US 20020107512A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2002/0107512 A1

Edwards (43) Pub. Date: Aug. 8, 2002

(54) SPHINCTER TREATMENT APPARATUS

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(21) Appl. No.: **09/943,646**

(22) Filed: **Aug. 30, 2001**

Related U.S. Application Data

(63) Continuation of application No. 09/070,490, filed on Apr. 30, 1998, now abandoned, which is a continuation-in-part of application No. 09/026,316, filed on Feb. 19, 1998, now Pat. No. 6,056,744.

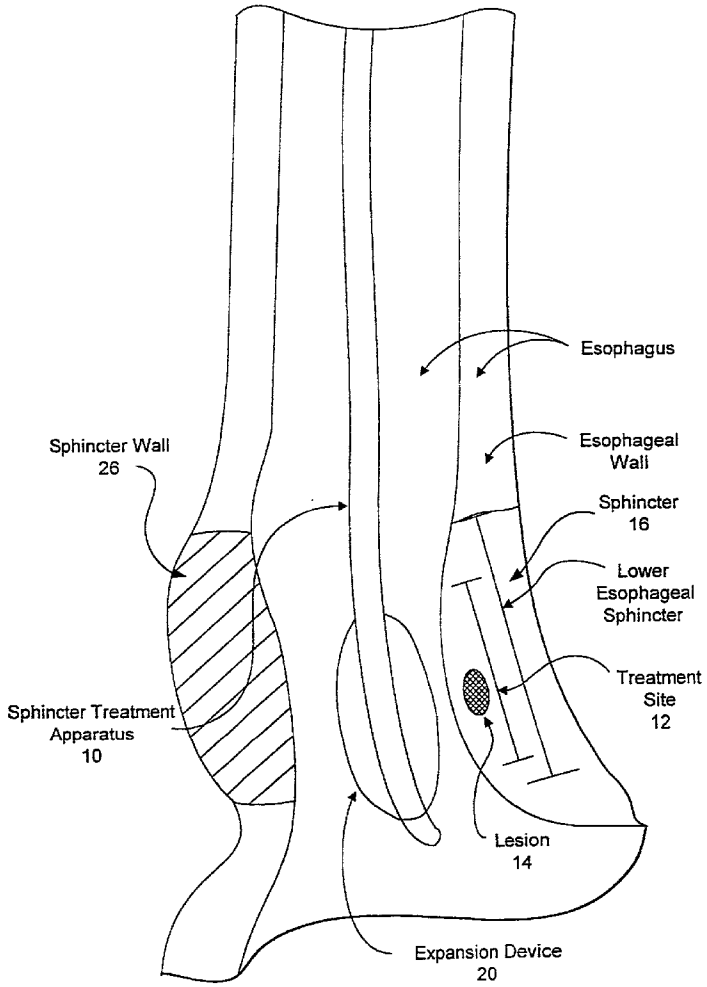
Publication Classification

(51) **Int. Cl.**[7] **A61B 18/18**

(52) **U.S. Cl.** **606/41**; 607/101; 607/133

(57) ABSTRACT

A sphincter treatment apparatus includes an energy delivery device introduction member including a plurality of arms. Each arm has distal and proximal sections. The distal sections of the arms are coupled as are the proximal sections of the arms. The energy delivery device introduction member is configured to be introduced in the sphincter in a non-deployed state, expand to a deployed state to at least partially expand the sphincter. A plurality of energy delivery devices are coupled to the energy delivery device introduction member. At least a portion of the plurality of energy delivery devices are controllably introducible from the energy delivery device introduction member into the sphincter.



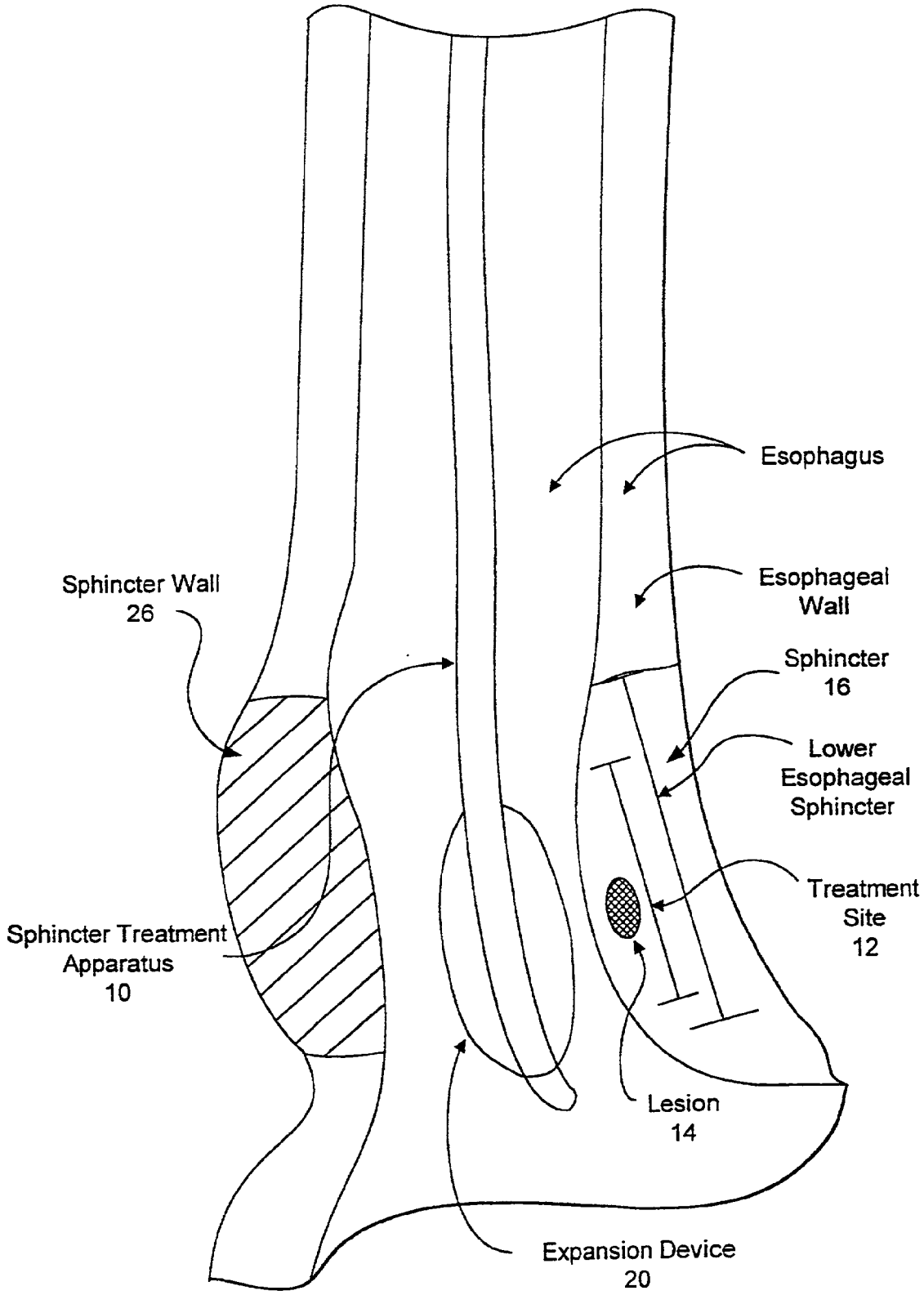

Esophagus
Esophageal Wall
Sphincter Wall 26
Sphincter 16
Lower Esophageal Sphincter
Treatment Site 12
Sphincter Treatment Apparatus 10
Lesion 14
Expansion Device 20

FIG. 1

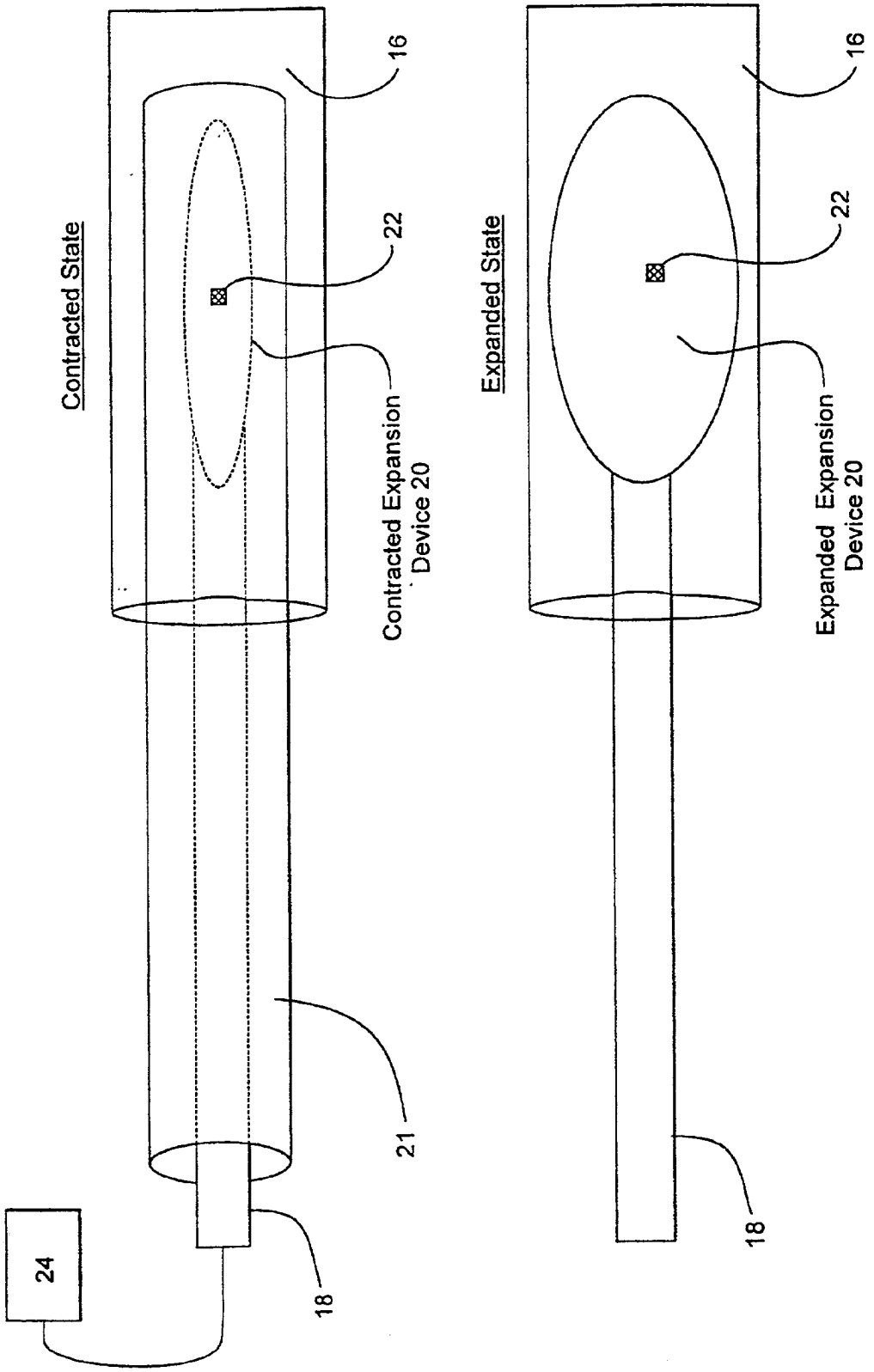

Contracted State
16
22
Contracted Expansion Device 20
21
18
24
Expanded State
16
22
Expanded Expansion Device 20
18

