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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 September 2007 (27.09.2007)

PCT

(10) International Publication Number
WO 2007/109554 A2

(51) International Patent Classification:
A61B 1/04 (2006.01)

(21) International Application Number:
PCT/US2007/064195

(22) International Filing Date: 16 March 2007 (16.03.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/783,494 17 March 2006 (17.03.2006) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, 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, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

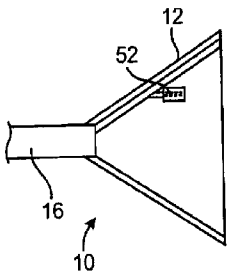
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** TISSUE VISUALIZATION AND MANIPULATION SYSTEMS



(57) **Abstract:** Tissue visualization and manipulation systems are described herein. Such a system may include a deployment catheter and an attached imaging hood deployable into an expanded configuration. In use, the imaging hood is placed against or adjacent to a region of tissue to be imaged in a body lumen that is normally filled with an opaque bodily fluid such as blood. A translucent or transparent fluid, such as saline, can be pumped into the imaging hood until the fluid displaces any blood, thereby leaving a clear region of tissue to be imaged via an imaging element in the deployment catheter. Additionally, any number of therapeutic tools can also be passed through the deployment catheter and into the imaging hood for treating the tissue region of interest.

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TISSUE VISUALIZATION AND MANIPULATION SYSTEMS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. Prov. Pat. App. Serial No. 60/783,494 filed March 17, 2006 and is a continuation-in-part of U.S. Pat. App. Serial No. 11/259,498 filed October 25, 2005 which claims the benefit of priority to U.S. Prov. Pat. App. Serial No. 60/649,246 filed February 2, 2005, each of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates generally to medical devices used for visualizing and/or manipulating regions of tissue within a body. More particularly, the present invention relates to apparatus and methods for visualizing and/or manipulating tissue regions within a body lumen, e.g., tissue surrounding or adjacent to valves within a heart, which are generally difficult to image because of surrounding opaque bodily fluids such as blood or the tissue of the inter-atrial septum for trans-septal procedures. However, it is understood that the systems described herein may be used in various parts of the anatomy.

BACKGROUND OF THE INVENTION

[0003] Conventional devices for visualizing interior regions of a body lumen are known. For example, ultrasound devices have been used to produce images from within a body *in vivo*. Ultrasound has been used both with and without contrast agents, which typically enhance ultrasound-derived images.

[0004] Other conventional methods have utilized catheters or probes having position sensors deployed within the body lumen, such as the interior of a cardiac chamber. These types of positional sensors are typically used to determine the movement of a cardiac tissue surface or the electrical activity within the cardiac tissue. When a sufficient number of points have been sampled by the sensors, a "map" of the cardiac tissue may be generated.

[0005] Another conventional device utilizes an inflatable balloon which is typically introduced intravascularly in a deflated state and then inflated against the tissue region to be examined. Imaging is typically accomplished by an optical fiber or other apparatus such as electronic chips for viewing the tissue through the membrane(s) of the inflated balloon.

Moreover, the balloon must generally be inflated for imaging. Other conventional ball utilize a cavity or depression formed at a distal end of the inflated balloon. This cavity or depression is pressed against the tissue to be examined and is flushed with a clear fluid to provide a clear pathway through the blood. Imaging may also use a fluorescence or gamma adapted visualization elements. Such elements may be able to distinguish between healthy and diseased tissue (e.g., infracted heart tissue).

[0006] However, such imaging balloons have many inherent disadvantages. For instance, such balloons generally require that the balloon be inflated to a relatively large size which may undesirably displace surrounding tissue and interfere with fine positioning of the imaging system against the tissue. Moreover, the working area created by such inflatable balloons are generally cramped and limited in size. Furthermore, inflated balloons may be susceptible to pressure changes in the surrounding fluid. For example, if the environment surrounding the inflated balloon undergoes pressure changes, e.g., during systolic and diastolic pressure cycles in a beating heart, the constant pressure change may affect the inflated balloon volume and its positioning to produce unsteady or undesirable conditions for optimal tissue imaging.

[0007] Accordingly, these types of imaging modalities are generally unable to provide desirable images useful for sufficient diagnosis and therapy of the endoluminal structure, due in part to factors such as dynamic forces generated by the natural movement of the heart. Moreover, anatomic structures within the body can occlude or obstruct the image acquisition process. Also, the presence and movement of opaque bodily fluids such as blood generally make *in vivo* imaging of tissue regions within the heart difficult.

[0008] Other external imaging modalities are also conventionally utilized. For example, computed tomography (CT) and magnetic resonance imaging (MRI) are typical modalities which are widely used to obtain images of body lumens such as the interior chambers of the heart. However, such imaging modalities fail to provide real-time imaging for intra-operative therapeutic procedures. Fluoroscopic imaging, for instance, is widely used to identify anatomic landmarks within the heart and other regions of the body. However, fluoroscopy fails to provide an accurate image of the tissue quality or surface and also fails to provide for instrumentation for performing tissue manipulation or other therapeutic procedures upon the visualized tissue regions. In addition, fluoroscopy provides a shadow of the intervening tissue onto a plate or sensor when it may be desirable to view the intraluminal surface c : to diagnose pathologies or to perform some form of therapy on it.

[0009] s, a tissue imaging system which is able to provide real-time *in vivo*

images of tissue regions within body lumens such as the heart through opaque media s blood and which also provide instruments for therapeutic procedures upon the visualized tissue are desirable.

BRIEF SUMMARY OF THE INVENTION

[0010] A tissue imaging and manipulation apparatus that may be utilized for procedures within a body lumen, such as the heart, in which visualization of the surrounding tissue is made difficult, if not impossible, by medium contained within the lumen such as blood, is described below. Generally, such a tissue imaging and manipulation apparatus comprises an optional delivery catheter or sheath through which a deployment catheter and imaging hood may be advanced for placement against or adjacent to the tissue to be imaged.

[0011] The deployment catheter may define a fluid delivery lumen therethrough as well as an imaging lumen within which an optical imaging fiber or assembly may be disposed for imaging tissue. In addition, the deployment catheter may have additional lumens for various functions. For example, additional lumens may allow aspiration of air bubbles or other substances that may interfere with visualization of the target tissue When deployed, the imaging hood may be expanded into any number of shapes, e.g., cylindrical, conical as shown, semi-spherical, etc., provided that an open area or field is defined by the imaging hood. The open area is the area within which the tissue region of interest may be imaged. The imaging hood may also define an atraumatic contact lip or edge for placement or abutment against the tissue region of interest. Moreover, the distal end of the deployment catheter or separate manipulatable catheters may be articulated through various controlling mechanisms such as push-pull wires manually or via computer control

[0012] The deployment catheter may also be stabilized relative to the tissue surface through various methods. For instance, inflatable stabilizing balloons positioned along a length of the catheter may be utilized, or tissue engagement anchors may be passed through or along the deployment catheter for temporary engagement of the underlying tissue.

[0013] In operation, after the imaging hood has been deployed, fluid may be pumped at a positive pressure through the fluid delivery lumen until the fluid fills the open area completely and displaces any blood from within the open area. The fluid may comprise any biocompatible fluid, e.g., saline, water, plasma, Fluorinert™, etc., which is sufficiently transparent to allow for relatively undistorted visualization through the fluid. The fluid may be pumpously or intermittently to allow for image capture by an optional processor

which may be in communication with the assembly.

[0014] The imaging hood may be formed into any number of configurations and the imaging assembly may also be utilized with any number of therapeutic tools which may be deployed through the deployment catheter.

[0015] Variations of the inventive assemblies and their features described herein may be used with other devices that provide bounded regions. For example, US Patent No. 6,755,811 and US Published Patent Application No. 2005/0059954, both to Constantz, describe methods and devices for reducing mineral content of a region of non-intimal vascular tissue. The entirety of each of which is incorporated by reference herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Fig. 1A shows a side view of one variation of a tissue imaging apparatus during deployment from a sheath or delivery catheter.

[0017] Fig. 1B shows the deployed tissue imaging apparatus of Fig. 1A having an optionally expandable hood or sheath attached to an imaging and/or diagnostic catheter.

[0018] Fig. 1C shows an end view of a deployed imaging apparatus.

[0019] Figs. 1D to 1F show the apparatus of Figs. 1A to 1C with an additional lumen, e.g., for passage of a guidewire therethrough.

[0020] Figs. 1G-1J illustrate additional variations of the assembly having visualization elements as well as illumination elements.

[0021] Figs. 2A and 2B show one example of a deployed tissue imager positioned against or adjacent to the tissue to be imaged and a flow of fluid, such as saline, displacing blood from within the expandable hood.

[0022] Fig. 3A shows an articulatable imaging assembly which may be manipulated via push-pull wires or by computer control.

[0023] Figs. 3B and 3C show steerable instruments, respectively, where an articulatable delivery catheter may be steered within the imaging hood or a distal portion of the deployment catheter itself may be steered.

[0024] Figs. 4A to 4C show side and cross-sectional end views, respectively, of another variation having an off-axis imaging capability.

[0025] Figs. 4D-4G illustrates cross-sectional views of a variation of a tissue imaging and manipulation assembly with off-axis visualization capabilities.

[0026] 5 shows an illustrative view of an example of a tissue imager advanced

intravascularly within a heart for imaging tissue regions within an atrial chamber.

[0027] Figs. 6A to 6C illustrate deployment catheters having one or more optional inflatable balloons or anchors for stabilizing the device during a procedure.

[0028] Figs. 7A and 7B illustrate a variation of an anchoring mechanism such as a helical tissue piercing device for temporarily stabilizing the imaging hood relative to a tissue surface.

[0029] Fig. 7C shows another variation for anchoring the imaging hood having one or more tubular support members integrated with the imaging hood; each support members may define a lumen therethrough for advancing a helical tissue anchor within.

[0030] Fig. 8A shows an illustrative example of one variation of how a tissue imager may be utilized with an imaging device.

[0031] Fig. 8B shows a further illustration of a hand-held variation of the fluid delivery and tissue manipulation system.

[0032] Figs. 9A to 9C illustrate an example of capturing several images of the tissue at multiple regions.

[0033] Figs. 10A and 10B show charts illustrating how fluid pressure within the imaging hood may be coordinated with the surrounding blood pressure; the fluid pressure in the imaging hood may be coordinated with the blood pressure or it may be regulated based upon pressure feedback from the blood.

[0034] Fig. 11A shows a side view of another variation of a tissue imager having an imaging balloon within an expandable hood.

[0035] Fig. 11B shows another variation of a tissue imager utilizing a translucent or transparent imaging balloon.

[0036] Fig. 12A shows another variation in which a flexible expandable or distensible membrane may be incorporated within the imaging hood to alter the volume of fluid dispensed.

[0037] Figs. 12B and 12C show another variation in which the imaging hood may be partially or selectively deployed from the catheter to alter the area of the tissue being visualized as well as the volume of the dispensed fluid.

[0038] Figs. 12D-12F show variations of the imaging hood with an inflatable members that displace fluids or other materials from the hood.

[0039] Figs. 13A and 13B show exemplary side and cross-sectional views, respectiv ther variation in which the injected fluid may be drawn back into the device fc ng fluid input into a body being treated.

[0040] Figs. 14A to 14D show various configurations and methods for configu imaging hood into a low-profile for delivery and/or deployment.

[0041] Figs. 15A and 15B show an imaging hood having an helically expanding frame or support.

[0042] Figs. 16A and 16B show another imaging hood having one or more hood support members, which are pivotably attached at their proximal ends to deployment catheter, integrated with a hood membrane.

[0043] Figs. 17A and 17B show yet another variation of the imaging hood having at least two or more longitudinally positioned support members supporting the imaging hood membrane where the support members are movable relative to one another via a torquing or pulling or pushing force.

[0044] Figs. 18A and 18B show another variation where a distal portion of the deployment catheter may have several pivoting members which form a tubular shape in its low profile configuration.

[0045] Figs. 19A and 19B show another variation where the distal portion of deployment catheter may be fabricated from a flexible metallic or polymeric material to form a radially expanding hood.

[0046] Figs. 20A and 20B show another variation where the imaging hood may be formed from a plurality of overlapping hood members which overlie one another in an overlapping pattern.

[0047] Fig. 20C shows a variation of a hood having a conforming section at the distal end.

[0048] Figs. 21A and 21B show another example of an expandable hood which is highly conformable against tissue anatomy with varying or non-uniform surfaces.

[0049] Fig. 22A shows yet another example of an expandable hood having a number of optional electrodes placed about the contact edge or lip of the hood for sensing tissue contact or detecting arrhythmias.

[0050] Fig. 22B shows another variation for conforming the imaging hood against the underlying tissue where an inflatable contact edge may be disposed around the circumference of the imaging hood.

[0051] Fig. 23 shows a variation of the system which may be instrumented with a transducer for detecting the presence of blood seeping back into the imaging hood.

[0052] . 24A and 24B show variations of the imaging hood instrumented with sensors i g various physical parameters; the sensors may be instrumented around

the outer surface of the imaging hood and also within the imaging hood.

[0053] Figs. 25A and 25B show a variation where the imaging hood may have one or more LEDs over the hood itself for providing illumination of the tissue to be visualized.

[0054] Figs. 26A and 26B show another variation in which a separate illumination tool having one or more LEDs mounted thereon may be utilized within the imaging hood.

[0055] Fig. 27 shows one example of how a therapeutic tool may be advanced through the tissue imager for treating a tissue region of interest.

[0056] Fig. 28 shows another example of a helical therapeutic tool for treating the tissue region of interest.

[0057] Fig. 29 shows a variation of how a therapeutic tool may be utilized with an expandable imaging balloon.

[0058] Figs. 30A and 30B show alternative configurations for therapeutic instruments which may be utilized; one variation is shown having an angled instrument arm and another variation is shown with an off-axis instrument arm.

[0059] Figs. 31A to 31C show side and end views, respectively, of an imaging system which may be utilized with an ablation probe.

[0060] Figs. 32A and 32B show side and end views, respectively, of another variation of the imaging hood with an ablation probe, where the imaging hood may be enclosed for regulating a temperature of the underlying tissue.

[0061] Figs. 33A and 33B show an example in which the imaging fluid itself may be altered in temperature to facilitate various procedures upon the underlying tissue.

[0062] Fig. 33C illustrates a variation of a system using ultrasound to treat the tissue under the hood.

[0063] Figs. 34A and 34B show an example of a laser ring generator which may be utilized with the imaging system and an example for applying the laser ring generator within the left atrium of a heart for treating atrial fibrillation.

[0064] Fig. 34C illustrates a variation of the system having a visualization element located at the end of the catheter and/or on the hood.

[0065] Fig. 34D illustrates another variation of a system according to the present invention using an inflatable member for advancing the device to a site.

[0066] Figs. 35A to 35C show an example of an extendible cannula generally comprising an elongate tubular member which may be positioned within the deployment catheter very and then projected distally through the imaging hood and optionally beyond.

[0067] Figs. 36A and 36B show side and end views, respectively, of an imagir having one or more tubular support members integrated with the hood for passing instruments or tools therethrough for treatment upon the underlying tissue.

[0068] Figs. 37A and 37B illustrate how an imaging device may be guided within a heart chamber to a region of interest utilizing a lighted probe positioned temporarily within, e.g., a lumen of the coronary sinus.

[0069] Figs. 38A and 38B show an imaging hood having a removable disk-shaped member for implantation upon the tissue surface.

[0070] Figs. 39A to 39C show one method for implanting the removable disk of Figs. 38A and 38B.

[0071] Figs. 40A and 40B illustrate an imaging hood having a deployable anchor assembly attached to the tissue contact edge and an assembly view of the anchors and the suture or wire connected to the anchors, respectively

[0072] Figs. 41A to 41D show one method for deploying the anchor assembly of Figs. 40A and 40B for closing an opening or wound.

[0073] Figs. 41E-41F illustrates tissue imaging and manipulation assemblies configured to deliver implants.

[0074] Fig. 42 shows another variation in which the imaging system may be fluidly coupled to a dialysis unit for filtering a patient's blood.

[0075] Figs. 43A and 43B show a variation of the deployment catheter having a first deployable hood and a second deployable hood positioned distal to the first hood; the deployment catheter may also have a side-viewing imaging element positioned between the first and second hoods for imaging tissue between the expanded hoods.

[0076] Fig. 43C illustrates another variation of a deployment catheter **480** having a series of deployable hoods arranged to produce a clear visual field.

[0077] Figs. 44A and 44B show side and end views, respectively, of a deployment catheter having a side-imaging balloon in an un-inflated low-profile configuration.

[0078] Figs. 45A to 45C show side, top, and end views, respectively, of the inflated balloon of Figs. 44A and 44B defining a visualization field in the inflated balloon.

[0079] Figs. 46A and 46B show side and cross-sectional end views, respectively, for one method of use in visualizing a lesion upon a vessel wall within the visualization field of the inflated balloon from Figs. 45A to 45C.

[0080] . 47A-47B illustrate a variation of a device according to the present inventio mponents of the system allow for blunt dissection of tissue.

[0081] Fig. 48A show a variation of a tissue imaging and manipulation assemb including an elongate bypass portion.

[0082] Figs. 48B-48C show the variation of Fig. 48A with a tissue support flap.

[0083] Fig. 48D illustrates an off-center hood located about a catheter.

[0084] Fig. 48E shows a variation of a tissue imaging and manipulation assembly including an elongate portion that supplies fluid to an area of tissue.

[0085] Fig. 48F shows a tissue imaging and manipulation assembly including an occlusion member or balloon.

[0086] Fig. 49A-49E illustrate the use of an elongate member having a plurality of openings to produce flow patterns within the hood.

[0087] Figs. 50A-50C illustrate variations of a tissue imaging and manipulation assembly designed to translate or "walk" across tissue surfaces when inserted within the body.

DETAILED DESCRIPTION OF THE INVENTION

[0088] A tissue-imaging and manipulation apparatus described below is able to provide real-time images *in vivo* of tissue regions within a body lumen such as a heart, which is filled with blood flowing dynamically therethrough and is also able to provide intravascular tools and instruments for performing various procedures upon the imaged tissue regions. Such an apparatus may be utilized for many procedures, e.g., facilitating trans-septal access to the left atrium, cannulating the coronary sinus, diagnosis of valve regurgitation/stenosis, valvuloplasty, atrial appendage closure, arrhythmogenic focus ablation, among other procedures.

[0089] One variation of a tissue access and imaging apparatus is shown in the detail perspective views of Figs. 1A to 1C. As shown in Fig. 1A, tissue imaging and manipulation assembly **10** may be delivered intravascularly through the patient's body in a low-profile configuration via a delivery catheter or sheath **14**. In the case of treating tissue, such as the mitral valve located at the outflow tract of the left atrium of the heart, it is generally desirable to enter or access the left atrium while minimizing trauma to the patient. To non-operatively effect such access, one conventional approach involves puncturing the intra-atrial septum from the right atrial chamber to the left atrial chamber in a procedure commonly called a trans-septal procedure or septostomy. For procedures such as percutaneous valve repair and replacen septal access to the left atrial chamber of the heart may allow for larger

devices to be introduced into the venous system than can generally be introduced percutaneously into the arterial system.

[0090] When the imaging and manipulation assembly **10** is ready to be utilized for imaging tissue, imaging hood **12** may be advanced relative to catheter **14** and deployed from a distal opening of catheter **14**, as shown by the arrow. Upon deployment, imaging hood **12** may be unconstrained to expand or open into a deployed imaging configuration, as shown in Fig. 1B. Imaging hood **12** may be fabricated from a variety of pliable or conformable biocompatible material including but not limited to, e.g., polymeric, plastic, or woven materials. One example of a woven material is Kevlar® (E. I. du Pont de Nemours, Wilmington, DE), which is an aramid and which can be made into thin, e.g., less than 0.001 in., materials which maintain enough integrity for such applications described herein. Moreover, the imaging hood **12** may be fabricated from a translucent or opaque material and in a variety of different colors to optimize or attenuate any reflected lighting from surrounding fluids or structures, i.e., anatomical or mechanical structures or instruments. In either case, imaging hood **12** may be fabricated into a uniform structure or a scaffold-supported structure, in which case a scaffold made of a shape memory alloy, such as Nitinol, or a spring steel, or plastic, etc., may be fabricated and covered with the polymeric, plastic, or woven material.

