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(54) **DEVICES AND METHODS FOR OCCLUSION OF THE UTERINE ARTERIES**

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(21) Appl. No.: **10/459,342**

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Related U.S. Application Data

(60) Continuation of application No. 09/835,402, filed on Apr. 17, 2001, now Pat. No. 6,602,251, which is a division of application No. 09/207,572, filed on Dec. 8, 1998, now Pat. No. 6,254,601.

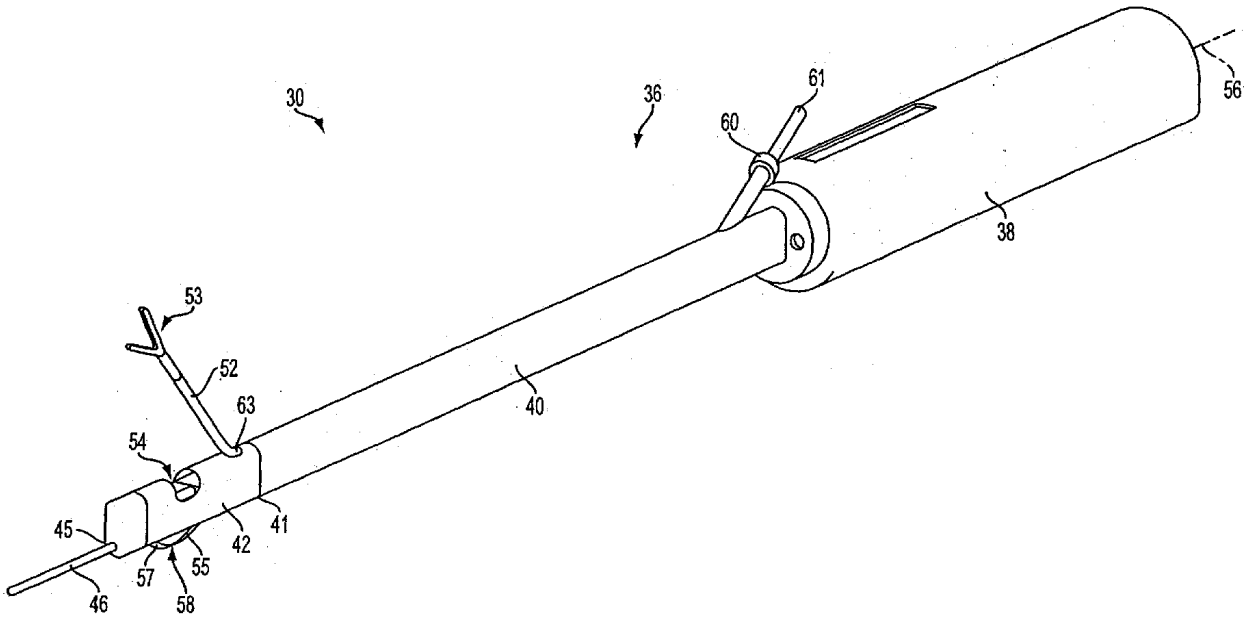
Publication Classification

(51) **Int. Cl.**[7] **A61B 17/08**

(52) **U.S. Cl.** **606/157**; 606/205; 606/139

(57) **ABSTRACT**

Devices and methods are disclosed for treating a uterine disorder which receive its blood supply from a uterine arteries. In particular, uterine fibroids are effectively treated by occluding the uterine arteries using trans-vaginal, trans-uterine, transrectal, or retroperitoneal approaches. The devices and methods are advantageous because the inventive procedures may be performed by a patient's gynecologist in the course of treatment, avoiding the need for referrals to specialist practitioners and for more radical treatments, such as hysterectomies. The methods include both temporary and permanent occlusion of the arteries. A cannula carries an imaging device and a member which will easily penetrate tissue, the member including a device which partially or completely, and temporarily or permanently, occludes a uterine artery.



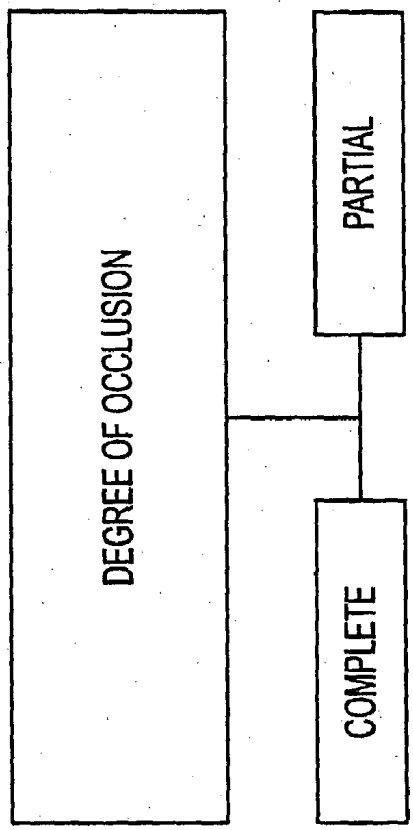

DEGREE OF OCCLUSION
PARTIAL
COMPLETE

FIG. 2

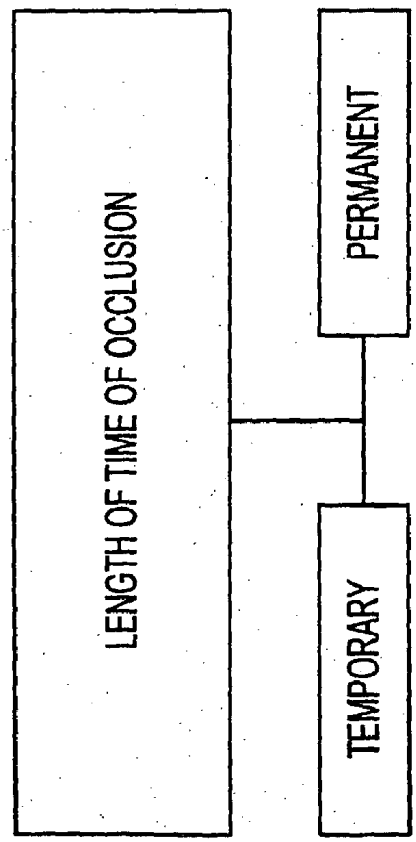

LENGTH OF TIME OF OCCLUSION
PERMANENT
TEMPORARY

FIG. 1

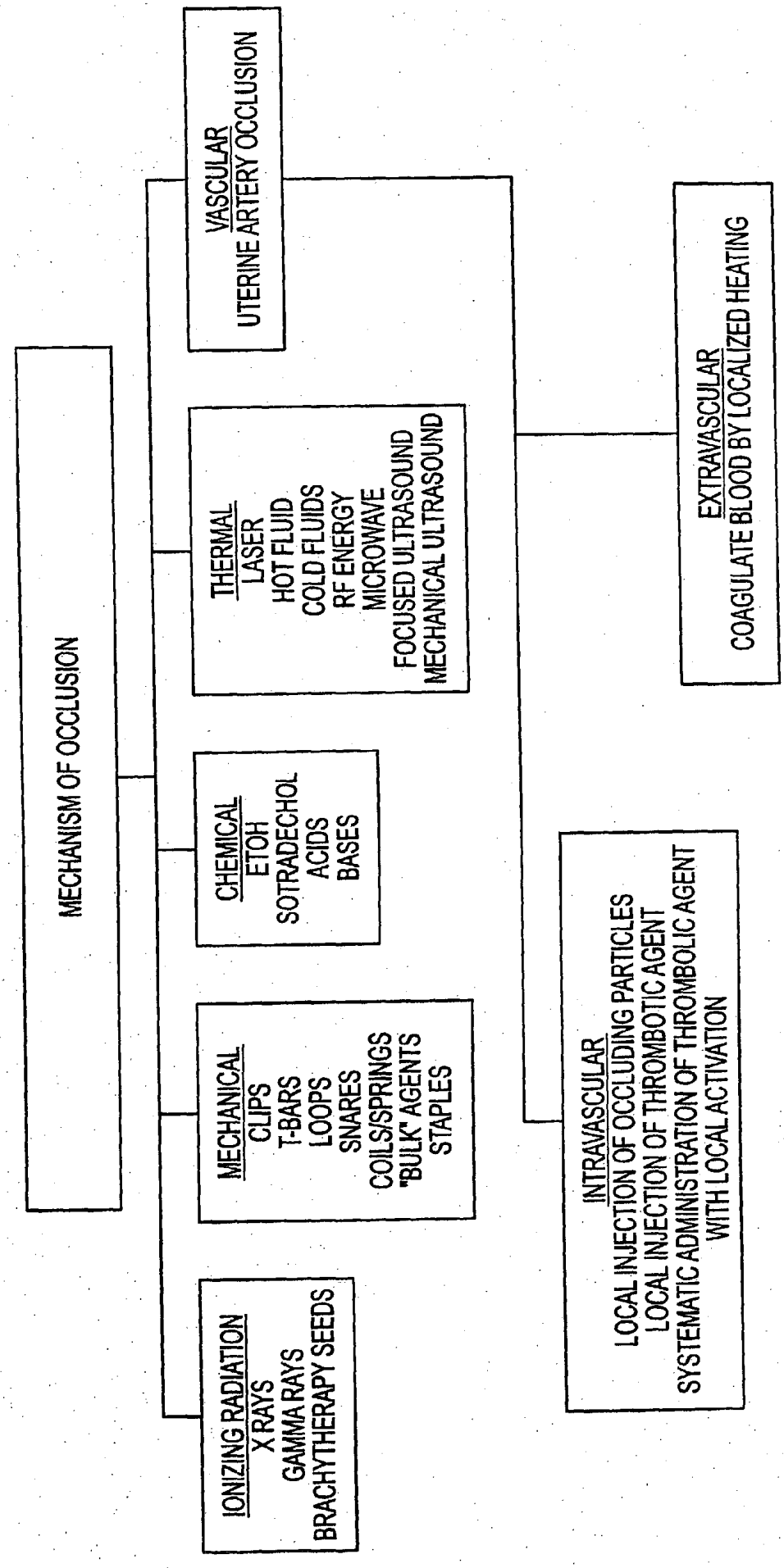

MECHANISM OF OCCLUSION
VASCULAR
UTERINE ARTERY OCCLUSION
THERMAL
LASER
HOT FLUID
COLD FLUIDS
RF ENERGY
MICROWAVE
FOCUSED ULTRASOUND
MECHANICAL ULTRASOUND
CHEMICAL
ETOH
SOTRADECHOL
ACIDS
BASES
MECHANICAL
CLIPS
T-BARS
LOOPS
SNARES
COILS/SPRINGS
"BULK" AGENTS
STAPLES
IONIZING RADIATION
X RAYS
GAMMA RAYS
BRACHYTHERAPY SEEDS
EXTRAVASCULAR
COAGULATE BLOOD BY LOCALIZED HEATING
INTRAVASCULAR
LOCAL INJECTION OF OCCLUDING PARTICLES
LOCAL INJECTION OF THROMBOTIC AGENT
SYSTEMATIC ADMINISTRATION OF THROMBOLIC AGENT
WITH LOCAL ACTIVATION

FIG. 3

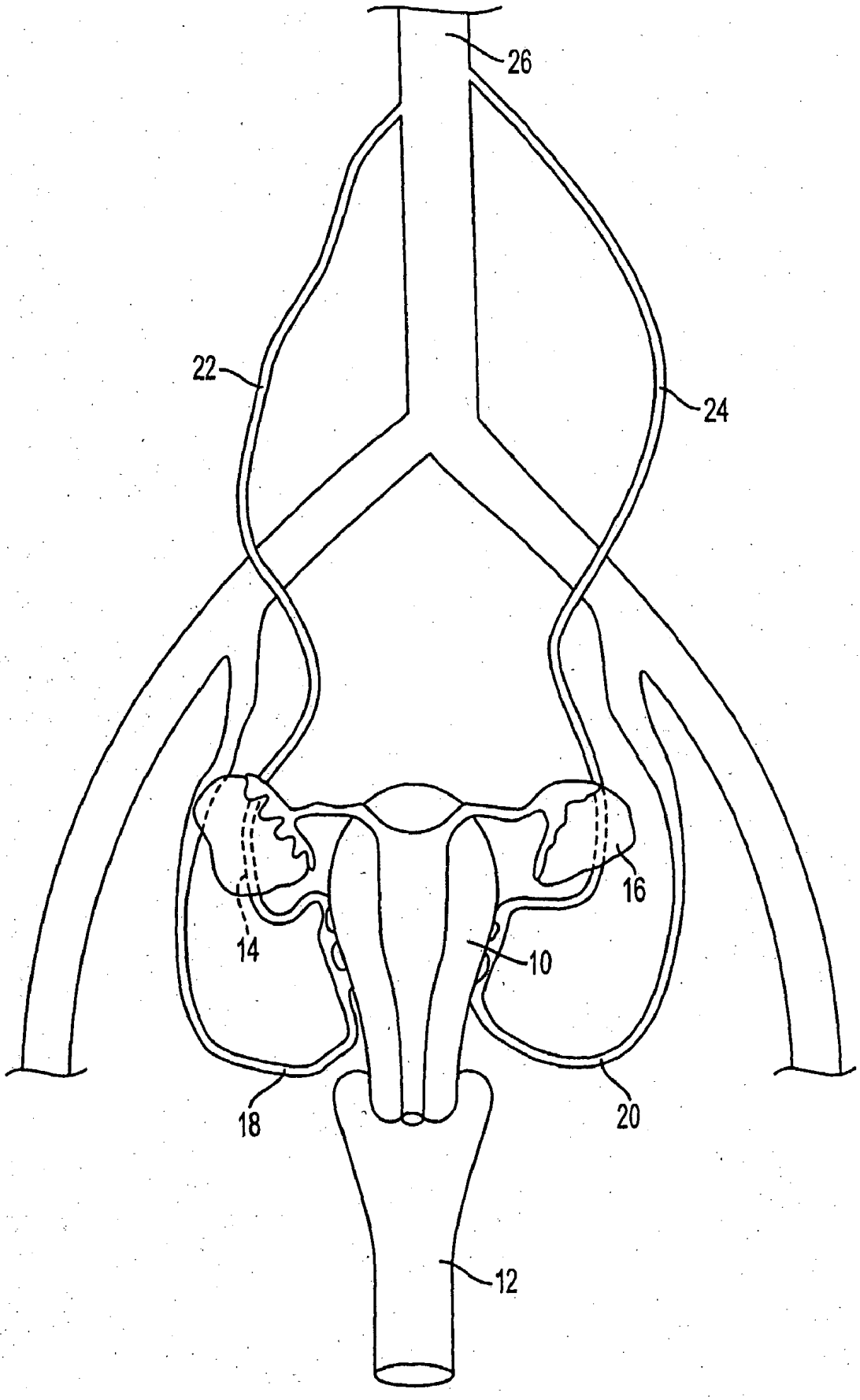


FIG. 4

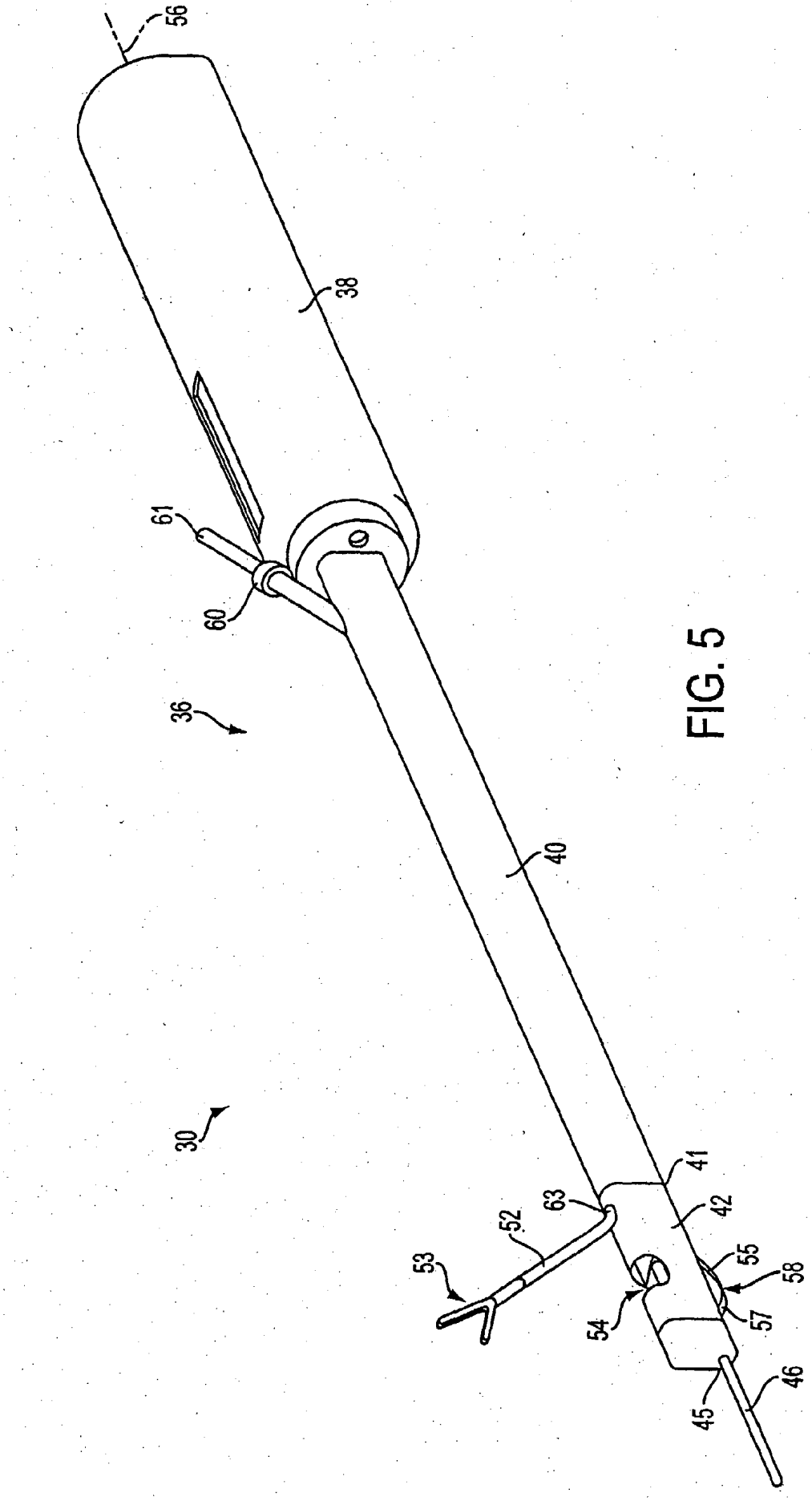


FIG. 5

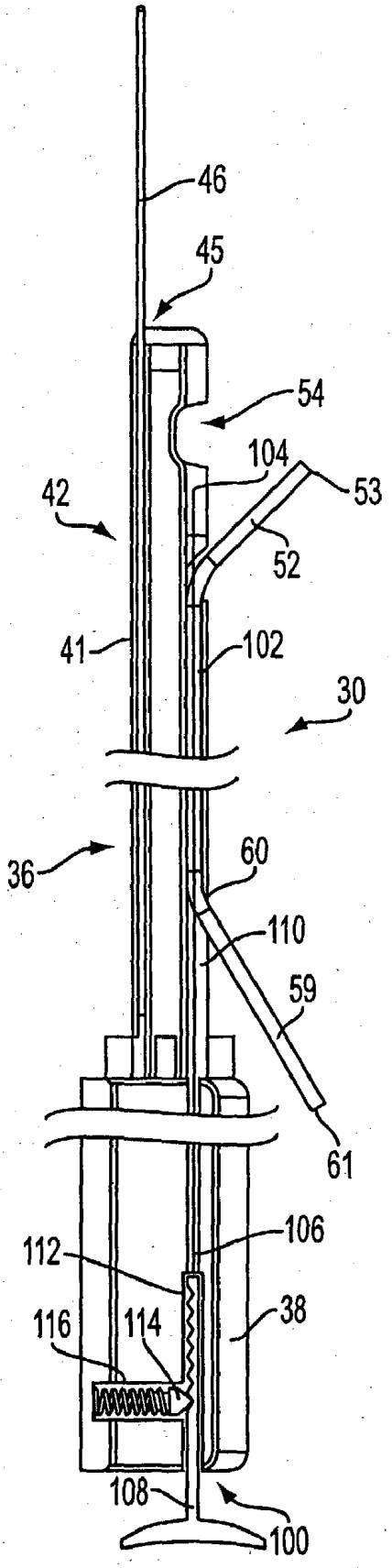

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FIG. 6

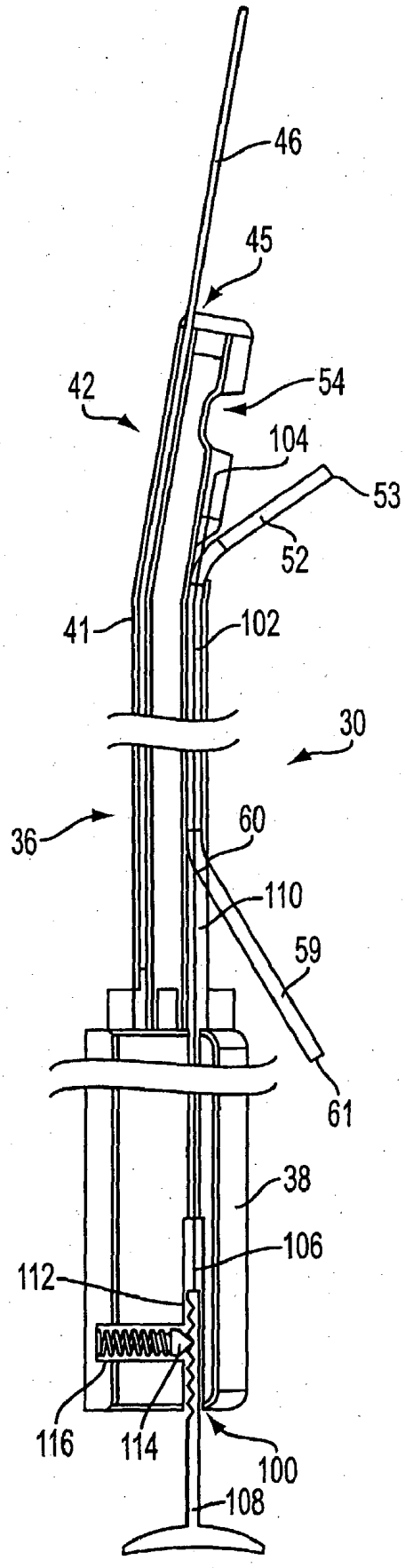
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FIG. 7

