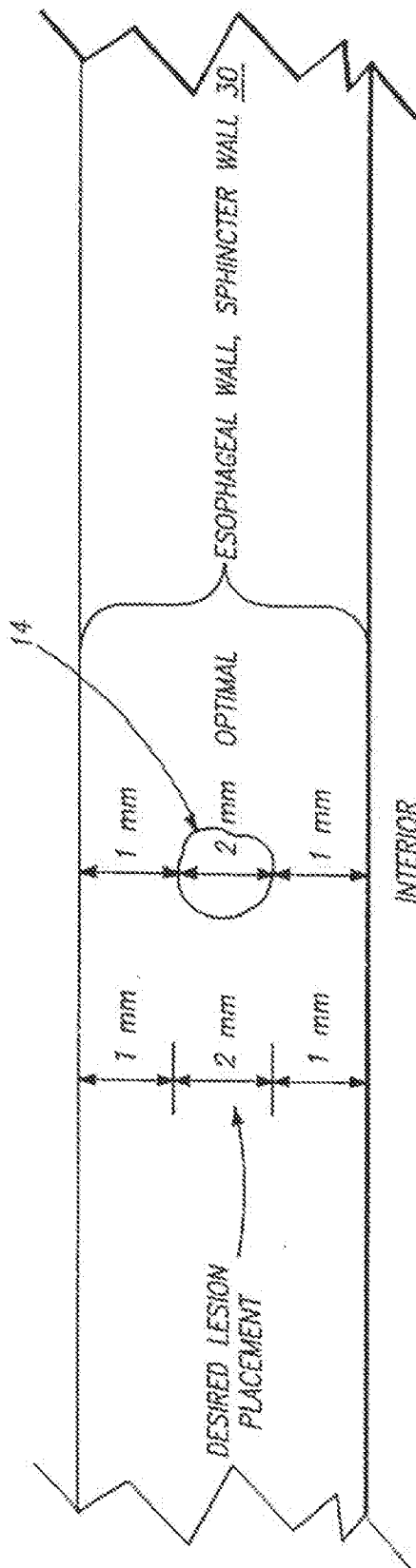


FIG. -19

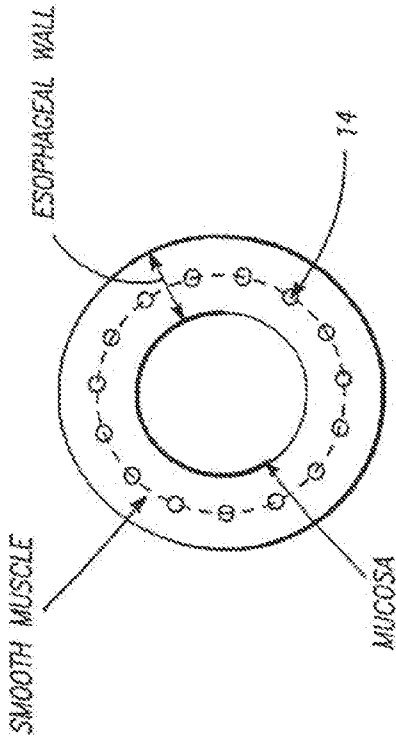


FIG. -20A

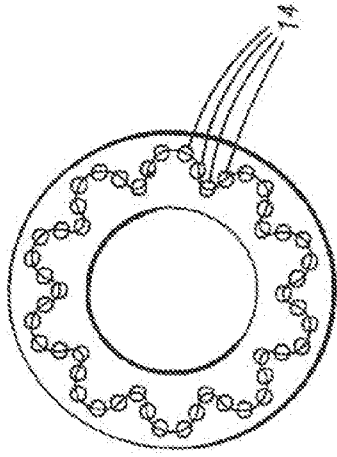


FIG. -20B

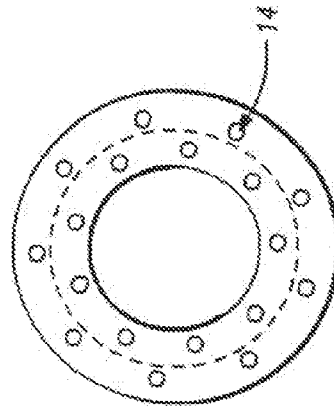


FIG. -20C

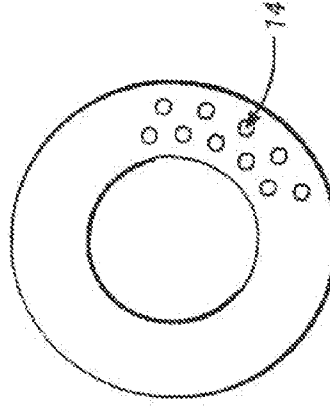


FIG. -20D

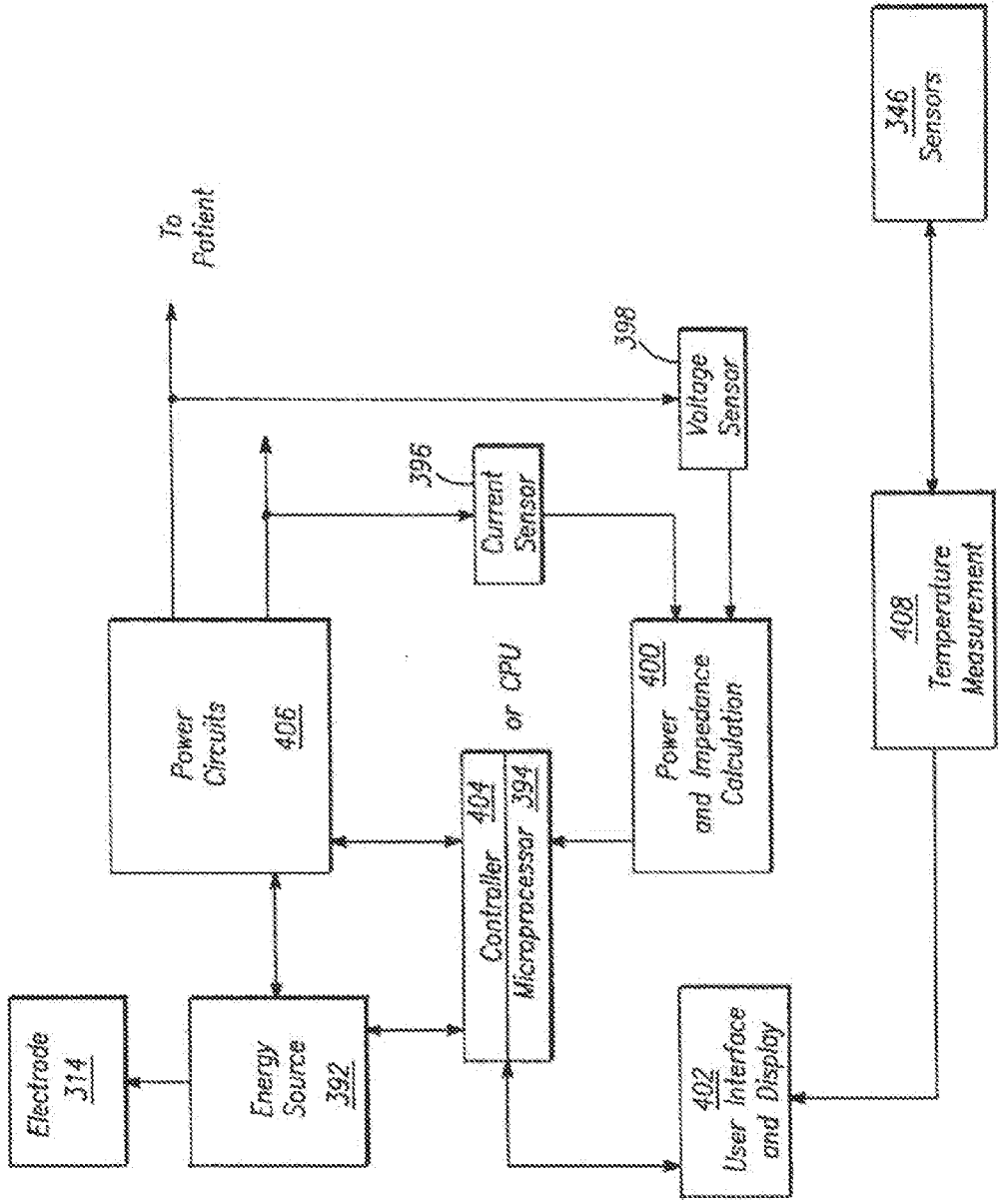


FIG. - 21

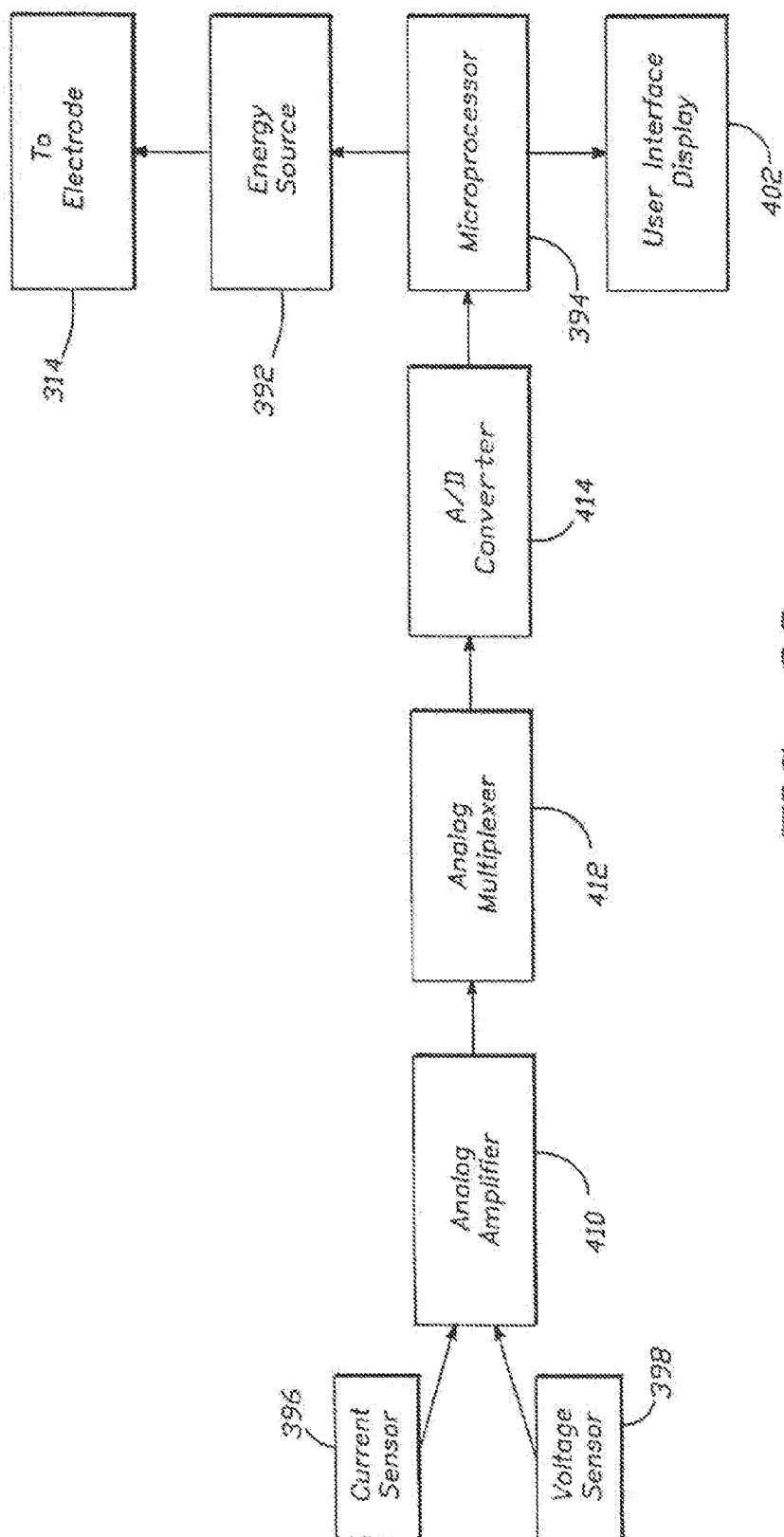


FIG. - 22

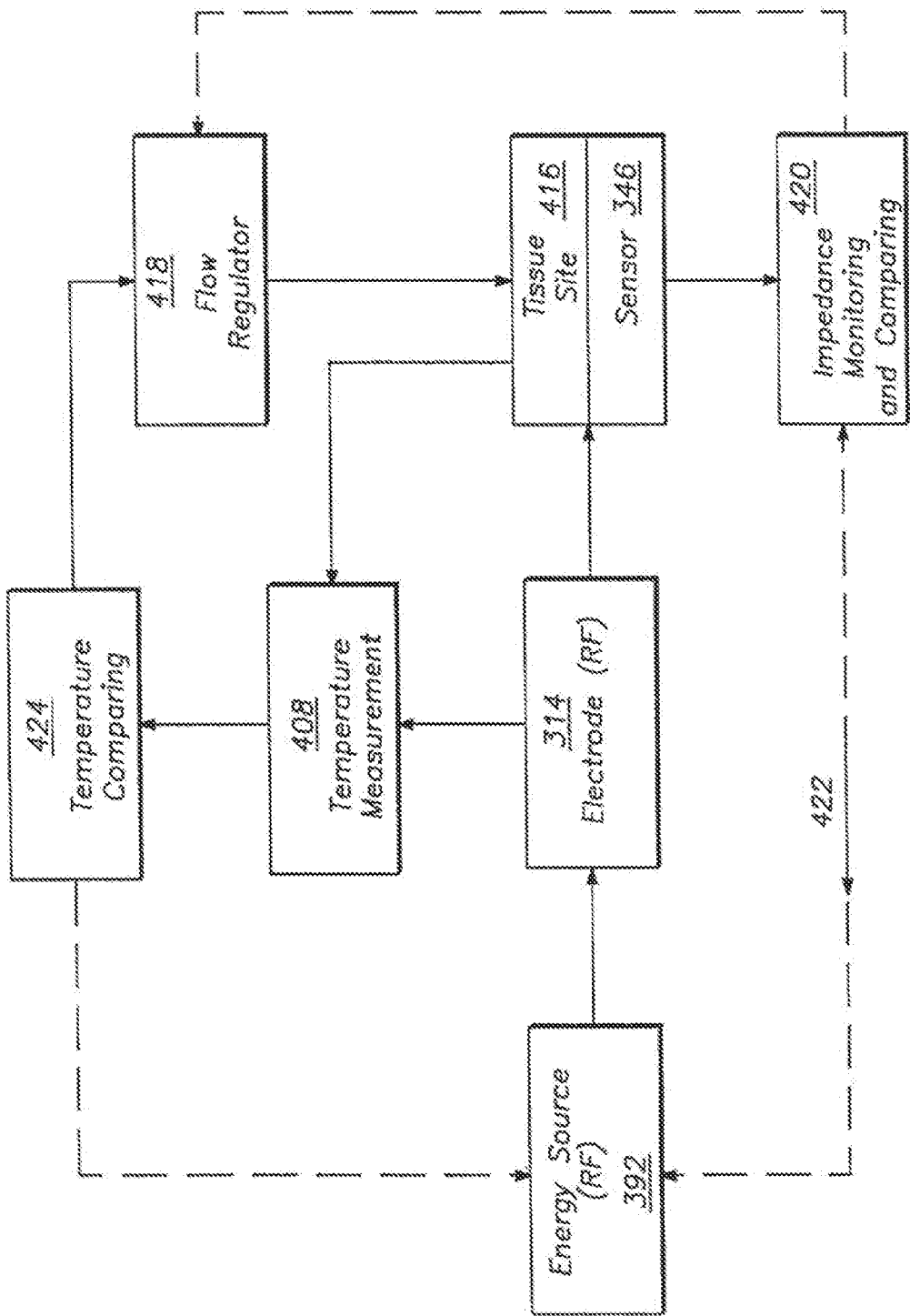


FIG. 23



## APPARATUS TO TREAT ESOPHAGEAL SPHINCTERS

### RELATED APPLICATIONS

**[0001]** This application is a continuation of co-pending patent application Ser. No. 12/927,354 filed 12 Nov. 2010, which is a divisional of patent application Ser. No. 11/638,952, filed 14 Dec. 2006, which is a divisional of patent application Ser. No. 10/838,212, which is a divisional of U.S. patent application Ser. No. 09/971,085, filed Oct. 4, 2001 (now U.S. Pat. No. 6,749,607), which is a continuation of U.S. patent application Ser. No. 09/036,092, filed Mar. 6, 1918, now abandoned.

### FIELD OF THE INVENTION

**[0002]** This invention relates generally to an apparatus to treat sphincters, and more particularly to an apparatus to treat esophageal sphincters.

### DESCRIPTION OF RELATED ART

**[0003]** Gastroesophageal reflux disease (GERD) is a common gastroesophageal disorder in which the stomach contents are ejected into the lower esophagus due to a dysfunction of the lower esophageal sphincter (LES). These contents are highly acidic and potentially injurious to the esophagus resulting in a number of possible complications of varying medical severity. The reported incidence of GERD in the U.S. is as high as 10% of the population (Castell D O; Johnston B T; Gastroesophageal Reflux Disease: Current Strategies For Patient Management. Arch Fam Med, 5(4):221-7; (1996 April)).