[0091] Imaging hood **12** may be attached at interface **24** to a deployment catheter **16** which may be translated independently of deployment catheter or sheath **14**. Attachment of interface **24** may be accomplished through any number of conventional methods. Deployment catheter **16** may define a fluid delivery lumen **18** as well as an imaging lumen **20** within which an optical imaging fiber or assembly may be disposed for imaging tissue. When deployed, imaging hood **12** may expand into any number of shapes, e.g., cylindrical, conical as shown, semi-spherical, etc., provided that an open area or field **26** is defined by imaging hood **12**. The open area **26** is the area within which the tissue region of interest may be imaged. Imaging hood **12** may also define an atraumatic contact lip or edge **22** for placement or abutment against the tissue region of interest. Moreover, the diameter of imaging hood **12** at its maximum fully deployed diameter, e.g., at contact lip or edge **22**, is typically greater relative to a diameter of the deployment catheter **16** (although a diameter of contact lip or edge **22** may be made to have a smaller or equal diameter of deployment catheter **16**). For instance, the contact edge diameter may range anywhere from 1 to 5 times (or eve as practicable) a diameter of deployment catheter **16**. Fig. 1C shows an end view o ng hood **12** in its deployed configuration. Also shown are the contact lip or

edge **22** and fluid delivery lumen **18** and imaging lumen **20**.

[0092] The imaging and manipulation assembly **10** may additionally define a guidewire lumen therethrough, e.g., a concentric or eccentric lumen, as shown in the side and end views, respectively, of Figs. 1D to 1F. The deployment catheter **16** may define guidewire lumen **19** for facilitating the passage of the system over or along a guidewire **17**, which may be advanced intravascularly within a body lumen. The deployment catheter **16** may then be advanced over the guidewire **17**, as generally known in the art.

[0093] In operation, after imaging hood **12** has been deployed, as in Fig. 1B, and desirably positioned against the tissue region to be imaged along contact edge **22**, the displacing fluid may be pumped at positive pressure through fluid delivery lumen **18** until the fluid fills open area **26** completely and displaces any fluid **28** from within open area **26**. The displacing fluid flow may be laminarized to improve its clearing effect and to help prevent blood from re-entering the imaging hood **12**. Alternatively, fluid flow may be started before the deployment takes place. The displacing fluid, also described herein as imaging fluid, may comprise any biocompatible fluid, e.g., saline, water, plasma, etc., which is sufficiently transparent to allow for relatively undistorted visualization through the fluid. Alternatively or additionally, any number of therapeutic drugs may be suspended within the fluid or may comprise the fluid itself which is pumped into open area **26** and which is subsequently passed into and through the heart and the patient body.

[0094] Fig. 1G illustrates another variation of a tissue imaging and manipulation assembly **10**. In this variation, the assembly **10** comprises one or more visualization element **52** located in an "off-axis" position within the hood **12**. The benefits of the "off-axis" configuration are discussed below. However, the assemblies of the present invention may comprise anywhere from a single visualization element **52** to several elements **52**. For example, some variations of the assembly **10** may include at least two visualization elements **52** to enable 3-dimensional imaging of the open area within the hood **12**. For example, the elements **52** may be sufficiently spaced around the perimeter of the hood **12** to allow generation of a 3-dimensional image. It is contemplated that optical fibers may be used in place of or in addition to the visualization elements shown in Fig. 1G. Additional means of obtaining a 3D image includes separating a single imaging element into two or more segments that can look at a target zone from two different angles. For example, such a stereoscopic visualization element may include a lenticular lens layer and light sensor array, the len ; layer includes a plurality of lenticular elements, the sight sensor array includ ty of light sensors, where selected light sensors detect light at a

predetermined range of wavelengths and where other light sensors detect light at anotl predetermined range of wavelengths, and where each of the lenticular elements is located in front of a selected group of the light sensors, to direct light from different directions to different light sensors within the selected group of the light sensors. Next, the views are processed producing a 3D image. Examples of such 3D imaging equipment is found in U.S. Patent Nos. 6,396,873 and 6,704,043 both to Goldstein et al. and entitled "Optical Device". The entirety of both of which are incorporated by reference. Such products may be supplied by Visionsense, Inc. of Petah Tivak, Israel. An additional way to create a 3D image is by using two image guides made from optical fibers and spacing them apart by a small distance (.1-10mm) and combining these two images in one cohesive 3D image.

[0095] Fig. 1H illustrates a cross-sectional view taken along the line 1H-1H of Fig. 1G. As illustrated, a variation of the catheter **16** may include co-extruded channels **32** to carry wires or optical fibers running along the length or a portion of a length of the catheter **16**. The channels **32** may permit connection of a visualization element to imaging equipment without taking up space from the remaining lumens **32**. These channels can also contain electrical wires that carry the signal from an imaging detector to a sensor/processor outside the patient.

[0096] Alternatively, the channels **32** may provide a light source or supply. Fig. 1I illustrates anther variation of a distal end of a catheter according to the present invention. In this variation, the catheter will include a variety of lumens **32**. As noted herein, the lumens **32** may be used for visualization, working channels, aspiration, delivery of tools, etc. The variation of Fig. 1I also illustrates the catheter **16** as having a number of illumination sources **36**. The illumination sources may small illumination optical fibers or any other illumination source as commonly used. In another variation of the invention, the lumens **38** may provide irrigation or other fluids.

[0097] Fig. 1J illustrates another variation of a tissue imaging and manipulation assembly **10**. In this variation, the hood **12** includes both a visualization component **52** and an illumination source **36** positioned on the interior surface of the hood **12**. Again, as noted above, although the figure illustrates the hood **12** as containing a single visualization element **52** and a single illumination source **36** (such as a fiber, a LED, other light emitting source) variations of the device may include additional elements **52** or illumination sources.

[0098] As seen in the example of Figs. 2A and 2B, deployment catheter **16** may be manipul ition deployed imaging hood **12** against or near the underlying tissue region o) be imaged, in this example a portion of annulus **A** of mitral valve **MV**

within the left atrial chamber. As the surrounding blood **30** flows around imaging hc and within open area **26** defined within imaging hood **12**, as seen in Fig. 2A, the underlying annulus **A** is obstructed by the opaque blood **30** and is difficult to view through the imaging lumen **20**. The translucent fluid **28**, such as saline, may then be pumped through fluid delivery lumen **18**, intermittently or continuously, until the blood **30** is at least partially, and preferably completely, displaced from within open area **26** by fluid **28**, as shown in Fig. 2B.

[0099] Although contact edge **22** need not directly contact the underlying tissue, it is at least preferably brought into close proximity to the tissue such that the flow of clear fluid **28** from open area **26** may be maintained to inhibit significant backflow of blood **30** back into open area **26**. Contact edge **22** may also be made of a soft elastomeric material such as certain soft grades of silicone or polyurethane, as typically known, to help contact edge **22** conform to an uneven or rough underlying anatomical tissue surface. Once the blood **30** has been displaced from imaging hood **12**, an image may then be viewed of the underlying tissue through the clear fluid **30**. This image may then be recorded or available for real-time viewing for performing a therapeutic procedure. The positive flow of fluid **28** may be maintained continuously to provide for clear viewing of the underlying tissue. Alternatively, the fluid **28** may be pumped temporarily or sporadically only until a clear view of the tissue is available to be imaged and recorded, at which point the fluid flow **28** may cease and blood **30** may be allowed to seep or flow back into imaging hood **12**. This process may be repeated a number of times at the same tissue region or at multiple tissue regions.

[0100] In desirably positioning the assembly at various regions within the patient body, a number of articulation and manipulation controls may be utilized. For example, as shown in the articulatable imaging assembly **40** in Fig. 3A, one or more push-pull wires **42** may be routed through deployment catheter **16** for steering the distal end portion of the device in various directions **46** to desirably position the imaging hood **12** adjacent to a region of tissue to be visualized. Depending upon the positioning and the number of push-pull wires **42** utilized, deployment catheter **16** and imaging hood **12** may be articulated into any number of configurations **44**. The push-pull wire or wires **42** may be articulated via their proximal ends from outside the patient body manually utilizing one or more controls. Alternatively, deployment catheter **16** may be articulated by computer control, as further described below.

[0101] Additionally or alternatively, an articulatable delivery catheter **48**, which may be articulated via one or more push-pull wires and having an imaging lumen and one or more workir may be delivered through the deployment catheter **16** and into imaging hood **12**. W portion of articulatable delivery catheter **48** within imaging hood **12**, the

clear displacing fluid may be pumped through delivery catheter **48** or deployment ca 16 to clear the field within imaging hood **12**. As shown in Fig. 3B, the articulatable delivery catheter **48** may be articulated within the imaging hood to obtain a better image of tissue adjacent to the imaging hood **12**. Moreover, articulatable delivery catheter **48** may be articulated to direct an instrument or tool passed through the catheter **48**, as described in detail below, to specific areas of tissue imaged through imaging hood **12** without having to reposition deployment catheter **16** and re-clear the imaging field within hood **12**.

[0102] Alternatively, rather than passing an articulatable delivery catheter **48** through the deployment catheter **16**, a distal portion of the deployment catheter **16** itself may comprise a distal end **49** which is articulatable within imaging hood **12**, as shown in Fig. 3C. Directed imaging, instrument delivery, etc., may be accomplished directly through one or more lumens within deployment catheter **16** to specific regions of the underlying tissue imaged within imaging hood **12**.

[0103] Visualization within the imaging hood **12** may be accomplished through an imaging lumen **20** defined through deployment catheter **16**, as described above. In such a configuration, visualization is available in a straight-line manner, i.e., images are generated from the field distally along a longitudinal axis defined by the deployment catheter **16**. Alternatively or additionally, an articulatable imaging assembly having a pivotable support member **50** may be connected to, mounted to, or otherwise passed through deployment catheter **16** to provide for visualization off-axis relative to the longitudinal axis defined by deployment catheter **16**, as shown in Fig. 4A. Support member **50** may have an imaging element **52**, e.g., a CCD or CMOS imager or optical fiber, attached at its distal end with its proximal end connected to deployment catheter **16** via a pivoting connection **54**.

[0104] If one or more optical fibers are utilized for imaging, the optical fibers **58** may be passed through deployment catheter **16**, as shown in the cross-section of Fig. 4B, and routed through the support member **50**. The use of optical fibers **58** may provide for increased diameter sizes of the one or several lumens **56** through deployment catheter **16** for the passage of diagnostic and/or therapeutic tools therethrough. Alternatively, electronic chips, such as a charge coupled device (CCD) or a CMOS imager, which are typically known, may be utilized in place of the optical fibers **58**, in which case the electronic imager may be positioned in the distal portion of the deployment catheter **16** with electric wires being routed proximally through the deployment catheter **16**. Alternatively, the electronic image wirelessly coupled to a receiver for the wireless transmission of images. Addit al fibers or light emitting diodes (LEDs) can be used to provide lighting for

the image or operative theater, as described below in further detail. Support member y be pivoted via connection **54** such that the member **50** can be positioned in a low-profile configuration within channel or groove **60** defined in a distal portion of catheter **16**, as shown in the cross-section of Fig. 4C. During intravascular delivery of deployment catheter **16** through the patient body, support member **50** can be positioned within channel or groove **60** with imaging hood **12** also in its low-profile configuration. During visualization, imaging hood **12** may be expanded into its deployed configuration and support member **50** may be deployed into its off-axis configuration for imaging the tissue adjacent to hood **12**, as in Fig. 4A. Other configurations for support member **50** for off-axis visualization may be utilized, as desired.

[0105] Fig. 4D illustrates another variation of a tissue imaging and manipulation assembly **10** with off-axis visualization capabilities. As shown in Fig. 4D, when the hood **12** is in a collapsed position (typically when navigated to a site.) In this variation, the visualization element **52** is adapted such that it may align with an axis of the assembly **10** especially during placement of the assembly **10** at a desired site.

[0106] Fig. 4E illustrates the assembly **10** of Fig. 4D when the device reaches the target site. As shown, the hood **12** expands to define the open area. Next, the visualization element **52** may articulate out of alignment with the catheter **16**. This configuration permits the device to have a low profile delivery state during delivery and subsequently expand to define the open area. The ability of the visualization element **52** to reposition "off-axis" allows the assembly **10** to accommodate large working instruments through the catheter **16** and substantially reduce the space requirements to accommodate the visualization element. The invention also contemplates placing optical fibers in a similar manner so that the fibers may reposition "off-axis" in a similar manner to the visualization element **52** as depicted. The off-axis visualization allows a more natural operating view akin to how a primate's eyes and hands are positioned relative to one another.

[0107] Fig. 4F and Fig. 4G illustrates the assembly **10** where the visualization element **52** is slidable in and out of the hood **12**. For instance, when deployed, as shown in Fig. 4F, the visualization element **52** is located along the interior of the hood **12**. When in a collapsed position, as shown in Fig. 4G, the visualization element **52** extends out of the hood **12**. This variation is useful to allow the hood **12** to compress or collapse to a smaller size without having to accommodate the visualization element **52**. Also, the visualization element **52** may hen navigating the device **10** to a desired site.

[0108] g. 5 shows an illustrative cross-sectional view of a heart **H** having tissue

regions of interest being viewed via an imaging assembly **10**. In this example, deliv catheter assembly **70** may be introduced percutaneously into the patient's vasculature and advanced through the superior vena cava **SVC** and into the right atrium **RA**. The delivery catheter or sheath **72** may be articulated through the atrial septum **AS** and into the left atrium **LA** for viewing or treating the tissue, e.g., the annulus **A**, surrounding the mitral valve **MV**. As shown, deployment catheter **16** and imaging hood **12** may be advanced out of delivery catheter **72** and brought into contact or in proximity to the tissue region of interest. In other examples, delivery catheter assembly **70** may be advanced through the inferior vena cava **IVC**, if so desired. Moreover, other regions of the heart **H**, e.g., the right ventricle **RV** or left ventricle **LV**, may also be accessed and imaged or treated by imaging assembly **10**.

[0109] In accessing regions of the heart **H** or other parts of the body, the delivery catheter or sheath **14** may comprise a conventional intra-vascular catheter or an endoluminal delivery device. Alternatively, robotically-controlled delivery catheters may also be optionally utilized with the imaging assembly described herein, in which case a computer-controller **74** may be used to control the articulation and positioning of the delivery catheter **14**. An example of a robotically-controlled delivery catheter which may be utilized is described in further detail in US Pat. Pub. 2002/0087169 A1 to Brock et al. entitled "Flexible Instrument", which is incorporated herein by reference in its entirety. Other robotically-controlled delivery catheters manufactured by Hansen Medical, Inc. (Mountain View, CA) may also be utilized with the delivery catheter **14**.

[0110] To facilitate stabilization of the deployment catheter **16** during a procedure, one or more inflatable balloons or anchors **76** may be positioned along the length of catheter **16**, as shown in Fig. 6A. For example, when utilizing a trans-septal approach across the atrial septum **AS** into the left atrium **LA**, the inflatable balloons **76** may be inflated from a low-profile into their expanded configuration to temporarily anchor or stabilize the catheter **16** position relative to the heart **H**. Fig. 6B shows a first balloon **78** inflated while Fig. 6C also shows a second balloon **80** inflated proximal to the first balloon **78**. In such a configuration, the septal wall **AS** may be wedged or sandwiched between the balloons **78, 80** to temporarily stabilize the catheter **16** and imaging hood **12**. A single balloon **78** or both balloons **78, 80** may be used. Other alternatives may utilize expandable mesh members, malecots, or any other temporary expandable structure. After a procedure has been accomplished, the balloon assembly **76** may be deflated or re-configured into a low-profile for removal of the deploy ›ter **16**.

[0111] › further stabilize a position of the imaging hood **12** relative to a tissue

surface to be imaged, various anchoring mechanisms may be optionally employed fo temporarily holding the imaging hood **12** against the tissue. Such anchoring mechanisms may be particularly useful for imaging tissue which is subject to movement, e.g., when imaging tissue within the chambers of a beating heart. A tool delivery catheter **82** having at least one instrument lumen and an optional visualization lumen may be delivered through deployment catheter **16** and into an expanded imaging hood **12**. As the imaging hood **12** is brought into contact against a tissue surface **T** to be examined, an anchoring mechanisms such as a helical tissue piercing device **84** may be passed through the tool delivery catheter **82**, as shown in Fig. 7A, and into imaging hood **12**.

[0112] The helical tissue engaging device **84** may be torqued from its proximal end outside the patient body to temporarily anchor itself into the underlying tissue surface **T**. Once embedded within the tissue **T**, the helical tissue engaging device **84** may be pulled proximally relative to deployment catheter **16** while the deployment catheter **16** and imaging hood **12** are pushed distally, as indicated by the arrows in Fig. 7B, to gently force the contact edge or lip **22** of imaging hood against the tissue **T**. The positioning of the tissue engaging device **84** may be locked temporarily relative to the deployment catheter **16** to ensure secure positioning of the imaging hood **12** during a diagnostic or therapeutic procedure within the imaging hood **12**. After a procedure, tissue engaging device **84** may be disengaged from the tissue by torquing its proximal end in the opposite direction to remove the anchor form the tissue **T** and the deployment catheter **16** may be repositioned to another region of tissue where the anchoring process may be repeated or removed from the patient body. The tissue engaging device **84** may also be constructed from other known tissue engaging devices such as vacuum-assisted engagement or grasper-assisted engagement tools, among others.

[0113] Although a helical anchor **84** is shown, this is intended to be illustrative and other types of temporary anchors may be utilized, e.g., hooked or barbed anchors, graspers, etc. Moreover, the tool delivery catheter **82** may be omitted entirely and the anchoring device may be delivered directly through a lumen defined through the deployment catheter **16**.

[0114] In another variation where the tool delivery catheter **82** may be omitted entirely to temporarily anchor imaging hood **12**, Fig. 7C shows an imaging hood **12** having one or more tubular support members **86**, e.g., four support members **86** as shown, integrated with the imaging hood **12**. The tubular support members **86** may define lumens therethrough each h al tissue engaging devices **88** positioned within. When an expanded imagin is to be temporarily anchored to the tissue, the helical tissue engaging

devices **88** may be urged distally to extend from imaging hood **12** and each may be t from its proximal end to engage the underlying tissue **T**. Each of the helical tissue engaging devices **88** may be advanced through the length of deployment catheter **16** or they may be positioned within tubular support members **86** during the delivery and deployment of imaging hood **12**. Once the procedure within imaging hood **12** is finished, each of the tissue engaging devices **88** may be disengaged from the tissue and the imaging hood **12** may be repositioned to another region of tissue or removed from the patient body.

[0115] An illustrative example is shown in Fig. 8A of a tissue imaging assembly connected to a fluid delivery system **90** and to an optional processor **98** and image recorder and/or viewer **100**. The fluid delivery system **90** may generally comprise a pump **92** and an optional valve **94** for controlling the flow rate of the fluid into the system. A fluid reservoir **96**, fluidly connected to pump **92**, may hold the fluid to be pumped through imaging hood **12**. An optional central processing unit or processor **98** may be in electrical communication with fluid delivery system **90** for controlling flow parameters such as the flow rate and/or velocity of the pumped fluid. The processor **98** may also be in electrical communication with an image recorder and/or viewer **100** for directly viewing the images of tissue received from within imaging hood **12**. Imager recorder and/or viewer **100** may also be used not only to record the image but also the location of the viewed tissue region, if so desired.

[0116] Optionally, processor **98** may also be utilized to coordinate the fluid flow and the image capture. For instance, processor **98** may be programmed to provide for fluid flow from reservoir **96** until the tissue area has been displaced of blood to obtain a clear image. Once the image has been determined to be sufficiently clear, either visually by a practitioner or by computer, an image of the tissue may be captured automatically by recorder **100** and pump **92** may be automatically stopped or slowed by processor **98** to cease the fluid flow into the patient. Other variations for fluid delivery and image capture are, of course, possible and the aforementioned configuration is intended only to be illustrative and not limiting.

[0117] Fig. 8B shows a further illustration of a hand-held variation of the fluid delivery and tissue manipulation system **110**. In this variation, system **110** may have a housing or handle assembly **112** which can be held or manipulated by the physician from outside the patient body. The fluid reservoir **114**, shown in this variation as a syringe, can be fluidly coupled to the handle assembly **112** and actuated via a pumping mechanism **116**, e.g., lead screw. Fluid reservoir **114** may be a simple reservoir separated from the handle assem i fluidly coupled to handle assembly **112** via one or more tubes. The fluid flow r: er mechanisms may be metered by the electronic controller **118**.