FIG. 2A

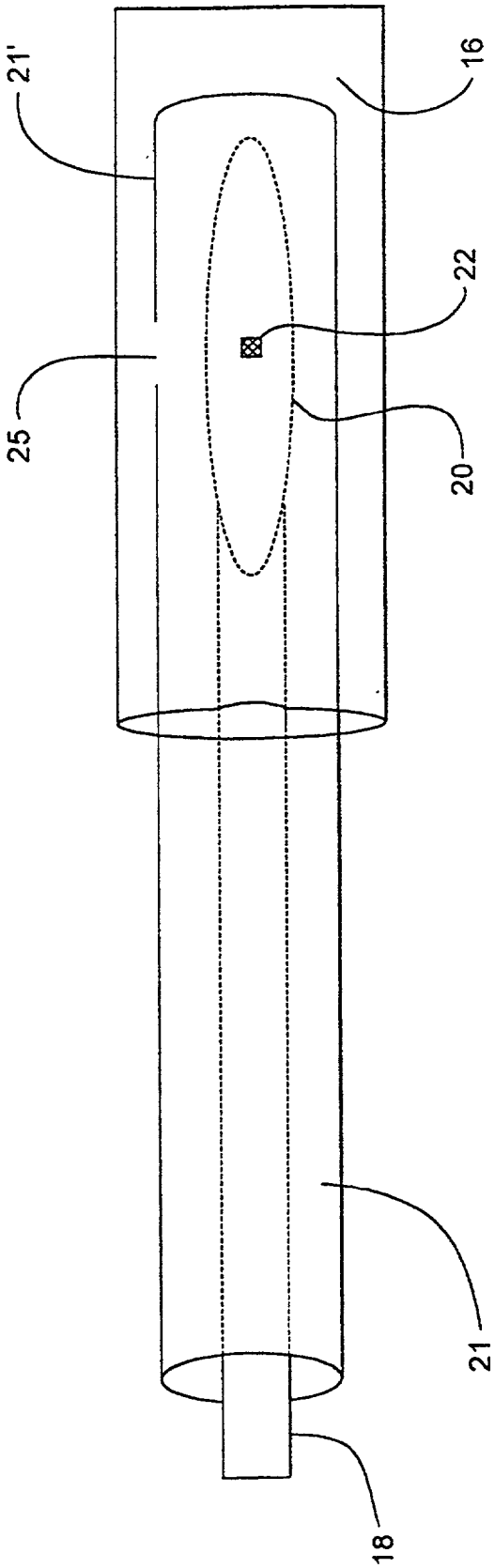


FIG. 2B

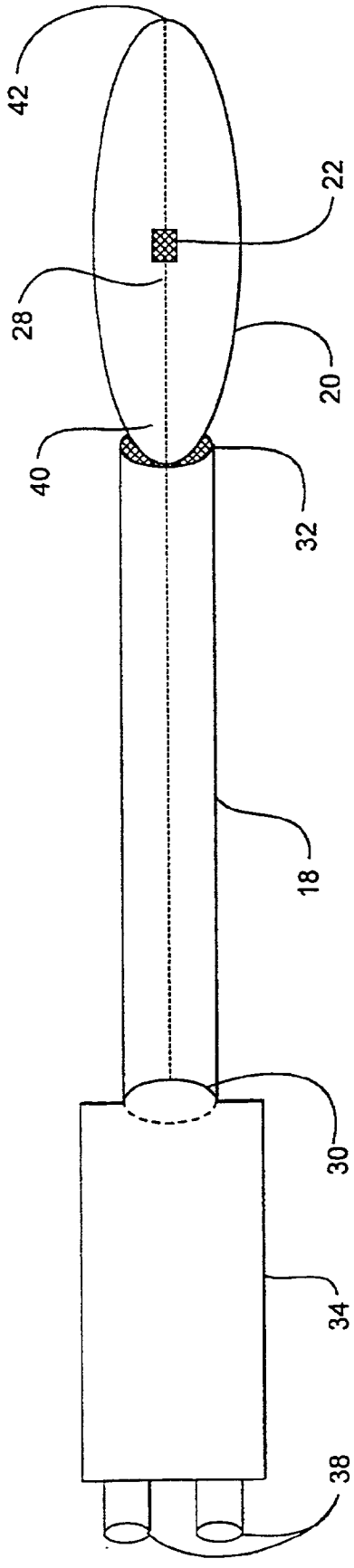


FIG. 3

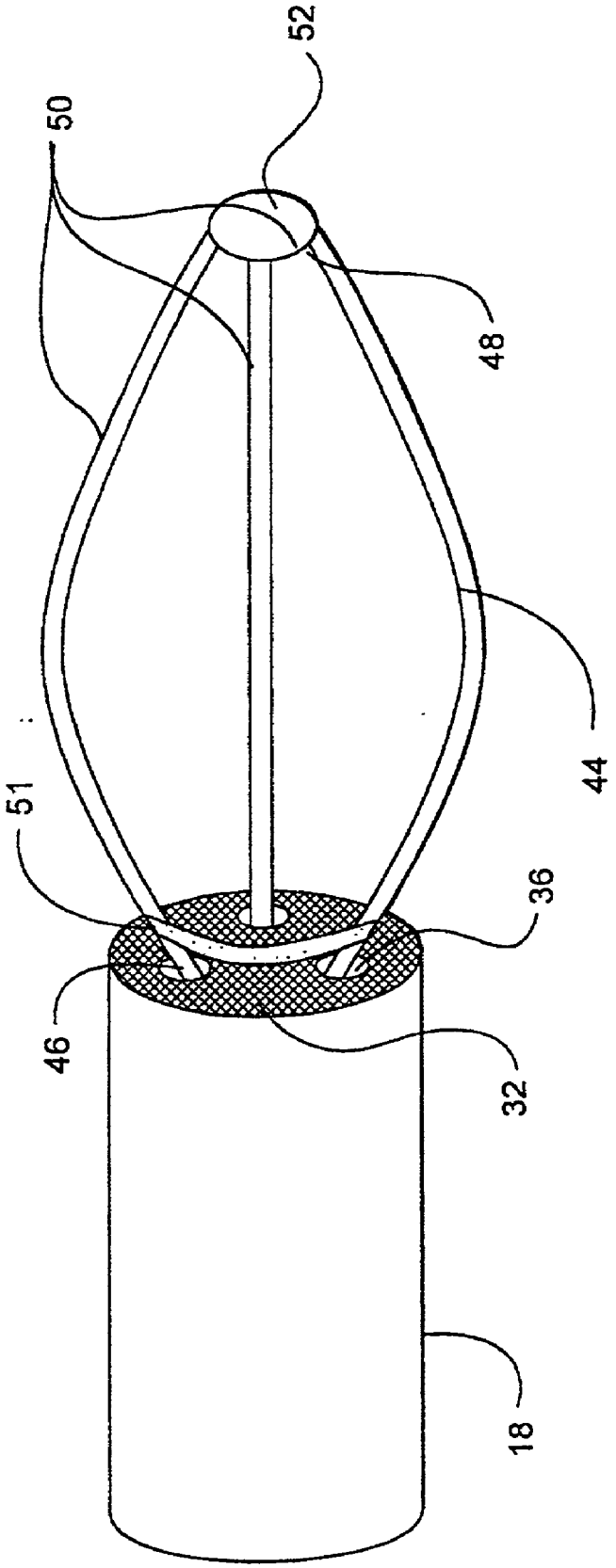


FIG. 4A

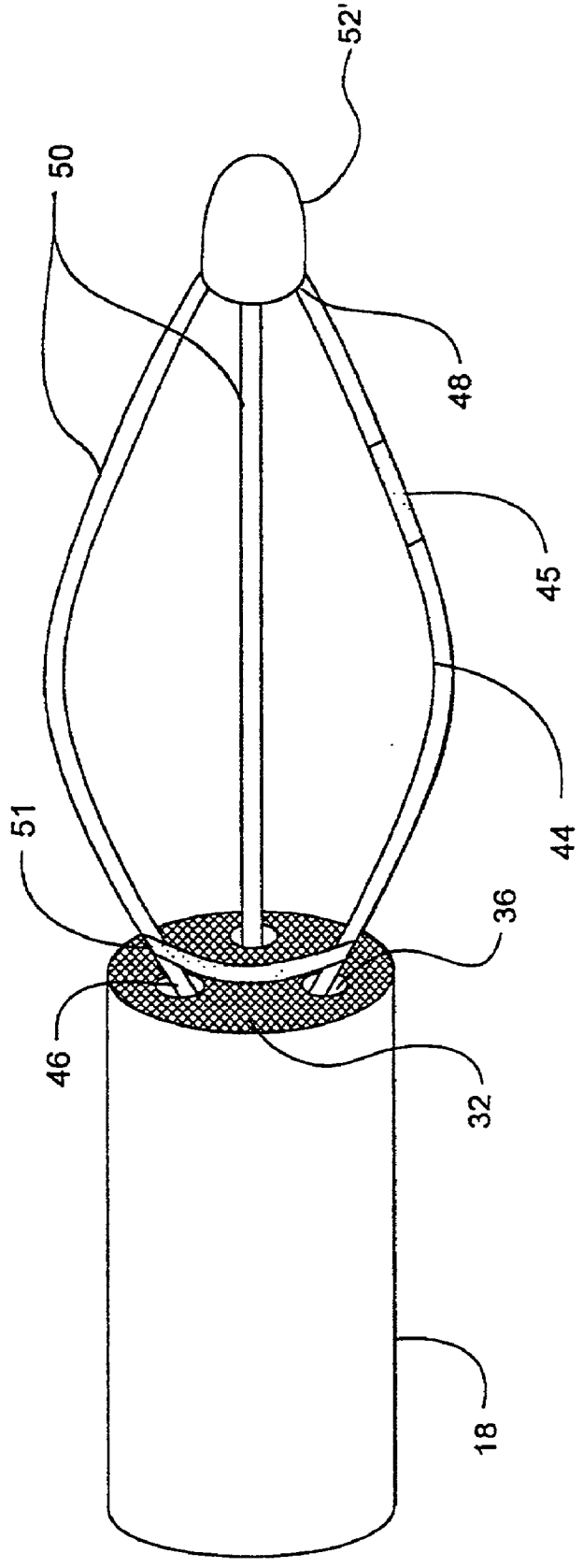


FIG. 4B

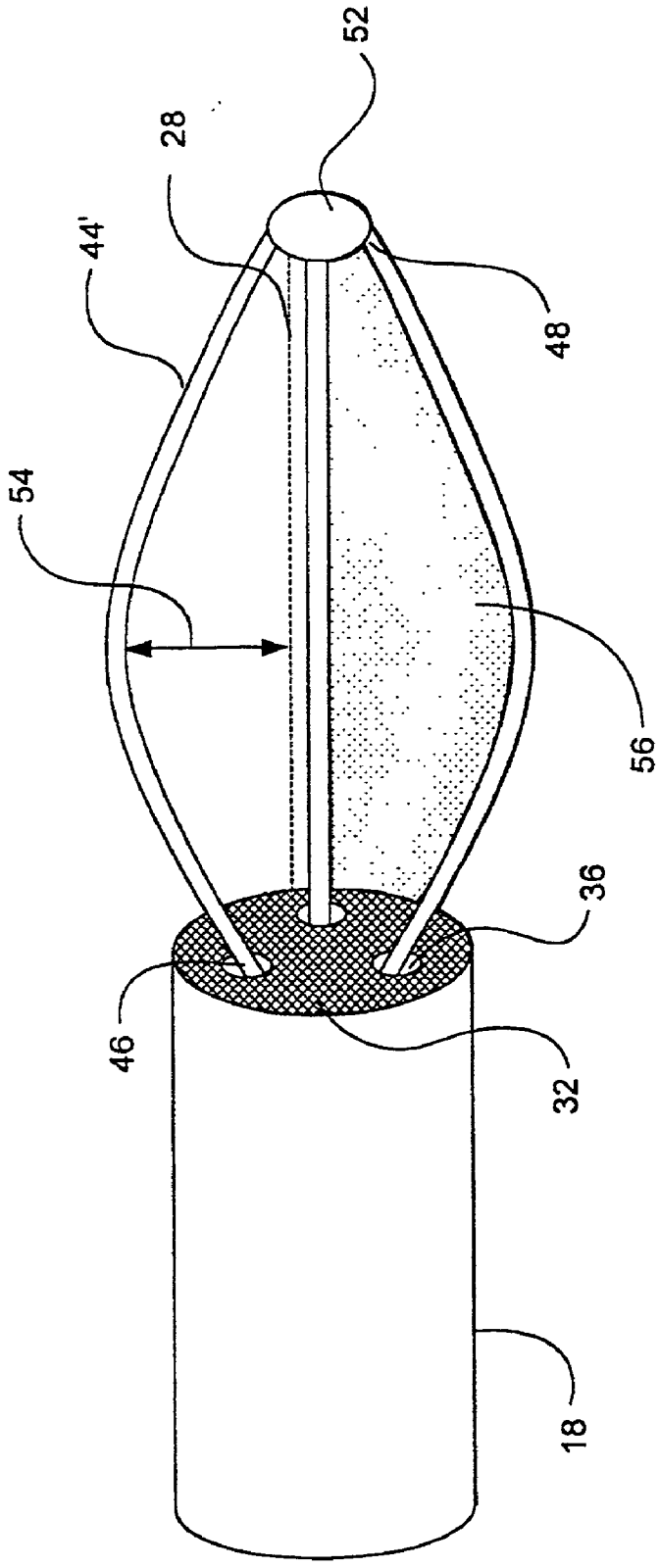


FIG. 5A

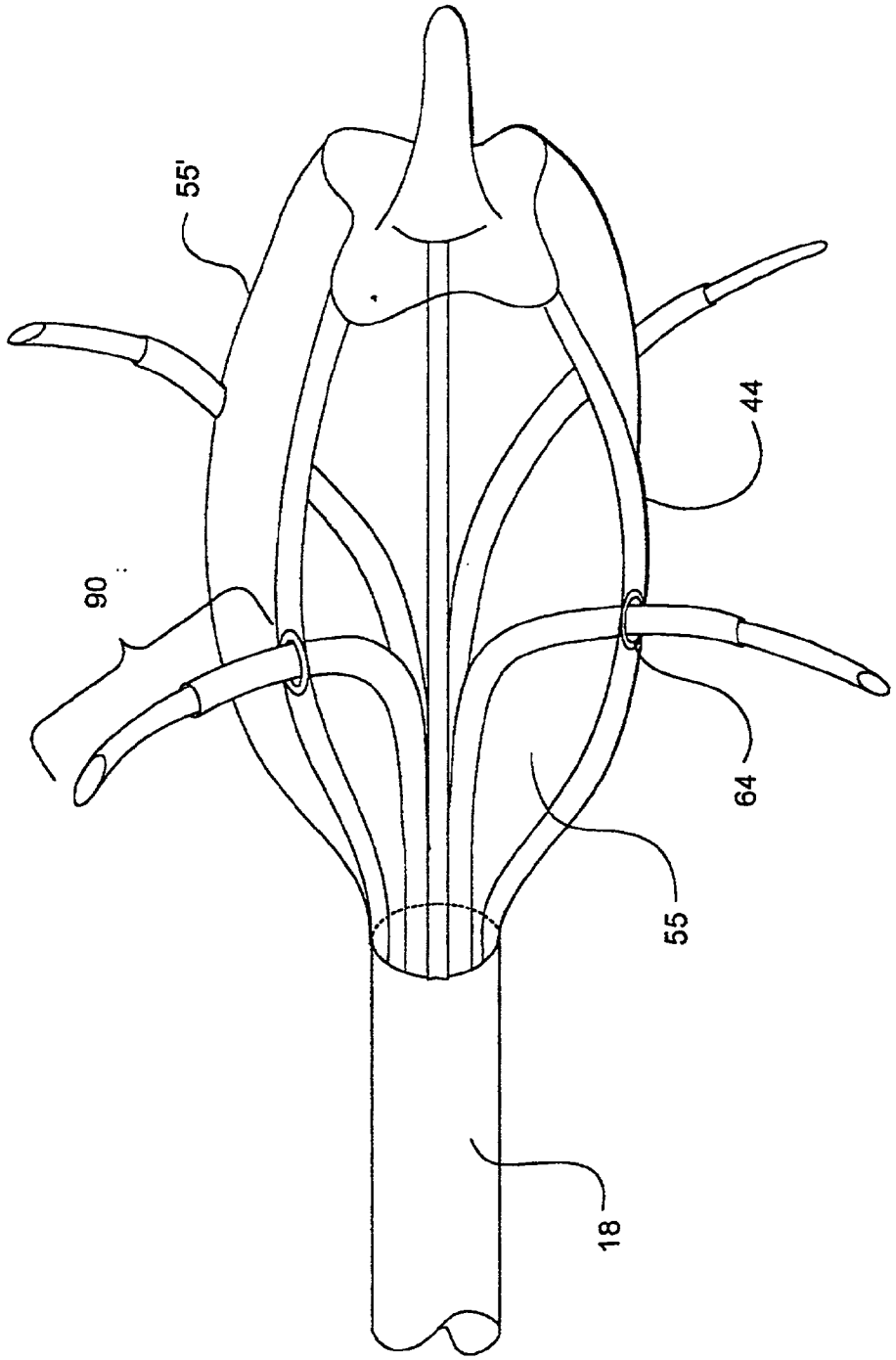


FIG. 5B

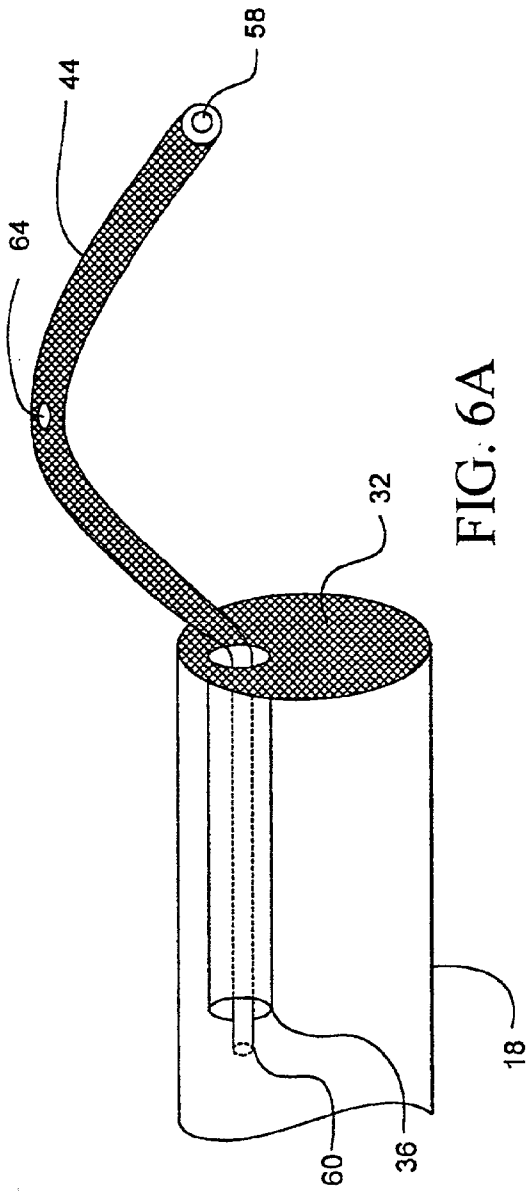


FIG. 6A

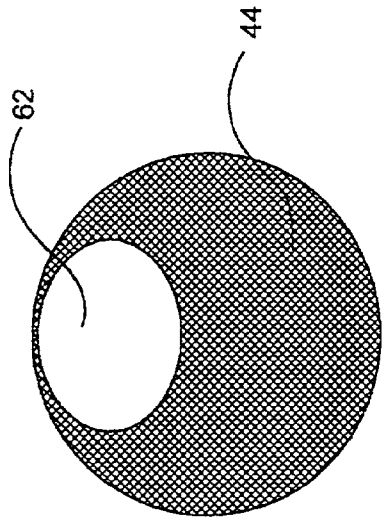


FIG. 6B

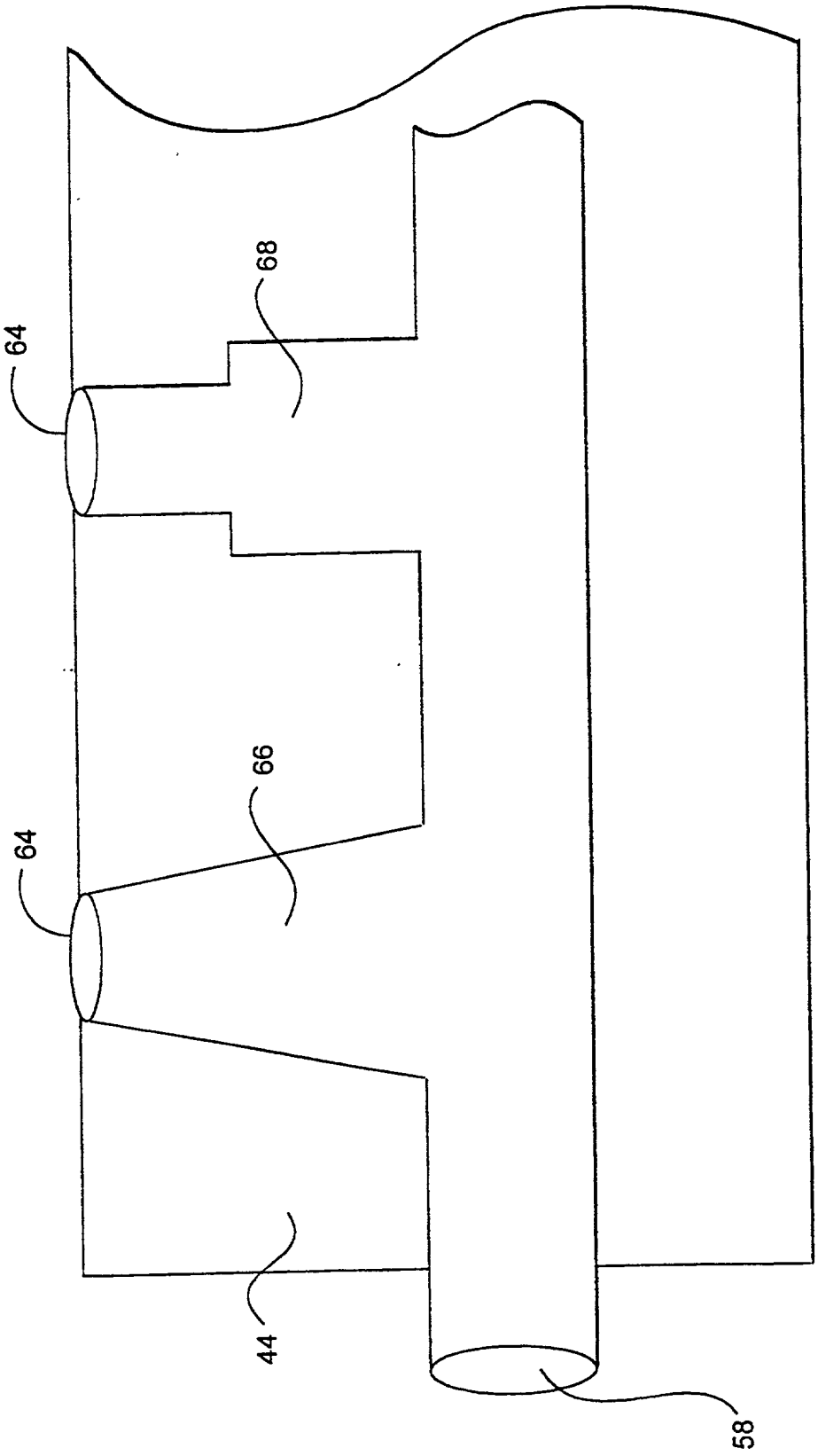


FIG. 7

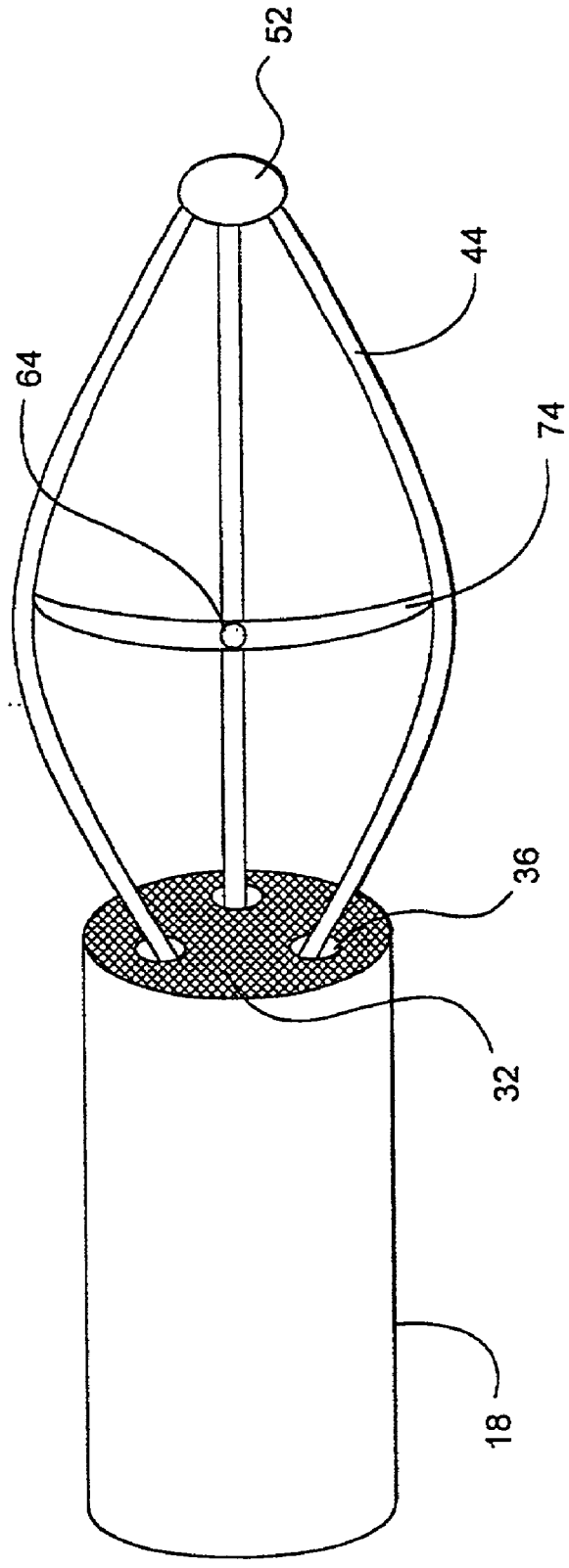


FIG. 8

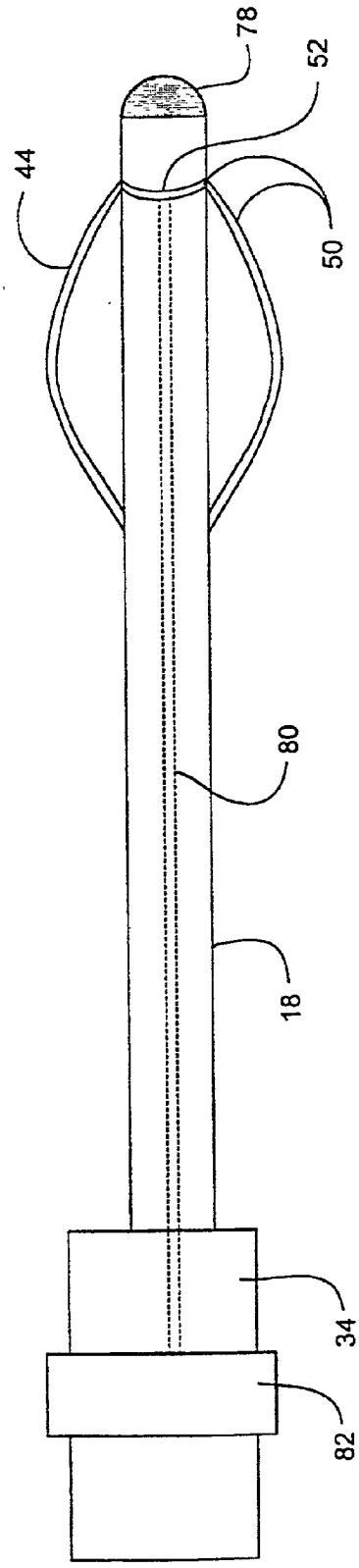

78
52
44
50
80
18
34
82

FIG. 9A

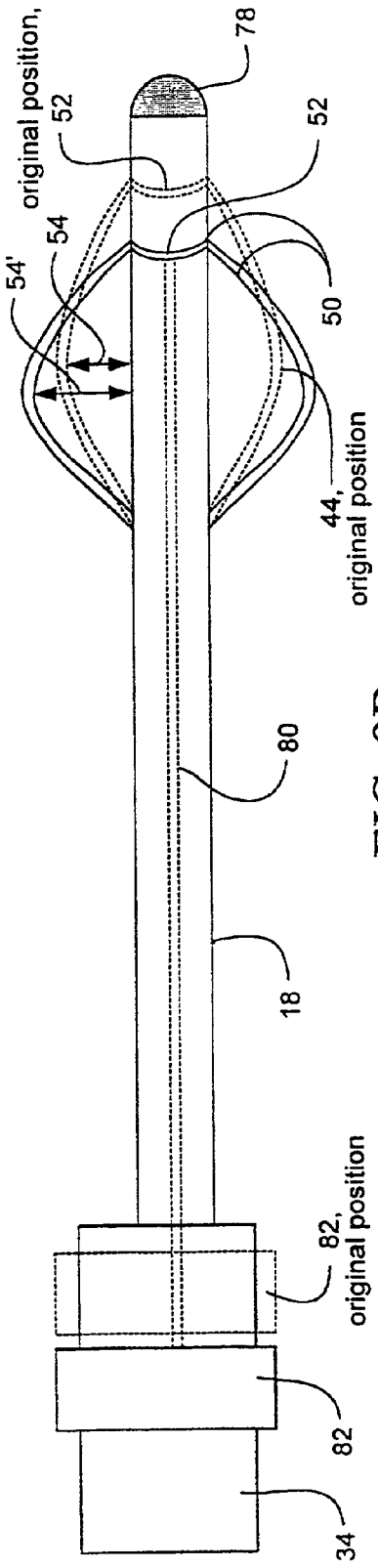

original position,
52
78
52
54
54'
50
44,
original position
80
18
82,
original position
82
34