**[0004]** Acute symptoms of GERD include heartburn, pulmonary disorders and chest pain. On a chronic basis, GERD subjects the esophagus to ulcer formation, or esophagitis and may result in more severe complications including esophageal obstruction, significant blood loss and perforation of the esophagus. Severe esophageal ulcerations occur in 20-30% of patients over age 65. Moreover, GERD causes adenocarcinoma, or cancer of the esophagus, which is increasing in incidence faster than any other cancer (Reynolds J C: Influence Of Pathophysiology, Severity, And Cost On The Medical Management Of Gastroesophageal Reflux Disease. Am J Health Syst Pharm, 53(22 Suppl 3):S5-12 (1996 Nov. 15)).

**[0005]** Current drug therapy for GERD includes histamine receptor blockers which reduce stomach acid secretion and other drugs which may completely block stomach acid. However, while pharmacologic agents may provide short term relief, they do not address the underlying cause of LES dysfunction.

**[0006]** Invasive procedures requiring percutaneous introduction of instrumentation into the abdomen exist for the surgical correction of GERD. One such procedure, Nissen fundoplication, involves constructing a new "valve" to support the LES by wrapping the gastric fundus around the lower esophagus. Although the operation has a high rate of success, it is an open abdominal procedure with the usual risks of abdominal surgery including: postoperative infection, herniation at the operative site, internal hemorrhage and perforation of the esophagus or of the cardia. In fact, a recent 10 year, 344 patient study reported the morbidity rate for this procedure to be 17% and mortality 1% (Urschel, J D: Complications Of Antireflux Surgery, Am J Surg 166(1): 68-70; (1993 July)). This rate of complication drives not both the medical cost and

convalescence period for the procedure and may exclude portions of certain patient populations (e.g., the elderly and immuno-compromised).