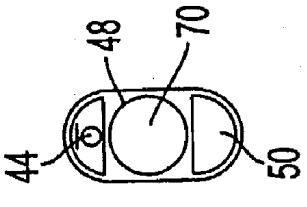
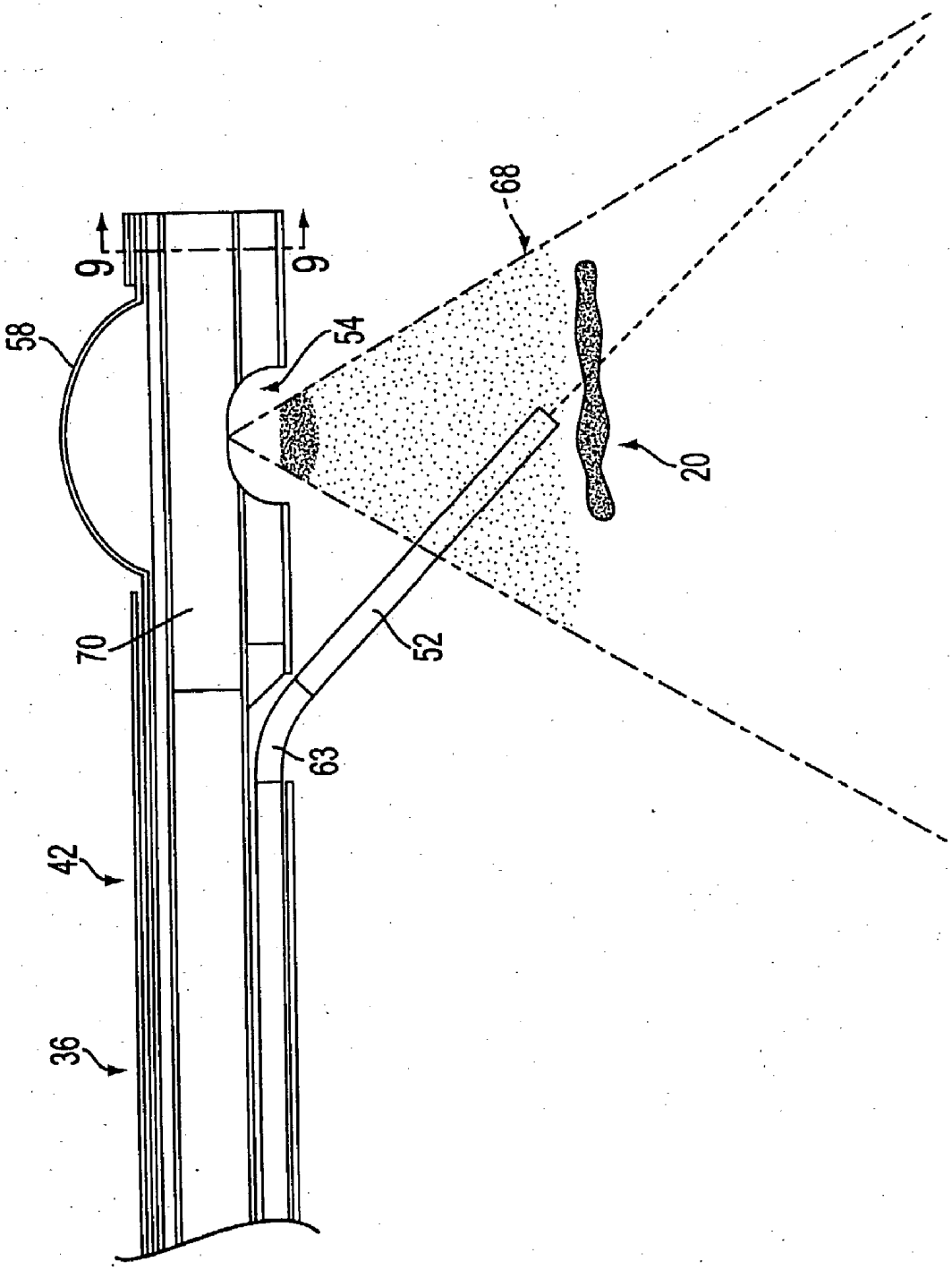


FIG. 9



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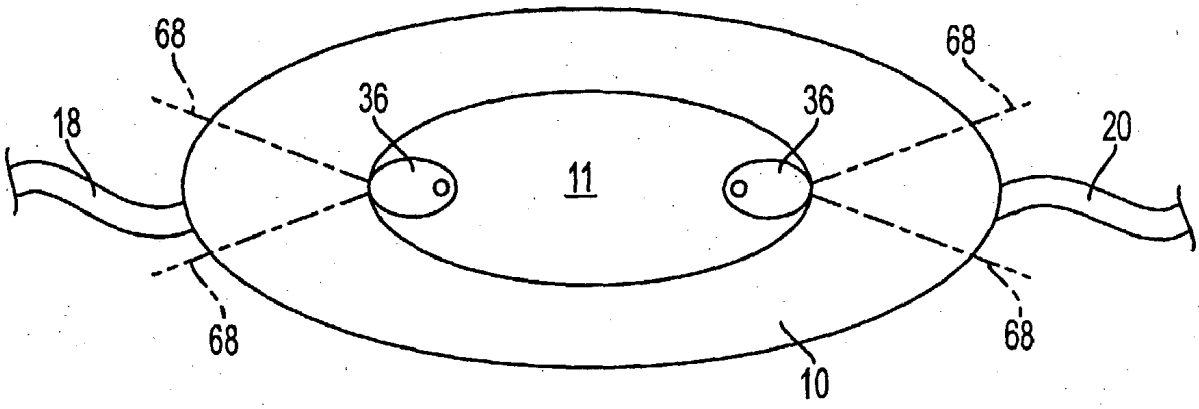


FIG. 10

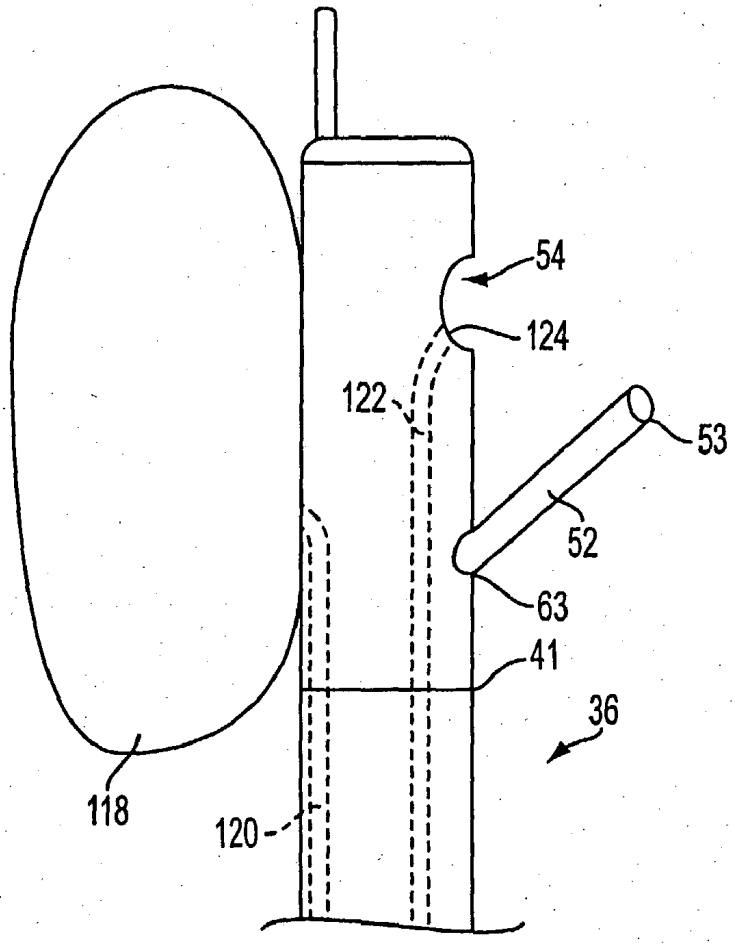


FIG. 11

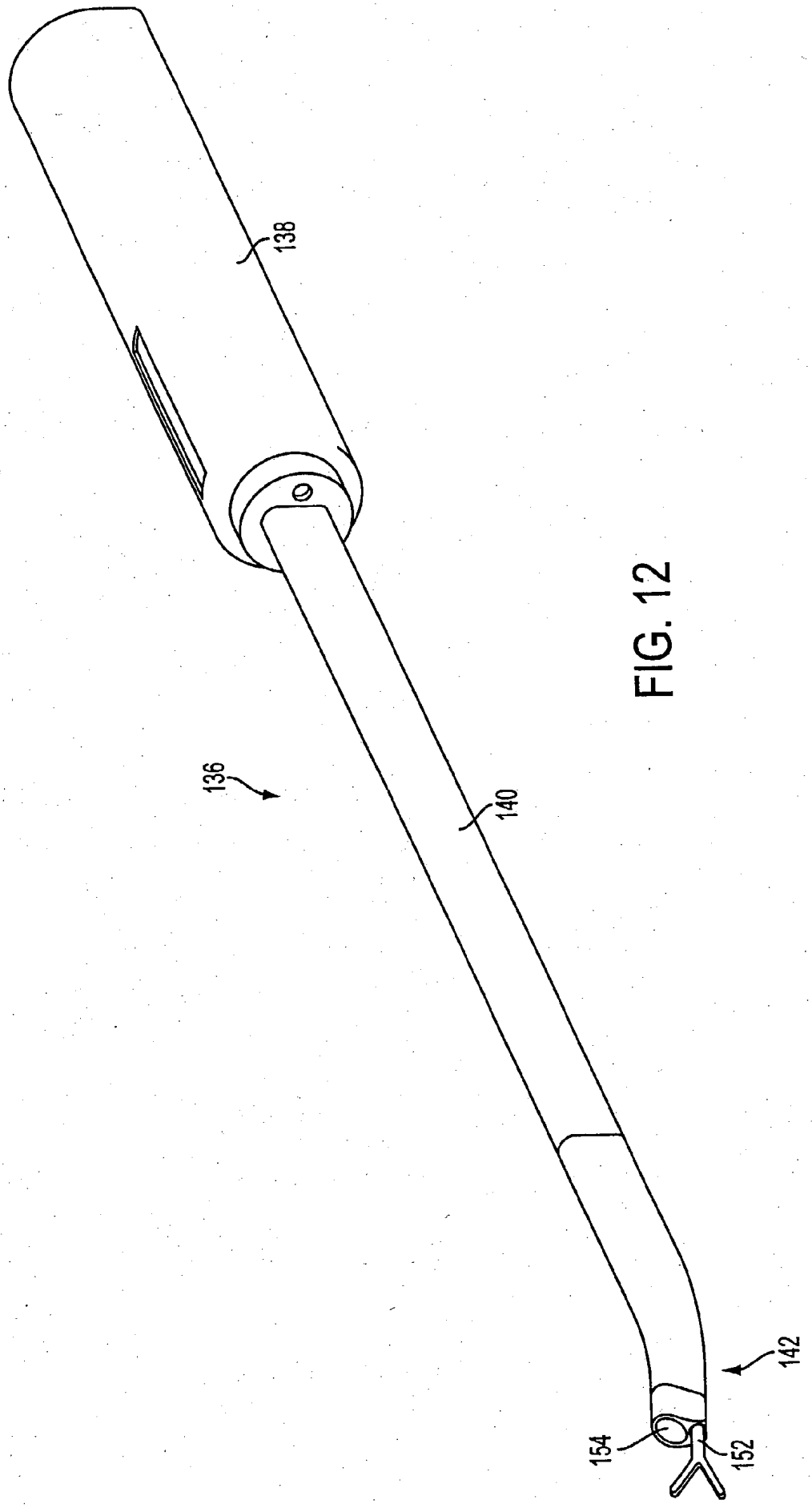


FIG. 12

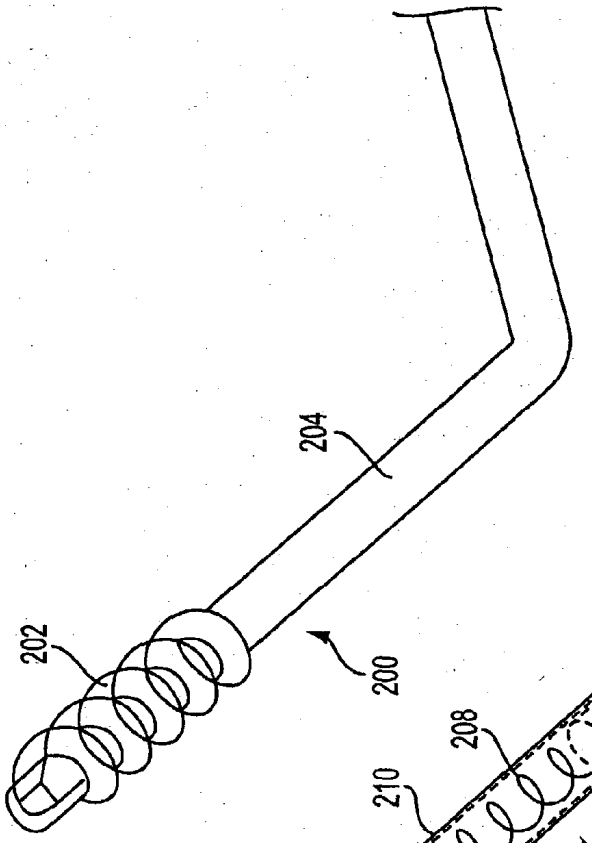


FIG. 16

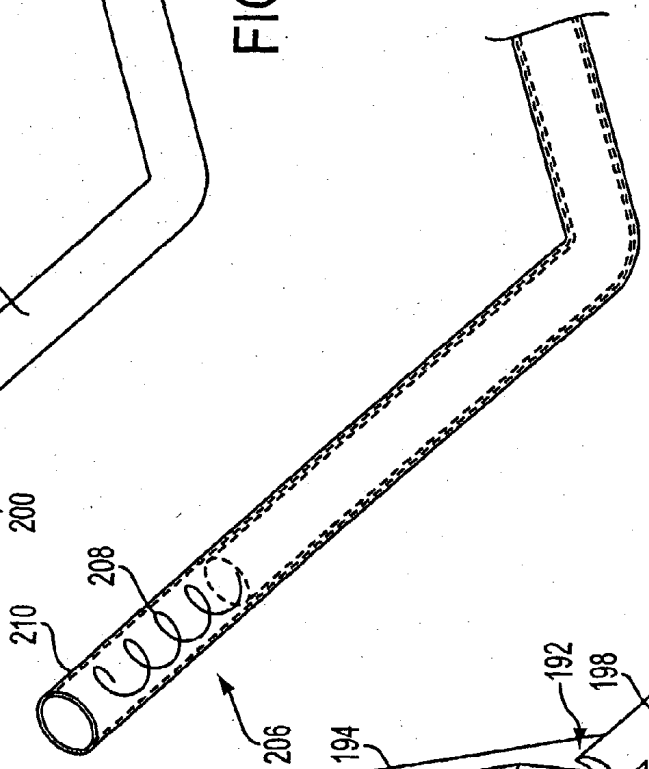


FIG. 17A

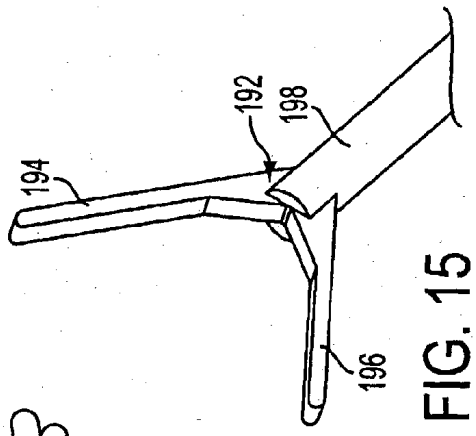


FIG. 15

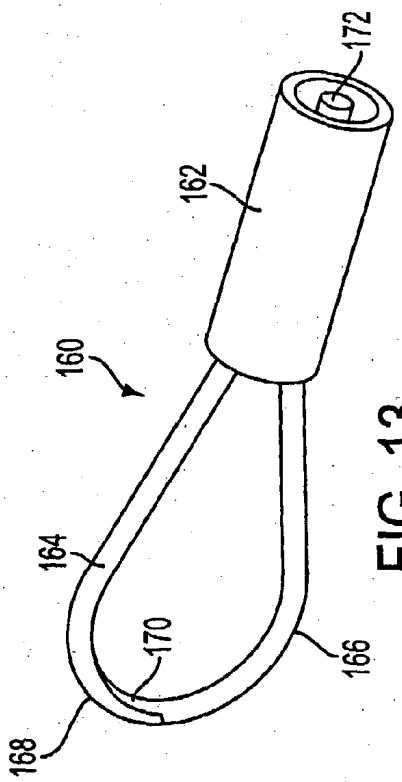


FIG. 13

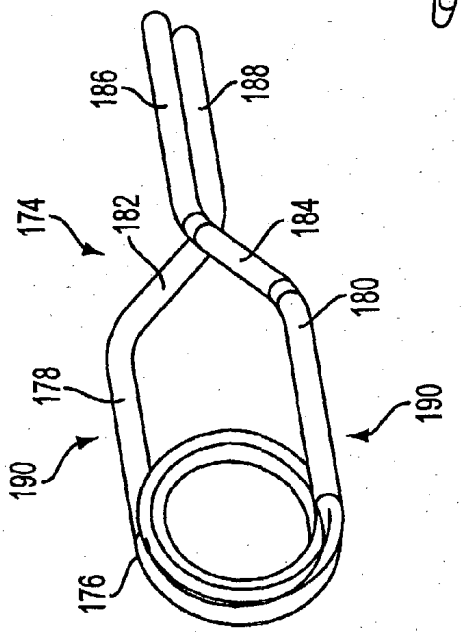


FIG. 14

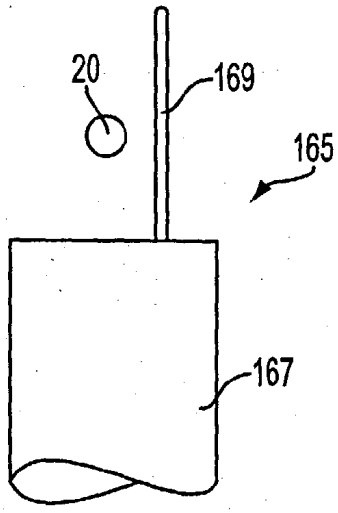


FIG. 17B

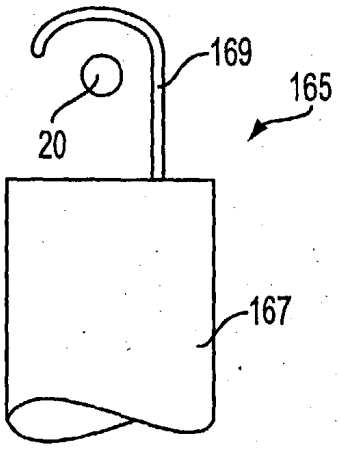


FIG. 17C

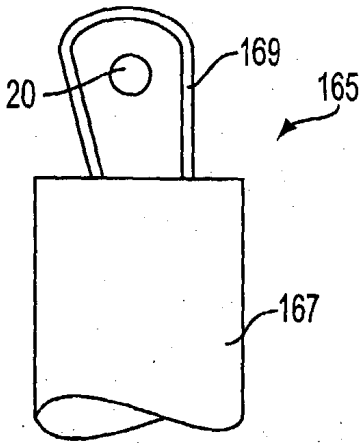


FIG. 17D

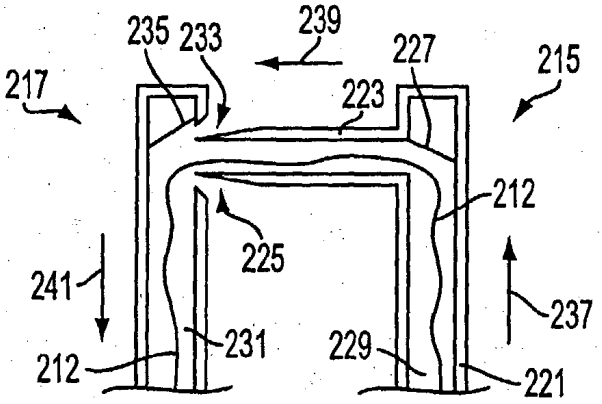


FIG. 18B

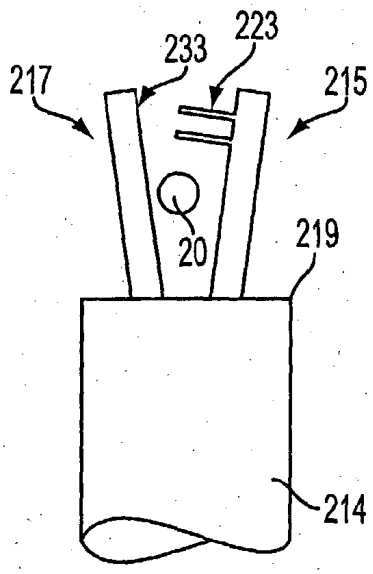
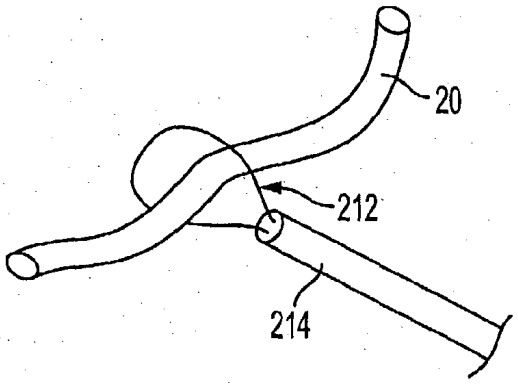