[0118] Deployment of imaging hood **12** may be actuated by a hood deployme switch **120** located on the handle assembly **112** while dispensation of the fluid from reservoir **114** may be actuated by a fluid deployment switch **122**, which can be electrically coupled to the controller **118**. Controller **118** may also be electrically coupled to a wired or wireless antenna **124** optionally integrated with the handle assembly **112**, as shown in the figure. The wireless antenna **124** can be used to wirelessly transmit images captured from the imaging hood **12** to a receiver, e.g., via Bluetooth® wireless technology (Bluetooth SIG, Inc., Bellevue, WA), RF, etc., for viewing on a monitor **128** or for recording for later viewing.

[0119] Articulation control of the deployment catheter **16**, or a delivery catheter or sheath **14** through which the deployment catheter **16** may be delivered, may be accomplished by computer control, as described above, in which case an additional controller may be utilized with handle assembly **112**. In the case of manual articulation, handle assembly **112** may incorporate one or more articulation controls **126** for manual manipulation of the position of deployment catheter **16**. Handle assembly **112** may also define one or more instrument ports **130** through which a number of intravascular tools may be passed for tissue manipulation and treatment within imaging hood **12**, as described further below. Furthermore, in certain procedures, fluid or debris may be sucked into imaging hood **12** for evacuation from the patient body by optionally fluidly coupling a suction pump **132** to handle assembly **112** or directly to deployment catheter **16**.

[0120] As described above, fluid may be pumped continuously into imaging hood **12** to provide for clear viewing of the underlying tissue. Alternatively, fluid may be pumped temporarily or sporadically only until a clear view of the tissue is available to be imaged and recorded, at which point the fluid flow may cease and the blood may be allowed to seep or flow back into imaging hood **12**. Figs. 9A to 9C illustrate an example of capturing several images of the tissue at multiple regions. Deployment catheter **16** may be desirably positioned and imaging hood **12** deployed and brought into position against a region of tissue to be imaged, in this example the tissue surrounding a mitral valve **MV** within the left atrium of a patient's heart. The imaging hood **12** may be optionally anchored to the tissue, as described above, and then cleared by pumping the imaging fluid into the hood **12**. Once sufficiently clear, the tissue may be visualized and the image captured by control electronics **118**. The first captured image **140** may be stored and/or transmitted wirelessly **124** to a monitor **128** for viewing by the physician, as shown in Fig. 9A.

[0121] e deployment catheter **16** may be then repositioned to an adjacent portion of mitral as shown in Fig. 9B, where the process may be repeated to capture a second

image **142** for viewing and/or recording. The deployment catheter **16** may again be repositioned to another region of tissue, as shown in Fig. 9C, where a third image **144** may be captured for viewing and/or recording. This procedure may be repeated as many times as necessary for capturing a comprehensive image of the tissue surrounding mitral valve **MV**, or any other tissue region. When the deployment catheter **16** and imaging hood **12** is repositioned from tissue region to tissue region, the pump may be stopped during positioning and blood or surrounding fluid may be allowed to enter within imaging hood **12** until the tissue is to be imaged, where the imaging hood **12** may be cleared, as above.

[0122] As mentioned above, when the imaging hood **12** is cleared by pumping the imaging fluid within for clearing the blood or other bodily fluid, the fluid may be pumped continuously to maintain the imaging fluid within the hood **12** at a positive pressure or it may be pumped under computer control for slowing or stopping the fluid flow into the hood **12** upon detection of various parameters or until a clear image of the underlying tissue is obtained. The control electronics **118** may also be programmed to coordinate the fluid flow into the imaging hood **12** with various physical parameters to maintain a clear image within imaging hood **12**.

[0123] One example is shown in Fig. 10A which shows a chart **150** illustrating how fluid pressure within the imaging hood **12** may be coordinated with the surrounding blood pressure. Chart **150** shows the cyclical blood pressure **156** alternating between diastolic pressure **152** and systolic pressure **154** over time **T** due to the beating motion of the patient heart. The fluid pressure of the imaging fluid, indicated by plot **160**, within imaging hood **12** may be automatically timed to correspond to the blood pressure changes **160** such that an increased pressure is maintained within imaging hood **12** which is consistently above the blood pressure **156** by a slight increase ΔP, as illustrated by the pressure difference at the peak systolic pressure **158**. This pressure difference, ΔP, may be maintained within imaging hood **12** over the pressure variance of the surrounding blood pressure to maintain a positive imaging fluid pressure within imaging hood **12** to maintain a clear view of the underlying tissue. One benefit of maintaining a constant ΔP is a constant flow and maintenance of a clear field.

[0124] Fig. 10B shows a chart **162** illustrating another variation for maintaining a clear view of the underlying tissue where one or more sensors within the imaging hood **12**, as described in further detail below, may be configured to sense pressure changes within the imaging ıd to correspondingly increase the imaging fluid pressure within imaging hood **12**. result in a time delay, ΔT, as illustrated by the shifted fluid pressure **160**

relative to the cycling blood pressure **156**, although the time delay ΔT may be negligib maintaining the clear image of the underlying tissue. Predictive software algorithms can also be used to substantially eliminate this time delay by predicting when the next pressure wave peak will arrive and by increasing the pressure ahead of the pressure wave's arrival by an amount of time substantially equal to the aforementioned time delay to essentially cancel the time delay out.

[0125] The variations in fluid pressure within imaging hood **12** may be accomplished in part due to the nature of imaging hood **12**. An inflatable balloon, which is conventionally utilized for imaging tissue, may be affected by the surrounding blood pressure changes. On the other hand, an imaging hood **12** retains a constant volume therewithin and is structurally unaffected by the surrounding blood pressure changes, thus allowing for pressure increases therewithin. The material that hood **12** is made from may also contribute to the manner in which the pressure is modulated within this hood **12**. A stiffer hood material, such as high durometer polyurethane or Nylon, may facilitate the maintaining of an open hood when deployed. On the other hand, a relatively lower durometer or softer material, such as a low durometer PVC or polyurethane, may collapse from the surrounding fluid pressure and may not adequately maintain a deployed or expanded hood.

[0126] Turning now to the imaging hood, other variations of the tissue imaging assembly may be utilized, as shown in Fig. 11A, which shows another variation comprising an additional imaging balloon **172** within an imaging hood **174**. In this variation, an expandable balloon **172** having a translucent skin may be positioned within imaging hood **174**. Balloon **172** may be made from any distensible biocompatible material having sufficient translucent properties which allow for visualization therethrough. Once the imaging hood **174** has been deployed against the tissue region of interest, balloon **172** may be filled with a fluid, such as saline, or less preferably a gas, until balloon **172** has been expanded until the blood has been sufficiently displaced. The balloon **172** may thus be expanded proximal to or into contact against the tissue region to be viewed. The balloon **172** can also be filled with contrast media to allow it to be viewed on fluoroscopy to aid in its positioning. The imager, e.g., fiber optic, positioned within deployment catheter **170** may then be utilized to view the tissue region through the balloon **172** and any additional fluid which may be pumped into imaging hood **174** via one or more optional fluid ports **176**, which may be positioned proximally of balloon **172** along a portion of deployment catheter **170**. Alternati on **172** may define one or more holes over its surface which allow for seepage of the fluid contained therein to escape and displace the blood from

within imaging hood **174**.

[0127] Fig. 11B shows another alternative in which balloon **180** may be utilized alone. Balloon **180**, attached to deployment catheter **178**, may be filled with fluid, such as saline or contrast media, and is preferably allowed to come into direct contact with the tissue region to be imaged.

[0128] Fig. 12A shows another alternative in which deployment catheter **16** incorporates imaging hood **12**, as above, and includes an additional flexible membrane **182** within imaging hood **12**. Flexible membrane **182** may be attached at a distal end of catheter **16** and optionally at contact edge **22**. Imaging hood **12** may be utilized, as above, and membrane **182** may be deployed from catheter **16** *in vivo* or prior to placing catheter **16** within a patient to reduce the volume within imaging hood **12**. The volume may be reduced or minimized to reduce the amount of fluid dispensed for visualization or may be reduced depending upon the area of tissue to be visualized.

[0129] Figs. 12B and 12C show yet another alternative in which imaging hood **186** may be withdrawn proximally within deployment catheter **184** or deployed distally from catheter **186**, as shown, to vary the volume of imaging hood **186** and thus the volume of dispensed fluid. Imaging hood **186** may be seen in Fig. 12B as being partially deployed from, e.g., a circumferentially defined lumen within catheter **184**, such as annular lumen **188**. The underlying tissue may be visualized with imaging hood **186** only partially deployed. Alternatively, imaging hood **186'** may be fully deployed, as shown in Fig. 12C, by urging hood **186'** distally out from annular lumen **188**. In this expanded configuration, the area of tissue to be visualized may be increased as hood **186'** is expanded circumferentially.

[0130] Fig 12D illustrates another variation of a tissue imaging and manipulation assembly **10**. In this variation, the hood **12** includes an inflatable member **520** (e.g., a balloon, bladder, or fillable membrane) that is coupled to a fluid source **522**. The inflatable member **520** may be constructed from a clear material. Upon expansion of the hood **12**, the inflatable member **520** fills with a clear fluid as shown in Fig. 12E. As the inflatable member **520** expands, it displaces fluids and other substances from within the hood **12** (as shown by the arrows). Because the member **520** and fluid are clear, the visualization element **52** is still able to visualize the tissue in the open area of the hood **12**. Fig. 12E illustrates yet another principle of an assembly **10** as described herein. In this variation, the hood **12** includes two or more inflatable members **520, 524**. The inflatable members **520, 524** function to displace fluids fr d **12** while permitting visualization. However, use of two or more inflatabl **520, 524** permits advancement of a tool or device **526** between the

inflatable members. In another variation, the inflatable member(s) is constructed from material having an index of refraction close to or matching that of the displacement liquid. This selection of the index of essentially allows the membrane to 'disappear" and not interfere with visualization.

[0131] Figs. 13A and 13B show perspective and cross-sectional side views, respectively, of yet another variation of imaging assembly which may utilize a fluid suction system for minimizing the amount of fluid injected into the patient's heart or other body lumen during tissue visualization. Deployment catheter **190** in this variation may define an inner tubular member **196** which may be integrated with deployment catheter **190** or independently translatable. Fluid delivery lumen **198** defined through member **196** may be fluidly connected to imaging hood **192**, which may also define one or more open channels **194** over its contact lip region. Fluid pumped through fluid delivery lumen **198** may thus fill open area **202** to displace any blood or other fluids or objects therewithin. As the clear fluid is forced out of open area **202**, it may be sucked or drawn immediately through one or more channels **194** and back into deployment catheter **190**. Tubular member **196** may also define one or more additional working channels **200** for the passage of any tools or visualization devices.

[0132] In deploying the imaging hood in the examples described herein, the imaging hood may take on any number of configurations when positioned or configured for a low-profile delivery within the delivery catheter, as shown in the examples of Figs. 14A to 14D. These examples are intended to be illustrative and are not intended to be limiting in scope. Fig. 14A shows one example in which imaging hood **212** may be compressed within catheter **210** by folding hood **212** along a plurality of pleats. Hood **212** may also comprise scaffolding or frame **214** made of a super-elastic or shape memory material or alloy, e.g., Nitinol, Elgiloy, shape memory polymers, electroactive polymers, or a spring stainless steel. The shape memory material may act to expand or deploy imaging hood **212** into its expanded configuration when urged in the direction of the arrow from the constraints of catheter **210**.

[0133] Fig. 14B shows another example in which imaging hood **216** may be expanded or deployed from catheter **210** from a folded and overlapping configuration. Frame or scaffolding **214** may also be utilized in this example. Fig. 14C shows yet another example in which imaging hood **218** may be rolled, inverted, or everted upon itself for deployment. In yet another example, Fig. 14D shows a configuration in which imaging hood **220** may be fabricate extremely compliant material which allows for hood **220** to be simply compres ow-profile shape. From this low-profile compressed shape, simply

releasing hood **220** may allow for it to expand into its deployed configuration, especi ı scaffold or frame of a shape memory or superelastic material, e.g., Nitinol, is utilized in its construction.

[0134] Another variation for expanding the imaging hood is shown in Figs. 15A and 15B which illustrates a helically expanding frame or support **230**. In its constrained low-profile configuration, shown in Fig. 15A, helical frame **230** may be integrated with the imaging hood **12** membrane. When free to expand, as shown in Fig. 15B, helical frame **230** may expand into a conical or tapered shape. Helical frame **230** may alternatively be made out of heat-activated Nitinol to allow it to expand upon application of a current.

[0135] Figs. 16A and 16B show yet another variation in which imaging hood **12** may comprise one or more hood support members **232** integrated with the hood membrane. These longitudinally attached support members **232** may be pivotably attached at their proximal ends to deployment catheter **16**. One or more pullwires **234** may be routed through the length of deployment catheter **16** and extend through one or more openings **238** defined in deployment catheter **16** proximally to imaging hood **12** into attachment with a corresponding support member **232** at a pullwire attachment point **236**. The support members **232** may be fabricated from a plastic or metal, such as stainless steel. Alternatively, the support members **232** may be made from a superelastic or shape memory alloy, such as Nitinol, which may self-expand into its deployed configuration without the use or need of pullwires. A heat-activated Nitinol may also be used which expands upon the application of thermal energy or electrical energy. In another alternative, support members **232** may also be constructed as inflatable lumens utilizing, e.g., PET balloons. From its low-profile delivery configuration shown in Fig. 16A, the one or more pullwires **234** may be tensioned from their proximal ends outside the patient body to pull a corresponding support member **232** into a deployed configuration, as shown in Fig. 16B, to expand imaging hood **12**. To reconfigure imaging hood **12** back into its low profile, deployment catheter **16** may be pulled proximally into a constraining catheter or the pullwires **234** may be simply pushed distally to collapse imaging hood **12**.

[0136] Figs. 17A and 17B show yet another variation of imaging hood **240** having at least two or more longitudinally positioned support members **242** supporting the imaging hood membrane. The support members **242** each have cross-support members **244** which extend diagonally between and are pivotably attached to the support members **242**. Each of the cro members **244** may be pivotably attached to one another where they intersect betwee ort members **242**. A jack or screw member **246** may be coupled to each

cross-support member **244** at this intersection point and a torquing member, such as a torqueable wire **248**, may be coupled to each jack or screw member **246** and extend proximally through deployment catheter **16** to outside the patient body. From outside the patient body, the torqueable wires **248** may be torqued to turn the jack or screw member **246** which in turn urges the cross-support members **244** to angle relative to one another and thereby urge the support members **242** away from one another. Thus, the imaging hood **240** may be transitioned from its low-profile, shown in Fig. 17A, to its expanded profile, shown in Fig. 17B, and back into its low-profile by torquing wires **248**.

[0137] Figs. 18A and 18B show yet another variation on the imaging hood and its deployment. As shown, a distal portion of deployment catheter **16** may have several pivoting members **250**, e.g., two to four sections, which form a tubular shape in its low profile configuration, as shown in Fig. 18A. When pivoted radially about deployment catheter **16**, pivoting members **250** may open into a deployed configuration having distensible or expanding membranes **252** extending over the gaps in-between the pivoting members **250**, as shown in Fig. 18B. The distensible membrane **252** may be attached to the pivoting members **250** through various methods, e.g., adhesives, such that when the pivoting members **250** are fully extended into a conical shape, the pivoting members **250** and membrane **252** form a conical shape for use as an imaging hood. The distensible membrane **252** may be made out of a porous material such as a mesh or PTFE or out of a translucent or transparent polymer such as polyurethane, PVC, Nylon, etc.

[0138] Figs. 19A and 19B show yet another variation where the distal portion of deployment catheter **16** may be fabricated from a flexible metallic or polymeric material to form a radially expanding hood **254**. A plurality of slots **256** may be formed in a uniform pattern over the distal portion of deployment catheter **16**, as shown in Fig. 19A. The slots **256** may be formed in a pattern such that when the distal portion is urged radially open, utilizing any of the methods described above, a radially expanded and conically-shaped hood **254** may be formed by each of the slots **256** expanding into an opening, as shown in Fig. 19B. A distensible membrane **258** may overlie the exterior surface or the interior surface of the hood **254** to form a fluid-impermeable hood **254** such that the hood **254** may be utilized as an imaging hood. Alternatively, the distensible membrane **258** may alternatively be formed in each opening **258** to form the fluid-impermeable hood **254**. Once the imaging procedure has been completed, hood **254** may be retracted into its low-profile configuration.

[0139] another configuration for the imaging hood may be seen in Figs. 20A and 20B whe ging hood may be formed from a plurality of overlapping hood members

260 which overlie one another in an overlapping pattern. When expanded, each of the members **260** may extend radially outward relative to deployment catheter **16** to form a conically-shaped imaging hood, as shown in Fig. 20B. Adjacent hood members **260** may overlap one another along an overlapping interface **262** to form a fluid-retaining surface within the imaging hood. Moreover, the hood members **260** may be made from any number of biocompatible materials, e.g., Nitinol, stainless steel, polymers, etc., which are sufficiently strong to optionally retract surrounding tissue from the tissue region of interest.

[0140] Fig. 20C illustrates another variation of a hood **12** under the present invention. In this variation, the hood **12** includes a plurality of sections **264** that overlap on at least one side. The overlapping sections **264** aid in conforming the distal end of the hood against irregularly shaped tissue. The overlapping sections **264** may be affixed to the end of the hood **12**. Alternatively, the overlapping sections may extend a substantial length of the hood (not shown). Any number of sections **264** may be used with the hood. For example, when used against tissue having an irregular surface, the device may include a large number of sections such that the end of the hood **12** has a "brush-like" appearance. Alternatively, a variation of the device may have fewer sections (as few as 2). Such a variation may be appropriately configured for use against relatively a smooth tissue surface. The sections **264** may be fabricated from a polymer, cloth, or membrane filled structure. Regardless of construction, the sections **264** improve conformation of the hood against tissue.

[0141] Although it is generally desirable to have an imaging hood contact against a tissue surface in a normal orientation, the imaging hood may be alternatively configured to contact the tissue surface at an acute angle. An imaging hood configured for such contact against tissue may also be especially suitable for contact against tissue surfaces having an unpredictable or uneven anatomical geography. For instance, as shown in the variation of Fig. 21A, deployment catheter **270** may have an imaging hood **272** that is configured to be especially compliant. In this variation, imaging hood **272** may be comprised of one or more sections **274** that are configured to fold or collapse, e.g., by utilizing a pleated surface. Thus, as shown in Fig. 21B, when imaging hood **272** is contacted against uneven tissue surface **T**, sections **274** are able to conform closely against the tissue. These sections **274** may be individually collapsible by utilizing an accordion style construction to allow conformation, e.g., to the trabeculae in the heart or the uneven anatomy that may be found inside the various body lumens.

[0142] :t another alternative, Fig. 22A shows another variation in which an imaging s attached to deployment catheter **280**. The contact lip or edge **284** may

comprise one or more electrical contacts **286** positioned circumferentially around conta edge **284**. The electrical contacts **286** may be configured to contact the tissue and indicate affirmatively whether tissue contact was achieved, e.g., by measuring the differential impedance between blood and tissue. Alternatively, a processor, e.g., processor **98**, in electrical communication with contacts **286** may be configured to determine what type of tissue is in contact with electrical contacts **286**. In yet another alternative, the processor **98** may be configured to measure any electrical activity that may be occurring in the underlying tissue, e.g., accessory pathways, for the purposes of electrically mapping the cardiac tissue and subsequently treating, as described below, any arrhythmias which may be detected.

[0143] Another variation for ensuring contact between imaging hood **282** and the underlying tissue may be seen in Fig. 22B. This variation may have an inflatable contact edge **288** around the circumference of imaging hood **282**. The inflatable contact edge **288** may be inflated with a fluid or gas through inflation lumen **289** when the imaging hood **282** is to be placed against a tissue surface having an uneven or varied anatomy. The inflated circumferential surface **288** may provide for continuous contact over the hood edge by conforming against the tissue surface and facilitating imaging fluid retention within hood **282**.

[0144] Aside from the imaging hood, various instrumentation may be utilized with the imaging and manipulation system. For instance, after the field within imaging hood **12** has been cleared of the opaque blood and the underlying tissue is visualized through the clear fluid, blood may seep back into the imaging hood **12** and obstruct the view. One method for automatically maintaining a clear imaging field may utilize a transducer, e.g., an ultrasonic transducer **290**, positioned at the distal end of deployment catheter within the imaging hood **12**, as shown in Fig. 23. The transducer **290** may send an energy pulse **292** into the imaging hood **12** and wait to detect back-scattered energy **294** reflected from debris or blood within the imaging hood **12**. If back-scattered energy is detected, the pump may be actuated automatically to dispense more fluid into the imaging hood until the debris or blood is no longer detected.