**[0007]** Efforts to perform Nissen fundoplication by less invasive techniques have resulted in the development of laparoscopic Nissen fundoplication. Laparoscopic Nissen fundoplication, reported by Dallemagne et al. Surgical Laparoscopy and Endoscopy, Vol. 1, No. 3, (1991), pp. 138-43 and by Hindler et al. Surgical Laparoscopy and Endoscopy, Vol. 2, No. 3, (1992), pp. 265-272, involves essentially the same steps as Nissen fundoplication with the exception that surgical manipulation is performed through a plurality of surgical cannula introduced using trocars inserted at various positions in the abdomen.

**[0008]** Another attempt to perform fundoplication by a less invasive technique is reported in U.S. Pat. No. 5,088,979. In this procedure, an invagination device containing a plurality of needles is inserted transorally into the esophagus with the needles in a retracted position. The needles are extended to engage the esophagus and fold the attached esophagus beyond the gastroesophageal junction. A remotely operated stapling device, introduced percutaneously through an operating channel in the stomach wall, is actuated to fasten the invaginated gastroesophageal junction to the surrounding involuted stomach wall.

**[0009]** Yet another attempt to perform fundoplication by a less invasive technique is reported in U.S. Pat. No. 5,676,674. In this procedure, invagination is done by a jaw-like device and fastening of the invaginated gastroesophageal junction to the fundus of the stomach is done via a transoral approach using a remotely operated fastening device, eliminating the need for an abdominal incision. However, this procedure is still traumatic to the LES and presents the postoperative risks of gastroesophageal leaks, infection and foreign body reaction, the latter two sequoia resulting when foreign materials such as surgical staples are implanted in the body.