FIG. 18C



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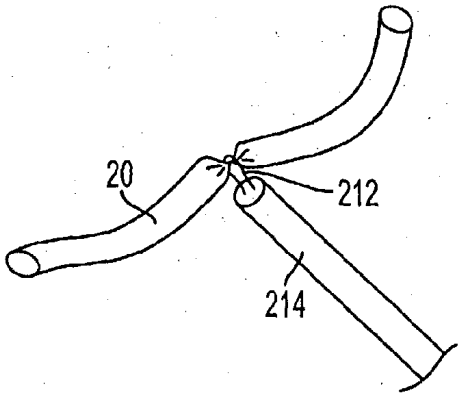

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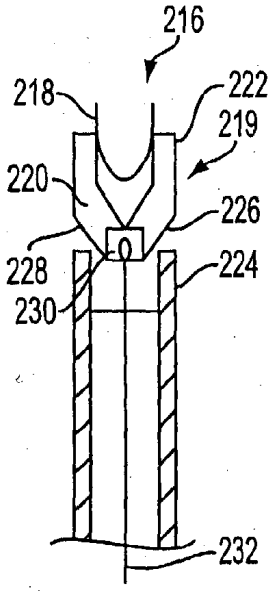


FIG. 20

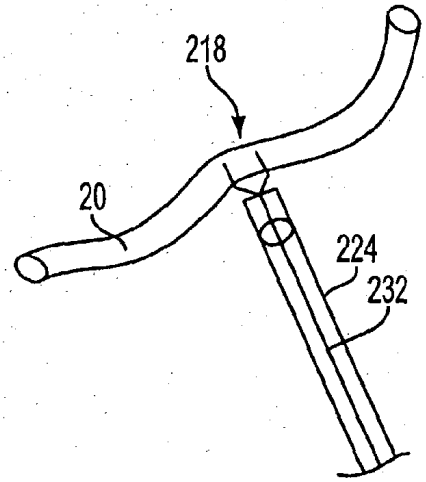


FIG. 21

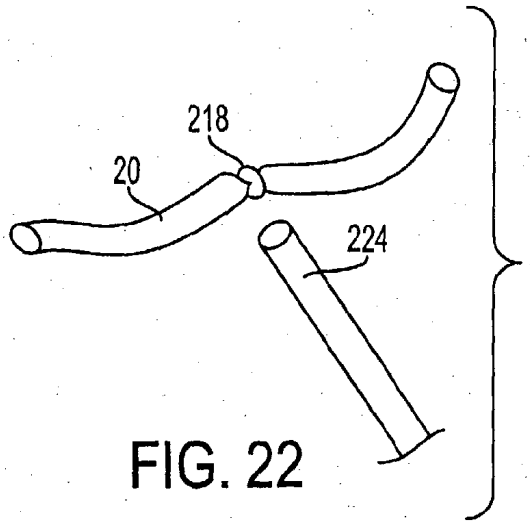


FIG. 22

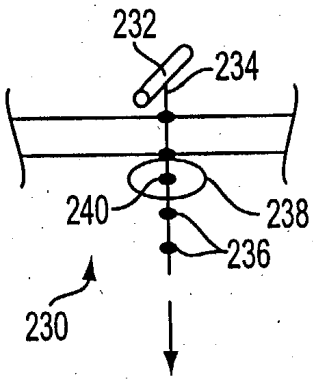


FIG. 23

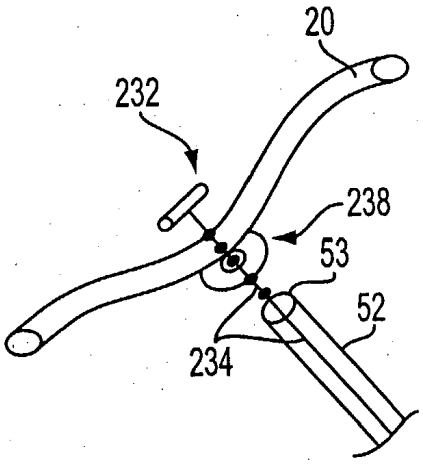


FIG. 24

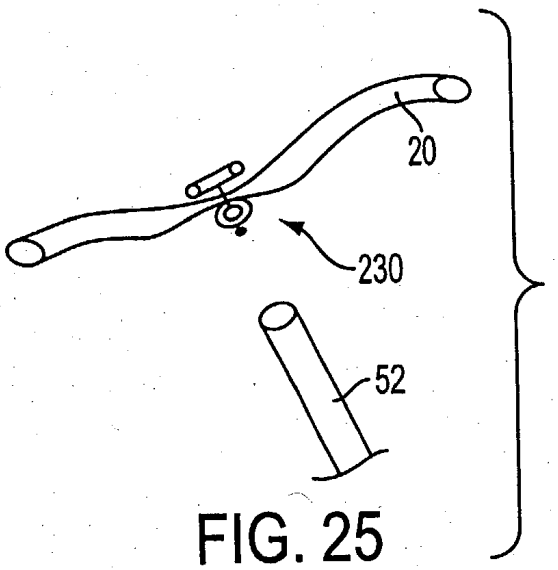


FIG. 25

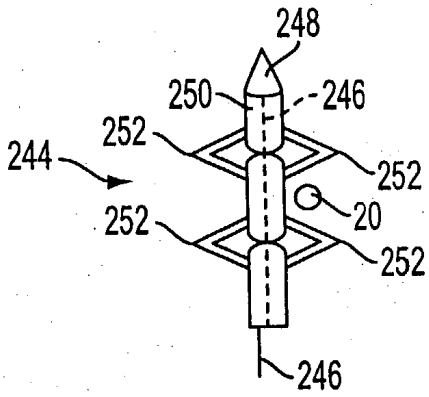
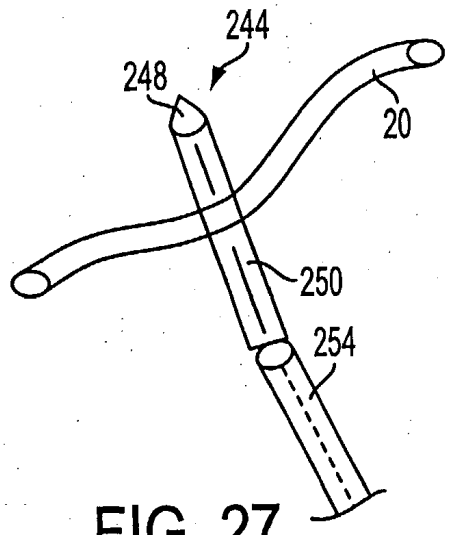


FIG. 26



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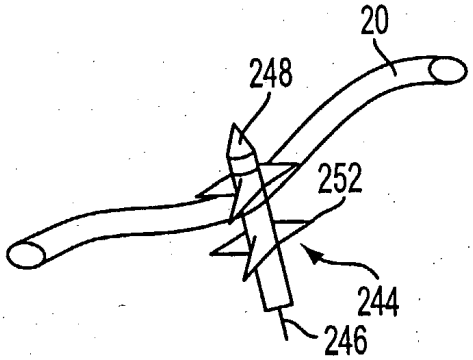

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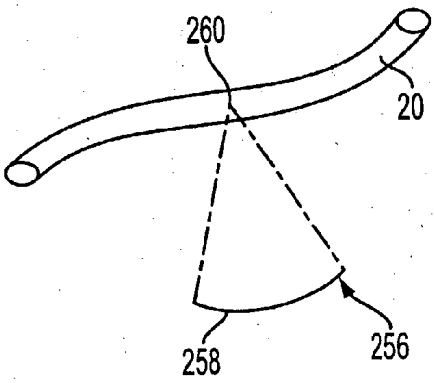

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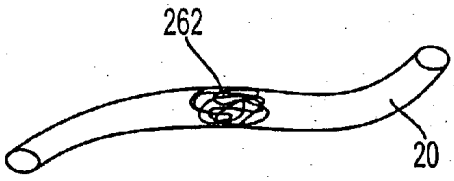

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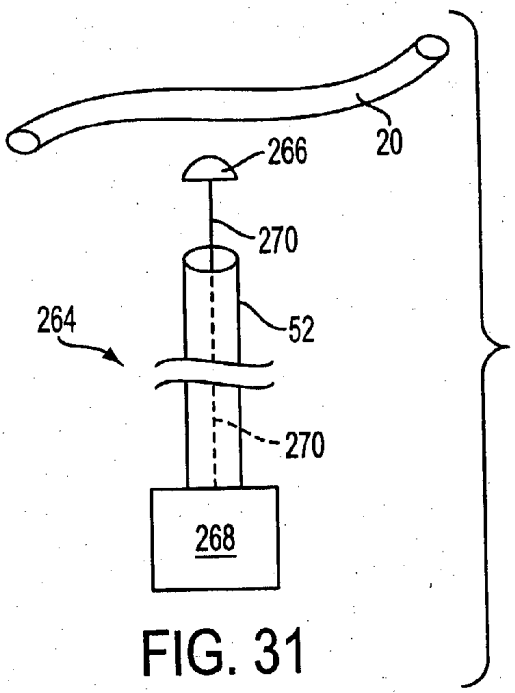


FIG. 31

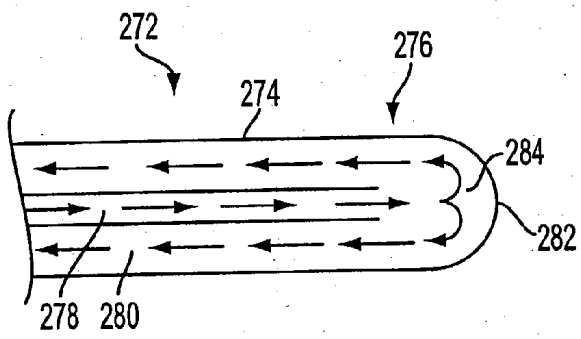


FIG. 32

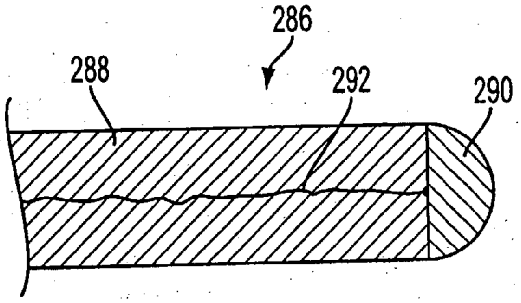


FIG. 33

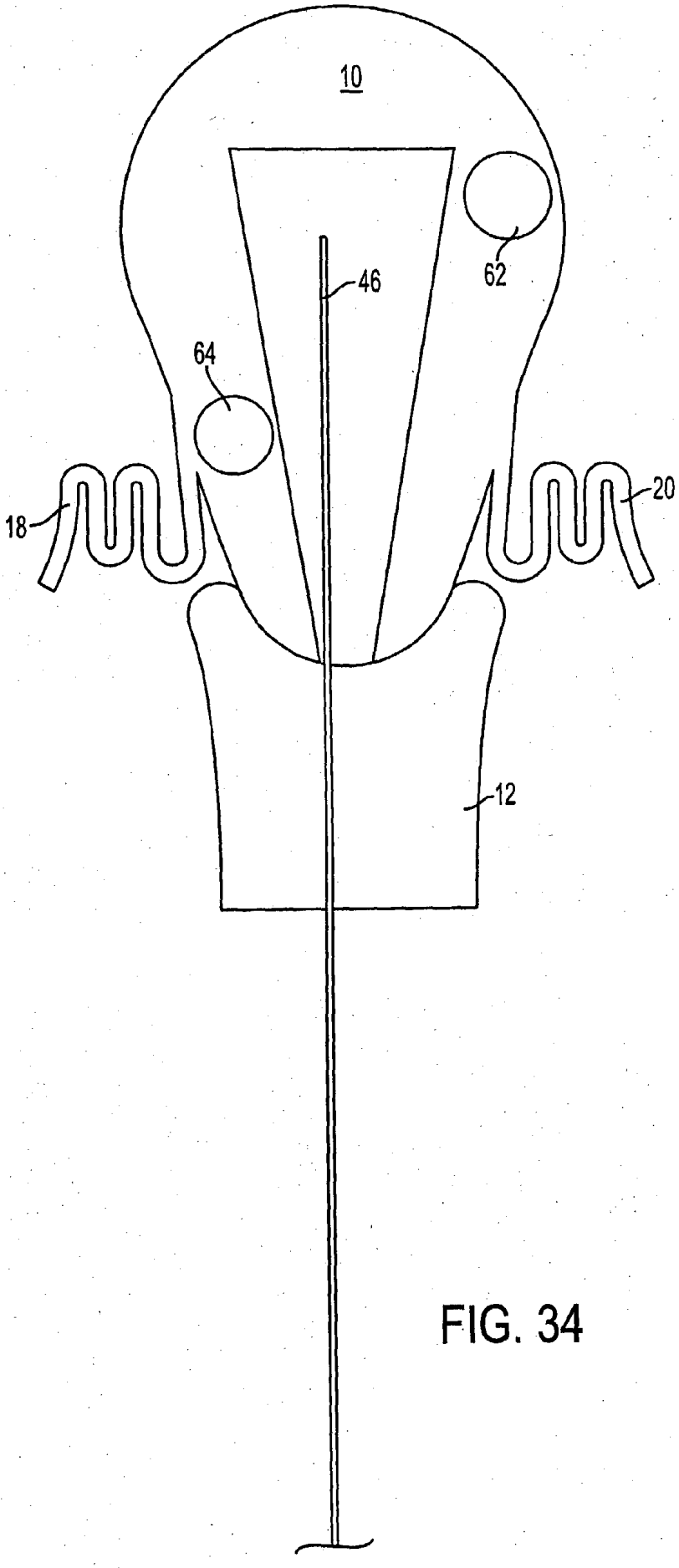


FIG. 34

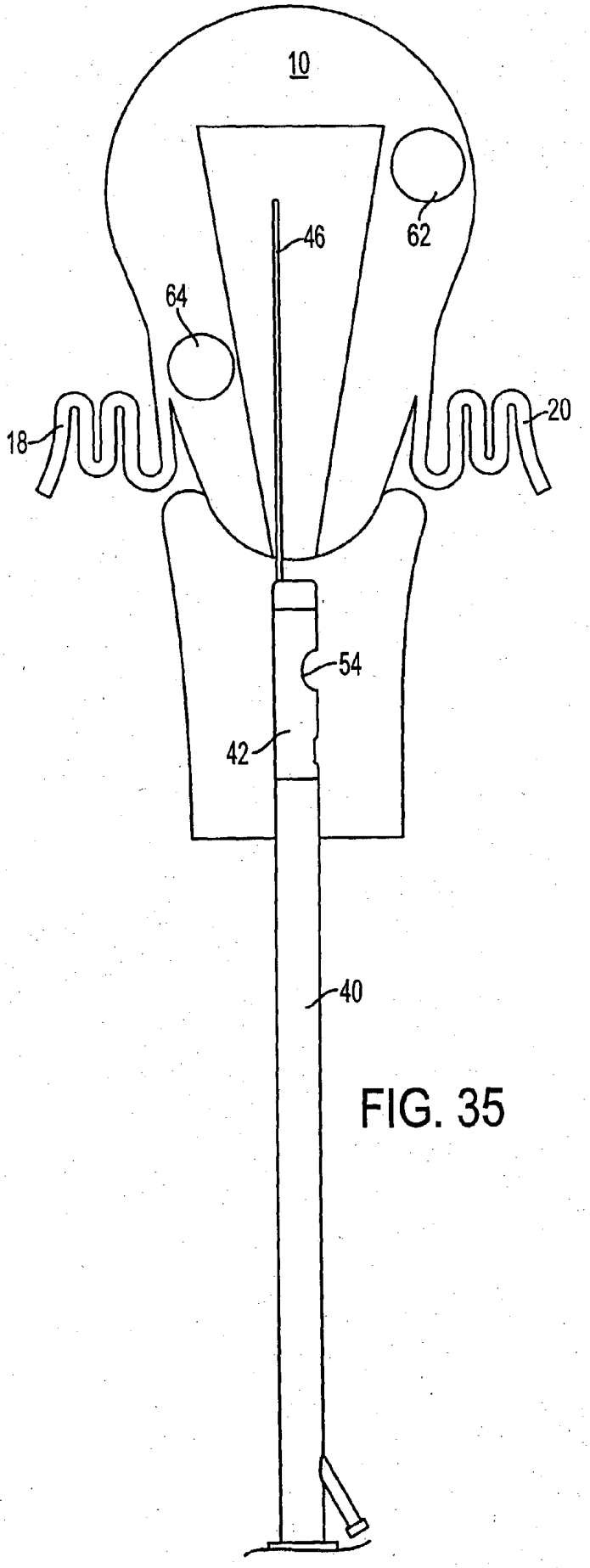
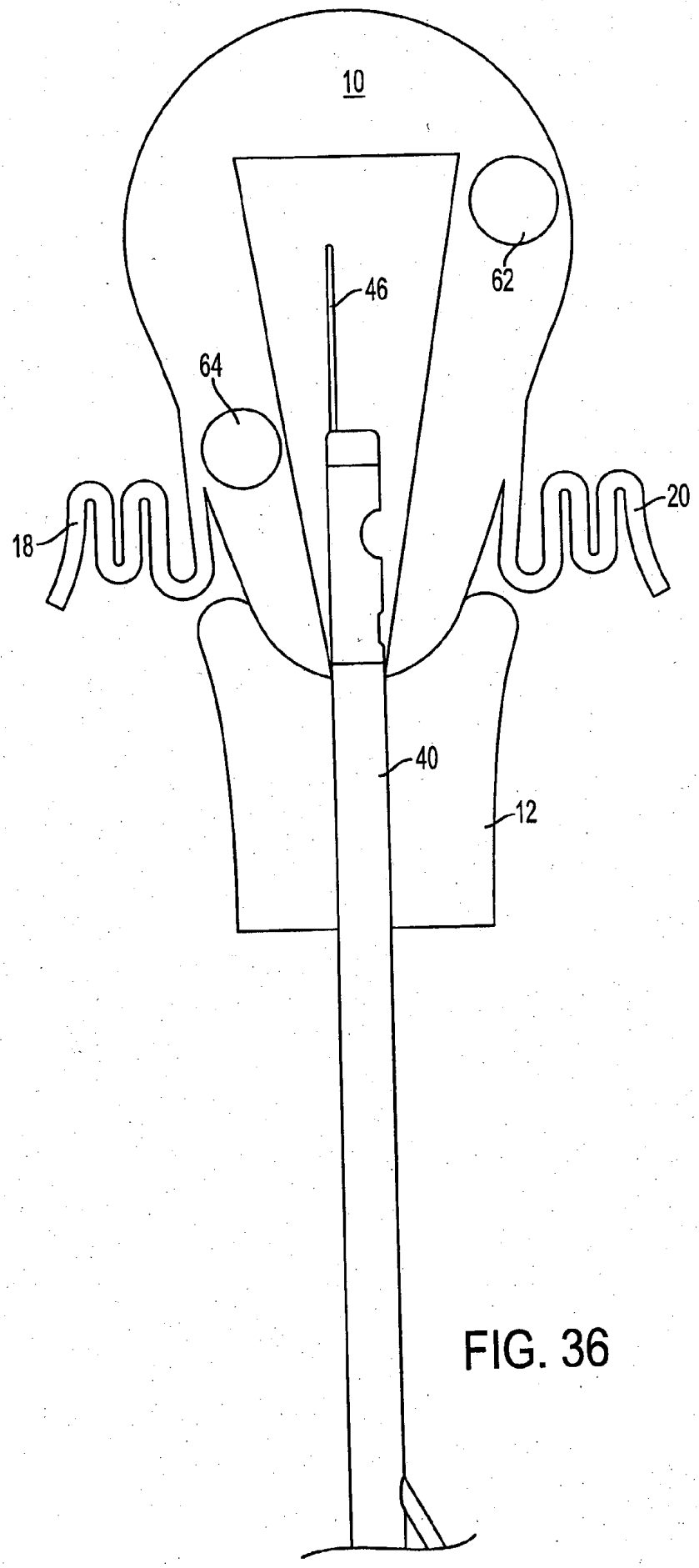