[0145] Alternatively, one or more sensors **300** may be positioned on the imaging hood **12** itself, as shown in Fig. 24A, to detect a number of different parameters. For example, sensors **300** may be configured to detect for the presence of oxygen in the surrounding blood, blood and/or imaging fluid pressure, color of the fluid within the imaging hood, etc lor may be particularly useful in detecting the presence of blood within the imaging utilizing a reflective type sensor to detect back reflection from blood.

Any reflected light from blood which may be present within imaging hood **12** may be optically or electrically transmitted through deployment catheter **16** and to a red colored filter within control electronics **118**. Any red color which may be detected may indicate the presence of blood and trigger a signal to the physician or automatically actuate the pump to dispense more fluid into the imaging hood **12** to clear the blood.

[0146] Alternative methods for detecting the presence of blood within the hood **12** may include detecting transmitted light through the imaging fluid within imaging hood **12**. If a source of white light, e.g., utilizing LEDs or optical fibers, is illuminated inside imaging hood **12**, the presence of blood may cause the color red to be filtered through this fluid. The degree or intensity of the red color detected may correspond to the amount of blood present within imaging hood **12**. A red color sensor can simply comprise, in one variation, a phototransistor with a red transmitting filter over it which can establish how much red light is detected, which in turn can indicate the presence of blood within imaging hood **12**. Once blood is detected, the system may pump more clearing fluid through and enable closed loop feedback control of the clearing fluid pressure and flow level.

[0147] Any number of sensors may be positioned along the exterior **302** of imaging hood **12** or within the interior **304** of imaging hood **12** to detect parameters not only exteriorly to imaging hood **12** but also within imaging hood **12**. Such a configuration, as shown in Fig. 24B, may be particularly useful for automatically maintaining a clear imaging field based upon physical parameters such as blood pressure, as described above for Figs. 10A and 10B.

[0148] Aside from sensors, one or more light emitting diodes (LEDs) may be utilized to provide lighting within the imaging hood **12**. Although illumination may be provided by optical fibers routed through deployment catheter **16**, the use of LEDs over the imaging hood **12** may eliminate the need for additional optical fibers for providing illumination. The electrical wires connected to the one or more LEDs may be routed through or over the hood **12** and along an exterior surface or extruded within deployment catheter **16**. One or more LEDs may be positioned in a circumferential pattern **306** around imaging hood **12**, as shown in Fig. 25A, or in a linear longitudinal pattern **308** along imaging hood **12**, as shown in Fig. 25B. Other patterns, such as a helical or spiral pattern, may also be utilized. Alternatively, LEDs may be positioned along a support member forming part of imaging hood **12**.

[0149] In another alternative for illumination within imaging hood **12**, a separate illumina[illegible]0 may be utilized, as shown in Fig. 26A. An example of such a tool may comprise[illegible] intravascular delivery member **312** having a carrier member **314**

pivotably connected **316** to a distal end of delivery member **312**. One or more LEDs **3** may be mounted along carrier member **314**. In use, delivery member **312** may be advanced through deployment catheter **16** until carrier member **314** is positioned within imaging hood **12**. Once within imaging hood **12**, carrier member **314** may be pivoted in any number of directions to facilitate or optimize the illumination within the imaging hood **12**, as shown in Fig. 26B.

[0150] In utilizing LEDs for illumination, whether positioned along imaging hood **12** or along a separate instrument, the LEDs may comprise a single LED color, e.g., white light. Alternatively, LEDs of other colors, e.g., red, blue, yellow, etc., may be utilized exclusively or in combination with white LEDs to provide for varied illumination of the tissue or fluids being imaged. Alternatively, sources of infrared or ultraviolet light may be employed to enable imaging beneath the tissue surface or cause fluorescence of tissue for use in system guidance, diagnosis, or therapy.

[0151] Aside from providing a visualization platform, the imaging assembly may also be utilized to provide a therapeutic platform for treating tissue being visualized. As shown in Fig. 27, deployment catheter **320** may have imaging hood **322**, as described above, and fluid delivery lumen **324** and imaging lumen **326**. In this variation, a therapeutic tool such as needle **328** may be delivered through fluid delivery lumen **324** or in another working lumen and advanced through open area **332** for treating the tissue which is visualized. In this instance, needle **328** may define one or several ports **330** for delivering drugs therethrough. Thus, once the appropriate region of tissue has been imaged and located, needle **328** may be advanced and pierced into the underlying tissue where a therapeutic agent may be delivered through ports **330**. Alternatively, needle **328** may be in electrical communication with a power source **334**, e.g., radio-frequency, microwave, etc., for ablating the underlying tissue area of interest.

[0152] Fig. 28 shows another alternative in which deployment catheter **340** may have imaging hood **342** attached thereto, as above, but with a therapeutic tool **344** in the configuration of a helical tissue piercing device **344**. Also shown and described above in Figs. 7A and 7B for use in stabilizing the imaging hood relative to the underlying tissue, the helical tissue piercing device **344** may also be utilized to manipulate the tissue for a variety of therapeutic procedures. The helical portion **346** may also define one or several ports for delivery of therapeutic agents therethrough.

[0153] ɛt another alternative, Fig. 29 shows a deployment catheter **350** having an expandal ʒ balloon **352** filled with, e.g., saline **356**. A therapeutic tool **344**, as

above, may be translatable relative to balloon **352**. To prevent the piercing portion 3 he tool from tearing balloon **352**, a stop **354** may be formed on balloon **352** to prevent the proximal passage of portion **346** past stop **354**.

[0154] Alternative configurations for tools which may be delivered through deployment catheter **16** for use in tissue manipulation within imaging hood **12** are shown in Figs. 30A and 30B. Fig. 30A shows one variation of an angled instrument **360**, such as a tissue grasper, which may be configured to have an elongate shaft for intravascular delivery through deployment catheter **16** with a distal end which may be angled relative to its elongate shaft upon deployment into imaging hood **12**. The elongate shaft may be configured to angle itself automatically, e.g., by the elongate shaft being made at least partially from a shape memory alloy, or upon actuation, e.g., by tensioning a pullwire. Fig. 30B shows another configuration for an instrument **362** being configured to reconfigure its distal portion into an off-axis configuration within imaging hood **12**. In either case, the instruments **360**, **362** may be reconfigured into a low-profile shape upon withdrawing them proximally back into deployment catheter **16**.

[0155] Other instruments or tools that may be utilized with the imaging system are shown in the side and end views of Figs. 31A to 31C. Fig. 31A shows a probe **370** having a distal end effector **372**, which may be reconfigured from a low-profile shape to a curved profile. The end effector **372** may be configured as an ablation probe utilizing radio-frequency energy, microwave energy, ultrasound energy, laser energy or even cryo-ablation. Alternatively, the end effector **372** may have several electrodes upon it for detecting or mapping electrical signals transmitted through the underlying tissue.

[0156] In the case of an end effector **372** utilized for ablation of the underlying tissue, an additional temperature sensor such as a thermocouple or thermistor **374** positioned upon an elongate member **376** may be advanced into the imaging hood **12** adjacent to the distal end effector **372** for contacting and monitoring a temperature of the ablated tissue. Fig. 31B shows an example in the end view of one configuration for the distal end effector **372** which may be simply angled into a perpendicular configuration for contacting the tissue. Fig. 31C shows another example where the end effector may be reconfigured into a curved end effector **378** for increased tissue contact.

[0157] Figs. 32A and 32B show another variation of an ablation tool utilized with an imaging hood **12** having an enclosed bottom portion. In this variation, an ablation probe, such a lation probe **380** having a distal end effector **382**, may be positioned through the im **12** such that the end effector **382** is placed distally of a transparent

membrane or enclosure **384**, as shown in the end view of Fig. 32B. The shaft of prot may pass through an opening **386** defined through the membrane **384**. In use, the clear fluid may be pumped into imaging hood **12**, as described above, and the distal end effector **382** may be placed against a tissue region to be ablated with the imaging hood **12** and the membrane **384** positioned atop or adjacent to the ablated tissue. In the case of cryo-ablation, the imaging fluid may be warmed prior to dispensing into the imaging hood **12** such that the tissue contacted by the membrane **384** may be warmed during the cryo-ablation procedure. In the case of thermal ablation, e.g., utilizing radio-frequency energy, the fluid dispensed into the imaging hood **12** may be cooled such that the tissue contacted by the membrane **384** and adjacent to the ablation probe during the ablation procedure is likewise cooled.

[0158] In either example described above, the imaging fluid may be varied in its temperature to facilitate various procedures to be performed upon the tissue. In other cases, the imaging fluid itself may be altered to facilitate various procedures. For instance as shown in Fig. 33A, a deployment catheter **16** and imaging hood **12** may be advanced within a hollow body organ, such as a bladder filled with urine **394**, towards a lesion or tumor **392** on the bladder wall. The imaging hood **12** may be placed entirely over the lesion **392**, or over a portion of the lesion. Once secured against the tissue wall **390**, a cryo-fluid, i.e., a fluid which has been cooled to below freezing temperatures of, e.g., water or blood, may be pumped into the imaging hood **12** to cryo-ablate the lesion **390**, as shown in Fig. 33B while avoiding the creation of ice on the instrument or surface of tissue.

[0159] As the cryo-fluid leaks out of the imaging hood **12** and into the organ, the fluid may be warmed naturally by the patient body and ultimately removed. The cryo-fluid may be a colorless and translucent fluid which enables visualization therethrough of the underlying tissue. An example of such a fluid is Fluorinert™ (3M, St. Paul, MN), which is a colorless and odorless perfluorinated liquid. The use of a liquid such as Fluorinert™ enables the cryo-ablation procedure without the formation of ice within or outside of the imaging hood **12**. Alternatively, rather than utilizing cryo-ablation, hyperthermic treatments may also be effected by heating the Fluorinert™ liquid to elevated temperatures for ablating the lesion **392** within the imaging hood **12**. Moreover, Fluorinert™ may be utilized in various other parts of the body, such as within the heart.

[0160] Fig. 33C illustrates another variation of a system according to the present invention. In this variation, an unltrasound beam **598** (for example, high frequency ultraso ıonly referred to as HIFU) transducer **600** is integrated into the hood **12** and/or). The beam **598** focuses on a region of interest in the tissue. This allows

cauterization or welding of tissue via the ultrasound beam. The clear solution assists tl operator in focusing the beam **598** accurately on the target tissue surface. Optionally, a laser pointer, LED or other pointing device/indicator **602** that coincides with the focal point **604** of the beam **598** can be used as a guide to ensure accurate placement of the beam **598** on the tissue surface.

[0161] One possible application for this variation is treatment of the PFO where the septum secundum is welded on to the septum primum to achieve closure. Alternatively, by just injuring the septum secundum with HIFU, the healing process can take over to close the tissue onto the septum primum.

[0162] Fig. 34A shows another variation of an instrument which may be utilized with the imaging system. In this variation, a laser ring generator **400** may be passed through the deployment catheter **16** and partially into imaging hood **12**. A laser ring generator **400** is typically used to create a circular ring of laser energy **402** for generating a conduction block around the pulmonary veins typically in the treatment of atrial fibrillation. The circular ring of laser energy **402** may be generated such that a diameter of the ring **402** is contained within a diameter of the imaging hood **12** to allow for tissue ablation directly upon tissue being imaged. Signals which cause atrial fibrillation typically come from the entry area of the pulmonary veins into the left atrium and treatments may sometimes include delivering ablation energy to the ostia of the pulmonary veins within the atrium. The ablated areas of the tissue may produce a circular scar which blocks the impulses for atrial fibrillation.

[0163] When using the laser energy to ablate the tissue of the heart, it may be generally desirable to maintain the integrity and health of the tissue overlying the surface while ablating the underlying tissue. This may be accomplished, for example, by cooling the imaging fluid to a temperature below the body temperature of the patient but which is above the freezing point of blood (e.g., 2° C to 35° C). The cooled imaging fluid may thus maintain the surface tissue at the cooled fluid temperature while the deeper underlying tissue remains at the patient body temperature. When the laser energy (or other types of energy such as radio frequency energy, microwave energy, ultrasound energy, etc.) irradiates the tissue, both the cooled tissue surface as well as the deeper underlying tissue will rise in temperature uniformly. The deeper underlying tissue, which was maintained at the body temperature, will increase to temperatures which are sufficiently high to destroy the underlying tissue. Meanwhile, the temperature of the cooled surface tissue will also rise but only to temperat e near body temperature or slightly above.

[0164] ordingly, as shown in Fig. 34B, one example for treatment may include

passing deployment catheter **16** across the atrial septum **AS** and into the left atrium **LA** patient's heart **H**. Other methods of accessing the left atrium **LA** may also be utilized. The imaging hood **12** and laser ring generator **400** may be positioned adjacent to or over one or more of the ostium **OT** of the pulmonary veins **PV** and the laser generator **400** may ablate the tissue around the ostium **OT** with the circular ring of laser energy **402** to create a conduction block. Once one or more of the tissue around the ostium **OT** have been ablated, the imaging hood **12** may be reconfigured into a low profile for removal from the patient heart **H**.

[0165] Fig. 34C also illustrates a variation of the system **10** having a visualization element **52** located at the end of the catheter **16** and/or on the hood **12**. The device **10** also includes a fiber **606** coupled to a laser source **608**. The fiber **606** is optionally moveable so that the laser beam may be focused on desired areas to treat tissue (e.g., the injury of the tissue leads to healing over time). The fiber **606** can direct the laser energy invarious patterns (e.g., spot treatment, rings, various geometries, etc.). The laser may be collimated or non-collimated (where a collimated laser beam will propagate with the lowest possible beam divergence for a given beam size).

[0166] Fig. 34D illustrates another variation of a system according to the present invention. In this variation, an inflatable member **520** the hood **12** to be expanded so that the device **10** may be advanced and pushed against tissue. This variation prevents the excessive use of saline or other fluid when the hood is not properly or partially sealed against a tissue surface. The inflatable member **520** may be fabricated to permit energy (e.g., such as laser or ultrasound as shown by line **521**) to be transmitted therethrough. For example, the inflatable member may be fabricated from silicone and a low thermal conductivity liquid is used to inflate the member **520**.

[0167] One of the difficulties in treating tissue in or around the ostium **OT** is the dynamic fluid flow of blood through the ostium **OT**. The dynamic forces make cannulation or entry of the ostium **OT** difficult. Thus, another variation on instruments or tools utilizable with the imaging system is an extendible cannula **410** having a cannula lumen **412** defined therethrough, as shown in Fig. 35A. The extendible cannula **410** may generally comprise an elongate tubular member which may be positioned within the deployment catheter **16** during delivery and then projected distally through the imaging hood **12** and optionally beyond, as shown in Fig. 35B.

[0168] In use, once the imaging hood **12** has been desirably positioned relative to the tissue, e. n in Fig. 35C outside the ostium **OT** of a pulmonary vein **PV**, the extendib **410** may be projected distally from the deployment catheter **16** while

optionally imaging the tissue through the imaging hood **12**, as described above. The extendible cannula **410** may be projected distally until its distal end is extended at least partially into the ostium **OT**. Once in the ostium **OT**, an instrument or energy ablation device may be extended through and out of the cannula lumen **412** for treatment within the ostium **OT**. Upon completion of the procedure, the cannula **410** may be withdrawn proximally and removed from the patient body. The extendible cannula **410** may also include an inflatable occlusion balloon at or near its distal end to block the blood flow out of the **PV** to maintain a clear view of the tissue region. Alternatively, the extendible cannula **410** may define a lumen therethrough beyond the occlusion balloon to bypass at least a portion of the blood that normally exits the pulmonary vein **PV** by directing the blood through the cannula **410** to exit proximal of the imaging hood.

[0169] Yet another variation for tool or instrument use may be seen in the side and end views of Fig. 36A and 36B. In this variation, imaging hood **12** may have one or more tubular support members **420** integrated with the hood **12**. Each of the tubular support members **420** may define an access lumen **422** through which one or more instruments or tools may be delivered for treatment upon the underlying tissue. One particular example is shown and described above for Fig. 7C.

[0170] Various methods and instruments may be utilized for using or facilitating the use of the system. For instance, one method may include facilitating the initial delivery and placement of a device into the patient's heart. In initially guiding the imaging assembly within the heart chamber to, e.g., the mitral valve **MV**, a separate guiding probe **430** may be utilized, as shown in Figs. 37A and 37B. Guiding probe **430** may, for example, comprise an optical fiber through which a light source **434** may be used to illuminate a distal tip portion **432**. The tip portion **432** may be advanced into the heart through, e.g., the coronary sinus **CS**, until the tip is positioned adjacent to the mitral valve **MV**. The tip **432** may be illuminated, as shown in Fig. 37A, and imaging assembly **10** may then be guided towards the illuminated tip **432**, which is visible from within the atrial chamber, towards mitral valve **MV**.

[0171] Aside from the devices and methods described above, the imaging system may be utilized to facilitate various other procedures. Turning now to Figs. 38A and 38B, the imaging hood of the device in particular may be utilized. In this example, a collapsible membrane or disk-shaped member **440** may be temporarily secured around the contact edge or lip of)od **12**. During intravascular delivery, the imaging hood **12** and the attached **40** may both be in a collapsed configuration to maintain a low profile for

delivery. Upon deployment, both the imaging hood **12** and the member **440** may exter their expanded configurations.

[0172] The disk-shaped member **440** may be comprised of a variety of materials depending upon the application. For instance, member **440** may be fabricated from a porous polymeric material infused with a drug eluting medicament **442** for implantation against a tissue surface for slow infusion of the medicament into the underlying tissue. Alternatively, the member **440** may be fabricated from a non-porous material, e.g., metal or polymer, for implantation and closure of a wound or over a cavity to prevent fluid leakage. In yet another alternative, the member **440** may be made from a distensible material which is secured to imaging hood **12** in an expanded condition. Once implanted or secured on a tissue surface or wound, the expanded member **440** may be released from imaging hood **12**. Upon release, the expanded member **440** may shrink to a smaller size while approximating the attached underlying tissue, e.g., to close a wound or opening.

[0173] One method for securing the disk-shaped member **440** to a tissue surface may include a plurality of tissue anchors **444**, e.g., barbs, hooks, projections, etc., which are attached to a surface of the member **440**. Other methods of attachments may include adhesives, suturing, etc. In use, as shown in Figs. 39A to 39C, the imaging hood **12** may be deployed in its expanded configuration with member **440** attached thereto with the plurality of tissue anchors **444** projecting distally. The tissue anchors **444** may be urged into a tissue region to be treated **446**, as seen in Fig. 39A, until the anchors **444** are secured in the tissue and member **440** is positioned directly against the tissue, as shown in Fig. 39B. A pullwire may be actuated to release the member **440** from the imaging hood **12** and deployment catheter **16** may be withdrawn proximally to leave member **440** secured against the tissue **446**.

[0174] Another variation for tissue manipulation and treatment may be seen in the variation of Fig. 40A, which illustrates an imaging hood **12** having a deployable anchor assembly **450** attached to the tissue contact edge **22**. Fig. 40B illustrates the anchor assembly **450** detached from the imaging hood **12** for clarity. The anchor assembly **450** may be seen as having a plurality of discrete tissue anchors **456**, e.g., barbs, hooks, projections, etc., each having a suture retaining end, e.g., an eyelet or opening **458** in a proximal end of the anchors **456**. A suture member or wire **452** may be slidingly connected to each anchor **456** through the openings **458** and through a cinching element **454**, which may be configured to slide uni-
directior he suture or wire **452** to approximate each of the anchors **456** towards one
another. ıe anchors **456** may be temporarily attached to the imaging hood **12**

through a variety of methods. For instance, a pullwire or retaining wire may hold each anchors within a receiving ring around the circumference of the imaging hood **12**. When the anchors **456** are released, the pullwire or retaining wire may be tensioned from its proximal end outside the patient body to thereby free the anchors **456** from the imaging hood **12**.