**[0010]** While the methods reported above are less invasive than an open Nissen fundoplication, some still involve making an incision into the abdomen and hence the increased morbidity and mortality risks and convalescence period associated with abdominal surgery. Others incur the increased risk of infection associated with placing foreign materials into the body. All involve trauma to LES and the risk of leaks developing at the newly created gastroesophageal junction.

**[0011]** Besides the LES, there are other sphincters in the body which if not functionally properly can cause disease states or otherwise adversely affect the lifestyle of the patient. Reduced muscle tone or otherwise aberrant relaxation of sphincters can result in a laxity of tightness disease states including, but not limited to, urinary incontinence.

**[0012]** There is a need to provide an apparatus to treat a sphincter and reduce a frequency of sphincter relaxation. Another need exists for an apparatus to create controlled cell necrosis in a sphincter tissue underlying a sphincter mucosal layer. Yet another need exists for an apparatus to create controlled cell necrosis in a sphincter and minimize injury to a mucosal layer of the sphincter. There is another need for an apparatus to controllably produce a lesion in a sphincter without creating a permanent impairment of the sphincter's ability to achieve a physiologically normal state of closure. Still a further need exists for an apparatus to create a tightening of a sphincter without permanently damaging anatomical structures near the sphincter. There is still another need for an

apparatus to create controlled cell necrosis in a lower esophageal sphincter to reduce a frequency of reflux of stomach contents into an esophagus.

#### SUMMARY OF THE INVENTION

**[0013]** Accordingly, an object of the present invention is to provide an apparatus that reduces a frequency of sphincter relaxation.

**[0014]** Another object of the invention is to provide an apparatus to create controlled cell necrosis in a sphincter tissue underlying a sphincter mucosal layer. Yet another object of the invention is to provide an apparatus to create controlled cell necrosis in a sphincter and minimize injury to a mucosal layer of the sphincter.

**[0015]** A further object of the invention is to provide an apparatus to controllably produce a lesion in a sphincter without creating a permanent impairment of the sphincter's ability to achieve a physiologically normal state of closure.

**[0016]** Still another object of the invention is to provide an apparatus to create a tightening of a sphincter without permanently damaging anatomical structures near the sphincter.

**[0017]** Another object of the invention is to provide an apparatus to create controlled cell necrosis in a lower esophageal sphincter to reduce a frequency of reflux of stomach contents into an esophagus.

**[0018]** These and other objects of the invention are provided in a sphincter treatment apparatus within an introducer means including a distal portion means. An expandable device means includes a plurality of arm means. Each arm means has a distal section means and a proximal section means. Each of the distal section means of the arm means are coupled and each of the proximal section means of the arm means are coupled to the introducer means distal portion means. The expandable device means is configured to at least partially dilate a sphincter in a deployed state. An energy delivery device means is introduceable from the introducer means into a selected site of the sphincter. The energy delivery device means is configured to deliver sufficient energy to reduce a frequency of relaxation of the sphincter.

**[0019]** In another embodiment, an expandable device means is coupled to an introducer distal portion means. The expandable device means includes a first arm means with a proximal and distal section means and a second arm means with proximal and distal section means. The first and second arm distal portion means are coupled. The expandable device means is configured to at least partially dilate a sphincter in a deployed state. An energy delivery device means is coupled to the expandable device means. The energy delivery device means is configured to deliver sufficient energy to reduce a frequency of relaxation of the sphincter while minimizing cell necrosis of a mucosal layer of the sphincter.

#### BRIEF DESCRIPTION OF THE DRAWINGS

**[0020]** FIG. 1 is an illustrated lateral view of the upper GI tract depicting the position of the sphincter treatment apparatus of the present invention in the lower esophageal sphincter.

**[0021]** FIG. 2 is a lateral view of the present invention illustrating the introducer, expansion device and energy delivery device.

**[0022]** FIGS. 3A and 3B depict lateral views of an embodiment of the invention that illustrates the use of a sheath to introduce and deploy the expansion device.

**[0023]** FIG. 4 illustrates a lateral view of the basket assembly used in an embodiment of the invention.

**[0024]** FIG. 5 is a lateral view of the basket assembly illustrating the placement of struts on the basket assembly.

**[0025]** FIG. 6A is a lateral view of the junction between the basket arms and the introducer illustrating a lumen in the basket arm that can be used for the advancement of energy delivery devices.

**[0026]** FIG. 6B is a frontal view of a basket arm in an alternative embodiment of the invention illustrating a track in the arm used to advance the movable wire.

**[0027]** FIG. 7A is a cross-sectional view of a section of a basket arm and an energy delivery device illustrating stepped and tapered sections in the basket arm apertures and energy delivery device.

**[0028]** FIG. 8A is a lateral view of the basket assembly illustrating the use of the advancement member and introducer to position energy delivery devices into the sphincter wall.

**[0029]** FIG. 8B is a lateral view of the basket assembly illustrating the use of the advancement member and basket arms to position energy delivery devices into the sphincter wall.

**[0030]** FIG. 9 is a cross sectional view illustrating the use of a needle electrode in combination with an angled aperture segment to select and maintain a constant penetration angle into the sphincter wall.

**[0031]** FIGS. 10A and 10B are lateral views illustrating the placement of needle electrodes into the sphincter wall by expansion of the basket assembly.

**[0032]** FIG. 11 is a lateral view illustrating the use of an insulation layer on the needle electrode to protect an area of tissue from RF energy.

**[0033]** FIG. 12 depicts the fluid source and flow path to deliver fluid to treatment site using the introducer.

**[0034]** FIG. 13 is a cross sectional view illustrating a visualization device coupled to an embodiment of the invention.

**[0035]** FIG. 14 is an enlarged lateral view illustrating the placement of sensors on/adjacent the energy delivery device and the coupling of sensors to a feedback control system.

**[0036]** FIG. 15 is a flow chart illustrating a sphincter treatment method using the apparatus of the present invention.

**[0037]** FIG. 16 is a lateral view of sphincter smooth muscle tissue illustrating electrical foci and electrically conductive pathways for the origination and conduction of aberrant electrical signals in the smooth muscle of the lower esophageal sphincter or other tissue.

**[0038]** FIG. 17 is a lateral view of a sphincter wall illustrating the infiltration of tissue healing cells into a lesion in the smooth tissue of a sphincter following treatment with the sphincter treatment apparatus of the present invention.

**[0039]** FIG. 18 is a view similar to that of FIG. 17 illustrating shrinkage of the lesion site caused by cell infiltration.

**[0040]** FIG. 19 is a lateral view of the esophageal wall illustrating the preferred placement of lesions in the smooth muscle layer of a esophageal sphincter.

**[0041]** FIGS. 20A-D are lateral views of the sphincter wall illustrating various patterns of lesions created by the apparatus of the present invention.

**[0042]** FIG. 21 depicts a block diagram of the feed back control system that can be used with an embodiment of the invention.

[0043] FIG. 22 depicts a block diagram of an analog amplifier, analog multiplexer and microprocessor used with the feedback control system of FIG. 21.

[0044] FIG. 23 depicts a block diagram of the operations performed in the feedback control system depicted in FIG. 21.