FIG. 35



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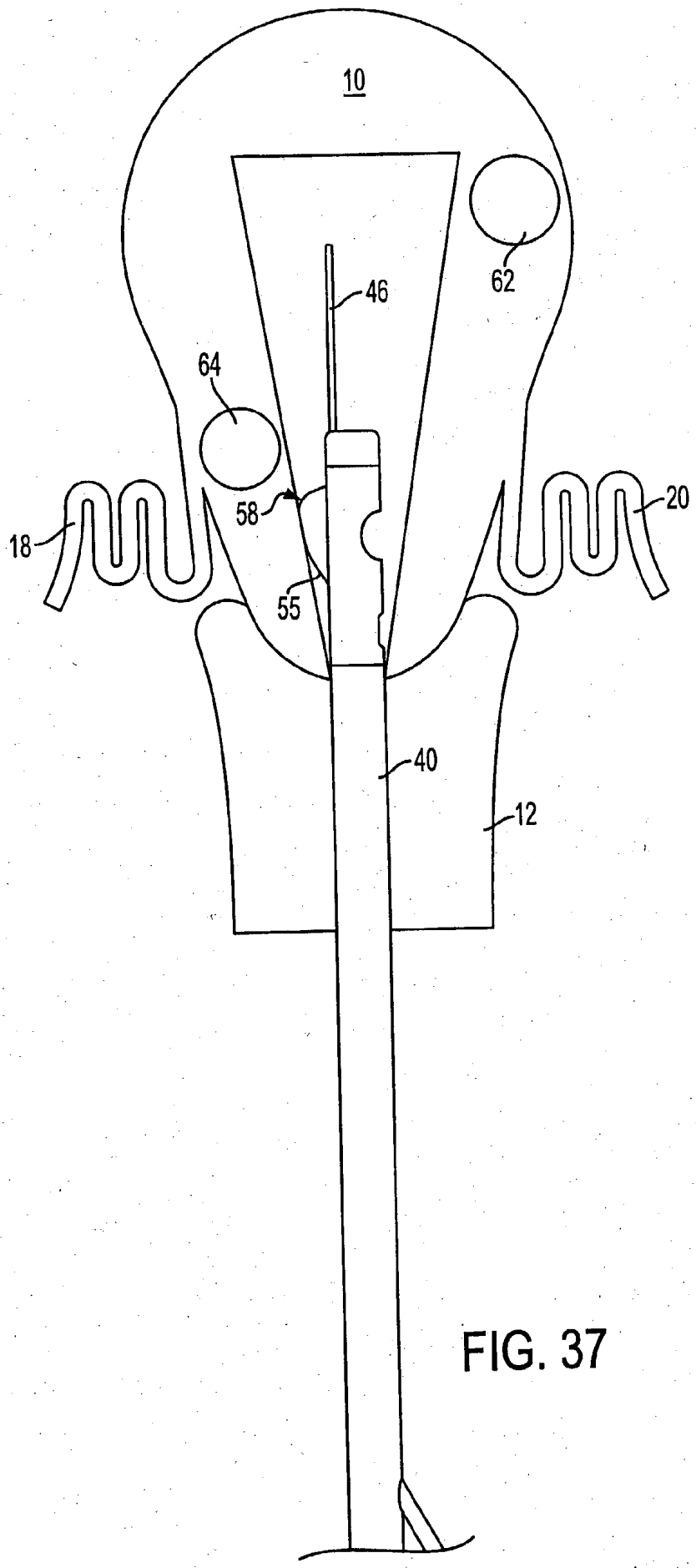

