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(54) **CUTTING DEVICE**

SCHNEIDEVORRICHTUNG

DISPOSITIF DE COUPE

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Description

Field of the Invention

[0001] Embodiments of this invention relate generally to medical devices, In particular, embodiments of the instant invention relate to medical devices for assisting in the capture and cutting of tissue or foreign matter from a body portion.

Background of the Invention

[0002] Organic material (e.g., blood clots, tissue, and biological concretions such as urinary, biliary, and pancreatic stones) or inorganic material (e.g., components of medical devices or other foreign matter) may sometimes obstruct or otherwise be present within the body's anatomical lumens, such as the biliary tree. For example, biological concretions can develop in certain parts of the body, such as kidneys, pancreas, and gallbladder. Minimally invasive medical procedures generally involve causing limited trauma to the tissues of the patient, and can be used to dispose of certain problematic biological concretions or similarly unwanted obstructions.

[0003] Many medical retrieval devices can be used to entrap an object, such as tissue or a stone fragment, and drag it through an ampulla (i.e., a small dilatation in the patient's anatomical lumen) to remove it. Such medical retrieval devices include, for example, retrieval baskets and may be used through an endoscope or laparoscope. However, occasionally an object may be too large to be extracted through an ampulla.

[0004] With many known retrieval assemblies, it is difficult to cut the entrapped material, such as tissue or a stone, once the material is entrapped to reduce the size of the material. For example, in some patients, a cicatrix or some other constriction that reduces the diameter of a body lumen may form within the lumen. The narrowed lumen may not interfere or prevent normal insertion of a retrieval device. However, after the retrieval device is inserted into the tract, the retrieval assembly expands, and an object is captured within the device. At this point, the diameter of the retrieval assembly containing the entrapped object may exceed the inner diameter of the narrowed lumen. Under these circumstances, it may be desirable to reduce the size of the entrapped object so that the retrieval assembly and the entrapped object may be safely removed from the lumen. Other circumstances may be encountered during a medical retrieval procedure that may also require cutting an entrapped object within a retrieval device.

[0005] The present disclosure provides medical retrieval devices that address some or all of the aforementioned shortcomings of the existing devices. The two part form of claim 1 is based on US 2008/0223171.

SUMMARY OF THE INVENTION

[0006] It is an object of the invention to provide a medical instrument, i.e., a medical retrieval device with features that permit retrieval of material within a body. The material can be biological material, such as tissue and stones, or foreign material, or any variety of other types of material within a body. The material can be located in a urinary or biliary tract or elsewhere in the body. The invention is described in claim 8. Preferred embodiments are described in the dependent claims.

[0007] Embodiments of the invention provide a medical device that assists practitioners in the removal of tissue or foreign matter from a desired body portion by entrapment and cuts the tissue or foreign matter when desired.

[0008] In accordance with an aspect of the present disclosure, a medical device includes a sheath having a proximal end and a distal end; a cutting device at the distal end of the sheath; a lumen extending longitudinally through both the sheath and the cutting device; an elongate member extending within the lumen and moveable relative to the sheath and the cutting device; and a retrieval assembly connected to the elongate member and retractable within and extendable from the lumen of the sheath.

[0009] Various embodiments of the invention may include one or more of the following aspects: the cutting device is hypotube having a sharp distal edge; the cutting device comprises a first material and the sheath comprises a second material different from the first material; the distal end of the cutting device has an edge configured to cut an object entrapped in the retrieval assembly; the edge may be circular and the distal end of the cutting device may include a wall that tapers to the circular edge; an outer diameter of the cutting device may be substantially constant, and an inner diameter of the cutting device may increase toward the edge; the distal end of the cutting device may further comprise a cutting wire; the retrieval assembly may comprise a plurality of legs, and at least one of the plurality of legs may comprise an inward facing sharp edge; and the medical device may comprise an energy generator configured to generate at least one of an RF energy, ultrasonic energy, and heat to a tissue sample positioned in the retrieval assembly.

[0010] A method of entrapping an object within a body is also disclosed. The method includes inserting a medical device into a body lumen, the medical device having a sheath having a proximal end and a distal end, a cutting device at the distal end of the sheath, a lumen extending longitudinally through both the sheath and the cutting device, an elongate member extending within the lumen and moveable relative to the sheath and cutting device, and a retrieval assembly connected to the elongate member and retractable within and extendable from the lumen of the sheath. The method further includes advancing the medical device to a site within the body lumen, extending the elongate member and retrieval assembly dis-

tally relative to the sheath and cutting device to deploy the retrieval assembly, and entrapping the object within the retrieval assembly.

[0011] Various methods may include one or more of the following aspects: the method may further comprise the step of generating at least one of RF energy, ultrasonic energy, and heat to cut a portion of the object, the step of retracting the elongate member and retrieval assembly proximally relative to the sheath and cutting device after the step of entrapping the object within the retrieval assembly to cut a portion of the object; the step of rotating the elongate member and retrieval assembly relative to the cutting device during the step of retracting the portion of the object; the distal end of the cutting device may have an edge configured to cut the portion of the object during the retracting step; the edge may be circular and the distal end of the cutting device may include a wall that tapers to the circular edge; an outer diameter of the cutting device may be substantially constant, and an inner diameter of the cutting device may increase toward the edge; and the retrieval assembly may comprise a plurality of legs, and the plurality of legs may comprise an inward facing sharp edge.

[0012] A further aspect of the present disclosure includes a method of cutting tissue from a tissue sample. The method includes inserting a medical device into a body lumen, the medical device having a device lumen having a distal end, a cutting device disposed at the distal end of the device lumen, an elongate member extending within and axially displaceable with respect to the device lumen, and a retrieval member disposed on a distal end of the elongate member. The method further includes advancing the medical device to a site within the body lumen, entrapping the tissue sample within the retrieval assembly, and axially displacing the elongate member and retrieval assembly relative to the cutting device to cut tissue from the tissue sample.

[0013] Various embodiments of the invention may include one or more of the following aspects: the distal end of the cutting device may further comprise a cutting wire; the distal end of the cutting device may have an edge configured to cut an object entrapped in the retrieval member; the edge may be circular and the distal end of the cutting device may include a wall that tapers to the circular edge; and the retrieval member may comprise a plurality of legs, and the plurality of legs may comprise an inward facing sharp edge.

[0014] Additional objects and advantages of the invention will be set forth in part in the description which follows, and in part will be obvious from the description, or may be learned by practice of the invention. The objects and advantages of the invention will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.

[0015] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principles of the invention.

Figure 1 is a schematic representation of a medical device in an expanded and extended position according to an embodiment of the present invention.
Figure 2 is a schematic representation of the device in Fig. 1 in a retracted and collapsed position.
Figure 3 is a schematic representation of the device in Fig. 1 in a partially retracted state.
Figure 4 is an isometric representation of a cutting device portion of the device in Fig. 1
Figure 5 is a schematic representation of a medical device in an expanded and extended position.
Figure 6 is a schematic representation of the device in Fig. 5 in a retracted and collapsed position.
Figure 7 is an isometric representation of a cutting device portion of a medical device.
Figure 8A is a schematic representation of a medical device in an expanded and extended position.
Figure 8B is an expanded view of a portion of a leg of the medical device in Fig. 8A.
Figure 8C is a cross-sectional view of the leg in Fig. 8B.
Figure 9 is a schematic representation of a medical device in an expanded and extended position according to an embodiment of the present invention.
Figure 10 is a schematic representation of a medical device in an expanded and extended position.

DESCRIPTION OF THE EMBODIMENTS

[0017] Reference will now be made in detail to exemplary embodiments of the invention, examples of which is are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts. As used in this disclosure, "distal" refers to a position or direction furthest from a user of the device and "proximal" refers to a position or direction opposite "distal" and closest to the user.

[0018] **FIGS. 1-4** depict certain configurations of an exemplary embodiment of a medical device **10.** The medical device **10** includes a sheath **11,** an elongate member **12,** a cutting device **13,** and a retrieval assembly **14.**

[0019] Sheath **11** includes a proximal end **11 a** and a distal end **11b,** and may be any suitable sheath or catheter known in the art. Sheath **11** may be fabricated by any known process such as, for example, extrusion. In addition, sheath **11** may be made from any suitable material that provides sufficient strength and flexibility for adequate operation, but which is soft enough to avoid trauma or irritation to a body lumen in which sheath **11**

may be deployed. Such material may include, but is not limited to, polyurethane and/or silicone. Sheath **11** may have any desired cross-sectional shape and/or configuration. For example, sheath **11** may also have one or more cross-sectional shapes and/or configurations along its length, and may be any desired dimension suitable for deployment within a desired body lumen. For example, sheath **11** may have dimensions adapted for placement in a biliary duct having a particular size. For instance, sheath **11** may have an outer periphery that is substantially the same size as, or a size less than, the inner periphery of a biliary duct. The overall length and diameter of sheath **11** may vary depending on the application. For example, a relatively long sheath **11** may be advantageous for retrieving stones or other concretions deep within the body of a patient. Sheath **11** is flexible along at least a portion of its length so that it may bend as it is advanced through tortuous body lumens.