[0175] One example for use of the anchor assembly **450** is shown in Figs. 41A to 41D for closure of an opening or wound **460**, e.g., patent foramen ovale (PFO). The deployment catheter **16** and imaging hood **12** may be delivered intravascularly into, e.g., a patient heart. As the imaging hood **12** is deployed into its expanded configuration, the imaging hood **12** may be positioned adjacent to the opening or wound **460**, as shown in Fig. 41A. With the anchor assembly **450** positioned upon the expanded imaging hood **12**, deployment catheter **16** may be directed to urge the contact edge of imaging hood **12** and anchor assembly **450** into the region surrounding the tissue opening **460**, as shown in Fig. 41B. Once the anchor assembly **450** has been secured within the surrounding tissue, the anchors may be released from imaging hood **12** leaving the anchor assembly **450** and suture member **452** trailing from the anchors, as shown in Fig. 41C. The suture or wire member **452** may be tightened by pulling it proximally from outside the patient body to approximate the anchors of anchor assembly **450** towards one another in a purse-string manner to close the tissue opening **462**, as shown in Fig. 41D. The cinching element **454** may also be pushed distally over the suture or wire member **452** to prevent the approximated anchor assembly **450** from loosening or widening.

[0176] Fig. 41E illustrates a tissue imaging and manipulation assembly **10** configured to deliver an implant **464**. In this variation, the implant comprises a shaft having a plurality of thrombogenic fibers **466**. The implant **464** further includes a tissue attachment member **468**. In use, the assembly **10** delivers the implant **464** to a tissue area or cavity. The implant may be rotated into tissue (or otherwise attached) using the attachment member **468**. The implant **464** may be combined with other procedures discussed herein, especially where occlusion of a cavity or opening is required.

[0177] Fig. 41F illustrates another variation of an assembly **10** according to the present invention. In this case, the implant **474** may comprise a stent, coil, patch, suture, or other such implant. The implant **474** may be delivered using a delivery catheter **473** or similar means.

[0178] Another example for an alternative use is shown in Fig. 42, where the deploym r **16** and deployed imaging hood **12** may be positioned within a patient body for lood **472** into deployment catheter **16**. The drawn blood **472** may be

pumped through a dialysis unit **470** located externally of the patient body for filtering t drawn blood **472** and the filtered blood may be reintroduced back into the patient.

[0179] Yet another variation is shown in Figs. 43A and 43B, which show a variation of the deployment catheter **480** having a first deployable hood **482** and a second deployable hood **484** positioned distal to the first hood **482**. The deployment catheter **480** may also have a side-viewing imaging element **486** positioned between the first and second hoods **482, 484** along the length of the deployment catheter **480**. In use, such a device may be introduced through a lumen **488** of a vessel **VS**, where one or both hoods **482, 484** may be expanded to gently contact the surrounding walls of vessel **VS**. Once hoods **482, 484** have been expanded, the clear imaging fluid may be pumped in the space defined between the hoods **482, 484** to displace any blood and to create an imaging space **490**, as shown in Fig. 43B. With the clear fluid in-between hoods **482, 484**, the imaging element **486** may be used to view the surrounding tissue surface contained between hoods **482, 484**. Other instruments or tools may be passed through deployment catheter **480** and through one or more openings defined along the catheter **480** for additionally performing therapeutic procedures upon the vessel wall.

[0180] Fig. 43C illustrates another variation of a deployment catheter **480** having a series of deployable hoods **482, 484** spaced close together. The deployment catheter **480** will include at least two fluid supply lumens **476, 478**, where each lumen is fluidly coupled to an open area within the outer **482** and inner **484** hoods. During use, the fluid running between the outer and inner hoods **482, 484** clears the blood, debris or other obstructions from around the inside hood **484**. One benefit is that this allows the device to have better visualization within the inner hood **484** by preventing bodily fluids from entering the open area. This is especially useful when the inner hood **484** abuts tissue and fluid from the outer hood **482** creates a flow pattern that opposes bodily fluids from entering the open area of the inner hood **484**.

[0181] Visualization elements may be placed within one or both hoods. In one variation of the device, the inner hood **484** may be fabricated from a clear material so that one or more visualization elements may be placed within the outer hood **482**. Alternatively, or in combination, the visualization elements may be placed to visualize the open area of the inner hood **484**. It should be noted that any number of hoods may be used.

[0182] Another variation of a deployment catheter **500** which may be used for imaging ıe side of the instrument may be seen in Figs. 44A to 45B. Figs. 44A and 44B sho end views of deployment catheter **500** having a side-imaging balloon **502**

in an un-inflated low-profile configuration. A side-imaging element **504** may be positi within a distal portion of the catheter **500** where the balloon **502** is disposed. When balloon **502** is inflated, it may expand radially to contact the surrounding tissue, but where the imaging element **504** is located, a visualization field **506** may be created by the balloon **502**, as shown in the side, top, and end views of Figs. 45A to 45B, respectively. The visualization field **506** may simply be a cavity or channel which is defined within the inflated balloon **502** such that the visualization element **504** is provided an image of the area within field **506** which is clear and unobstructed by balloon **502**.

[0183] In use, deployment catheter **500** may be advanced intravascularly through vessel lumen **488** towards a lesion or tumor **508** to be visualized and/or treated. Upon reaching the lesion **508**, deployment catheter **500** may be positioned adjacently to the lesion **508** and balloon **502** may be inflated such that the lesion **508** is contained within the visualization field **506**. Once balloon **502** is fully inflated and in contact against the vessel wall, clear fluid may be pumped into visualization field **506** through deployment catheter **500** to displace any blood or opaque fluids from the field **506**, as shown in the side and end views of Figs. 46A and 46B, respectively. The lesion **508** may then be visually inspected and treated by passing any number of instruments through deployment catheter **500** and into field **506**.

[0184] Figs. 47A-47B illustrate a variation of a device according to the present invention where components of the system **560** allow for dissection/blunt dissection of tissue. As shown, a hood **564** extends from a catheter **562**, where the hood **564** comprises a plurality of rigid sections **566** or leaflets. The leaflets **566, 568, 570** may be fabricated from a stiff metal or polymer. Moreover, a variation of the device may include leaflets **566, 568, 570** having alternating constructions (e.g., a flexible leaflet interspaced between stiff leaflets, a soft leaflet interspaced between stiff or hard leaflets, etc.) Although the leaflets are illustrated as having tapered profiles towards a tip **572** of the device **560**, the tip **572** of the device may be sufficiently blunted so as to avoid unnecessary trauma to the tissue.

[0185] Fig. 47A illustrates the device **560** as it approaches adjacent layers of tissue **2, 4**. As illustrated in Fig. 47B, once appropriately positioned, the device **560** dissects tissue by opening or repeatedly opening and closing to separate the layers of tissue **2, 4**. Fig. 47B also illustrates the dissector hood **564** as having a flexible material or webbing **576** located between adjacent leaflets **566, 568, 570**. This flexible material/webbing **576** permits the hood to form a the hood is placed adjacent to a tissue surface. As illustrated, the leaflets **566, 568** overlap (as shown by the overlapping portion **569**).

[0186] Fig. 48A illustrates a variation of a tissue imaging and manipulation ass **10** further including an elongate bypass portion **580**. The elongate bypass portion **580** includes at least one bypass lumen **582** that allows a fluid path between proximal opening **584** in the catheter **16** and a distal opening **586** located distally of the hood **16**. The bypass lumen **582** allows fluid to pass around the open area during a surgical procedure. Furthermore, the hood **12** may include one or more visualization element **52** to allow visualization of the open area. A variation of the assembly **10** may include a pump-type device **578** to assist in moving fluid through the assembly **10**.

[0187] The elongate bypass portion **580** may be moveable relative to the hood **12** or catheter **16**. In addition, the elongate bypass portion **580** may include one or more structures to facilitate various procedures. For example, Fig. 48B illustrates a variation of the system **10** of Fig. 48A with the addition of a support flap **588**. The support flap **588** is preferably fabricated from a material that allows the flap **588** to assume a reduced profile for delivery. Upon expansion, the flap **588** provides a semi-rigid support when placed against tissue. In one application of this configuration, the assembly **10** may be passed through a valve (e.g., a mitral valve), such that the hood **12** creates a first open area over the valve. The flap **588** may then support the distal surface of the valve. Accordingly, devices may be advanced through the catheter **16** and to within the open area to perform surgical repair of the valve. In an additional variation, the region between proximal openings **584** and the distal end of the catheter **586** contains a valve (e.g., a one-way valve) to control the flow of fluid (in the case of a one-way valve fluid would only flow in a single direction).

[0188] Fig. 48C illustrates a cross-sectional view of the flap **588** placed against a distal surface of tissue (or a valve). As shown, the hood **16** creates an open area over the tissue so that devices **592** may be advanced through the catheter **16** to repair or treat the tissue. As discussed above, the elongate portion **580** may be withdrawn relative to the catheter **16** to secure the tissue between the hood **12** and flap **588**. Fig. 48C also illustrates a variation of an assembly **10** where the elongate portion **580** further includes a tissue attachment member **590**. In this variation, the tissue attachment member **590** comprises a helical member.

[0189] Fig. 48D illustrates a variation of an assembly **10** according to the present invention where the expanded hood **12** is off-center relative to the catheter **16**. Variations include assemblies where the elongate portion **580** is also be off-center relative to the hood **12** when The visualization element **52** may be placed on a side of the hood **12** to give opti ıg of the open area. However, the invention also contemplates placement

of one or more visualization elements at any location and on any structure within the area. It is also contemplated that variations of the assembly with an off-set hood configuration, such as that shown in Fig. 48D, may or may not incorporate a support flap as shown in Figs. 48A-48C.

[0190] Fig. 48E illustrates another variation of an assembly **10** with an elongate portion **580**. In this variation, the elongate portion **580** supplies fluid that is ultimately evacuated through the catheter **16**. As shown, as the fluid enters the target site via the elongate portion **580** the hood **12** prevents the fluid from escaping beyond the open area. A lumen in fluid communication with the open area evacuates the fluid and may also aspirate blood located in the left atrial appendage **LAA**. Such a variation is useful for work in the left atrial appendage **LAA**. A variation of the assembly **10** may include a tissue attachment member **590** to stabilize the assembly **10** at the target site. In use, the device is advanced through the right atrium **RA** through the heart wall and into the left atrial appendage **LAA** in the left atrium **LA**. The tissue attachment member **590** may be rotated into the tissue to secure the hood **12** and elongate member **580** within the appendage **LAA**. As noted above, the elongate member **580** may be moveable relative to the catheter **16** and hood **12**. Accordingly, pulling the elongate member **580** when the tissue attachment member **590** is coupled to tissue could assist in creating a compressive force between the hood **12** and the opening of the appendage **LAA**.

[0191] Fig. 48F illustrates another variation of tissue imaging and manipulation assembly **10**. In this variation, the assembly **10** includes an elongate member **580** having a balloon **594** coupled to a balloon lumen **596**. The balloon **594** may function as an occlusion balloon. As such, the elongate member **580** may be configured to permit passage of a guidewire or other guiding means. The elongate portion **580** may also be configured to have a bypass lumen as shown in Fig. 48A to allow fluid to move from an area proximally to the hood **12** to an area distally of the balloon.

[0192] Fig. 49A-49E illustrate the use of an elongate member **528** having a plurality of openings **530**. Fig. 49A shows an elongate member **528** and openings **530** that act as an irrigator/aspirator to circulate fluid between the catheter **16** and open area of the hood **12**. The elongate member may have a tissue attaching member, as discussed herein, attached to a distal end. Moreover, the catheter may have a flow distributor **532** to encourage laminar flow of fluid. Although not illustrated, a pump may be used in any of the described systems to allow t e member **528** or catheter **16** to aspirate fluid out of the open area of the hood **1** tions of the assembly **10**, the elongate member **528** may move in and out of

the catheter. It should be noted that in any of the variations discussed herein, the flo fluid may be the reverse of that shown. In such cases, the hood or other structure may require a slight structural change to handle any vacuum forces.

[0193] Fig. 49B illustrates another variation of an assembly **10**. In this variation, the hood **12** comprises a double layer with a plurality of openings **534** in the interior layer. Accordingly, fluid passes from the catheter **16** into the hood **12** and out of the openings **534**. Again, the elongate member **528** draws fluid from within the open area of the hood **12**. Fig. 49C illustrates a similar assembly to 49B. However, in this variation, the base of the hood **12** contains the openings **534** that provide fluid into the open area of the hood **12**. Fluid returns through the catheter **16**.

[0194] Fig. 49D illustrates another variation of a hood **12** under the present invention. In this variation, the hood **12** includes a plurality of elongate members **528** each having openings **530** that allow for circulation of fluid. One or more of the elongate members **528** are attached to the surface of the hood while a separate elongate member **528** extends through the catheter **16**. Fig. 49E illustrates a similar variation where two elongate members **528** extend through the catheter **16** rather than being attached to the hood.

[0195] Figs. 50A-50C illustrate variations of a tissue imaging and manipulation assembly **10** designed to translate or "walk" across tissue surfaces when inserted within the body. In a first variation, the assembly **10** includes an outer sheath **536** having an articulating section or joint **538** allowing for at least one degree of motion. The assembly **10** further includes a catheter **16** being axially moveable, as shown by arrows **540**, relative to the sheath **536**. The catheter **16** may further include a second joint **542** that allows for angular rotation of the hood **12**, as shown by arrows **544**. Accordingly, the joints of the assembly **10** allow for repositioning of the hood **12** as it sweeps or walks across tissue.

[0196] Fig. 50B illustrates another variation of a tissue imaging and manipulation assembly **10** designed to translate or "walk" across tissue surfaces. In this variation, one or more "fingers" **546**, **548** are moveably located within the hood **12**. Each finger **546**, **548** is designed to move axially relative to the hood **12**, as illustrated by arrows **550**, as well as angularly relative to the hood **12**, as illustrated by arrows **552**. Accordingly, as one finger extends beyond the hood **12**, the finger **548** raises it off of the tissue surface, as shown in Fig. 50C. Once raised off of the tissue, the second finger **546** advances in the desired direction and extends to contact tissue as the first finger **548** retracts. Thus, this walking motion of the fingers precise movement of the hood across tissue.

[0197] e user controls to actuate and control movement are not illustrated but may

be those controls conventionally used by medical practitioner. Alternatively, the a y 10 may be coupled to a robotic manipulation system as described above.

[0198] The applications of the disclosed invention discussed above are not limited to certain treatments or regions of the body, but may include any number of other treatments and areas of the body. Modification of the above-described methods and devices for carrying out the invention, and variations of aspects of the invention that are obvious to those of skill in the arts are intended to be within the scope of this disclosure. Moreover, various combinations of aspects between examples are also contemplated and are considered to be within the scope of this disclosure as well.

CLAIMS

What is claimed is:

1. A tissue imaging and manipulation system, comprising:

a deployment catheter defining at least one lumen therethrough;

an expandable hood projecting distally from the deployment catheter and such that when expanded defines an open area therein, wherein the open area is in fluid communication with the at least one lumen; and

a visualization element positionable along an interior of the hood off-axis relative to a longitudinal axis of the deployment catheter, wherein the visualization element is adapted to image tissue adjacent to the open area when the open area is filled with a translucent fluid.

2. The system of claim 1 further comprising a delivery catheter through which the deployment catheter is deliverable.

3. The system of claim 1 wherein the deployment catheter is steerable.

4. The system of claim 3 wherein the deployment catheter is steered via at least one pull-wire.

5. The system of claim 3 wherein the deployment catheter is steered via computer control.

6. The system of claim 1 wherein the hood is collapsible.

7. The system of claim 1 wherein the hood is comprised of a compliant material.

8. The system of claim 1 wherein the hood defines a contact edge for placement against a tissue surface.

9. The system of claim 1 wherein the hood is adapted to be reconfigured from a low-profile delivery configuration to an expanded deployed configuration.

10. The system of claim 9 wherein the hood is adapted to self-expand into the expanded configuration.

ystem of claim 9 wherein the hood comprises a frame of superelastic or

shape memory alloy.

12. The system of claim 1 wherein the hood defines a pleated surface.

13. The system of claim 1 wherein the hood is conically shaped.

14. The system of claim 1 wherein the hood is selectively deployable from the catheter such that the open area is selectively variable.

15. The system of claim 1 wherein the hood comprises a non-inflatable membrane.

16. The system of claim 1 wherein the hood comprises at least one support member.

17. The system of claim 16 wherein the at least one support member is actuatable via a corresponding pull-wire.

18. The system of claim 1 wherein the visualization element comprises at least one optical fiber, CCD imagers, or CMOS imagers.

19. The system of claim 1 further comprising at least one additional visualization element positionable along the interior of the hood off-axis relative to the longitudinal axis of the catheter.

20. The system of claim 1 wherein the visualization element is disposed upon a longitudinally translatable member extending from a distal end of the deployment catheter.

21. The system of claim 20 wherein the visualization element is articulatable off-axis relative to the longitudinal axis of the deployment catheter.

22. The system of claim 1 further comprising a pump for urging fluid into the hood.

23. The system of claim 1 further comprising at least one light emitting diode disposed upon the hood for illuminating the tissue adjacent to the open area.

24. The system of claim 1 further comprising a tissue engager deliverable through the deployment catheter.

25. The system of claim 1 further comprising an ablation probe deliverable through the dep itheter.

26. The system of claim 1 wherein the translucent fluid comprises saline, pl water, or perfluorinated liquid.

27. The system of claim 1 further comprising an inflatable member located within the hood, the inflatable member having a transparent membrane and coupled to a fluid source, such that upon expansion with the fluid, the inflatable member occupies the open area displacing other fluids.

28. The system of claim 27 wherein the transparent membrane comprises an index of refraction close to or matching an index of refraction of the fluid.

29. The system of claim 27 further comprising at least a second inflatable member located within the hood.

30. The system of claim 29 wherein the first and second inflatable members are positioned relative to one another within the hood such that an instrument is advanceable from the deployment catheter between the first and second inflatable members in their expanded state.

31. The system of claim 27 wherein the inflatable member is adapted to expand beyond a distal lip of the hood when expanded with the fluid.

32. The system of claim 1 further comprising an elongate bypass portion extending distally of the hood, the elongate bypass portion having at least one proximal opening located proximally of the hood, at least one distal opening located distally of the hood, and a bypass lumen extending therebetween allowing fluid to flow between the proximal openings and distal openings.

33. The system of claim 1 further comprising an outer sheath through which the deployment catheter is movable, the outer sheath having at least one articulating section for controlling a position of deployment catheter relative to the tissue.

34. The system of claim 33 wherein the deployment catheter further comprises at least one articulating section.

35. A method for imaging an immersed region of tissue, comprising:

g a hood projecting distally from a deployment catheter against or adjacent

to the region of tissue to be imaged;

urging a translucent fluid into the hood via the deployment catheter such that an opaque fluid is displaced from the hood; and

visualizing the region of tissue through the translucent fluid via a visualization element positionable along an interior of the hood off-axis relative to a longitudinal axis of the deployment catheter.

36. The method of claim 35 positioning a hood comprises advancing the deployment catheter intravascularly into a chamber of a heart.

37. The method of claim 35 wherein positioning a hood comprises deploying the hood from a low-profile delivery configuration into an expanded deployed configuration.

38. The method of claim 35 wherein positioning a hood comprises steering the deployment catheter to the region of tissue.

39. The method of claim 35 wherein positioning a hood comprises stabilizing a position of the hood relative to the tissue.

40. The method of claim 35 wherein urging a translucent fluid comprises pumping the translucent fluid into the hood through a fluid delivery lumen defined through the deployment catheter.

41. The method of claim 40 wherein urging a translucent fluid comprises urging saline, plasma, water, or perfluorinated liquid into the hood such that blood is displaced from the hood.

42. The method of claim 35 wherein visualizing the region of tissue further comprises illuminating the region of tissue.

43. The method of claim 35 further comprising treating the region of tissue with a therapeutic tool advanced through the deployment catheter.

44. The method of claim 35 further comprising repositioning the hood to a second region of tissue to be imaged.

ıethod of claim 35 wherein positioning a hood further comprises inflating at

least one inflatable member located within the hood until the inflatable member disp other fluids within the open area.

46. The method of claim 45 further comprising visualizing through the inflatable member which has an index of refraction close to or matching an index of refraction of the fluid.

47. The method of claim 45 further comprising inflating at least a second inflatable member located within the hood.

48. The method of claim 47 further comprising advancing an instrument from the deployment catheter between the first and second inflatable members in their expanded state.

49. The method of claim 45 wherein inflating at least one inflatable member comprises expanding the inflatable member beyond a distal lip of the hood.

50. The method of claim 45 further comprising urging a portion of the inflatable member against the region of tissue such that the tissue is visible through the inflatable member via the visualization element.