FIG. 37

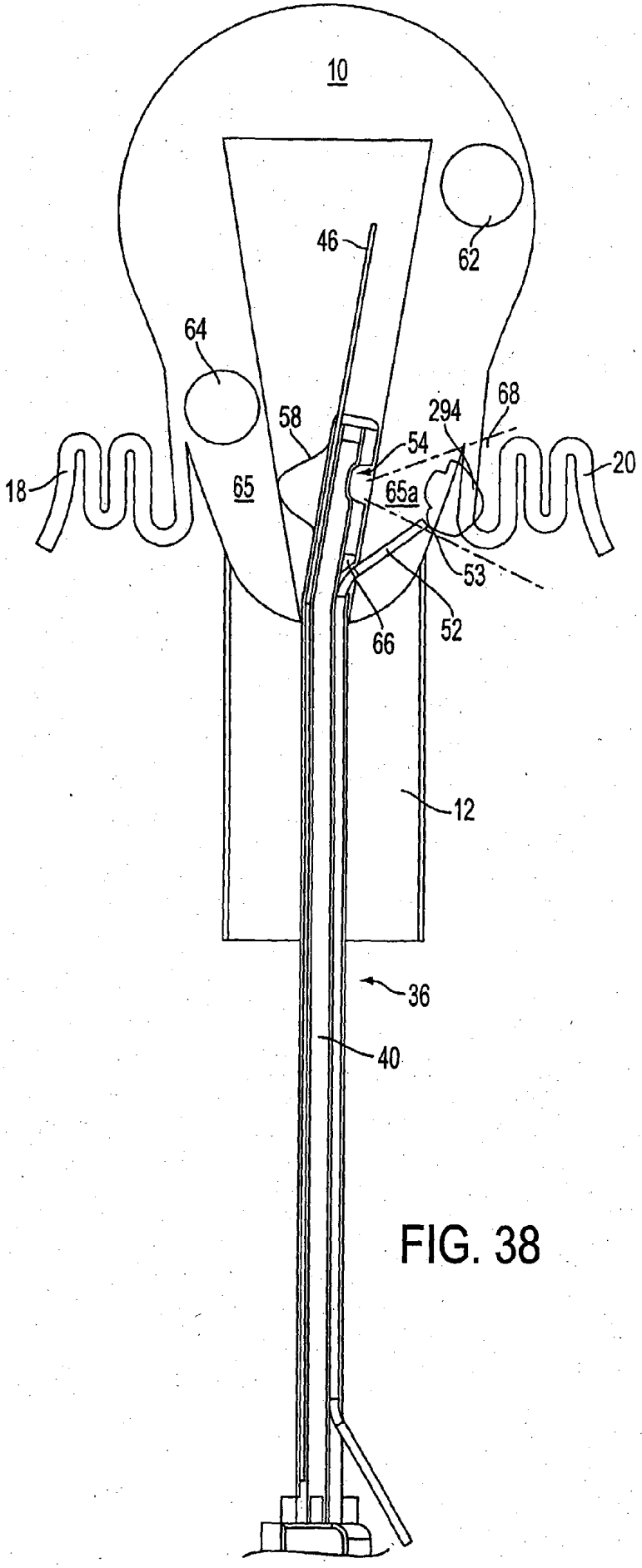

FIG. 38

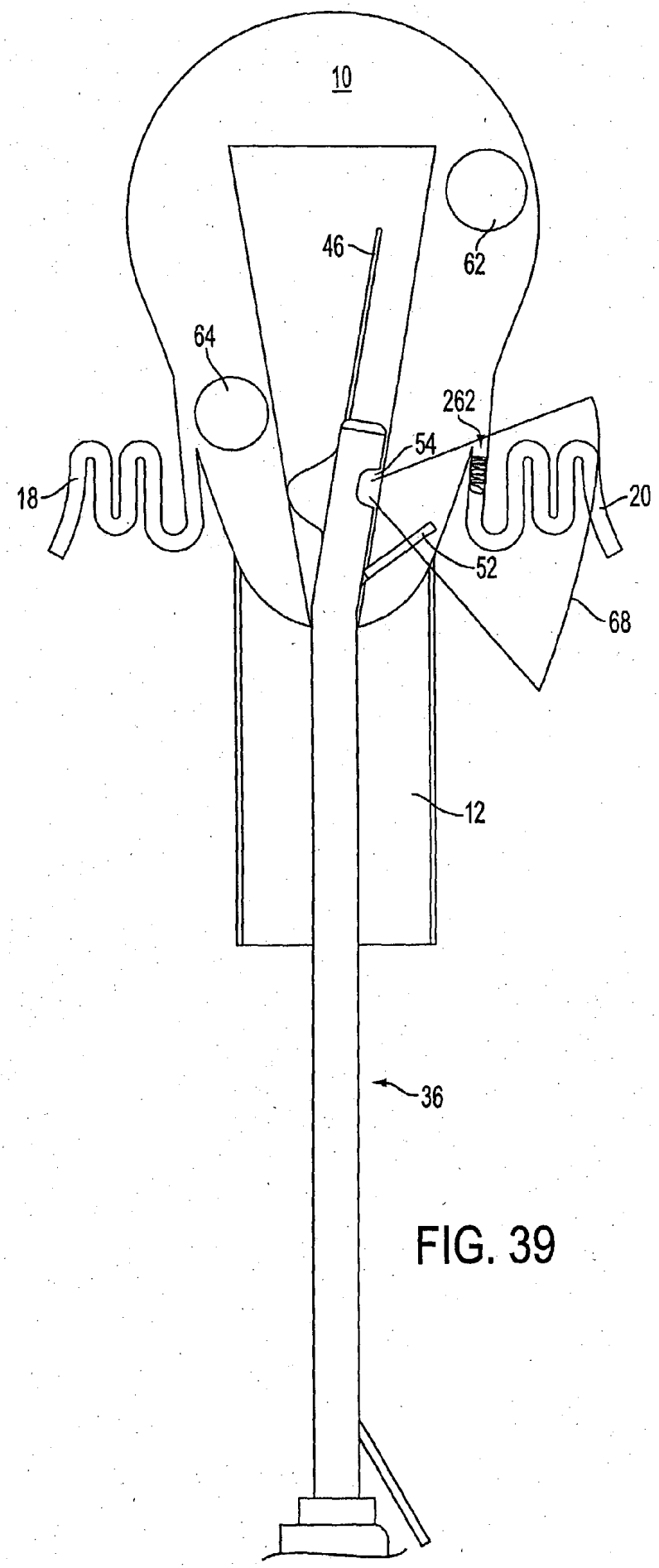

FIG. 39

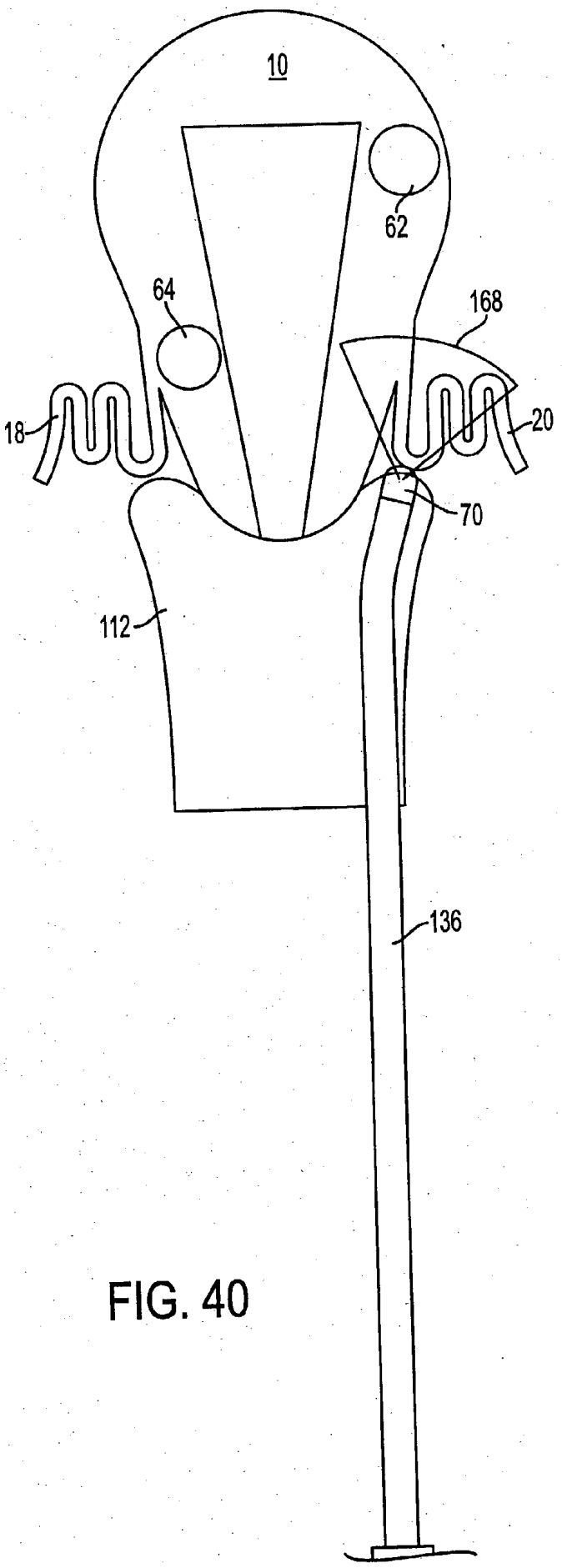

FIG. 40

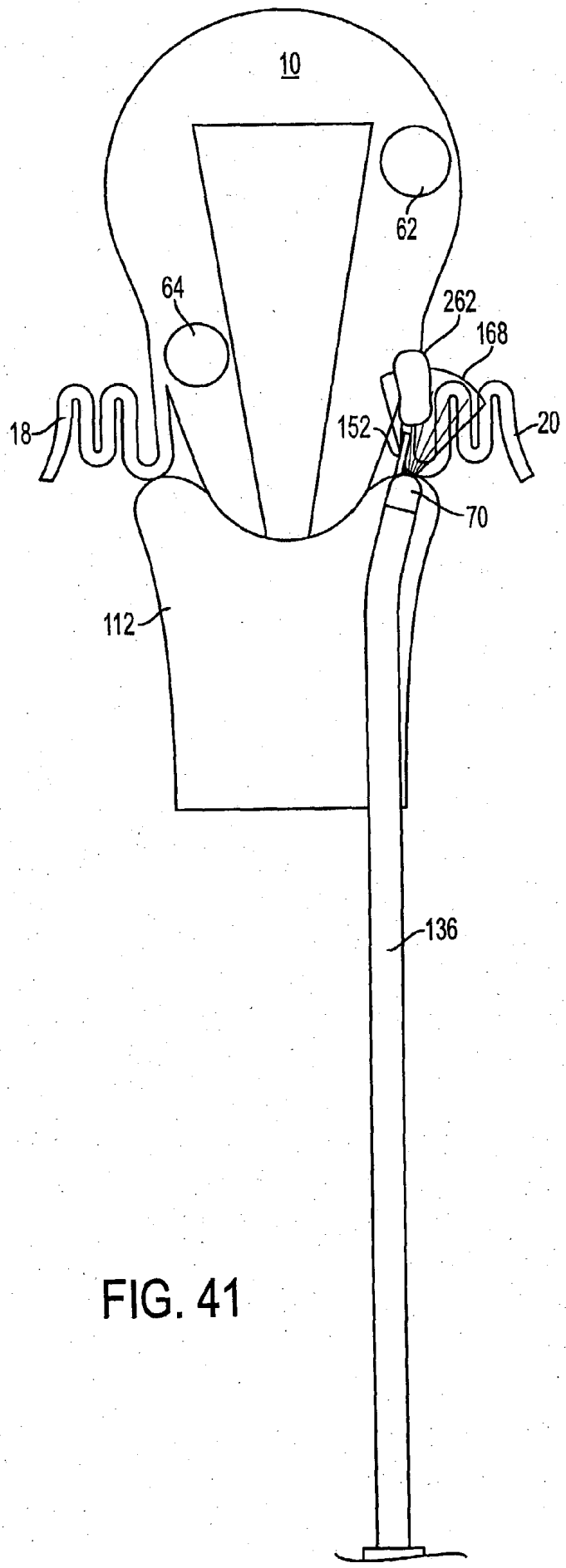

FIG. 41

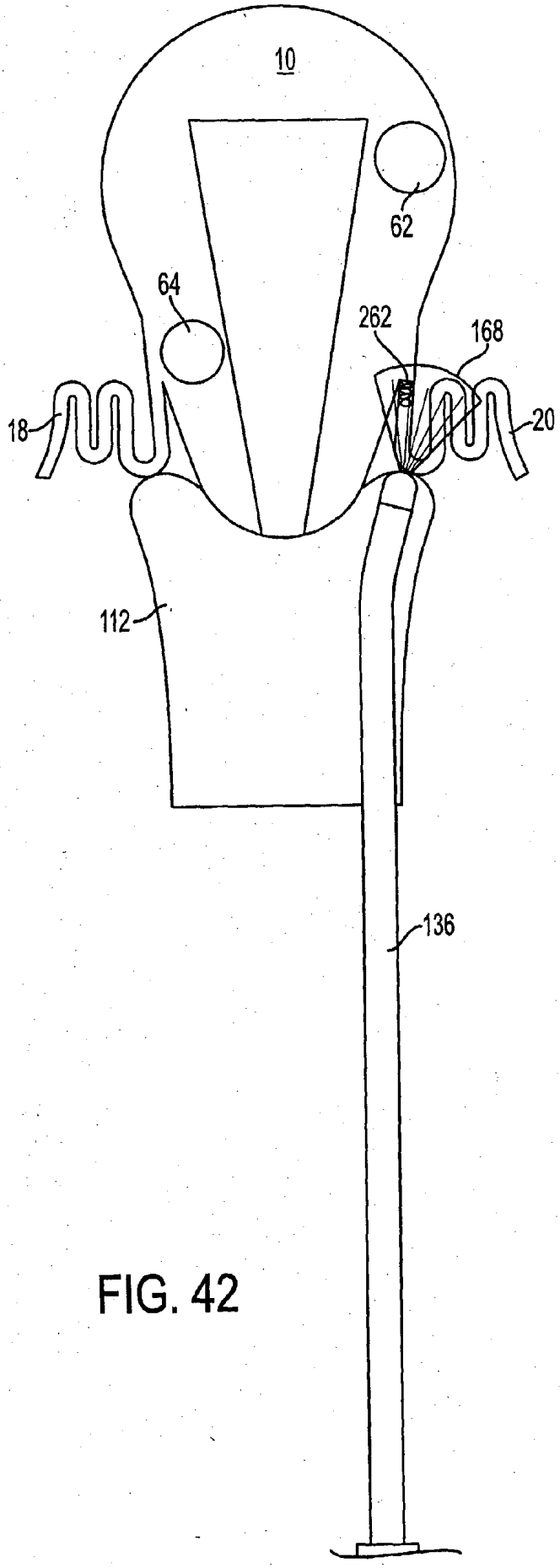

FIG. 42

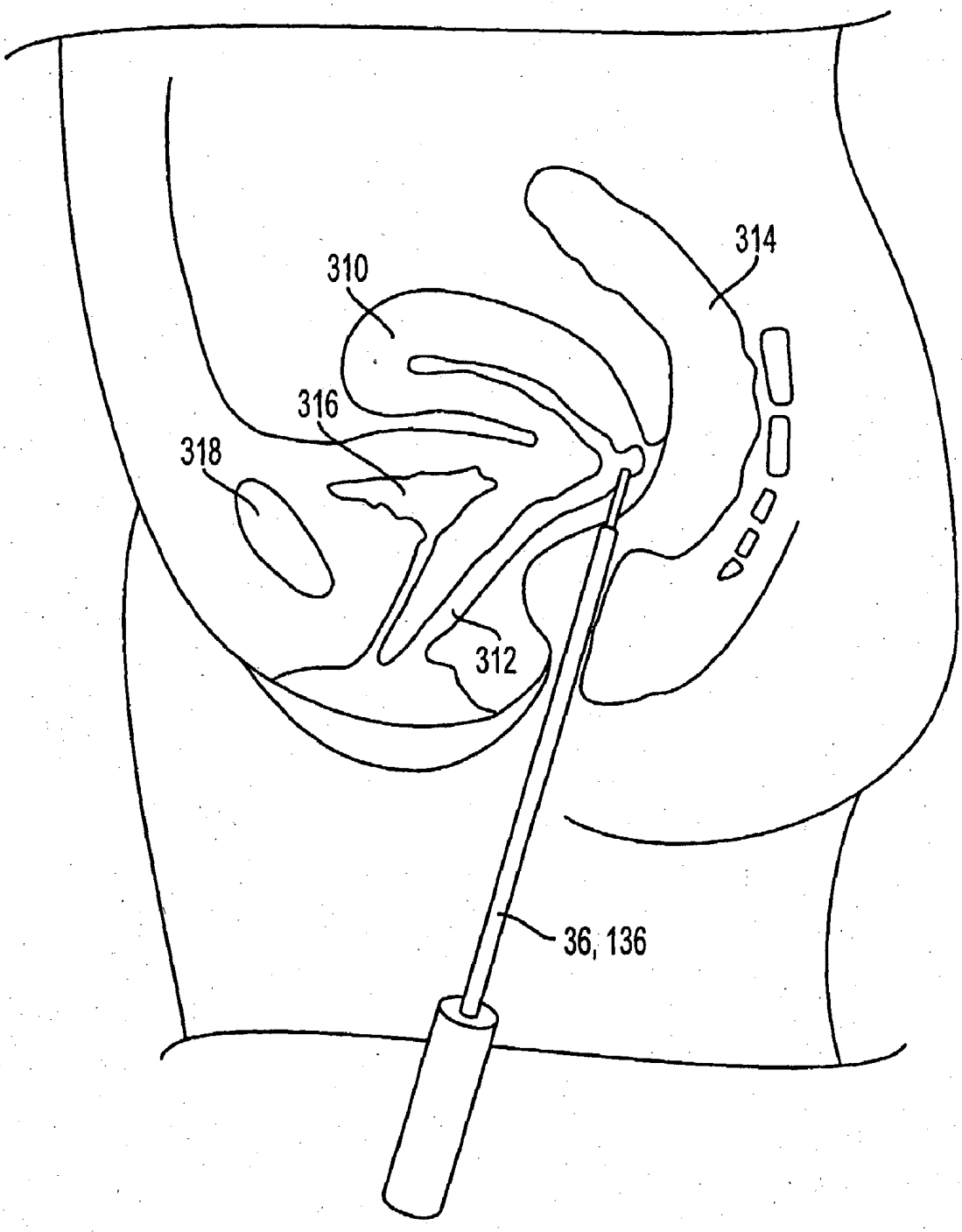

FIG. 43

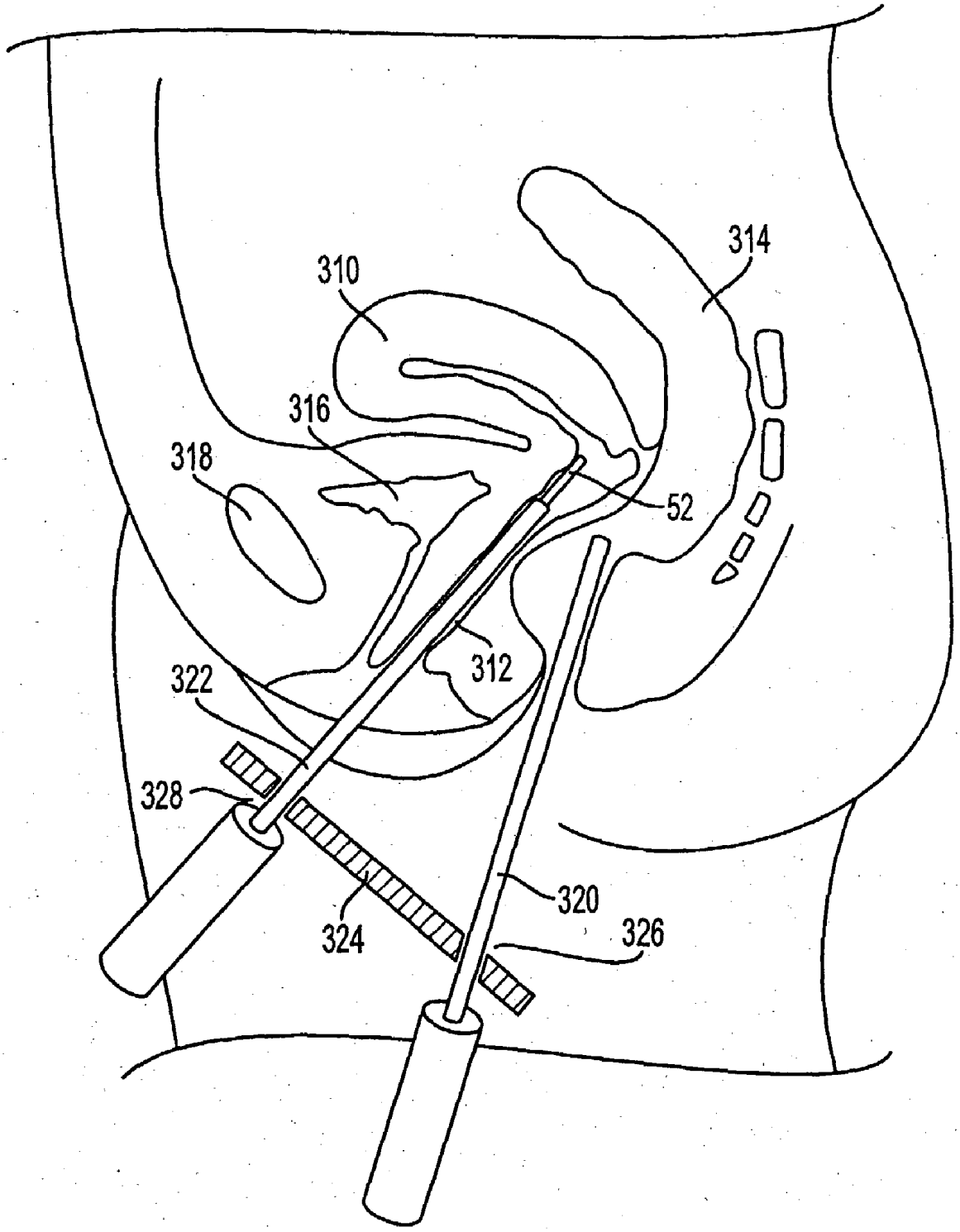

FIG. 44

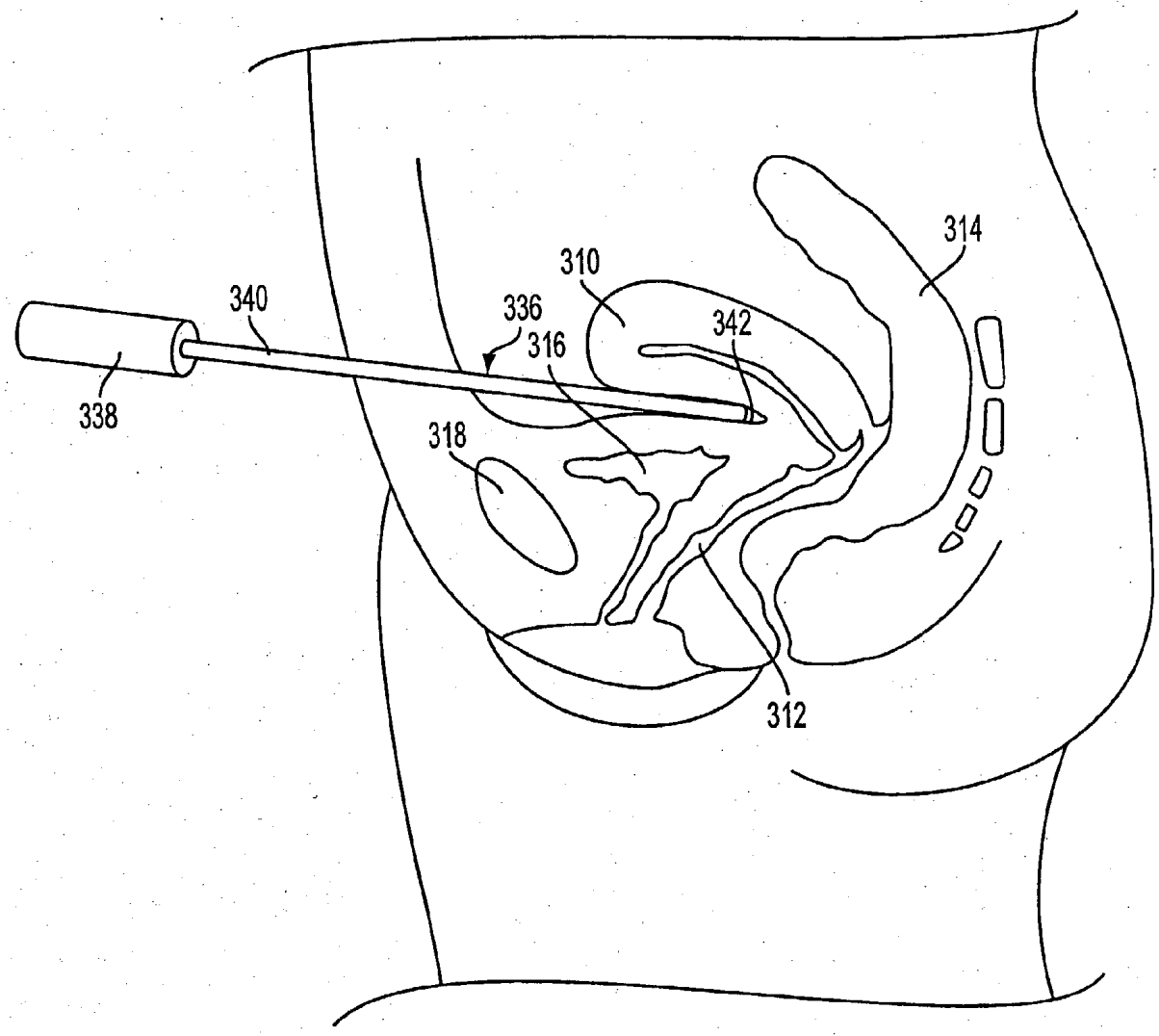

FIG. 45

DEVICES AND METHODS FOR OCCLUSION OF THE UTERINE ARTERIES

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention

[0002] The present invention relates generally to the treatment of disorders which receive blood flow from the uterine arteries, and more particularly to devices and methods for occlusion of the uterine arteries.

[0003] 2. Brief Description of the Related Art

[0004] Hysterectomy (surgical removal of the uterus) is performed on approximately 600,000 women annually in the United States. For approximately 340,000 women, hysterectomy is probably the best current therapeutic choice for the treatment of their diseases (uterine cancer, endometriosis, menorrhagia, and prolapse). For approximately 60,000 women with dysfunctional uterine bleeding (abnormal menstual bleeding that has no discrete anatomic explanation such as a tumor or growth), newer endometrial ablation techniques may be an alternative to hysterectomy. For approximately 200,000 women with benign but symptomatic (excessive bleeding, pain, and "bulk" sensations) muscular tumors of the uterus, known as leiomyoma or fibroids, newer treatment methods have been developed which may spare these women a hysterectomy, as well.

[0005] Hysterectomy for treating uterine fibroid disorders, though effective, has many undesirable characteristics. Thus, any method which can approximate the therapeutic result of a hysterectomy without removing the uterus (and commonly the ovaries since they are closely adjacent to the uterus) would be a significant improvement in this field.

[0006] The undesirable characteristics of hysterectomy include a known mortality rate of 0.5 deaths per 1000 hysterectomies. Stated another way, the risk of death within 30 days of hysterectomy is thirty times greater for women who have had a hysterectomy than for women of similar ages and backgrounds who have not had a hysterectomy. Morbidity (medical symptoms and problems short of death) associated with hysterectomy include possible injury to adjacent organs (the bladder, the ureters, and bowel), hospital stay of approximately one week, five to six weeks of slow recovery to normal activity three weeks of absence from work, direct medical expenses of at least $10,000, indirect cost of time away from work, a future three-fold increase in the incidence of cardiovascular disease, decreased sexual pleasure in approximately thirty percent of women, and depression and anxiety for many years after the hysterectomy for approximately eight percent of women.

[0007] The endometrium is a glandular mucous membrane of the uterus, the thickness and structure of which varies with the phase of the menstrual lining. It is normal for portions of the lining to slough off and bleed during menstruation, but many women suffer from painful dysfunctional uterine bleeding or endometritis. Thus, endometrial ablation (removal or destruction of the endometrium) may be an alternative to hysterectomy for approximately 60,000 women. A great many new devices have been invented to perform endometrial ablation to treat dysfunctional uterine bleeding. To distinguish the present invention and its applications from endometrial ablation devices, the endometrial ablation devices will be briefly described. Endometrial devices can be categorized into two major groups: devices which require direct visualization of the endometrium to apply an energy source to ablate the endometrium; and those that do not require visualization for their application.

[0008] Direct visualization of the lining of the uterus is accomplished by placing a hysteroscope through the vagina and into the uterus via the cervical os (opening). The hysteroscope image is then displayed as a color image on a TV monitor adjacent to the patient. The gynecologist then manipulates the hysteroscope and endometrial ablation instrument to ablate the lining of the uterus. Endometrial lining ablation instruments directed by hysteroscope include radiofrequency or electrosurgery loops, roller-balls, and lasers. The goal of all of these hysteroscopic endometrial ablation instruments is to transfer heat energy to the endometrium sufficiently to heat and thereby destroy it. An ablated endometrium cannot respond physiologically or pathologically to hormonal stimulation and cannot, therefore, proliferate and bleed.

[0009] To treat all of the endometriu, it must be entirely visible through the hysteroscope. However, visualization of all of the endometrium is difficult. The uterus must be distended like a water balloon to allow adequate visualization. In this distension process, some women become water intoxicated and hyponatremic. Furthermore, the uterine cavity is an awkward shape, somewhat triangular and often angulated. Directly visualizing each and every square millimeter of endometrial surface and ablating each and every square millimeter is seldom achieved. Consequently, portions of the dysfunctional endometrium may persist and dysfunctional bleeding may continue.

[0010] Because of these hysteroscopic visualization and ablation limitations, alternative methods have been invented to destroy the lining of the uterus without the need at all for visualization of the uterine lining. On such method uses a prototypic instrument, the ThermaChoice™ balloon, which is produced by GyneCare, a division of Ethicon, Inc. (see U.S. Pat. No. 5,776,129, incorporated in its entirety herein). This device is inserted through the vagina into the uterus via the cervical os. The balloon is shaped like a triangle to conform to the shape of the uterus. Once in place, hot fluid is added to the balloon to heat and destroy the uterine lining. Treatment only occurs where the balloon is in adequate contact with the uterine lining. As an alternative, hot fluids can be directly introduced into the uterus (e.g., ENABL brand system manufactured by Innerdyne, Inc., and marketed by U.S. Surgical Corporation).

[0011] Endometrial destruction can also be brought about with chemical damage, photochemical injury, or thermal damage (heat or cold). Energy that reaches and destroys the cells of the endometrial lining of the uterus potentially destroys the uterine lining and thereby treats dysfunctional uterine bleeding.

[0012] Surgically removing fibroids or in situ ablation of uterine fibroids is a bit like eradicating ants in the pantry—they are not all seen from one perspective and there may be a lot of them. Commonly, a diagnosis of uterine fibroids involves the presence of multiple fibroids, often averaging ten fibroids or more per afflicted uterus. Consequently, it is difficult to know which fibroid is causing symptoms to the patient (bleeding, pain, and bulk effects on adjacent organs). Furthermore, fibroids occur at different layers in the uterus.

Uterine fibroids can occur adjacent to the lining of the uterus (submucosal fibroid), in the myometrium (intramural fibroid), or adjacent to the outer layer of the uterus (subserosal fibroid). Consequently, if one is directly observing the uterus from the peritoneal cavity, only subserosal fibroids would be seen. If one is directly observing the uterus from the endometrial surface of the uterus, only the submucosal would be seen. Fibroids deep within the wall of the uterus are poorly visualized from either surface. Finally, since fibroids come in all sizes, only the larger fibroids will be seen in any case.

[0013] Clearly, the strategy of identifying which individual fibroid is causing symptoms (when there are often many), finding that fibroid, and then either removing or destroying that individual fibroid is a rather complex strategy. It is therefore easy to understand why the hysterectomy is such a common surgical choice. With hysterectomy, all uterine fibroids are removed in one stroke.

[0014] In 1995, it was demonstrated that fibroids, in a uterus that contained one or multiple fibroids, could be treated without hysterectomy using a non-surgical therapy, specifically comprising bilateral intraluminal occlusion of the uterine arteries (Ravina et al., "Arterial Embolization to Treat Uterine Myomata", Lancet Sep. 9, 1995; Vol. 346; pp. 671-672, incorporated in its entirety herein). This technique is known as "uterine artery embolization". The technique uses standard interventional radiology angiographic techniques and equipment, whereby the uterine arteries are accessed via a transvascular route from a common femoral artery into the left and right uterine arteries.

[0015] Three facts explain the success of uterine artery embolization. First, it has been established that pelvic bleeding from a wide variety of sources (e.g., auto accidents, surgical errors, and post partum hemorrhage) can be effectively controlled with embolization techniques using coils placed in arterial and venous lumens (U.S. Pat. Nos. 4,994,069, 5,226,911, and 5,549,824, all of which are incorporated in their entireties herein) (available from Target Therapeutics), or particles (GELFOAM pledgets, available from Upjohn, Kalamazoo, Mich., or IVALON particles, available from Boston Scientific).

[0016] Second, fibroids live a tenuous vascular life with very little ability to recruit a new blood supply from the host when the primary blood supply is compromised. Third, the uterus has a dual (or redundant) blood supply; the primary blood supply is from the bilateral uterine arteries, the secondary blood supply from the bilateral ovarian arteries (see **FIG. 4**).

[0017] Consequently, when both uterine arteries are occluded, i.e. bilateral vessel occlusion, the uterus and the fibroids contained within the uterus are both deprived of their blood supply. However, as demonstrated by Ravina et al., the effect on the fibroid is greater than the effect on the uterus. In most instances, the fibroid withers and ceases to cause clinical symptoms.

[0018] The uterine artery embolization technique utilized by Ravina et al. uses standard transvascular equipment, available in typical interventional radiology angiography suite. This equipment includes guide catheters to selectively enter the tortuous right and left uterine arteries, Ivalon or Gelfoam particles, and intravascular coils. With skill and these standard angiographic tools, the uterine arteries can be occluded bilaterally and fibroid disease treated through a **2** mm hole in the right groin and through the right common femoral artery. Following the procedure, the arterial puncture site is held with manual pressure for fifteen minutes. While post-procedural pain is often significant, and requires intravenously delivered pain medication, the patient is typically fully recovered in a few days.

[0019] The problem with uterine artery embolization is simple. The physicians who know how to do the procedure are interventional radiologists, who do not take care of gynecology problems. The physicians who take care of gynecology problems do not possess the skill necessary to perform catheter based uterine artery embolization. Accordingly, only hundreds of uterine artery embolizations have been performed, worldwide, over the past three years, whereas hundreds of thousands of hysterectomies have been performed each year for uterine fibroids which are symptomatic.

[0020] What is needed, therefore, are devices and methods which allow an average gynecologist to occlude the uterine arteries through a transvaginal approach, the standard site of access for evaluating and treating gynecologic disease.

SUMMARY OF THE INVENTION

[0021] In accordance with a first exemplary embodiment of the present invention, a system for treating disorders which receive blood from the uterine arteries by causing at least partial occlusion of a uterine artery comprises means for sensing a location of a uterine artery; and means for at least partially penetrating an anatomical structure in the region of the uterine artery to cause at least partial occlusion of the uterine artery to thereby decrease the blood flow to the uterus and said disorder.

[0022] In accordance with a second exemplary embodiment of the present invention, a system for treating disorders in a human female, which receive blood from at least one of the uterine arteries, by causing at least partial occlusion of a uterine artery comprises a cannula having a proximal end and a distal end, an ultrasonic transducer positioned adjacent said distal end, said ultrasonic transducer capable of sensing the location of anatomical structures in a sensing plane when energized, and a tissue penetrating member having a distal end and being movable relative to said cannula between a retracted position and a extended position, said tissue penetrating member distal end being substantially in said sensing plane when said tissue penetrating member is in said extended position.

[0023] In accordance with a third exemplary embodiment of the present invention, a system for treating disorders in a human female, which receive blood from at least one of the uterine arteries, by effecting at least partial occlusion of a uterine artery comprises a locating cannula having a proximal end and a distal end, said locating cannula including a locating device positioned adjacent said distal end, said locating device capable of sensing the location of anatomical structures in at least a sensing plane when energized, and a tissue penetrating cannula having a distal end and including a tissue penetrating member, said tissue penetrating cannula being movable independent from and relative to said locating cannula between a retracted position and a extended position, said tissue penetrating member distal end being

substantially in said sensing plane when said tissue penetrating member is in said extended position.

[0024] In accordance with a fourth exemplary embodiment of the present invention, a method of treating a disorder that receives blood from at least one uterine artery by at least partially cutting off the blood supply to said disorder comprises the steps of penetrating tissue to reach a point adjacent said uterine artery, and occluding said uterine artery to at least partially cut of the blood supply to said disorder.

[0025] Still other objects, features, and attendant advantages of the present invention will become apparent to those skilled in the art from a reading of the following detailed description of embodiments constructed in accordance therewith, taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] The invention of the present application will now be described in more detail with reference to preferred embodiments of the apparatus and method, given only by way of example, and with reference to the accompanying drawings, in which:

[0027] **FIG. 1** is an illustration of a treatment option in accordance with the present invention;

[0028] **FIG. 2** is an illustration of a second treatment option in accordance with the present invention;

[0029] **FIG. 3** is an illustration of relationships between several mechanisms of occlusion of uterine arteries in accordance with the present invention;

[0030] **FIG. 4** is a schematic view illustrating the reproductive anatomy of a typical human female patient, including, in particular, the vagina, the uterus, and the left and right uterine arteries;

[0031] **FIG. 5** is a perspective illustration of a first exemplary embodiment of an apparatus in accordance with the present invention;

[0032] **FIGS. 6 and 7** are perspective illustrations of a second exemplary embodiment of an apparatus in accordance with the present invention;

[0033] **FIG. 8** is a schematic illustration of a distal end portion of an apparatus in accordance with the present invention, and illustrating an imaging plane;

[0034] **FIG. 9** is a cross-sectional view of the embodiment illustrated in **FIG. 8**, taken at line **9-9**;

[0035] **FIG. 10** is an illustration of a cross-section of a uterus in which an apparatus in accordance with the present invention has been located;

[0036] **FIG. 11** is a schematic illustration of a yet another exemplary embodiment of an apparatus in accordance with the present invention;

[0037] **FIG. 12** is a schematic illustration of an endviewing embodiment of an apparatus in accordance with the present invention;

[0038] FIGS. **13-33** schematically illustrate several additional exemplary embodiments of apparatus in accordance with the present invention;

[0039] FIGS. **34-39** illustrate an exemplary method of occluding a uterine artery in accordance with the present invention;

[0040] FIGS. **40-42** illustrate a second exemplary method of occluding a uterine artery in accordance with the present invention;

[0041] **FIG. 43** illustrates yet another exemplary method of occluding a uterine artery in accordance with the present invention, by a transrectal approach;

[0042] **FIG. 44** illustrates yet another exemplary method of occluding a uterine artery in accordance with the present invention, by a combined transrectal and transvaginal approach; and

[0043] **FIG. 45** illustrates yet another exemplary method of occluding a uterine artery in accordance with the present invention, by a retroperitoneal approach.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0044] Neither image-directed endometrial ablation nor non-image-directed endometrial ablation is presently utilized to treat uterine fibroids, the subject of the present application. In fact, the presence of uterine fibroids may be a contraindication for the use of any of the endometrial ablation techniques, since the fibroid might be eroded by the endometrial ablation and thereby be stimulated to bleed uncontrollably.

