(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
28 January 2010 (28.01.2010)

PCT

(10) International Publication Number
WO 2010/011695 A1

(51) **International Patent Classification**:
A61B 1/32 (2006.01)

(21) **International Application Number**:
PCT/US2009/051317

(22) **International Filing Date**:
21 July 2009 (21.07.2009)

(25) **Filing Language**: English

(26) **Publication Language**: English

(30) **Priority Data**:
61/082,449 21 July 2008 (21.07.2008) US

(71) **Applicant** *(for all designated States except US)*: **ARSTASIS, INC.** [US/US]; 1021 Howard Avenue, San Carlos, CA 94070 (US).

(72) **Inventors; and**
(75) **Inventors/Applicants** *(for US only)*: **DREWS, Michael** [US/US]; 4033 Campana Drive, Palo Alto, CA 94306 (US). **MODESITT, D., Bruce** [US/US]; 120 Wingate Avenue, San Carlos, CA 94070 (US).

(74) **Agents**: **KOPCZYNSKI, Jeffie** et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).

(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

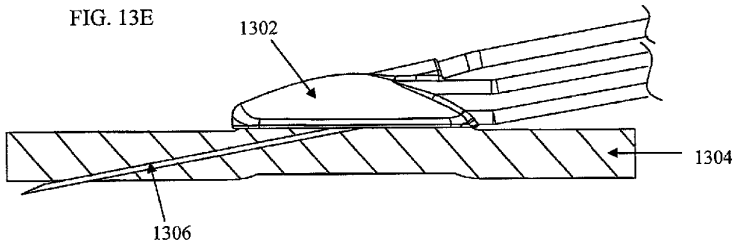
(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) **Title**: DEVICES, METHODS, AND KITS FOR FORMING TRACTS IN TISSUE

FIG. 13E



(57) **Abstract**: Described here are methods and devices for forming tracts in tissue. Some of the devices comprise an elongate member, a suction member coupled to a distal portion of the elongate member, and a tissue-piercing member slidably housed within the elongate member for forming a tract in tissue. Other devices comprise more than one suction member. Methods for forming tracts in tissue are also described here. In some methods, a device is advanced adjacent tissue, where the device comprises one or more suction members and a tissue-piercing member. Suction is applied so that the tissue is drawn against the one or more suction members, and a tissue-piercing member is advanced in a first direction through the drawn tissue to form a tract in or through the tissue. Kits incorporating one or more of the devices described here, in conjunction with one or more tools or the like, are also described here.

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DEVICES, METHODS, AND KITS FOR FORMING TRACTS IN TISSUE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 61/082,449, filed July 21, 2008, the disclosure of which is incorporated herein by reference in its entirety.

FIELD

[0002] In general, the methods, devices, and kits described herein are useful for forming tracts in tissue. More specifically, the methods, devices, and kits described herein are useful for forming tracts in tissue using one or more suction members.

BACKGROUND

[0003] A number of devices and methods have previously been described for forming tracts in or through tissue. For example, U.S. Pat. App. Nos. 10/844,247, 11/544,196, 11/545,272, 11/544,365, 11/544,177, 11/544,149, 10/888,682, 11/432,982, 11/544,317, 11/788,509, 11/873,957 all of which are incorporated by reference in their entirety herein, describe devices and methods for forming tracts in tissue. In general, the tracts described there self-seal or seal with minimal or no need for supplemental closure devices or techniques. These tracts may be quite useful in providing access to a tissue location (e.g., an organ lumen) so that one or more tools may be advanced through the tract, and a procedure may be performed. Given the tremendous applicability of such methods, additional devices and methods of forming tracts in tissue would be desirable.

BRIEF SUMMARY

[0004] Described here are methods and devices for forming tracts in tissue. In some variations, the devices comprise an elongate member, a suction member coupled to a distal portion of the elongate member, and a tissue-piercing member slidably housed within the elongate member for forming a tract in tissue. The elongate member may or may not be flexible. In some variations, the suction member is coupled to the elongate member via a flexible portion, e.g., a hinge or the like.

[0005] The elongate member may be articulatable, the tissue-piercing member may be articulatable, the suction member may be articulatable, or any combination of the foregoing members may be articulatable. These members may be articulatable for instance, using one or more pull wires, one or more hinges, or the like.

[0006] In some variations, the tissue-piercing member is a needle. The needle may be hollow or solid, and may have any suitable tip. That is, the tip may have any suitable shape (conical, offset conical, etc.), may be blunt, sharpened or pointed, and may be beveled or non-beveled.

[0007] The suction member may be connected to one or more vacuum sources. For example, the elongate member may have one or more lumens, slots, holes, openings, etc. for facilitating connection of the suction member to a vacuum source. In some variations, the suction member has one or more tissue apposition members thereon. The tissue apposition member may be, for example, a contoured surface, such as a rib. Any number of tissue apposition members may be used as desirable or appropriate. Similarly, the suction members may comprise one or more heating elements, one or more electrodes, or one or more sensors (e.g., Doppler, pressure, nerve sensors, ultrasound sensors, etc.), one or more drug delivery ports along a surface thereof, one or more traction members, or the like. The suction member may have any suitable geometry. In some variations, the basal surface of the suction member is generally elliptical in shape. In other variations, the basal surface of the suction member is generally circular in shape. In still other variations, the basal surface of the suction member has an irregular geometry.

[0008] Other devices for forming tracts in tissue comprise an elongate member, a first suction member coupled to a distal portion of the elongate member and positionable against tissue, a second suction member opposed to the first suction member, and a tissue-piercing member for forming a tract in tissue. The tissue-piercing member may be slidably housed within the elongate member, slidably housed within the first or second suction members, or both slidably housed within the elongate member and within either the first or second suction member. The first suction member may be coupled to a distal portion of the elongate member via a flexible portion, e.g., a hinge. Similarly, the second suction member may be coupled to a distal portion of the elongate member, or the first and second suction members may be coupled together, e.g., via a flexible portion such as a hinge. One or more

suction members may be movable with respect to the elongate member, with respect to other suction members, or both.

[0009] In these variations, the elongated shaft may be articulatable, flexible, or both. Of course, the elongated shaft may also be non-articulatable and/or rigid. The first and second suction members may be connected to a vacuum source, may be moveable relative to one another, and may have any suitable geometry (e.g., generally elliptical, generally circular, generally semi-circular, etc.). Either the first or second suction members may have one or more tissue apposition members thereon, e.g., a contoured surface or rib. Similarly, either the first or second suction members may comprise one or more heating elements, one or more electrodes, or one or more sensors (e.g., Doppler, pressure, etc.), one or more traction members, one or more ports, and the like. In some variations, the tissue-piercing member is a needle. As with the devices described above, the needle may be hollow or solid, and may have any suitable tip. That is, the tip may have any suitable shape (conical, offset conical, etc.), may be blunt, sharpened or pointed, and may be beveled or non-beveled.

[0010] In some variations, the device further comprises one or more energy applicators and the method further comprises applying energy to the tissue. The energy may come from any suitable energy source (e.g., energy selected from the group consisting of ultrasound, RF, light, magnetic, or combinations thereof). In some variations, the device comprises one or more sensors and the method further comprises sensing at least one useful parameter, e.g., temperature, pressure, tissue identification or location (e.g., nerves or various anatomical structures), blood flow within a vessel, and combinations thereof. For example, in some variations, the parameter is blood flow within a vessel, and the method further comprises repositioning the device if blood flow within a vessel is detected. Kits incorporating one or more of the devices described here, in conjunction with one or more tools or the like, are also described here.

[0011] Methods for forming tracts in tissue are also described here. In accordance with some methods, a device is advanced adjacent tissue, where the device comprises one or more suction members and a tissue-piercing member. Suction is applied so that the tissue is drawn against the one or more suction members, and a tissue-piercing member is advanced in a first direction through the drawn tissue to form a tract in or through the tissue. The methods may further comprise, articulating the tissue-piercing member and

advancing the tissue-piercing member in a second direction. In some variations, the method further comprises articulating the one or more suction members to reposition the tissue, with or without advancing the tissue-piercing member through the repositioned tissue. The methods may further comprise rotating the device to rotate the tissue, and advancing the tissue-piercing member through the rotated tissue. Of course, the methods may also include visualizing the tissue, advancing one or more tools through the tissue tract, performing a procedure adjacent to, through, or on the tissue, determining the location of the device with respect to the tissue, combinations thereof, and the like.

[0012] The methods described here may also comprise delivering one or more fluids or agents to the tissue. The fluids may be useful, for example, for irrigation, sterilization, treatment of tissue (therapeutic, etc.), or the like. The fluids may comprise any suitable agent or combination of agents. For example, the agent may be selected from the group consisting of antibiotics, antiseptics, sterilizing agents, chemotherapeutics, non-steroidal anti-inflammatory drugs (NSAIDs), cyclooxygenase-1 (COX-1) inhibitors, cyclooxygenase-2 (COX-2) inhibitors, opioids, or any other drug or agent, and mixtures and combinations thereof. The fluid may also comprise one or more cryogenic agents, e.g., to freeze tissue, reduce inflammation, cause localized cell death, some combination of the foregoing, or the like. The cryogenic agent may be, for example, liquid nitrogen or some other cryogenic agent. Furthermore, a metal or polymer tubular conduit may be located within, outside, around, or adjacent to, the suction member, and may be coupled to a conduit located in, around, or adjacent to the elongated member, such that the cryogenic agent passes from one conduit to the next without ever directly contacting the tissue. In this way, a heat exchanger of sorts is created, so that he heat is removed from within the suction member and the temperature of the tissue is reduced to a therapeutic level. In some variations, as will be described in more detail below, the tissue-piercing member is configured to provide for injection of an agent.

[0013] The methods may be used with any suitable tissue. In some variations, the tissue is an organ, e.g., an organ of the cardiovascular system, an organ of the digestive system, an organ of the respiratory system, an organ of the excretory system, an organ of the reproductive system, or an organ of the nervous system. In some variations, the organ is an organ of the cardiovascular system, e.g., an artery. When the methods described here are used, the tract may seal in a relatively short amount of time, and may seal with or without

additional aid. In some variations, the tract seals within 15 minutes or less, within 12 minutes or less, within 10 minutes or less, within 5 minutes or less, within 3 minutes or less, or within 1 minute or less. Of course, pressure or suction may be applied to the tract after it has been formed to aid in sealing. In addition, one or more closure devices may also be used.

[0014] In accordance with the methods described here, the tissue-piercing member may be advanced in an undulating fashion, or may be rotated during advancement. In some variations, the tissue-piercing member enters the tissue at a first location, and exits the tissue at a second location, and the length between the first location and the second location is greater than the thickness of the tissue. In some variations, the length of the tract is greater than the thickness of the tissue. In some variations, the methods further comprise enlarging the cross-sectional area of the tract.

[0015] Some variations of methods described here may be used to form a single self-sealing tract in tissue, or may be used to form one or more self-sealing tracts in tissue by advancing a single tissue-piercing member into the tissue. This may, for example, result in minimal stress on the tissue. Moreover, the tissue may recover relatively quickly, thereby resulting in relatively short procedure time.

[0016] Certain variations of the methods described here may comprise forming a tract in tissue by advancing a first tissue-piercing member (e.g., a needle, such as a hollow needle) in a first direction through the tissue, where formation of the tract requires advancement of only the first tissue-piercing member through the tissue, and where the tract is self-sealing. The methods may also comprise advancing a device comprising the first tissue-piercing member adjacent to the tissue prior to advancing the first tissue-piercing member through the tissue. In some variations, the methods may comprise applying suction to the tissue to position the tissue. For example, the device may further comprise one or more suction members, and the methods may comprise applying suction to the tissue to draw the tissue against the suction member or members. In certain variations, the first tissue-piercing member may be advanced in the first direction through the drawn tissue. In some variations, the tract may be formed in the tissue after the tissue has been positioned by the application of suction. The tract may, for example, be an arteriotomy.

[0017] Some variations of the methods described here may comprise advancing a tissue-piercing member in a first direction through tissue to form a single tract in the tissue,

where the single tract is self-sealing. Certain variations of the methods described here may comprise advancing a device adjacent tissue, where the device comprises at least one tissue-piercing member. The methods may further comprise forming a tract in the tissue by advancing the tissue-piercing member or members through the tissue. Formation of the tract may require advancement only of the tissue-piercing member or members through the tissue. The tract may be self-sealing.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] FIG. 1 is an illustrative depiction of the distal end of an exemplary device that may be used to form tracts in tissue as described here.

[0019] FIGS. 2A-2F depict various suitable configurations of how elongate members and suction members may be coupled to one other including depictions of the lumen configurations associated therewith.

[0020] FIGS. 3A and 3B provide depictions of an illustrative device as described herein, in an unflexed and flexed state respectively.

[0021] FIG. 4A depicts an illustrative suction member having one or more tissue apposition members, here in the form of four ribs and one peripheral rib (forming a generally cross-shape configuration). FIG. 4B is a close-up of the device of FIG. 4A taken along detail C.

[0022] FIG. 5 depicts an illustrative suction member having one or more tissue apposition members, here in the form of eight ribs and one peripheral rib (forming a generally star-shape configuration).

[0023] FIG. 6 provides an illustration of a suction member having a mesh or screen covering the suction ports.

[0024] FIG. 7A depicts an illustrative suction member having a central circular rib in addition to the four joining ribs and one peripheral rib.

[0025] FIGS. 7B and 7C depict a suction member where the peripheral rib is collapsible or inwardly distortable, shown in its non-collapsed and collapsed state respectively.

[0026] FIG. 7D shows a variation of a suction member having tongs to capture tissue therebetween.

[0027] FIG. 7E shows a variation of a suction member having needles to puncture tissue.

[0028] FIGS. 8A and 8B provide an illustration of tissue-piercing member deployment when the tissue-piercing member exits within or through the suction member.

[0029] FIG. 8C shows a variation of a suction member where the tissue-piercing member exits within or through the suction member, where the suction member is toroidal or donut shaped defining one or more apertures therethrough.

[0030] FIGS. 9A and 9B provide an illustration of tissue-piercing member deployment when the tissue-piercing member exits within or through the suction member, where the tissue apposition members have one or more traction members thereon.

[0031] FIGS. 9C-9F depict illustrative traction members.

[0032] FIGS. 9G and 9H provide an illustration of tissue-piercing member deployment when the tissue-piercing member exits within or through the suction member, where the tissue suction member comprises a ridge having one or more teeth.

[0033] FIG. 9I is an illustrative cross-sectional depiction of how tissue may fold around and/or underneath the ridge of the suction member depicted in FIGS. 9G and 9H.

[0034] FIGS. 9J and 9K provide an illustrative cross-sectional depiction of how tissue may fold around and/or underneath an illustrative articulatable or moveable ridge of a suction member.

[0035] FIG. 9L depicts an illustrative suction member comprising a ridge having teeth and also channels for distributing vacuum. FIG. 9M is a cross-sectional view of the device of FIG. 9L taken along line A-A to better illustrate channels for distributing vacuum.

[0036] FIG. 9N shows a variation of a suction member having one or movable members to clamp tissue therebetween where the members are in the form of ridges with teeth.

[0037] FIGS. 9O depicts a basal surface of a suction member, where the basal surface of the suction member defines a series of apertures or windows.

[0038] FIGS. 9P and 9Q are cross-sectional views of the suction member of FIG. 9O depicting how tissue may be captured against one ore more walls defining the windows or apertures.

[0039] FIGS. 9R-9U depict how an expandable or other tissue-contacting member may be used to contact or engage tissue opposite the basal surface of the suction member so that tissue may be stretched across the basal surface of the suction member.

[0040] FIGS. 10A-10D depict illustrative suction members where the suction members have one or more discrete features thereon or therein, such as electrodes, heating elements, sensors, markers, cameras, or the like.

[0041] FIGS. 11A-11D provide illustrative variations of elongate member-suction member attachments, detailing various suitable angles of attachment.

[0042] FIGS. 12A and 12B depict one variation of a device having two suction members, shown in an open and collapsed configuration respectively.

[0043] FIGS. 13A-13M depict an illustrative method for forming a tract in or through tissue with FIGS. 13G and 13H specifically depicting suitable distal expandable features of a guide wire for use with the methods described herein.

[0044] FIGS. 13N-13P depict one variation of a method for detecting a tissue location or boundary.

[0045] FIGS. 14A-14C depict another illustrative method for forming a tract in or through tissue, here where the device is articulated to redirect the tissue-piercing member.

[0046] FIG. 15A is an overview illustration of how the devices described herein may advanced through a natural body orifice and used to form a tract in or through tissue, in this case, the stomach.

[0047] FIGS. 15B and 15C provide illustrative variations of fluid delivery and collection configurations.

[0048] FIGS. 15D and 15E provide an illustrative depiction of an articulatable elongate member.

[0049] FIGS. 15F and 15G depict illustrative handles for use with the devices described herein.

[0050] FIGS. 15H and 15I depict illustrative cross-sectional views of portions of illustrative elongate members.

[0051] FIGS. 16A-16I depict an illustrative method for forming a tract in or through stomach tissue.

[0052] FIGS.17A-17D depict an illustrative method of accessing the pericardial space in connection with the methods described herein.

[0053] FIGS. 18A-18K depict an illustrative method for forming a tract in or through heart tissue.

DETAILED DESCRIPTION

[0054] Described here are methods and devices for forming tracts in tissue. In general, the devices described here comprise one or more suction members for drawing tissue thereagainst, for facilitating advancement of a tissue-piercing member therethrough. The devices may take on a variety of forms and may have a number of additional or useful features, as will be described in detail below. The devices may be used to form tracts through any type of tissue. The tissue may be tissue of the cardiovascular system, the digestive system, the respiratory system, the excretory system, the reproductive system, the nervous system, or the like.

[0055] In general, when the devices described here are used to form tracts in or through the tissue, the tracts are capable of self-sealing with minimal or no additional sealing efforts, as described, for example, in U.S. Pat. App. Nos. 10/844,247, 11/544,196, 11/545,272, 11/544,365, 11/544,177, 11/544,149, 10/888,682, 11/432,982, 11/544,317, 11/788,509, 11/873,957, 12/467,251, 61/119,316, and 61/178,895, each of which is incorporated by reference herein in their entirety. It should be understood from the outset, however, that the devices and methods described here may be complemented by the use of one or more additional closure mechanisms or techniques (e.g., closure devices, delivery of energy, application of pressure, etc.). Kits incorporating one or more of the devices described here, in conjunction with one or more tools or the like, are also described here. Variations of the devices, methods, and kits will now be described.

I. DEVICES

[0056] FIG. 1 provides an illustrative device (100) for forming tracts in tissue in accordance with the methods described herein. Shown there is suction member (102) coupled to an elongate member (104). The elongate member may be any suitable member that serves to connect the suction member (102) to the proximal end of the device (not shown). The elongate member (104) may comprise one or more lumens for providing additional features or controls for the device. For example, the elongate member (104) may comprise a lumen for vacuum or suction (106), a lumen for housing a tissue-piercing member therein, or the like. The elongate member (104) may also comprise one or more lumens for housing one or more pull wires (110), optical or electrical connections (e.g., to deliver power, to connect sensors, to provide visualization, etc.), and the like.

[0057] Additional variations of suitable lumen and elongate member configurations will be described with reference to FIGS. 2A-2F below. Proximal control will be described in more detail below with reference to the methods, however, it is noted at the outset that proximal controls may include one or more buttons, switches, or sliders to actuate one or more features of the device (e.g., to actuate a tissue-piercing member, to actuate delivery of fluid, to actuate vacuum, to actuate delivery of energy, to actuate visualization, etc.). Of course, the proximal control may also include (alone or in combination with those controls just described) one or more valves (e.g., two-way or three-way valves) to help turn on or off the vacuum, on or off a flush line, and the like.

[0058] When pull wires are used, they may be used, for example, to help facilitate movement, control, or actuation of the device. In the variation shown in FIG. 1, pull wire (110) is used to articulate the suction member (102) at region (112). Region (112) may comprise a region of reduced thickness or greater flexibility when compared with the remainder of the suction member (102) or the elongate member (104). Region (112) may be made of the same or different material than the suction or elongate members. For example, region (112) may comprise a softer material, a thinner material, a more flexible material, or other different material than the suction or elongate members, or region (112) may be made of the same general material as the suction or elongate members with one or more physical or chemical property modifications. Region (112) may also comprise one or more joints or hinges (e.g., single or multiple flexure joints, revolute joints, pivot hinges, molded plastic live hinges, ball and socket joints, slidable tubes with counter-opposed flexure elements, etc).

[0059] Of course, the elongate member may be made of any suitable biocompatible material. For example, it may comprise or be made of stainless steels, for example, 304, 304L, 316, 316L, 440C, or the like, titanium alloys, for example 6Al-4V or the like, nickel-titanium alloys (Nitinol), cobalt-chromium alloys, for example Elgiloy® (Elgiloy Specialty Metals, Elgin, IL), MP35N® (SPS Technologies, Inc, Jenkintown, PA), Phynox® (Imphy Ugine Precision, France), or the like, aluminum, polymers, for example, ABS, nylon, acetal, high-density polyethylene (HDPE), low-density polypolyethylene (LDPE) polyester, polyurethane, polypropylene, polyolefin, urethane, silicone, polyvinylchloride (PVC), polycarbonate, polyetherimide (PEI), polyethersulfone, polyarylethersulfone, polysulfone, ultrahighmolecularweightpolyethlene (UHMW-PE), polyetheretherketone (PEEK), polyetherketoneketone (PEKK), PEBAX® (Colombes Cedex, France), polytetrafluroethylene (PTFE), or any other polymer, polymer blend, or filled polymer, for example, glass-fiber, carbon-fiber, or other suitable carbon based material. Additionally, any compound/agent to improve the polymers radioopacity may be incorporated, for example, barium sulphate, platinum, gold, tungsten, or the like. The elongate member may also be made to have one or more scalloped or contoured edges (e.g., top, bottom, side) to help impart flexibility.

[0060] Similarly, the suction member may be made of any suitable biocompatible material. For example, the suction member may comprise or be made from stainless steels, for example, 304, 304L, 316, 316L, 440C, or the like, titanium alloys, for example 6Al-4V or the like, nickel-titanium alloys (Nitinol), cobalt-chromium alloys, for

example Elgiloy® (Elgiloy Specialty Metals, Elgin, IL), MP35N® (SPS Technologies, Inc, Jenkintown, PA), Phynox® (Imphy Ugine Precision, France), or the like, polymers, for example, ABS, nylon, acetal, high-density polyethylene (HDPE), low-density polypolyethylene (LDPE) polyester, polyurethane, polypropylene, polyolefin, urethane, silicone, polyvinylchloride (PVC), polycarbonate, polyetherimide (PEI), polyethersulfone, polyarylethersulfone, polysulfone, ultrahighmolecularweightpolyethlene (UHMW-PE), polyetheretherketone (PEEK), polyetherketoneketone (PEKK), PEBAX® (Colombes Cedex, France), polytetrafluroethylene (PTFE), polyimide, or any other polymer or polymer blend or filled polymer, for example, glass-fiber, carbon-fiber, or any other suitable carbon-based material. Additionally, any compound/agent to improve the polymers radioopacity may be incorporated, for example, barium sulphate, platinum, gold, tungsten, or the like.