FIG. 9B

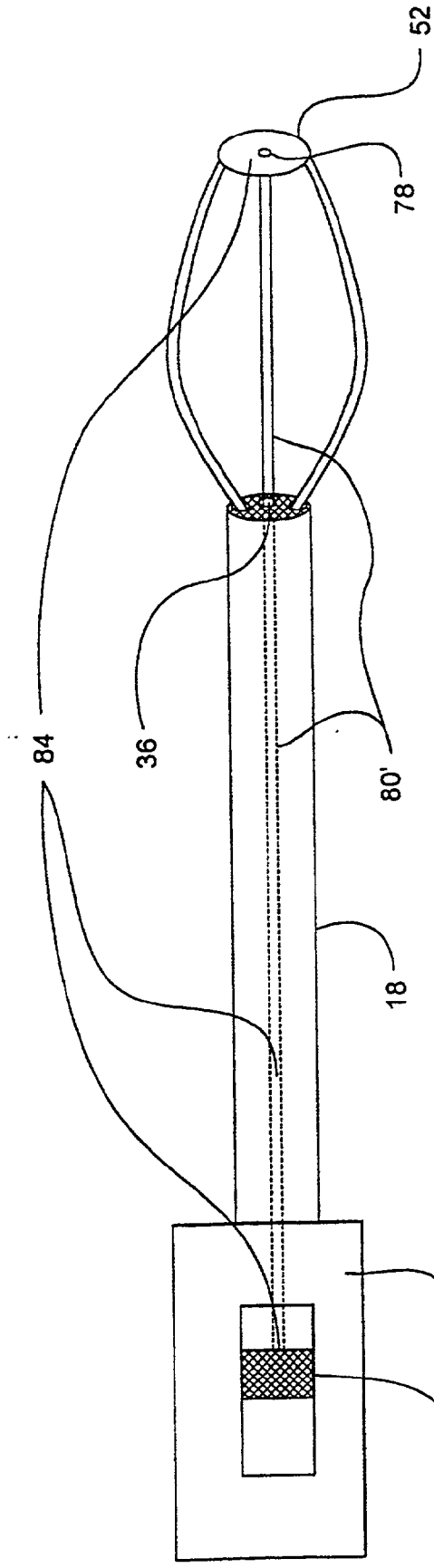


FIG. 10

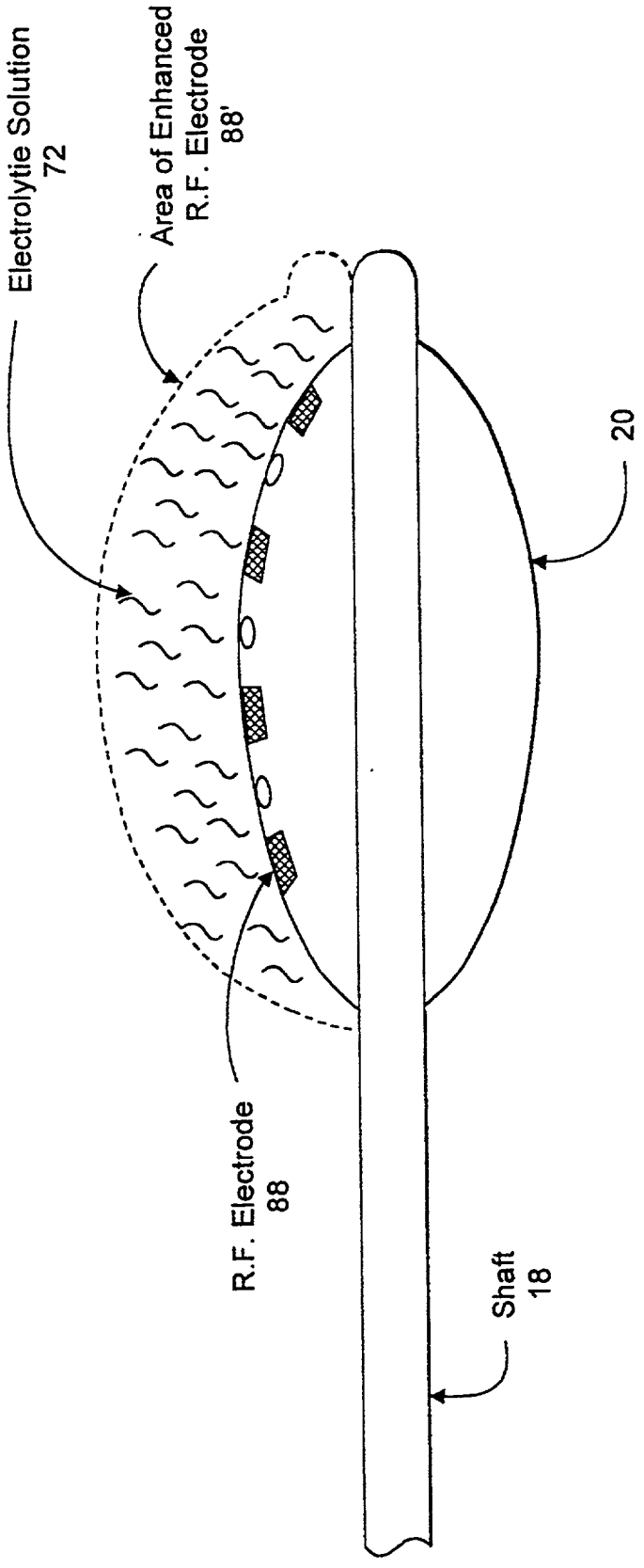

Electrolytie Solution
72
Area of Enhanced
R.F. Electrode
88'
20
R.F. Electrode
88
Shaft
18

FIG.11

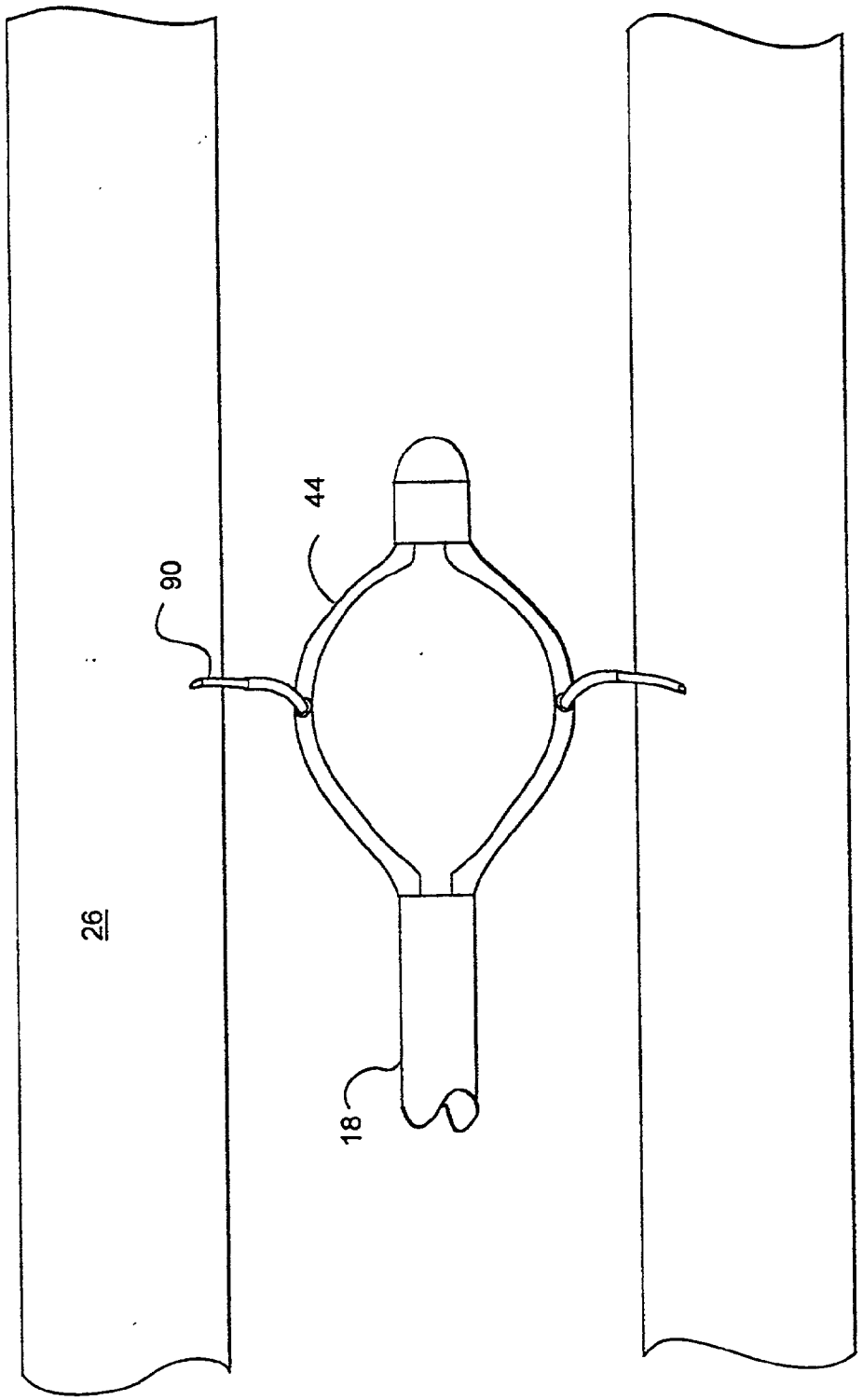


FIG. 12

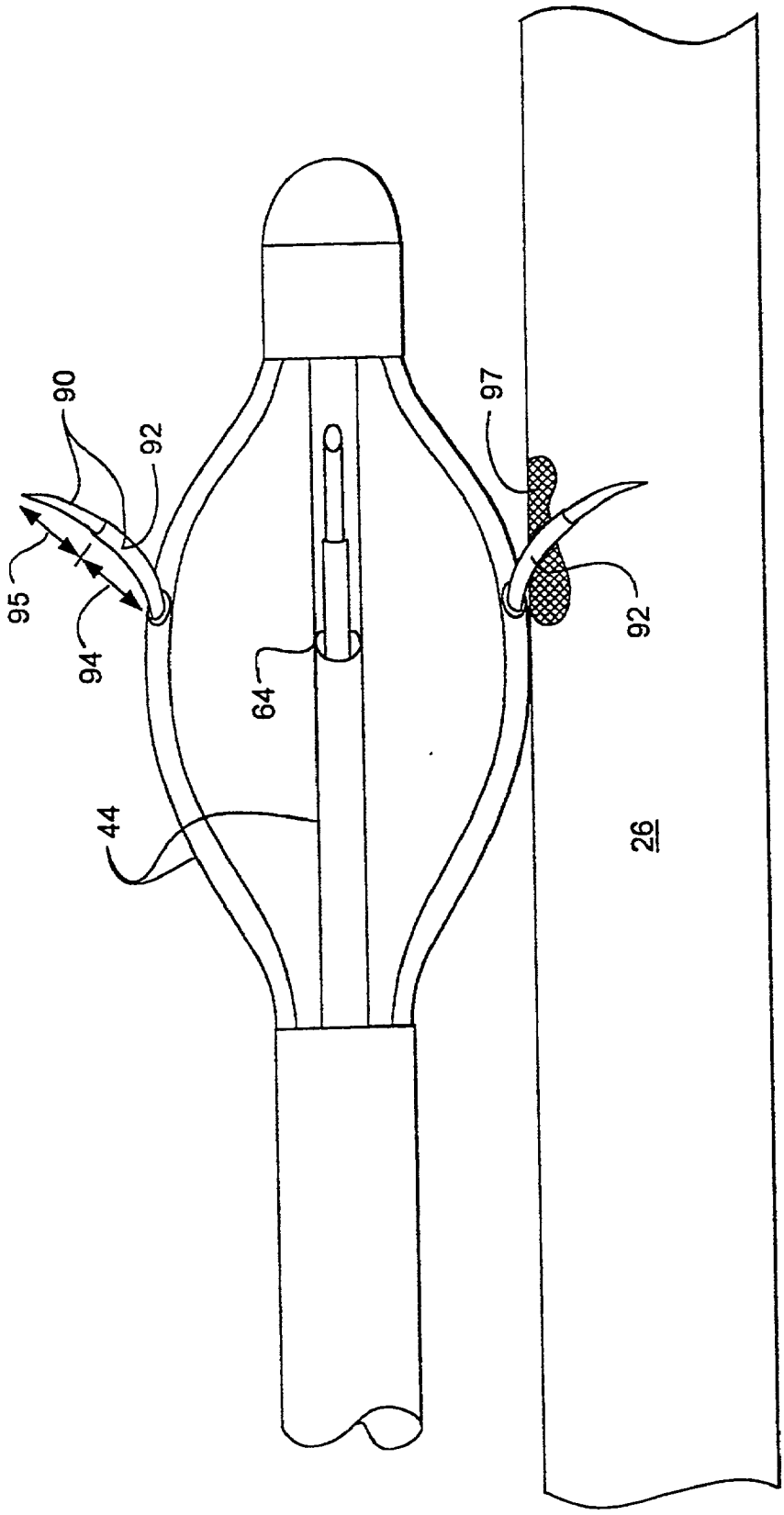


FIG. 13

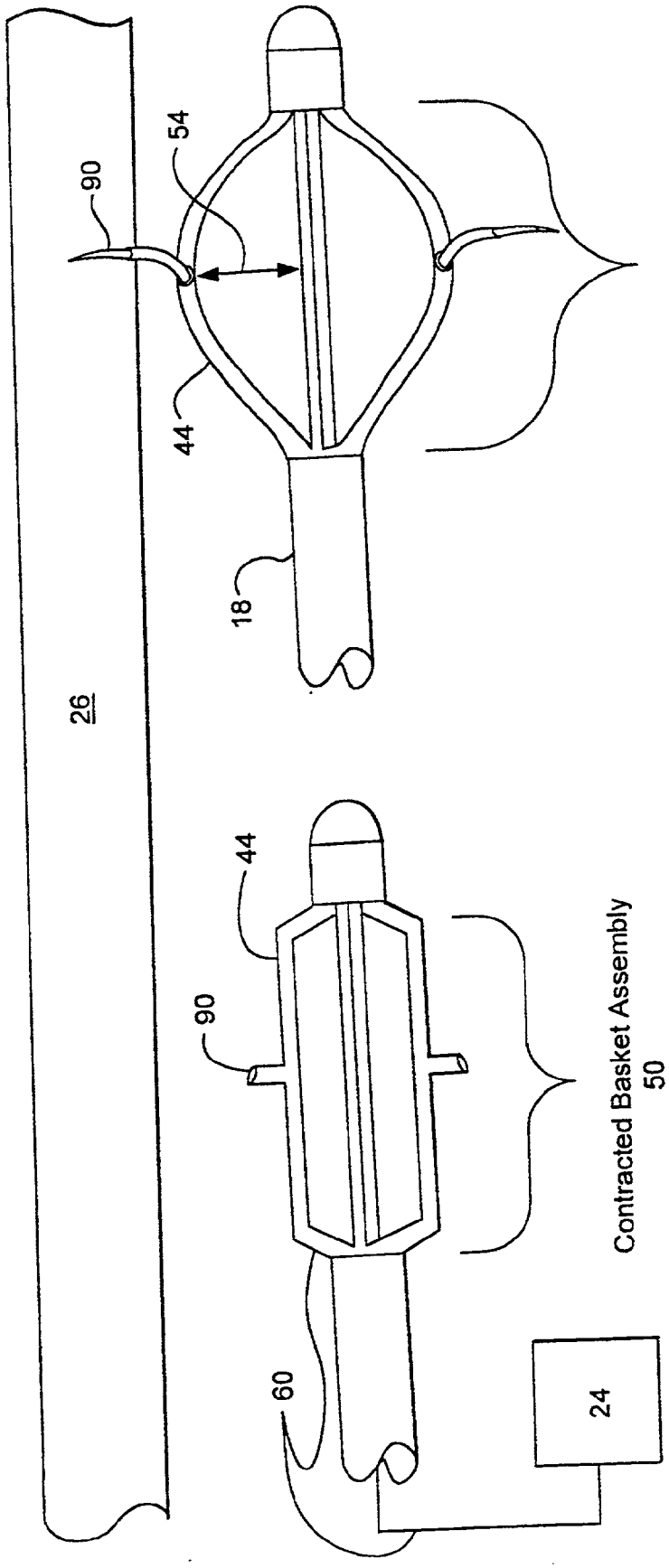

26
90
54
44
18
Expanded Basket Assembly
50
44
90
Contracted Basket Assembly
50
60
24