[0045] The present invention is directed to the problem of treating the **200,000** women who annually undergo hysterectomy for symptomatic fibroid disease. Therapies have been devised to also treat uterine fibroids without hysterectomy. For example, surgical methods (both open, interventional surgery and endoscopic/hysteroscopic surgery) have been developed to destroy fibroids (myomas) in situ (myolysis). Myomectomy uses standard or miniature surgical instruments to cut a fibroid away from the uterus. After the fibroid is cut away, the uterine muscle is then sutured back together. Myolysis is a process by which probes are used to focus energy directly into the fibroid to heat the fibroid tissue sufficiently to destroy the fibroid. Energy sources such as laser, radiofrequency energy, and microwave energy have been used for this purpose.

[0046] The present invention solves the problems outlined above by providing devices and methods for treating uterine disorders, particularly uterine fibroids, by occluding the uterine arteries using trans-vaginal, trans-uterine, trans-rectal, and retroperitoneal approaches. An important advantage of the invention is that the inventive procedures may be performed by a patient's gynecologist in the course of treatment, avoiding the need for referrals to specialist practitioners and for more radical treatments, such as hysterectomies.

[0047] Referring to the drawing figures, like reference numerals designate identical or corresponding elements throughout the several figures.

[0048] **FIGS. 1 and 2** illustrate two different treatment options or variables the values of which can be achieved with systems and processes in accordance with the present invention. **FIG. 1** illustrates that the present invention is usable for both temporary and permanent occlusion of the

uterine artery or arteries, while **FIG. 2** illustrates that the present invention is usable for either complete or partial occlusion. The four permutations available through these different modalities enable the practitioner to customize treatment for a particular patient based upon the doctor's evaluation of the patient's clinical symptoms, as well as other factors which bear on the decision to treat uterine myomas with the system and processes of the present invention.

[**0049**] **FIG. 3** illustrates relationships between the mechanisms of occluding the uterine arteries which form a part of the system and processes of the present invention. There are at least five general mechanisms which can be used, either individually or in combinations, to occlude the uterine arteries. Ionizing radiation, which includes X rays, gamma rays, and radiation from brachytherapy seeds (radioactive particles), can be focused on the uterine arteries and surrounding tissues at high energy levels to kill this tissue, which initiates a clotting sequence in the uterine artery leading to total occlusion. Mechanical occlusion, including occlusion using clips, T-bars, loops, snares, coils or springs, "bulk" agents, and staples, involves capturing and crushing the uterine artery (and likely adjacent tissue) to mechanically reduce or cut off the flow of blood therethrough.

[**0050**] Chemical occlusion of the uterine arteries in accordance with the present invention includes injecting or otherwise exposing the uterine artery and adjacent tissue, if convenient or necessary, to chemical agents which cause tissue necrosis, which also initiates a clotting sequence. Such chemical agents include ethyl alcohol (EtOH), Sotradechol, and generally strong acids and bases which can be locally administered without causing systemic toxicity. Thermal occlusion can include lasers, hot fluids, cold fluids, radio frequency (RF) energy, microwave energy, focused ultrasound, and mechanical ultrasound, by which the uterine arteries are heated to temperatures which cause cell death, typically above 45° C., preferably between about 60° C. and about 70° C., which also initiates a cascade which causes vessel occlusion.

[**0051**] Vascular uterine artery occlusion involves at least intravascular and extravascular modalities. Intravascular initiation of an embolism that will cause uterine occlusion, in accordance with the present invention, includes injection of occluding particles and/or thrombotic agents directly into the uterine arteries so that a clotting sequence is rapidly commenced, terminating in uterine artery occlusion. In a similar manner, an agent which can initiate a clotting sequence can be administered systemically, yet only activated in the uterine artery (e.g, by EM radiation, heat transfer, or chemical interaction) by localizing and focusing an activation energy or compound only in the uterine arteries. Extravascular initiation of embolism in the uterine arteries can be accomplished by, e.g, heating the blood extravascularly in the uterine arteries to coagulate the blood, thereby initiating a clotting sequence.

[**0052**] As will be readily appreciated by one of ordinary skill in the art, the modalities described above are merely exemplary, and other equivalent modalities are also within the spirit and scope of the present invention. For example, combining two or more modalities for occlusion of a single uterine artery is also within the scope of the present invention. By specific example, and not by way of limitation, a embolism in and occlusion of a uterine artery can be effected in accordance with the present invention by mechanically closing a uterine artery, and injecting an agent into the artery (and surrounding tissue, if necessary or convenient) which initiates a clotting sequence in the quiescent arterial blood, waiting a proscribed time to allow the blood to fully clot, and removing the mechanical clamping, leaving the uterine artery relatively intact, yet fully occluded. Other combinations of two or more mechanisms of occlusion of the uterine arteries will be readily apparent to one of ordinary skill in the art.

[**0053**] **FIG. 4** illustrates a typical reproductive system for a human female patient, including a uterus **10**, vagina **12**, right ovary **14**, and left ovary **16**. Blood is supplied to the uterus **10** primarily via the right uterine artery **18** and the left uterine artery **20**, and secondarily via the right ovarian artery **22** and the left ovarian artery **24**, all of which are supplied by the aorta **26**.

[**0054**] **FIG. 5** illustrates a first exemplary embodiment of an intrauterine instrument **30** in accordance with the present invention constructed to enable a practitioner to readily occlude the uterine arteries. Instrument **30** includes a proximal handle **38** and a cannula **36**. Cannula **36** includes a rigid shaft **40** and a distal portion **42**. Cannula **36** preferably includes a first lumen **44** (see **FIG. 9**) which extends from the proximal end of instrument **30** to a distal port **45**. A guidewire **46** is positioned in lumen **44** and is movable out distal port **45** and sufficiently rigid to guide cannula **36** into the uterus of a patient, yet flexible enough to conform to the shape of a uterus without damaging it.

[**0055**] A supporting member **58** is positioned in distal portion **42**, and extends or is extendable away from cannula **36** to push against a uterine wall, deflect distal portion **42** toward an opposite uterine wall, and support the cannula in the uterine cavity, as described in greater detail below. Distal portion **42** of cannula **36** also includes an imaging window **54** on a side of the cannula opposite supporting member **58**, so that when the supporting member bears against a uterine wall, the window is pressed up against an opposite uterine wall.

[**0056**] As illustrated in **FIG. 5**, supporting member **58** includes a band or belt **55** which is laterally flexible, to allow the belt to be flexed in and out, yet longitudinally rigid, so the supporting member does not collapse. Suitable materials for belt **55** include some stainless steels, nickel/titanium alloys, polymers, composite materials, and other materials which will be readily apparent to one of ordinary skill in the art. The distal end **57** of belt **55** is preferably attached to cannula **36**. The proximal end of belt **55** (not illustrated) is preferably longitudinally movable to flex or bow the belt in and out to bear against a uterine wall, causing cannula **36** to move toward the opposite uterine wall. According to an alternate embodiment of the present invention, the proximal end of belt **55** can also be immovably attached to cannula **36**, with a middle section which protrudes away from cannula **36** as illustrated in **FIG. 5**. In this alternate embodiment, belt **55** presses against a uterine wall a predetermined amount when inserted into a uterine cavity.

[**0057**] Cannula **36** is further provided with a tissue, preferably uterine tissue, penetrating member **52**, which extends distally through rigid shaft **40** from a proximal port **60** to a distal guide port **63** in distal portion **42**. Member **52** is

guided by and extendable out of guide port **63** so that a distal end **53** of the tissue penetrating member is substantially in the same plane as an imaging, viewing, or sensing plane of a locating device carried by instrument **30**, described in greater detail below. Guide port **63** guides member **52** so that distal end **53** remains in this plane (see **FIG. 8**), so that procedures which are performed by means of the tissue penetrating member can be viewed by the practitioner without the need for aligning a viewing device and the tissue penetrating member.

[**0058**] Member **52** includes a device on distal end **53** which allows the member to penetrate the muscular uterine wall tissue. In accordance with a first embodiment of the present invention, this penetrating device is a hollow needle including a bore large enough to pass instruments therethrough. In accordance with a second embodiment of the present invention, penetrating device includes an RF energy cutting element and an RF energy conducting wire extending from the cutting element proximally through instrument **30** to an RF generator (not illustrated). RF energy is preferably utilized in the present invention for penetrating the uterine wall, because it cauterizes as it cuts through tissue, resulting in substantially less bleeding. Furthermore, RF energy cutting very efficiently cuts tissue, resulting in relatively effortless advancement of tissue penetrating member **52** into and through the uterine wall toward the uterine artery.

[**0059**] The junction **41** between rigid shaft **40** and distal portion **42** can be either rigid or flexible, and if rigid, either straight or angled. Preferably, junction **41** is flexible so that distal portion **42** can be deflected to one side of longitudinal axis **56** by supporting member **58**, as described above. Optionally, instrument **30** can include a pullwire system, described in greater detail below with reference to **FIGS. 6 and 7**, which operates in conjunction with or in place of supporting member **58** to deflect distal portion **42**. Less preferably, yet still within the scope of the present invention, junction **41** can be rigid. Distal portion **42** can be rigidly attached to rigid shaft **40** at a predetermined angle (not illustrated) which would allow the practitioner to insert instrument into a uterine cavity and easily press viewing window **54** against a uterine wall, while supporting member **58** maintains this orientation. Even less preferable, yet still within the scope of the present invention, junction **41** can be rigid and straight.

[**0060**] Turning now to **FIGS. 6 and 7**, yet another embodiment of instrument **30** is schematically illustrated. In the embodiment illustrated in **FIGS. 6 and 7**, junction **41** is flexible so that distal portion **42** can be flexed from a straight orientation (**FIG. 6**) to a flexed orientation (**FIG. 7**), for the reasons stated above. **FIGS. 6 and 7** also illustrate a pullwire system **100** which assists in flexing or bending cannula **36** at junction **41**, in addition to or instead of supporting member **58**, and holding the cannula in this orientation. Pullwire system **100** includes a longitudinally rigid wire **102** extending from a distal end **104** which is rigidly attached to cannula **36** in distal portion **42**, and a proximal end **106** which is attached to a pullwire handle **108**. Handle **108** is slidably received in handle **38**, and pullwire **102** is slidably received in a lumen **110** which extends parallel to tissue penetrating member **52**. Handle **108** includes a set of teeth **112** against which a detent **114** is forced by a spring **116**. The combination of spring **116**, detent **114**, and teeth **112** result in handle **108** being held in discrete, particular longitudinal positions. As will be readily appreciated by one of ordinary skill in the art, pulling proximally on handle **108** results in pullwire **102** deflecting distal portion to the right in **FIGS. 6 and 7**, which position is maintained without further user action by detent **114** acting on teeth **116**.

[**0061**] **FIGS. 8 and 9** illustrate cannula. **36** being used to visualize, provide an image of, or otherwise sense the position and location of a uterine artery **20**. A locating device **70** is mounted in distal portion **42**. Locating device **70** can be an ultrasonic imaging device, a gray scale color 2D (Duplex) Doppler ultrasound system, available, for example, from Diasonics, of Santa Clara, Calif., Doppler audio ultrasound systems or other locating systems which are generally available to and used in gynecological practice, including other conventional ultrasound systems as will be readily apparent to one of ordinary skill in the art. Locating device can be a combination of systems, e.g., a 2D (Duplex) Doppler ultrasound system with a Doppler audio ultrasound system, a less complicated, single system, e.g., Doppler audio ultrasound system alone, or even a simple landmarking system, e.g., markings on the outer wall of the cannula so a practitioner can visually determine the location of the cannula relative to anatomical features of the patient. A Doppler audio ultrasound system can advantageously be used by the practitioner listening for an increase in the magnitude of sound produced by the system, which indicates an increase in blood flow velocity near the focal point of the system. Additional details of such Doppler audio ultrasound systems will be readily apparent to one of ordinary skill in the art.

[**0062**] In the embodiment illustrated in **FIG. 8**, ultrasound imaging device **70** generates an image in a plane or portion of a plane **68**, which is pointed or directed through viewing window **54**. As discussed above, tissue penetrating member **52** is extendable into and along this plane **68**, so that distal tip **53** (not illustrated in **FIG. 8** for ease of visualization) of member **52** can be visualized by device **70** while penetrating the uterine wall toward uterine artery **20**. The alignment of the sensing or viewing plane of device **70** and tissue penetrating member **52** allows the gynecologist to easily find and occlude the uterine artery with instruments and processes in accordance with the present invention.

[**0063**] **FIG. 9** illustrates a cross-sectional view of cannula **36**, taken at line **9-9** in **FIG. 8**. A lumen **44** is illustrated through which guidewire **46** (not illustrated in **FIGS. 8 and 9**) extends, a lumen **48** in which viewing device **70** is mounted, and a lumen **50** through the proximal portions of which tissue penetration member **52** extends.

[**0064**] **FIG. 10** is a schematic illustration of a cross-sectional view of a uterus **10** in which a cannula **36** has been inserted. Uterus **10** includes a uterine cavity **11**, and is supplied blood primarily by uterine arteries **18** and **20**. Cannula **36** is insertable into uterine cavity **11** (described in greater detail below) and deflectable, either by flexing at junction **41** (see FIGS. **5-7**) or by deflection of a rigid cannula, so that the cannula bears against a uterine wall. Cannula **36** can be rotated around axis **56** (not illustrated in **FIG. 10**; see **FIG. 5**) so that viewing plane **68** can sweep out a volume in which the uterine arteries lie. Thus, the uterine arteries can be readily located through the uterine wall via a intrauterine approach.

[0065] **FIG. 11** illustrates yet another exemplary embodiment of an instrument in accordance with the present invention. Similar to the embodiments previously described, cannula **36** has a junction **41**, and a tissue penetrating member **52** having a distal end **53** extends out a guide port **63**. A viewing window **54** is provided for an imaging device (not illustrated). An inflatable balloon **118** is provided in the place of belt **55**, and is inflatable by injecting fluid through a lumen **120** which extends proximally through cannula **36**. Inflatable balloon **118** is inflatable to bear against a uterine wall to support cannula **36** against an opposite uterine wall. Cannula **36** further includes a lumen **122** which extends proximally from a distal port **124**. Lumen **122** is provided to allow a liquid, gel, or other medium which acts as an acoustic coupler for an ultrasound device mounted within cannula **36**, to be injected out or immediately adjacent to viewing window **54**. As will be readily appreciated by one of ordinary skill in the art, proper visualization using ultrasound equipment requires that the ultrasound transducer **70** not be separated from the tissue through which it is viewing by any air gap. An air gap between the transducer and the tissue causes reflections, which do not allow the ultrasound waves to travel into the tissue. An acoustic coupling medium, such as a commercially available ultrasound gel, eliminates such air gaps. Thus, lumen **122** is provided to allow a practitioner to inject such an acoustic coupling medium into the viewing window so an ultrasound viewing device **70** can properly produce an image of the uterine tissues.

[0066] **FIG. 12** illustrates yet another embodiment in accordance with the present invention. A cannula **136** includes a rigid shaft **140** to which a handle **138** is attached. Cannula **136** does not include a flexible portion, but may optionally include a bent distal portion **142**. A viewing window **154** is provided at the distal end of cannula **136**, directed distally. Similarly, a tissue penetrating member **152** is provided which is extendable distally from the distal end of cannula **136**. Similar to the embodiments previously described, tissue penetrating member **152** is extendable into and along the plane of an imaging device (not illustrated in **FIG. 12**) which is mounted in the distal end of cannula **136**, and which directs its viewing plane distally of the cannula distal end.

[0067] FIGS. **13-33** illustrate numerous exemplary embodiments of devices for at least partially, and optionally completely occluding a uterine artery. The numerous devices are preferably used as expedients for achieving the four permutations described with reference to **FIGS. 1 and 2**, and are merely representative of mechanisms of occlusion within the spirit and scope of the present invention. The embodiments illustrated in FIGS. **13-33** preferably share at least one common characteristic: they are each extendable through or with tissue penetrating member **52** or **152** through the uterine or vaginal wall of a patient to the uterine artery of interest. For this purpose, tissue penetrating member **52** or **152** further includes a lumen **59** extending between a proximal end **61** and distal end **53**, which allows a practitioner to push one of the devices through the tissue penetrating member **52** or **152** to effect occlusion of a uterine artery.

[0068] Turning now to the individual drawing figures, **FIG. 13** illustrates a snare **160** which is sized to pass through lumen **59**. Snare **160** includes a tubular shaft **162** which is resiliently flexible to allow the snare to be extended through lumen lumen **59**, and rigid enough to avoid kinking. Snare **160** includes two interlocking fingers **164, 166** which extend out of shaft **162** and include interlocking portions **168, 170** at their respective distal end. The proximal ends of fingers **164, 166** (not illustrated) are hinged together, and are attached to a longitudinally extending actuating rod **172**. Fingers **164, 166** are biased away from each other by their own resilience, so that interlocking portions **168, 170** open to allow snare **160** to be advanced over a uterine artery.

[0069] To use snare **160** to occlude a uterine artery, shaft **162** is advanced out the distal end **53, 153** of tissue penetrating member **52, 152** after the member has penetrated the uterine wall and is adjacent the uterine artery of interest. Imaging device **70** allows a practitioner to accurately position distal end **53, 153** adjacent the uterine artery. Rod **172** is then pushed, allowing fingers **164, 166** to separate. The snare is then advanced over the uterine artery and adjacent tissues, and rod **172** is pulled back. Snare **160** is sized so that when interlocking portions **168, 170** meet, snare **160** crushes the uterine artery, and immediately adjacent tissues if necessary or convenient, thus forming an occlusion. These steps are then reversed for removing snare **160**, leaving the uterine artery crushed and occluded.

[0070] **FIG. 14** illustrates a clip **174**, similar in structure to a typical aneurysm clip. Clip **174** includes a spring formed of a resilient material, such as a titanium or stainless steel alloy, and having a coiled spring **176**. The ends of spring **176** are connected to two actuation portions **178, 180**, each actuation portion having an angled extension **182, 184** which angle toward each other. A pair of jaws **186, 188** are provided on the ends of the extensions **182, 184**. As will be readily appreciated by one of ordinary skill in the art, jaw **186, 188** are biased toward each other by spring **176**. When angled extensions **178, 180** are pressed toward each other by an opening force along vector **190**, the jaws open against a spring reaction force generated by the spring; when the opening force along vector **190** is zero, the spring biases the jaws toward each other to close the jaws, illustrated in **FIG. 14**.

[0071] To use clip **174** to occlude a uterine artery, the clip is advanced out of distal end **53, 153** of tissue penetrating member **52, 152** with an actuator (not illustrated) which applies a force along vector **190** to open jaws **186, 188**. The open jaws **186,188** are advanced around a uterine artery of interest, and adjacent tissues if convenient. The actuator then releases clip **174**, which clamps onto the uterine artery, crushing and occluding it. Clip **174** is left in position on the uterine artery, and the actuator is retracted.

[0072] **FIG. 15** illustrates a clamp or staple applier **192** which can be used in a fashion similar to snare **160**. Clamp **192** includes two jaws **194, 196** which are biased apart and are hinged to an actuating rod **198**. The use of clamp **192** to occlude a uterine artery is somewhat similar to the use of snare **160**, except that jaws **194, 196** are forced closed by distal end **53,153** of tissue penetrating member **52, 152**, in a manner similar to shaft **162**. Jaws **194, 196** are advanced out of distal end **53, 153** and around a uterine artery of interest. Tissue penetrating member **52, 152** is then further distally advanced to bear on the outer portions of jaws **194, 196**, forcing the jaws toward each other to crush the uterine artery between them. When used as a staple applier **192**,

jaws **194, 196** include an anvil (not illustrated) therebetween for a staple to be deformed against.

[**0073**] A discussed briefly above, another example of incorporating multiple mechanisms of occlusion (see **FIG. 3**) of a uterine artery is to form actuating rod **198** and jaws **194, 196** of a material which allows the jaws to function as a heater to close, seal, or otherwise occlude the uterine artery and adjacent tissue caught between them. By connecting rod **198** to an appropriate electric source, and forming jaws **194, 196** of a resistive heating material, the partially or completely crushed uterine artery can be further occluded by heating the vessel tissues, blood, or both sufficiently to cause an embolism to form in the uterine artery. As will be readily appreciated by one of ordinary skill in the art, combining two or more mechanisms of occlusion in accordance with the principles of the present invention allows a practitioner to more confidently occlude a uterine artery, because the plurality of mechanisms provides a redundancy of occlusion modalities which greatly increases the success rate of vessel occlusion.

[**0074**] **FIG. 16** illustrates an RF energy probe **200** including an RF energy tip **202** and a conducting rod **204**. Conducting rod **204** is in electrical communication with an RF energy generator (not illustrated) proximal of handle **38, 138**. In a manner which will be readily appreciated by one of ordinary skill in the art, probe **200** can be advanced out distal end **53, 153** of tissue penetrating member **52, 152** to a point adjacent a uterine artery. RF energy is then allowed to flow through conducting rod **204** to tip **202**, to heat the uterine artery, adjacent tissues, and blood in the uterine artery to cause the uterine artery to be occluded. According to yet another embodiment, probe **200** can used instead of tissue penetrating member **52, 152**, and operated at different power levels: a high power level to advance through the uterine wall; and a lower energy lever to heat the uterine artery, blood in the uterine artery, or both to cause occlusion.

[**0075**] **FIG. 17** illustrates a microwave probe **206** including a microwave antenna **208** housed within a protecting sleeve **210**. In a manner similar to probe **200**, probe **206** can be advanced to a point adjacent a uterine artery of interest, and microwave energy can be emitted from antenna **208** to heat the uterine artery, adjacent tissues, and blood in the uterine artery to cause the uterine artery to be occluded.