[0061] The suction member, the elongate member, or both members may be made of one or more materials to impart flexibility, rigidity, or any other suitable characteristic. It should also be understood that a variety of different materials may be used for each of these members, and that the members may be constructed accordingly. For example, the suction member (102) may be made with a flexible periphery using an overmolding technique, understood by those having ordinary skill in the art. Also, while the suction member (102) is shown in FIG. 1 as having a generally elliptical basal (or tissue contacting) surface, it should be understood that the basal surface of the suction member may have any suitable or desirable geometry (e.g., circular, rectangular, triangular, toroidal, etc.). Of course, the geometry need not be symmetric, uniform, regular, or easily describable. As will be described in more detail below, the suction member (102) may also comprise one or more additional features (e.g., contoured surfaces, electrodes, sensors, tissue apposition members, traction members, channels, ports, cameras, markers, etc.).

[0062] FIGS. 2A-2D provide illustrative depictions of suitable devices detailing various suitable suction member-elongate member junctions. Shown in FIG. 2A is device (200) comprising a suction member (202) and elongate portion (204). In this variation, the elongate portion (204) comprises discrete elongate bodies (206 and 208), each separately defining a lumen. Elongate body (206) may provide a conduit for vacuum or suction, while elongate body (208) may serve to slidably house a tissue-piercing member therein. In the variation shown in FIG. 2A, both elongate members (206 and 208) are connected or attached to (e.g., by overlapping fit, edge-to edge, fit etc.) connector (210), which in turn is connected

to the suction member (202). The connection between connector (210) and suction member (202) may be effected in any suitable manner. For example, the connector (210) and the suction member (202) may be connected via welding (ultrasonic, heat, chemical, etc.), snap-fit, press-fit, using inter-locking features, using one or more adhesives or glues, using one or more mechanical features or fixtures (e.g., screws, clamps, crimps, rivets, tabs, bolts, etc.), or the like.

[0063] The variation depicted in FIG. 2A may find particular utility in instances where greater flexibility is desirable (e.g., when maneuvering through tortuous anatomy). It should be understood that the connector (210) may be integral with the suction member (202) (i.e., the connector and suction member may be formed from a single piece of material), but need not be. It should also be understood that while the elongate bodies (206 and 208) depicted in FIG. 2A have generally circular cross-sections, the elongate bodies may have cross-sections having any suitable geometry.

[0064] FIG. 2B provides an alternative variation of a device for use with the methods described herein. Shown in FIG. 2B is a device (212) comprising suction member (214) and elongate member (216). In this variation, the elongate member (216) defines discrete lumens (218, 220, 222) as shown in FIG. 2C. In variations where additional flexibility may be desirable, the elongate member (216) of FIG. 2B may have one or more scalloped or contoured edges as described above.

[0065] Any of the lumens described herein may be used for any suitable purpose (e.g., facilitating vacuum or suction, delivering fluids or drugs, housing one or more electrodes, housing one or more pull wires, housing one or more tissue-piercing members, etc.). It should be understood that more than one lumen may be used for the same general purpose (e.g., two lumens for housing two pull wires, two lumens for delivering two separate drugs, etc.), and that the lumens may have any suitable cross-sectional geometry (whether the same or different). It should also be understood, that a single lumen may be useful in facilitating more than one function (e.g., a single lumen may house a pull wire (211), and serve as a conduit for vacuum or suction, as with the variation shown in FIG. 2A above). The lumens may be concentric and may or may not define complete enclosures (e.g., one or more lumens may approximate a slit or groove). The lumens may also be variously positioned about or along the elongate member. For example, the lumens may be vertically positioned

as shown in FIG. 2C, horizontally positioned, randomly positioned, or selectively positioned along a plane to help impart additional flexibility to the device. The lumens may or may not be positioned in accordance with any given pattern.

[0066] FIG. 2D depicts a device (224) similar to that of FIG. 2B, except that the elongate member (228) is connected to the suction member (226) via connector (230). FIG. 2E provides a cross-sectional representation of the device (224) taken along line B-B. The lumens shown there (232, 234, 236) may have any of the features or characteristics described just above. The variations shown in FIGS. 2B and 2D may be of particular utility when device rigidity and/or torquability is desired.

[0067] FIG. 2F provides an illustration of a device having both integral lumens, and a discrete connector for vacuum. Shown there is device (238) comprising suction member (240), elongate member (242), and vacuum hose or connector (244). In this variation, the tissue-piercing member is configured to exit within the suction member (240), as will be discussed in more detail below. Thus, the basal surface of the elongate member need not extend beyond the basal surface of the suction member. This may be useful, for instance, in that it may impart a reduced profile to the device, and may help prevent unwanted potential interference with tissue.

[0068] FIGS. 3A and 3B provide depictions of an illustrative device in an unflexed and flexed state respectively. Flexure and articulation of the device along with redirection of the tissue-piercing member will be discussed in greater detail below with reference to the methods. Shown in FIGS. 3A and 3B is device (300), comprising suction member (302) and elongate member (304). In both figures, elongate member (304) has been removed along a proximal portion for ease of explanation. As shown there, elongate member houses tissue-piercing member (306) slidably therein (e.g., in a lumen defined by the elongate member). In FIG. 3A the device is shown in an actuated, but unflexed fashion (i.e., the tissue-piercing member has been advanced out of exit port (308), but has not been flexed).

[0069] The initial (i.e., unflexed or unarticulated) angle (A) defined by the basal surface of the suction member (302) and the tissue-piercing member (306) may be any suitable angle. For example, the angle may be from about 0° to about 180°, from about 0° to about 90°, from about 90° to about 180°, from about 0° to about 60°, from about 0° to about 30°, from about 3° to about 10°, about 5°, or the like.

[0070] FIG. 3B shows device (300) after pull wire (310) has been pulled proximally causing flexure at region (312). In the variation shown in FIG. 3B, flexure of the device changes the angle (A) defined by the basal surface of the suction member (302) and the tissue-piercing member (306) (e.g., increases or decreases the angle) as the tissue-piercing member lumen is deflected downward. The tissue-piercing member shown in FIGS. 3A and 3B is a beveled needle, though the tissue-piercing member need not be a needle (e.g., the tissue-piercing member may be a wire, energy delivery device, etc.). In variations, where the tissue-piercing member is a needle, the needle may be solid or hollow, may have two or more concentric needle members, may be beveled or non-beveled, and may be pointed, sharpened, or blunt. When needles are used, the needle tip may have any suitable geometry, e.g., conical, offset conical, rounded, or the like. The tissue-piercing member may be individually, discretely, or separately articulated by one or more pull wires. Of course, in instances where the tissue-piercing member is housed within one or more lumens of the elongate member or the like, the tissue-piercing member may be sterilized and kept sterilized prior to use.

[0071] It should also be understood that while tissue-piercing member lumen (308) is shown in FIGS. 3A and 3B as exiting adjacent to the suction member (302), the lumen may instead exit within or through the suction member (302), as will be described in more detail below. Of course, the elongate member may comprise any number of ports (e.g., for multiple tissue-piercing members, for additional tools, or the like), which in turn may be connected to one or more lumens.

[0072] FIGS. 4-10 depict illustrative variations of suitable suction members for use with the devices and methods described here. These figures provide views of the underside of the suction members. Beginning with FIGS. 4A and 4B, a suction member (400) is shown having one or more tissue apposition members. In this variation, the tissue apposition member comprises one or more joining ribs (402) connected to a peripheral or bounding rib (404). It should be understood that while four ribs (402) are shown connected to the peripheral rib (404), any number of ribs (e.g., 0, 1, 2, 3, 4, 5 to a great many ribs) may be used, as will be apparent below. Indeed, in some variations, the suction member has only a peripheral or bounding rib, which is not joined by or connected to any other ribs. In other variations, the suction member has only a peripheral or bounding rib and a single central rib (positioned laterally or longitudinally) connected thereto.

[0073] The peripheral and joining ribs need not be separate members (i.e., the entire tissue apposition member may be formed from a single piece of material). In some instances, whether the tissue apposition member is formed from a single piece of material or is formed by connection of more than one member, it may be desirable to provide for one or more recesses (406) where the peripheral and joining ribs connect, as shown in FIG. 4A and in more detail in FIG. 4B. This may, for example, be desirable in order to provide a better vacuum seal along the basal surface of the suction member by providing a greater contact surface with the tissue. This in turn may make the seal less prone to disruption by tissue movement.

[0074] The ribs may be useful, for example, to keep the tissue at a distance from the vacuum ports (shown in FIG. 4A as (408)) to help prevent tissue from plugging those ports, and to help facilitate even distribution of vacuum (which in turn provides for greater uniformity in tissue apposition). The ribs may also help provide lateral traction for the suction member, since the boundaries of the ribs form discrete regions where tissue may enter. The number and geometry of the ribs may be selected to effect greater or lesser traction as desirable. When the methods and devices described here are used with very soft, compliant, or thin tissue (e.g., intestinal tissue), a greater number of ribs may be desirable.

[0075] Also shown in FIGS. 4A and 4B is lumen (410) within elongate member (412). Lumen (410), for example, may be useful for housing a tissue-piercing member slidably therein. Of course, the lumen may also be used for any of the purposes described above.

[0076] FIG. 5 provides an illustration of a suction member (500) having eight ribs (502) connected to peripheral rib (504), forming a generally star-shaped configuration. FIG. 6 provides an illustration of a suction member (600) having four ribs (602) connected to a peripheral rib (604). In the variation shown here, a mesh or screen (606) is provided that covers the suction ports. In this way, tissue may be prevented from entering and plugging the ports. While the screen (606) shown in FIG. 6 is positioned immediately adjacent to the suction ports, the screen may be placed at any suitable distance from the ports. That is, the screen (606) may be located at any depth within the suction member, and the depth may be selected as desirable, e.g., to affect tissue traction.

[0077] FIG. 7A provides another variation of a suction member (700), here having four joining ribs (702), one circular central rib (706), and a peripheral rib (704). Of course, the central circular rib (706) may itself be made from several ribs, or the central circular rib, in addition to the entire tissue apposition member, may be made from a single piece of material. It should be clear that while a circular central rib (706) is shown in FIG. 7A, any rib geometry may be used for the central rib member. Indeed, it should be clear that any number and geometry (width, length, depth, shape, etc.) of ribs may be used as desirable, and that these ribs may be separate or integrally formed.

[0078] The ribs may be made from any suitable biocompatible material or combination of materials. For example, the ribs may be made from stainless steel, for example, 304, 304L, 316, 316L, 440C, or the like, titanium alloys, for example 6Al-4V or the like, nickel-titanium alloys (Nitinol), cobalt-chromium alloys, for example Elgiloy® (Elgiloy Specialty Metals, Elgin, IL), MP35N® (SPS Technologies, Inc, Jenkintown, PA), Phynox® (Imphy Ugine Precision, France), or the like, polymers, for example, ABS, nylon, acetal, high-density polyethylene (HDPE), low-density polypolyethylene (LDPE) polyester, polyurethane, polypropylene, polyolefin, urethane, silicone, polyvinylchloride (PVC), polycarbonate, polyetherimide (PEI), polyethersulfone, polyarylethersulfone, polysulfone, ultrahighmolecularweightpolyethlene (UHMW-PE), polyetheretherketone (PEEK), polyetherketoneketone (PEKK), PEBAX® (Colombes Cedex, France), polytetrafluroethylene (PTFE), polyimide, or any other polymer or polymer blend or filled polymer, for example, glass-fiber, carbon-fiber, or other suitable carbon-based materials.

[0079] The ribs may also comprise or have one or more discrete members or features thereon, as will be described in greater detail below. The joining or peripheral ribs may also be collapsible, movable, or otherwise articulatable to provide greater maneuverability of the suction member along the tissue, or to enable gripping of tissue after the vacuum has been turned off. For example, the peripheral rib may be collapsible or inwardly distortable to capture tissue between its edges, as shown in FIGS. 7B and 7C. In this variation, the peripheral rib (707) distorts or collapses inwardly upon pushing wire (708). Of course, the peripheral rib (707) may be distortable by other mechanisms as well (e.g., pull wire, shape memory actuation, etc.). Also, while FIGS. 7B and 7C show a variation where the peripheral rib (707) is distorted in an elongated fashion, the peripheral rib may also be distorted in a lateral fashion, or an inwardly radial fashion.

[0080] FIG. 7D shows a variation of suction member (710) having tongs (712). One or both of the tongs may be actuatable, and the tongs may be actuatable in any suitable fashion (e.g., push-pull wire, etc.). This variation may be useful to capture or clamp tissue after the vacuum has pulled the tissue into the suction member cavity. While tongs are shown here, any suitable type of clamping, or gripping mechanism may be used. Of course, any of the suction members described here may have any number of clamping or gripping mechanisms. FIG. 7E is a similar variation to FIG. 7D, but here having needles (714) to puncture and hold tissue, instead of tongs (712).

[0081] FIGS. 8A and 8B provide an illustration of tissue-piercing member deployment when the tissue-piercing member exits within or through the suction member. That is, in contrast to those devices described above where the tissue-piercing member exits immediately adjacent the suction member, the tissue-piercing member shown in FIGS. 8A and 8B exits within the suction member itself. Of course, it should be understood that (while not shown in FIGS. 8A and 8B), the elongate member may comprise or define one or more ports immediately adjacent to the suction member for one or more purposes unrelated to tissue-piercing members, as described above. Shown in FIG. 8A is device (800) comprising a suction member (802) and elongate member (804). As described above, the tissue-piercing member (806) in this variation exits within the suction member (802). FIG. 8B shows tissue-piercing member (806) being further deployed. This for example, may be effected via the use of one or more pull wires or other controls, or manually by the user advancing the tissue-piercing member (806) distally.

[0082] FIG. 8C shows another variation of a suction member (810), where the tissue-piercing member (812) exits within the suction member cavity. A device of this configuration may help facilitate tissue traction as the device is moved along tissue. In this variation, the suction member (810) is generally donut shaped, or generally toroidal and defines a central opening or aperture (814). The suction member (810) of this variation comprises two toroidal shaped cavities (816, 818), which may be of the same or different height or depth, and which may independently be configured to allow for a particular volume of tissue therein. The device of this variation also comprises main vacuum port (820) connected via opening or conduit to inner vacuum port (822). In this way, suction may be facilitated about both toroidal cavities (816, 818). Of course, the suction member (810) may include any number of suitable vacuum or suction ports, placed at any suitable location, as

described above. Importantly, the toroidal shape of the suction member is just one shape that may be used with the devices described herein. As described hereinthroughout, the suction member may have any suitable geometry.

[0083] FIGS. 9A and 9B are similar to FIGS. 8A and 8B except that the device (900) of FIGS. 9A and 9B comprise tissue apposition members (902) having one or more traction members (904) thereon. This may be useful, for example, to increase tissue apposition and traction without having to alter the number of ribs or particularly select their geometry, and may be particularly useful or helpful during deployment of the tissue-piercing member. The traction members themselves may have any suitable geometry, size, or configuration, and may be made of, or coated with, any suitable material. Illustrative traction members are shown, for example, in FIGS. 9C-9F. Any of the traction members may have one or more ports, lumens, or apertures for delivery of agents or fluids therethrough. In this way, the traction members may additionally be used to locally deliver drugs (e.g., antibiotics for local sterilization purposes, etc.) or to flush the tissue adjacent to the traction members and/or suction member. It should be understood that while the suction member shown in FIGS. 9A and 9B only have traction members on the joining ribs, it should be understood that traction members may also be placed along or about the peripheral rib, in any suitable location or fashion.

[0084] FIGS. 9G and 9H show an alternative variation of a tissue suction member (910), here having a ridge (912) with teeth (913). Also shown in this variation is tissue-piercing member exit port (914, FIG. 9G) and tissue-piercing member (916, FIG. 9H) advanced out of tissue-piercing member exit port (914). In this variation, tissue may fold around and/or underneath ridge (912) when suction is applied, as shown in FIG. 9I (here shown with two tissue layers 920, 922). In this way, traction and gripping of tissue may be enhanced as the edge of the teeth (913) provide a tortuous path for the tissue to cross, while clogging of the suction port or ports may be mitigated, as previously described. This variation may be particularly useful when the devices are used with tissue that is slippery, amorphous, mucousy, or otherwise difficult to manipulate. Additionally, as with all variations having teeth described hereinthroughout, the teeth (913) may be oriented in any suitable manner. For example, the teeth (913) may be oriented in a direction that opposes the direction of the tissue-piercing member as it is advanced into tissue. Having a space (918) between the outer rim of the suction member and the ridge (912) may help to further increase

the ability of the tissue to collapse about the ridge (912) and further enhance the robustness of the vacuum seal by minimizing the disruption of the tissue during normal amounts of manipulation (or handling) that could otherwise lead to a vacuum leak.

[0085] The orientation and or geometry of the ridge (912) may be modified to affect more or less tissue capture in the suction member cavity. Similarly, the number and geometry (length, width, shape, etc.) of the teeth may be modified as desirable to affect tissue capture. For example, the ridge may include one tooth, two teeth, four teeth, six teeth, or even more teeth, and these teeth may be inwardly biased or outwardly biased, and may have any suitable shape. The teeth (913) need not be made from the same material as the ridge (912), and the teeth may or may not be planar with the ridge (912). The ridge (912) may be made from a single molded piece of material, as generally shown in FIGS. 9G and 9H, or may be made from a separate piece of material, and then clamped, welded, glued, or otherwise fastened or affixed to the suction member. Of course, the ridge may be made of any suitable biocompatible material (e.g., stainless steel, plastic, combination of materials, etc.).

[0086] Of course, when ridges are used in combination with the suction members described herein, they may be articulatable, controllable, tiltable, disengageable, or otherwise moveable. For example, FIG. 9J and FIG. 9K, depict one variation of a ridge (912') that is articulatable or rotatable within the suction member cavity. In this way, teeth (913') disengage from the tissue (shown in FIG. 9K), which may help the suction member release tissue that has been captured therein. This may be useful, for example, when attempting to remove, withdraw, or reposition the device. For example, in some variations, vacuum or suction may be maintained after the ridge (912') has been rotated into the suction member cavity so that the device can be translated along the approximated tissue surface. Once the device has been advanced to a second location, the ridge (912') may be redeployed or rotated back to its original position in order to "lock" onto or into or otherwise engage captured tissue. The ridge (912') may be actuated or rotated or otherwise controlled in any suitable manner. For example, one or more push-pull wires, spring(s) acting about the axis of articulation in conjunction with a pull-wire, pneumatic or hydraulic actuation, or the like. Of course, the rotatable ridge described here is just one variation of a suitable ridge. As described herein throughout, any moveable ridge, having any of the features described here

may be used with the devices and methods described here. One specific alternative variation of a moveable ridge is described in FIG. 9N below.

[0087] FIG. 9L depicts another variation of a suction member (924) having a ridge (926) with one or more teeth (928) thereon, where the suction member (924) has one or more channels (930) therein. FIG. 9M provides a cross-sectional view of the device of FIG. 9L taken along line A-A. This variation functions similarly to the variation of FIG. 9G described just above, with the addition of having channels. The channels may be useful, for example, to facilitate (or deliver and/or distribute) vacuum or suction, or delivery or collection of fluid, as will be described, e.g., with respect to FIGS. 15B and 15C below. Of course, the channels (930) may be used in conjunction with one or more ports located along or within the suction member to provide for delivery of one or more useful fluids (e.g., therapeutic, sterilization, flushing, etc.), as described hereinthroughout. FIG. 9N depicts yet another variation of a suction member (932), here having one or more moveable ridge members (934) to facilitate capture of tissue. As with the devices described just above, members (934) may have any number of teeth (936), may have any suitable geometry, and may be made of any suitable material.

[0088] FIGS. 9O-9Q depict another variation of a suitable suction member, here having one or more apertures or windows for capturing tissue thereagainst. Specifically, FIG. 9O depicts the basal surface of a suction member (940) where the basal surface defines a series of apertures or windows (942). In this variation, four apertures are provided, but any suitable number of apertures may be used, and they may have any geometry and be oriented about the basal surface in any fashion. Also shown in FIG. 9O are arms (944) which when articulated pull tissue against one or more of the aperture walls (945) thereby capturing tissue. This variation may be particularly useful when it is desirable to capture or accommodate excess tissue. This variation may also be particularly useful when used with thin tissue or tissue of a tubular organ or the like. FIGS. 9P and 9Q are cross-sectional representations of the suction member of FIG. 9O taken along line A-A where the arms are in an initial and actuated state respectively. As depicted by those figures, as push-pull wire (946) is withdrawn proximally, arms (944) move proximally and pull tissue against one or more walls (945) of the apertures (942). Of course a push-pull wire (946) is just but one way to actuate arms (944). Any suitable actuation mechanism may be used. Once the tissue has been captured in this fashion, a tissue-piercing member (not shown) may be advanced

through the tissue in the same or opposite direction as the tension applied to the captured tissue.

[0089] FIGS. 9R-9U depict various alternative ways to accommodate excess tissue, and as with the variations described just above, these variations may be particularly useful when dealing with thin tissue, tissue of a tubular or small geometry organ, or the like. In general, in these variations, an expandable member or other tissue-contacting member is actuated or activated so that it abuts, contacts, or apposes tissue opposite the basal surface of the suction member. In this way, excess tissue is displaced and target tissue becomes taught or tensioned across the basal surface of the suction member, resulting in better tissue capture. The variation shown in FIGS. 9R and 9S is an expandable member (948) in its unexpanded and expanded state respectively. The expandable member (948) may be any suitable expandable member. For example, it may be a balloon, expandable polymeric member, etc., which may be expanded in any suitable fashion, e.g., pressurized saline, water, air, etc. FIG. 9T depicts another variation of an expandable or articulatable member, here shown as an expandable wire or strut (950). The wire may be made of any suitable material. FIG. 9U shows yet another variation of an articulatable member, in this case, a rotatable or articulatable arm (952). Again, the arm (952) may be made of any suitable material.

[0090] FIGS. 10A-10D provide additional variations of suction members. FIG. 10A shows suction member (1000) from the underside, where the suction member is shown having a number of discrete features (1002). Features (1002) may be one or more heating elements, one or more electrodes (e.g., for delivering energy, such as RF, ultrasound, light, magnetic, combinations of the foregoing, etc.), one or more sensors (e.g., Doppler sensor, pressure sensor, temperature sensor, and the like), one or more radio-opaque markers to facilitate visualization, a camera to facilitate direct visualization, one or more ports, etc. The features may be placed in accordance with a predetermined pattern or be placed randomly along or about the suction member or its tissue apposition members. The spacing between the features may be uniform, as shown in FIG. 10A, but need not be. Similarly, the features need not have a uniform size or shape. Any number and combination of features may be used.

[0091] Of course, while a camera has been described here as a potential feature, it should be understood that a camera with or without a corresponding light or illumination

source, may be placed on the device at any suitable location to facilitate direct visualization of the tissue (e.g., located at a position along the elongate member). This may be particularly useful, for example, when the device is used as stand alone device, and not introduced through an endoscope, gastroscope, or other similar sheathed structure that provides for visualization of the working area. Methods for using the devices described here, alone or in combination with sheathed structures, will be described in more detail below.