[0020] Sheath **11** may further include at least one lumen **15** extending therethrough. In some embodiments, lumen **15** may be defined as an internal passageway with an entrance and an exit, and may be formed by any suitable process such as, for example, extrusion. Alternatively, sheath **11** may include a plurality of lumens (not shown) that may or may not differ in size. In such embodiments, the plurality of lumens may provide passageways useful in delivering, or removing, for example, medical devices, fluids, and/or structures to or from a treatment site. Lumen **15** provided within sheath **11** may have any cross-sectional shape, dimension, and/or configuration. For example, in some embodiments, lumen **15** may have a substantially circular cross-section.

[0021] Cutting device **13** may be located at distal end **11b** of sheath **11.** In some embodiments, cutting device **13** may be fabricated independently from sheath **11** as depicted in **FIG. 1.** for example, cutting device **13** may be a hypotube blade. In addition, cutting device **13** may be configured to retract into and extend from sheath **11.** Alternatively, according to the invention, cutting device **13** is formed integral with sheath **11.** Cutting device **13** may be formed by any suitable process such as, for example, extrusion. In addition, cutting device **13** may be made from any suitable material that provides sufficient strength to cut a material within a body, such as tissue and stones, or foreign material, or any variety of other types of material within a body. Such material may include, but is not limited to, nylon, urethane, polyamide, PEBAX, stainless steel (such as 300 and 400 series including 316L, 304, 445), cobalt, chromium, nickel, titanium, nitinol, thermoforming plastic, polytetrafluoroethylene ("PTFE"), and expanded polytetrafluoroethylene ("ePTFE"). The materials stainless steel, cobalt, chromium, nickel, titanium and nitinol do not form part of the invention. Cutting device **13** is formed of a material that is stiffer than the material forming sheath **11.** Lumen **15** also extends through cutting device **13.**

[0022] Cutting device **13** may have a distal end **13a** with an edge **16.** Distal end **13a** of cutting device **13** may taper at edge **16.** Distal end **13a** of cutting device **13** may have an inner diameter that increases toward edge **16.** For example, cutting device **13** may have a constant outer diameter and an inner diameter that increases toward edge **16** such that edge **16** is sharp.

[0023] Alternatively, or in addition to, cutting device **13** tapering toward edge **16,** cutting device **13** may include a cutting wire **22** at proximal end **13a,** as shown in **FIG. 7.** The cutting wire **22** may be sufficiently thin and therefore sharp that the cutting wire **22** cuts tissue when brought into contact with and/or moved relative to the desired tissue. The cutting wire **22** may be electrically active (having either a monopolar or bipolar configuration) so as to assist in cutting tissue. If conductive, the cutting wire **22** may be electrically connected to a suitable power source known in the art (e.g., RF generator) via suitable electrical connections known in the art (e.g., electrical leads and/or wires). The power source may be disposed anywhere on or relative to the medical device **10,** for example, at or connected to a handle **19.**

[0024] Elongate member **12** is longitudinally disposed and slideably moveable in lumen **15** of sheath **11** and cutting device **13.** Elongate member **12** may be formed from, for example, a rod, tube, cannula, wire, stent, or other like structure. Alternatively, the elongate member **12** may also be formed from a portion of a cylindrical piece of material, or from a flat sheet of material. If formed from a flat sheet, elongate member **12** may be formed into a cylindrical shape to facilitate the fabrication of retrieval assembly **14.**

[0025] Elongate member **12** may be formed from any biocompatible material known in the art. Such materials may include, but are not limited to, stainless steel, cobalt chromium, nickel, titanium, nitinol, thermoforming plastics, PTFE, and EPTFE. In addition, elongate member **12** may also be a metal with one or more coatings such as, for example, a polymer.

[0026] Elongate member **12** may have any desired cross-sectional shape and/or configuration. For example, elongate member **12** may have a substantially circular cross-section. In addition, elongate member **12** may have one or more cross-sectional shapes and/or configurations along its length, and may have any desired dimension suitable for deployment in a desired body lumen, and retraction into sheath **11** and cutting device **13.** For example, elongate member **12** may have an outer periphery that facilitates insertion into sheath **11,** and permits longitudinal movement of elongate member **12** relative to sheath **11.** The overall length and diameter of elongate member **12** may vary depending on the application. For example, a relatively long elongate member **12** may be advantageous for retrieving tissue, stones, or other unwanted objects deep within the body of a patient. In addition, elongate member **12,** having a relatively small diameter, may be advantageous for retrieving unwanted objects from restricted passageways within the human urinary tract.

[0027] Elongate member **12** may include a number of

any desired flexibility features (not shown) to increase maneuverability of the device **10** while the device 10 is within the body of a patient. The flexibility features, for example, may be cut into a distal portion of elongate member **12.** However, flexibility features may be positioned anywhere along the length of the elongate member **12,** and may be created by any suitable process known in the art.

[0028] In some embodiments, elongate member **12** may further include one or more internal lumens (not shown) extending therethrough. In such embodiments, the lumens may provide passageways useful in delivering, or removing, for example, medical devices such as laser fibers, fluids, and/or other structures to or from a treatment site.

[0029] Retrieval assembly **14** extends distally from a distal end of elongate member **12,** and may be, for example, a basket having any desired number of legs **17.** In addition, retrieval assembly **14** may be retractable within and extendable from lumen **15** of sheath **11** and cutting device **13.** The retrieval assembly **14** may be manufactured from any suitable biocompatible material, for example, one or more metals and/or composites, such as, but not limited to, 400 series stainless steel, Ti-Beta-3 titanium alloys, cobalt chromium alloys, and nitinol. Retrieval assembly **14** may have desired cross-sectional shape and/or configuration. For example, retrieval assembly **14** may also have one or more cross-sectional shapes and/or configurations along its length, and any desired dimensions suitable for deployment in a desired body lumen. For example, retrieval assembly **14** may have dimensions adapted for placement in a biliary duct having a particular size. For instance, retrieval assembly **14,** in an expanded state, may have an outer periphery that is substantially the same size as, or less than, the inner periphery of a biliary duct. In addition, retrieval assembly **14** may have configurations, dimensions, and/or material properties that permit longitudinal movement of retrieval assembly **14** relative to sheath **11** and cutting device **13** and extension and retraction into and out of sheath **11** and cutting device **13.** The overall length and diameter of retrieval assembly **14** may vary depending on the application. For example, a relatively small diameter may be advantageous for retrieving tissue, stones, or other unwanted objects from restricted passageways within the human urinary tract. Retrieval assembly **14** may also be collapsible so that it may be more easily advanced through body lumens in its collapsed state, and when desired expandable for deployment. For example, retrieval assembly **14** may be made from certain materials and according to certain methods so that retrieval assembly **14** may self-expand when extended from lumen **15** of sheath **11** and cutting device **13,** as is known in the art. Alternatively, retrieval assembly **14** may be expanded in any other suitable manner known in the art.

[0030] Retrieval assembly **14** may be made out of the same piece of material as elongate member **12.** Alternatively, retrieval assembly **14** may be fabricated independently by any known means, and may then be made integral with elongate member **12** through connection of a proximal end **14a** of retrieval assembly **14** to a region of elongate member **12,** such as the distal end of elongate member **12.** Connection of proximal end **14a** of retrieval assembly **14** to elongate member **12** may be accomplished through any suitable means of fixedly connecting retrieval assembly **14** to elongate member **12.** For example, possible connections may include, but are not limited to, welding, soldering, and/or crimping.

[0031] Legs **17** of retrieval assembly **14** may be formed by, for example, laser cutting, chemical etching, die cutting, or mechanically slicing a single piece of material. As a result, the width of the cuts may define the width and mechanical behavior of each of legs **17,** and the desired width of the cuts may vary depending on the particular application. For example, it may be advantageous to have relatively narrow basket legs when retrieving a relatively large unwanted object from within the body. In certain instances, legs **17 may** be formed by, for example, welding, soldering, tying, or otherwise connecting separate pieces of wire or other material together. In such instances, legs **17** may or may not be made with the same materials.

[0032] Although **FIG. 1** shows that retrieval assembly **14** comprises six legs, retrieval assembly **14** may include any number of legs to facilitate retrieval of unwanted objects from within a patient's body. Legs **17** may have any desired pattern, configuration, and characteristic suitable for entrapping objects within an anatomical lumen. For example, legs **17** may be cylindrical, flat, square, semi-circular, rectangular, or any other suitable shape suitable for entrapping objects from within a patient's body. In addition, legs **17** may be any cross-sectional shape known in the art including, but not limited to, circular, flat, square, or ovular. Additionally, legs **17** may be made of a material exhibiting shape memory, as is known in the art.

[0033] In some embodiments, at least a portion of at least one of the legs **17** may include an inward facing surface textured to improve the retrieval capabilities of device **10.** For example, possible structures that may be used as texture may include, but are not limited to, indentations, teeth, spikes, treads, and serrations. The texture of the inward facing surface may provide multi-point contact with objects targeted for entrapment and may be pointed away from the sensitive tissue within the body structure so as not to cause trauma thereto. Furthermore, at least a point of at least one of the legs **17** may be coated with, for example, a layer of PTFE, EPTFE, polyvinylethylene, or any other material suitable for protecting legs **17** during processes such as, for example, laser lithotripsy.