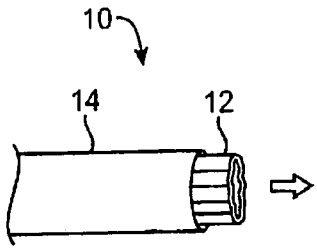

FIG. 1A

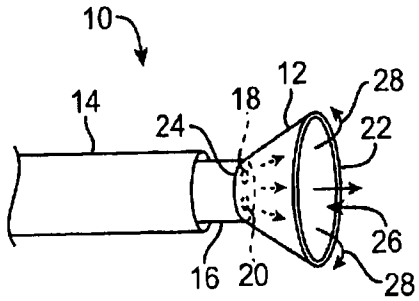

FIG. 1B

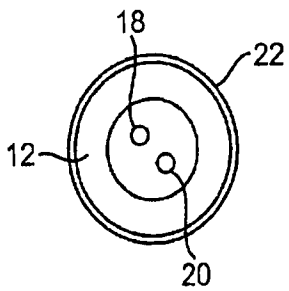

FIG. 1C

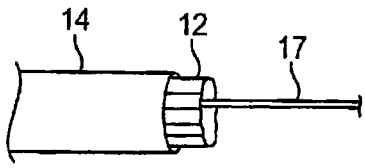

FIG. 1D

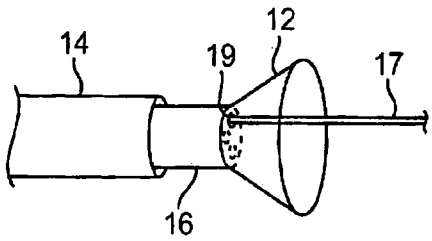

FIG. 1E

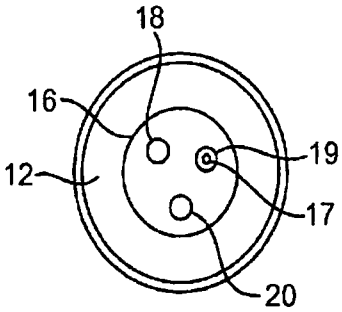

FIG. 1F

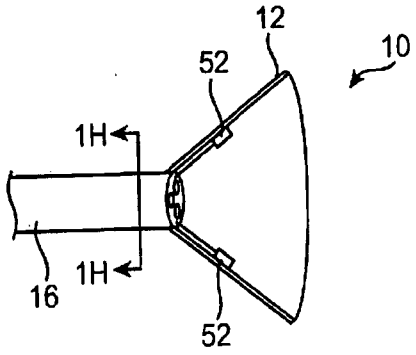

FIG. 1G

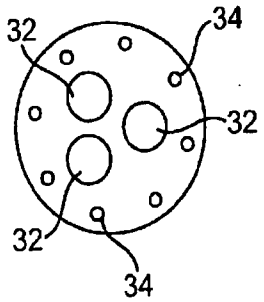

FIG. 1H

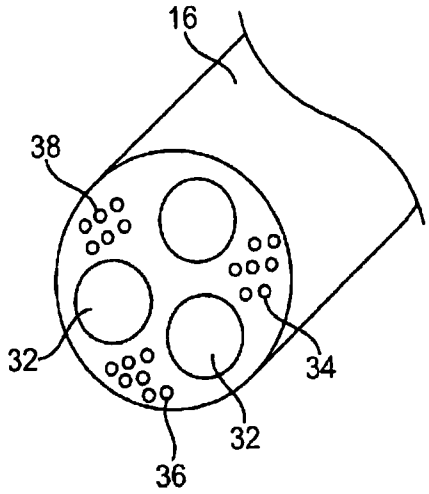

FIG. 1I

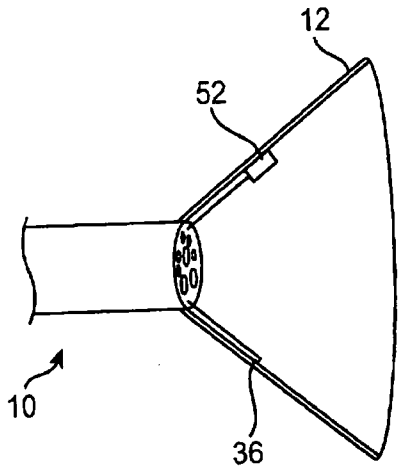

FIG. 1J

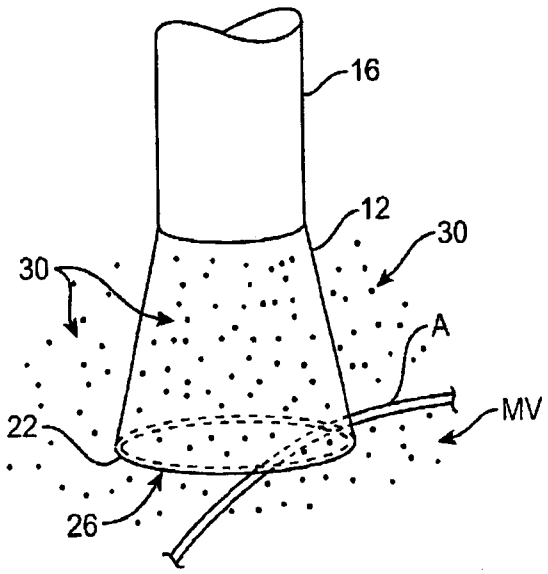

FIG. 2A

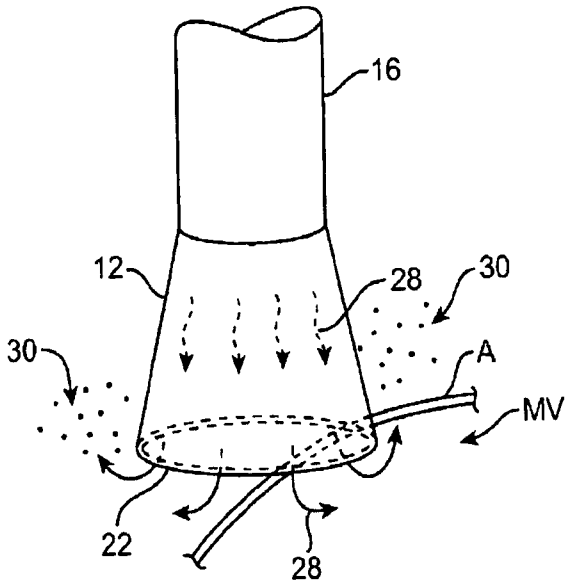

FIG. 2B

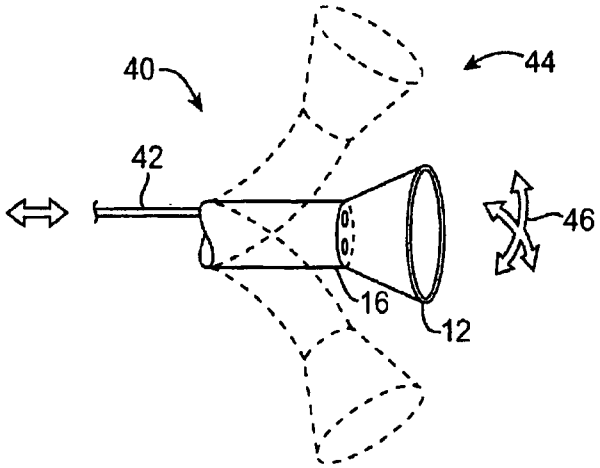

FIG. 3A

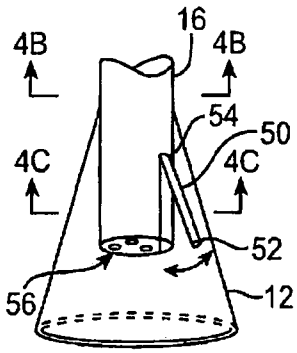

FIG. 4A

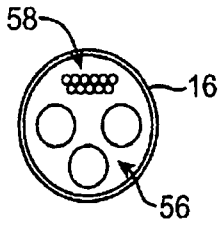

FIG. 4B

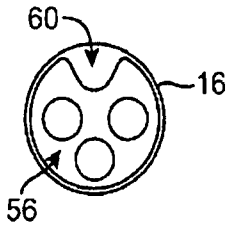

FIG. 4C

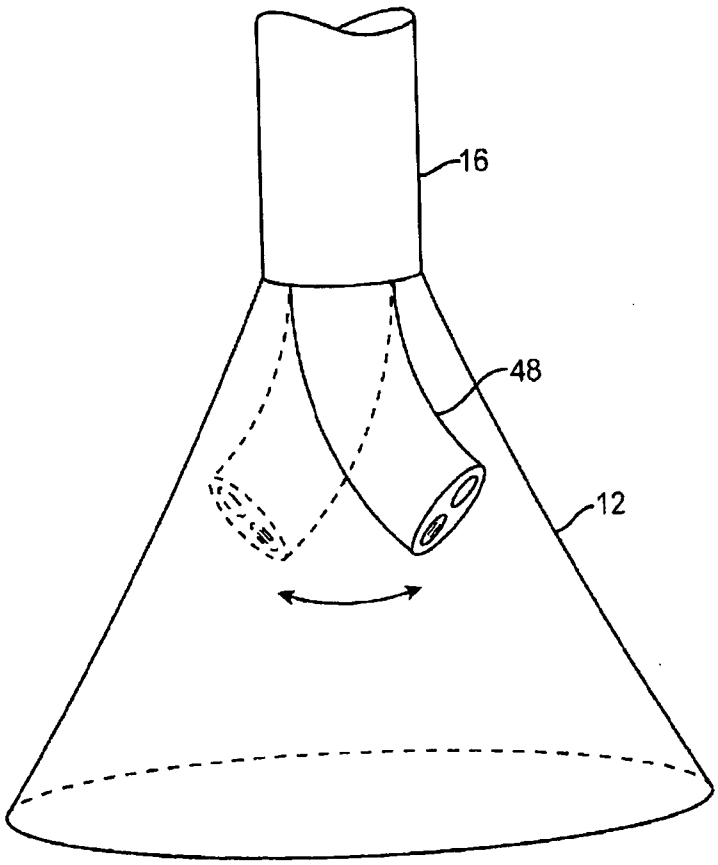

FIG. 3B

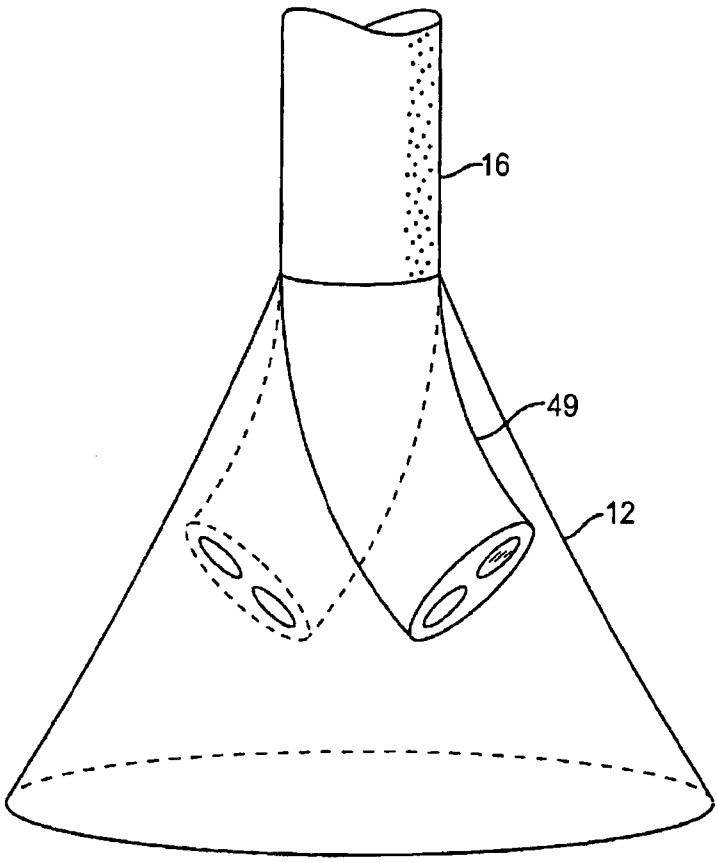

FIG. 3C

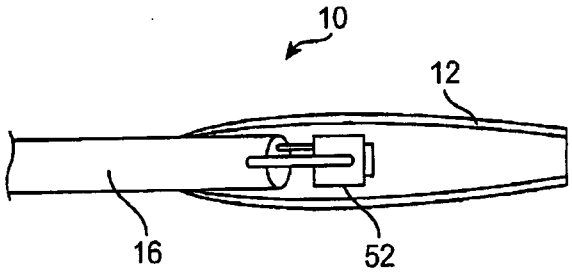

FIG. 4D

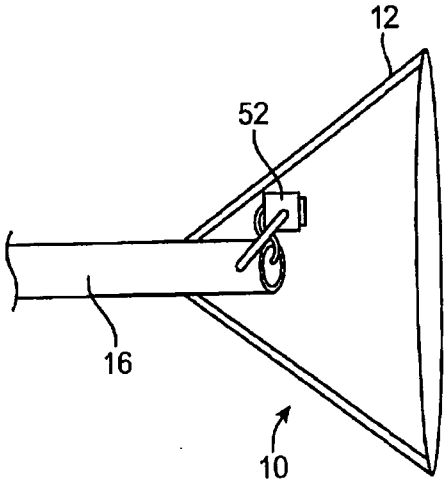

FIG. 4E

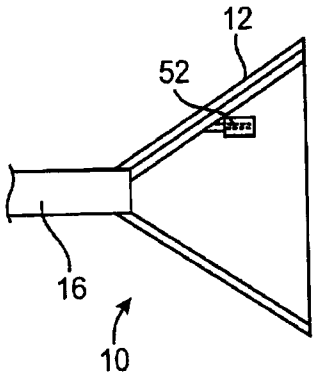

FIG. 4F

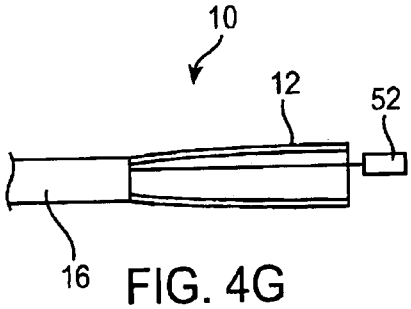

FIG. 4G

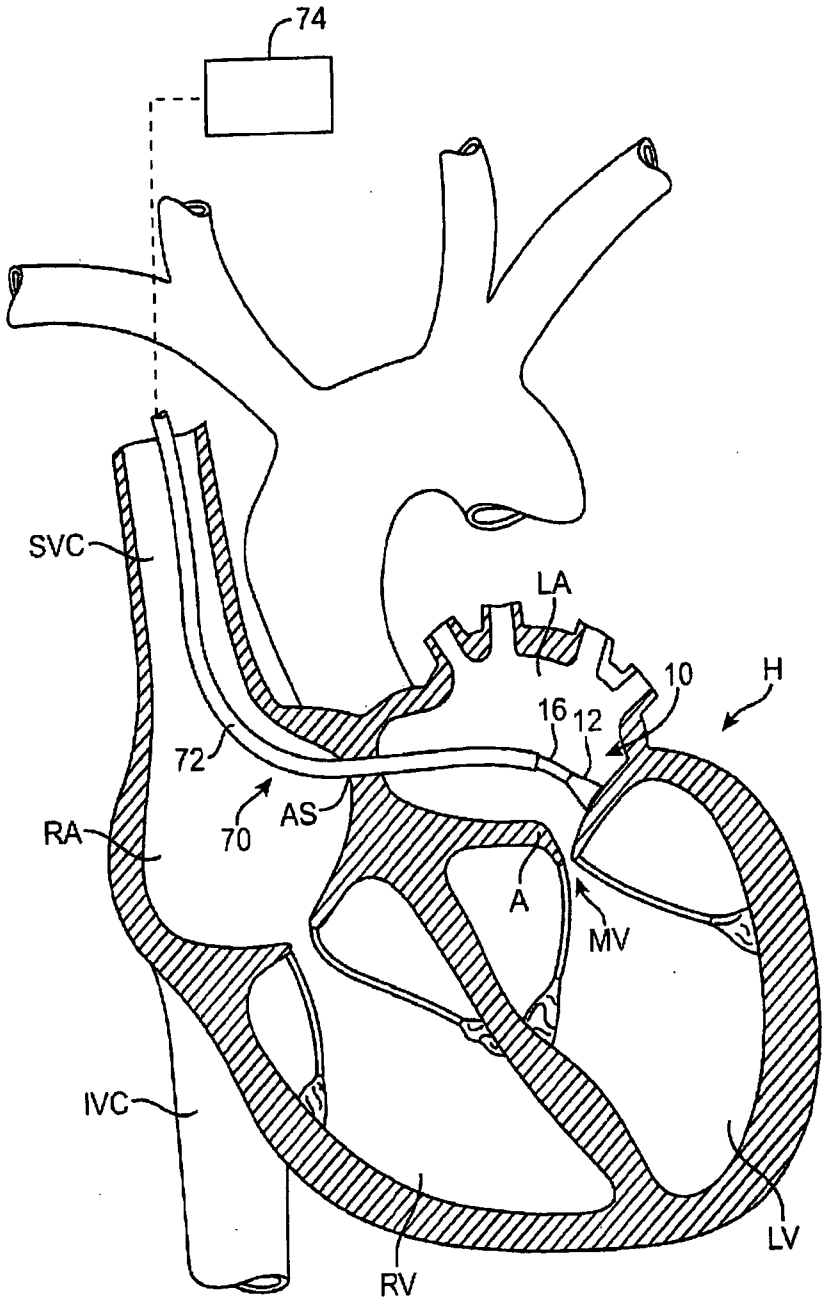

FIG. 5

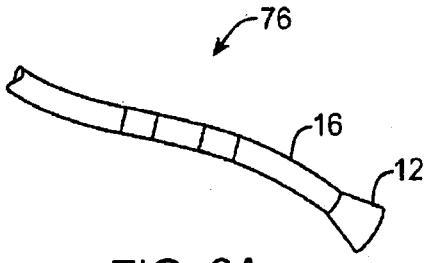

FIG. 6A

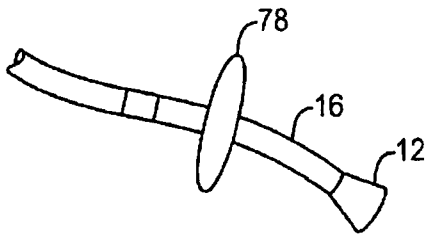

FIG. 6B

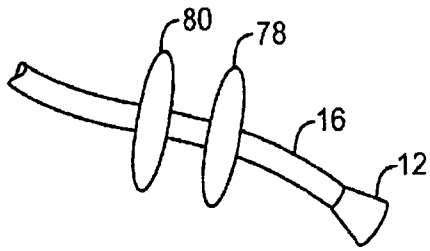

FIG. 6C

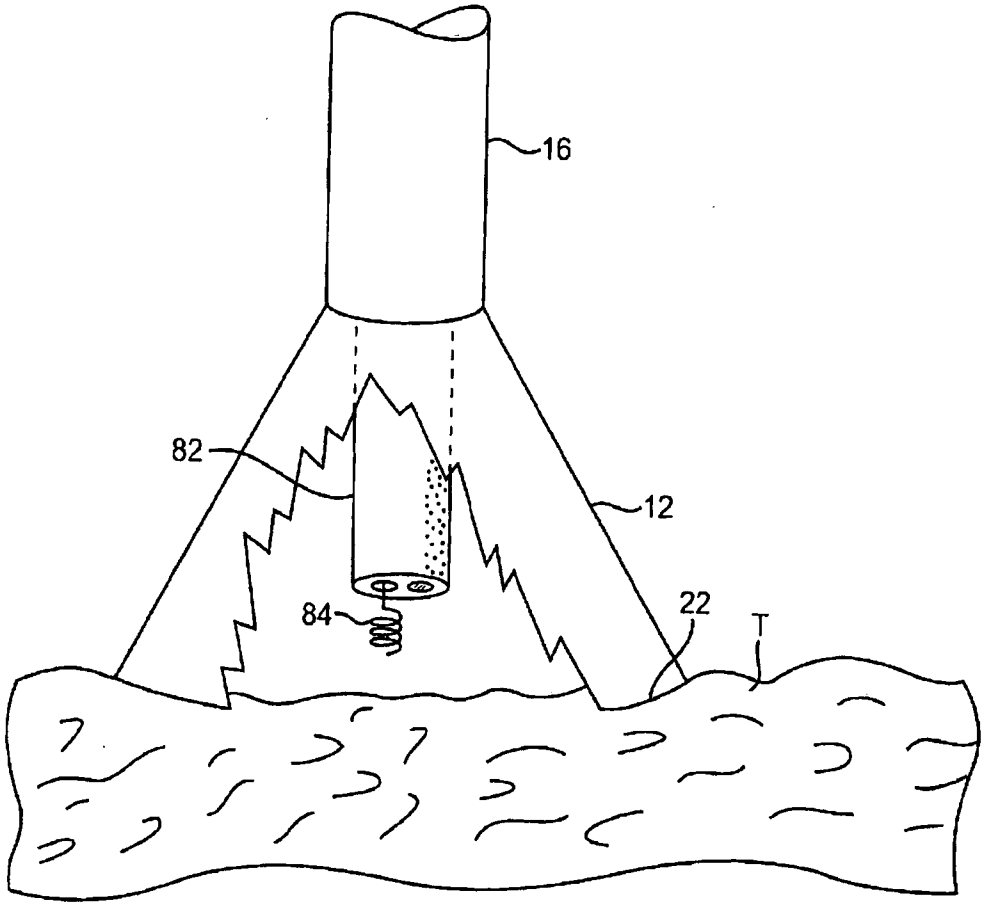

FIG. 7A

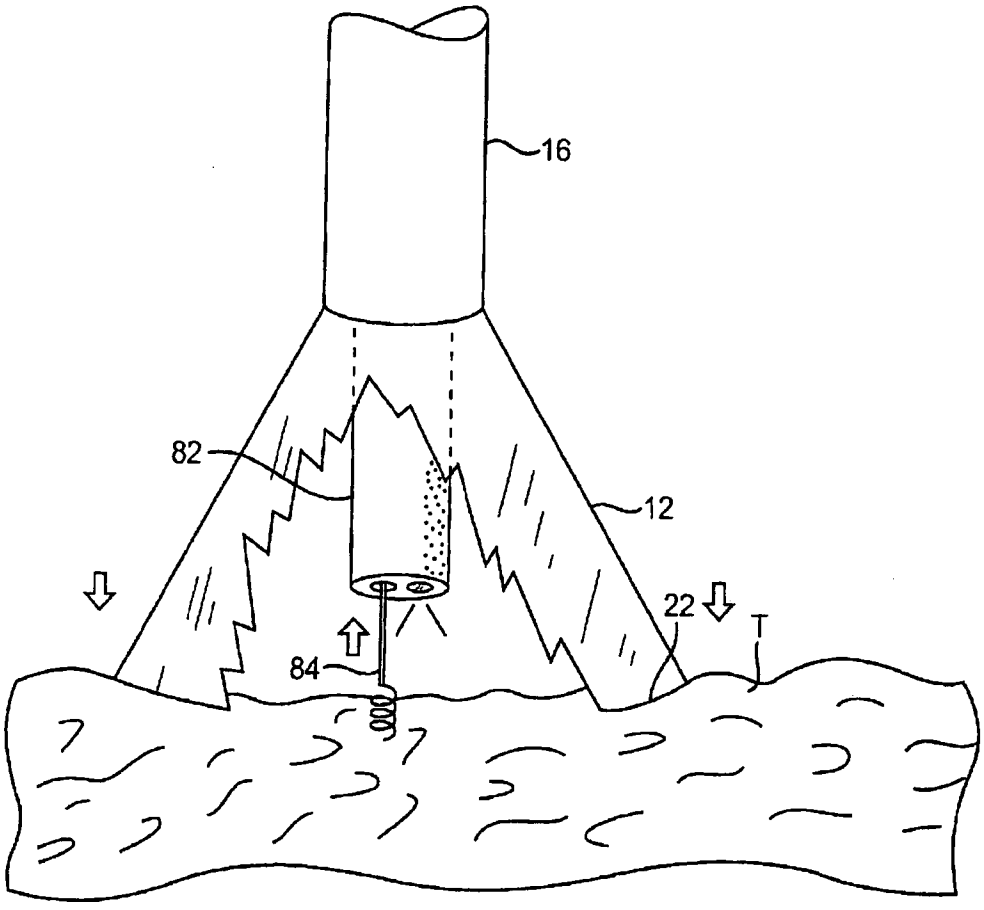

FIG. 7B

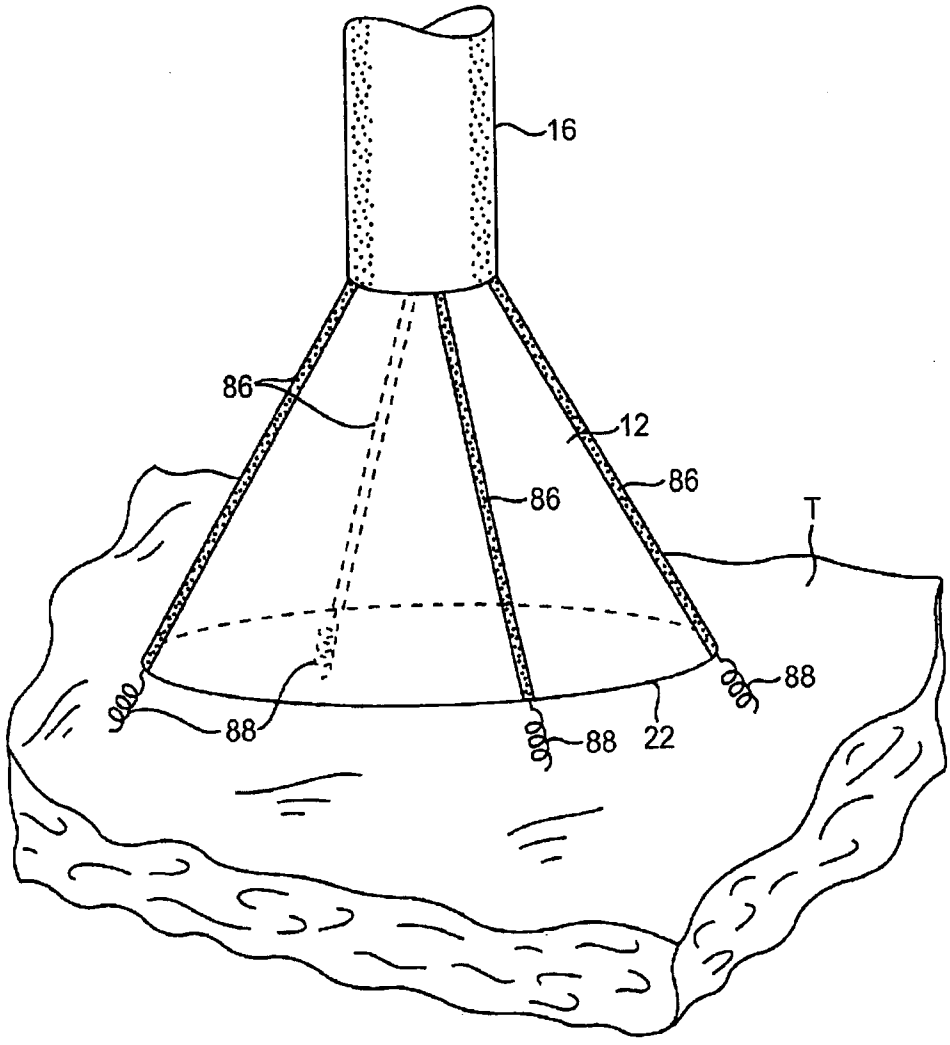

FIG. 7C