[0092] FIG. 10B depicts a device (1004) similar to the device (1000) of FIG. 10A, except that the device (1004) of FIG. 10B has an additional peripheral feature (1008). The peripheral feature (1008) may be any of those features described just above, e.g., heating elements, electrodes, sensors, ports, illumination, etc., or some combination thereof. In some variations, feature (1008) is an electrode for delivering energy for ablation or sealing, while features (1006) comprise one or more sensors for sensing one or more useful parameters (e.g., temperature, pressure, movement, such as blood flow, etc.). Of course, the features need not be different from one another. For example, feature (1008) may be of the same general nature as features (1006) (for example, both features may be for sensing). Similarly, feature (1008) may be of the same general nature as features (1006), where the two features are used in concert to accomplish a particular task. For example, feature (1008) and features (1006) may both be electrodes that may be used separately or in concert to detect, sense, or measure a particular tissue parameter or property (e.g., resistance, impedance, conductivity, capacitance, or the like). The features may be oriented in any suitable or desirable way to map, sense, detect, measure, etc., any suitable or desirable tissue parameter or property. Of course, these are just a few illustrative examples. It should be understood that any combination of the described features may be used.

[0093] FIGS. 10C and 10D provide additional depictions of feature locations and configurations within and about the suction member. FIG. 10C shows a device (1010) comprising a suction member (1012) and an elongate member (1014). The suction member (1012) comprises tissue apposition members in the form of ribs, having features thereon. The peripheral rib (1015) has four discretely located features (1016) and the joining ribs (1017) have a plurality of discretely located features (1018) thereon. In FIG. 10D, the suction member (1022) of device (1020) comprises a tissue apposition member in the form of ribs, having features thereon, as well as having features along an inner surface of the suction member (1022). Specifically, shown there are joining ribs (1024) having a plurality of

discretely located features (1026) thereon, and features (1028) located along an inner surface of the suction member (1022). Again, the features may be any of those features described above, and may be of any suitable number, size, shape, or configuration.

[0094] FIGS. 11A-11D provide illustrative variations the angle of attachment between an elongate member and a suction member. Shown there are the various angles of connection or attachment, from substantially acute, as shown in FIG. 11A to perpendicular as shown in FIG. 11D. The angle of attachment may be selected depending on the indication or use. For example, in some instances it may be quite desirable to have the suction member positioned so that it is relatively isolated from the elongate member and the attachment point. In this way, the suction member is free to move about or traverse tissue without interference from the elongate member or the attachment point, for example as shown in FIGS. 11C and 11D. Of course it should be appreciated that the attachment angle may be selected to accomplish a particular or desired angle of approach (e.g., based on tissue location), may be selected to help facilitate ergonometric use of the device, may be selected to help facilitate control of the device, or may be selected based upon some combination of these factors. In addition, it should be understood that the elongate member need not be attached in a perpendicular or substantially perpendicular to the surface of the suction member. Indeed, the attachment itself may be angled or straight, with any amount of lateral displacement from the basal surface of the device.

[0095] Devices having more than one suction member are also contemplated. For example, the device may comprise two, three, four, five, or even more suction members. In some variations, the device comprises two suction members, as shown for example, in FIGS. 12A and 12B. In general, at least one of the suction members is movable with respect to the other suction member, and in some variations, both suction members are movable with respect to one another. These variations may be particularly useful when clamping tissue between two surfaces is helpful or required, e.g., with thin, soft, or flexible tissue such as stomach or intestinal wall tissue.

[0096] Each suction member may be connected to an elongate member, or only one suction member may be coupled to the elongate member, and the suction members may be coupled to the elongate member in any suitable fashion. In some variations, the one or more suction members are coupled to the elongate member via a flexible portion, which in

some instances may be a hinge. The suction members of these variations may have any suitable geometry, and may comprise or include, any of the features or any combination of the features (traction members, apposition members, electrodes, sensors, cameras, light sources, etc.) described above.

[0097] Turning now to the figures, FIGS. 12A and 12B depict one variation of a device (1200) having two suction members (1202, 1204), here, shown in an open and collapsed configuration respectively. The suction members may transition between their collapsed and expanded configuration by movement of a slidable actuator having any particular geometry (e.g., a helical cam structure (1207a, 1207b), a wedged cam structure, a push-pull wire, or the like). In this variation, suction members (1202, 1204) have basal surfaces that are generally semi-elliptical in shape, although, the suction members may have any suitable geometry as described above. Tissue apposition members are also shown, and in this variation, are in the form of ribs (1203, 1205).

[0098] In this variation, each suction member is connected to the elongate body (1201) via a hinge mechanism. Specifically, retention pin or shaft (1209) is retained by retaining tabs (1208a and 1208b), leaving the suction member (1202) free to rotate about pin (1209). Suction member (1202) is thus moveable with respect to both the elongate member (1201) and suction member (1204). In this variation, suction member (1204) is also moveable with respect to the elongate member (1201) and suction member (1202). In a corresponding manner to suction member (1202), here, pin or shaft (1211) is retained by retention tabs (1210a and 1210b). Of course, other hinge mechanisms may also be used e.g., single or multiple flexure joints, revolute joints, molded plastic live hinges, ball and socket joints, slidable tubes with counter-opposed flexure elements, etc. Also shown in these figures is tissue-piercing member exit port (1206). Again, it should be understood that FIGS. 12A and 12B are merely illustrative. Finally, it should be understood that any of the devices or tools described herein may be robotically operated or used in combination with robotic devices or systems.

II. METHODS

[0099] Methods of using devices for forming tracts in tissue are also described here. In accordance with some methods, a device having one or more suction members is advanced adjacent to tissue, suction is applied to draw tissue against the one or more suction

members, and then a tissue-piercing member is advanced through the drawn tissue to form a tract in or through the tissue. The device may be advanced to the target tissue site using any suitable devices and/or methods. As an example, in some variations, the device may be disposed within a lumen of a trocar, and the trocar may be advanced to the target tissue site. Once at the target tissue site, the device may be deployed from the trocar and used to form a tissue tract. As another example, in some variations the device may be relatively small and easy to navigate, and may be advanced through tissue without being positioned in any other devices. In some such variations, the device may include one or more regions (e.g., edges) that are sharpened, serrated, etc., such that the device may relatively easily cut a path through tissue surrounding the target site. In certain such variations, the device may include one or more relatively rigid portions (e.g., to provide enhanced pushability). Devices may in some cases be guided to a target tissue site using one or more imaging techniques, such as ultrasound, and/or using one or more localization techniques (e.g., by measuring blood flow with vascular Doppler).

[0100] The device may be, for example, any of the devices described above. For example, the device may comprise one or more suction members, one or more energy applicators (e.g., ultrasound, RF, light, magnetic, combinations thereof, etc.), one or more sensors (e.g., to sense temperature, pressure, blood flow, combinations thereof, etc.), more than one tissue-piercing member, etc. The suction members may have any of the above described features. When devices having more than one suction member are used, the devices may be advanced when the suction members are in their open configuration, collapsed configuration, or some intermediate configuration therebetween. It should be noted that some variations of devices may not comprise any suction members, and/or some variations of methods may not include applying suction to tissue. For example, a device may be used to form a single self-sealing tract in tissue by advancing only a tissue-piercing member through the tissue, and without applying any suction to the tissue.

[0101] The methods described here may be used to form tracts in any tissue in connection with any technique or procedure. The tissue may be any tissue where it is desirable to form a tract therethrough. For example, it may be tissue of the cardiovascular system, digestive system, respiratory system, excretory system, reproductive system, nervous system, etc. In some variations the tissue is tissue of the cardiovascular system, such as an artery, or a heart. In other variations the tissue is tissue that is accessed through a natural

orifice (e.g., to perform natural orifice translumenal endoscopic surgery "NOTES"), such as tissue of the reproductive system, excretory system, digestive system, or the like. Of course, it should be understood that methods of forming multiple tracts in tissue, whether through similar or different tissue, are also contemplated.

[0102] As will be described in more detail below, the methods may include creating a tract that self-seals within a period of time (e.g., 15 minutes or less, 12 minutes or less, 10 minutes or less, 5 minutes or less, 3 minutes or less, 1 minute or less, etc.). Of course, tracts that may otherwise self-seal after a period of time may be nevertheless have sealing expedited by other mechanisms as well (e.g., application of mechanical pressure, application of suction, application of one or more sealing agents, etc.). The methods may also comprise application of energy, delivery of one or more fluids or useful agents, delivery of one or more useful tools to a tissue site, performing a procedure, visualization, determining the location of the device with respect to the tissue, combinations thereof, and the like. The device may be rotated, repositioned, or otherwise manipulated during these methods, as will be described below.

[0103] With specific reference now to the figures, FIGS. 13A-13M depict one illustrative method for forming a tract in tissue. As shown in FIG. 13A, device (1300) comprising one or more suction members (1302) is advanced adjacent to tissue (1304). Suction may then be applied to the suction member so that the suction member is pulled toward the tissue until it contacts the tissue, as shown in FIG. 13B, and against the suction member as shown by the arrows in FIG. 13C. Of course, suction may be applied at any stage of the method. For example, suction may always remain on, and the device may be advanced while suction remains on. Conversely, the device may be advanced adjacent to tissue and then suction applied, as shown here. Alternatively, suction may be toggled on and off, regulated, or otherwise modulated, to control the vacuum strength or flow using, e.g., any of the proximal controls described hereinthroughout.

[0104] Returning to the figures, once the tissue has been drawn against the suction member, a tissue-piercing member may be advanced through the drawn tissue to form a tract in the tissue as shown in FIG. 13D. The tract may be of any length, and may traverse through the tissue as shown in FIG. 13E. Once a tract has been formed, one or more tools

may be advanced through the tract. For example, in FIG. 13F, a guide wire (1308), may be advanced through the tissue-piercing member, and through the tract.

[0105] The guide wire (1308) may be any guide wire having a diameter suitable for use with the corresponding tissue-piercing member (1306). The guide wire (1308) may also have one or more expandable members (e.g., expandable balloon as shown in FIG. 13G, expandable cage or flower wire formation as shown in FIG. 13H, expandable arms, etc.) or similar such features on its distal end (1310). In this way, the distal end of the guide wire may be used to help locate or position the device with respect to the tissue and to maintain its position for a portion of the procedure. For example, the guide wire (1308) may be advanced through the tissue (1304), and the distal expandable feature expanded. The guide wire (1308) may then be gently pulled proximally, (i.e., in the direction of the tissue). Once the expandable member abuts the tissue (as determined via tactile feedback, for example), the location of tissue has been determined and this information may be used as a guide for the rest of the procedure. Of course, these tissue location methods may not be necessary when indirect (e.g., fluoroscopic guidance, ultrasound, etc.) or direct (e.g., camera, scope, etc.) visualization is employed, which visualization techniques may be used with any of the methods described here. Vacuum checks may also be useful in determining the location of the tissue, or the device with respect to tissue. An additional useful method for determining the location of tissue is described in more detail below with respect to FIGS. 13N-P.

[0106] Turning back now to FIG. 13I, after the guide wire (1308) has been advanced through tissue (via a lumen in the tissue-piercing member for example), the tissue-piercing member (1306) may be withdrawn. Suction may be turned off, if desired, and the device may be withdrawn proximally, as shown in FIG. 13J. One or more dilators (or a single step-up dilator) or introducers (1312) may then be advanced over the guide wire (1308) if necessary to expand the tissue tract. Once sufficient access to the target site has been obtained, the guide wire (1308) may be withdrawn, as shown in FIGS. 13K-13M. One or more additional tools may then be introduced through the introducer, to carry out any suitable procedure. In some variations, the method described just here is used to carry out an arteriotomy to provide access to the vasculature. Once all procedures have been performed, the tools and introducer may be removed, allowing the tract to self-seal. Of course, as described above, sealing of the tract may be facilitated or expedited by mechanical pressure,

delivery of energy (RF, ultrasound, microwave, etc.), or the use of one or more agents or a closure device, a combination of the foregoing, or the like.

[0107] As briefly mentioned above, in some instances, it may be desirable to identify, detect, or otherwise locate one or more tissue surfaces or boundaries while employing the devices or methods described herein. FIG. 13N provides one illustrative system (1320) variation for detecting a tissue (1322) boundary or the like. Shown there is a pressurized fluid (1324), here in the form of fluid in a hanging IV bag, which is connected to tissue-piercing member (1330). In this variation, valve (1328) controls release of the pressurized fluid (1324), which may be saline, an antibiotic, a sterilizing agent, or any agent. Pressure is detected in this variation via gauge (1326). As the tissue-piercing member (1330) is advanced into tissue (1322), and while the tissue-piercing member (1330) is within tissue, the pressure should be relatively high, or higher than the initial pressure, as shown in FIG. 13O. Once the tissue-piercing member is advanced through the boundary of the tissue, the fluid may flow more freely through it, and the pressure should drop again, as depicted by FIG. 13P. Additionally, a radioopaque marker or band (e.g., in a distal region or at the tip of the tissue-piercing member) may be used to further verify tissue boundaries when the device is used with fluoroscopy. Of course, the viscosity of the fluid may be chosen to accommodate the size and length of the needle, in addition to other factors. Similarly, while pressure in this variation is shown measured on the proximal end of the system, it may be measured at any desirable distance from the tissue-piercing member tip. In some variations, for example, it might be desirable to measure fluid pressure close to the tissue-piercing member tip.

[0108] FIGS. 14A-14C depict another method for forming a tract in tissue. In this variation, once the tissue-piercing member (1402) has been advanced into tissue (1404), the device (1400) may be articulated to redirect the tissue-piercing member (1402). The tissue-piercing member (1402) may then be advanced through the tissue (1404) in the repositioned direction. Similar to the method described just above, a guide wire (1406) may then be advanced through the tissue tract (via a lumen in the tissue-piercing member, for example), and one or more introducers may then be advanced over the guide wire (1406) for facilitating passage of tools therethrough.

[0109] Of course, it should be understood that the suction member may be articulated, the elongate member may be articulated, the suction member may be rotated to rotate the tissue prior to advancing a tissue-piercing member therethrough, and the like. Indeed, any of the methods of manipulating tissue described in U.S. Pat. App. No. 11/873,957, which application is hereby incorporated by reference in its entirety, may be used here.

[0110] FIG. 15A is an overview illustration of how the devices described herein may be used to form tracts in tissue within or through the stomach, or stomach tissue. In this variation, the device is not used with a separate gastroscope, and here visualization is enabled by a series of cameras or other visualization devices (1502) in combination with light or illumination source (1504). This particular method may be quite useful, for example, in natural orifice transluminal endoscopic surgeries. FIG. 15A also details an illustrative proximal control of the device (1500), here in the form of a slide actuator (1506). The slide actuator (1506) may be used, for example, to advance and retract the tissue-piercing member, may be used to turn on and off one or more visualization devices (1502), may be used to turn on and off the illumination source (1504), or some combination thereof. Of course, the device (1500) may include any number and type of proximal controls (slides, switches, buttons, etc.) to control any number or combination of functions (e.g., vacuum, visualization, actuation of tissue-piercing member, illumination, fluid flush, etc.).

[0111] Also shown in FIG. 15A is the illustrative use of suction, fluid injection, and the like. Here, a three-way valve (1508) is shown, which connects to and helps control use of vacuum (1510), bag infuser (1512), and syringe injector (1514). That is, the three-way valve (1508) may be toggled between its various positions to turn off or on the vacuum, or fluid (via bag infuser or syringe injection). Having the ability to turn on and off the vacuum, for example, may be particularly useful in instances where the device has become stuck on or against one or more tissue surfaces. Turning on and off fluid injection or delivery, for example, may be particularly useful when it is desirable to flush, irrigate, unclog, or deliver one or more substances to the tissue. Of course, the control depicted in FIG. 15A is just one way to control or operate the described functions. It should be understood that any suitable configuration (having a two-way valve to control certain features, but not others, having additional proximal controls, combinations of the foregoing, and the like) may be used.

[0112] FIGS. 15B and 15C schematically represent variations where one or more fluids (therapeutic, flushing, sterilizing, etc.) are delivered to the tissue (1524) while the suction member (1520) is still under vacuum. For example, FIG. 15B depicts a suction member (1520) having one or more peripheral ports (1522) thereon or therealong for delivery or passage of one or more fluids therethrough (shown by arrows 1523). In this variation, fluids may be injected or delivered through the one or more peripheral (1522) or other ports (e.g., needle port, traction member port, etc.), and then collected through a vacuum port (1526) while the tissue (1524) remains captured by suction. The suction member of FIG. 9J, for example, may be useful in performing this method. FIG. 15C depicts an alternative variation where the fluid is not collected through a vacuum port (1536). Shown there is suction member (1530) having one or more peripheral ports (1532) thereon or therealong for delivering one or more fluids (e.g., therapeutic, flushing, sterilizing, etc.) to tissue (1538). In this variation, the fluid is injected through a first syringe (1540) or other delivery system, and is collected by a separate second syringe (1542) or other suitable collection system, so that the vacuum port (1536) need not function to collect fluid. The push pull syringe of this variation may, for example, help prevent the vacuum from emptying syringe contents.

[0113] FIGS. 15D and 15E provide depictions of articulatable elongate members that may be used in connection with any of the devices and methods described here, shown in an unarticulated and articulated state respectively. The elongate member (1560) in these variations may comprise a series of links (1562) connected via a series of wires or cables (1564). Also shown in these figures is distal-most link (1566), comprising two discrete sets of features (1568, 1570). The features may be any of the features described above, and in one variation, features (1568) are cameras while features (1570) are illumination sources. Any combination, location, and number of features may be used as described above. Having the features located on or about the distal-most link (1566) is just one illustrative variation of a suitable location. It should also be understood that the individual links of the elongate member (1560) need not be exposed. The elongate member (1560) may be sheathed or otherwise covered. In addition, the elongate member of these variations, as with all the described device variations may be robotically or remotely controlled.

[0114] FIGS. 15F and 15G depict various handles or proximal controls for use with any of the described devices. Specifically, FIG. 15F depicts handle (1572) having a joystick type control (1574). In this variation, the joystick type control (1574) may be used to control movement of the elongate member in a way that corresponds to movement of the control (1574) itself. For example, movement of the control (1574) in a forward direction may effect movement of an elongate member in a forward direction. Similarly, movement of the control (1574) to the right may effect movement of an elongate member to the right, and so forth. This type of control may be particularly useful when it is desirable to have intuitive control of the device, which may help with user adoption and ease of use. FIG. 15G depicts another handle (1576) where all controls are enclosed therein. For example, handle (1576) may house one or more motors, linear actuators, pneumatic cylinders, or other electronic features. This type of handle (1576) may be particularly useful as a robotic interface.

[0115] FIGS. 15H and 15I depict cross-sectional and perspective views of illustrative distal-most links in connection with the articulatable devices described above. The link of FIG. 15H is shown without having additional features. Shown there are through-lumens or apertures (1578) for passage of one or more wires or cables therethrough. The link of FIG. 15I is shown having one or more additional features, for example, like the distal-most link (1566) described just above with reference to FIGS. 15D and 15E. Shown in this variation, are discrete features (1582) and (1584), which may be cameras and illumination sources, as described just above, or any other described feature. Also shown in cross-sectional view are through-lumens (1580) for passage of connecting cables or wires.

[0116] FIGS. 16A-I depict a method of forming a tract in or through stomach tissue. It should be understood that just the distal portion of the device is shown in these figures, and that this method may be used to form tissue tracts as depicted, whether or not the device is a stand alone device, or is used with a gastroscope or advanced through some other sheathed structure (including instances where the device is back-loaded into the working channel of any type of gastroscope, endoscope, laparoscope, etc., with or without steering, visualization, illumination, etc.). Turning now to FIG. 16A, the device (1600) comprising a suction member (1602) is shown advanced adjacent to tissue, here stomach tissue. In FIG. 16B, vacuum or suction has been turned on, and tissue is drawn against, or pulled into, the suction member (1602) as indicated by the arrows in that figure. Next, a tissue-piercing

member (1604) (e.g., a needle or other tissue-piercing cannula) is advanced from the device and through the drawn tissue to form a tract in the tissue as shown in FIG. 16C.

[0117] Once the tract has been formed, a guide wire (1606), guide element, or the like may be advanced through the tract (e.g., by advancing through a lumen in the tissue-piercing member), as shown in FIG. 16D, and the tissue-piercing element (1604) is withdrawn as shown in FIG. 16E. A stepped-up dilator (1608) or series of dilators (not shown) may then be advanced over the guide wire (1606) as shown in FIG. 16F. In this way, for example, the cross-sectional area of the tract may be expanded or enlarged. After the tract has been expanded, an introducer (1610), which may be part of the dilator (1608) can be left in place and used as a conduit for introducing additional tools through the tract, as shown in FIG. 16G. FIG. 16H shows one illustrative method where a tool (1612) having an end effector, e.g., grippers (1614) has been advanced through introducer (1610) for use in a procedure. Any number or type of tools may be advanced through the introducer in this way. After the procedure has been performed, the tools and introducer are removed leaving tract (1616) to self-seal. Of course, sealing may be enhanced any suitable additional mechanism (e.g., via mechanical pressure, via ultrasound, via one or more closure devices, and the like).

[0118] FIG. 17A-17D depict one method of advancing a device described herein into the pericardial space in order to form a tract through tissue of the heart (H). As shown in those figures, an incision (1700) may be made (e.g., sub-xyphoid, etc.) and a port (1702) placed therethrough to provide for suitable delivery or exchange of tools therethrough. Once the port (1702) has been placed, any of the devices (1704) described here may be placed through the port (1702) to form a tract in or through tissue of the heart (H), as will be described in more detail with reference to FIGS. 18A-18K.

[0119] Turning to FIG. 18A, a device (1800) comprising a suction member (1802) is advanced adjacent to heart tissue. The device may be advanced adjacent to heart tissue in any suitable fashion, e.g., through port (1702) described above. Vacuum or suction may then be applied to draw heart tissue against or into suction member (1802) as shown in FIG. 18B. A tissue-piercing member (1804) may then be advanced from the device (e.g., through the suction member) and through the drawn tissue to form a tissue tract as shown in FIG. 18C. A guide wire (1806) or other suitable such guide element may then be advanced through the tract, e.g., by advancing through a lumen in the tissue-piercing member (1804),

as shown in FIG. 18D. The tissue-piercing member (1804) and device (1800) may then be removed, as shown by FIGS. 18E and 18F respectively.

[0120] A stepped-up dilator (1808) or series of dilators (not shown) may then be advanced over the guide wire (1806) as shown in FIG. 18G. In this way, for example, the cross-sectional area of the tract may be expanded or enlarged. After the tract has been expanded, an introducer (1810), which may be part of the dilator (1808) can be left in place and used as a conduit for introducing additional tools through the tract, as shown in FIG. 18H. FIG. 18I shows one illustrative method where a tool (1812) has been advanced through introducer (1810) for use in a procedure. Here left ventricular access has been accomplished, and therefore, use of these methods in conjunction with repair or replacement of the aortic or mitral valve may find particular utility. Any number or type of tools may be advanced through the introducer in this way. After the procedure has been performed, the tools and introducer are removed leaving tract (1814) to self-seal, as shown by FIGS. 18J and 18K. Of course, sealing may be enhanced by any suitable additional mechanism (e.g., via mechanical pressure, via ultrasound, via one or more closure devices, and the like).