[**0076**] **FIGS. 17***a*-**17***c* illustrate a probe **165** which includes a tubular member **167** and a wire **169**. Wire **169** is movable longitudinally relative to probe **165** to advance the wire distally of the distal end of the probe. Wire **169** is formed of a material which has "memory," i.e., will change shape from a first shape to a second shape when a particular stimulus affects the wire. Preferably, wire **169** is formed of a shape memory alloy (SMA) which has been formed to have a first, straight shape, illustrated in **FIG. 17***a*, and a second, curved shaped, illustrated in **FIG. 17***c*. More preferably, wire **169** is formed of a shape memory alloy having a transition temperature between about 65° F. (18.3° C.) and about 100° F. (37.8° C.), so that the wire has an open configuration below the transition temperature and a closed configuration above the transition temperature. The details of SMAs and their uses will be understood by one of ordinary skill in the art.

[**0077**] In order to use probe **165** to occlude a uterine artery **20** of interest, probe **165** is maintained at a temperature below its transition temperature, and therefor wire **169** remains in its first, straight shape. It is then advanced through tissue penetrating member **52, 152** to a point adjacent to a uterine artery in a manner so that its temperature remains below the SMAs transition temperature. Wire **169** then heats up because of its intimate contact with tissue, and continues to heat up to reach a steady state temperature near that of the tissue in which it is inserted. As wire **169** heats up to a temperature above the transition temperature of the SMA of which it is formed, the wire begins to change shape toward its second, curved shape, illustrated in **FIG. 17***b*. As wire **169** changes shape as it heats up, the wire loops around uterine artery **20**. As wire **169** reaches a temperature close to the temperature of the tissue in which it has been inserted, the wire has completed the transition to its second, curved shape and has snared uterine artery **20** (see **FIG. 17***c*). At this point, wire **169** can be pulled back to crush the uterine artery, and immediately adjacent tissues if necessary or convenient, thus forming an occlusion. Thereafter, wire **169** can be detached from probe **167** and left around uterine artery **20**. Alternatively, wire **169** can be cooled by injection of cold fluid, e.g. saline, down tubular member **167** to cause the wire to straighten, because the wire's temperature is dropped below the SMA transition temperature, as will be readily appreciated by one of ordinary skill in the art. When wire **169** is straight, it can then be withdrawn.

[**0078**] FIGS. **18-19** illustrate a probe **214** which can be used to position a loop or suture **212** around a uterine artery **20** and cinched closed to crush the uterine artery (**FIG. 19**). Probe **214** includes two tubular members **215, 217** which are movable both proximally and distally relative to a tube **219**, but also can pivot toward and away from each other in a manner which will be readily apparent to one of ordinary skill in the art. Tubular member **215** includes a first guide tube **221** and a second guide tube **223** connected to first guide tube **221** at an angle. Second guide tube **223** extends toward and is open toward tubular member **217**, and preferably includes a sharpened end **225**. First guide tube **221** preferably includes a barrier **227** inside lumen **229**, to guide suture **212** into second guide tube **223**. Tubular member **217** includes a lumen **231** which opens at a port **233**. Preferably, tubular member **217** includes a barrier **235** to guide suture **212** proximally down lumen **231**.

[**0079**] To use probe **214** to occlude a uterine artery, the probe is advanced out of a tissue penetrating member **52, 152** so that tubular members **215, 217** are positioned on opposite sides of a uterine artery **20** of interest (see **FIG. 18***b*). Suture material **212** is loaded into lumen **229**, preferably by advancing the suture material distally, as indicated by arrow **237**. Tubular member **215,217** are then pivoted toward each other to that sharpened end **225** of second guide tube **223** moves through tissue around uterine artery **20** and seats itself in port **233** of tubular member **217** (see **FIG. 18***a*). A length of suture material **212** is then pushed out of second guide tube **223** in the direction indicated by arrow **239**, through port **233**, and into lumen **231**. Barrier **235** guides suture **212** proximally along lumen **231**, in the direction indicated by arrow **241**. Then, tubular members **215, 217** are pivoted away from each other and withdrawn into tube **219**, leaving a loop of suture material around uterine artery **20** (see **FIG. 18**). Loop **212** can be either left around uterine artery **20**, or released after a predetermined length of time sufficient to ensure that the uterine artery is occluded. If loop **212** is left in place, cinched around artery

20 (see **FIG. 19**), loop **212** may optionally be formed of a resorbable material which slowly dissolves over time.

[**0080**] FIGS. **20-22** illustrate a clip applier assembly **216** which includes a clip **218** of a nonresilient, deformable material, and a clamp **219** which both holds the clip and selectively crushes the clip around a uterine artery. Clamp **219** includes a pair of opposed jaws **220**, **222**, which hold clip **218** between them. Jaws **220**, **222** are hinged at a hinge **230**. Jaws **220**, **222** include bearing surfaces **226**, **228**, which bear against the distal end of a tube **224** which carries clamp **219** and clip **218**. A pullwire **232** extends proximally from hinge **230** to handle **38**, **138**, and is accessible to the practitioner.

[**0081**] In operation, illustrated in **FIGS. 21 and 22**, clip applier assembly **216** is advanced through tissue penetrating member **52**, **152** to a uterine artery **20** of interest. Clip **218** is advanced around uterine artery **20** (see **FIG. 21**). Pullwire **232** is then pulled proximally, which pulls clamp **219** partially into tube **224**. Bearing surfaces **226**, **228** bear against the distal end of tube **224**, causing jaws **220**, **222** to close and crush both clip **218** and uterine artery **20** therein. Because clip **218** is formed of a non-resilient material, the clip can be left in place around uterine artery **20** (see **FIG. 22**) either partially or completely occluding the uterine artery.

[**0082**] FIGS. **23-25** illustrate a T-bar assembly **230** in accordance with the present invention. T-bar **230** includes an end member **232** having two ends, and an adjustment member **234** attached to the end member between the two ends. Adjustment member **234** includes at least one, and preferably several (five being illustrated in FIGS. **23-25**), locking enlargements **236**. T-bar assembly **230** also includes a backup disk **238** having a hole **240** therein. As illustrated in FIGS. **2325**, adjustment member **234** extends through backup disk hole **240**.

[**0083**] Backup disk **238** is preferably formed of an elastic material having an elastic limit, and backup disk hole **240** is sufficiently smaller than locking enlargement **236**, so that the locking enlargement(s) can be pulled through the backup disk hole without exceeding the elastic limit of said elastic material. Thus, adjustment member **234**, and therefore the end member **232**, can be pulled closer to backup disk **238** and held in this orientation.

[**0084**] According to another embodiment of the present invention, locking enlargement **236** has an asymmetrical shape and backup disk hole **240** is substantially the same shape as the locking enlargement. Backup disk **238** and adjustment member **234** are rotatable relative to each other, so that when the locking enlargement is pulled through the backup disk hole, the locking enlargement and the backup disk hole can be rotated relative to each other so that the locking enlargement asymmetrical shape does not line up with the backup disk hole. Thus, the adjustment member, and therefore the end member **232**, are pulled and held closer to the back up disk.

[**0085**] Turning now to **FIGS. 24 and 25**, T-bar assembly has been advanced to a position adjacent to uterine artery **20** through tissue penetrating member **52**, with end member **232** distal of the artery. A proximal end of adjustment member **234** is pulled proximally, while distal end **53** of the tissue penetrating member pushes distally on backup disk **238**. The result of these counteracting forces on T-bar assembly **230** is to pinch uterine artery **20** between end member **232** and backup disk **238** as locking enlargements **236** pass through hole **240**, and lock the backup disk and end member on either side of the artery. Partial or complete occlusion of uterine artery **20** can be selectively achieved by monitoring blood flow through the artery on an appropriate locating device, e.g., duplex doppler ultrasound device, as adjustment member **234** is pulled proximally.

[**0086**] FIGS. **26-28** illustrate a malecot **244** which can be used to occlude a uterine artery **20** in accordance with the present invention. Malecot **244** includes an inner member having a tip **248**, and an outer member **250** surrounding the inner member. Outer member **250** and inner member **246** are movable relative to each other, because the outer member includes at least two wings **252** which collapse under pressure. When wings **252** collapse, the wings bend away from inner member **246**. Thus, when inner member **246** moves proximally relative to outer member **250**, wings **252** bend away from the inner member and toward each other. As illustrated in **FIGS. 26 and 28**, by positioning uterine artery **20** between wings **252**, the uterine artery can be partially or completely occluded.

[**0087**] To occlude a uterine artery **20** with malecot **244**, the malecot is advanced through tissue penetrating member **52**, **152** (not illustrated in FIGS. **26-28**) with a tube **254** to a position adjacent the uterine artery. A proximal end (not illustrated) of inner member **246** is pulled proximally, while tube **254** keeps outer member **250** adjacent to uterine artery **20**. The counteracting forces on outer member **250** transmitted by tip **248** and tube **254** cause wings **252** to collapse outward, crushing the uterine artery between them (see **FIG. 28**). As illustrated in **FIG. 28**, wings **252** can include several radially separated wings, and at least two sets of wings which are axially separated. Malecot **244** can be left in place, crushing uterine artery **20**, by providing a locking mechanism between inner member **246** and outer member **250** (for example, a mechanism like that described with reference to FIGS. **23-25**), or can be removed after a predetermined period of time.

[**0088**] **FIGS. 29 and 30** illustrate yet another exemplary embodiment of a device which causes occlusion of a uterine artery in accordance with the present invention. As illustrated in **FIG. 29**, an ultrasonic energy source **256** includes an ultrasonic focusing element **258** which focuses ultrasonic energy at a point **260** in uterine artery **20**, and preferably in the sensing plane of the locating device **70** (not illustrated in **FIG. 29**). The ultrasonic energy thus focused causes high, localized heating within uterine artery **20**, which initiates a clotting sequence in the blood therein to form a clot **262**. The embodiment illustrated in **FIGS. 29 and 30** can be advanced by tissue penetrating member **52**, **152** to a position close to uterine artery **20**, or alternatively can be housed in cannula **36** with locating device **70**, and focused on the uterine artery to initiate blood clotting. Preferably, **256** ultrasonic energy source is capable of emitting ultrasonic energy at a frequency and magnitude sufficient to initiate clotting of human blood by a mechanism including, but not limited, generating cavitation bubbles in human blood, heating human blood, rupturing blood cells, and combinations thereof.

[**0089**] **FIG. 31** illustrates yet another exemplary embodiment of a device which causes occlusion of a uterine artery

in accordance with the present invention. A mechanical ultrasonic energy source **264** includes an anvil **266** which can be extended distally from tissue penetration member **52**, **152**. An ultrasonic frequency vibrational energy generator **268** generates ultrasonic energy, and transmits the energy to anvil **266** through a transmission member **270** which extends between the anvil and the ultrasonic frequency vibrational energy generator. Preferably, ultrasonic frequency generator **268** is capable of generating vibrational energy sufficient-to initiate a clotting sequence in uterine artery **20** when anvil **266** vibrates. More preferably, ultrasonic frequency generator **268** is capable of generating vibrational energy at a frequency between about 20 kHz and about 50 kHz at a magnitude up to about 0.001 inches (2.54×10^{-3} cm).

[**0090**] Anvil **266** is preferably advanced through tissue penetrating member **52**, **152** to a point adjacent uterine artery **20**. Ultrasonic frequency vibrational energy generator **268** generates ultrasonic energy, which is transmitted through member **270** to anvil **266**, which vibrates and emits vibrational energy. The pressure waves created by the vibrating anvil **266** locally heats uterine artery **20**, the blood therein, and the adjacent tissue to a level sufficient to initiate a clotting sequence in the blood, and to disrupt cells in the artery wall. Thus, uterine artery **20** is caused to occlude.

[**0091**] **FIG. 32** illustrates yet another exemplary embodiment of a device which causes occlusion of a uterine artery in accordance with the present invention. A probe **272** includes a cannula **274** having a distal end **276** and two lumens **278**, **280** which are fluidly isolated from each other along the length of the cannula. The inner lumen **278** preferably conducts a heat transfer fluid distally from proximal portions of the cannula, and outer lumen **280** preferably conducts the heat transfer fluid proximally from the distal tip **282**. In distal tip **282**, lumens **278**, **280** both open into a space **284**. Preferably, space **284** provides the only fluid communication between lumens **278**, **280**. The heat transfer fluid can be either a liquid or a gas, and is at a temperature significantly different from the temperature of a uterine artery of interest. The heat transfer fluid can be either hot, to transfer heat to the uterine artery and adjacent tissues to heat the uterine artery, blood therein, and adjacent tissues. Alternatively, the heat transfer fluid can be cold, e.g., cryogenic, to transfer heat from the uterine artery and adjacent tissues.

[**0092**] To occlude a uterine artery with probe **272**, a source of heat transfer fluid (not illustrated) capable of delivering a heat transfer fluid, e.g., hot saline for heating, or liquid nitrogen, liquid oxygen, or other liquified gas for cooling, is placed in fluid communication with inner lumen **278**. Probe **272** is advanced distally through tissue penetrating member **52**, **152** to a point adjacent a uterine artery of interest, and heat transfer fluid is pumped distally down inner lumen **278**. The heat transfer fluid flows to tip **282**, reverses direction in space **284**, and is drawn proximally up outer lumen **280**. Preferably, outer lumen **280** and inner lumen **278** are coaxial. Distal tip **282** becomes and remains at a temperature very different from that of the surrounding tissue, due to the presence of heat transfer fluid in space **284**, which induces heat transfer with the uterine artery and adjacent tissues. This heat transfer quickly effects these tissues by heating or cooling the tissues, including the uterine artery, causing the artery wall's cells to die, which initiates a clotting sequence ending in occlusion of the uterine artery.

[**0093**] **FIG. 33** illustrates yet another exemplary embodiment of a device which causes occlusion of a uterine artery in accordance with the present invention. An electric heating ablation probe **286** includes a shaft **288**, which can be either solid or tubular and hollow, a resistive heating element tip **290** at a distal end of the shaft, and an electrical power transmission wire **292** extending proximally from the resistive heating element tip. As will be readily appreciated by one of ordinary skill in the art, in order to occlude a uterine artery using probe **286**, the probe is advanced distally through tissue penetrating member **52**, **152** to a point adjacent a uterine artery of interest. Current is allowed to flow through wire **292** to tip **290**, which heats up. The heat transfer from tip **290** to the uterine artery, blood therein, and adjacent tissues initiates a clotting sequence ending in occlusion of the uterine artery.

[**0094**] Processes of occluding a uterine artery in accordance with the present invention will now be described with reference to FIGS. **34-45**. As will be readily appreciated by one of ordinary skill in the art, the foregoing discussion of particular embodiments of devices in accordance with the present invention is intended to merely provide examples of apparatus and systems that are within the spirit and scope of the present invention. Furthermore, specific features of these several embodiments will not be discussed in the following description of methods of occluding a uterine artery, in order to emphasize these methods. Familiarity with specific features, in particular locating device **70**, imaging plane **68**, and tissue penetrating member **52**, **152** are presumed in the following description.

[**0095**] As illustrated in **FIG. 34, a** patient's uterus **10** is affiicted with two representative fibroids or myomas **62** and **64**, which are to be treated using the inventive procedures. Initially, guidewire **46** is extended distally from distal portion **42** of instrument **30** into uterus **10**. Then, as illustrated in **FIG. 35**, cannula **36** is advanced through vagina **12** along guidewire **46**, until it is placed within the uterus **10** (**FIG. 36**).

[**0096**] It should be noted at this point that guidewire **46**, although preferred, may optionally not be used, if desired. Alternatively, for example, an integrated dilator at the instrument tip may be employed, which would reduce the required procedural steps.

[**0097**] Once cannula **36** is in place within uterus **10**, the practitioner is ready to initiate the occluding process with respect to left uterine artery **20**. First, as illustrated in **FIG. 37**, the supporting and deflection element **58**, preferably a belt **55** as illustrated, is actuated to extend radially outwardly in the direction shown, so that, as shown in **FIG. 38**, belt **55** bears against rigid wall **65** of uterus **10**, thereby pushing the cannula in the opposing direction. This action ensures that viewing window **54** is disposed against uterine wall **65***a* adjacent to the uterine artery to be occluded (in this example the left uterine artery **20**). This has the further advantage of aiding imaging qualities, because when viewing window **54** actually contacts the uterine wall, the ultrasound gel contact clears the image conveyed to the practitioner and stability of the image is thereby improved. In this regard, it should be noted that in preferable embodiments the portions of shaft **40** proximal and distal of flexible portion **41** are rigid, so that distal portion **42** is moved responsive to extension of supporting and deflection element **58**.

[0098] Following radial extension of deflection belt **58**, tissue penetrating member **52** is advanced toward artery **20**, by the practitioner pushing distally on proximal portions of the member. To assist tissue penetrating member **52** in extending laterally relative to the axis **56** and directly into and along imaging or sensing plane **68**, a guide ramp **66** is preferably provided (see **FIG. 38**) for the distal end of tissue penetrating member **52** to push against as it is displaced distally. During the distal advancement of tissue penetrating member **52** into uterine wall **65***a*, RF energy may be supplied to the tissue penetrating member to simultaneously cut a channel into which to advance the member, and cauterize the channel.

[0099] **FIG. 39** illustrates cannula **36** when tissue penetrating member **52** is disposed with distal end **53** adjacent to uterine artery **20**. In the embodiment illustrated in **FIG. 39, a** chemical occluding agent, e.g., EtOH 294, has been injected along lumen **59** (see **FIG. 6**) of the tissue penetrating member and into the tissues surrounding the artery. Preferably, lumen **59** is constructed of or coated with a material which is non-reactive to the chemical occluding agent. As described in greater detail above, the chemical occluding agent, e.g. EtOH, will kill the tissues with which it makes contact, including left uterine artery **20**, and thus initiates a clotting sequence which results in occlusion of the uterine artery. As illustrated in **FIG. 39**, an imaging (preferably ultrasonic) plane **68** is transmitted through viewing window **54** to guide the practitioner as tissue penetrating member **52** is maneuvered radially outwardly to approach uterine artery **20** to be occluded. An occlusion **262** forms in the artery as a result.

[0100] After artery **20** is occluded, as illustrated in **FIG. 39**, cannula **36** may be withdrawn from the uterus along guidewire **46**. Then, if artery **18** has not yet been occluded, the practitioner will preferably repeat the procedural steps outlined supra with cannula **36** oppositely oriented in order to occlude artery **18**.

[0101] Instead of injecting EtOH 294, any of the mechanisms of occlusion within the scope of the present invention can be employed to occlude the uterine artery. As described in greater detail above, all of the modalities and mechanisms in accordance with the present invention are capable of occluding the uterine artery; the foregoing description which made reference to FIGS. **34-39** is merely exemplary, and one of ordinary skill in the art will readily appreciate the processes of employing these mechanisms to occlude a uterine artery.

[0102] It is also within the scope of this invention that, alternatively to the employment of an imaging system as described above, a simple landmark/anatomical reference point approach may be employed, wherein cannula **36** may be moved distally a predetermined distance past the cervical os, usually using a set of reference-markings (i.e., bands) on the cannula outer surface so that the practitioner knows with certainly the depth to which the instrument has been inserted. Once inserted to the proper position, the instrument is then rotated to a predetermined clock position (i.e., 3 o'clock) to occlude an artery, and to a second predetermined clock position (i.e. 9 o'clock) to occlude a second artery (see **FIG. 10**).

[0103] Rather than using an intrauterine approach to occlude arteries **18** and **20**, a transvaginal approach may alternatively be used in accordance with the present invention. This approach may be particularly advantageous if the patient has a uterine configuration which increases the difficulty of employing the intrauterine procedure described above. For example, a retroflex or anteflex uterine configuration might indicate a transvaginal approach. Cannula **136**, illustrated in **FIG. 12**, is suitable for occluding a uterine artery in such a procedure.

[0104] Turning to **FIG. 40**, cannula **136** is inserted through the vagina **112** until it approaches the artery **20** to be occluded. Then, image plane **168** from locating device **70** is utilized to advance cannula **136** to a position adjacent to artery **20**. Once in position, tissue penetrating member **152**, which may be any of the embodiments previously described, is activated to occlude the artery (see **FIG. 41**). Tissue penetrating member **152** is thereafter withdrawn, as illustrated in **FIG. 42**, leaving an occlusion **262**. The procedure may then be repeated to occlude the other artery **18**. As discussed supra, bilateral occlusion is important to ensure that the fibroids **62**, **64** are fully treated.

[0105] While the preferred application of the present invention is the bilateral occlusion of the uterine arteries, either trans-vaginally or trans-uterally, it is within the scope of the invention to employ a trans-rectal or retroperitoneal procedure as well, and/or to utilize apparatus in accordance with the present invention to occlude other arteries or vessels. For example, as illustrated in **FIG. 43**, there is shown a trans-rectal approach for occluding the uterine arteries. Thus, by way of orientation, **FIG. 43** illustrates the uterus **310**, vagina **312**, rectum **314**, urinary bladder **316**, and pubic bone **318**.

[0106] When it is desired to occlude one or more uterine arteries, which extend in and out of the plane of **FIG. 43** and are, therefore, not illustrated, cannula **36**, **136** is inserted through the rectum using known imaging techniques, until its distal portion **42**, **142** (see **FIGS. 5 and 12**) is disposed adjacent to the uterine artery to be occluded, at which point the occluding tip (not shown) is actuated to occlude the artery, in a manner similar to that disclosed supra with respect to the previous embodiments. Either cannula type (i.e., sideviewing cannula **36** or endviewing cannula **136**) may be utilized in this trans-rectal procedure, although the latter instrument, having an "end-view" window **154**, may be preferred in most instances.