[0034] Retrieval assembly **14** may include a plurality of cells or spaces **20** between legs **17.** Spaces **20** may be of any suitable shape, size, and/or configuration, and may be configured to accommodate and allow objects to

pass into the interior of the retrieval assembly **14** for entrapment and, if desired, subsequent removal from the body. Furthermore, the size of spaces **20** between legs **17** may vary or be consistent.

[0035] The distal end of each of legs **17** may connect at tip **18** as depicted in **FIG. 1.** Tip **18** may further be sized and shaped to assist in the capture and retrieval of unwanted objects within a patient's body. For example, tip **18** may be blunt, rounded, flat, smooth, knotted, or any other atraumatic shape known in the art, and may or may not be composed of the same material as legs **17.** Tip **18** may be as small as possible so as not to interfere with the capture and retrieval of the targeted object. Furthermore, tip **18** may be formed by soldering, welding, cementing, tying, or otherwise connecting the distal ends of legs **18** together, and may or may not contain fillers such as, for example, epoxy. Alternatively, the distal end of each of legs **17** may be free.

[0036] Retrieval assembly **14,** depicted and described in **FIGS. 1-3,** is an exemplary retrieval assembly that may be used in the method and device of the present invention. Any other suitable retrieval assembly capable of entrapping, releasing, and/or removing objects from within a body lumen may be used.

[0037] Retrieval assembly **140,** depicted and described in **FIGS. 5 and 6,** is a further exemplary retrieval assembly that may be used in the method and device of the present invention. Retrieval assembly **140** may include the features discussed above with respect to retrieval assembly **14** unless otherwise noted. For example, retrieval assembly **140** may be manufactured by similar processes and materials as retrieval assembly **14.**

[0038] Retrieval assembly **140** extends distally from a distal end of elongate member **12,** and may be, for example, a grasper. Although **FIG. 5** shows that retrieval assembly **140** comprises four legs, retrieval assembly **140** may include any number of legs to facilitate retrieval of unwanted objects from within a patient's body. In some embodiments, at least a portion of at least one of the legs **170** may include an inward facing surface textured to improve the retrieval capabilities of device **100.** For example, legs **170** may include inwardly facing barbs on a distal end of each of legs **170.** Furthermore, possible structures that may be used as texture may include, but are not limited to, indentations, teeth, spikes, treads, and serrations.

[0039] As depicted in **FIGS. 1, 2, 5, and 6,** retrieval assembly **14,140** may be configured to collapse and expand as desired. For example, retrieval assembly **14, 140** may be configured to be collapsible such that it facilitates retraction into lumen **15** of sheath **11** as depicted in **FIGS. 2 and 6,** and/or advanced out of sheath **11,** such that retrieval assembly **14,140** at least partially expands and/or fully expands as depicted in **FIGS. 1 and 5.** In such an example, retrieval assembly **14, 140** may be collapsed and retracted into lumen **15** of sheath **11** and cutting device **13,** while sheath **11** and cutting device **13** are being advanced through a body lumen to a desired body location. Once sheath **11** is positioned in the desired body location, retrieval assembly **14, 140** may be advanced out of sheath **11** and cutting device **13** for expansion.

[0040] Retrieval assembly **14, 140** may be retracted into and/or advanced out of lumen **15** using any method known in the art. For example, by means of the connection between proximal end **14a, 140a** and elongate member **12,** movement of elongate member **12** relative to sheath **11** and cutting device **13** causes retrieval assembly **14, 140** to also move relative to sheath **11** and cutting device **13** allowing retrieval assembly **14, 140** to be retracted into and/or advanced out of sheath **11** and cutting device **13.** Any suitable known handle **19** may be used at the proximal user end of sheath **11** and/or elongate member **12** for actuation.

[0041] Retrieval assembly **240,** depicted and described in **FIGS. 8A-8C,** is a further exemplary retrieval assembly that may be used in the method and device of the present invention. Retrieval assembly **240** may include the features discussed above with respect to retrieval assembly **14, 140** unless otherwise noted. For example, retrieval assembly **240** may be manufactured by similar processes and materials as retrieval assembly **14,140.**

[0042] Retrieval assembly **240** extends distally from a distal end of elongate member **12,** and may be, for example, a basket. Although **FIG. 8A** shows that retrieval assembly **240** comprises six legs, retrieval assembly **240** may include any number of legs to facilitate retrieval of unwanted objects from within a patient's body. In some embodiments, at least one of legs **270** may include an inward facing sharp cutting edge **23** as depicted in **FIG. 8C.** In an embodiment, each of legs **270** includes a sharp edge **23.** A cross-section of leg **270** may be a triangular or a-three-sided shape with two curved, concave sides forming the sharp cutting edge **23.**

[0043] In some embodiments, retrieval assembly **240** may be used in conjunction with sheath **11** and cutting device **13.** In alternative embodiments, retrieval device **240** may be used in conjunction with sheath **11** and without cutting device **13.**

[0044] Retrieval assembly **340,** depicted and described in **FIG. 9,** is a further exemplary retrieval assembly that may be used in the method and device of the present invention. Retrieval assembly **340** may include the features discussed above with respect to retrieval assembly **14, 140, 240** unless otherwise noted. For example, retrieval assembly **340** may be manufactured by similar processes and materials as retrieval assembly **14, 140, 240.**

[0045] Retrieval assembly **340** extends distally from a distal end of elongate member **12,** and may be, for example, a basket. Although **FIG. 9** shows that retrieval assembly **340** comprises three legs, retrieval assembly **340** may include any number of legs to facilitate retrieval of unwanted objects from within a patient's body. In some embodiments, retrieval assembly **340** may be connected

to a radio frequency generator **24.** Generator **24** may be integral with handle **19,** or generator **24** may be a separate structure that is coupled to handle **19** through any suitable connection. Generator **24** is electrically connected to elongate member **12** and legs **370** through any suitable electrical connection. In some embodiments, legs **370** may be formed from nitinol. Alternatively, legs **370** may be formed of the same materials as legs **17.** Furthermore, retrieval assembly **340** may be greater than 24 French size when in the expanded configuration, and sheath **12** may be 8 French size. Alternatively, retrieval assembly **340** and sheath **12** may be alternative sizes.

[0046] In some embodiments, retrieval assembly **340** may be used in conjunction with sheath **11** and cutting device **13.** In alternative embodiments, retrieval device **340** may be used in conjunction with sheath **11** and without cutting device **13.**

[0047] Retrieval assembly **440,** depicted and described in **FIG. 10,** is a further exemplary retrieval assembly that may be used in the method and device of the present invention. Retrieval assembly **440** may include the features discussed above with respect to retrieval assembly **14,140, 240, 340** unless otherwise noted. For example, retrieval assembly **440** may be manufactured by similar processes and materials as retrieval assembly **14,140, 240, 340.**

[0048] Retrieval assembly **440** extends distally from a distal end of elongate member **12,** and may be, for example, a basket. Although **FIG. 10** shows that retrieval assembly **440** comprises six legs, retrieval assembly **440** may include any number of legs to facilitate retrieval of unwanted objects from within a patient's body. In some embodiments, retrieval assembly **440** may be connected to an emitter **25** which emits for example either ultrasonic energy or heat. Emitter **25** may be integral with handle **19,** or emitter **25** may be a separate structure that is coupled to handle **19** through any suitable connection. Emitter **25** is electrically connected to elongate member **12** and legs **17** through any suitable electrical connection.

[0049] In some embodiments, retrieval assembly **440** may be used in conjunction with sheath **11** and cutting device **13.** In alternative embodiments, retrieval device **240** may be used in conjunction with sheath **11** and without cutting device **13.**

[0050] In reference to **FIGS. 1-10,** methods of using the medical device **10, 100, 200, 300, 400** of the present disclosure to retrieve tissue are provided, stones, and other unwanted materials located in the bladder, ureter, kidney, or other body structures. Medical device **10, 100, 200, 300, 400** may be used in an environment that is relatively fluid filled or that is relatively dry. The medical device **10, 100, 200, 300,400** may be inserted through the urethra of a patient or, alternatively, the medical device may be inserted percutaneously. The medical device **10, 100, 200, 300, 400** may be used in any location of the body in which a passageway or orifice includes unwanted material to be removed and/or is being at least partially blocked.

[0051] The medical device **10, 100, 200, 300, 400** may be advanced to a treatment site in a number of different ways. For example, the device **10, 100, 200, 300,400** may be advanced to a desired body location over a guide wire (not shown), wherein the desired body location may correspond to the vicinity of a tissue, stone, or another object targeted for removal. The medical device **10, 100, 200, 300, 400** may also be advanced to the treatment site through an access sheath or any other access device known in the art.