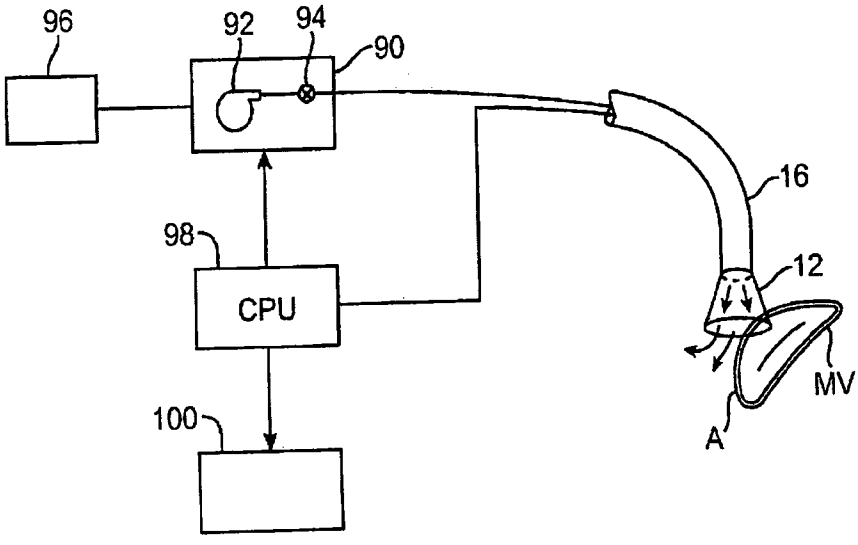

FIG. 8A

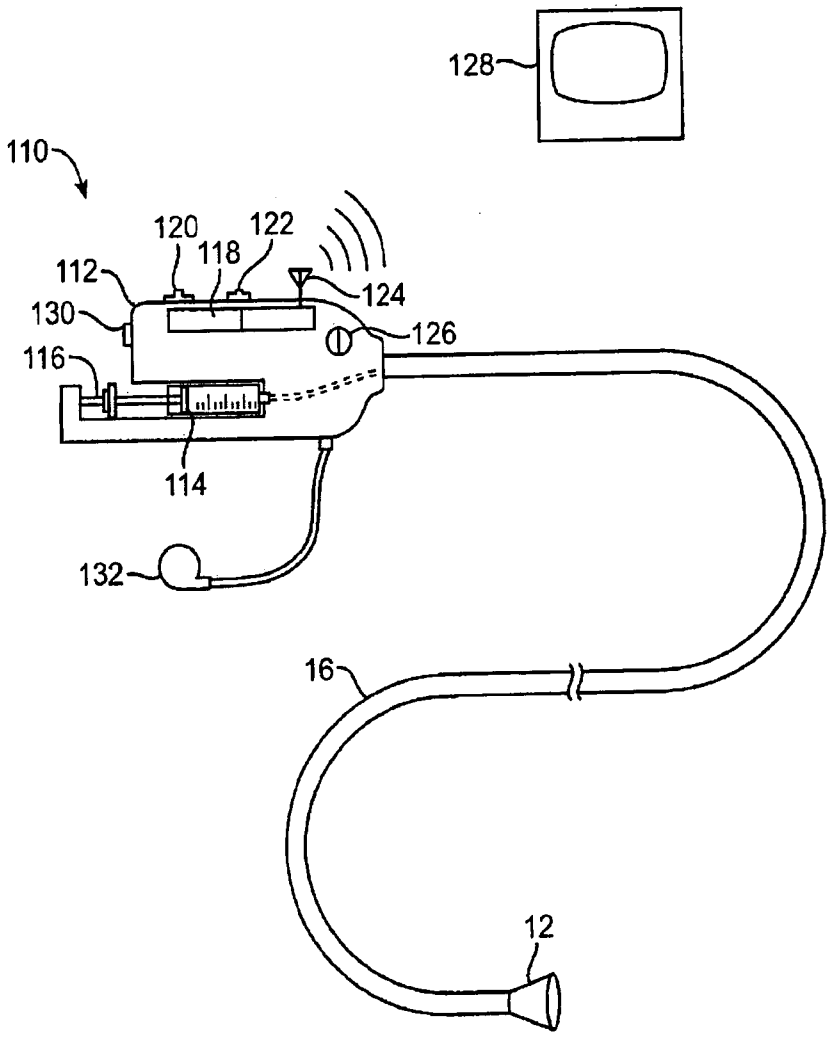

FIG. 8B

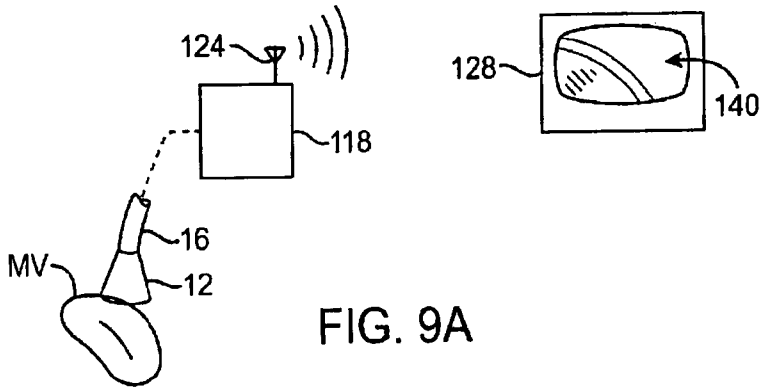

FIG. 9A

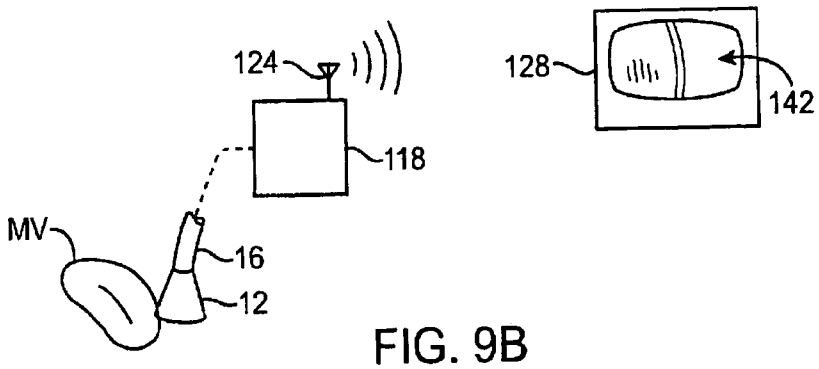

FIG. 9B

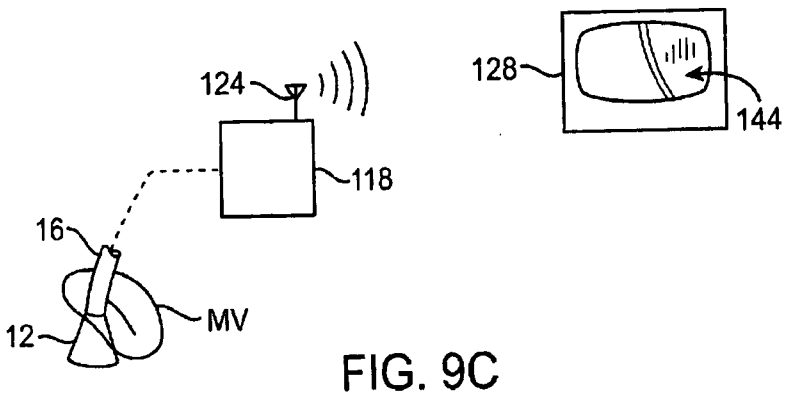

FIG. 9C

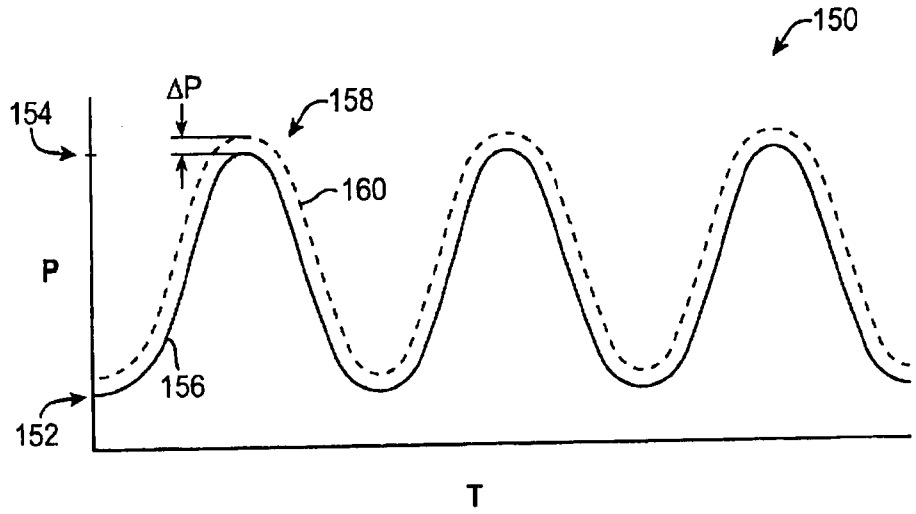

FIG. 10A

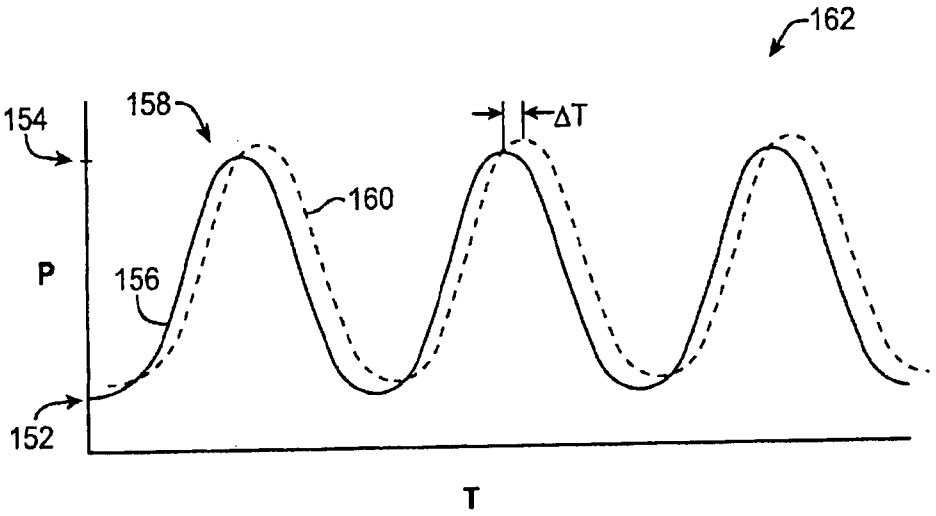

FIG. 10B

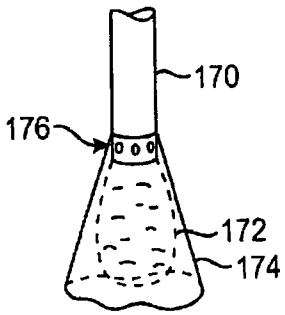

FIG. 11A

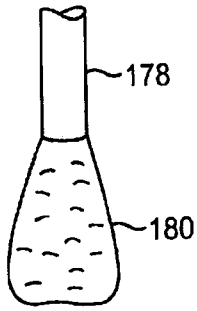

FIG. 11B

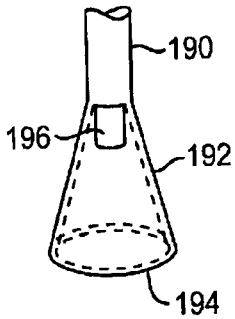

FIG. 13A

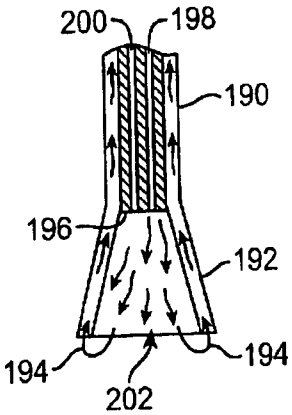

FIG. 13B

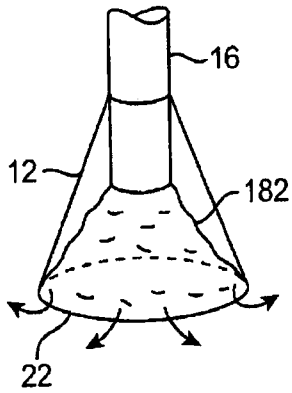

FIG. 12A

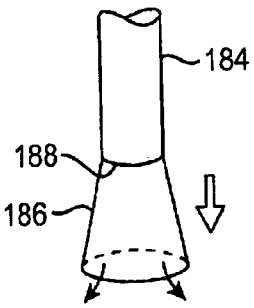

FIG. 12B

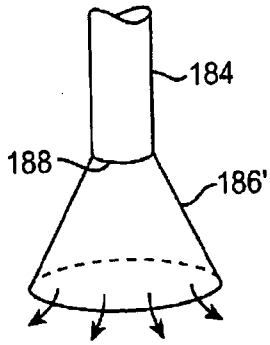

FIG. 12C

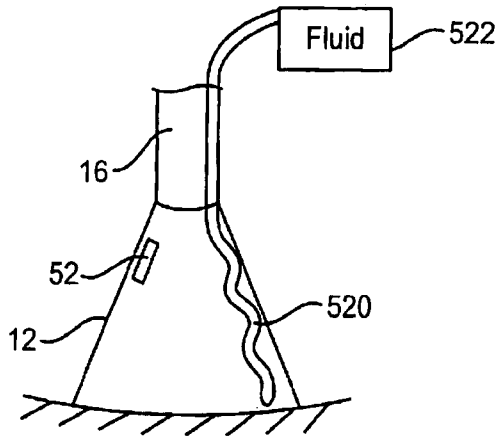

FIG. 12D

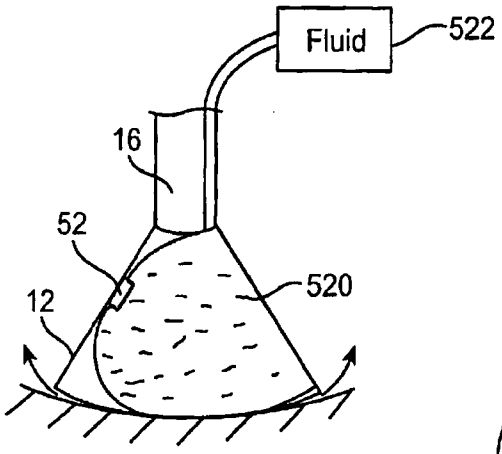

FIG. 12E

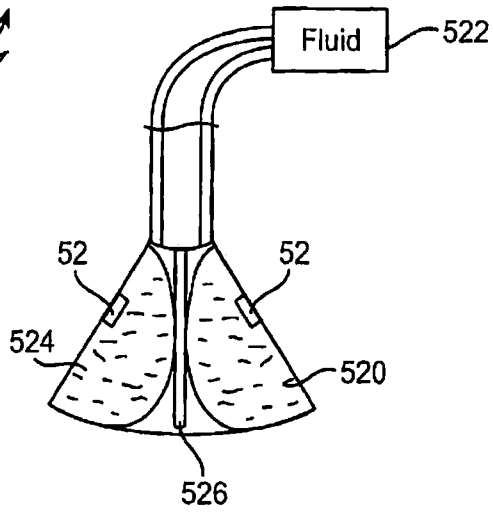

FIG. 12F

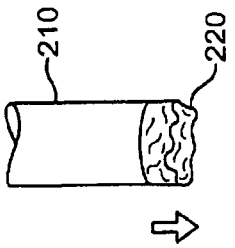

FIG. 14D

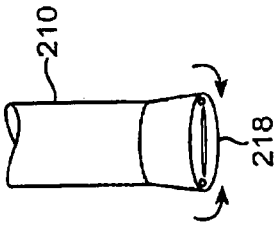

FIG. 14C

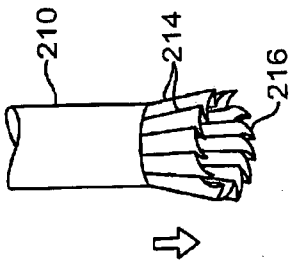

FIG. 14B

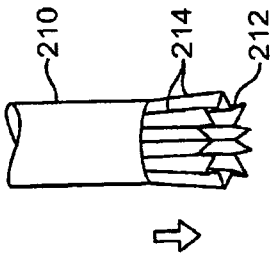

FIG. 14A

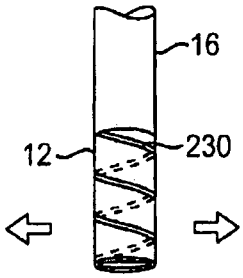

FIG. 15A

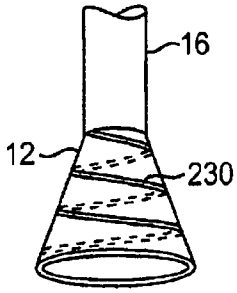

FIG. 15B

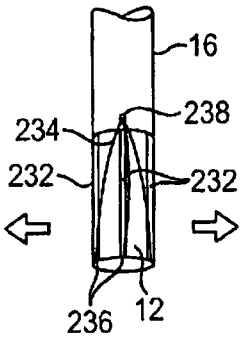

FIG. 16A

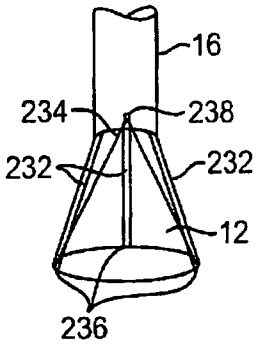

FIG. 16B

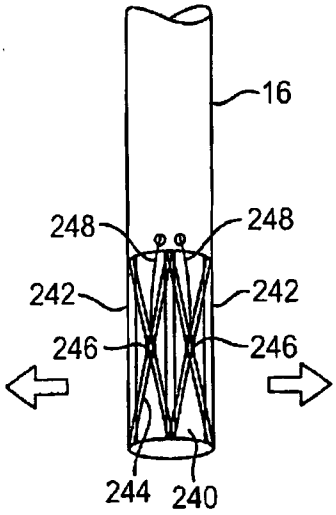

FIG. 17A

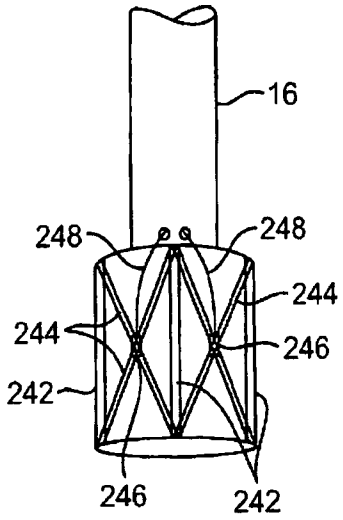

FIG. 17B

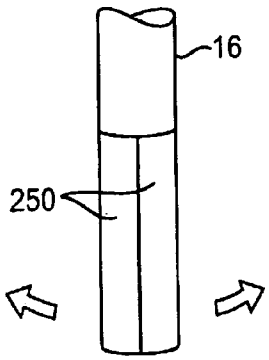

FIG. 18A

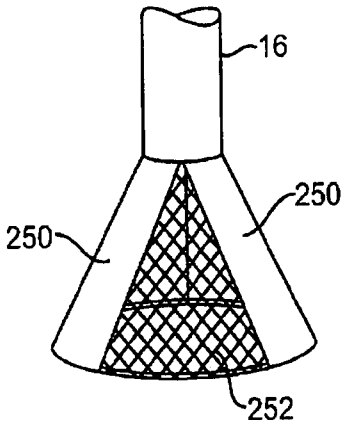