#### DETAILED DESCRIPTION

[0045] Referring to FIGS. 1 and 2, one embodiment of a sphincter treatment apparatus 10 delivers energy to a treatment site 12 to produce lesions 14 in a sphincter 16, such as the lower esophageal sphincter (LES). In this embodiment, sphincter treatment apparatus 10 comprises a flexible elongate shaft 18, also called introducer 18, coupled to an expansion device 20, in turn coupled with one or more energy delivery devices 22. Introducer 18 has a distal extremity also called introducer end 19. Energy delivery devices 22 are configured to be coupled to a power source.

[0046] Expansion device 20 comprises a plurality of arms 24, with proximal and distal arms ends 25 and 26. Proximal arm ends 25 are coupled to introducer end 19. Expansion device 20 has a central longitudinal axis 28 and is moveable between contracted and expanded/deployed states substantially there along. Expansion device 20 is configured to be positionable in a sphincter 16 (such as the LES) or adjacent anatomical structure (such as the cardia of the stomach) and is further configured to partially dilate sphincter 16 when in the deployed state. Energy delivery devices 22 are configured to be introduceable from introducer 18 and to contact and/or penetrate a targeted treatment site 12 in a sphincter wall 30 or adjoining anatomical structure. They are further configured to deliver energy to treatment site 12.

[0047] Referring now to FIG. 2, introducer 18 is configured to be coupled to expansion device 20 and has sufficient length to position expansion device 20 in the LES and/or stomach using a transoral approach. Typical lengths for introducer 18 include a range of 40-180 cm. Introducer 18 may be circular or oval in cross section. Also, introducer 18 may be flexible, articulated, coil-reinforced, or steerable, or any combination thereof. Suitable materials for introducer 18 include polyethylenes, polyurethanes, silicones and other biocompatible polymers known to those skilled in the art. Introducer 18 may also be coated with a lubricious coating as is well known to those skilled in the art.

[0048] Introducer 18 may have one or more lumens 32, that extend the full length of introducer 18, or only a portion thereof. Lumens 32 may be used as paths for the delivery of fluids and gases, as well as providing channels for cables, catheters, guide wires, pull wires, insulated wires, and optical fibers.

[0049] In another embodiment of the invention depicted in FIGS. 3A and 3B, an introduction member 34, also called a sheath 34, is used to introduce sphincter treatment apparatus 10 into the LES. Sheath 34 can also function as a sheath for expansion device 20 to keep it in a nondeployed or contracted state during introduction into the LES. To facilitate this function, sheath 34 contains a sheath lumen 36 of sufficient inner diameter to allow free movement of sphincter treatment apparatus 10 within sheath lumen 36. Sheath 34, sheath lumen 36 and sphincter treatment apparatus 10 are configured to allow expansion device 20 to go from a contracted state to an expanded state and vice versa by either i) the retraction or advancement of sheath 34, or ii) the advancement or withdrawal of sphincter treatment apparatus 10. Sheath 34 may be

flexible, articulated, coil-reinforced or steerable, or any combination thereof. Suitable materials for sheath 34 include polyethylenes, polyurethanes, silicones, polytetrafluoroethylenes and other biocompatible polymers known to those skilled in the art. Typical diameters for sheath lumen 36 include 0.1 to 2 inches, while typical lengths include 40-180 cms.

[0050] Referring now to FIG. 4, in another embodiment of the present invention, expansion device 20 comprises one or more elongated arms 24 that are joined at their proximal ends 25 and distal ends 26 to form a basket assembly 38. Proximal arm end 25 is attached to a supporting structure, which can be distal end 19 of introducer 18 or a proximal cap 40. Likewise, distal arm end 26 is also attached to a supporting structure which can be a distal basket cap 42 or introducer 18. Arms 24 are of a sufficient number, two or more, to sufficiently open and efface the folds of sphincter 16 to allow treatment with sphincter treatment apparatus 10, while preventing herniation of sphincter wall 30 into the spaces 44 between arms 24.

[0051] Arms 24 may form a variety of geometric shapes including, curved, rectangular, trapezoidal, triangular, or any combination thereof. Also, arms 24 can have an outwardly bowed shaped memory for expanding basket assembly 38 into engagement with sphincter wall 30. Arms 24 may be preshaped at time of manufacture or shaped by the physician. Arms 24 can have a variety of cross sectional geometries including, circular, rectangular and crescent-shaped. The circumferential spacing of arms 24 can be symmetrical or asymmetrical with respect to a circumference around longitudinal axis 28. Suitable materials for arms 24 include spring steel, stainless steel, superelastic shape memory metals such as nitinol, or stiff shaft plastic tubing as is well known to those skilled in the art. Arms 24 may also be color-coded to facilitate their identification via visual medical imaging methods and equipment, such as endoscopic methods, which are well known to those skilled in the art.

[0052] In another embodiment of the invention depicted in FIG. 5, a supporting member 46 is attached to two or more arms 24. Supporting member 46, also called strut 46, can be attached to arms 24 along a circumference of basket assembly 38. Strut 46 may also contain apertures 50 in one or more places that extend through strut 46 to arm 24 as will be discussed herein. The cross sectional geometry of strut 46 can be rectangular, circular or crescent-shaped. Suitable materials for strut 46 include spring steel, stainless steel, superelastic shape memory metals such as nitinol, or stiff shaft plastic tubing as is well known to those skilled in the art.

[0053] Referring now to FIG. 6A, arms 24 may be solid or hollow with a continuous arm lumen 48 that may be coupled with introducer lumens 32. Also arms 24 may have one or more apertures 50 that may coupled to arm lumen 48. Coupled lumens 32 and 48, and apertures 50 provide a path for the delivery of a fluid or energy delivery device 22 from introducer 18 to the surface or interior of sphincter wall 30. As shown in FIG. 6B, arms 24 may also have a partially open channel 52, also called a track 52, that functions as a guide track for the travel of an advancement member (discussed herein) and/or energy delivery device 22 that permit the controlled placement of energy delivery devices 22 at or into sphincter wall 30. Referring now to FIG. 7, apertures 50 may have tapered sections 54 and/or stepped sections 56 in all or part of their length, that are used to control the penetration depth of energy delivery devices 22 into sphincter wall 30 as

will be discussed herein. Energy delivery devices 22 may have similar tapered sections 54' and/or stepped sections 56'.

[0054] Referring now to FIGS. 8A and 8B, in another embodiment of the invention, energy delivery devices 22 can be coupled to an energy device delivery member 57, also called an advancement member 57. Advancement member 57 can be an insulated wire, an insulated guide wire, a plastic-coated stainless steel hypotube with internal wiring or a plastic catheter with internal wiring as is well known to those skilled in the art. Advancement member 57 is configured to be able to introduce energy delivery device 22 into sphincter wall 30 via introducer 18 (see FIG. 8A) or basket assembly 38 as will be discussed herein (see FIG. 8B). Advancement member 57 is of sufficient length to position energy delivery device 22 in the LES and/or stomach using a transoral approach. Typical lengths for advancement member 57 include a range of 40-180 cms.