[0052] Alternatively, the medical device **10, 100, 200, 300, 400** may be fed to the desired body location by means of an imaging device, and may travel through the body without the use of a guide wire or access sheath. To facilitate such feeding, sheath **11** may include radiopaque bands (not shown) detectable by x-ray or other imaging means. Thus, the user may monitor the position of the medical device **10, 100, 200, 300, 400** and movement thereof through the use of an imaging device.

[0053] As yet another alternative, the medical device **10, 100, 200, 300, 400** may be used in conjunction with an endoscope (not shown) or any other type of intracorporeal scope known in the art. The endoscope may travel through the body to the treatment site in any conventional manner. Once the endoscope is positioned adjacent to the treatment site, the medical device **10, 100, 200, 300,400** may be fed through an access port of the endoscopic sheath to gain access to the object targeted for retrieval, such as tissue.

[0054] The object targeted for retrieval may be, for example, tissue sample **21.** The object targeted for retrieval may include any unwanted object commonly removed from a body structure or passageway. The objects may be of any size and/or shape. Furthermore, the medical device **10, 100, 200, 300, 400** may be used to remove objects that are both impacted and free floating.

[0055] In clinical applications where an endoscope (not shown) or other similar access device is used for access, the endoscope may be advanced through a tortuous body lumen and to a desired body location. With retrieval assembly **14, 140, 240, 340, 440** disposed inside of sheath **11** and in a collapsed and retracted state, the medical device **10, 100, 200, 300, 400 may** then be inserted into the body lumen by feeding the medical device **10, 100, 200, 300, 400** through an access port in the endoscopic sheath to the desired body location. For example, the medical device **10, 100, 200, 300,400** may be advanced until the distal end **13a** of cutting device **13** or the distal end of sheath **11** has reached a desired location, such as, a short distance past an object targeted for entrapment and/or removal. The method is not limited to the use with any particular object, and may also be used with one or more intracorporeal and/or extracorporeal objects at various locations and of various geometries and compositions.

[0056] Once the distal end **13a** of cutting device **13** or the distal end **11** is advanced past a targeted object, the elongate member **12** may then be advanced distally out

of sheath **11** and/or cutting device **13,** so that retrieval assembly **14, 140, 240, 340, 440** may deploy and self-expand. For example, this may be achieved by pulling sheath **11** proximally relative to elongate member **12.** Any suitable known handle assemblies may be used to effect deployment and expansion of retrieval assembly **14, 140, 240, 340, 440.** When fully deployed, retrieval assembly **14,140, 240, 340, 440** may be substantially cylindrically shaped or have any other configuration suitable to the particular size and shape of both the targeted object and/or the environment it is located in. The proximal end **14a, 140a, 240a, 340a, 440a** of retrieval assembly **14, 140, 240, 340, 440** may remain in a collapsed state and/or disposed within the sheath **11,** and may be the narrowest portion of retrieval assembly **14,140, 240, 340, 440.**

[0057] Once elongate member **12** has been sufficiently advanced out of sheath **11** to allow at least partial deployment and/or expansion of retrieval assembly **14, 140, 240, 340, 440,** the medical device may be moved proximally, and sometimes repeatedly, such that the object targeted for entrapment enters the retrieval assembly **14, 140, 240, 340, 440.**

[0058] The medical device, along with the entrapped object, may then be moved to any desired location, or may be allowed to remain stationary. For example, medical device **10, 100, 200, 300,400** may be used as an extraction device and removed from the body, assist in immobilizing objects and used as a backstop, or moved to a location more conducive to any additional procedures, such as lithotripsy, surgery, or any other process known in the art.

[0059] In certain circumstances, it may be desired to cut the entrapped object to reduce the entrapped object's size before removing the object from the body. To do so, elongate member **12** and retrieval assembly **14,140, 240, 340, 440** may be retracted into sheath **11** and cutting device **13** while the entrapped object is held in the retrieval assembly **14, 140, 240, 340, 440.** For example, this may be accomplished by pulling elongate member **12** proximally relative to sheath **11** so that retrieval assembly **14, 140, 240, 340, 440** begins to retract and collapse into cutting device **13,** and consequently, a portion of the entrapped object extending outside of legs **17, 170, 270, 370** in a radial direction is cut away from the remaining portion of the entrapped object inside of legs **17, 170, 270, 370** as depicted in **FIG. 3.** To assist in cutting away the portion of the entrapped object extending outside of legs **17, 170, 270, 370,** elongate member **12** may be rotated relative to sheath **11** and cutting device **13** while being pulled in the proximal direction. Subsequently, the entrapped objected may be pulled completely into lumen **15.**

[0060] Alternatively, or in addition to, the above-described method for cutting the entrapped object to reduce the entrapped object's size before removing the object from the body, several other methods of reducing the entrapped object's size before removing the object from the body are available. First, for example, elongate member **12** and retrieval assembly **240** may be retracted into sheath **11** while the entrapped object is held in the retrieval assembly **240.** For example, this may be accomplished by pulling elongate member **12** proximally relative to sheath **11** so that retrieval assembly **240** begins to retract and collapse into sheath **11,** and consequently, a portion of the entrapped object is cut into multiple pieces by the inward facing sharp cutting edges **23** of legs **270.** Subsequently, the multiple pieces of the entrapped objected may be pulled completely into lumen **15** or passed naturally though the patient's anatomy.

[0061] Second, for example, retrieval assembly **340** may be connected to the radio frequency generator **24.** The radio frequency generator **24** may be activated to send RF energy to the retrieval assembly **340.** Elongate member **12** and retrieval assembly **340** may then be retracted into sheath **11** while the entrapped object is held in the retrieval assembly **340** such that legs **317** cut the entrapped object into multiple pieces. For example, legs **317** of the retrieval assembly **340** depicted in **Fig. 9** would cut the entrapped object into three wedge-shaped pieces. Subsequently, the multiple pieces of the entrapped objected may individually be pulled completely into lumen **15** or passed naturally through the patient's anatomy. Also, prior to activating the radio frequency generator **24,** the user may take a sample of the entrapped object by retracting elongate member **12** and retrieval assembly **340** into sheath **11** and cutting device **13** while the entrapped object is held in the retrieval assembly **340** such that a portion of the entrapped object is cut by cutting device **13** and a sample of the cut entrapped object is held in sheath **11** for subsequent testing. The cut portion is, for example, a core of the entrapped object. Alternatively, the cut portion may be a sliver from an edge of the entrapped object.

[0062] Third, for example, retrieval assembly **440** may be connected to the emitter 25 which emits for example either ultrasonic energy or heat. The emitter **25** may be activated to send ultrasonic energy or heat to the retrieval assembly **440** and break down the entrapped object into smaller pieces. Subsequently, the multiple pieces of the entrapped objected may be pulled completely into lumen **15** or passed naturally through the patient's anatomy.

[0063] By way of example, one advantage of using retrieval assembly **14,140, 240, 340, 440** with cutting device **13,** the sharp cutting edge **23** of legs **270,** radio frequency generator **24,** and/or emitter **25** is that in cases where the entrapped object may be too large for successful removal from the body, the entrapped object may be reduced in size and safely removed from the body.

[0064] Embodiments of the invention may be used in any medical or non-medical procedure wherein removal of an,object from within a body lumen is desired. In addition, as least certain aspects of the aforementioned embodiments may be combined with other aspects of the embodiments, or removed, without departing from the scope of the invention.

[0065] Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope of the invention being indicated by the following claims.

Claims

1. A medical device (10), comprising:

a sheath (11) having a proximal end (11 a) and a distal end (11b), wherein the sheath (11) is flexible along at least a portion of its length;
a cutting device (13) at the distal end (11 b) of the sheath (11);
a lumen (15) extending longitudinally through both the sheath (11) and the cutting device (13);
an elongate member (12) extending within the lumen (15) and moveable relative to the sheath (11) and the cutting device (13); and
a retrieval assembly (14) connected to the elongate member (12) and retractable within and extendable from the lumen (15) of the sheath (11) and the cutting device (13); **characterised in that**
the cutting device (13) is a hypotube formed integral with the sheath (11) and having a sharp distal edge (16),
wherein the cutting device (13) is made from a first material and the sheath is made from a second material different from the first material, wherein the first material is stiffer than the second material, wherein the first material includes nylon, urethane, polyamide, polyether block amide, thermoforming plastic, polytetrafluoroethylene, and/or expanded polytetrafluoroethylene.

2. The device (10) of claim 1, wherein the second material includes polyurethane and/or silicone.

3. The medical device (10) of claim 1, wherein the distal edge (16) of the cutting device (13) is configured to cut an object (21) entrapped in the retrieval assembly (14); and
wherein the edge (16) is curvilinear and the distal end (13a) of the cutting device includes a wall that tapers to the curvilinear edge (16).

4. The medical device (10) of claim 3, wherein an outer diameter of the cutting device (13) is substantially constant; and
wherein an inner diameter of the cutting device (13) increases toward the edge.

5. The medical device (10) of claim 3, wherein the distal end (13a) of the cutting device (13) further comprises a cutting wire (22).

6. The medical device (10) of claim 1, wherein the retrieval assembly (14) comprises a plurality of legs (17).

7. The medical device (10, 200) of claim 6, wherein at least one of the plurality of legs (17, 270) comprises an inward facing sharp edge (23).