III. KITS

[0121] Kits are also described here. In some variations, the kits include a device for forming a tract through tissue, where the device comprises one or more suction members as described above, and one or more additional tools. For example, the tools may be those that are advanced through the tract during the performance of a procedure (e.g., guide wires, scissors, grippers, ligation instruments, etc.), one or more supplemental tools for aiding in closure (e.g., an energy delivering device, a closure device, and the like), one or more tools for aiding in the procedure (e.g., gastroscope, endoscope, cameras, light sources, etc.), combinations thereof, and the like. Of course, instructions for use may also be provided with the kits.

CLAIMS

What we claimed is:

1. A device for forming a tract in tissue comprising:

   an elongate member;

   a suction member coupled to a distal portion of the elongate member; and

   a tissue-piercing member slidably housed within the elongate member for forming a tract in tissue.

2. The device of claim 1, wherein the elongate member is flexible.

3. The device of claim 1, wherein the suction member is coupled to the elongate member via a flexible portion.

4. The device of claim 3, wherein the flexible portion is a hinge.

5. The device of claim 1, wherein the elongate member is articulatable.

6. The device of claim 1, wherein the tissue-piercing member is articulatable.

7. The device of claim 1, wherein the suction member is articulatable.

8. The device of claim 1, wherein the suction member has one or more tissue apposition members thereon.

9. The device of claim 8, wherein the tissue apposition member is a rib.

10. The device of claim 1, further comprising one or more sensors.

11. The device of claim 1, wherein the tissue-piercing member is a needle.

12. The device of claim 11, wherein the needle is hollow.

13. The device of claim 1, wherein the suction member is connected to a vacuum source.

14. The device of claim 1, wherein the elongate member has one or more lumens therethrough.

15. A device for forming a tract in tissue comprising:

an elongate member;

a first suction member coupled to a distal portion of the elongate member, and positionable against tissue;

a second suction member opposed to the first suction member; and

a tissue-piercing member for forming a tract in tissue.

16. The device of claim 15, wherein the tissue-piercing member is slidably housed within the elongate member.

17. The device of claim 15, wherein the first and second suction members are coupled together.

18. The device of claim 17, wherein the first and second suction members are coupled together via a flexible portion.

19. The device of claim 18, wherein the flexible portion is a hinge.

20. The device of claim 15, wherein the first and second suction members are movable relative to one another.

21. The device of claim 15, wherein the tissue-piercing member is a needle.

22. A method for forming a tract in tissue comprising:

advancing a device adjacent tissue, wherein the device comprises one or more suction members and a tissue-piercing member;

applying suction so that the tissue is drawn against the one or more suction members; and

advancing the tissue-piercing member in a first direction through the drawn tissue, to form a tract in the tissue.

23. The method of claim 22, further comprising articulating the tissue-piercing member.

24. The method of claim 23, further comprising advancing the tissue-piercing member in a second direction.

25. The method of claim 22, wherein the device further comprises one or more sensors and the method further comprises sensing at least one useful parameter.

26. The method of claim 25, wherein the parameter is selected from the group consisting of temperature, pressure, blood flow within a vessel, and combinations thereof.

27. The method of claim 22, wherein the tissue comprises an organ.

28. The method of claim 27, wherein the organ is selected from the group consisting of an organ of the cardiovascular system, an organ of the digestive system, an organ of the respiratory system, an organ of the excretory system, an organ of the reproductive system, and an organ of the nervous system.

29. The method of claim 28, wherein the organ is an organ of the cardiovascular system.

30. The method of claim 29, wherein the organ is an artery.

31. The method of 22, further comprising withdrawing the tissue-piercing member from the tissue, wherein the tract seals after the tissue-piercing member has been withdrawn.

32. The method of claim 31, wherein the tract seals within 12 minutes or less.

33. The method of claim 22, further comprising advancing one or more tools through the tract.

34. The method of claim 22, wherein the tissue-piercing member enters the tissue at a first location, and exits the tissue at a second location, wherein the length between the first location and the second location is greater than the thickness of the tissue.

35. The method of claim 22, wherein the length of the tract is greater than the thickness of the tissue.

36. The method of claim 22, wherein the tract self-seals.

37. The method of claim 36, wherein the tract seals within 15 minutes or less.

38. The method of claim 36, wherein the tract seals within 5 minutes or less.

39. The method of claim 36, wherein the tract seals within 1 minute or less.

40. A method comprising:

forming a tract in tissue by advancing a first tissue-piercing member in a first direction through the tissue,

wherein formation of the tract requires advancement of only the first tissue-piercing member through the tissue, and wherein the tract is self-sealing.

41. The method of claim 40, wherein the first tissue-piercing member comprises a needle.

42. The method of claim 40, further comprising advancing a device comprising the first tissue-piercing member adjacent to the tissue prior to advancing the first tissue-piercing member through the tissue.

43. The method of claim 42, wherein the device further comprises one or more suction members.

44. The method of claim 43, further comprising applying suction to the tissue to draw the tissue against the one or more suction members.

45. The method of claim 44, wherein the first tissue-piercing member is advanced in the first direction through the drawn tissue.

46. The method of claim 40, further comprising applying suction to the tissue to position the tissue.

47. The method of claim 46, wherein the tract is formed in the tissue after the tissue has been positioned by the application of suction.

48. The method of claim 40, wherein the tissue comprises an organ.

49. The method of claim 48, wherein the organ is selected from the group consisting of an organ of the cardiovascular system, an organ of the digestive system, an organ of the respiratory system, an organ of the excretory system, an organ of the reproductive system, and an organ of the nervous system.

50. The method of claim 40, wherein the tissue comprises a vessel.

51. The method of claim 50, wherein the tissue comprises an artery, and the tract is an arteriotomy.

52. The method of claim 40, further comprising rotating the tissue.

53. The method of claim 52, further comprising advancing the first tissue-piercing member through the rotated tissue.

54. The method of claim 40, further comprising withdrawing the first tissue-piercing member from the tissue, wherein the tract seals after the first tissue-piercing member has been withdrawn.

55. The method of claim 54, wherein the tract seals within 15 minutes or less.

56. The method of claim 54, wherein the tract seals within 5 minutes or less.

57. The method of claim 54, wherein the tract seals within 1 minute or less.

58. The method of claim 40, further comprising advancing one or more tools through the tract.

59. A method for forming a tract in tissue comprising:

advancing a tissue-piercing member in a first direction through the tissue to form a single tract in the tissue,

wherein the single tract is self-sealing.

60. The method of claim 59, wherein the tissue comprises a vessel.

61. The method of claim 60, wherein the tissue comprises an artery, and the tract is an arteriotomy.

62. The method of claim 59, further comprising withdrawing the tissue-piercing member from the tissue, wherein the tract seals after the tissue-piercing member has been withdrawn.

63. The method of claim 62, wherein the tract seals within 15 minutes or less.

64. The method of claim 62, wherein the tract seals within 5 minutes or less.

65. The method of claim 62, wherein the tract seals within 1 minute or less.

66. A method for forming a tract in tissue comprising:

advancing a device adjacent tissue, wherein the device comprises at least one tissue-piercing member; and

forming a tract in the tissue by advancing the at least one tissue-piercing member through the tissue,

wherein formation of the tract requires advancement only of the at least one tissue-piercing member through the tissue, and wherein the tract is self-sealing.

67. The method of claim 66, wherein the tissue comprises a vessel.

68. The method of claim 67, wherein the tissue comprises an artery, and the tract is an arteriotomy.

69. The method of claim 66, further comprising withdrawing the at least one tissue-piercing member from the tissue, wherein the tract seals after the at least one tissue-piercing member has been withdrawn.

70. The method of claim 69, wherein the tract seals within 15 minutes or less.

71. The method of claim 69, wherein the tract seals within 5 minutes or less.

72. The method of claim 69, wherein the tract seals within 1 minute or less.

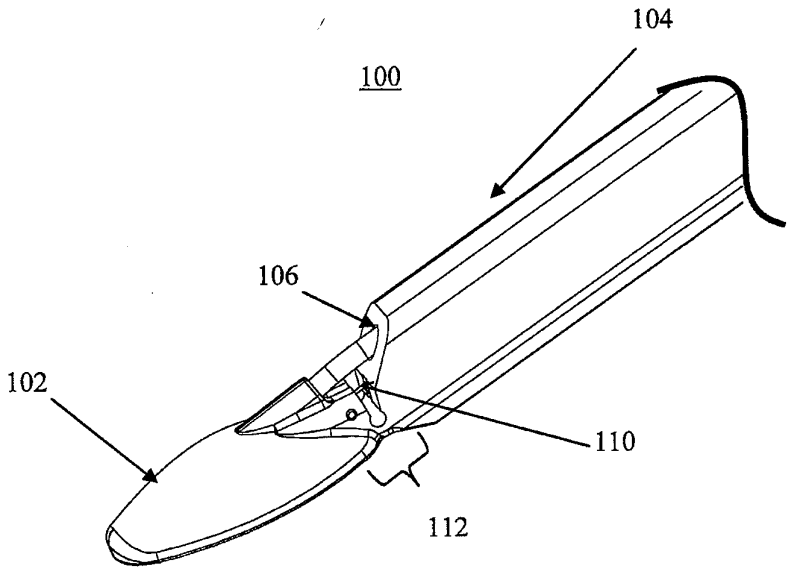


FIG. 1

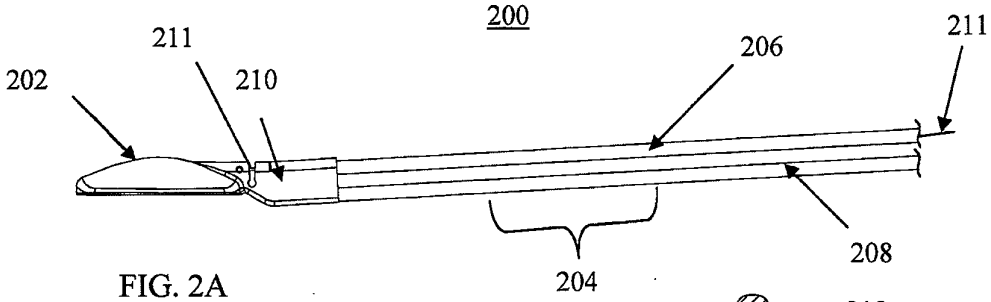


FIG. 2A

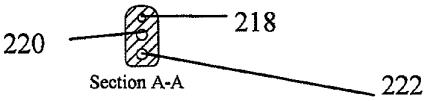


FIG. 2C

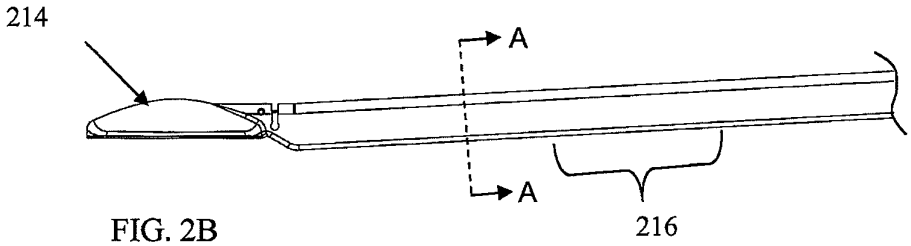


FIG. 2B

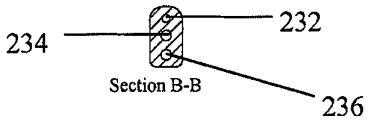


FIG. 2E

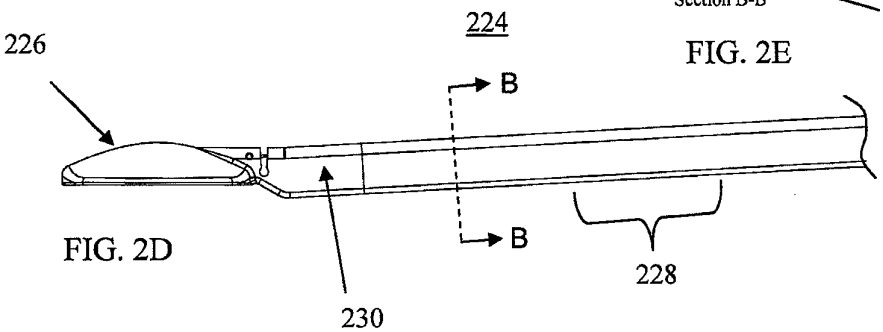


FIG. 2D

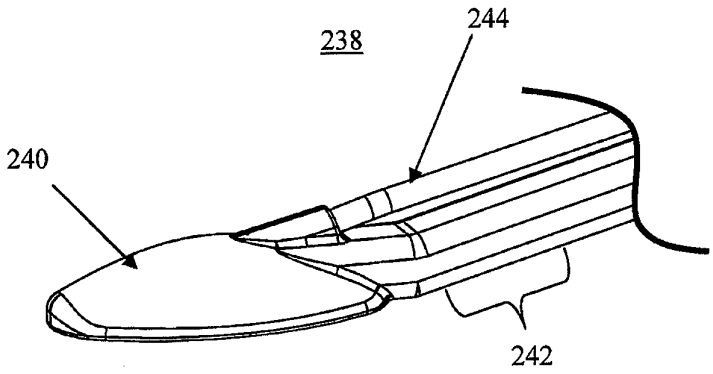


FIG. 2F

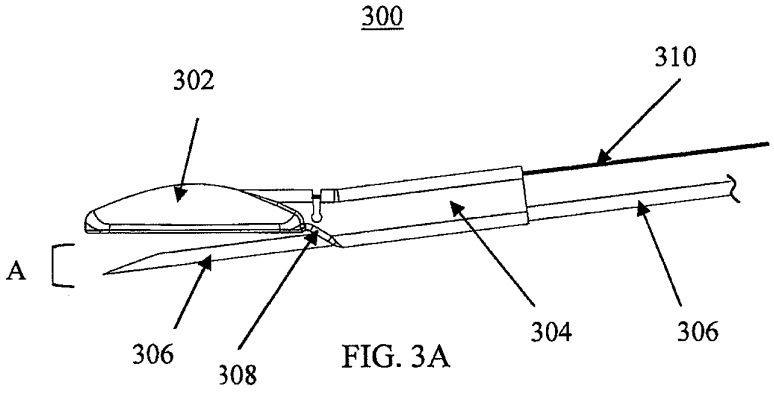


FIG. 3A

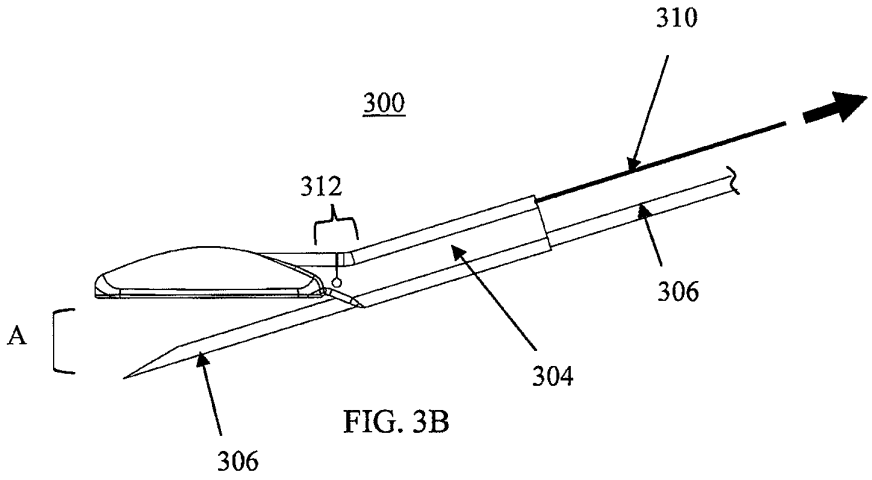


FIG. 3B

FIG. 4A

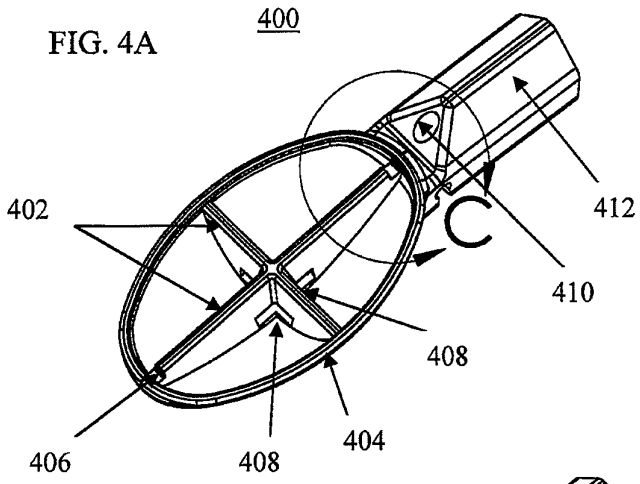


FIG. 4B

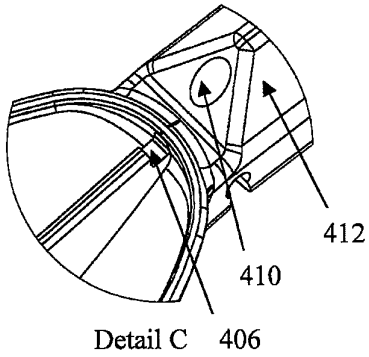


FIG. 5

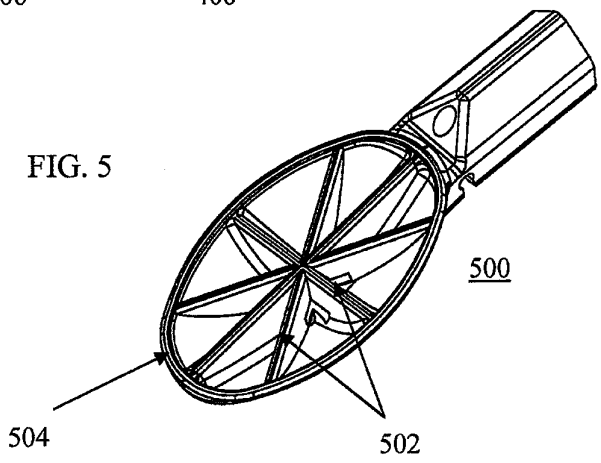
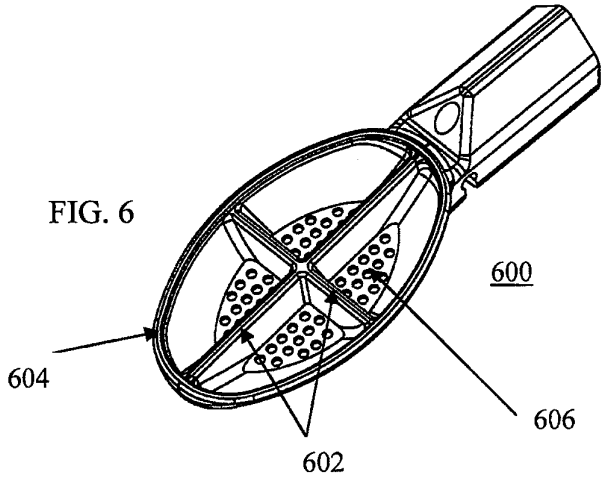


FIG. 6



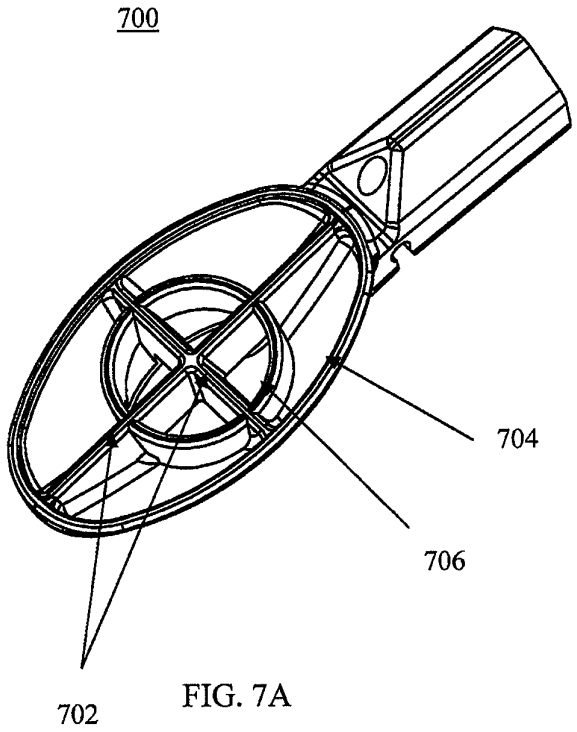


FIG. 7A

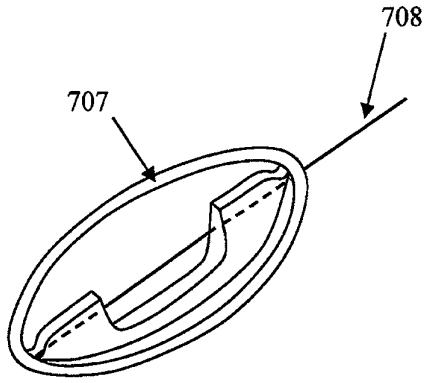


FIG. 7B

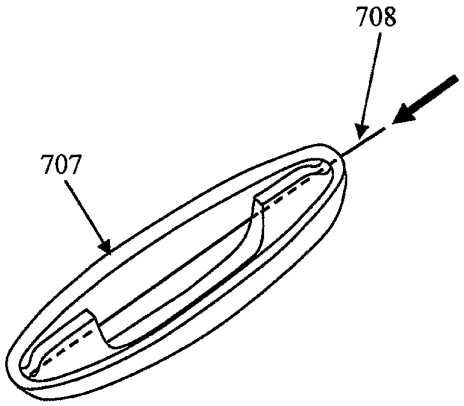


FIG. 7C

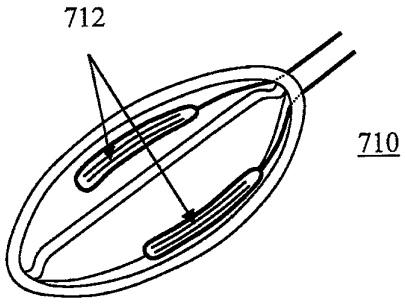


FIG. 7D

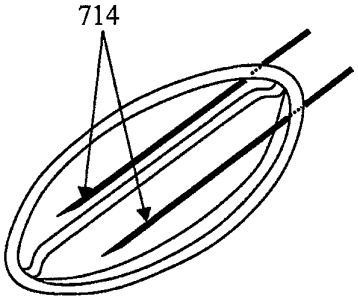
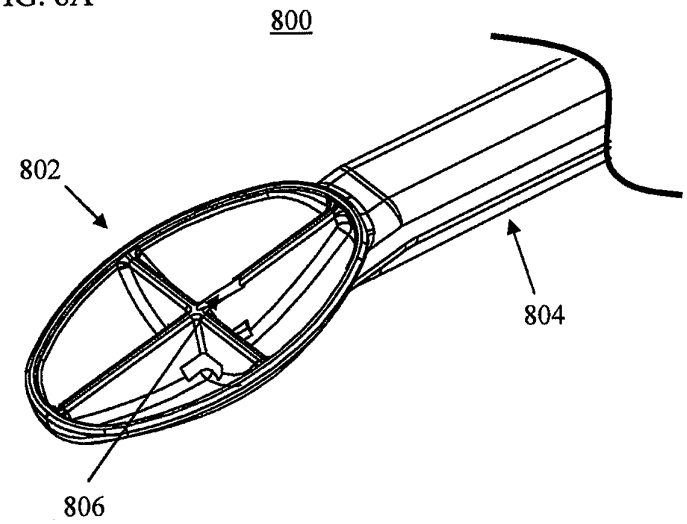