[0055] In another embodiment of the invention depicted in FIG. 9, energy delivery device 22 has a distal portion 58 that is configured to penetrate sphincter wall 30 with a minimum amount of tearing of the mucosal and submucosal layers 60 and 62 of sphincter 16. This is facilitated by maintaining a constant angle of penetration 64, also called penetration angle 64, of distal portion 58 into sphincter wall 30 during the time that energy delivery device 22 is advanced into sphincter wall 30. The typical range for penetration angle 64 lies between 1 and 90°. This can be accomplished through the use of a needle 58' for distal energy delivery device portion 58, coupled with an angled aperture segment 50' having a preselected penetration angle 64. Needle 58' is of sufficient sharpness and length to penetrate into the smooth muscle of sphincter wall 30. In a further embodiment, needle 58' can be a needle electrode 58. Distal portion 58, including needle 58' and needle electrode 58 can also be stepped or tapered to enable control of energy delivery device (see FIG. 7). Suitable materials for needle 58' and needle electrodes 58" include 304 stainless steel and other metals known to those skilled in the art.

[0056] In another embodiment of the invention, energy delivery device 22 is coupled to arm 24. As shown in FIG. 10, this can be accomplished by attaching needle 58' to arm 24. When sphincter treatment apparatus 10 is properly positioned at the treatment site 12, needles 58' are deployed by expansion of basket assembly 38, resulting in the protrusion of needle 58' into the smooth muscle tissue of sphincter wall 30 (see FIG. 10). Referring back to FIG. 9, coupling can also be accomplished by employing arm 24 to introduce energy delivery device 22 into sphincter wall 30 via use of arm lumen 48.

[0057] Turning now to a discussion of energy delivery, suitable power sources and energy delivery devices 22 that can be employed in one or more embodiments of the invention include or more of the following: (i) a radio-frequency (RF) source coupled to an RF electrode, (ii) a coherent source of light coupled to an optical fiber, (iii) an incoherent light source coupled to an optical fiber, (iv) a heated fluid coupled to a catheter with a closed channel configured to receive the heated fluid, a heated fluid coupled to a catheter with an open channel configured to receive the heated fluid, (vi) a cooled fluid coupled to a catheter with a closed channel configured to receive the cooled fluid, (vii) a cooled fluid coupled to a catheter with an open channel configured to receive the cooled fluid, (viii) a cryogenic fluid, (ix) a resistive heating source, (x) a microwave source providing energy from 915 MHz to 2.45 GHz and coupled to a microwave antenna, or (xi)

an ultrasound power source coupled to an ultrasound emitter, wherein the ultrasound power source produces energy in the range of 300 KHZ to 3 GHz. For ease of discussion for the remainder of this application, the power source utilized is an RF source and energy delivery device 22 is one or more RF electrodes 66, also described as electrodes 66. However, all of the other herein mentioned power sources and energy delivery devices are equally applicable to sphincter treatment apparatus 10.

[0058] For the case of RF energy, RF electrode 66 may be operated in either bipolar or monopolar mode with a ground pad electrode. In a monopolar mode of delivering RF energy, a single electrode 66 is used in combination with an indifferent electrode patch that is applied to the body to form the other electrical contact and complete an electrical circuit. Bipolar operation is possible when two or more electrodes 66 are used. Multiple electrodes 66 may be used. These electrodes may be cooled as described herein. Electrodes 66 can be attached to advancement member 57 by the use of soldering methods which are well known to those skilled in the art.

[0059] Referring now to FIG. 11, RF electrodes 66 can have an insulating layer 68, covering an insulated segment 70 except for an exposed segment 72. For purposes of this disclosure, an insulator or insulation layer is a barrier to either thermal or electromagnetic energy flow including RF energy flow. Insulated segment 70 is of sufficient length to extend into sphincter wall 30 and minimize the transmission of RF energy to a protected site 74 near or adjacent to insulated segment 70. Typical lengths for insulated segment 70 include, but are not limited to 1-4 mm. Suitable materials for insulating layer 68 include electrically insulating plastics and other materials well known to those skilled in the art.

[0060] In another embodiment of the invention, the depth of penetration of energy delivery device 22 into sphincter wall 30 is controllable. This can be accomplished by the selection and control of the dimensional relationships (e.g. the amount of clearance between inner and outer diameters) of energy delivery devices 22 and/or advancement member 57 to one or more of the following elements: arm lumen 48, apertures 50 and track 52. Control of penetration depth can also be accomplished through the use of tapered and/or stepped sections in one or more of the preceding elements as is discussed herein. In another embodiment, penetration depth control can be accomplished by the use of one or more of a variety of positional control means, known to those skilled in the art, that are coupled to sphincter treatment apparatus 10. Such positional control means include stepper motor systems, indexing mechanisms and micromanipulators.

[0061] Referring now to FIG. 12, in another embodiment of the invention, fluid can be delivered to treatment site 12 via introducer 18. This is accomplished by the coupling of introducer 18 to a fluid source 76 via introducer lumen 32.

[0062] Referring now to FIG. 13, another embodiment of sphincter treatment apparatus 10 includes a visualization device 78 coupled to, introducer 18. Visualization device 78 can include a combination of one or more of the following: a viewing scope, an expanded eyepiece, fiber optics (both imaging and illuminating fibers), video imaging devices and the like.

[0063] As shown in FIG. 14, one or more sensors 80 may be positioned adjacent to or on electrode 66 for sensing the physical properties of sphincter tissue at treatment site 12. Sensors 80 permit accurate determination of the physical properties of sphincter wall 30 at an electrode-tissue interface

**82.** Such physical properties include temperature, electrical conductivity, electrical capacitance, thermal conductivity, density, thickness, strength, elasticity, moisture content, optical reflectance, optical transmittance, optical absorption, acoustical impedance and acoustical absorption. Sensors **80** can be positioned at any position on expansion device **20**, electrode **66** or basket assembly **38**. Suitable sensors that may be used for sensor **80** include: thermocouples, fiber optics, photomultipliers, resistive wires, thermocouple IR detectors, thin film sensors, anemometric sensors and ultrasound sensors. Sensor **80** can be coupled to a feedback control system **84**, described herein. The coupling of sensor **80** to feedback control system **84** can be used to regulate the delivery of energy, fluids and gases to one or more of the following locations: treatment site **12**, sphincter wall **30**, and electrode tissue interface **82**.

**[0064]** FIG. **15** is a flow chart illustrating a method for using sphincter treatment apparatus **10**. First, sphincter treatment apparatus **10** is introduced into the esophagus under local anesthesia and positioned at treatment site **12**. Sphincter treatment apparatus **10** can be introduced into the esophagus by itself or through a lumen in an endoscope (not shown), such as disclosed in U.S. Pat. Nos. 5,448,990 and 5,275,608, incorporated herein by reference, or a similar esophageal access device known to those skilled in the art. Basket assembly **38** is expanded as described herein. This serves to temporarily dilate the LES sufficiently to efface all or a portion of the folds of the LES. In an alternative embodiment, esophageal dilation and subsequent LES fold effacement can be accomplished by insufflation of the esophagus (a known technique) using gas introduced into the esophagus through introducer lumen **32**, an endoscope, or others esophageal access devices known to those skilled in the art. Once treatment is completed, basket assembly **38** is returned to its predeployed or contracted state and sphincter treatment apparatus **10** is withdrawn from the esophagus. This results in the LES returning to approximately its pretreatment state and diameter. It will be appreciated that the above procedure is applicable in whole or part to the treatment of other sphincters in the body.