8. The medical device (10) of claim 1, further comprising an energy generator (24) configured to generate at least one of a RF energy, ultrasonic energy, and heat to a tissue sample positioned in the retrieval assembly.

9. The medical device (10) of any one of claims 1 to 8, wherein the sheath (11) is formed by extrusion.

10. The medical device (10) of any one of claims 1 to 9, wherein the cutting device (13) is formed by extrusion.

11. The medical device (10) of any one of claims 1 to 10, wherein the cutting device (13) extends distally from the distal end (11b) of the sheath (11).

12. The medical device (10) of any one of claims 1 to 11, wherein a proximal end of the cutting device (13) is adjacent to the distal end (11 b) of the sheath (11).

Patentansprüche

1. Medizinische Vorrichtung (10), welche aufweist:

eine Hülle (11) mit einem proximalen Ende (11a) und einem distalen Ende (11b), wobei die Hülle (11) zumindest entlang eines Teils ihrer Länge flexibel ist;
eine Schneidvorrichtung (13) an dem distalen Ende (11b) der Hülle (11);
ein Lumen (15), das sich in Längsrichtung durch sowohl die Hülle (11) als auch die Schneidvorrichtung (13) erstreckt;
ein längliches Teil (12), das sich innerhalb des Lumens (15) erstreckt und relativ zu der Hülle (11) und der Schneidvorrichtung (13) bewegbar ist; und
eine Rückholanordnung (14), die mit dem länglichen Teil (12) verbunden und innerhalb des Lumens (15) der Hülle (11) und der Schneidvorrichtung (13) zurückziehbar und von diesem erstreckbar ist;
dadurch gekennzeichnet, dass
die Schneidvorrichtung (13) ein Hyporohr ist, das einstückig mit der Hülle (11) gebildet ist und

eine scharfe distale Kante (16) hat,
wobei die Schneidvorrichtung (13) aus einem ersten Material besteht und die Hülle aus einem zweiten Material besteht, das unterschiedlich von dem ersten Material ist, wobei das erste Material steifer als das zweite Material ist, und wobei das erste Material Nylon, Urethan, Polyamid, Polyetherblockamid, wärmeformbaren Kunststoff,
Polytetrafluorethylen und/oder expandiertes Polytetrafluorethylen enthält.

2. Vorrichtung (10) nach Anspruch 1, bei der das zweite Material Polyurethan und/oder Silikon enthält.

3. Medizinische Vorrichtung (10) nach Anspruch 1, bei der die distale Kante (16) der Schneidvorrichtung (13) konfiguriert ist, ein in der Rückholanordnung (14) gehaltenes Objekt (21) zu schneiden; und
bei der die Kante (16) krummlinig ist und das distale Ende (13a) der Schneidvorrichtung eine Wand enthält, die zu der krummlinigen Kante (16) hin konisch verläuft.

4. Medizinische Vorrichtung (10) nach Anspruch 3, bei der ein äußerer Durchmesser der Schneidvorrichtung (13) im Wesentlichen konstant ist; und
bei der ein innerer Durchmesser der Schneidvorrichtung (13) zu der Kante hin zunimmt.

5. Medizinische Vorrichtung (10) nach Anspruch 3, bei der das distale Ende (13a) der Schneidvorrichtung (13) weiterhin einen Schneiddraht (22) aufweist.

6. Medizinische Vorrichtung (10) nach Anspruch 1, bei der die Rückholanordnung (14) mehrere Beine (17) aufweist.

7. Medizinische Vorrichtung (10, 200) nach Anspruch 6, bei der zumindest eines von den mehreren Beinen (17, 270) eine nach innen gewandte scharfe Kante (23) aufweist.

8. Medizinische Vorrichtung (10) nach Anspruch 1, weiterhin aufweisend einen Energiegenerator (24), der konfiguriert ist zum Erzeugen zumindest einer von einer HF-Energie, einer Ultraschallenergie und Wärme für eine Gewebeprobe, die sich in der Rückholanordnung befindet.

9. Medizinische Vorrichtung (10) nach einem der Ansprüche 1 bis 8, bei der die Hülle (11) durch Extrusion gebildet ist.

10. Medizinische Vorrichtung (10) nach einem der Ansprüche 1 bis 9, bei der die Schneidvorrichtung (13) durch Extrusion gebildet ist.

11. Medizinische Vorrichtung (10) nach einem der Ansprüche 1 bis 10, bei der die Schneidvorrichtung (13) sich von dem distalen Ende (11b) der Hülle (11) distal erstreckt.

12. Medizinische Vorrichtung (10) nach einem der Ansprüche 1 bis 11, bei der ein proximales Ende der Schneidvorrichtung (13) angrenzend an das distale Ende (11b) der Hülle (11) ist.

Revendications

1. Dispositif médical (10), comprenant :

une gaine (11) comportant une extrémité proximale (11a) et une extrémité distale (11 b), dans lequel la gaine (11) est flexible suivant au moins une partie de sa longueur;
un dispositif de coupe (13) au niveau de l'extrémité distale (11b) de la gaine (11) ;
une lumière (15) qui s'étend longitudinalement au travers à la fois de la gaine (11) et du dispositif de coupe (13) ;
un élément allongé (12) qui s'étend à l'intérieur de la lumière (15) et qui est mobile par rapport à la gaine (11) et au dispositif de coupe (13) ; et
un assemblage de récupération (14) connecté à l'élément allongé (12), lequel peut être rétracté à l'intérieur de et peut être étendu depuis la lumière (15) de la gaine (11) et du dispositif de coupe (13),
caractérisé en ce que :

le dispositif de coupe (13) est un hypotube formé d'un seul tenant avec la gaine (11) et comportant une arête distale tranchante (16),
dans lequel le dispositif de coupe (13) est réalisé à partir d'un premier matériau et la gaine est réalisée à partir d'un second matériau différent du premier matériau , dans lequel le premier matériau est plus rigide que le second matériau, dans lequel le premier matériau inclut nylon, uréthane, polyamide, polyéther block amide, matière plastique thermoformante, polytétrafluoréthylène et/ou polytétrafluoréthylène expansé.

2. Dispositif (10) selon la revendication 1, dans lequel le second matériau inclut polyuréthane et/ou silicone.

3. Dispositif médical (10) selon la revendication 1, dans lequel l'arête distale (16) du dispositif de coupe (13) est configurée de manière à couper un objet (21) piégé dans l'assemblage de récupération (14) ; et
dans lequel l'arête (16) est curviligne et l'extrémité

distale (13a) du dispositif de coupe inclut une paroi qui est à flancs évasés en direction de l'arête curviligne (16).

4. Dispositif médical (10) selon la revendication 3, dans lequel un diamètre externe du dispositif de coupe (13) est sensiblement constant ; et
dans lequel un diamètre interne du dispositif de coupe (13) croît en direction de l'arête.

5. Dispositif médical (10) selon la revendication 3, dans lequel l'extrémité distale (13a) du dispositif de coupe (13) comprend en outre un fil de coupe (22).

6. Dispositif médical (10) selon la revendication 1, dans lequel l'assemblage de récupération (14) comprend une pluralité de pattes (17).

7. Dispositif médical (10, 200) selon la revendication 6, dans lequel au moins l'une de la pluralité de pattes (17, 270) comprend une arête tranchante dirigée vers l'intérieur (23).

8. Dispositif médical (10) selon la revendication 1, comprenant en outre un générateur d'énergie (24) configuré pour générer au moins un flux pris parmi une énergie RF, une énergie ultrasonore et de la chaleur sur un échantillon de tissu positionné dans l'assemblage de récupération.

9. Dispositif médical (10) selon l'une quelconque des revendications 1 à 8, dans lequel la gaine (11) est formée par extrusion.

10. Dispositif médical (10) selon l'une quelconque des revendications 1 à 9, dans lequel le dispositif de coupe (13) est formé par extrusion.

11. Dispositif médical (10) selon l'une quelconque des revendications 1 à 10, dans lequel le dispositif de coupe (13) s'étend de façon distale depuis l'extrémité distale (11b) de la gaine (11).

12. Dispositif médical (10) selon l'une quelconque des revendications 1 à 11, dans lequel une extrémité proximale du dispositif de coupe (13) est adjacente à l'extrémité distale (11b) de la gaine (11).