FIG. 7E

FIG. 8A



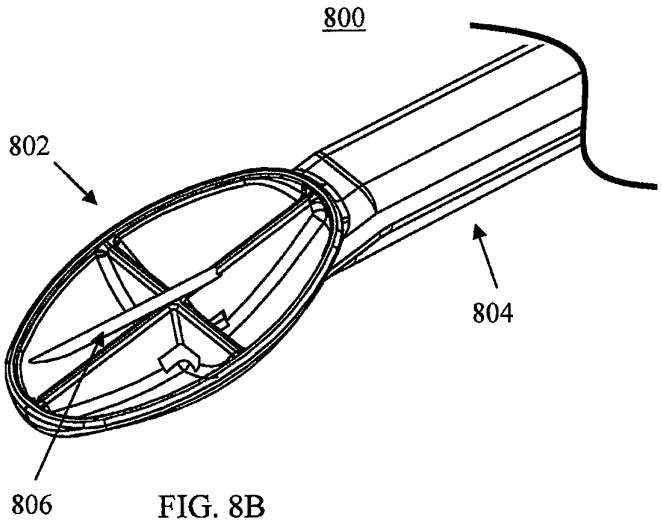


FIG. 8B

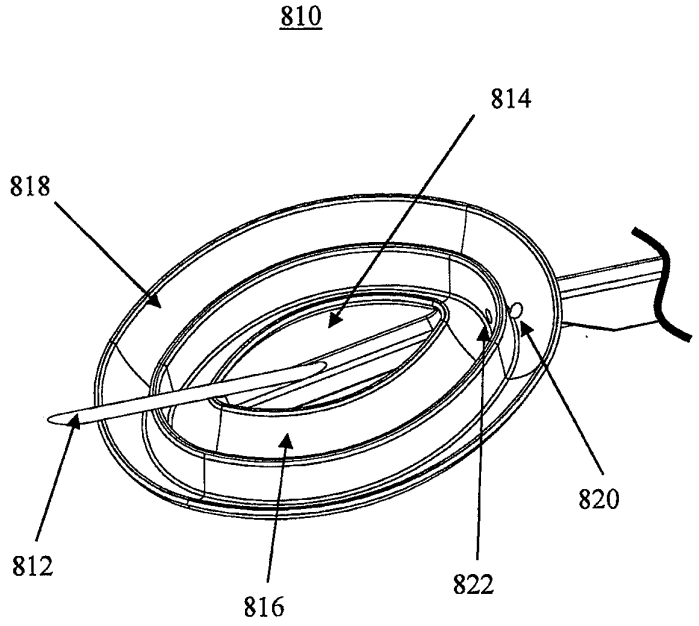


FIG. 8C

FIG. 9A

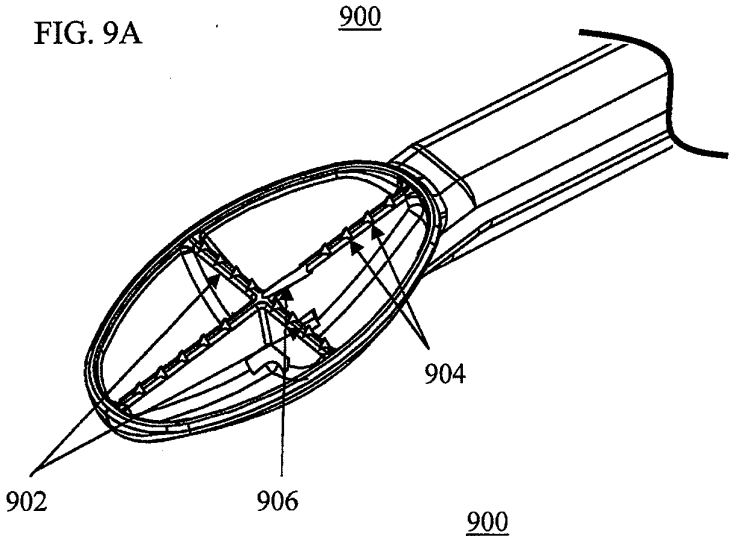


FIG. 9B

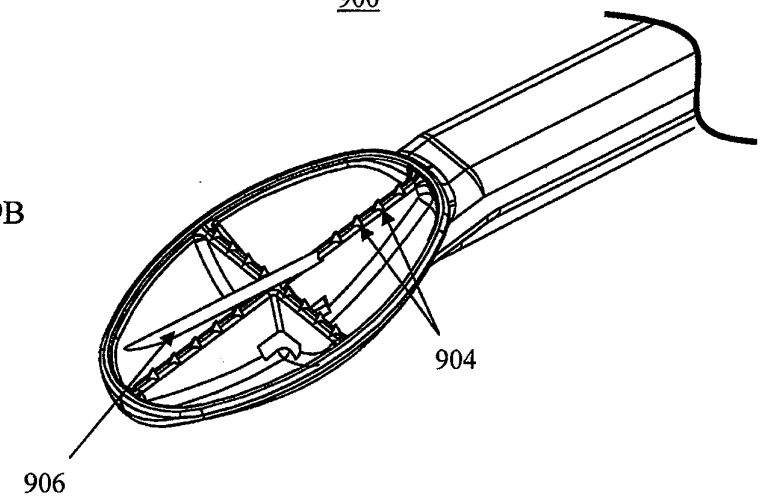


FIG. 9C

FIG. 9D

FIG. 9E

FIG. 9F

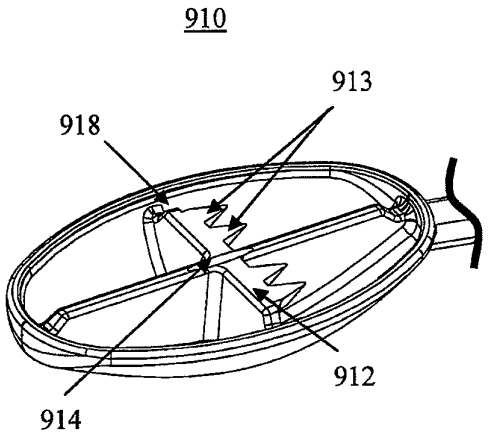


FIG. 9G

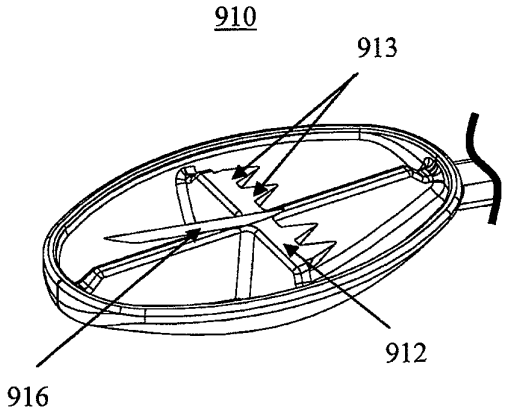


FIG. 9H

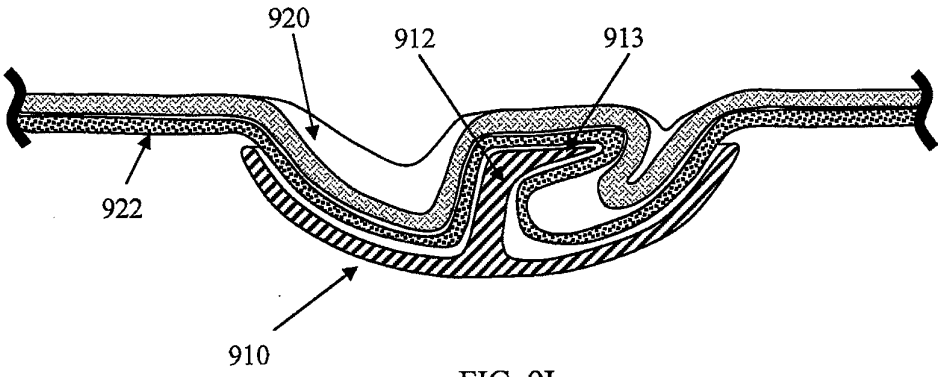


FIG. 9I

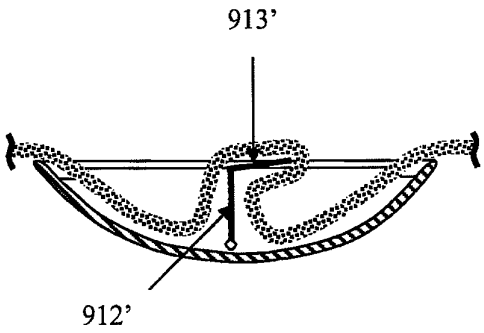


FIG. 9J

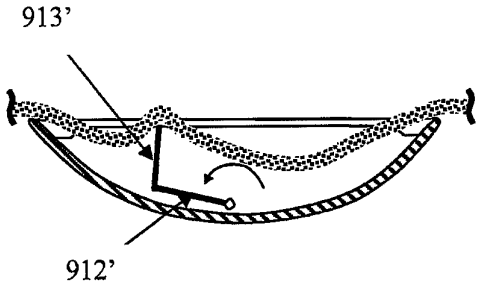


FIG. 9K

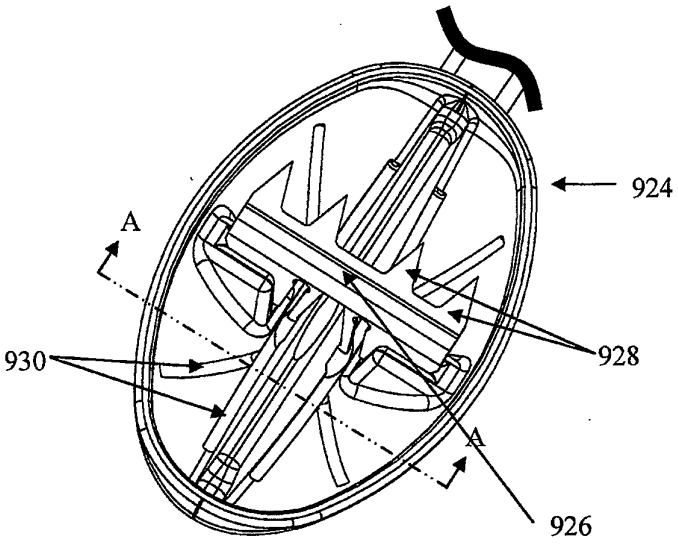


FIG. 9L

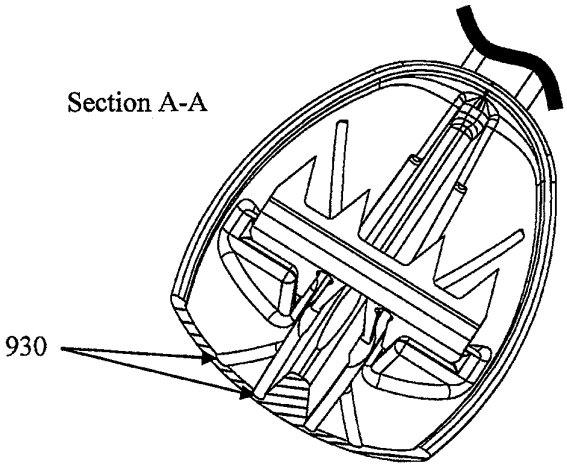


FIG. 9M

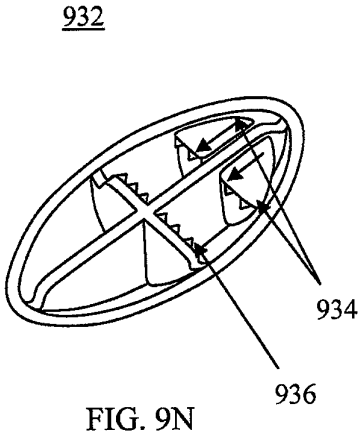


FIG. 9N

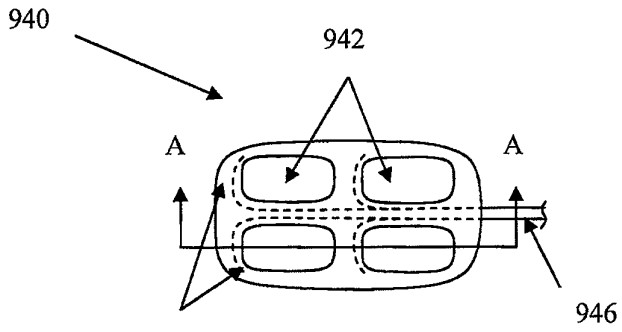


FIG. 9O

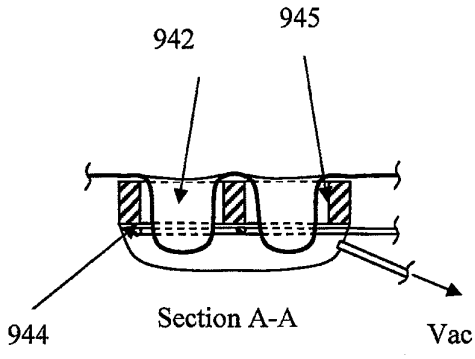


FIG. 9P

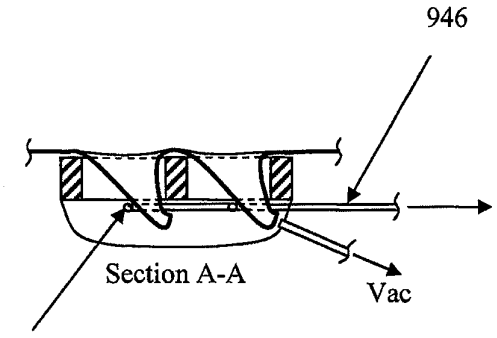


FIG. 9Q

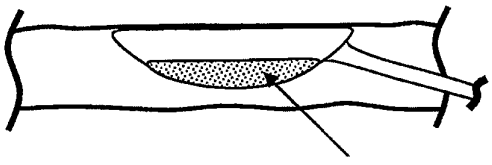


FIG. 9R

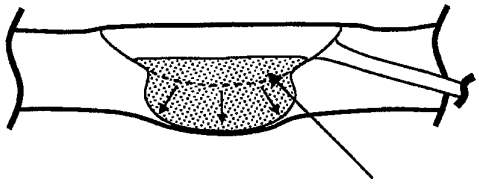


FIG. 9S

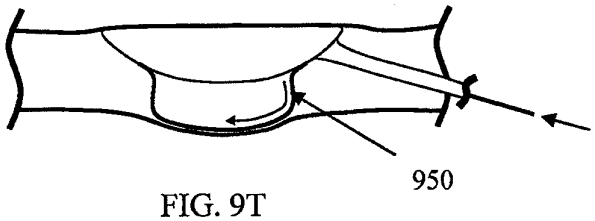


FIG. 9T

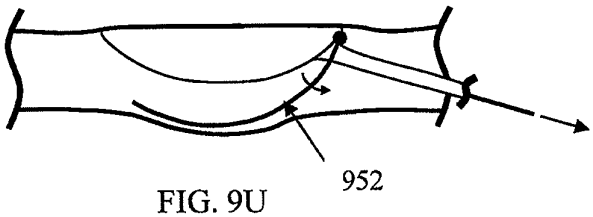


FIG. 9U

FIG. 10A

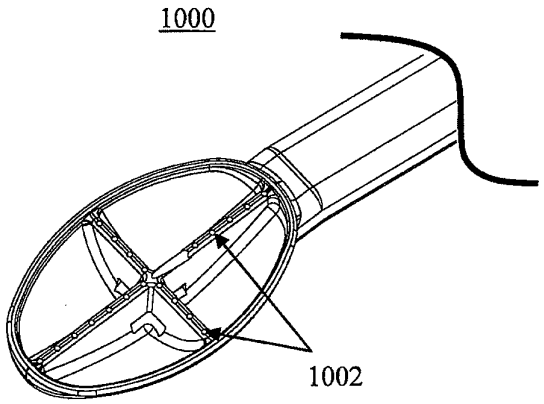


FIG. 10B

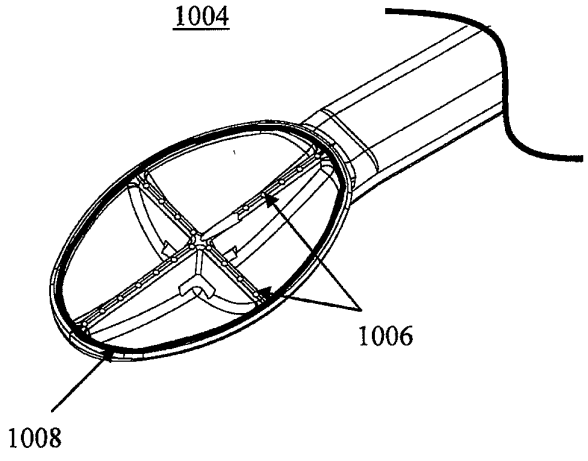


FIG. 10C

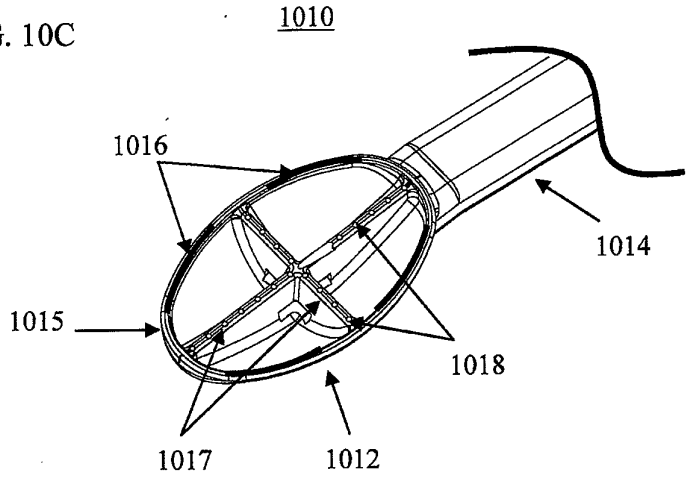


FIG. 10D

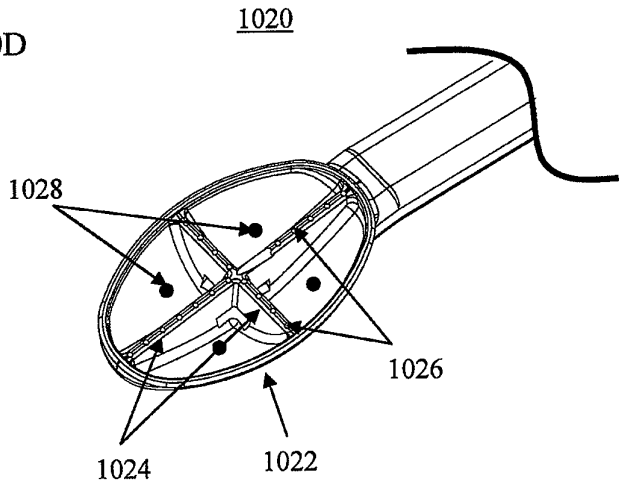


FIG. 11A

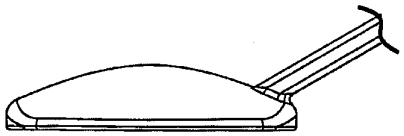


FIG. 11B

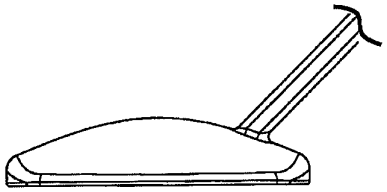


FIG. 11C

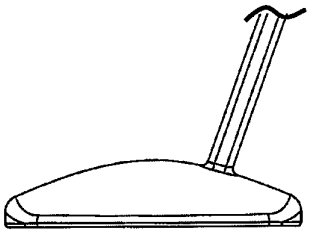
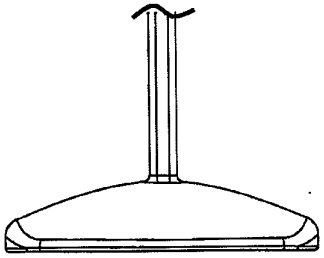