FIG. 14

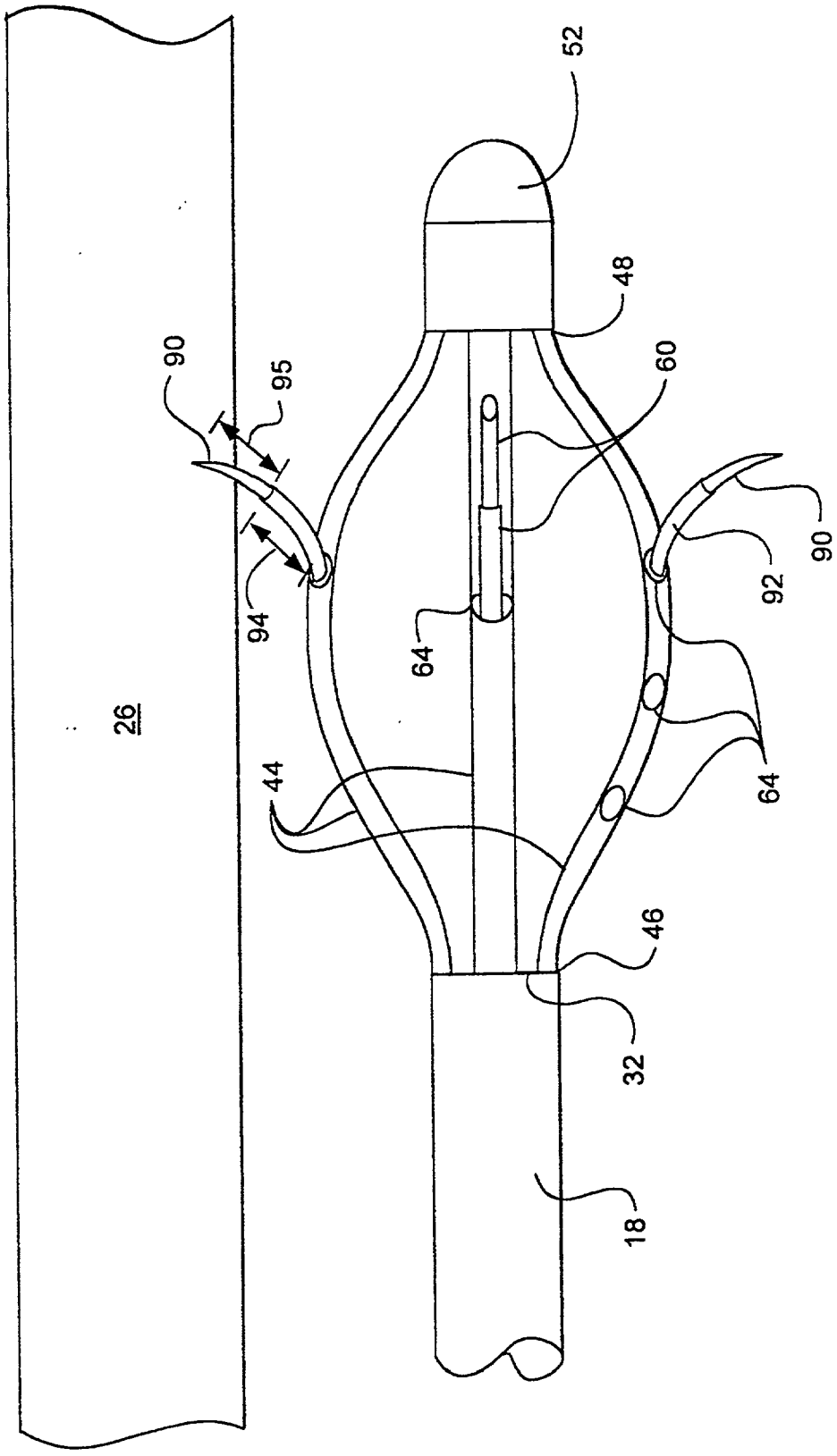


FIG. 15

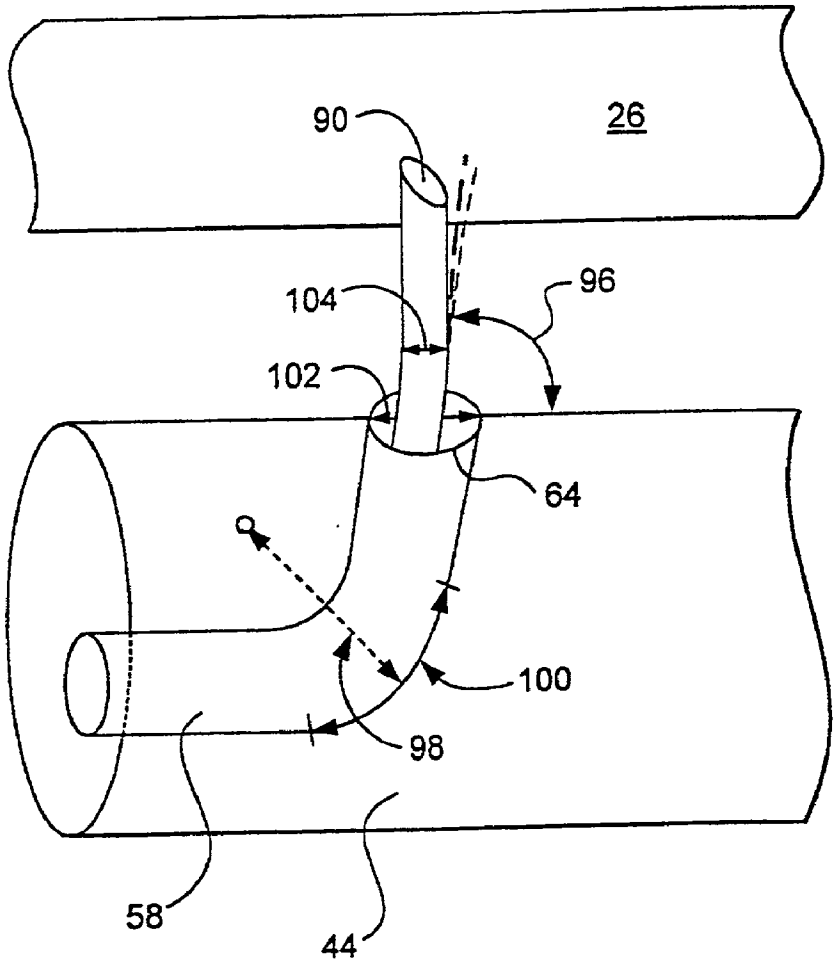


FIG. 16

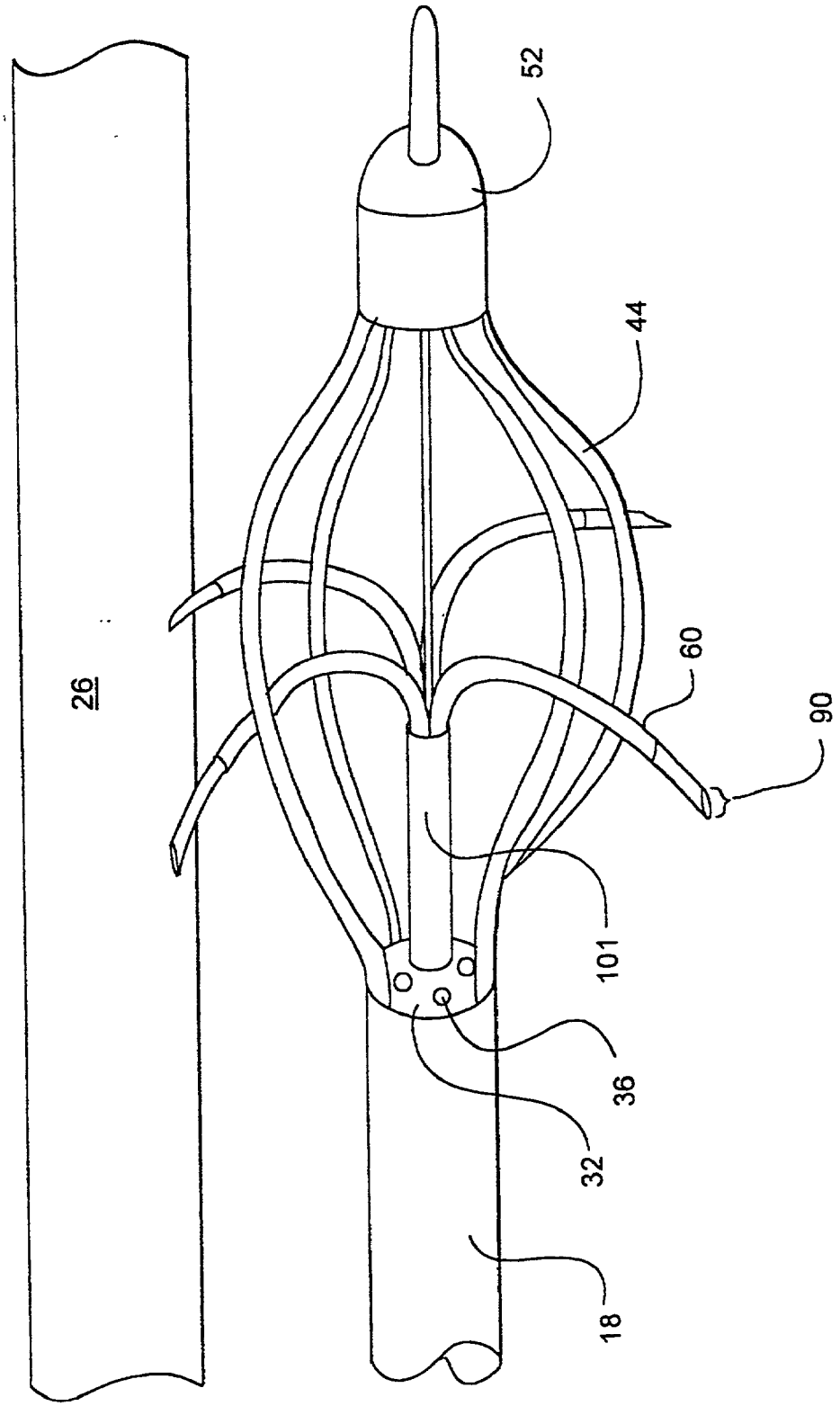


FIG. 17A

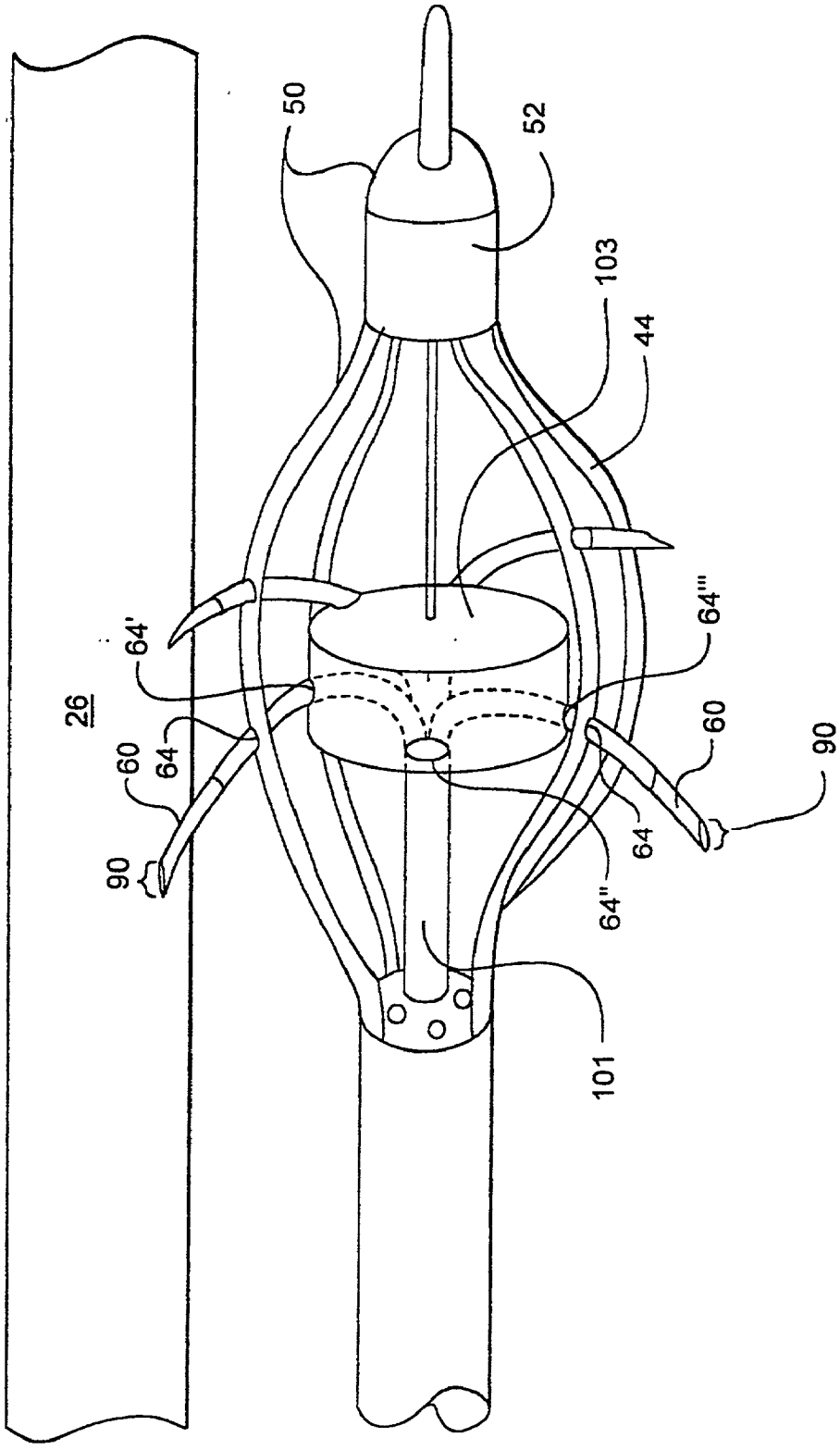


FIG. 17B

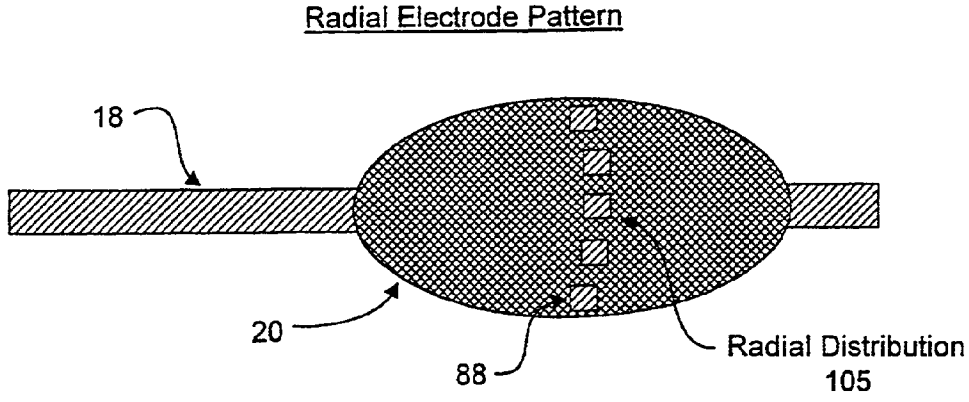


FIG. 18A

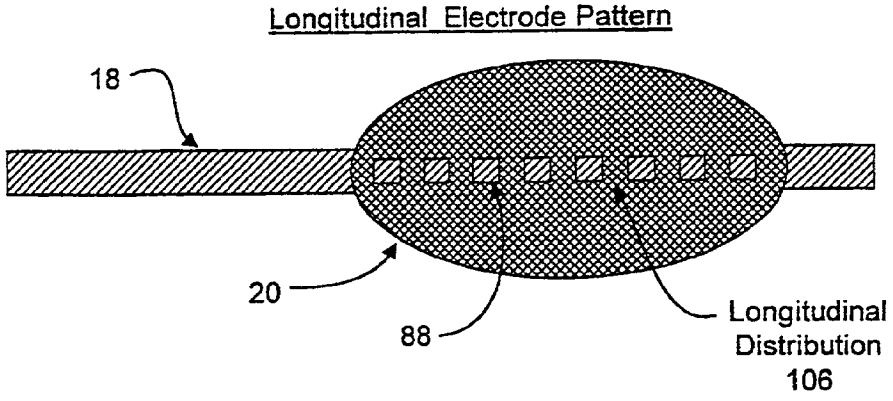


FIG. 18B

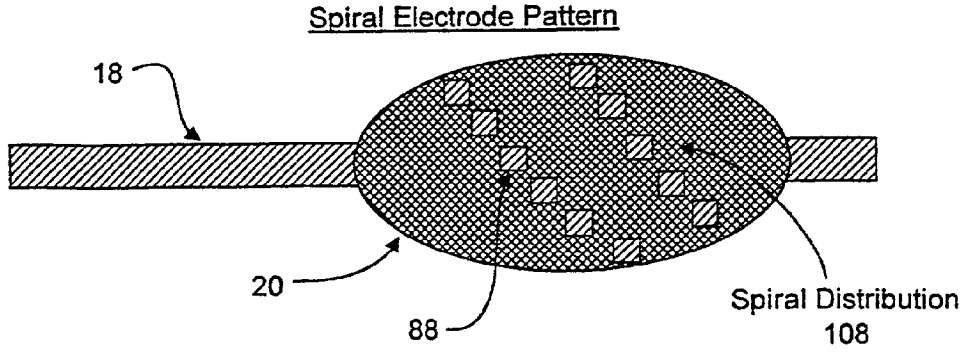


FIG. 18C

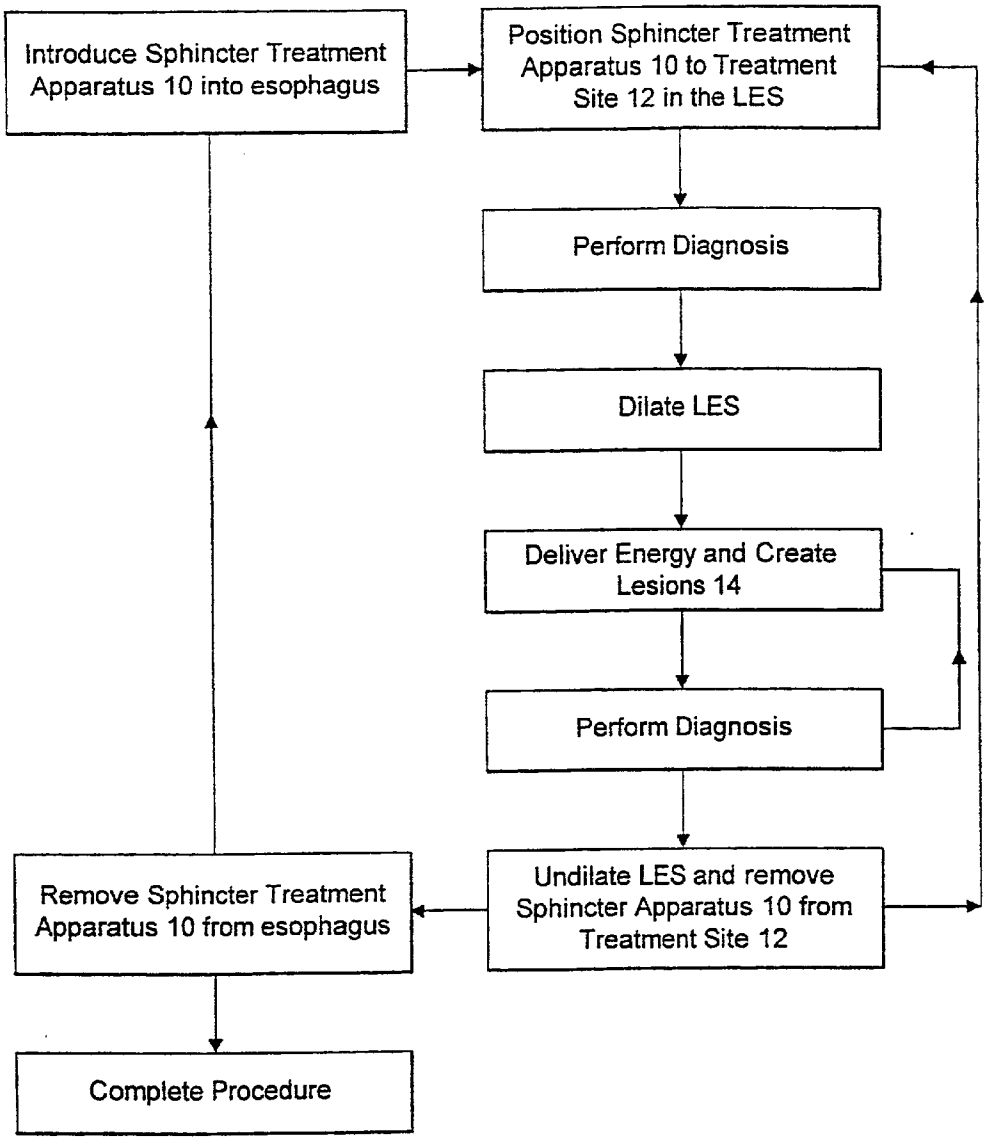

Introduce Sphincter Treatment Apparatus 10 into esophagus
Position Sphincter Treatment Apparatus 10 to Treatment Site 12 in the LES
Perform Diagnosis
Dilate LES
Deliver Energy and Create Lesions 14
Perform Diagnosis
Undilate LES and remove Sphincter Apparatus 10 from Treatment Site 12
Remove Sphincter Treatment Apparatus 10 from esophagus
Complete Procedure