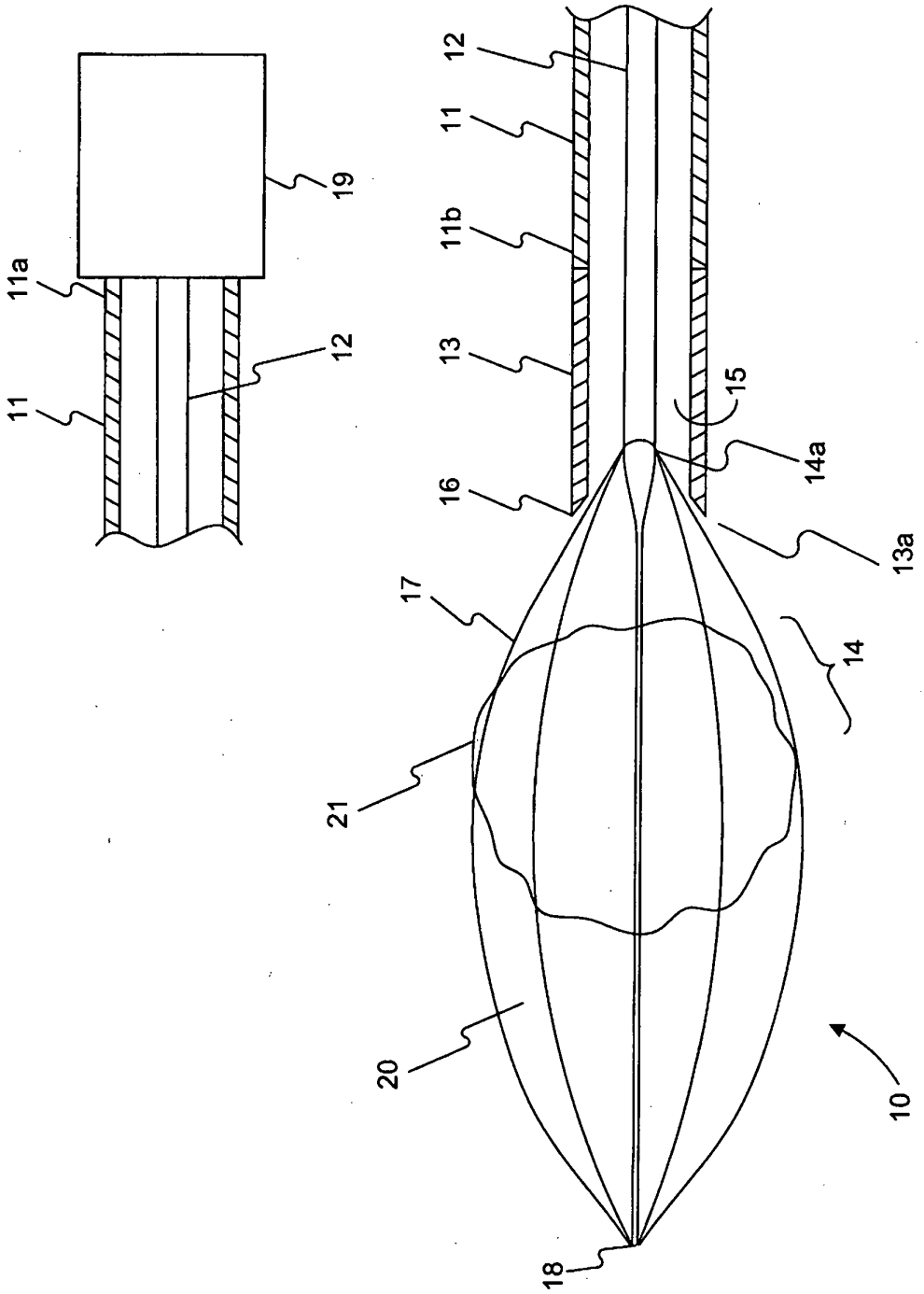

Figure 1

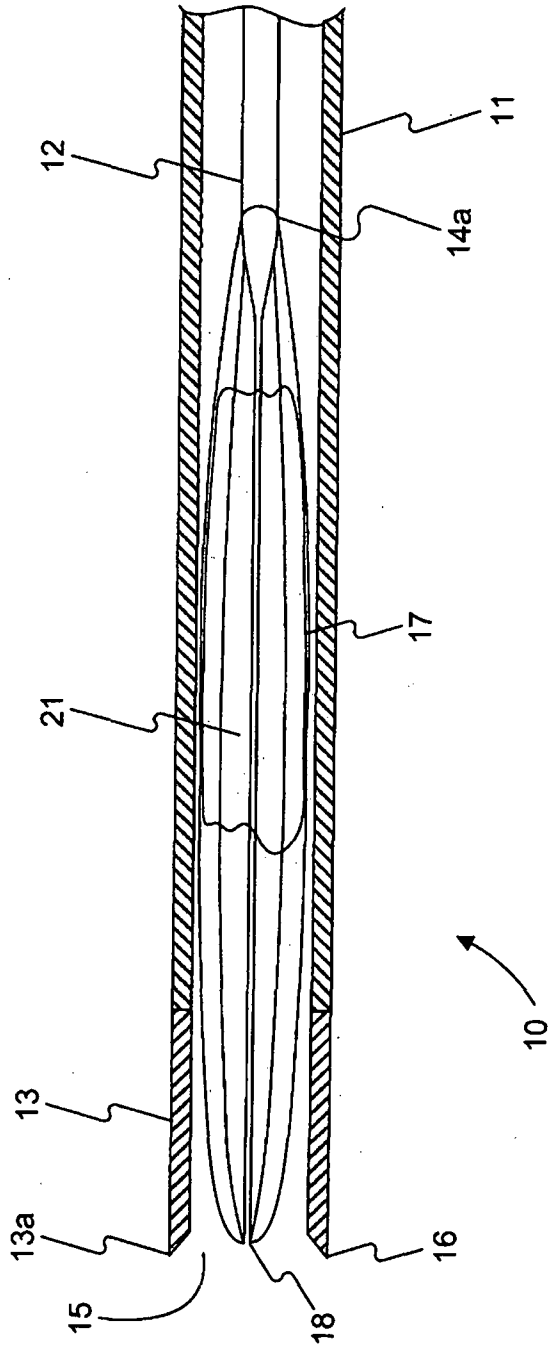

Figure 2

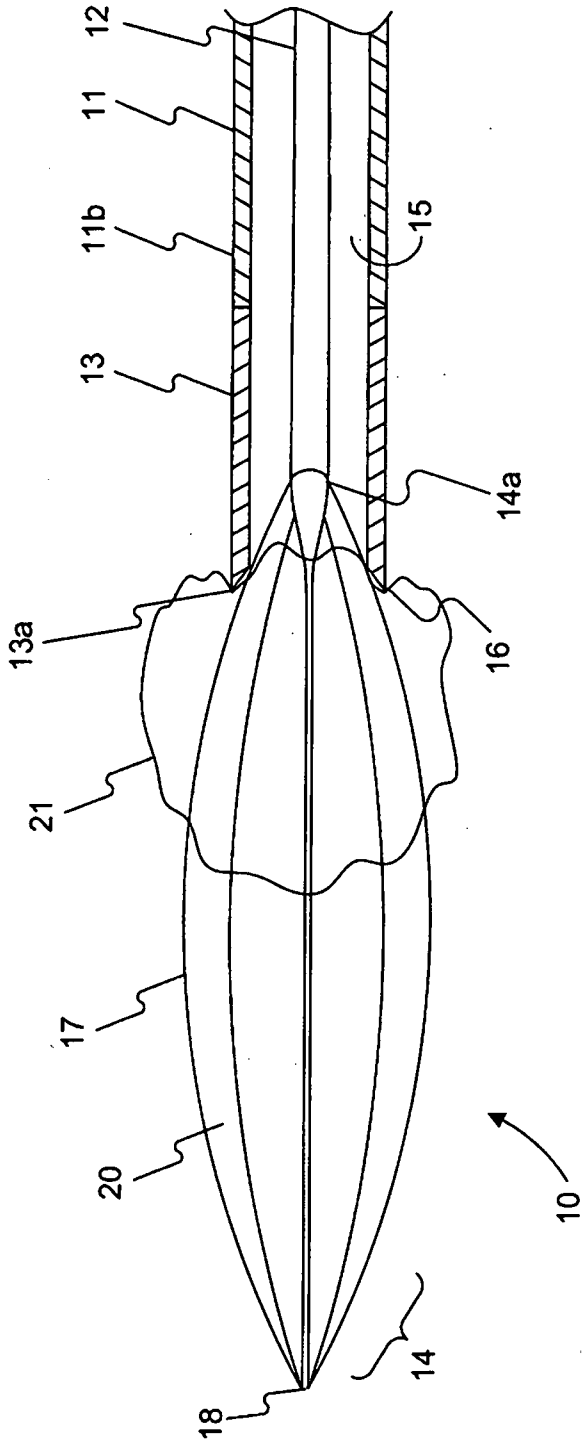

Figure 3

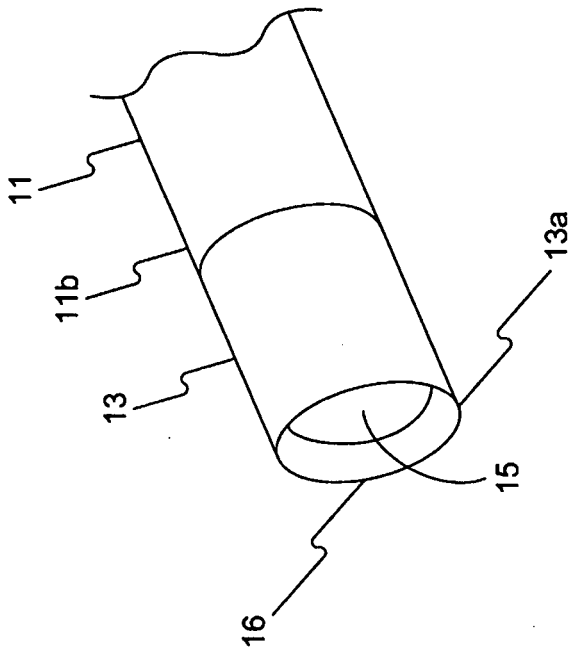

Figure 4

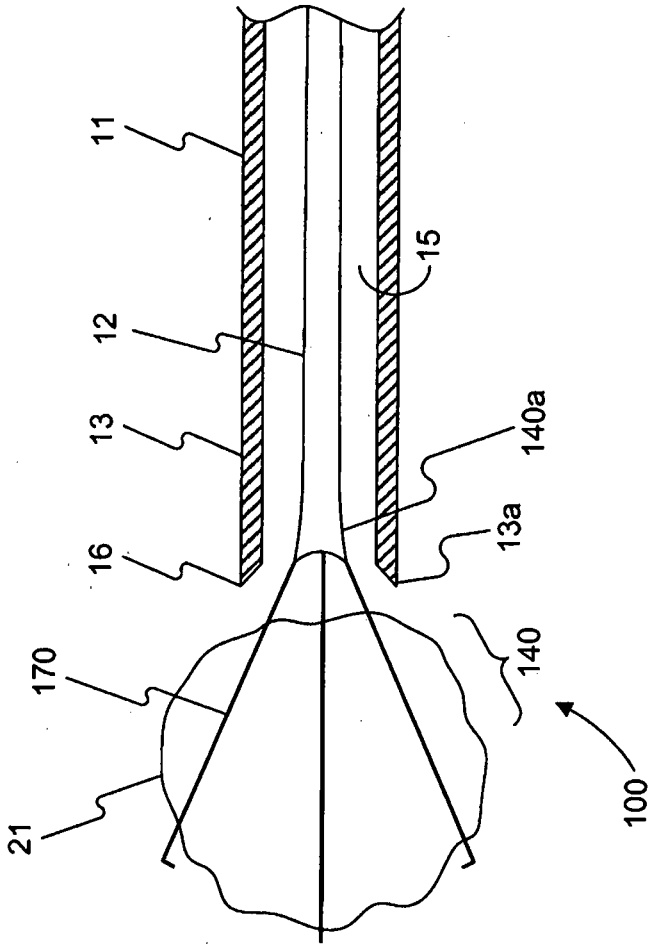

Figure 5

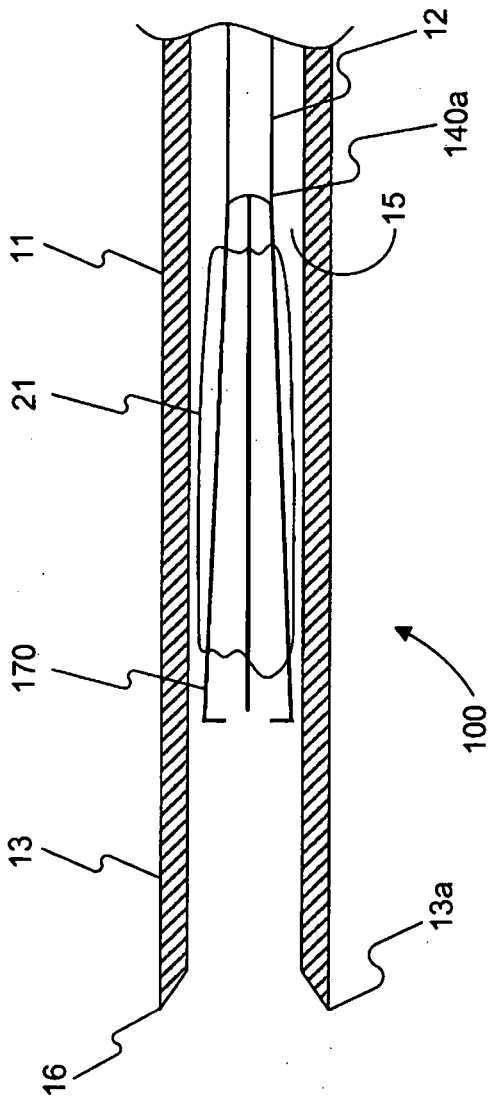