**[0065]** The diagnostic phase of the procedure then begins and can be performed using a variety of diagnostic methods known to those skilled in the art including the following: (i) visualization of the interior surface of the esophagus via an endoscope or other viewing apparatus inserted into the esophagus, (ii) visualization of the interior morphology of the esophageal well using ultrasonography to establish a baseline for the tissue to be treated, (iii) impedance measurement to determine the electrical conductivity between esophageal mucosal and submucosa layers **60** and **62** and sphincter treatment apparatus **10**, and (iv) measurement and surface mapping of electropotential signals of the LES and surrounding anatomical structures during varying time intervals which may include such events as depolarization, contraction and repolarization of gastroesophageal smooth muscle tissue. This latter technique is done to determine target treatment sites **12** in the LES or adjoining anatomical structures that are acting as electrical foci **107** or electrically conductive pathways **109** for abnormal or inappropriate polarization and relaxation of the smooth muscle of the LES (Refer to FIG. **16**).

**[0066]** After diagnosis, the treatment phase of the procedure begins. In this phase of the procedure, the delivery of energy to treatment site **12** can be conducted under feedback control, manually or by a combination of both. Feedback

control (described herein) enables sphincter treatment apparatus **10** to be positioned and retained in the esophagus during treatment with minimal attention by the physician. Electrodes **66** can be multiplexed in order to treat the entire targeted treatment site **12** or only a portion thereof. Feedback can be included and is achieved by the use of one or more of the following methods: (i) visualization, (ii) impedance measurement, (iii) ultrasonography, (iv) temperature measurement; and, (v) contractile force measurement via manometry. The feedback mechanism permits the selected on-off switching of different electrodes **66** in a desired pattern, which can be sequential from one electrode **66** to an adjacent electrode **66**, or can jump around between non-adjacent electrodes **66**. Individual electrodes **66** are multiplexed and volumetrically controlled by a controller.

**[0067]** The area and magnitude of cell injury in the LES or sphincter **16** can vary. However, it is desirable to deliver sufficient energy to the targeted treatment site **12** to be able to achieve tissue temperatures in the range of 59-95° C. and produce lesions **14** at depths ranging from 1-4 mm from the interior surface of the LES or sphincter wall **30**. Typical energies delivered to the esophageal or stomach wall include, but are not limited to, a range between 100 and 50,000 joules per electrode **66**. It is also desirable to deliver sufficient energy such that resulting lesions **14** have a sufficient magnitude and area of cell injury to cause an infiltration of lesion **14** by fibroblasts **110**, myofibroblasts **112**, macrophages **114** and other cells involved in the tissue healing process (refer to FIG. **17**). As shown in FIG. **18**, these cells cause a contraction of tissue around lesion **14**, decreasing its volume and/or altering the biomechanical properties at lesion **14** so as to result in a tightening of the LES or sphincter **16**. These changes are reflected in transformed lesion **14'**. The diameter of lesions **14** can vary between 0.1 to 4 mm. It is preferable that lesions **14** are less than 4 mm in less than 4 mm in diameter in order to reduce the risk of thermal damage to mucosal and submucosal layers **60** and **62**. In one embodiment, a 2 mm diameter lesion **14** centered in the wall of the smooth muscle provides a 1 mm buffer zone on either side of lesion **14** to prevent damage to mucosal and submucosal layers **60** and **62** and the adventitia (not shown), while still allowing for cell infiltration and subsequent sphincter tightening on approximately 50% of the thickness of the wall of the smooth muscle (refer to FIG. **19**).

**[0068]** It is desirable that lesions **14** are predominantly located in the smooth muscle layer of selected sphincter **16** at the depths ranging from 1 to 4 mm from the interior surface of sphincter wall **30**. However, lesions **14** can vary both in number and position within sphincter wall **30**, it may be desirable to produce a pattern of multiple lesions **14** within the sphincter smooth muscle tissue in order to obtain a selected degree of tightening of the LES or other sphincter **16**. Typical lesion patterns shown in FIGS. **20 A-D** include, but are not limited to, (i) a concentric circle of lesions **14** all at fixed depth in the smooth muscle layer evenly spaced along the radial axis of sphincter **16**, (ii) a wavy or folded circle of lesions **14** at varying depths in the smooth muscle layer evenly spaced along the radial axis of sphincter **16**, (iii) lesions **14** randomly distributed at varying depths in the smooth muscle, but evenly spaced in a radial direction and, (iv) an eccentric pattern of lesions **14** in one or more radial locations in the smooth muscle wall. Accordingly, the depth of RF and thermal energy penetration into sphincter **16** is controlled and selectable. The selective application of energy to sphincter **16** may be the

even delivery of RF energy to the entire targeted treatment site **12**, a portion of it, or applying different amounts of RF energy to different sites depending on the condition of sphincter **16**. If desired, the area of cell injury can be substantially the same for every treatment event.

[0069] A second diagnostic phase may be included after the treatment is completed. This provides an indication of LES tightening treatment success, and whether or not a second phase of treatment, to all or only a portion of the esophagus, now or at some later time, should be conducted. The second diagnostic phase is accomplished through one or more of the following methods: (i) visualization, (ii) measuring impedance, (iii) ultrasonography, (iv) temperature measurement, or (v) measurement of LES tension and contractile force via manometry.

[0070] In one embodiment of the invention, sensor **80** is coupled to an open or closed loop feedback control system **84**. Referring now to FIG. **21**, an open or closed loop, feedback system **84** couples sensor **80**, now described as sensor **346**, to an energy source **392**. In this embodiment, an energy delivery device **314** is one or more RF electrodes **314**; however, in various other embodiments, energy delivery device **314** may include others described herein. Similarly, in this embodiment, sensor **346** senses temperature, but in various other embodiments, sensor **346** may sense other physical properties described herein.

[0071] The temperature of the tissue, or of RF electrode **314**, is monitored, and the output power of energy source **392** adjusted accordingly. The physician can, if desired, override the closed or open loop system **84**. A microprocessor **394** can be included and incorporated in the closed or open loop system to switch power on and off, as well as modulate the power. The closed loop system **84** utilizes microprocessor **394** to serve as a controller, monitor the temperature, adjust the RF power, analyze the result, refeed the result, and then modulate the power.

[0072] With the use of sensor **346** and feedback control system **84**, tissue adjacent to RF electrode **314** can be maintained at a desired temperature for a selected period of time without causing a shut down of the power circuit to electrode **314** due to the development of excessive electrical impedance at electrode **314** or adjacent tissue. Each RF electrode **314** is connected to resources which generate an independent output. The output maintains a selected energy at RF electrode **314** for a selected length of time.