FIG. 11D



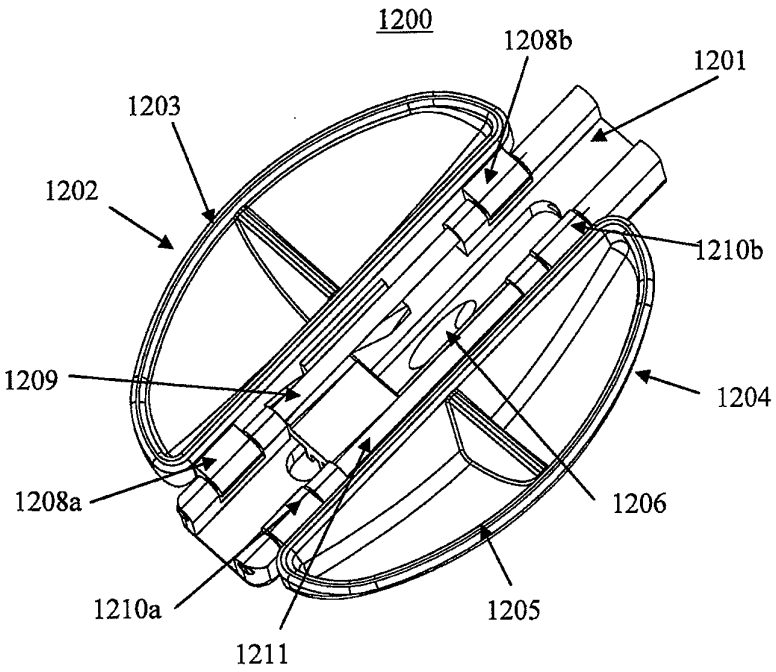


FIG. 12A

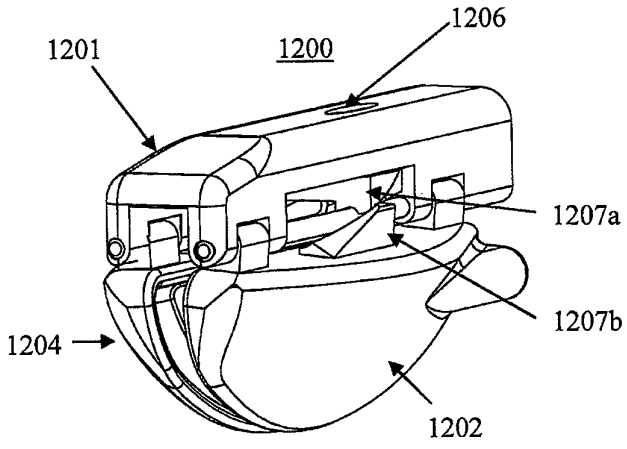


FIG. 12B

FIG. 13A

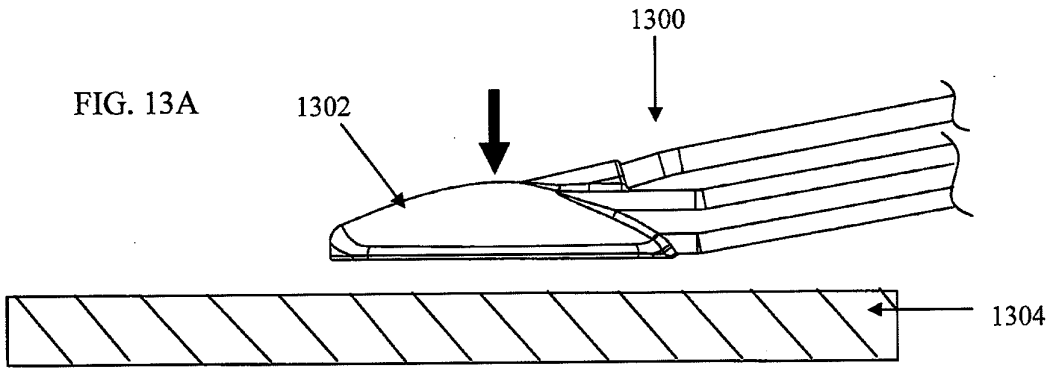


FIG. 13B

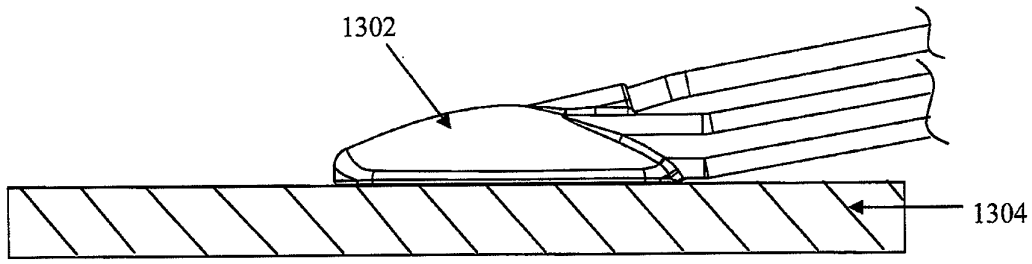


FIG. 13C

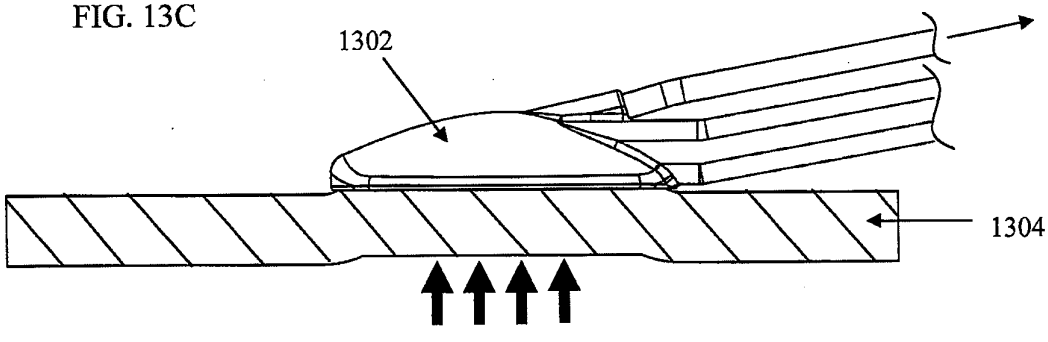


FIG. 13D

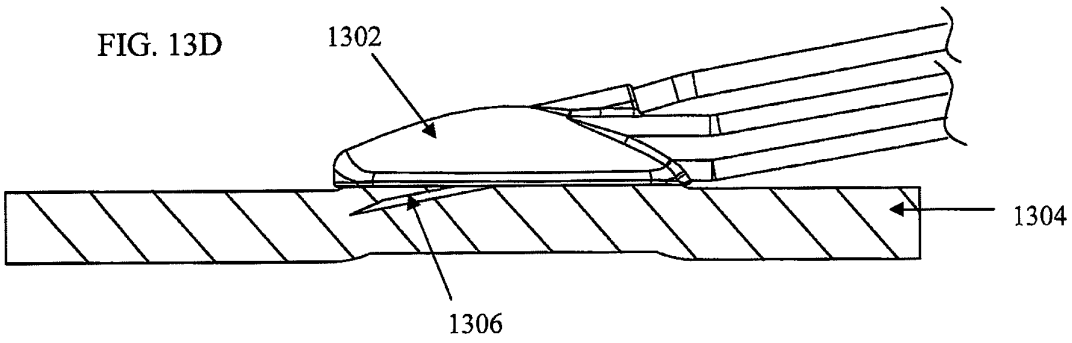


FIG. 13E

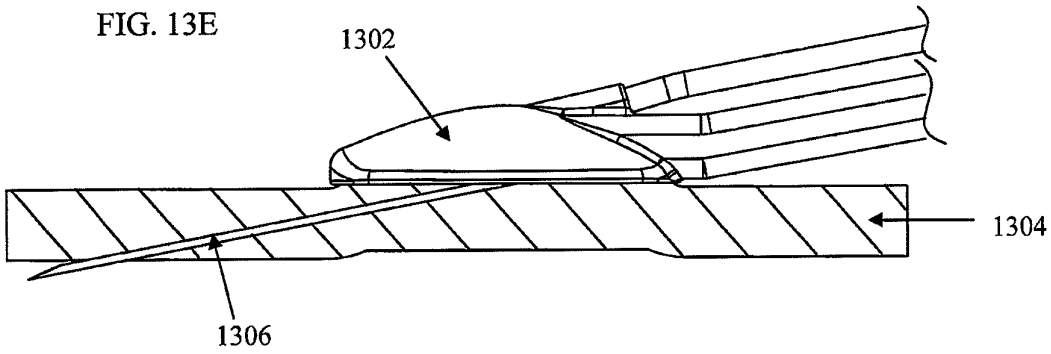
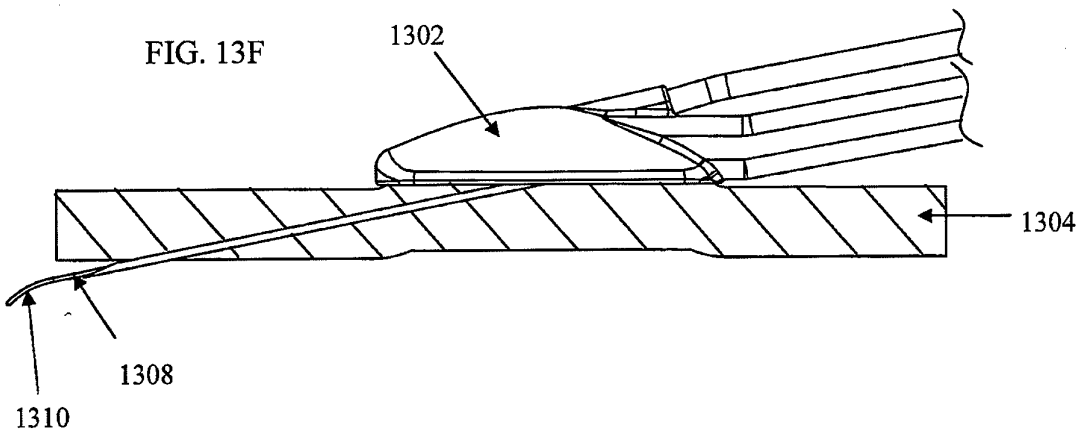


FIG. 13F



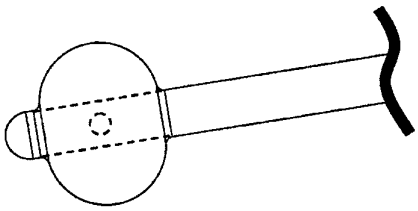


FIG. 13G

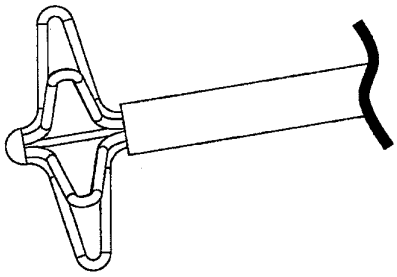


FIG. 13H

FIG. 13I

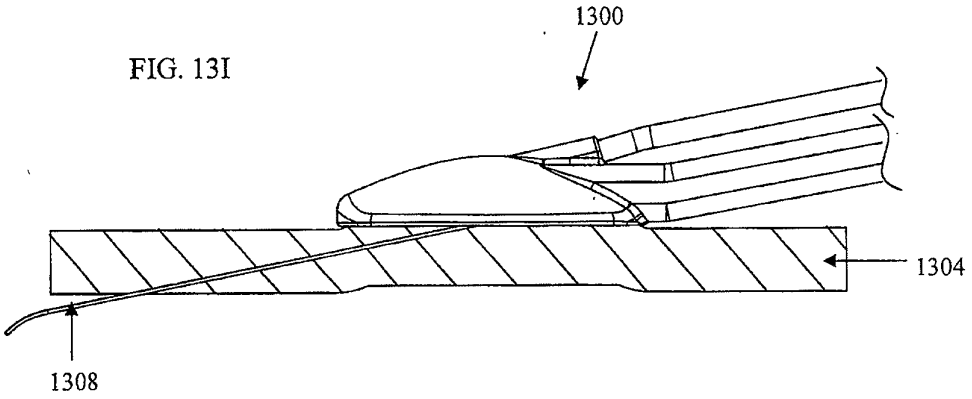


FIG. 13J

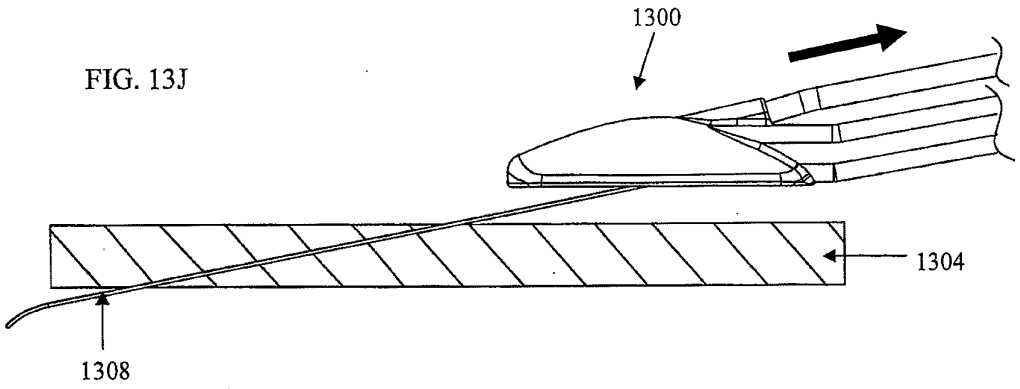


FIG. 13K

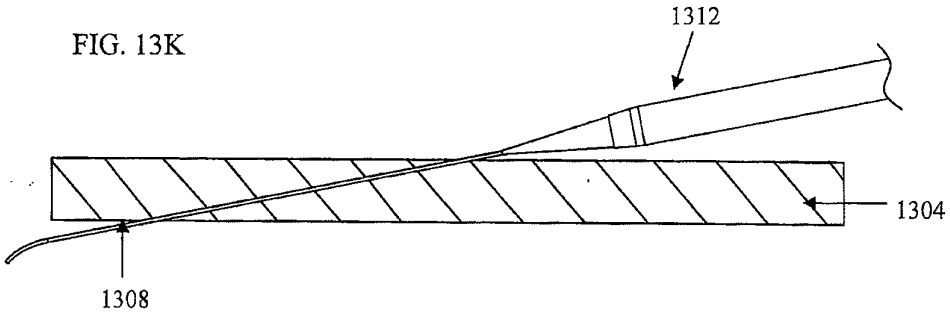


FIG. 13L

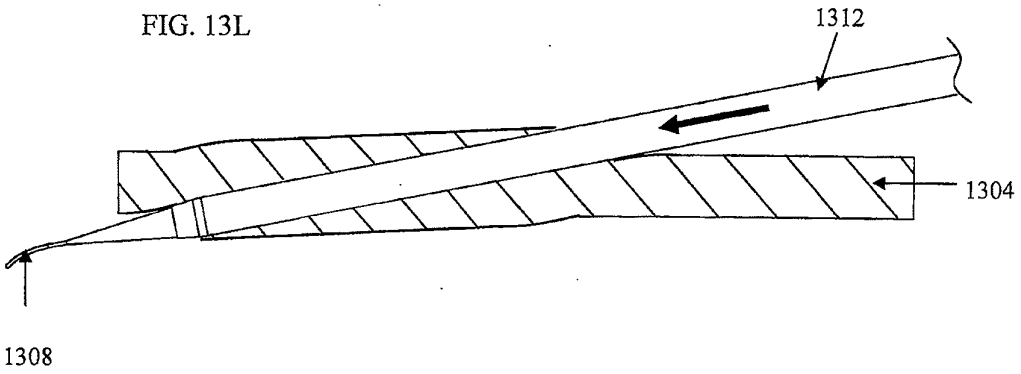
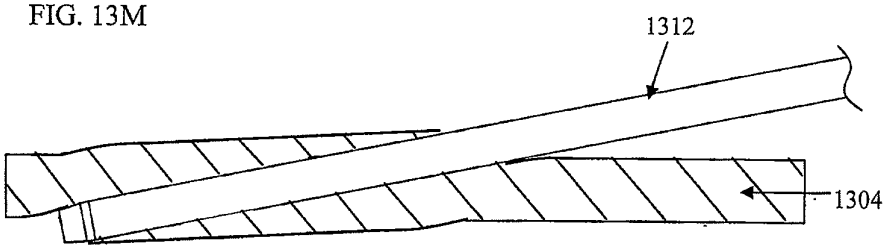


FIG. 13M



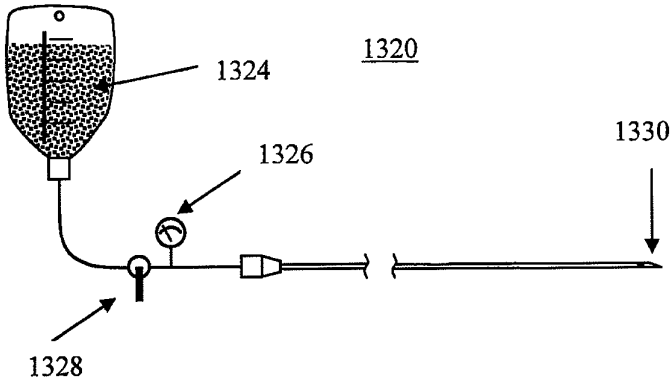


FIG. 13N

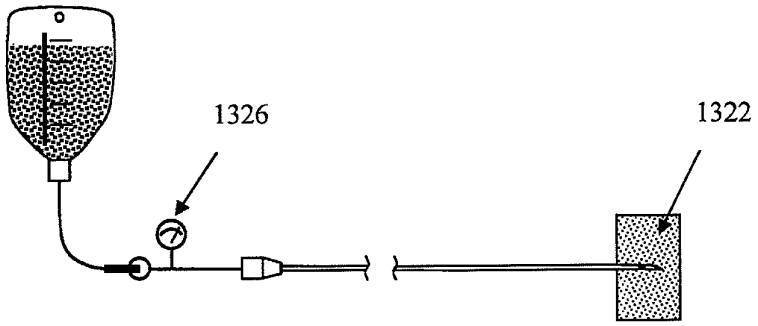


FIG. 13O

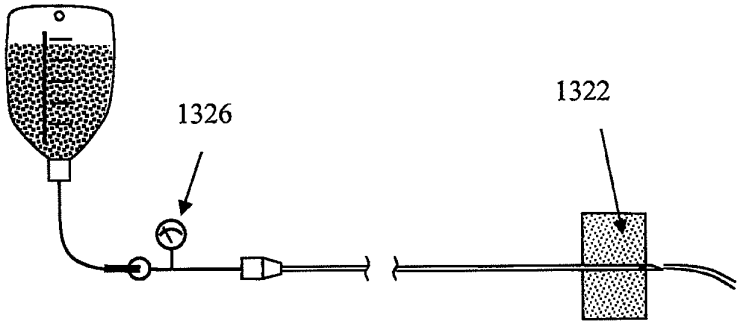


FIG. 13P

FIG. 14A

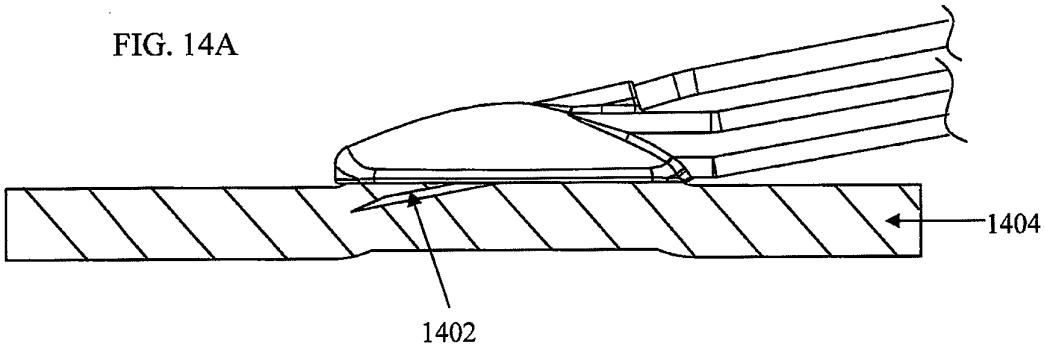


FIG. 14B

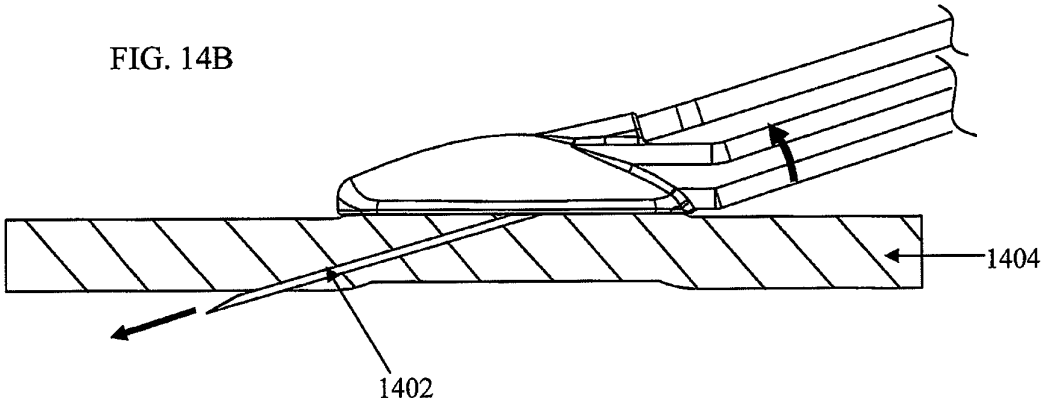
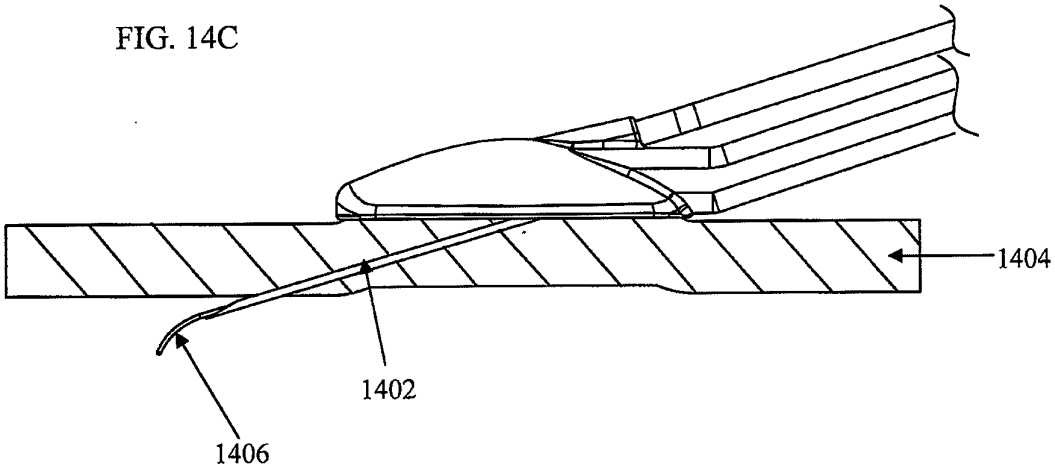