FIG. 19

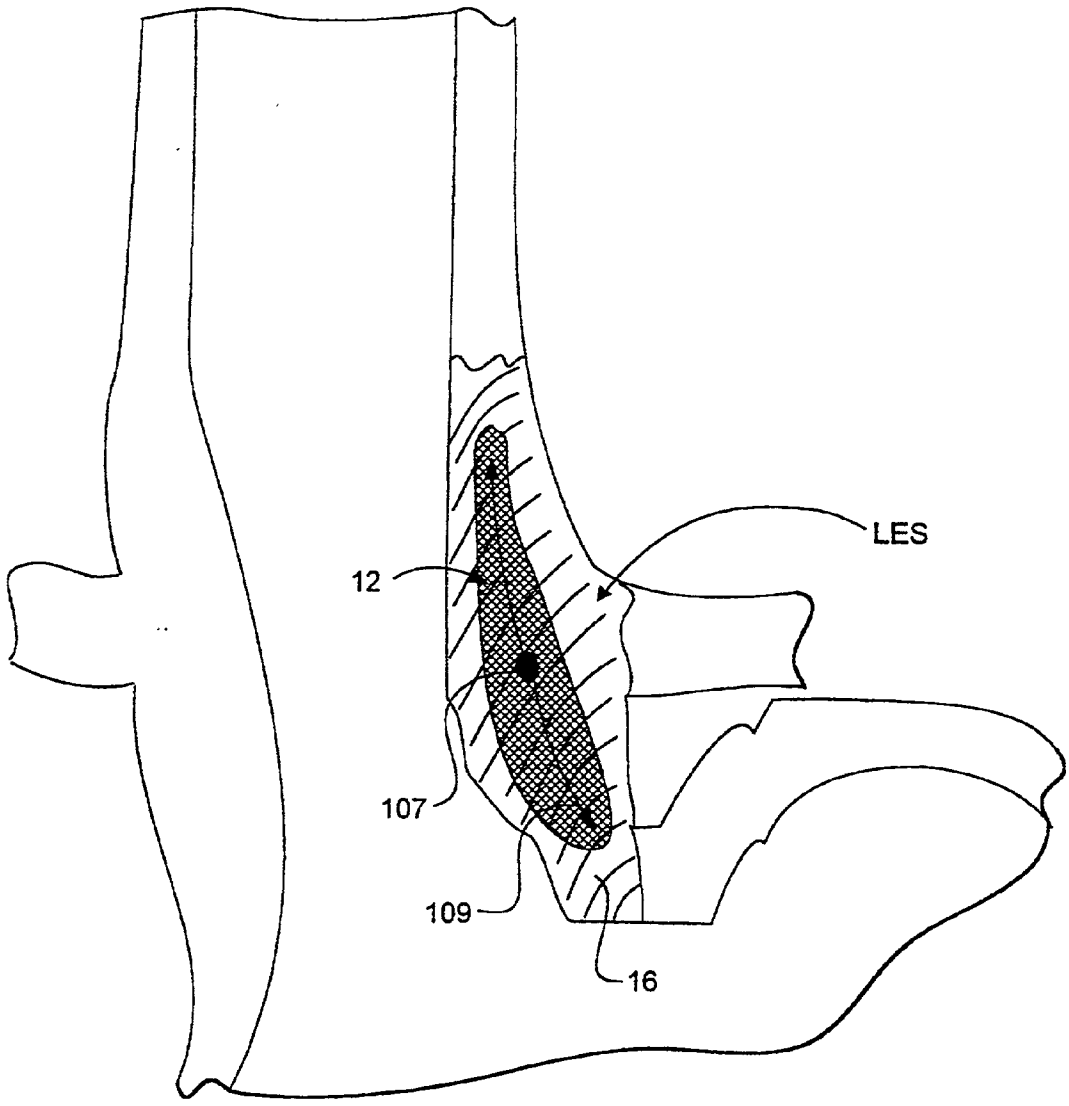


FIG. 20

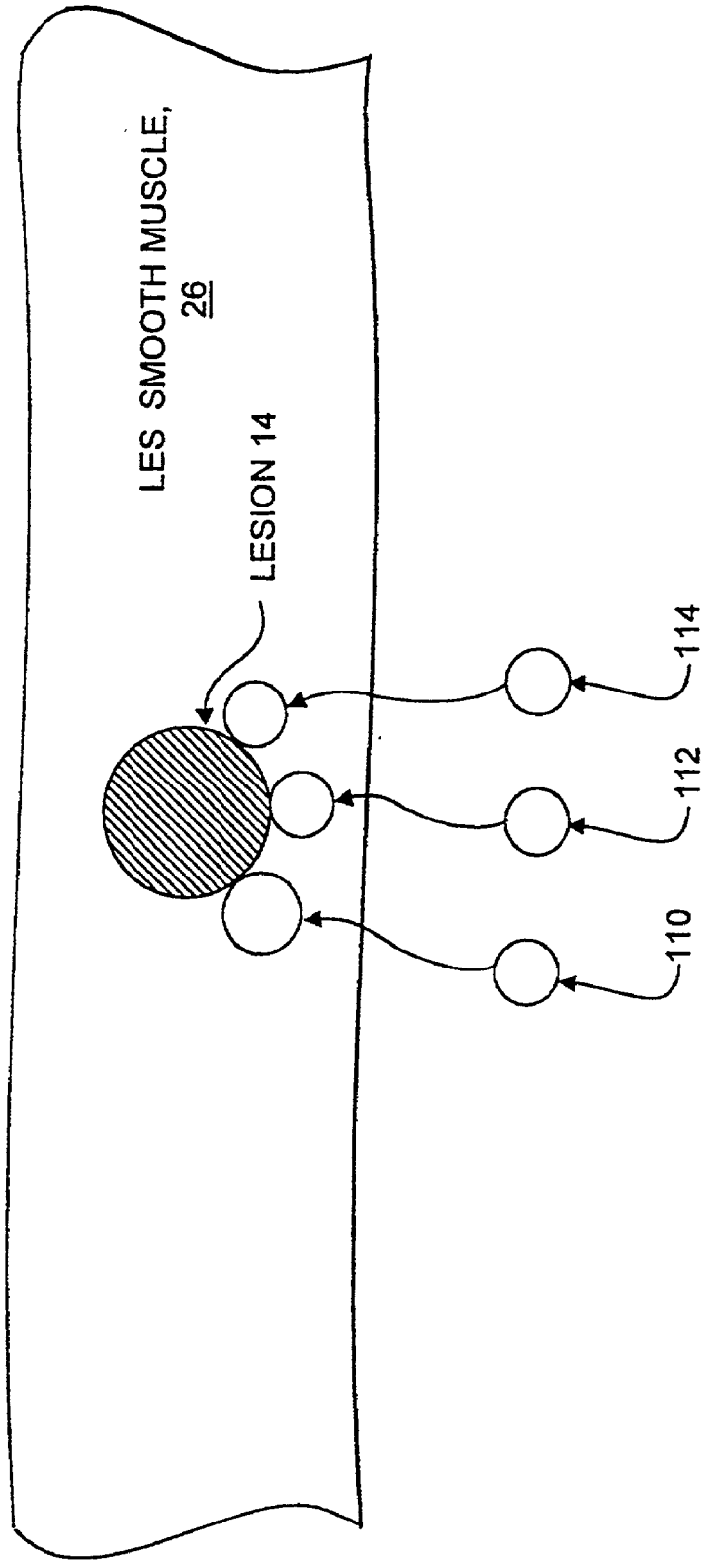


FIG. 21

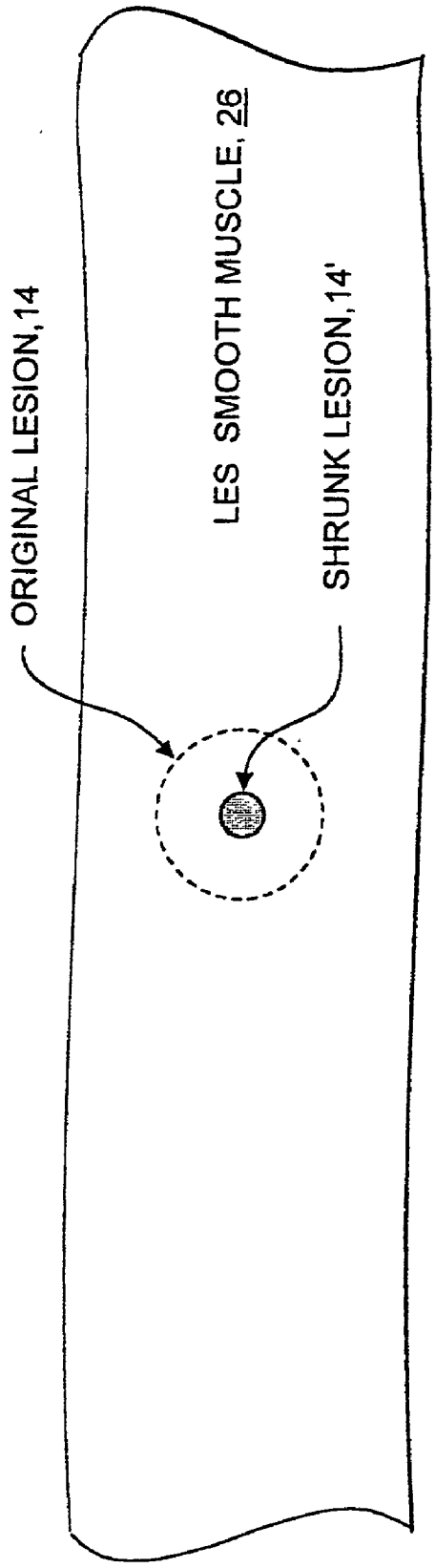


FIG. 22

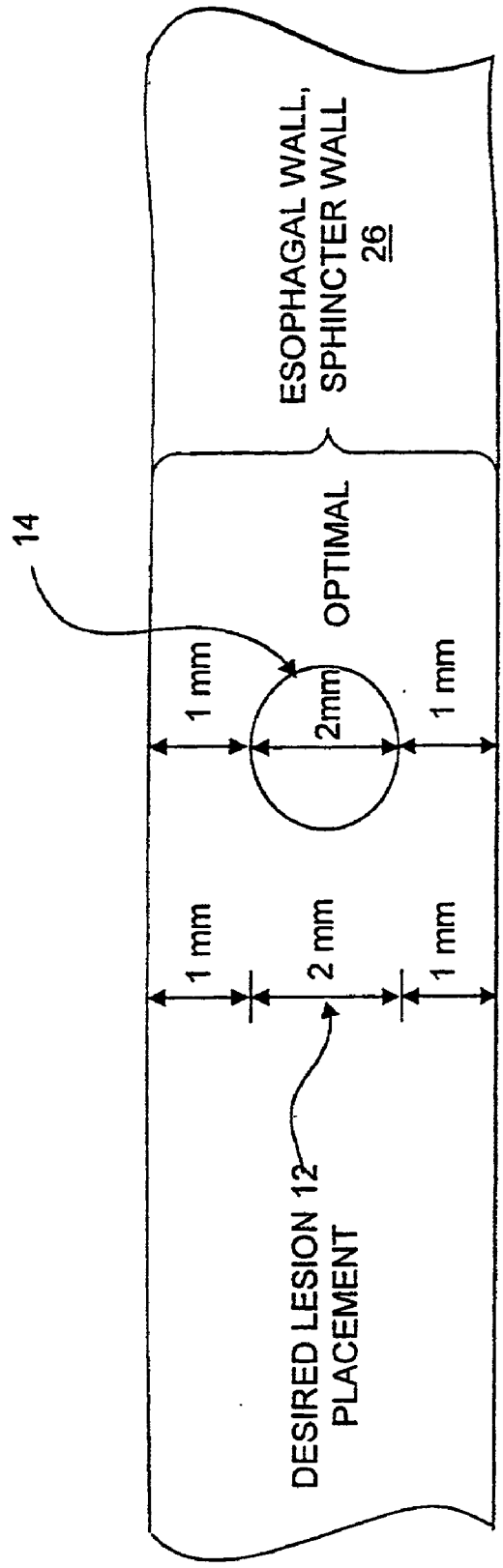

ESOPHAGAL WALL, SPHINCTER WALL 26
14
OPTIMAL
1 mm
2mm
1 mm
INTERIOR
1 mm
2 mm
1 mm
DESIRED LESION 12 PLACEMENT

FIG. 23

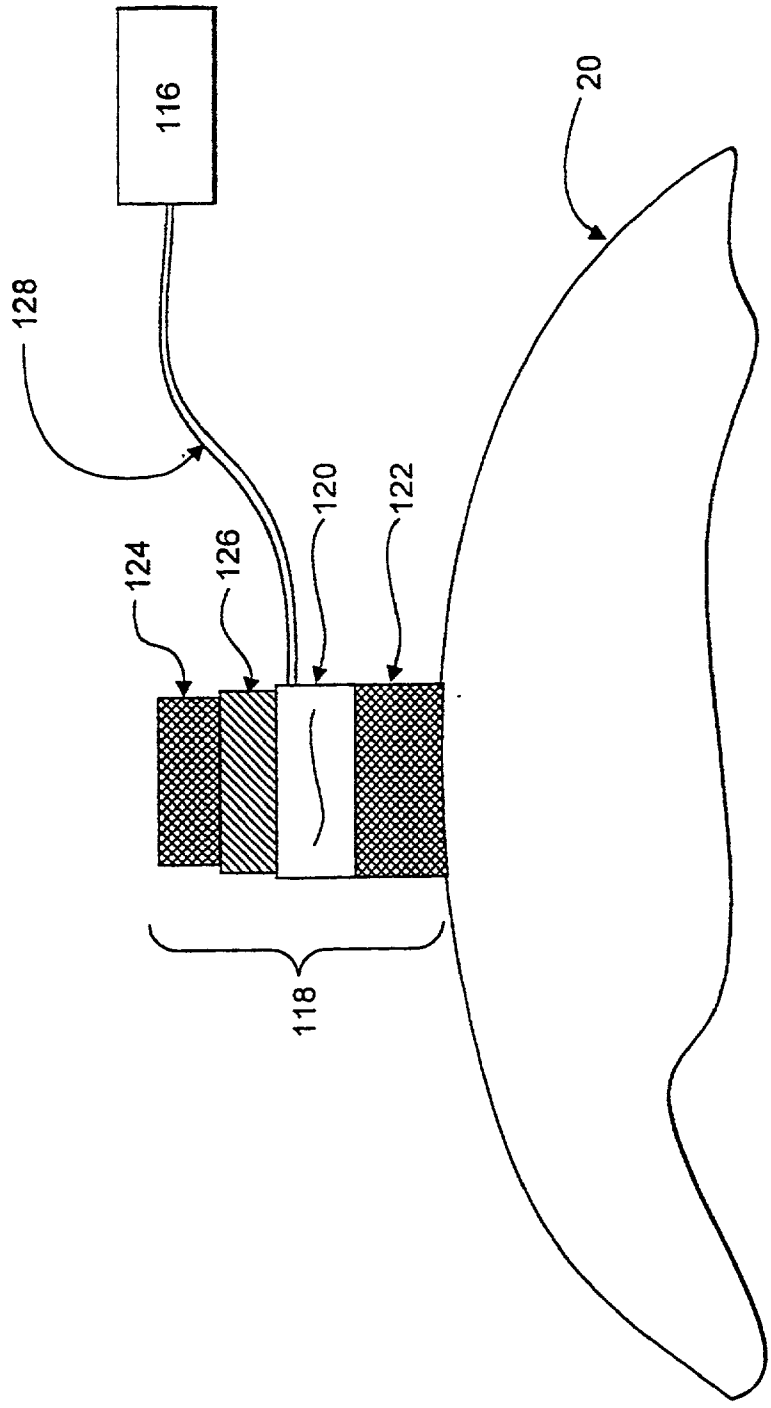


FIG. 24

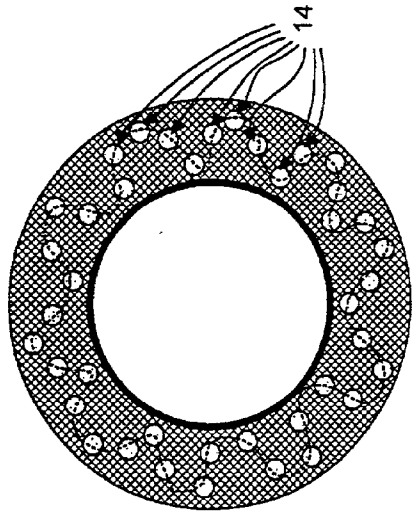


FIG. 25B

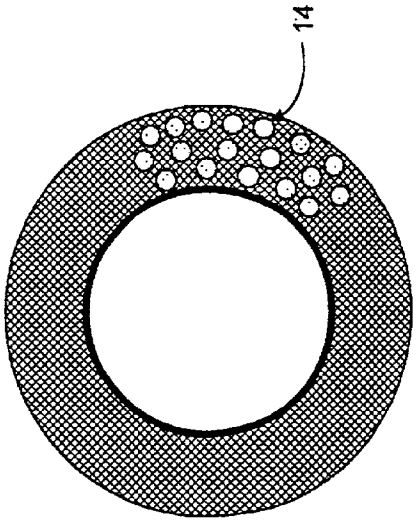


FIG. 25D

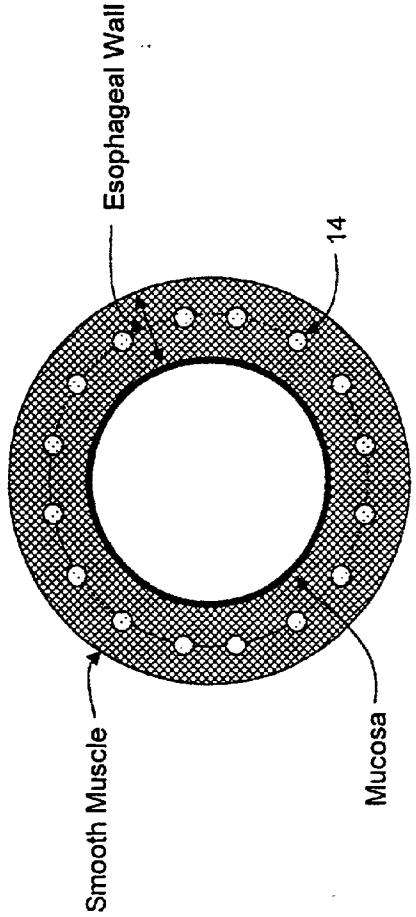


FIG. 25A

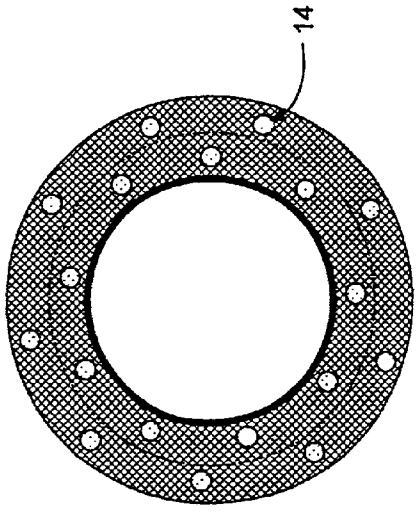


FIG. 25C

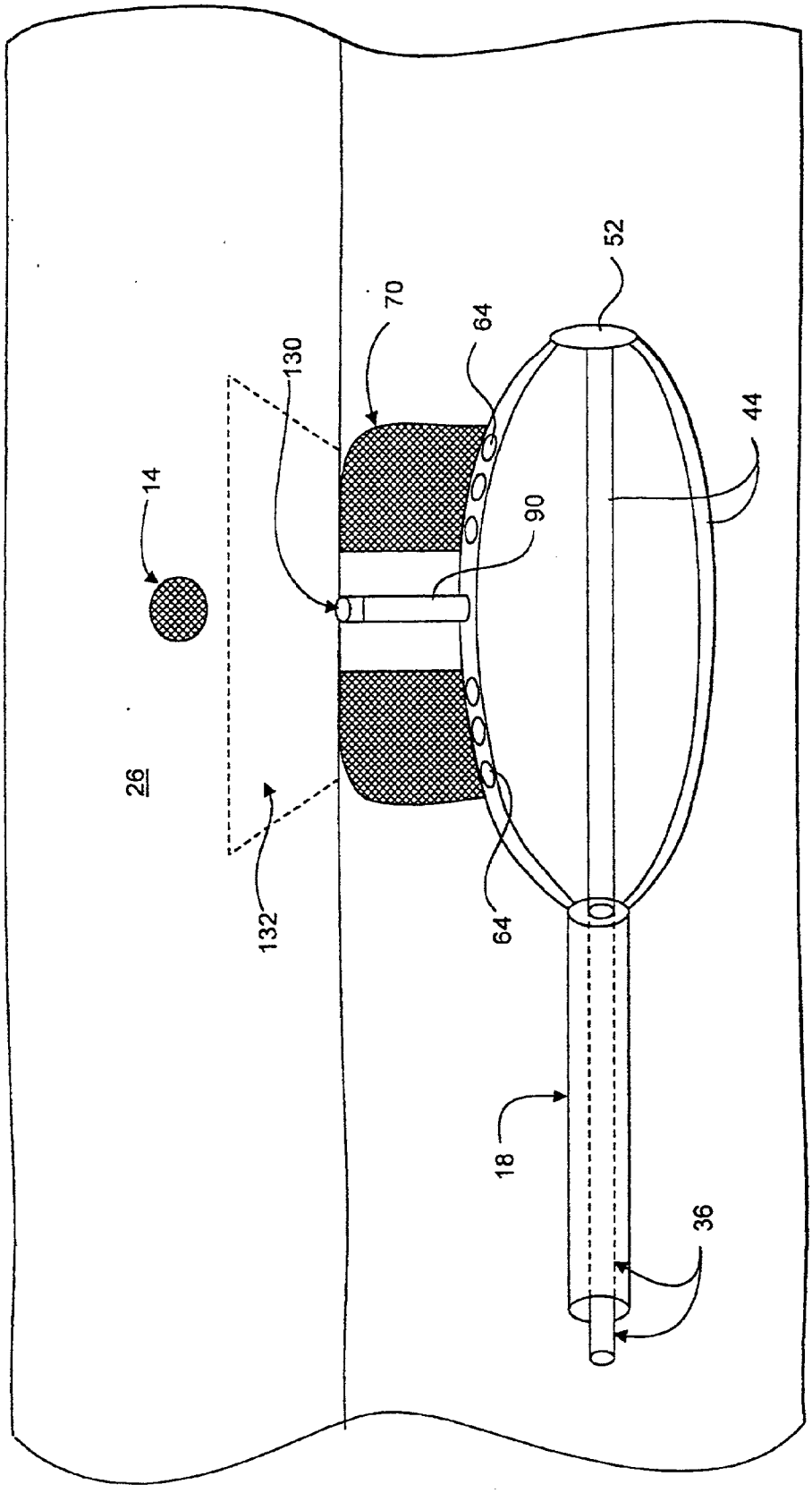


FIG. 26

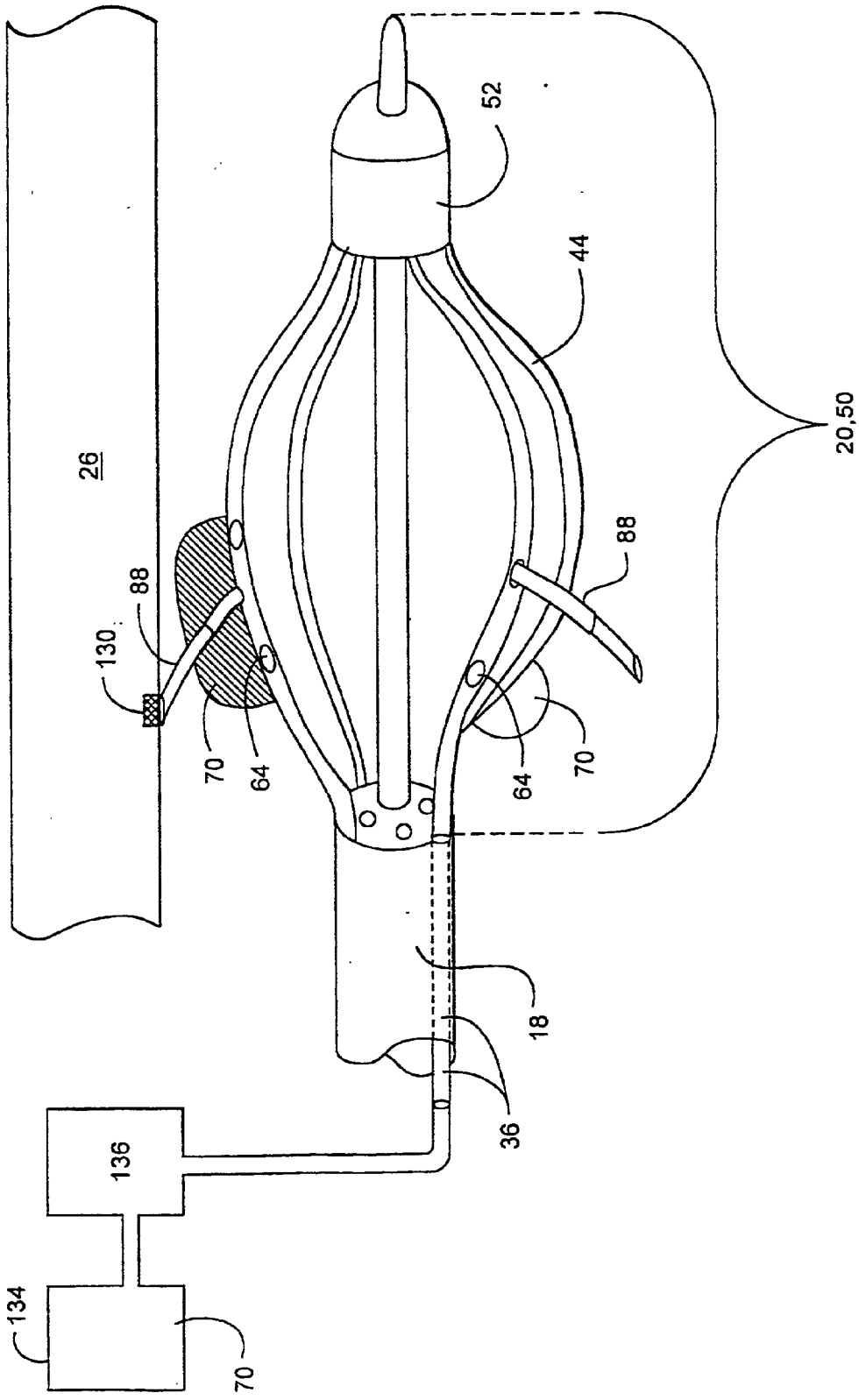


FIG. 27

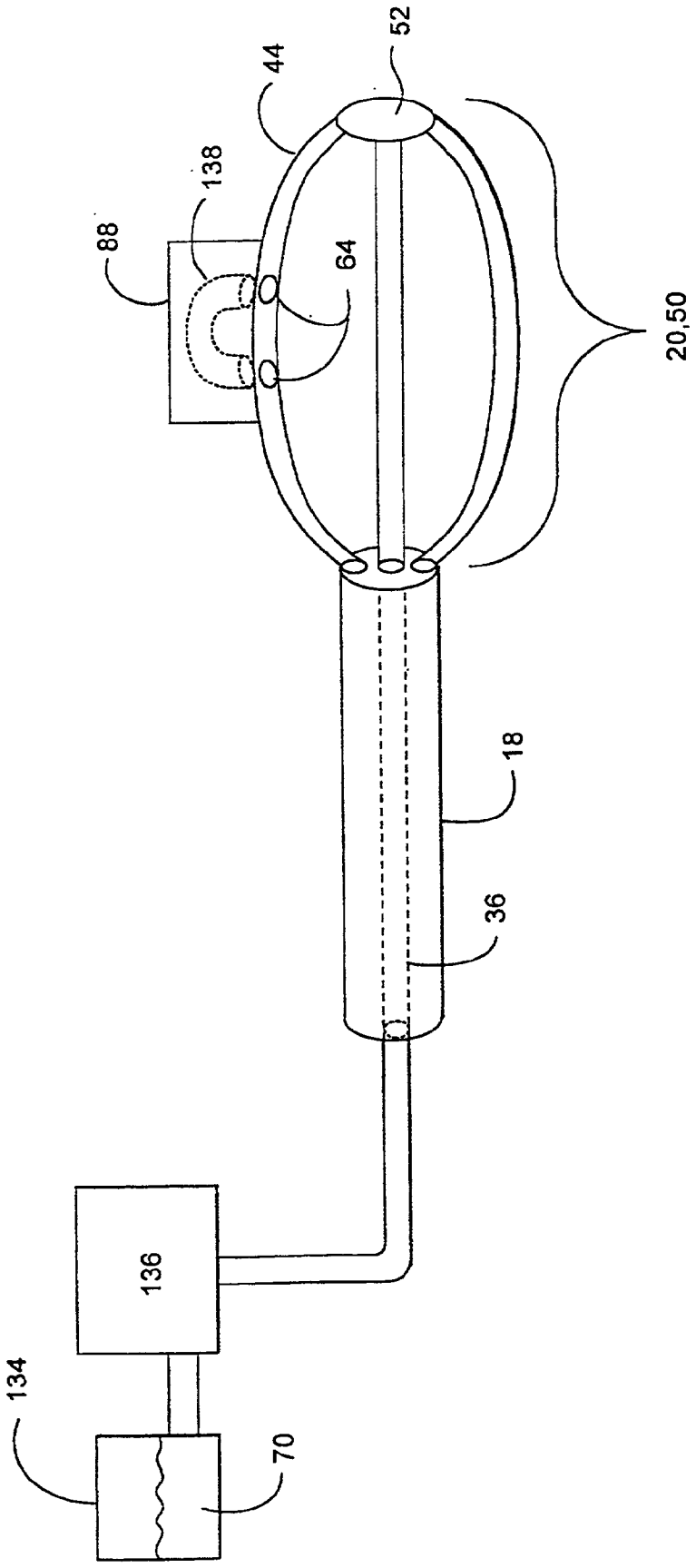


FIG. 28

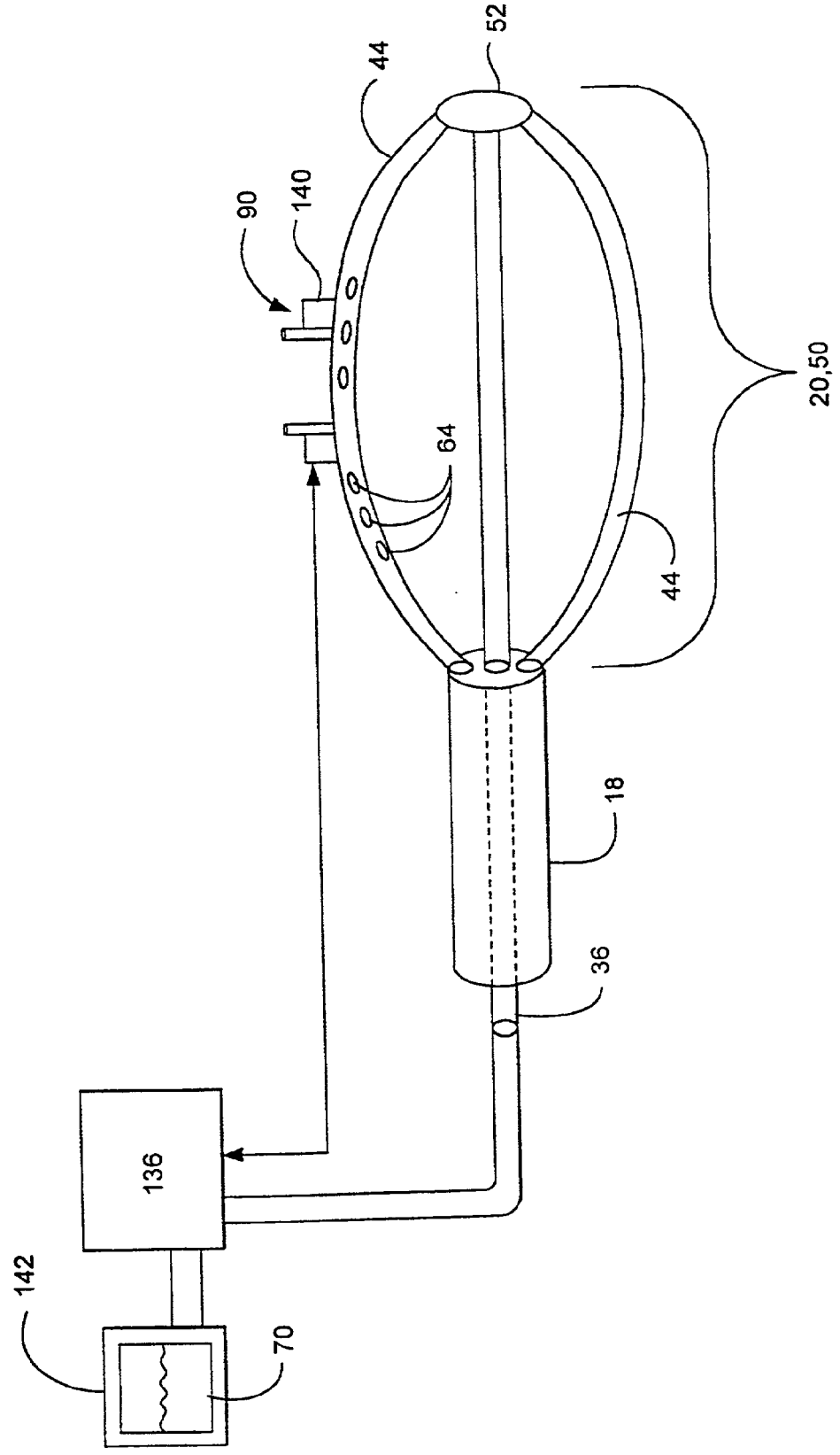


FIG. 29

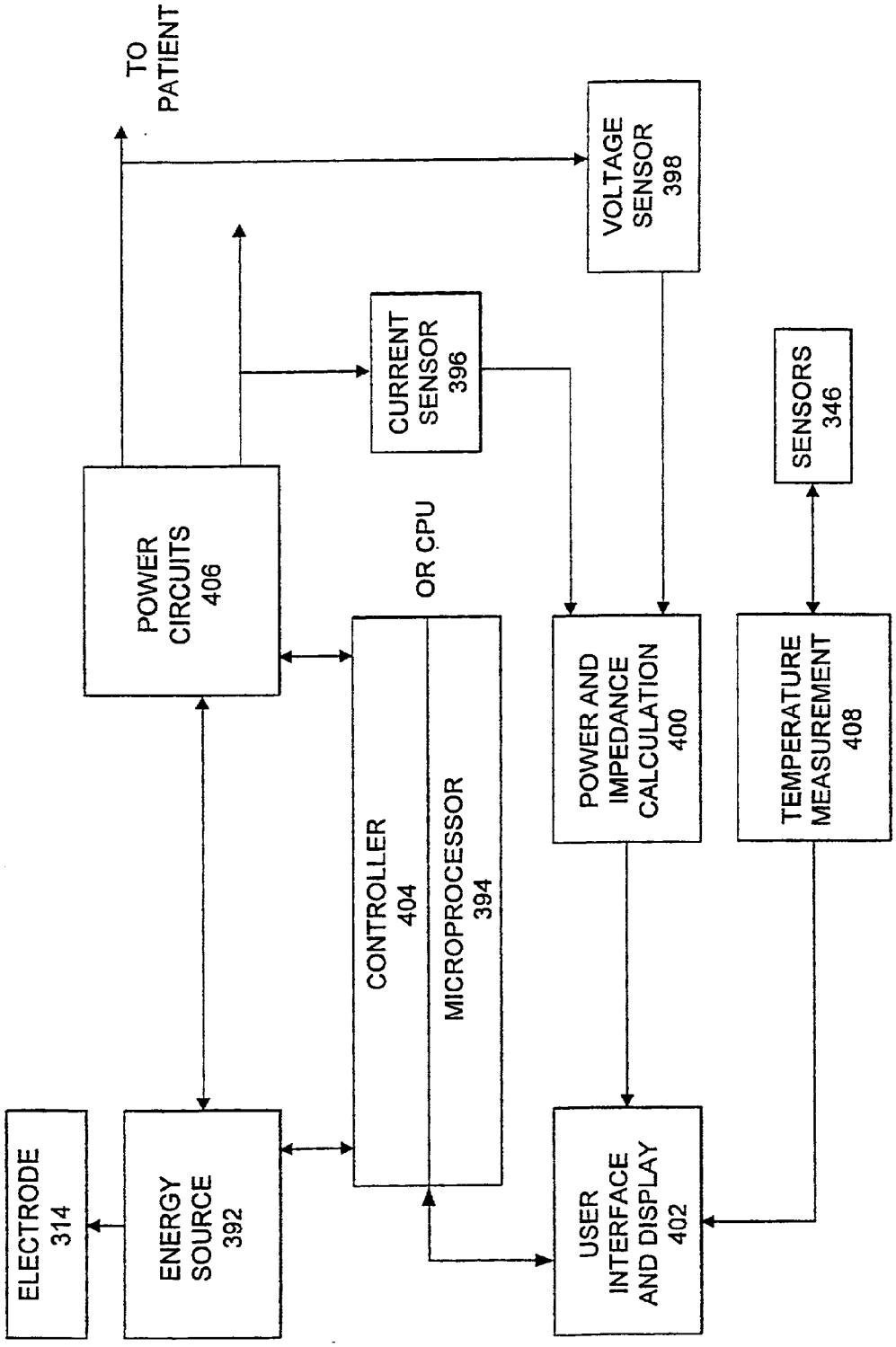

TO PATIENT
VOLTAGE SENSOR 398
CURRENT SENSOR 396
SENSORS 346
POWER CIRCUITS 406
OR CPU
CONTROLLER 404
MICROPROCESSOR 394
POWER AND IMPEDANCE CALCULATION 400
TEMPERATURE MEASUREMENT 408
ELECTRODE 314
ENERGY SOURCE 392
USER INTERFACE AND DISPLAY 402

FIG.30

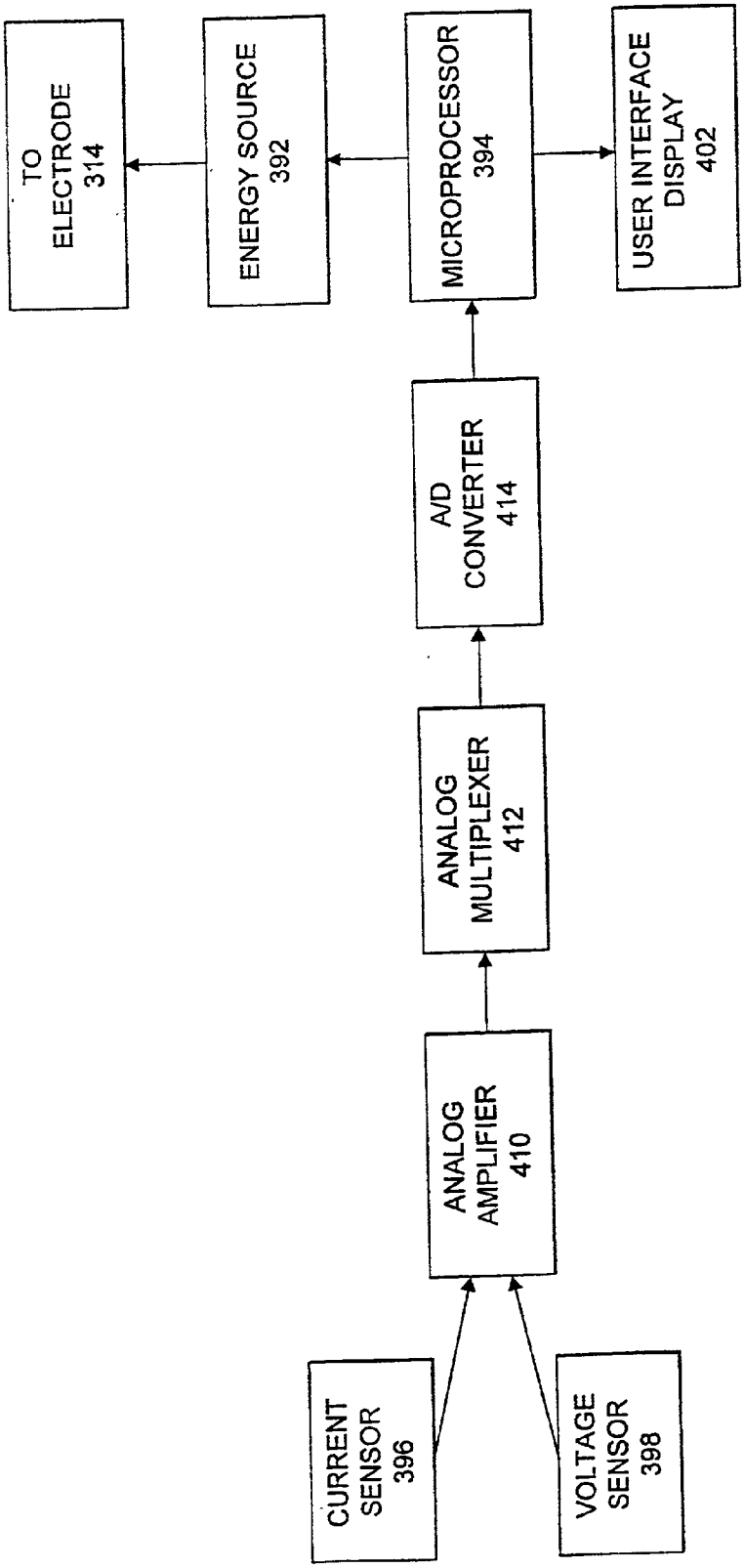

TO ELECTRODE 314
ENERGY SOURCE 392
MICROPROCESSOR 394
USER INTERFACE DISPLAY 402
A/D CONVERTER 414
ANALOG MULTIPLEXER 412
ANALOG AMPLIFIER 410
CURRENT SENSOR 396