[0073] Current delivered through RF electrode **314** is measured by current sensor **396**. Voltage is measured by voltage sensor **398**. Impedance and power are then calculated at power and impedance calculation device **400**. These values can then be displayed at user interface and display **402**. Signals representative of power and impedance values are received by a controller **404**.

[0074] A control signal is generated by controller **404** that is proportional to the difference between an actual measured value, and a desired value. The control signal is used by power circuits **406** to adjust the power output an appropriate amount in order to maintain the desired power delivered at respective RF electrodes **314**.

[0075] In a similar manner, temperatures detected at sensor **346** provide feedback for maintaining a selected power. Temperature at sensor **346** is used as a safety means to interrupt the delivery of power when maximum pre-set temperatures are exceeded. The actual temperatures are measured at temperature measurement device **404**, and the temperatures are

displayed at user interface and display **402**. A control signal is generated by controller **404** that is proportional to the difference between an actual measured temperature and a desired temperature. The control signal is used by power circuits **406** to adjust the power output an appropriate amount in order to maintain the desired temperature delivered at the sensor **346**. A multiplexer can be included to measure current, voltage and temperature, at the sensor **346**, and energy can be delivered to RF electrode **314** in monopolar or bipolar fashion.

[0076] Controller **404** can be a digital or analog controller, or a computer with software. When controller **404** is a computer it can include a CPU coupled through a system bus. This system can include a keyboard, a disk drive, or other non-volatile memory systems, a display, and other peripherals, as are known in the art. Also coupled to the bus is a program memory and a data memory.

[0077] User interface and display **402** includes operator controls and a display. Controller **404** can be coupled to imaging systems including, but not limited to, ultrasound, CT scanners, X-ray, MRI, mammographic X-ray and the like. Further, direct visualization and tactile imaging can be utilized.

[0078] The output of current sensor **396** and voltage sensor **398** are used by controller **404** to maintain a selected power level at RF electrode **314**. The amount of RF energy delivered controls the amount of power. A profile of the power delivered to electrode **314** can be incorporated in controller **404** and a preset amount of energy to be delivered may also be profiled.

[0079] Circuitry, software and feedback to controller **404** result in process control, the maintenance of the selected power setting which is independent of changes in voltage or current, and is used to change the following process variables: (i) the selected power setting, (ii) the duty cycle (e.g., on-off time), (iii) bipolar or monopolar energy delivery; and, (iv) fluid delivery, including flow rate and pressure. These process variables are controlled and varied, while maintaining the desired delivery of power independent of changes in voltage or current, based on temperatures monitored at sensor **346**.

[0080] Referring now to FIG. **22**, current sensor **396** and voltage sensor **398** are connected to the input of an analog amplifier **410**. Analog amplifier **410** can be a conventional differential amplifier circuit for use with sensor **346**. The output of analog amplifier **410** is sequentially connected by an analog multiplexer **412** to the input of A/D converter **414**. The output of analog amplifier **410** is a voltage which represents the respective sensed temperatures. Digitized amplifier output voltages are supplied by A/D converter **414** to microprocessor **394**. Microprocessor **394** may be a type 68HC11 available from Motorola. However, it will be appreciated that any suitable microprocessor or general purpose digital or analog computer can be used to calculate impedance or temperature.

[0081] Microprocessor **394** sequentially receives and stores digital representations of impedance and temperature. Each digital value received by microprocessor **394** corresponds to different temperatures and impedances.

[0082] Calculated power and impedance values can be indicated on user interface and display **402**. Alternatively, or in addition to the numerical indication of power or impedance, calculated impedance and power values can be compared by microprocessor **394** to power and impedance limits. When the values exceed predetermined power or impedance values, a warning can be given on user interface and display **402**, and additionally, the delivery of RF energy can be reduced, modi-

fied or interrupted. A control signal from microprocessor 394 can modify the power level supplied by energy source 392.

[0083] FIG. 23 illustrates a block diagram of a temperature and impedance feedback system that can be used to control the delivery of energy to tissue site 416 by energy source 392 and the delivery of a cooling medium to electrode 314 and/or tissue site 416 by flow regulator 418. Energy is delivered to RF electrode 314 by energy source 392, and applied to tissue site 416. A monitor 420 ascertains tissue impedance, based on the energy delivered to tissue, and compares the measured impedance value to a set value. If measured impedance is within acceptable limits, energy continues to be applied to the tissue. However if the measured impedance exceeds the set value, a disabling signal 422 is transmitted to energy source 392, ceasing further delivery of energy to RF electrode 314.

[0084] The control of the delivery of cooling medium to electrode 314 and/or tissue site 416 is done in the following manner. During the application of energy, temperature measurement device 408 measures the temperature of tissue site 416 and/or RF electrode 314. A comparator 424 receives a signal representative of the measured temperature and compares this value to a pre-set signal representative of the desired temperature. If the measured temperature has not exceeded the desired temperature, comparator 424 sends a signal to flow regulator 418 to maintain the cooling solution flow rate at its existing level. However if the tissue temperature is too high, comparator 424 sends a signal to a flow regulator 418 (connected to an electronically controlled micropump, not shown) representing a need for an increased cooling solution flow rate.

[0085] The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

We claim:

1. A sphincter treatment apparatus comprising:  
an introducer having an introducer lumen,  
an expandable device coupled to the introducer, the expandable device including a first arm with a proximal section and a distal section and a second arm with a proximal section and a distal section, the first and second arm distal sections being coupled, at least one of the first and second arms including an arm lumen coupled in fluid communication with the introducer lumen for delivery of a fluid, the expandable device being configured to at least partially dilate a sphincter in a deployed state, and

an energy delivery device coupled to the expandable device.

2. An apparatus as in claim 1 wherein at least a portion of the energy delivery device is advanceable into the sphincter.

3. An apparatus as in claim 1 wherein the at least one of the first and second arms includes an aperture coupled to the introducer lumen and adapted to provide a path for delivery of the fluid from the introducer.

4. An apparatus as in claim 3 wherein the fluid is cooling fluid.

5. A method of treating a sphincter comprising:  
providing an introducer, the introducer carrying an expandable device,

providing an energy delivery device coupled to the expandable device,

deploying the introducer to a targeted tissue site at or near a sphincter,

expanding the expandable device to at least partially dilate the sphincter,

delivering energy from the energy delivery device to the targeted tissue site, and

delivering a cooling fluid from the introducer.

6. A method as in claim 5 wherein the expandable device includes a first arm with a proximal section and a distal section and a second arm with a proximal section and a distal section, the first and second arm distal sections being coupled.

7. A method as in claim 6 wherein at least one of the first and second arms includes a lumen.

8. A method as in claim 5 wherein the introducer includes a lumen.

9. A method as in claim 5 wherein the cooling fluid is delivered at a sensed flow rate, further comprising,  
measuring the temperature of at least one of the tissue site and the energy delivery device, and  
comparing the measured temperature to a pre-set desired temperature.

10. A method as in claim 9, further comprising  
maintaining the flow rate if the measured temperature does not exceed the desired temperature.

11. A method as in claim 9, further comprising  
increasing the flow rate if the measured temperature exceeds the desired temperature.

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