FIG. 14C



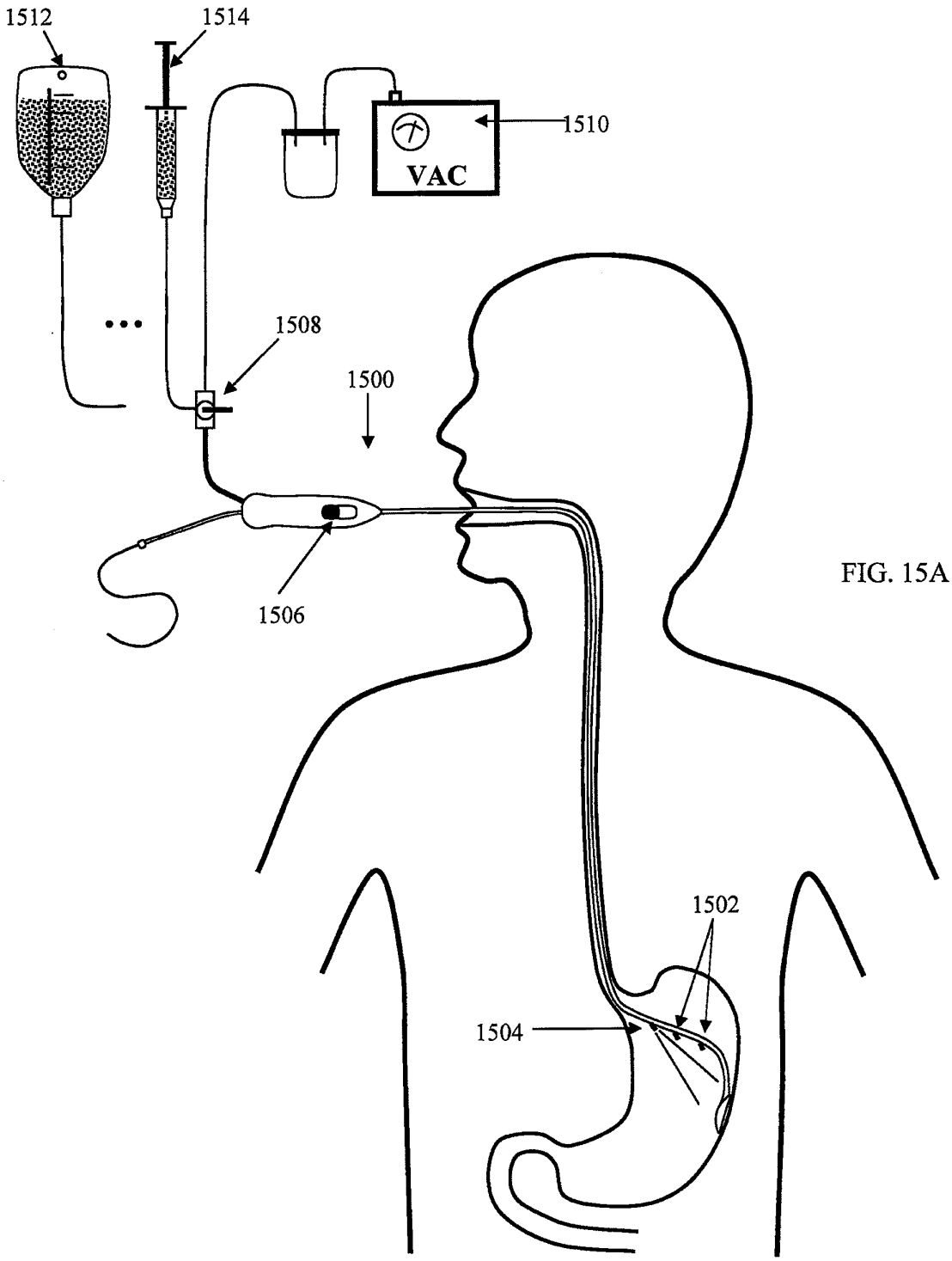


FIG. 15A

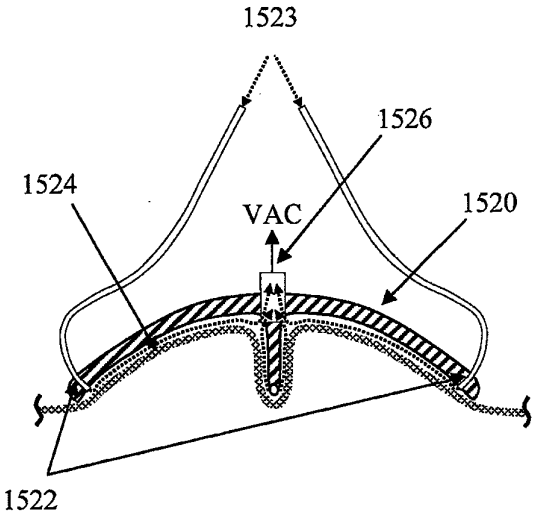


FIG. 15B

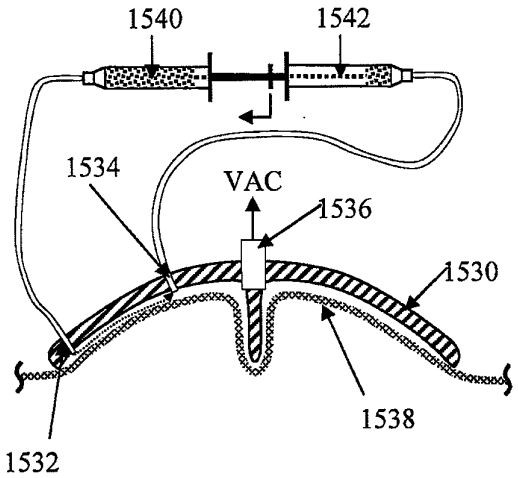


FIG. 15C

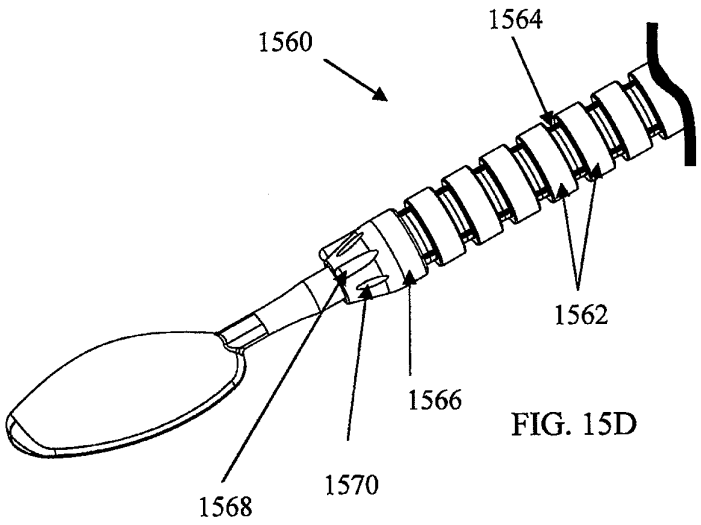


FIG. 15D

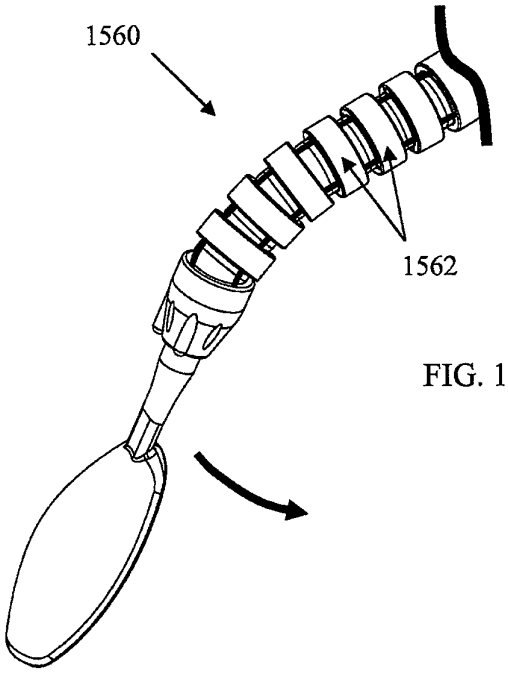


FIG. 15E

FIG. 15F

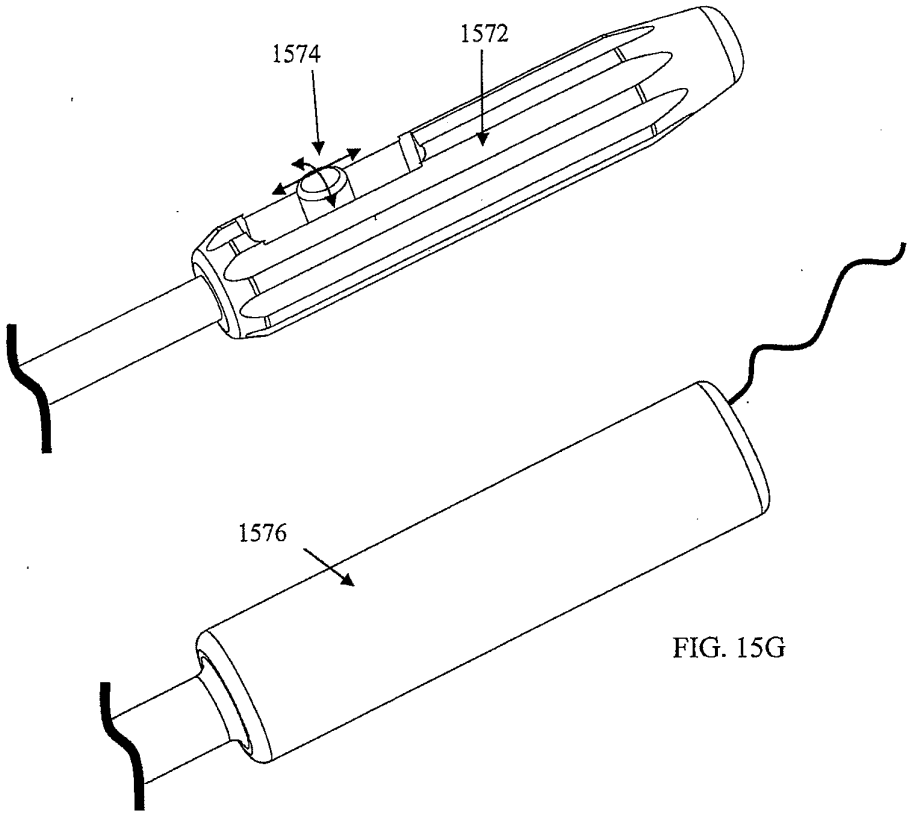


FIG. 15G

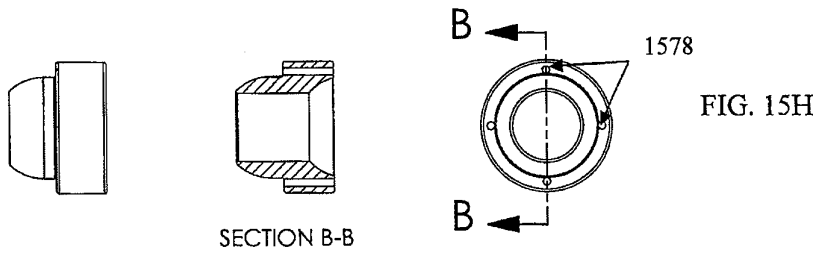


FIG. 15H

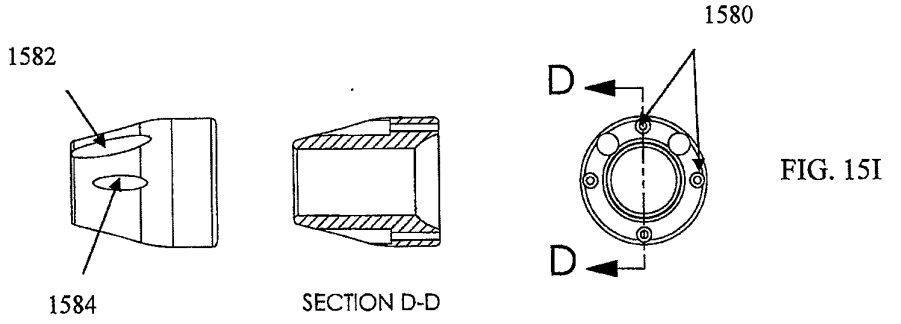


FIG. 15I

FIG. 16A

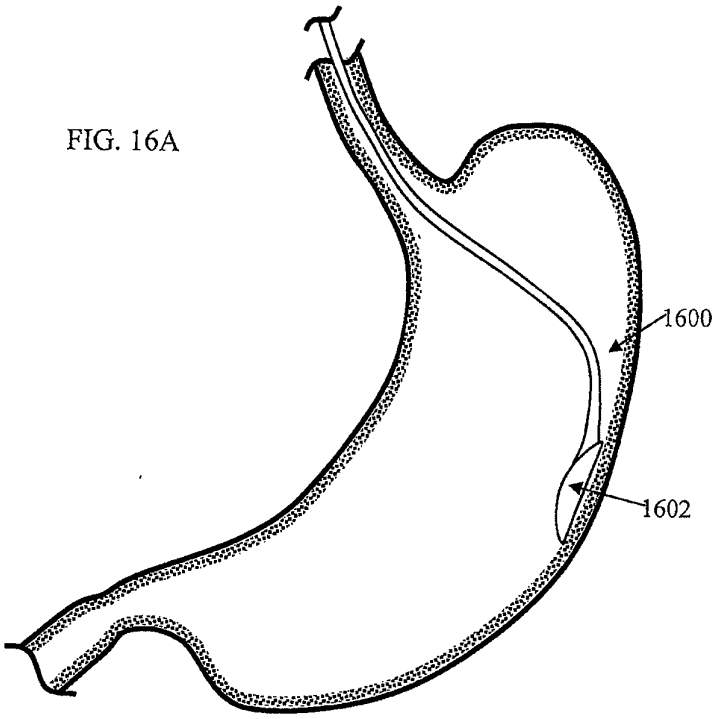


FIG. 16B

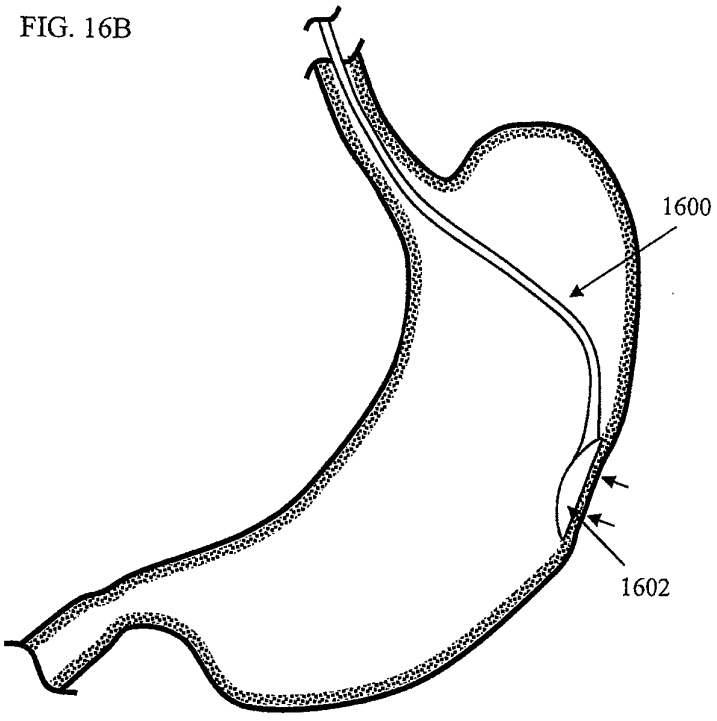


FIG. 16C

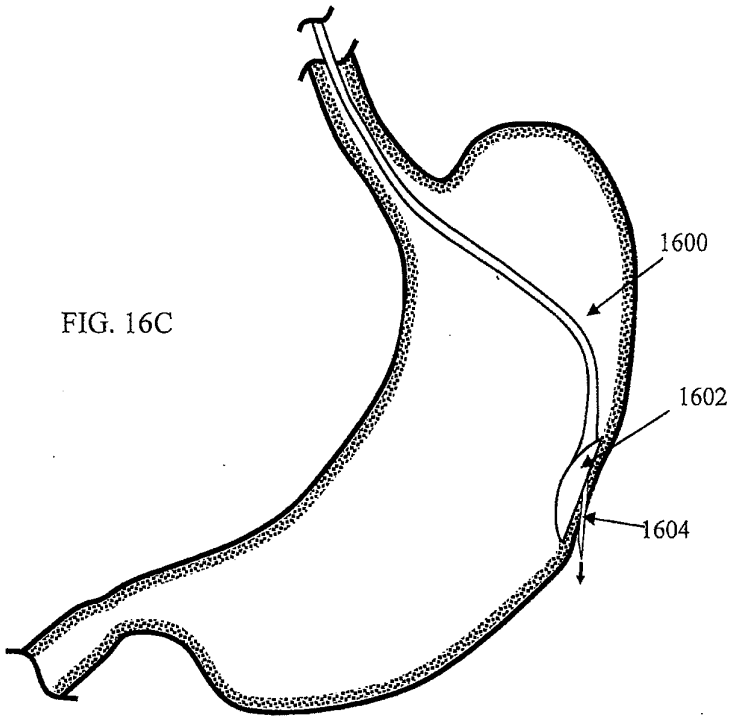


FIG. 16D

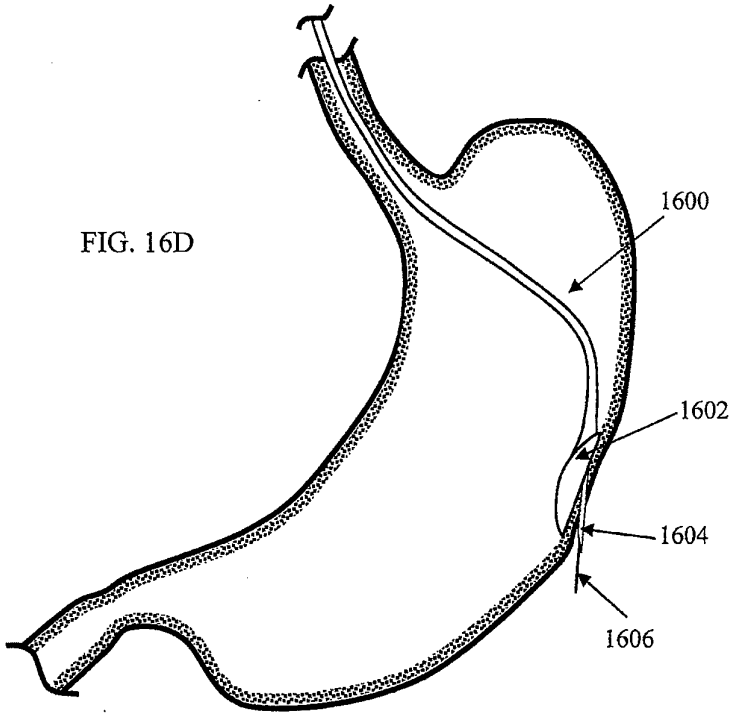


FIG. 16E

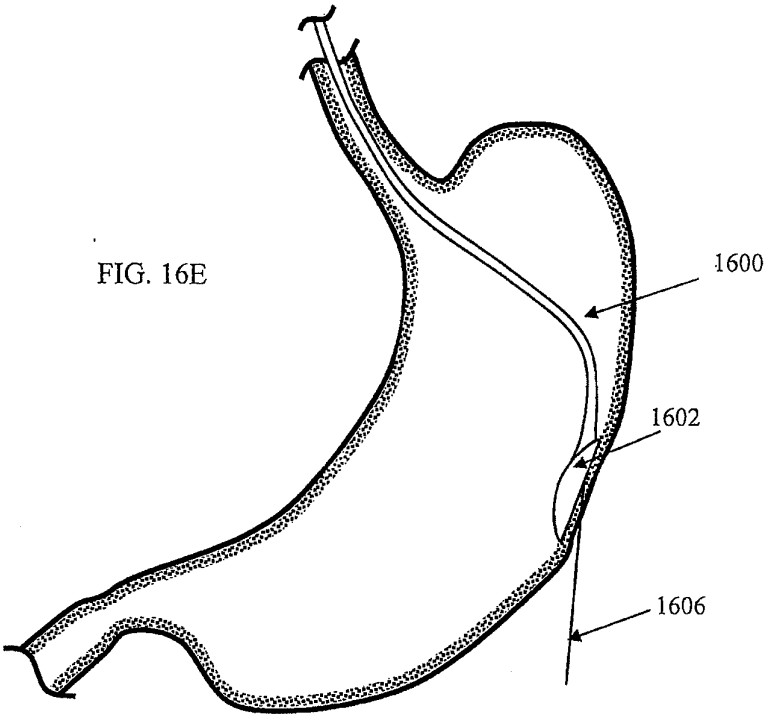
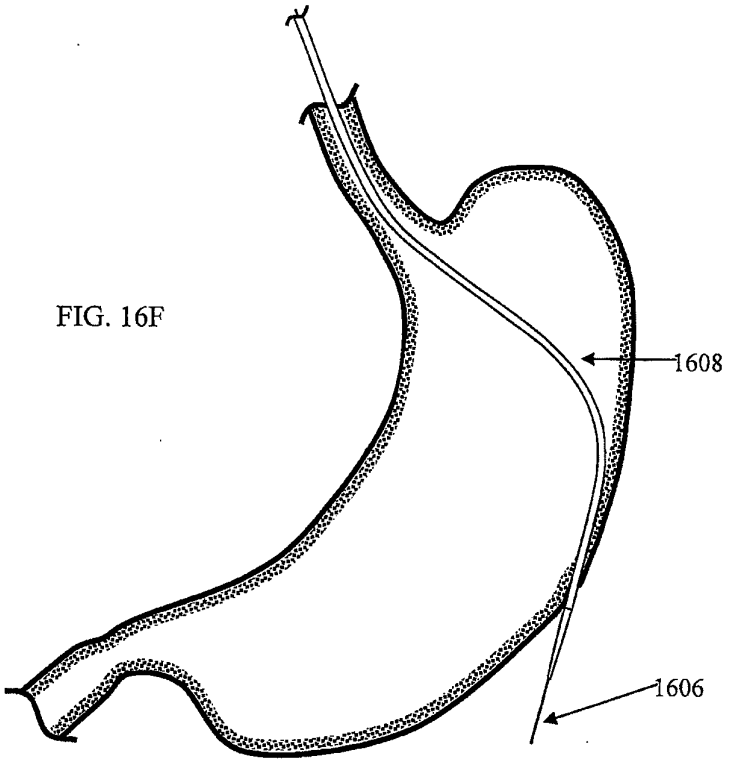