VOLTAGE SENSOR 398

FIG. 31

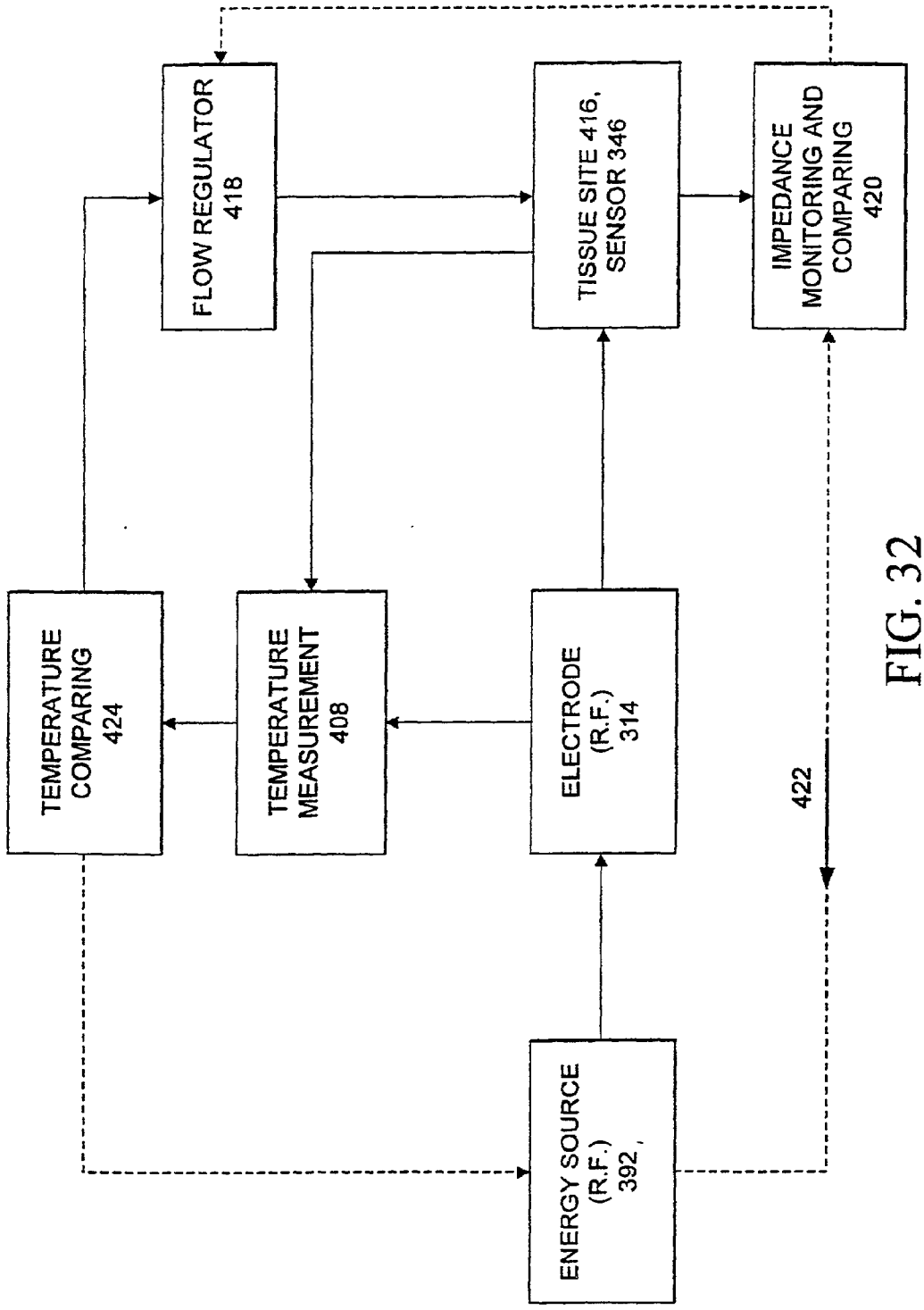

FLOW REGULATOR
418
TISSUE SITE 416,
SENSOR 346
IMPEDANCE
MONITORING AND
COMPARING
420
TEMPERATURE
COMPARING
424
TEMPERATURE
MEASUREMENT
408
ELECTRODE
(R.F.)
314
422
ENERGY SOURCE
(R.F.)
392

FIG. 32

SPHINCTER TREATMENT APPARATUS

CROSS-RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. patent application Ser. No. 09/026,316 filed Feb. 19, 1998, which is a continuation-in-part of U.S. patent application Ser. No. 08/731,372, filed Oct. 11, 1996, which is a continuation-in-part of U.S. patent application Ser. No. 08/319,373, filed Oct. 6, 1994, which is a continuation-in-part of U.S. application Ser. No. 08/286,862, filed Aug. 4, 1994, which is a continuation-in-part of U.S. patent application Ser. No. 08/272,162, filed Jul. 7, 1994, which is a continuation-in-part of U.S. patent application Ser. No. 08/265,459, filed Jun. 24, 1994, and is related to concurrently filed Application entitled "GERD Treatment Apparatus and Method" identified as Attorney Docket 14800-748, all with named inventor Stuart D. Edwards, and all of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] This invention relates generally to an apparatus for the treatment of sphincters, and more specifically to an apparatus that treats esophageal sphincters.