Figure 6

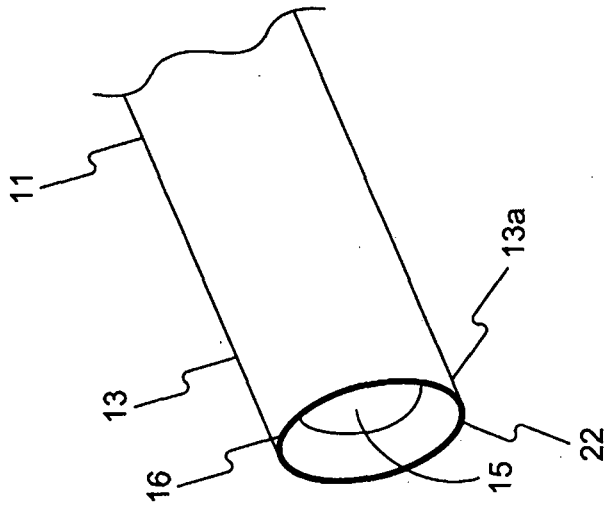

Figure 7

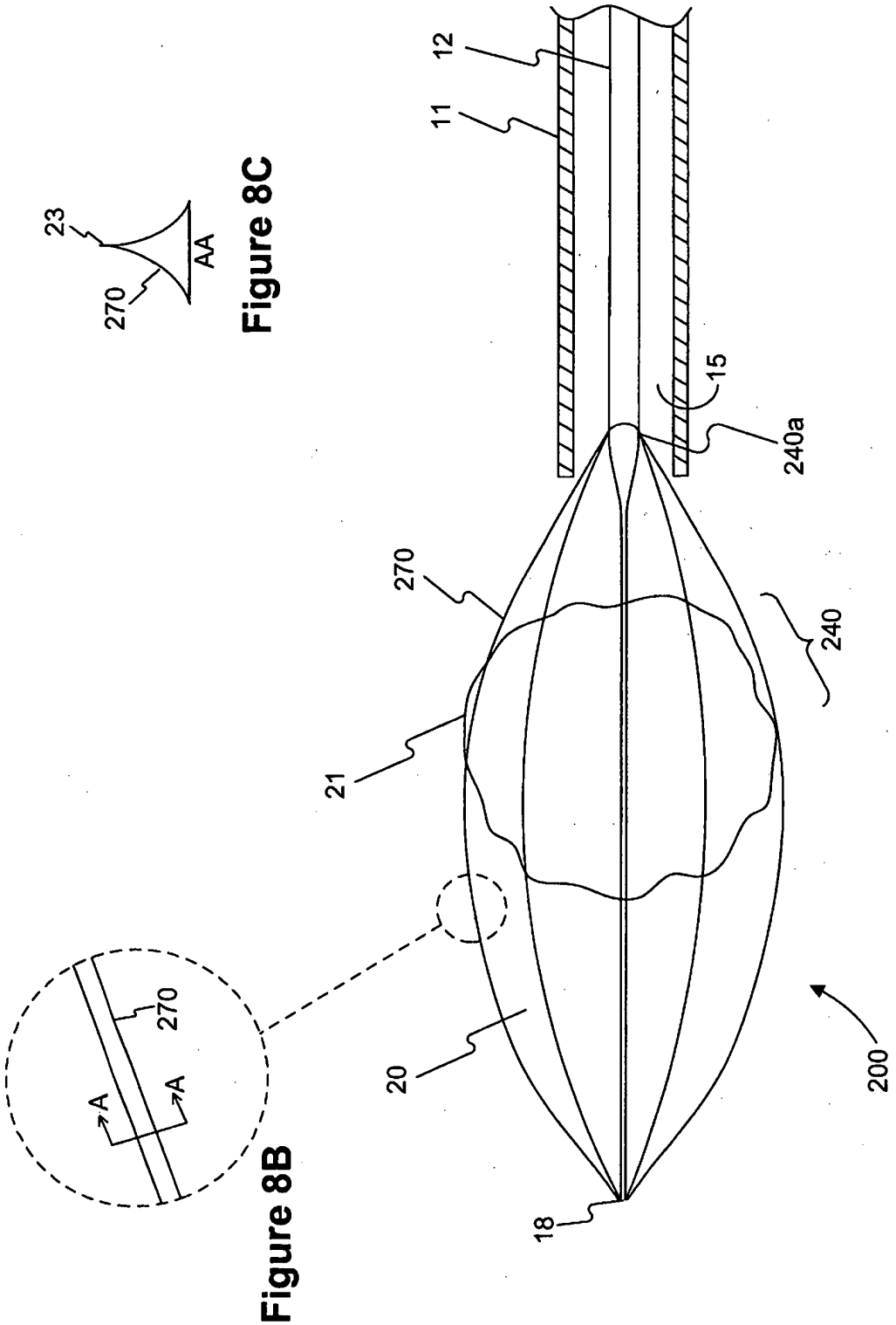

Figure 8A

Figure 8B

Figure 8C

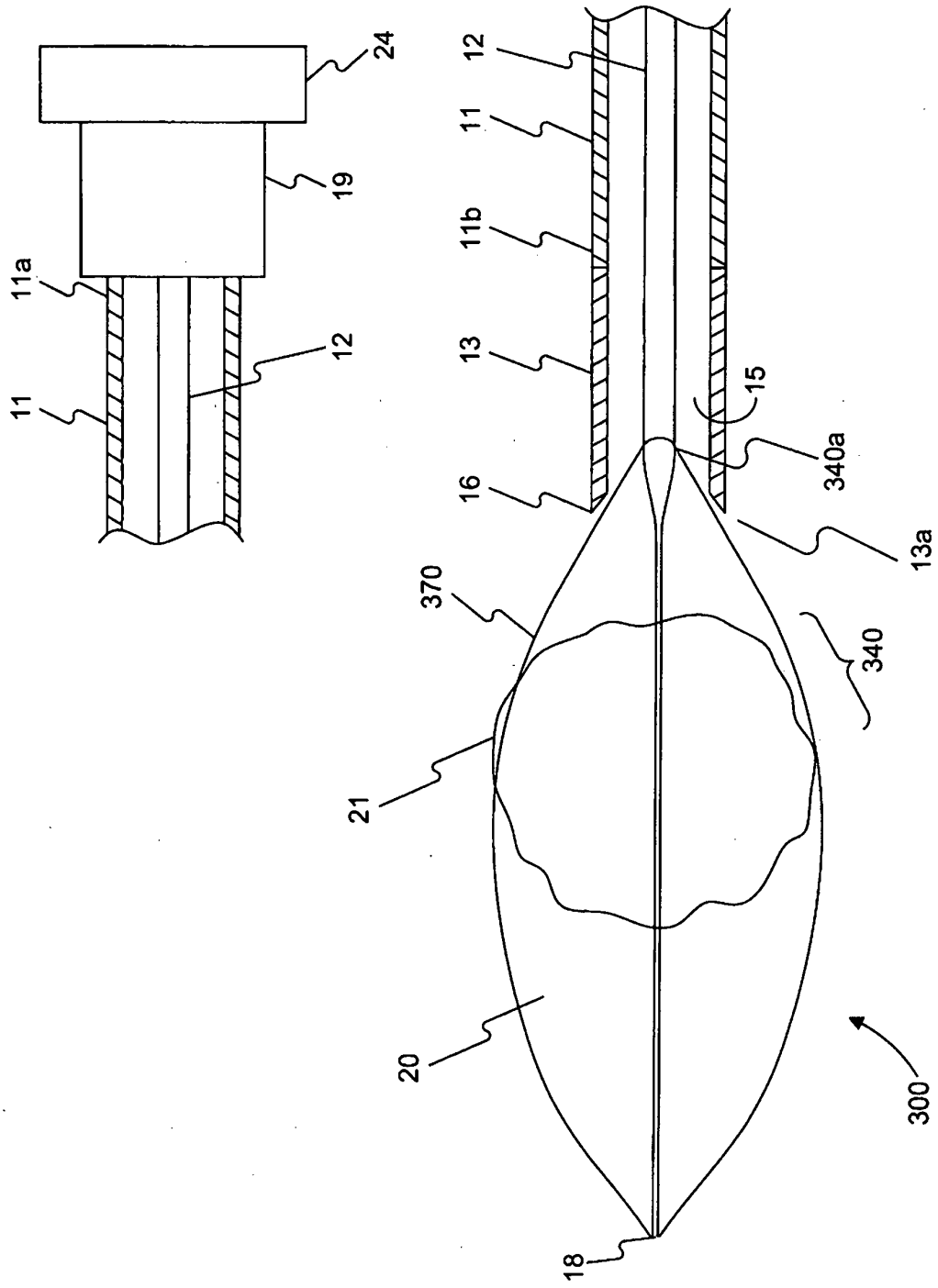

Figure 9

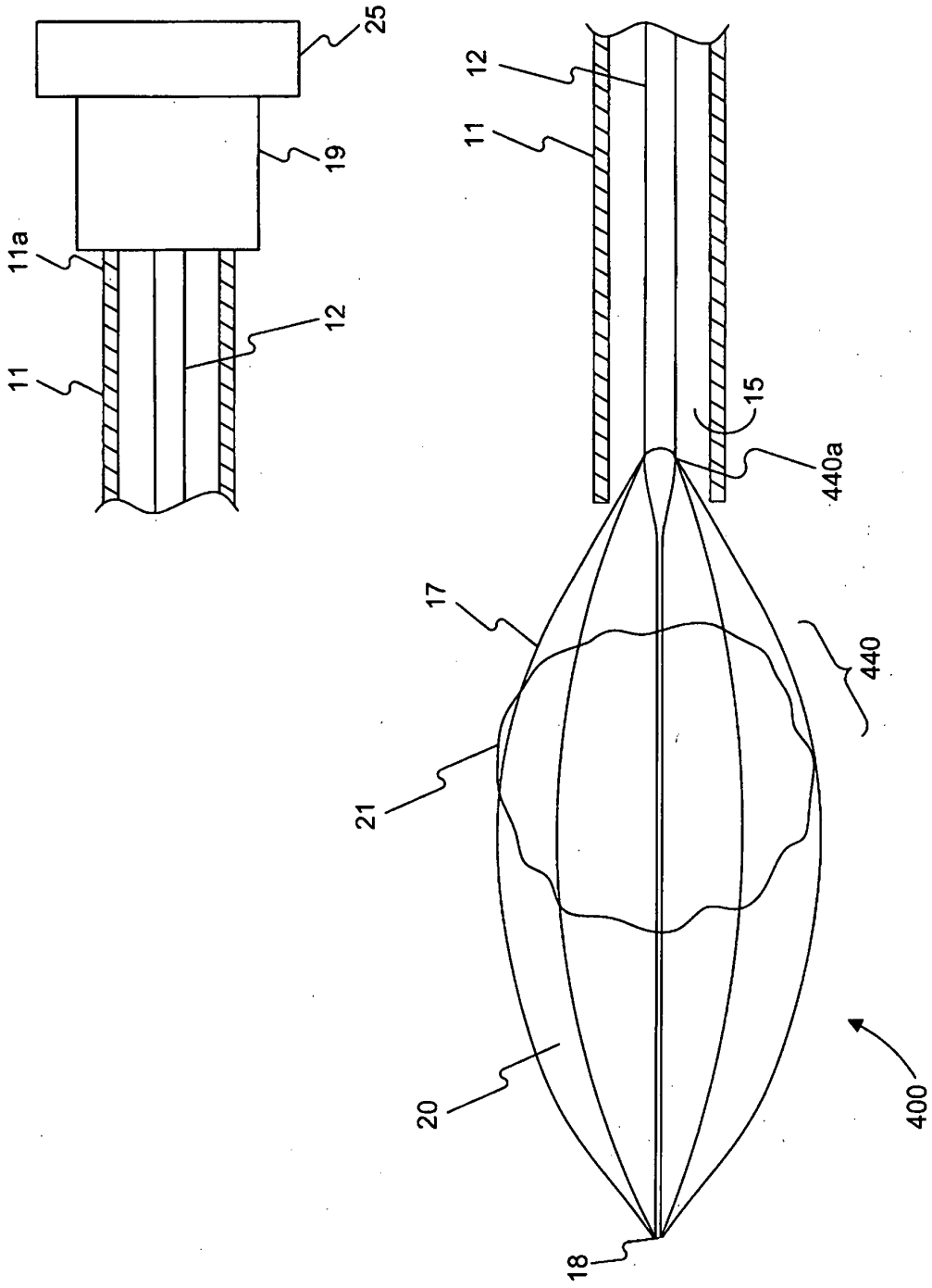

Figure 10

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 20080223171 A **[0005]**

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摘要(译)

提供了一种装置和相关的使用方法，用于捕获和移除体内解剖腔内存在的各种不需要的物体。在本公开的一个实施例中，所述装置包括护套，切割装置，细长构件和回收组件，所述回收组件连接到细长构件并且可在延伸穿过护套和切割装置的内腔中伸缩并且可从内腔延伸。

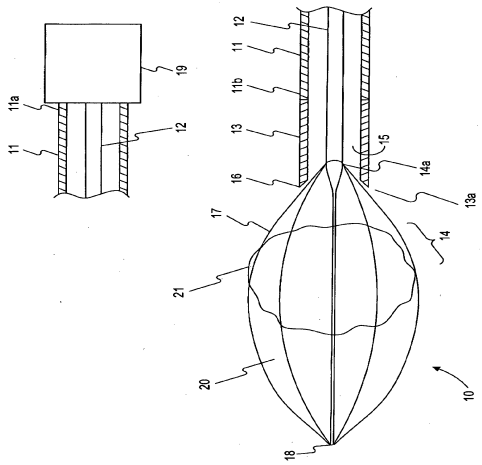

Figure 1