FIG. 16F



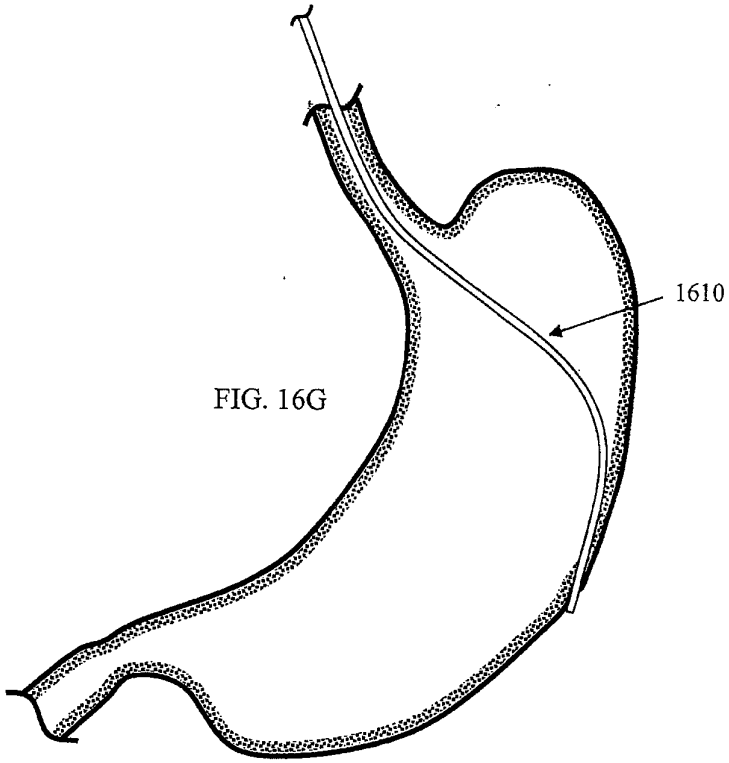


FIG. 16G

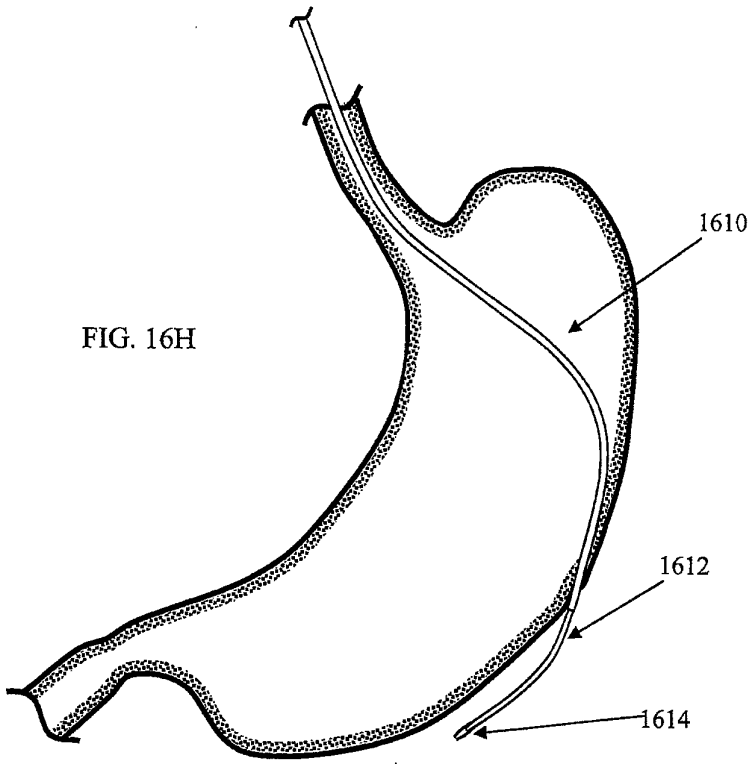


FIG. 16H

FIG. 16I

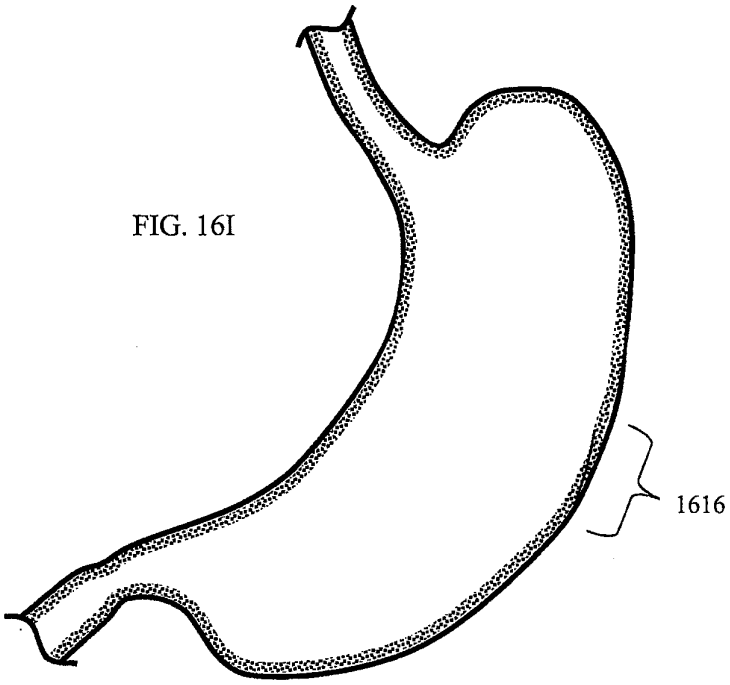


FIG. 17A

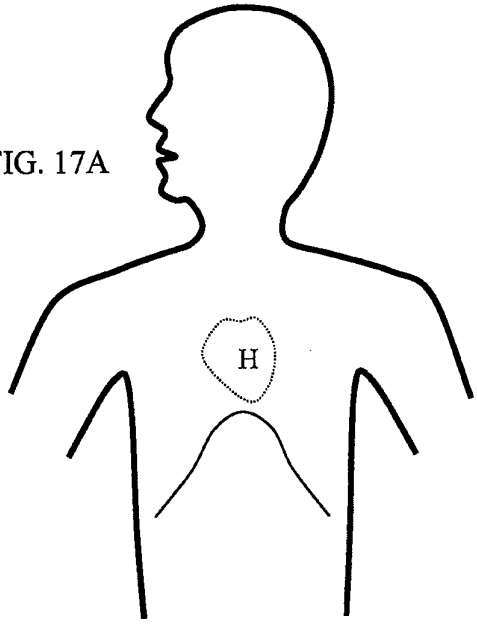


FIG. 17B

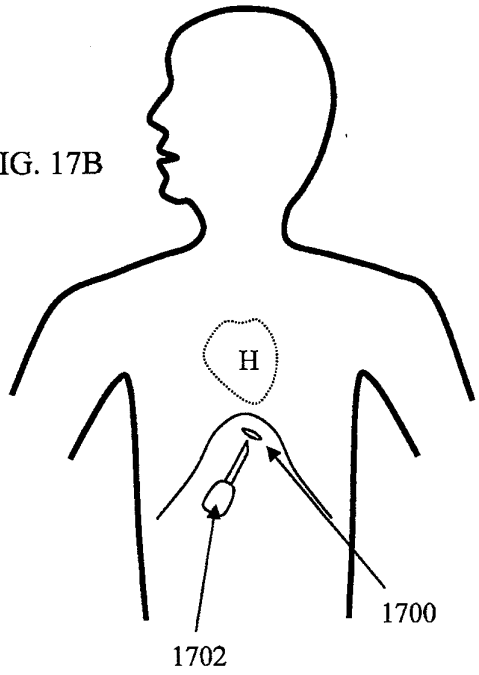


FIG. 17C

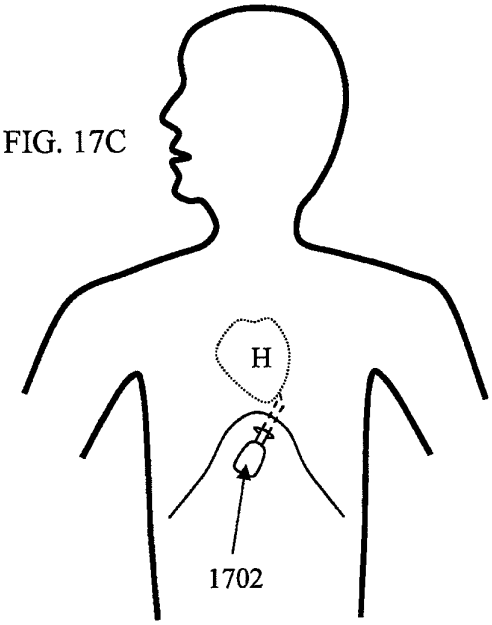
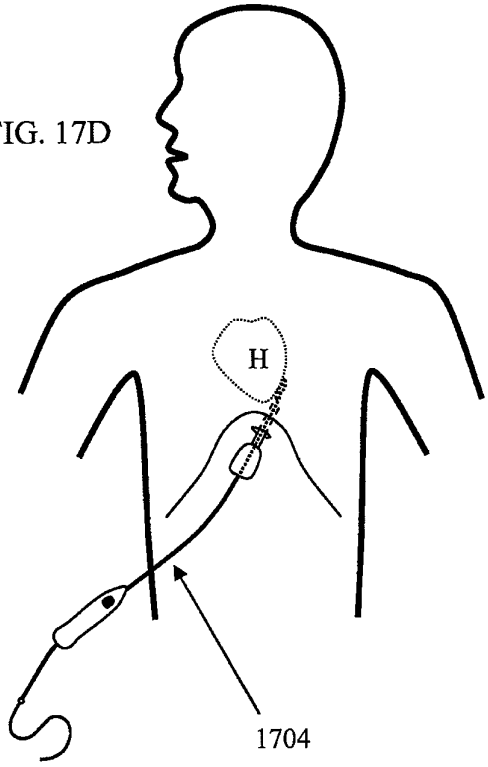


FIG. 17D



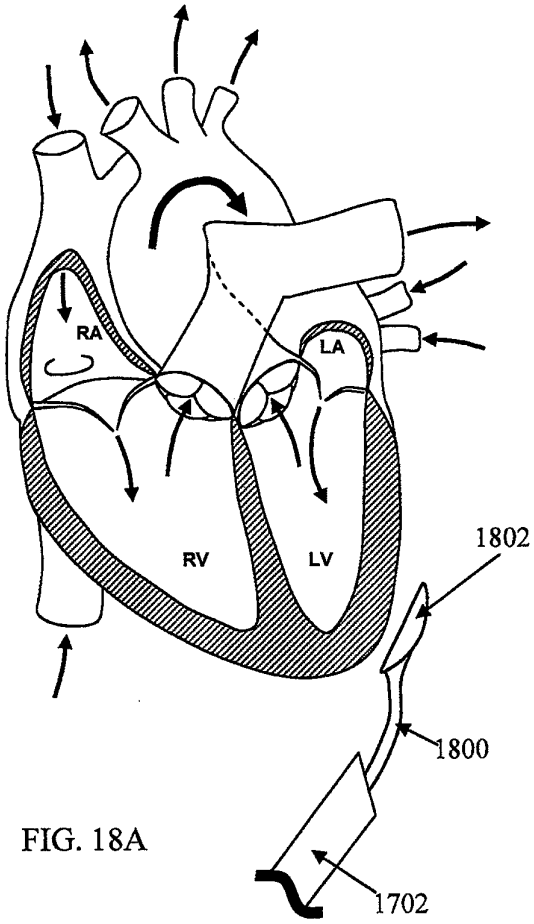


FIG. 18A

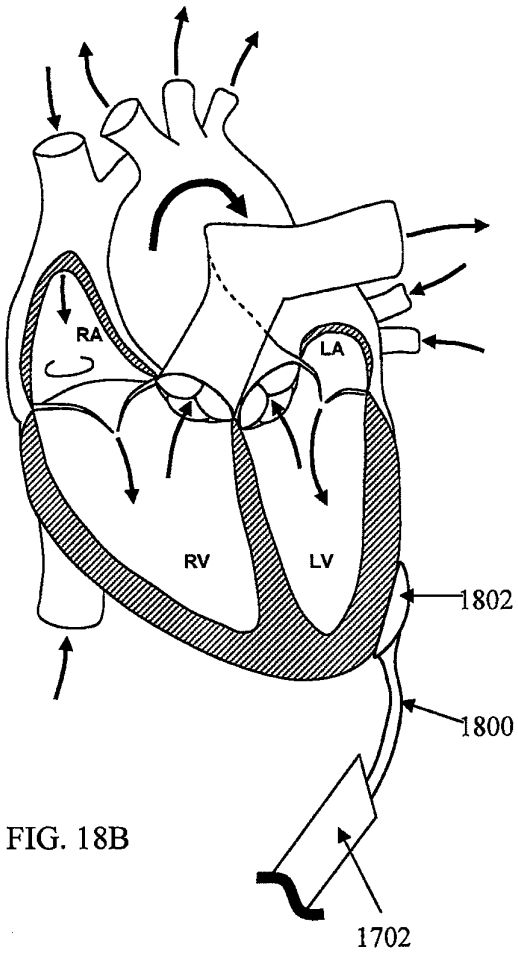


FIG. 18B

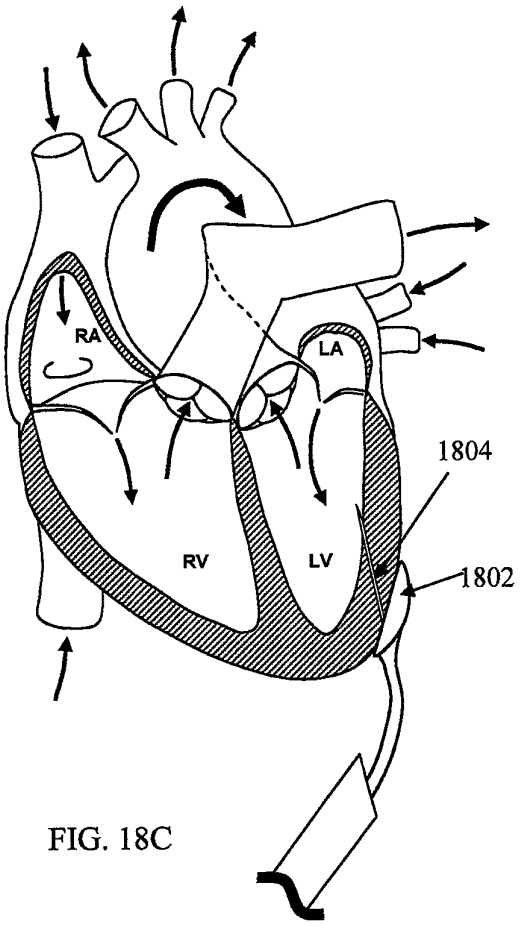


FIG. 18C

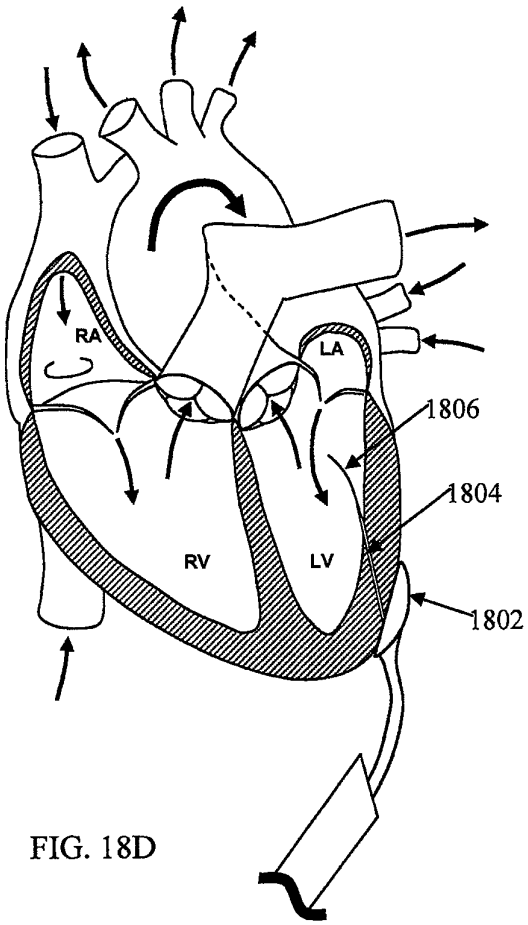


FIG. 18D

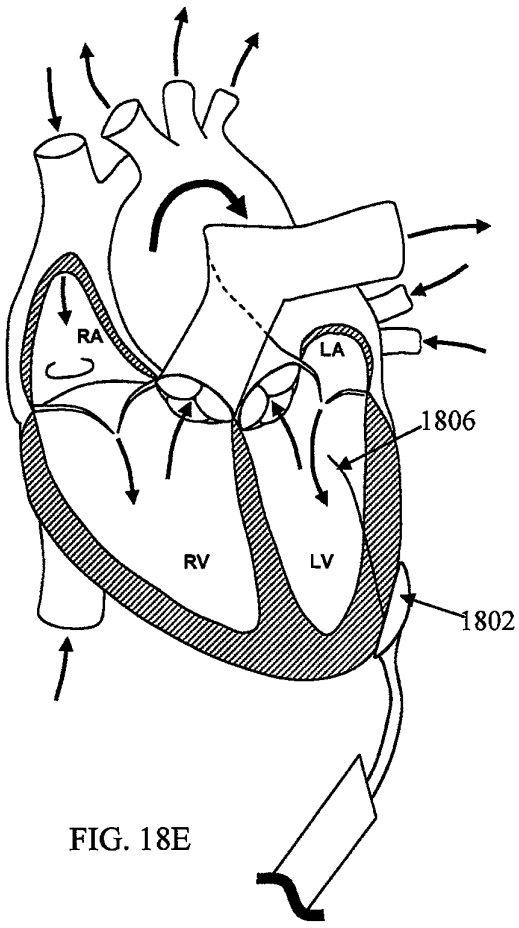


FIG. 18E

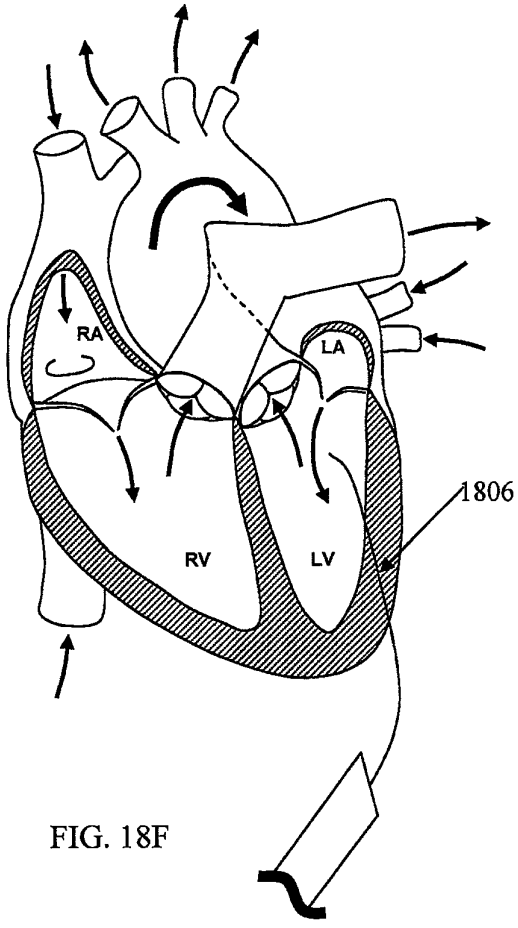


FIG. 18F

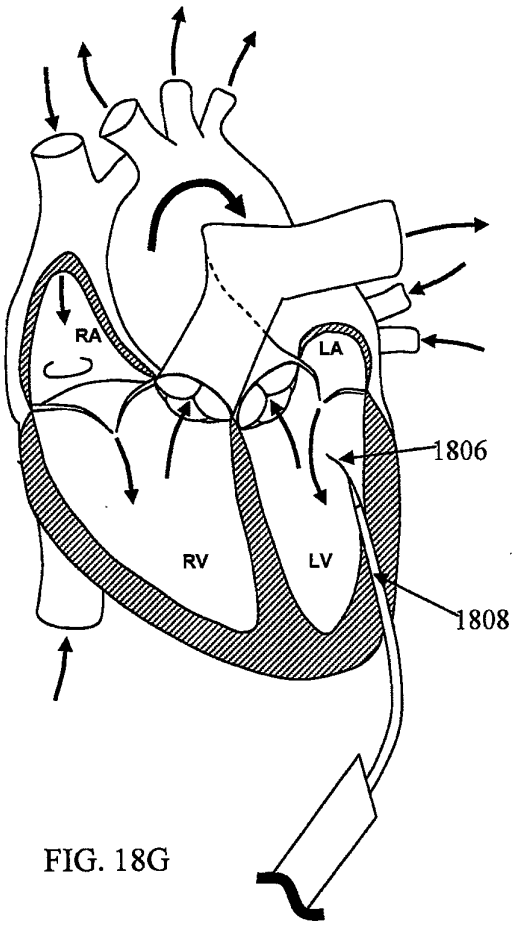


FIG. 18G

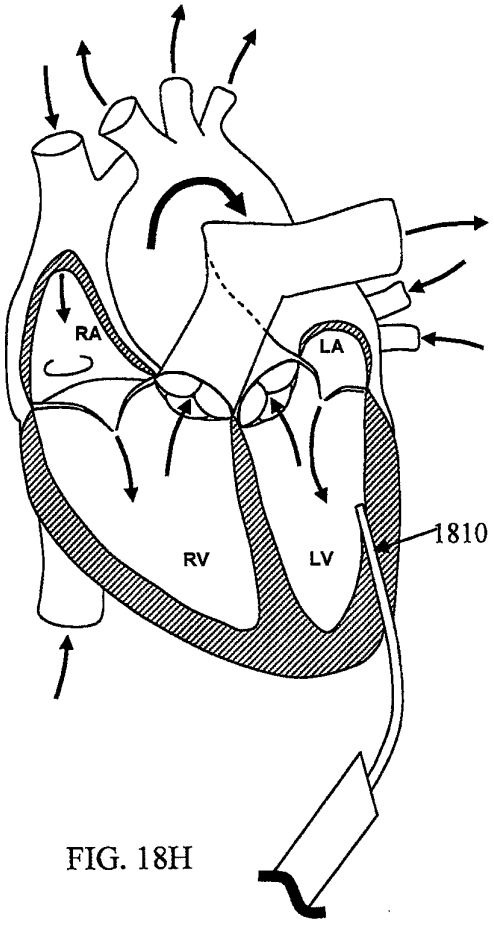


FIG. 18H

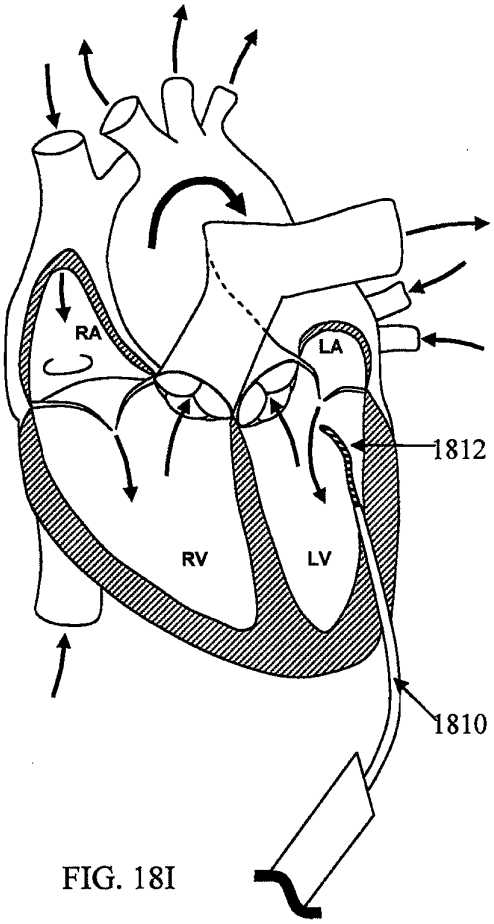


FIG. 18I

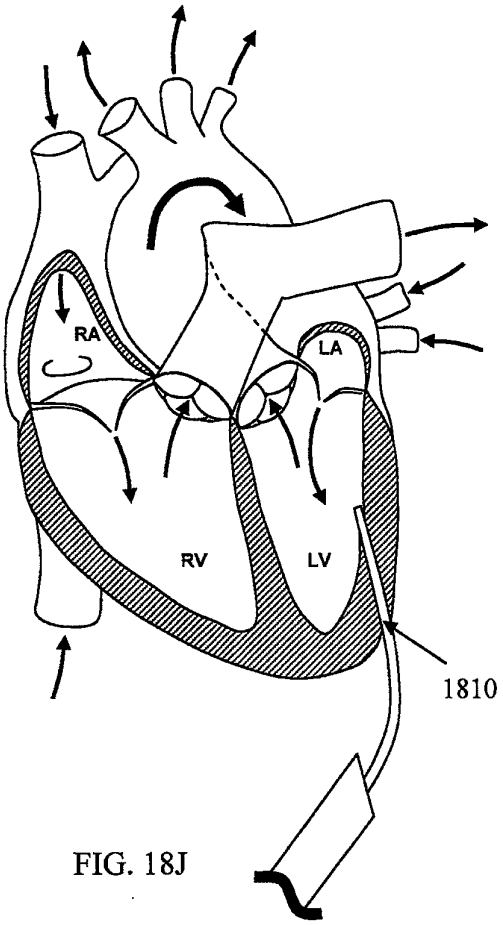


FIG. 18J

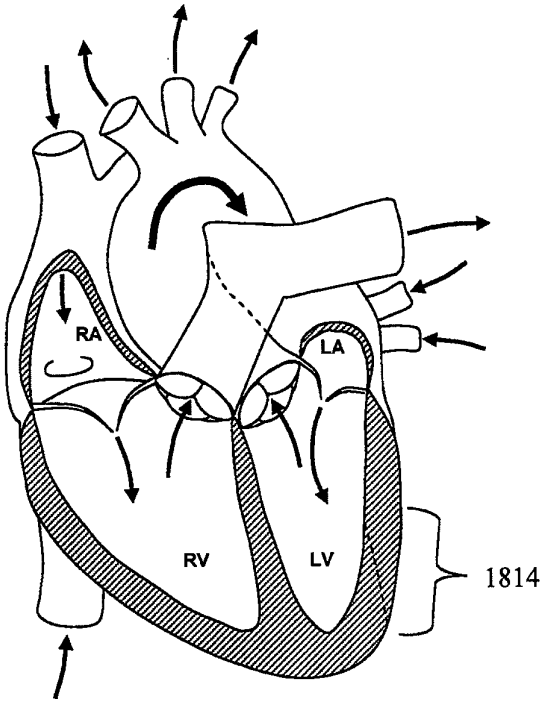


FIG. 18K