[0004] 2. Description of Related Art

[0005] 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 Fain Med, 5(4):221-7; (1996 April)).

[0006] 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)).

[0007] One of the possible causes of GERD may be aberrant electrical signals in the LES or cardia of the stomach. Such signals may cause a higher than normal frequency of relaxations of the LES allowing acidic stomach contents to be repeatedly ejected into the esophagus and cause the complications described above. Research has shown that unnatural electrical signals in the stomach and intestine can cause reflux events in those organs (Kelly K A, et al: *Duodenal-gastric Reflux and Slowed Gastric Emptying by Electrical Pacing of the Canine Duodenal Pacesetter Potential*. Gastroenterology. 1977 Mar; 72(3): 429-433). In particular, medical research has found that sites of aberrant electrical activity or electrical foci may be responsible for those signals (Karlstrom L H, et al.: *Ectopic Jejunal Pacemakers and Enterogastric Reflux after Roux Gastrectomy: Effect Intestinal Pacing*. Surgery. 1989 Sep; 106(3): 486-495). Similar aberrant electrical sites in the heart which cause contractions of the heart muscle to take on life threatening patterns or dysrhythmias can be identified and treated using mapping and ablation devices as described in U.S. Pat. No. 5,509,419. However, there is no current device or associated medical procedure available for the electrical mapping and treatment of aberrant electrical sites in the LES and stomach as a means for treating GERD.

[0008] 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.

[0009] 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 up 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).

[0010] 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.

[0011] 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.

[0012] 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 ajaw-like device and fastening of the invaginated gastroesophageal junction to the findus 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 sequela resulting when foreign materials such as surgical staples are implanted in the body.

[0013] 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 the LES and the risk of leaks developing at the newly created gastroesophageal junction.

[0014] 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.

[0015] 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 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 cell necrosis in a lower esophageal sphincter to reduce a frequency of reflux of stomach contents into an esophagus.

SUMMARY OF THE INVENTION

[0016] Accordingly, an object of the present invention is to provide an apparatus to treat a sphincter and reduce a frequency of sphincter relaxation.

[0017] Another object of the invention is to provide an apparatus to create controlled cell necrosis in a sphincter tissue underlying a sphincter mucosal layer.

[0018] Yet another object of the invention is to provide an apparatus to create cell necrosis in a sphincter and minimize injury to a mucosal layer of the sphincter.

[0019] 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.

[0020] 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.

[0021] Another object of the invention is to provide an apparatus to create cell necrosis in a lower esophageal sphincter to reduce a frequency of reflux of stomach contents into an esophagus.

[0022] Yet another object of the invention is to provide an apparatus to reduce the frequency and severity of gastroesophageal reflux events.

[0023] These and other objects of the invention are provided in a sphincter treatment apparatus. The apparatus includes an energy delivery device introduction member including a plurality of arms. Each arm has distal and proximal ends. The distal ends of the arms are coupled as are the proximal ends of the arms. The energy delivery device introduction member is configured to be introduced in the sphincter in a non-deployed state, expand to a deployed state to at least partially dilate the sphincter. A plurality of energy delivery devices are coupled to the energy delivery device introduction member. At least a portion of the plurality of energy delivery devices are controllably introducible from the energy delivery device introduction member into the sphincter.

[0024] In another embodiment, the sphincter treatment apparatus has an expandable basket structure. An expandable basket structure includes a first arm with a distal and a proximal section, a second arm with a distal and a proximal section, and a third arm with a distal and a proximal section. The proximal sections of the first, second and third arms are coupled to each other. The distal sections of the first, second and third arms are coupled to each other. The expanded basket structure has a non-deployed state and a deployed state where the first, second and third arms distend away from each other. A first energy delivery device is coupled to the first arm and includes a distal portion controllably advanceable from the first arm into the sphincter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] **FIG. 1** is an illustrated lateral view of the upper GI tract including the esophagus and lower esophageal sphincter and the positioning of the sphincter treatment apparatus of the present invention in the lower esophageal sphincter.

[0026] **FIG. 2A** is a lateral view of the present invention illustrating the energy delivery device, power supply and expansion device in an expanded and contracted state.

[0027] **FIG. 2B** is a lateral view of an embodiment of the invention illustrating the use of a slotted introducer to facilitate contact of the expansion device with esophageal wall.

[0028] **FIG. 3** depicts a lateral view of the present invention that illustrates components on the flexible shaft including a proximal fitting, connections and proximal and distal shaft segments.

[0029] **FIG. 4A** illustrates a lateral view of the basket assembly used in an embodiment of the invention.

[0030] **FIG. 4B** illustrates a lateral view of a basket assembly with a tapered tip.

[0031] **FIG. 5A** is a lateral view of the basket assembly that illustrates the range of camber in the basket assembly.

[0032] **FIG. 5B** is a perspective view illustrating a balloon coupled to the basket assembly.

[0033] **FIG. 6A** is a lateral view of the junction between the basket arms and the shaft illustrating the pathway used for advancement of the movable wire or the delivery of fluids.

[0034] **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.

[0035] **FIG. 7** is a cross-sectional view of a section of the basket arm illustrating stepped and tapered sections in basket arm apertures.

[0036] **FIG. 8** is a lateral view of the basket assembly illustrating the placement of the radial supporting member.

[0037] **FIG. 9A** is a lateral view of the sphincter treatment apparatus illustrating the mechanism used in one embodiment of the invention to increase the camber of the basket assembly.

[0038] **FIG. 9B** is a similar view to **9A** showing the basket assembly in an increased state of camber.

[0039] **FIG. 10** is a lateral view of the sphincter treatment apparatus illustrating the deflection mechanism.

[0040] **FIG. 11** is a lateral view illustrating the use of electrolytic solution to create an enhanced RF electrode.

[0041] **FIG. 12** is a lateral view of the basket assembly illustrating the use of needle electrodes.

[0042] **FIG. 13** is a lateral view illustrating the use of an insulation segment on the needle electrode to protect an area of tissue from RF energy.

[0043] **FIG. 14** is a lateral view illustrating the placement of needle electrodes into the sphincter wall by expansion of the basket assembly.

[0044] **FIG. 15** is a lateral view illustrating placement of needle electrodes into the sphincter wall by advancement of an electrode delivery member out of apertures in the basket arms.

[0045] **FIG. 16** is a cross sectional view illustrating the configuration of a basket arm aperture used to select and maintain a penetration angle of the needle electrode into the sphincter wall.

[0046] **FIG. 17A** is a lateral view illustrating placement of needle electrodes into the sphincter wall by advancement of an electrode delivery member directly out of the distal end of the shaft.

[0047] **FIG. 17B** is a lateral view illustrating the use of a needle hub to facilitate placement of needle electrodes into the sphincter wall.

[0048] **FIG. 18A** is a lateral view illustrating a radial distribution of electrodes on the expansion device of the invention.

[0049] **FIG. 18B** is a lateral view illustrating a longitudinal distribution of electrodes on the expansion device of the invention.

[0050] **FIG. 18C** is a lateral view illustrating a spiral distribution of electrodes on the expansion device of the invention.

[0051] **FIG. 19** is a flow chart illustrating a sphincter treatment method using the apparatus of the present invention.

[0052] **FIG. 20** is a lateral view of sphincter smooth muscle tissue illustrating electromagnetic foci and pathways for the origination and conduction of aberrant electrical signals in the smooth muscle of the lower esophageal sphincter or other tissue.

[0053] **FIG. 21** 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.

[0054] **FIG. 22** is a view similar to that of **FIG. 21** illustrating shrinkage of the lesion site caused by cell infiltration.

[0055] **FIG. 23** is a lateral view of the esophageal wall illustrating the preferred placement of lesions in the smooth muscle layer of a esophageal sphincter.

[0056] **FIG. 24** is a lateral view illustrating the ultrasound transducer, ultrasound lens and power source of an embodiment of the present invention.

[0057] FIGS. **25**A-D are lateral views of the sphincter wall illustrating various patterns of lesions created by the apparatus of the present invention.

[0058] **FIG. 26** is a lateral view of the sphincter wall illustrating the delivery of cooling fluid to the electrode-tissue interface and the creation of cooling zones.

[0059] **FIG. 27** depicts the flow path, fluid connections and control unit employed to deliver fluid to the electrode-tissue interface.

[0060] **FIG. 28** depicts the flow path, fluid connections and control unit employed to deliver fluid to the RF electrodes.

[0061] **FIG. 29** is an enlarged lateral view illustrating the placement of sensors on the expansion device or basket assembly.

[0062] **FIG. 30** depicts a block diagram of the feed back control system that can be used with the sphincter treatment apparatus.

[0063] **FIG. 31** depicts a block diagram of an analog amplifier, analog multiplexer and microprocessor used with the feedback control system of **FIG. 30**.

[0064] **FIG. 32** depicts a block diagram of the operations performed in the feedback control system depicted in **FIG. 30**.

DETAILED DESCRIPTION

[0065] Referring now to **FIGS. 1 and 2**, one embodiment of sphincter treatment apparatus **10** that is used to deliver energy to a treatment site **12** to produce lesions **14** in a sphincter **16**, such as the lower esophageal sphincter (LES), comprises a flexible elongate shaft **18**, also called shaft **18**, coupled to a expansion device **20**, in turn coupled with one or more energy delivery devices **22**. Energy delivery devices **22** are configured to be coupled to a power source **24**. The 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. Expansion device **20** is further configured to facilitate the positioning of energy delivery devices **22** to a selectable depth in a sphincter wall **26** or adjoining anatomical structure. Expansion device **20** has a central longitudinal axis **28** and is moveable between contracted and expanded positions substantially there along.

This can be accomplished by a ratchet mechanism as is known to those skilled in the art. At least portions of sphincter treatment apparatus **10** may be sufficiently radiopaque in order to be visible under fluoroscopy and/or sufficiently echogenic to be visible under ultrasonography. Also as will be discussed herein, sphincter treatment apparatus **10** can include visualization capability including, but not limited to, a viewing scope, an expanded eyepiece, fiber optics, video imaging and the like.

[**0066**] Referring to **FIG. 2**A, shaft **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 shaft **18** include, but are not limited to, a range of 40-180 cms. In various embodiments, shaft **18** is flexible, articulated and steerable and can contain fiber optics (including illumination and imaging fibers), fluid and gas paths, and sensor and electronic cabling. In one embodiment, shaft **18** can be a multi-lumen catheter, as is well known to those skilled in the art.

[**0067**] In another embodiment, an introducing member **21**, also called an introducer, is used to introduce sphincter treatment apparatus **10** into the LES. Introducer **21** can also function as a sheath for expansion device **20** to keep it in a nondeployed or contracted state during introduction into the LES. In various embodiments, introducer **21** is flexible, articulated and steerable and contains a continuous lumen of sufficient diameter to allow the advancement of sphincter treatment apparatus **10**. Typical diameters for introducer **21** include 0.1 to 2 inches, while typical length include 40-180 cms. Introducer **21** may be of sufficient length and width to extend into a portion of or past the LES and provide structural support to and/or immobilize the esophagus. This serves to reduce movement of the esophagus and/or expansion device **20** so as to facilitate introduction of a needle electrode (described herein) into sphincter wall **26**. As shown in **FIG. 2**B, introducer **21** may also contain slots **25** near introducer distal end **21'** or at other points along its length. Slots **25** are of sufficient length and width to allow expansion device **20** to engage sphincter wall **26** when it is put into a deployed state inside introducer **21**. Suitable materials for introducer **21** include coil-reinforced plastic tubing as is well known to those skilled in the art.

[**0068**] Referring now to **FIG. 3**, the flexible elongate shaft **18** is circular in cross section and has proximal and distal extremities (also called ends) **30** and **32**. Shaft **18** may also be coupled at its proximal end **32** to a proximal fitting **34**, also called a handle, used by the physician to manipulate sphincter treatment apparatus **10** to reach treatment site **12**. Shaft **18** may have one or more lumens **36**, that extend the full length of shaft **18**, or part way from shaft proximal end **30** to shaft distal end **32**. Lumens **36** may be used as paths for catheters, guide wires, pull wires, insulated wires and cabling, fluid and optical fibers. Lumens **36** are connected to and/or accessed by connections **38** on or adjacent to proximal fitting **34**. Connections **38** can include luer-lock, lemo connector, swage and other mechanical varieties well known to those skilled in the art. Connections **38** can also include optical/video connections which allow optical and electronic coupling of optical fibers and/or viewing scopes to illuminating sources, eye pieces and video monitors. In various embodiments, shaft **18** may stop at the proximal extremity **40** of expansion device **20** or extend to, or past, the distal extremity **42** of expansion device **20**. Suitable materials for shaft **18** include, but are not limited to, polyethylenes, polyurethanes and other medical plastics known to those skilled in the art.

[**0069**] Referring now to **FIG. 4**A, in one embodiment of the present invention expansion device **20** comprises one or more elongated arms **44** that are joined at their proximal ends **46** and distal ends **48** to form a basket assembly **50**. Proximal arm end **46** is attached to a supporting structure, which can be the distal end **32** of shaft **18** or a proximal cap **51**. Likewise, distal arm end **48** is also attached to a supporting structure which can be a basket cap **52** or shaft **18**. In one embodiment shown in **FIG. 4**B, basket cap **52** can be a tapered cap **52'** to facilitate insertion through the folds of the LES.

[**0070**] Attached arms **44** may form a variety of geometric shapes including, but not limited to, curved, rectangular, trapezoidal and triangular. Arms **44** can have a variety of cross sectional geometries including, but not limited to, circular, rectangular and crescent-shaped. Also, arms **44** are of a sufficient number (two or more), and have sufficient spring force (0.01 to 0.5 lbs. force) so as to collectively exert adequate force on sphincter wall **26** to sufficiently open and efface the folds of sphincter **16** to allow treatment with sphincter treatment apparatus **10**, while preventing herniation of sphincter wall **26** into the spaces **53** between arms **44**. Suitable materials for arms **44** include, but are not limited to, spring steel, stainless steel, superelastic shape memory metals such as nitinol or wire reinforced plastic tubing as is well known to those skilled in the art. In another embodiment, arms **44** may have an external layer of texturized material **45** that has sufficient friction to immobilize the area near and around sphincter wall **26** contacted by arm **44**. Suitable materials for texturized material **45** include knitted Dacron® and Dacron velour.

[**0071**] Referring to **FIG. 5**A, arms **44** can have an outwardly bowed shaped memory for expanding the basket assembly into engagement with sphincter wall **26** with the amount of bowing, or camber **54** being selectable from a range 0 to 2 inches from longitudinal axis **28** of basket assembly **50**. For the case of a curve-shaped arm **44'**, expanded arms **44** are circumferentially and symmetrically spaced-apart. In various other embodiments (not shown), arms **44** may be asymmetrically spaced and/or distributed on an arc less than 360°. Also, arms **44** may be preshaped at time of manufacture or shaped by the physician.

[**0072**] In another embodiment shown in **FIG. 5**B, an expandable member **55**, which can be a balloon, is coupled to an interior or exterior of basket assembly **50**. Balloon **55** is also coupled to and inflated by lumen **36** using gas or liquid. Balloon **55** may be made of a textured material, or have a texturized layer **55'** that when engaged with sphincter wall **26**, provides sufficient friction to at least partially immobilize the surface of sphincter wall **26**. Suitable materials for texturized layer **55'** include knitted Dacron and Dacron velour.

[**0073**] Referring now to **FIG. 6**A, arms **44** may also be solid or hollow with a continuous lumen **58** that may be coupled with shaft lumens **36**. These coupled lumens provide a path for the delivery of a fluid or electrode delivery member **60** (also called an advancement member) from shaft **18** to any point on basket assembly **50**. In various embodi-

ments electrode delivery member **60** 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, all of which are known to those skilled in the art. As shown in **FIG. 6**B, arms **44** may also have a partially open channel **62**, also called a track **62**, that functions as a guide track for electrode delivery member **60**. Referring back to **FIG. 6**A, arms **44** may have one or more apertures **64** at any point along their length that permit the controlled placement of energy delivery devices **22** at or into sphincter wall **26**. Referring now to **FIG. 7**, apertures **64** may have tapered sections **66** or stepped sections **68** in all or part of their length, that are used to control the penetration depth of energy delivery devices **22** into sphincter wall **26**. Referring back to **FIG. 6**A, apertures **64** in combination with arm lumens **58** and shaft lumens **36** may be used for the delivery of cooling solution **70** or electrolytic solution **72** to treatment site **12** as described herein. Additionally, arms **44** can also carry a plurality of longitudinally spaced apart radiopaque and or echogenic markers or traces, not shown in the drawings, formed of suitable materials to permit viewing of basket assembly **50** via fluoroscopy or ultrasonography. Suitable radiopaque materials include platinum or gold, while suitable echogenic materials include gas filled microparticles as described in U.S. Pat. Nos. 5,688,490 and 5,205,287. Arms **44** 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.

[**0074**] In another embodiment of the present invention, a supporting member **74** is attached to two or more arms **44**. Supporting member **74**, also called a strut, can be attached to arms **44** along a circumference of basket assembly **50** as shown in **FIG. 8**. Apertures **64** can extend through radial supporting member **74** in one or more places. Radial supporting member **74** serves the following functions: i) facilitates opening and effacement of the folds of sphincter **16**, ii) enhances contact of Apertures **64** with sphincter wall **26**; and, iii) reduces or prevents the tendency of arms **44** to bunch up. The cross sectional geometry of radial supporting member **74** can be rectangular or circular, though it will be appreciated that other geometries are equally suitable.

[**0075**] In one embodiment shown in **FIG. 9**, arms **44** are attached to basket cap **52** that in turn, moves freely over shaft **18**, but is stopped distally by shaft cap **78**. One or more pull wires **80** are attached to basket cap **52** and also to a movable fitting **82** in proximal fitting **34** of sphincter treatment apparatus **10**. When pull wire **80** is pulled back by movable fitting **82**, the camber **54** of basket assembly **50** increases to **54'**, increasing the force and the amount of contact applied by basket assembly **50** to sphincter wall **26** or an adjoining structure. Basket assembly **50** can also be deflected from side to side using deflection mechanism **80**. This allows the physician to remotely point and steer the basket assembly within the body. In one embodiment shown in **FIG. 10**, deflection mechanism **84** includes a second pull wire **80'** attached to shaft cap **78** and also to a movable slide **86** integral to proximal fitting **34**.

[**0076**] Turning now to a discussion of energy delivery, suitable power sources **24** and energy delivery devices **22** that can be employed in one or more embodiments of the invention include: (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, (v) 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, (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, or (xii) a microwave source. 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 **88**, also described as electrodes **88**. However, all of the other herein mentioned power sources and energy delivery devices are equally applicable to sphincter treatment apparatus **10**.

[**0077**] For the case of RF energy, RF electrode **88** may operated in either bipolar or monopolar mode with a ground pad electrode. In a monopolar mode of delivering RF energy, a single electrode **88** 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 **88** are used. Multiple electrodes **88** may be used. These electrodes may be cooled as described herein. Electrodes **88** can be attached to electrode delivery member **60** by the use of soldering methods which are well known to those skilled in the art. Suitable solders include Megabond Solder supplied by the Megatrode Corporation (Milwaukee, Wis.).

[**0078**] Suitable electrolytic solutions **72** include saline, solutions of calcium salts, potassium salts, and the like. Electrolytic solutions **72** enhance the electrical conductivity of the targeted tissue at the treatment site **12**. When a highly conductive fluid such as electrolytic solution **72** is infused into tissue the electrical resistance of the infused tissue is reduced, in turn, increasing the electrical conductivity of the infused tissue. As a result, there will be little tendency for tissue surrounding electrode **88** to desiccate (a condition described herein that increases the electrical resistance of tissue) resulting in a large increase in the capacity of the tissue to carry RF energy. Referring to **FIG. 11, a** zone of tissue which has been heavily infused with a concentrated electrolytic solution **72** can become so conductive as to actually act as an enhanced electrode **88'**. The effect of enhanced electrode **88'** is to increase the amount of current that can be conducted to the treatment site **12**, making it possible to heat a much greater volume of tissue in a given time period.