[0107] Alternatively, two of the functions of cannulae **36**, **136**, i.e., locating and occluding, can be separately performed by separate cannulae, as illustrated in **FIG. 44**. Still utilizing a trans-rectal approach similar to that illustrated in **FIG. 43**, an imaging cannula **320** is inserted into rectum **314**, while cannula **322**, which includes a tissue penetrating member **52** extending out a distal end thereof, is inserted into vagina **312** in a manner similar to the method described above with reference to **FIG. 40**. Cannulae **320**, **322** are preferably held together by a template or block **324**, which includes holes **326**, **328** through which cannulae **320**, **322** are slidably held. Block **324** is designed so that tissue penetrating member **52** will extending into imaging plane **68** (not illustrated) of cannula **320**, in a manner similar to the prior embodiments.

[0108] **FIG. 45** illustrates an inventive retroperitoneal approach for occluding the uterine arteries, in accordance with the principles of the present invention. Using a retro-

peritoneal approach, a standard laparoscopic procedure is initiated, typically employing a trocar (not illustrated) for providing access for cannula **336**, moving the bowel and insulating the abdomen. Either an endoscope or an ultrasound imaging system is preferably used to guide advancement of the instrument through the abdomen to the vicinity of the uterine artery to be occluded, at which point a tissue penetrating member (not illustrated) is actuated to occlude the artery, in a manner similar to that disclosed above with respect to the numerous prior embodiments. Either cannula type may be utilized in this retropentoneal procedure, although the latter instrument, having an "end-view" window **154**, may be preferred in most instances.

[**0109**] In accordance with yet another embodiment of the present invention, the locating function performed by the devices described above can be performed by an external device, such as a CT scan (with or without contrast agents), fluoroscopy, radiocontrast angiography, or a MRI device. These locating devices can be used to generate a coordinate system in the patient to which the practitioner correlates the position of an instrument similar to instrument **30**. In this embodiment, however, the instrument does not include a locating system in the cannula, but rather includes the structures of cannula **36** for penetrating tissue to gain access to the uterine arteries. By locating the uterine artery of interest with the locating system's cursor, the practitioner can then correlate the position of the cursor with the position of the tissue penetrating member, and thereby carry out the methods described above with the cannula Because these locating devices provide three dimensional images of anatomical structures, and will also reveal the relative location of the cannula to the uterine arteries, the locating devices can be used to guide the practitioner to the uterine artery of interest with accuracy.

[**0110**] While the invention has been described in detail with reference to preferred embodiments thereof, it will be apparent to one skilled in the art that various changes can be made, and equivalents employed, without departing from the scope of the invention.

What is claimed is:

1. A system for treating a disorder that receives blood from a uterine artery by causing at least partial occlusion of a uterine artery, comprising:

means for sensing a location of a uterine artery; and

means for at least partially penetrating an anatomical structure in the region of the uterine artery to cause at least partial occlusion of the uterine artery to thereby decrease the blood flow to the uterus and said disorder.

2. A system in accordance with claim 1, wherein said means for sensing is directed to sense in a plane, and said means for at least partially penetrating is movable in said plane.

3. A system in accordance with claim 1, wherein said means for at least partially penetrating is movable is first direction, and further comprising means for supporting said means for at least partially penetrating against a wall of a uterus in a second direction, said second direction being substantially opposite said first direction.

4. A system in accordance with claim 3, wherein said means for supporting comprises an inflatable member.

5. A system in accordance with claim 3, wherein said means for supporting comprises a belt having a distal end fixedly attached to said system, said belt being formed of a material and having dimensions such that said belt can bow away from said means for at least partially penetrating and press against a uterine wall.

6. A system in accordance with claim 1, wherein said means for at least partially penetrating comprises a distal end and a burrowing element on said distal end.

7. A system in accordance with claim 1, wherein said means for at least partially penetrating comprises a cutting RF probe.

8. A system in accordance with claim 1, wherein said means for at least partially penetrating comprises a needle.

9. A system in accordance with claim 1, wherein said means for at least partially penetrating comprises a tubular cannula, said tubular cannula comprising a distal end and an RF cutting probe mounted on said tubular cannula distal end.

10. A system in accordance with claim 1, further comprising a cannula in which said means for sensing and said means for at least partially penetrating are located, said cannula having a proximal end and a distal end, said cannula comprising a pullwire system capable of deflecting said cannula distal end, said pullwire system including a wire attached to said cannula at a point adjacent said cannula distal end and extending proximally along said cannula, a first locking member attached to said wire proximal of said point, and a second locking member attached to said cannula which can engage with said first locking member to fix a position of said wire.

11. A system in accordance with claim 1, wherein said means for sensing a location of a uterine artery comprises means for imaging a uterine artery.

12. A system in accordance with claim 1, further comprising means for guiding said means for sensing and said means for at least partially penetrating into a uterus.

13. A system in accordance with claim 1, wherein said means for sensing a location of a uterine artery comprises a two-dimensional ultrasonic transducer and a Doppler imaging device.

14. A system in accordance with claim 1, wherein said means for sensing a location of a uterine artery comprises an ultrasonic transducer.

15. A system in accordance with claim 1, wherein said means for sensing a location of a uterine artery consists essentially of a two-dimensional ultrasonic transducer.

16. A system in accordance with claim 1, wherein said means for sensing consists essentially of a Doppler ultrasonic transducer.

17. A system for treating disorders in a human female, which receive blood from at least one of the uterine arteries, by causing at least partial occlusion of a uterine artery, comprising:

a cannula having a proximal end and a distal end;

an ultrasonic transducer positioned adjacent said distal end, said ultrasonic transducer capable of sensing the location of anatomical structures in a sensing plane when energized; and

a tissue penetrating member having a distal end and being movable relative to said cannula between a retracted position and a extended position, said tissue penetrating member distal end being substantially in said sensing plane when said tissue penetrating member is in said extended position.

18. A system for treating disorders in a human female in accordance with claim 17, wherein said tissue penetrating member further comprises means for at least partially occluding said uterine artery.

19. A system for treating disorders in a human female in accordance with claim 18, wherein said means for at least partially occluding said uterine artery comprises a snare, said tissue penetrating member including a cavity at its distal and, said snare being extendable between a retracted position in said cavity and an extended position wherein said snare extends beyond said tissue penetrating member distal end.

20. A system for treating disorders in a human female in accordance with claim 19, wherein said snare is formed of a shape memory alloy having a transition temperature between about 65° F. (18.3° C.) and about 100° F. (37.8° C.), said snare having an open configuration below said transition temperature and a closed configuration above said transition temperature.

21. A system for treating disorders in a human female in accordance with claim 18, wherein said means for at least partially occluding said uterine artery comprises a clip formed of a resilient material, said clip having a spring with two ends, a pair of jaws biased toward each other by said spring, and an actuation portion between said jaws and said spring, said actuation portion comprising two spaced apart angled extensions of said jaws each of which is joined to one of said two spring ends, said angled extensions forming angles with said jaws so that when said angled extensions are pressed toward each other by an opening force, said jaws open against a spring reaction force generated by said spring, and when said opening force is zero, said spring biases said jaws toward each other.

22. A system for treating disorders in a human female in accordance with claim 18, wherein said means for at least partially occluding said uterine artery comprises a microwave antenna positioned in said tissue penetrating member distal end.

23. A system for treating disorders in a human female in accordance with claim 18, wherein said means for at least partially occluding said uterine artery comprises a clip formed of a deformable material, a clamp, and a clamp actuating wire extending from said clamp toward said cannula proximal end, said clip being positioned in said clamp, said clamp being movable between an open orientation in which said clamp holds said clip, and a closed orientation in which said clamp deforms said clip.

24. A system for treating disorders in a human female in accordance with claim 18, wherein said clamp comprises a pair of jaws and a pivot point at which said pair of jaws are pivotally attached, said pair of jaws including at least one cam surface which bears against said tissue penetrating member, said clamp actuating wire attached to one of said pair of jaws, whereby when said clamp actuating wire is proximally retracted, said clamp actuating wire pulls said clamp at least partially into said tissue penetrating member, and said tissue penetrating member bears against said cam surface to force said jaws to at least partially close and deform said clip.

25. A system for treating disorders in a human female in accordance with claim 18, wherein said means for at least partially occluding said uterine artery comprises a cinching member including an end member having two ends, an adjustment member attached to said end member and having at least one locking enlargement, and a backup disk having a hole therein, said adjustment member extending through said backup disk hole.

26. A system for treating disorders in a human female in accordance with claim 25, wherein said cinching member comprises a T-bar having said two ends, and wherein said adjustment member is attached to said T-bar between said two ends.

27. A system for treating disorders in a human female in accordance with claim 25, wherein said backup disk is formed of an elastic material having an elastic limit, and said backup disk hole is sufficiently smaller than said locking enlargement that said locking enlargement can be pulled through said backup disk hole without exceeding said elastic limit of said elastic material.

28. A system for treating disorders in a human female in accordance with claim 25, wherein said locking enlargement has an asymmetrical shape and said backup disk hole is substantially the same shape as said locking enlargement, said backup disk and said adjustment member being rotatable relative to each other, whereby when said locking enlargement is pulled through said backup disk hole, said locking enlargement and said backup disk hole can be rotated relative to each other so that said locking enlargement asymmetrical shape does not line up with said backup disk hole shape.

29. A system for treating disorders in a human female in accordance with claim 18, wherein said means for at least partially occluding said uterine artery comprises a malecot having an inner member and an outer member surrounding said inner member, said outer member and said inner member being movable relative to each other, said outer member including a distal end, at least one distal wing, and at least one proximal wing positioned proximal of said at least one distal wing, said at least one distal wing and said at least one proximal wing being bendable away from said inner member, whereby when said outer member moves proximally relative to said inner member, said at least one distal wing and said at least one proximal wing bend away from said inner member.

30. A system for treating disorders in a human female in accordance with claim 18, wherein said means for at least partially occluding said uterine artery comprises an ultrasonic energy source mounted on one of said cannula and said tissue penetrating member, said ultrasonic energy source capable of emitting ultrasonic energy at a frequency and magnitude sufficient to initiate clotting of human blood by a mechanism selected from the group consisting of generating cavitation bubbles in human blood, heating human blood, rupturing blood cells, and combinations thereof.

31. A system for treating disorders in a human female in accordance with claim 30, wherein said ultrasonic energy source comprises an ultrasonic focusing element which focuses said ultrasonic energy at a point substantially in said sensing plane when said ultrasonic energy source emits ultrasonic energy.

32. A system for treating disorders in a human female in accordance with claim 30, wherein said ultrasonic energy source comprises an anvil distally movable from said tissue penetration member, an ultrasonic frequency vibrational energy generator, and a ultrasonic vibrational energy transmission member extending between said anvil and said ultrasonic frequency vibrational energy generator, whereby when said ultrasonic frequency generator generates vibra-

tional energy, said energy is transmitted along said ultrasonic vibrational energy transmission member to said anvil.

33. A system for treating disorders in a human female in accordance with claim 32, wherein said tissue penetrating member and said means for at least partially occluding said uterine artery both comprise said ultrasonic energy source, said ultrasonic energy source being operable at a first set of frequencies and magnitudes which generate heat sufficient to allow said tissue penetrating member to advance from said cannula at least partially through a uterine wall, said ultrasonic energy source being operable at a second set of frequencies and magnitudes which generate heat sufficient to occlude said uterine artery.

34. A system for treating disorders in a human female in accordance with claim 32, wherein said ultrasonic frequency generator is capable of generating vibrational energy at a frequency between about 20 kHz and about 50 kHz at a magnitude up to about 0.001 inches (2.54×10^{-3} cm).

35. A system for treating disorders in a human female in accordance with claim 18, wherein said means for at least partially occluding said uterine artery comprises an RF ablation probe positioned at said tissue penetrating member distal end.

36. A system for treating disorders in a human female in accordance with claim 18, wherein said means for at least partially occluding said uterine artery comprises a lumen extending proximally from said tissue penetrating member distal end, said lumen having a sidewall formed of a material which is nonreactive to a chemical occluding agent.

37. A system for treating disorders in a human female in accordance with claim 36, wherein said chemical occluding agent is EtOH.

39. A system for treating disorders in a human female in accordance with claim 18, wherein said means for at least partially occluding said uterine artery comprises a heat transfer cannula having a distal end, said tissue penetrating member comprising a lumen and a opening at said tissue penetrating member distal end, said heat transfer cannula positioned in said lumen and extendable from a retracted position and an extended position in which said heat transfer cannula distal end extends distally of said tissue penetrating member distal end, said heat transfer cannula comprising two lumens which are fluidly isolated from each other along the length of said cyrogenic cannula, said heat transfer cannula further comprising a sealed distal tip, said two lumens being in fluid communication in said heat transfer cannula only at said sealed distal tip.

40. A system for treating disorders in a human female in accordance with claim 18, wherein said means for at least partially occluding said uterine artery comprises a heating ablation element positioned on said tissue penetrating member distal end and a power transmission wire extending proximally from said heating ablation element.

41. A system for treating disorders in a human female in accordance with claim 18, wherein said cannula further comprises a lumen extending proximally from said distal end, and a guidewire having an atraumatic distal tip, said guidewire being in said lumen and movable between a retracted position and an extended position in which said guidewire atraumatic tip is distal of said cannula distal end.

42. A system for treating disorders in a human female in accordance with claim 18, wherein said cannula distal end has a longitudinal axis extending proximally from said distal end, and wherein said ultrasonic transducer is oriented in said cannula so that said sensing plane extends in a direction substantially perpendicular to said longitudinal axis.

43. A system for treating disorders in a human female in accordance with claim 18, wherein said ultrasonic transducer is oriented in said cannula so that said sensing plane extends distally from said distal end.

44. A system for treating disorders in a human female in accordance with claim 18, said cannula further comprises a guide port proximal of said distal end and a guide lumen extending proximally from said guide port, and wherein said tissue penetrating member is positioned in said guide lumen and movable in said guide lumen between a retracted position and an extended position in which said tissue penetrating member extends out of said guide port.

45. A system for treating disorders in a human female in accordance with claim 18, wherein said cannula further comprises a guide member at a distal end of said guide lumen adjacent said guide port, said guide member directing said tissue penetrating member into said sensing plane when moved from said retracted position and said extended position.

46. A system for treating disorders in a human female in accordance with claim 18, wherein said cannula is formed of a substantially rigid material, said cannula further comprises a bent portion proximal of said cannula distal end.

47. A system for treating disorders in a human female in accordance with claim 18, wherein said cannula further comprises a resilient flexible portion proximal of said cannula distal end.

48. A system for treating disorders in a human female in accordance with claim 47, wherein said cannula flexible portion includes a proximal end, and said cannula further comprises a stabilizing member at least portions of which are distal to said cannula flexible portion proximal end, said stabilizing member including uterine wall engaging portions which are positioned on said cannula opposite said sensing plane.

49. A system for treating disorders in a human female in accordance with claim 48, wherein said stabilizing member is movable from a retracted position in which said uterine wall engaging portions do not substantially extend beyond said cannula, and an extended position in which said uterine wall engaging portions extend from said cannula, whereby when said cannula is in a human uterus and said stabilizing member is in said extended position, said stabilizing member bears against a uterine wall and bends said cannula at said resilient flexible portion toward said sensing plane.

50. A system for treating disorders in a human female in accordance with claim 48, wherein said stabilizing member comprises a resilient belt having a distal end fixedly attached to said cannula at a point adjacent said cannula distal end, said resilient belt extending proximally from said resilient belt distal end, said resilient belt being longitudinally relatively rigid and laterally less rigid.

51. A system for treating disorders in a human female in accordance with claim 48, wherein said stabilizing member comprises an inflatable member and an inflation lumen in fluid communication with said dilator, said inflation lumen extending proximally from said inflatable member.

52. A system for treating disorders in a human female in accordance with claim 18, wherein said tissue penetrating member comprises a hollow needle at said tissue penetrating member distal end, said needle having a distal tip sufficiently sharp to penetrate the tissue of a female human uterine wall.

53. A system for treating disorders in a human female in accordance with claim 18, wherein said tissue penetrating member comprises an RF energy cutting member at said tissue penetrating member distal tip and an RF energy transmission element extending through said tissue penetrating member to said RF energy cutting member.

54. A system for treating disorders in a human female, which receive blood from at least one of the uterine arteries, by effecting at least partial occlusion of a uterine artery, comprising:

a locating cannula having a proximal end and a distal end, said locating cannula including a locating device positioned adjacent said distal end, said locating device capable of sensing the location of anatomical structures in at least a sensing plane when energized; and

a tissue penetrating cannula having a distal end and including a tissue penetrating member, said tissue penetrating cannula being movable independent from and relative to said locating cannula between a retracted position and a extended position, said tissue penetrating member distal end being substantially in said sensing plane when said tissue penetrating member is in said extended position.

55. A system for treating disorders in a human female in accordance with claim 54, further comprising a template including two holes, a first one of said two holes sized to receive said tissue penetrating cannula therein, a second one of said two holes sized to receive said locating cannula therein.

56. A method of treating a disorder that receives blood from at least one uterine artery by at least partially cutting off the blood supply to said disorder, comprising the steps of:

penetrating tissue to reach a point adjacent said uterine artery; and

occluding said uterine artery to at least partially cut of the blood supply to said disorder.

57. A method of treating a disorder in accordance with claim 56, wherein said penetrating step comprises penetrating tissue with a system in accordance with claim 1.

58. A method of treating a disorder in accordance with claim 56, wherein said penetrating step comprises penetrating tissue with a system in accordance with claim 17.

59. A method of treating a disorder in accordance with claim 56, wherein said penetrating step comprises penetrating tissue with a system in accordance with claim 54.

60. A method of treating a disorder in accordance with claim 56, wherein said disorder is a uterine fibroid.

61. A method of treating a disorder in accordance with claim 56, further comprising:

locating said uterine artery with a locating device selected from the group consisting of a CT scanner, a fluoroscope, X ray, a MRI device, Doppler audio device, a gray scale color 2D Doppler ultrasound device, a landmark system, and combinations thereof.

62. A method of treating a disorder in accordance with claim 56, wherein said step of penetrating tissue comprises penetrating tissue along a path selected from the group consisting of through a uterine wall, through a vaginal wall, along a rectal wall, and through the peritoneal cavity.

63. A method of treating a disorder in accordance with claim 56, wherein said step of occluding said uterine artery comprises temporarily occluding said uterine artery.

64. A method of treating a disorder in accordance with claim 56, wherein said step of occluding said uterine artery comprises permanently occluding said uterine artery.

65. A method of treating a disorder in accordance with claim 56, wherein said step of occluding said uterine artery comprises completely occluding said uterine artery.

66. A method of treating a disorder in accordance with claim 56, wherein said step of occluding said uterine artery comprises occluding said uterine artery with a form of ionizing radiation selected from the group consisting of X rays, gamma rays, and implanting brachytherapy seeds.

67. A method of treating a disorder in accordance with claim 56, wherein said step of occluding said uterine artery comprises occluding said uterine artery with a mechanism selected from the group consisting of a clip, a T-bar, a loop, a snare, a coil, a bulk agent, and a staple.

68. A method of treating a disorder in accordance with claim 56, wherein said step of occluding said uterine artery comprises occluding said uterine artery with a chemical agent selected from the group consisting of EtOH, Sotradechol, acids, and bases.

69. A method of treating a disorder in accordance with claim 56, wherein said step of occluding said uterine artery comprises occluding said uterine artery with heat transfer selected from the group consisting of lasers, hot fluid, cold fluid, RF energy, microwave, focused ultrasound, and mechanical ultrasound.

70. A method of treating a disorder in accordance with claim 56, wherein said step of occluding said uterine artery comprises occluding said uterine artery with forming a embolism in said uterine artery by performing step selected from the group consisting of injecting occluding particles into said uterine artery, injecting a thrombolytic agent into said uterine artery, systemically administering an agent to a vasculature which leads to said uterine artery and locally activating said agent, and coagulating blood in said uterine artery by localized heating of said blood.

* * * * *

专利名称(译)	用于阻塞子宫动脉的装置和方法		
公开(公告)号	US20030216759A1	公开(公告)日	2003-11-20
申请号	US10/459342	申请日	2003-06-10
[标]申请(专利权)人(译)	血流控制SYST		
申请(专利权)人(译)	血管CONTROL SYSTEMS，INC.		
当前申请(专利权)人(译)	血管CONTROL SYSTEMS，INC.		
[标]发明人	BURBANK FRED JONES MICHAEL LUBOCK PAUL		
发明人	BURBANK, FRED JONES, MICHAEL LUBOCK, PAUL		
IPC分类号	A61B18/20 A61B8/12 A61B17/12 A61B17/42 A61B18/00 A61B18/12 A61B18/14 A61B18/18 A61M25/00 A61M25/01 A61B17/08		
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其他公开文献	US7771357		
外部链接	Espacenet USPTO		

摘要(译)

公开了用于治疗子宫疾病的装置和方法，所述子宫疾病从子宫动脉接受血液供应。特别地，通过使用经阴道，经子宫，经直肠或腹膜后方法闭塞子宫动脉来有效地治疗子宫肌瘤。所述装置和方法是有利的，因为本发明的程序可以由患者的妇科医生在治疗过程中执行，避免需要转诊给专科医师和更彻底的治疗，例如子宫切除术。该方法包括动脉的暂时和永久闭塞。套管携带成像装置和将容易穿透组织的构件，该构件包括部分或完全，暂时或永久地封闭子宫动脉的装置。