[**0079**] Also when the power source is RF, power source **24**, which will now be referred to as RF power source **24**, may have multiple channels, delivering separately modulated power to each electrode **88**. This reduces preferential heating that occurs when more energy is delivered to a zone of greater conductivity and less heating occurs around electrodes **88** which are placed into less conductive tissue. If the level of tissue hydration or the blood infusion rate in the tissue is uniform, a single channel RF power source **24** may be used to provide power for generation of lesions **14** relatively uniform in size.

[0080] Electrodes **88** can have a variety of shapes and sizes. Possible shapes include, but are not limited to, circular, rectangular, conical and pyramidal. Electrode surfaces can be smooth or textured and concave or convex. The conductive surface area of electrode **88** can range from 0.1 mm^2 to 100 cm^2. It will be appreciated that other geometries and surface areas may be equally suitable. In one embodiment, electrodes **88** can be in the shape of needles and of sufficient sharpness and length to penetrate into the smooth muscle of the esophageal wall, sphincter **16** or other anatomical structure. In this embodiment shown in **FIGS. 12 and 13**, needle electrodes **90** are attached to arms **44** and have an insulating layer **92**, covering an insulated segment **94** except for an exposed segment **95**. For purposes of this disclosure, an insulator or insulation layer is a barrier to either thermal, RF or electrical energy flow. Insulated segment **94** is of sufficient length to extend into sphincter wall **26** and minimize the transmission of RF energy to a protected site **97** near or adjacent to insulated segment **94** (see **FIG. 13**). Typical lengths for insulated segment **94** include, but are not limited to, 1-4 mms. Suitable materials for needle electrodes **90** include, but are not limited to, **304** stainless steel and other stainless steels known to those skilled in the art. Suitable materials for insulating layer **92** include, but are not limited to, polyimides and polyamides.

[0081] During introduction of sphincter treatment apparatus **10**, basket assembly **50** is in a contracted state. Once sphincter treatment apparatus **10** is properly positioned at the treatment site **12**, needle electrodes **90** are deployed by expansion of basket assembly **50**, resulting in the protrusion of needle electrodes **90** into the smooth muscle tissue of sphincter wall **26** (refer to **FIG. 14**). The depth of needle penetration is selectable from a range of 0.5 to 5 mms and is accomplished by indexing movable fitting **82** so as to change the camber **54** of arm **44** in fixed increments that can be selectable in a range from 0.1 to 4 mms. Needle electrodes **90** are coupled to power source **24** via insulated wire **60**.

[0082] In another embodiment of sphincter treatment apparatus **10** shown in **FIG. 15**, needle electrodes **90** are advanced out of apertures **64** in basket arms **44** into the smooth muscle of the esophageal wall or other sphincter **16**. In this case, needle electrodes **90** are coupled to RF power source **24** by electrode delivery member **60**. In this embodiment, the depth of needle penetration is selectable via means of stepped sections **66** or tapered sections **68** located in apertures **64**. Referring to **FIG. 16**, apertures **64** and needle electrodes **90** are configured such that the penetration angle **96** (also called an emergence angle **96**) of needle electrode **90** into sphincter wall **26** remains sufficiently constant during the time needle electrode **90** is being inserted into sphincter wall **26**, such that there is no tearing or unnecessary trauma to sphincter wall tissue. This is facilitated by the selection of the following parameters and criteria: i) the emergence angle **96** of apertures **64** which can vary from 1 to 90°, ii) the arc radius **98** of the curved section **100** of aperture **64** which can vary from 0.001 to 2 inch, iii) the amount of clearance between the aperture inner diameter **102** and the needle electrode outside diameter **104** which can very between 0.001" and 0.1"; and, iv) use of a lubricous coating on electrode delivery member **60** such as a Teflon® or other coatings well known to those skilled in the art. Also in this embodiment, insulated segment **94** can be in the form of an sleeve that may be adjustably positioned at the exterior of electrode **90**.

[0083] In another alternative embodiment shown in **FIG. 17A** , electrode delivery member **60** with attached needle electrodes **90**, can exit from lumen **36** at distal shaft end **32** and be positioned into contact with sphincter wall **26**. This process may be facilitated by use of a hollow guiding member **101**, known to those skilled in the art as a guiding catheter, through which electrode delivery member **60** is advanced. Guiding catheter **101** may also include stepped sections **66** or tapered sections **68** at it distal end to control the depth of penetration of needle electrode **90** into sphincter wall **26**.

[0084] In an alternative embodiment shown in **FIG. 17B**, needle electrodes **90** can be advanced through an aperture **64'** in needle hub **103** (located inside basket assembly **50**) and subsequently advanced through aperture **64** in arm **44** and into sphincter wall **26**. Aperture **64'** has proximal and distal ends **64"** and **64'"**. Also needle hub **103** is configured to be coupled to delivery member **60** or basket assembly **50** and serves as a guiding tool to facilitate penetration of needle electrode **90** into sphincter wall **26**. In one embodiment, proximal and distal ends **64"** and **64'"** of apertures **64'** are located in different planes.

[0085] RF energy flowing through tissue causes heating of the tissue due to absorption of the RF energy by the tissue and ohmic heating due to electrical resistance of the tissue. This heating can cause injury to the affected cells and can be substantial enough to cause cell death, a phenomenon also known as cell necrosis. For ease of discussion for the remainder of this application, cell injury will include all cellular effects resulting from the delivery of energy from electrode **88** up to, and including, cell necrosis. Cell injury can be accomplished as a relatively simple medical procedure with local anesthesia. In one embodiment, cell injury proceeds to a depth of approximately 1-4 mms from the surface of the mucosal layer of sphincter **16** or that of an adjoining anatomical structure.

[0086] Referring now to **FIGS. 18A, 18B** and 18C, electrodes **88** and/or apertures **64** may be distributed in a variety of patterns along expansion device **20** or basket assembly **50** in order to produce a desired placement and pattern of lesions **14**. Typical electrode and aperture distribution patterns include, but are not limited to, a radial distribution **105** (refer to **FIG. 18A**) or a longitudinal distribution **106** (refer to **FIG. 18B**). It will be appreciated that other patterns and geometries for electrode and aperture placement, such as a spiral distribution **108** (refer to **FIG. 18C**) may also be suitable. These electrodes may be cooled as described hereafter.

[0087] **FIG. 19** is a flow chart illustrating one embodiment of the procedure for using sphincter treatment apparatus **10**. In this embodiment, sphincter treatment apparatus **10** is first introduced into the esophagus under local anesthesia. 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 similar esophageal access device known to those skilled in the art. Basket assembly **50** is expanded and can be done through slots **25** in introducer **21** as described herein. This serves to

temporarily dilate the LES or sufficiently to efface a portion of or all 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 shaft lumen **36**, or an endoscope or similar esophageal access device as described above. Once treatment is completed, basket assembly **50** 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.

[**0088**] The diagnostic phase of the procedure can be performed using a variety of diagnostic methods, including, but not limited to, 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 wall using ultrasonography to establish a baseline for the tissue to be treated, (iii) impedance measurement to determine the electrical conductivity between the esophageal mucosal layers and sphincter treatment apparatus **10** and (iv) measurement and surface mapping of the electropotential of the LES during varying time periods which may include such events as depolarization, contraction and repolarization of LES 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 foci **107** or pathways **109** for abnormal or inappropriate polarization and relaxation of the smooth muscle of the LES (Refer to **FIG. 20**).

[**0089**] In the treatment 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 **88** 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) sphincter contractile force measurement via manometry. The feedback mechanism permits the selected on-off switching of different electrodes **88** in a desired pattern, which can be sequential from one electrode **88** to an adjacent electrode **88**, or can jump around between non-adjacent electrodes **88**. Individual electrodes **88** are multiplexed and volumetrically controlled by a controller.

[**0090**] 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 55-95° C. and produce lesions **14** at depths ranging from 1-4 mms from the interior surface of the LES or sphincter wall **26**. Typical energies delivered to the esophageal wall include, but are not limited to, a range between 100 and 50,000 joules per electrode **88**. It is also desirable to deliver sufficient energy such that the 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. 21**). As shown in **FIG. 22**, 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 LES or sphincter **16**. These changes are reflected in transformed lesion **14'** shown in **FIG. 19B**. The diameter of lesions **14** can vary between 0.1 to 4 mms. It is preferable that lesions **14** are less than 4 mms in diameter in order to reduce the risk of thermal damage to the mucosal layer. In one embodiment, a 2 mm diameter lesion **14** centered in the wall of the smooth muscle provides a 1 mm buffer zone to prevent damage to the mucosa, submucosa and adventitia, 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. 23**).

[**0091**] From a diagnostic standpoint, it is desirable to image the interior surface and wall of the LES or other sphincter **16**, including the size and position of created lesions **14**. It is desirable to create a map of these structures which can input to a controller and used to direct the delivery of energy to the treatment site. Referring to **FIG. 24**, this can be accomplished through the use of ultrasonography (a known procedure) which involves the use of an ultrasound power source **116** coupled to one or more ultrasound transducers **118** that are positioned on expansion device **20** or basket assembly **50**. An output is associated with ultrasound power source **116**.

[**0092**] Each ultrasound transducer **118** can include a piezoelectric crystal **120** mounted on a backing material **122** that is in turn, attached to expansion device **20** or basket assembly **50**. An ultrasound lens **124**, fabricated on an electrically insulating material **126**, is mounted over piezoelectric crystal **120**. Piezoelectric crystal **120** is connected by electrical leads **128** to ultrasound power source **116** Each ultrasound transducer **118** transmits ultrasound energy into adjacent tissue. Ultrasound transducers **118** can be in the form of an imaging probe such as Model 21362, manufactured and sold by Hewlett Packard Company, Palo Alto, Calif. In one embodiment, two ultrasound transducers **118** are positioned on opposite sides of expansion device **20** or basket assembly **50** to create an image depicting the size and position of lesion **14** in selected sphincter **16**.

[**0093**] 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 mms from the interior surface of sphincter wall **26**. However, lesions **14** can vary both in number and position within sphincter wall **26**. 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. **25**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 sphincter **16** is controlled and selectable. The selective application of energy to

sphincter **16** may be the even penetration 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.

[**0094**] Referring to **FIG. 26**, it may be desirable to cool all or a portion of the area near the electrode-tissue interface **130** before, during or after the delivery of energy in order to reduce the degree and area of cell injury. Specifically, the use of cooling preserves the mucosal layers of sphincter wall **26** and protects, or otherwise reduces the degree of cell damage to cooled zone **132** in the vicinity of lesion **14**. Referring now to **FIG. 27**, this can be accomplished through the use of cooling solution **70** that is delivered by apertures **64** which is in fluid communication with shaft lumen **36** that is, in turn, in fluid communication with fluid reservoir **134** and a control unit **136**, whose operation is described herein, that controls the delivery of the fluid.

[**0095**] Similarly, it may also be desirable to cool all or a portion of the electrode **88**. The rapid delivery of heat through electrode **88**, may result in the build up of charred biological matter on electrode **88** (from contact with tissue and fluids e.g., blood) that impedes the flow of both thermal and electrical energy from electrode **88** to adjacent tissue and causes an electrical impedance rise beyond a cutoff value set on RF power source **24**. A similar situation may result from the desiccation of tissue adjacent to electrode **88**. Cooling of the electrode **88** can be accomplished by cooling solution **70** that is delivered by apertures **64** as described previously. Referring now to **FIG. 28**, electrode **88** may also be cooled via a fluid channel **138** in electrode **88** that is in fluid communication with fluid reservoir **134** and control unit **136** .

[**0096**] As shown in **FIG. 29**, one or more sensors **140** may be positioned adjacent to or on electrode **88** for sensing the temperature of sphincter tissue at treatment site **12**. More specifically, sensors **140** permit accurate determination of the surface temperature of sphincter wall **26** at electrode-tissue interface **130**. This information can be used to regulate both the delivery of energy and cooling solution **70** to the interior surface of sphincter wall **26**. In various embodiments, sensors **140** can be positioned at any position on expansion device **20** or basket assembly **50**. Suitable sensors that may be used for sensor **140** include: thermocouples, fiber optics, resistive wires, thermocouple IR detectors, and the like. Suitable thermocouples for sensor **140** include: T type with copper constantene, J type, E type and K types as are well known those skilled in the art.

[**0097**] Temperature data from sensors **140** are fed back to control unit **136** and through an algorithm which is stored within a microprocessor memory of control unit **136**. Instructions are sent to an electronically controlled micro-pump (not shown) to deliver fluid through the fluid lines at the appropriate flow rate and duration to provide control temperature at the electrode-tissue interface **130** (refer to **FIG. 27**).

[**0098**] The reservoir of control unit **136** may have the ability to control the temperature of the cooling solution **70** by either cooling the fluid or heating the fluid. Alternatively, a fluid reservoir **134** of sufficient size may be used in which the cooling solution **70** is introduced at a temperature at or near that of the normal body temperature. Using a thermally insulated reservoir **142**, adequate control of the tissue temperature may be accomplished without need of refrigeration or heating of the cooling solution **70**. Cooling solution **70** flow is controlled by control unit **136** or another feedback control system (described herein) to provide temperature control at the electrode-tissue interface **130**.

[**0099**] 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.

[**0100**] In one embodiment, sphincter treatment apparatus **10** is coupled to an open or closed loop feedback system. Referring now to **FIG. 30**, an open or closed loop feedback system couples sensor **346** to energy source **392**. In this embodiment, electrode **314** is one or more RF electrodes **314**.

[**0101**] 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. 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 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.

[**0102**] With the use of sensor **346** and the feedback control system a 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 as is discussed herein. 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.

[**0103**] 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**.

[**0104**] 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 in an appropriate amount in order to maintain the desired power delivered at respective RF electrodes **314**.

[**0105**] 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 energy when maximum pre-set temperatures are exceeded. The actual temperatures are

measured at temperature measurement device **408**, 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 in 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.

[**0106**] 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.

[**0107**] 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.

[**0108**] 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.

[**0109**] 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**.

[**0110**] Referring now to **FIG. 31**, 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 AID converter **414** to microprocessor **394**. Microprocessor **394** may be a type 68HCII 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.

[**0111**] 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.

[**0112**] 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, modified or interrupted. A control signal from microprocessor **394** can modify the power level supplied by energy source **392**.

[**0113**] **FIG. 32** 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 cooling solution **70** 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 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**. If measured impedance is within acceptable limits, energy continues to be applied to the tissue.

[**0114**] The control of cooling solution **70** 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 preset signal representative of the desired temperature. 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. 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.

[**0115**] 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.

What is claimed is:

1. A sphincter treatment apparatus, comprising:

an energy delivery device introduction member;

a first energy delivery device coupled to the energy delivery device introduction member, the first energy delivery device having a distal portion, wherein the energy delivery device introduction member is configured to be introduced in the sphincter in a non-deployed state, and expand to a deployed state to at least partially expand the sphincter; and

a retainer member coupled to the energy delivery device introduction member and configured to controllably position the energy delivery device introduction member in an orifice of a sphincter.

2. The apparatus of claim 1, wherein the retainer member retains the energy delivery device introduction member along a longitudinal axis of the sphincter.

3. The apparatus of claim 1, wherein the retainer member reduces a movement of the energy delivery device introduction member in the orifice along a longitudinal axis of the sphincter.

4. The apparatus of claim 1, wherein the retainer member reduces a lateral movement of the energy delivery device introduction member in the orifice along a longitudinal axis of the sphincter.

5. The apparatus of claim 1, wherein the first energy delivery device distal portion is introducible into an interior of the sphincter.

6. The apparatus of claim 5, wherein the first energy delivery device is an electrode.

7. The apparatus of claim 6, wherein the electrode has a tissue piercing distal end.

8. The apparatus of claim 1, wherein the energy delivery device introduction member is expandable.

9. The apparatus of claim 8, wherein the energy delivery device introduction member is a balloon.

10. The apparatus of claim 8, wherein the energy delivery device introduction member is a basket device.

11. The apparatus of claim 1, wherein the retainer member is made of a polymeric material.

12. The apparatus of claim 11, wherein the retainer member is a catheter

13. The apparatus of claim 11, wherein the retainer member is an endoscope

14. The apparatus of claim 1, wherein the retainer member reduces a movement of an esophagus.

15. The apparatus of claim 1, wherein the retainer member has sufficient rigidity to reduce a movement of the sphincter.

16. The apparatus of claim 15, wherein the retainer member has sufficient rigidity to reduce a movement of an esophagus.

17. The apparatus of claim 1, wherein the first energy delivery device is an RF needle electrode.

18. The apparatus of claim 17, wherein the retainer member has sufficient rigidity to reduce a movement of the sphincter and reduce an amount of tearing of a sphincter mucosa upon an introduction of the RF needle electrode into the sphincter.

19. The apparatus of claim 17, wherein the retainer member has sufficient rigidity to reduce movement of the sphincter and permit maintenance of a constant angle of penetration of the RF needle electrode through a sphincter surface.

20. The apparatus of claim 17, wherein the retainer member has sufficient rigidity to reduce movement of the sphincter and facilitate introduction of the RF needle electrode into the sphincter.

21. The apparatus of claim 1, wherein the retainer member at least partially surrounds the energy delivery device introduction member to reduce a movement of the energy delivery device introduction member within the sphincter.

22. The apparatus of claim 1, wherein the retainer member at least partially surrounds the energy delivery device introduction member and includes a slot to enhance an engagement of the energy delivery device introduction member with the sphincter.

23. The apparatus of claim 17, wherein the retainer member at least partially surrounds the energy delivery device introduction member and includes a slot to enhance an engagement of the energy delivery device introduction member with the sphincter and facilitate introduction of the RF needle electrode into the sphincter.

24. The apparatus of claim 17, wherein the retainer member at least partially surrounds the energy delivery device introduction member and includes a slot to enhance an engagement of the energy delivery device introduction member with the sphincter and reduce an amount of tearing of a sphincter mucosa upon an introduction of the RF needle electrode into the sphincter.

25. The apparatus of claim 17, wherein the retainer member at least partially surrounds the energy delivery device introduction member and includes a slot to enhance an engagement of the energy delivery device introduction member with the sphincter and permit maintenance of a constant angle of penetration of the RF needle electrode through a sphincter surface.

26. The apparatus of claim 9, wherein the balloon has a tapered tip to facilitate introduction into a sphincter.

27. The apparatus of claim 10, wherein the basket device has a tapered tip to facilitate introduction into a sphincter.

28. The apparatus of claim 1, wherein the at least a portion of the energy delivery device introduction member is in a contacting relationship with a surface of the sphincter in the deployed configuration.

29. The apparatus of claim 28, wherein the energy delivery device introduction member has a texturized surface with a sufficient coefficient of friction to reduce a movement of a sphincter surface.

30. The apparatus of claim 28, wherein the energy delivery device introduction member has a texturized surface with a sufficient coefficient of friction to reduce a movement of an energy delivery device introduction member.

31. The apparatus of claim 28, wherein the energy delivery device introduction member has a texturized surface with a sufficient coefficient of friction to reduce a movement of a sphincter surface and facilitate introduction of the RF needle electrode into the sphincter.

32. The apparatus of claim 28, wherein the energy delivery device introduction member has a texturized surface with a sufficient coefficient of friction to reduce a movement of a sphincter surface and reduce an amount of tearing of a sphincter mucosa upon an introduction of the RF needle electrode into the sphincter.

33. The apparatus of claim 28, wherein the energy delivery device introduction member has a texturized surface with a sufficient coefficient of friction to reduce a movement of a sphincter surface and permit maintenance of a constant angle of penetration of the RF needle electrode through a sphincter surface.

34. The apparatus of claim 17, wherein the energy delivery device introduction member is a basket device and the RF electrode is coupled to an electrode delivery member having proximal and distal ends.

35. The apparatus of claim 34, further comprising:

a guiding tool coupled to the electrode delivery member, the guiding tool having at least one aperture with a proximal end and a distal end, wherein the RF electrode is advanced through the aperture in the guiding tool and the introduction of the RF needle electrode into the sphincter is facilitated.

36. The apparatus of **35** wherein the aperture proximal end and the aperture distal end are located in a different plane.

37. The apparatus of claim 35, wherein the RF electrode is advanced through an aperture in the energy delivery device introduction member.

38. The apparatus of claim 17, wherein the energy delivery device introduction member is a basket device and the RF electrode is coupled to an electrode delivery member having proximal and distal ends.

39. The apparatus of claim 38, further comprising:

a guiding tool coupled to the energy delivery device, the guiding tool having at least one aperture with a proximal end and a distal end, wherein the RF electrode is advanced through the aperture in the guiding tool and the introduction of the RF needle electrode into the sphincter is facilitated.

40. The apparatus of **39**, wherein the aperture proximal end and the aperture distal end are located in a different plane.

41. The apparatus of claim 39, wherein the RF electrode is advancable through an aperture in the energy delivery device introduction member.

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