FIG. 18B

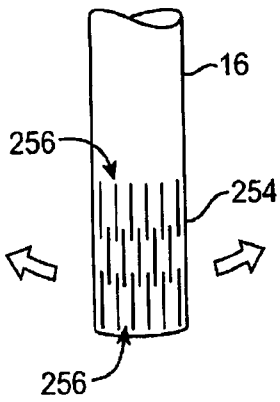

FIG. 19A

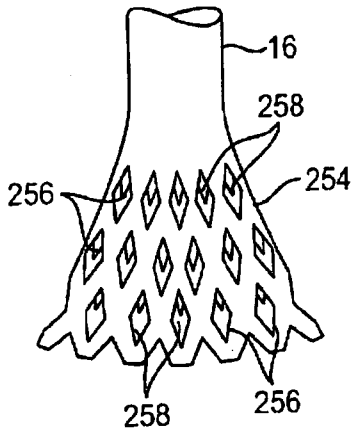

FIG. 19B

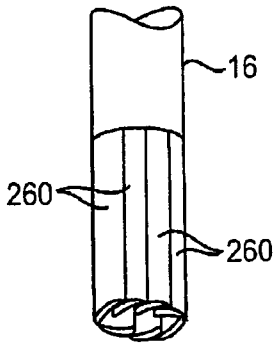

FIG. 20A

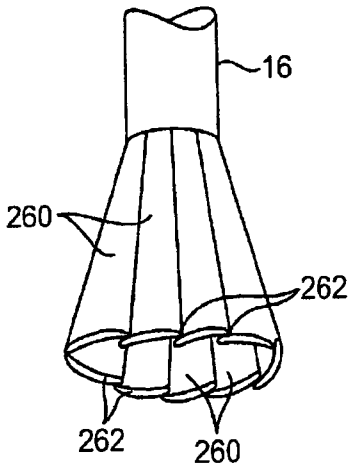

FIG. 20B

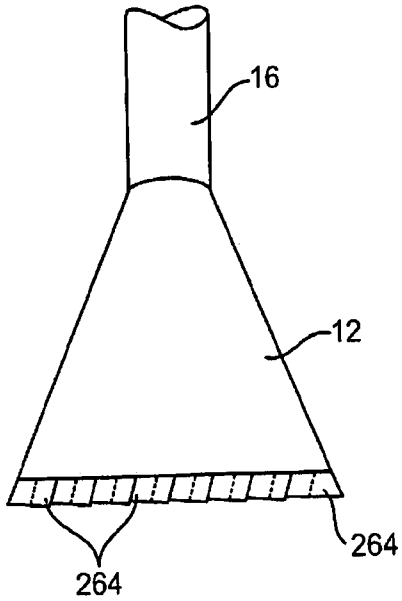

FIG. 20C

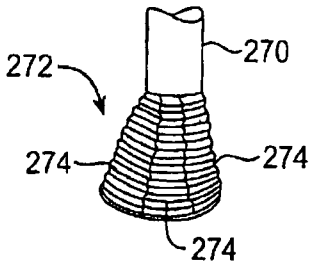

FIG. 21A

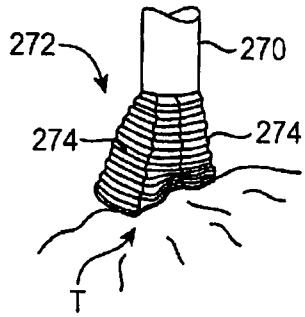

FIG. 21B

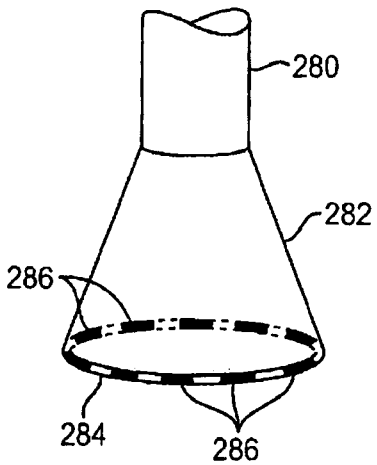

FIG. 22A

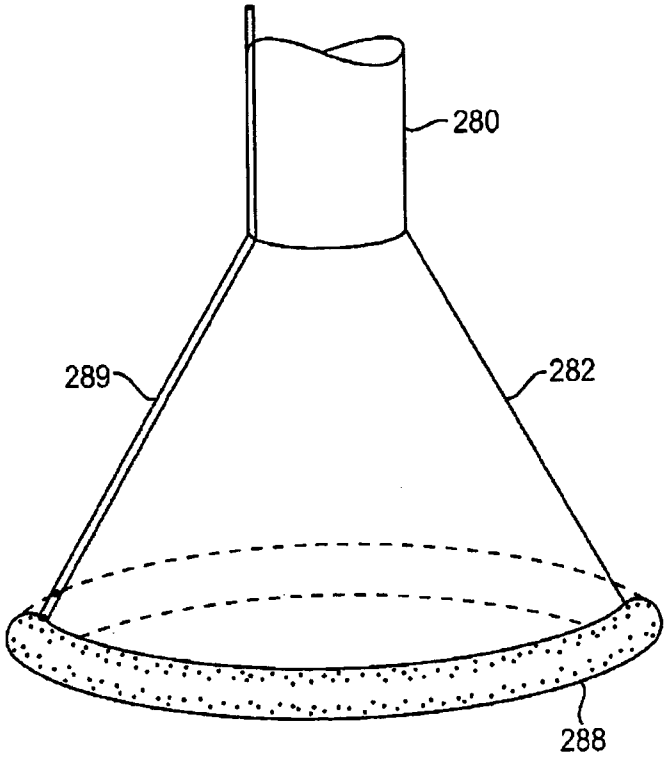

FIG. 22B

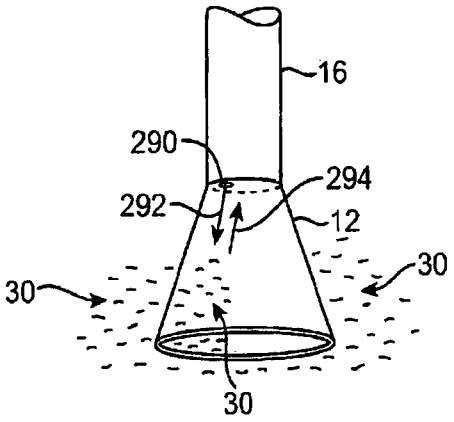

FIG. 23

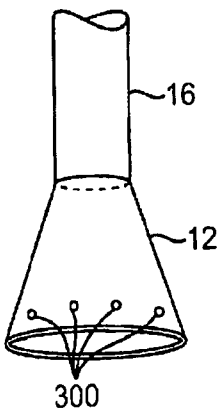

FIG. 24A

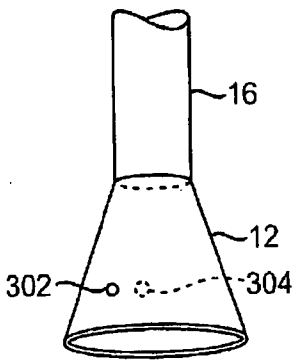

FIG. 24B

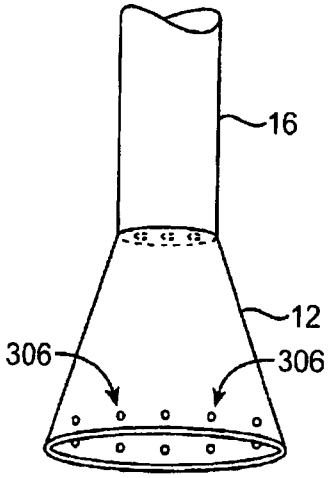

FIG. 25A

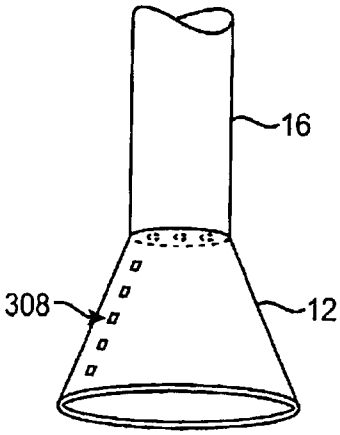

FIG. 25B

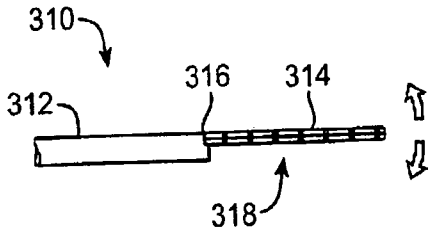

FIG. 26A

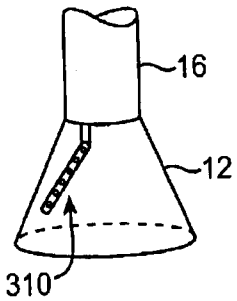

FIG. 26B

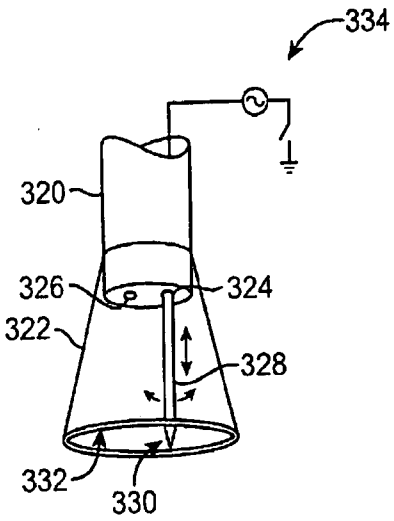

FIG. 27

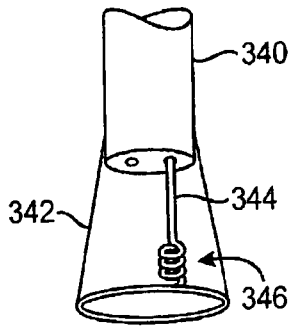

FIG. 28

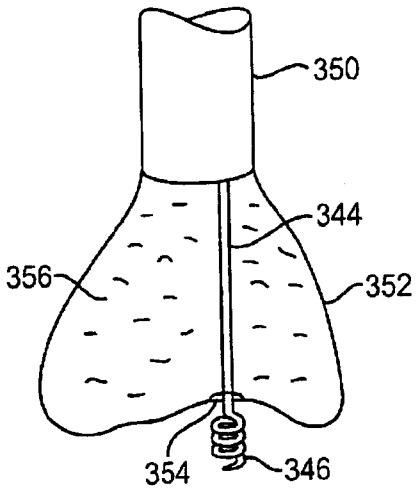

FIG. 29

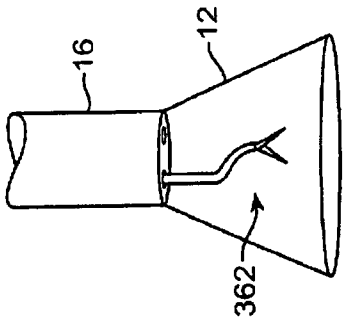

FIG. 30B

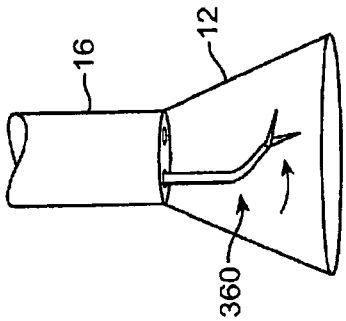

FIG. 30A

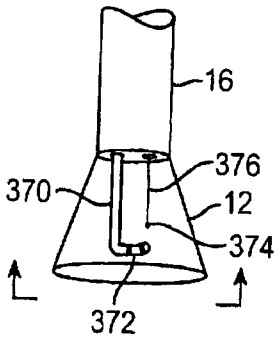

FIG. 31A

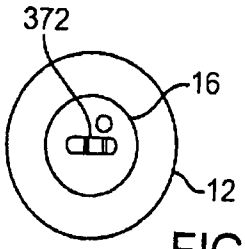

FIG. 31B

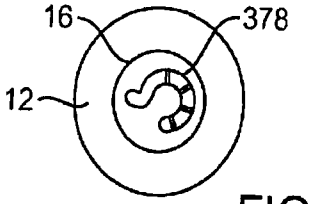

FIG. 31C

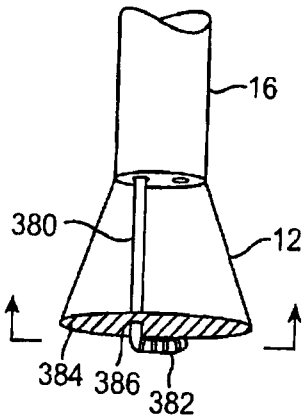

FIG. 32A

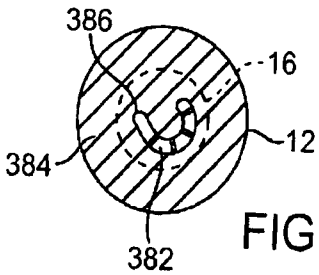

FIG. 32B

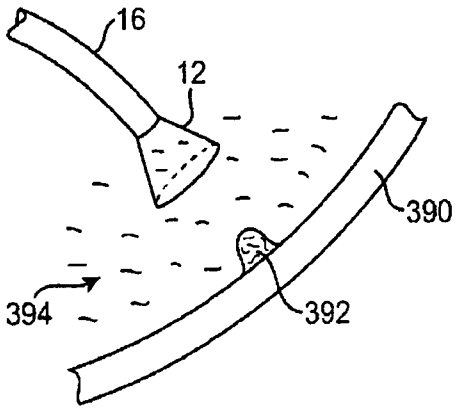

FIG. 33A

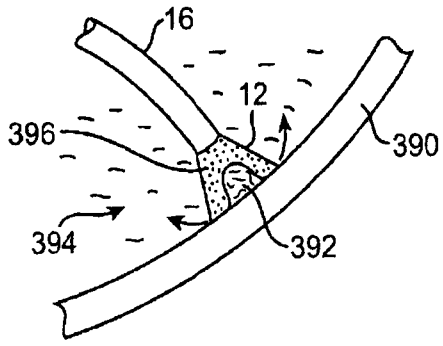

FIG. 33B

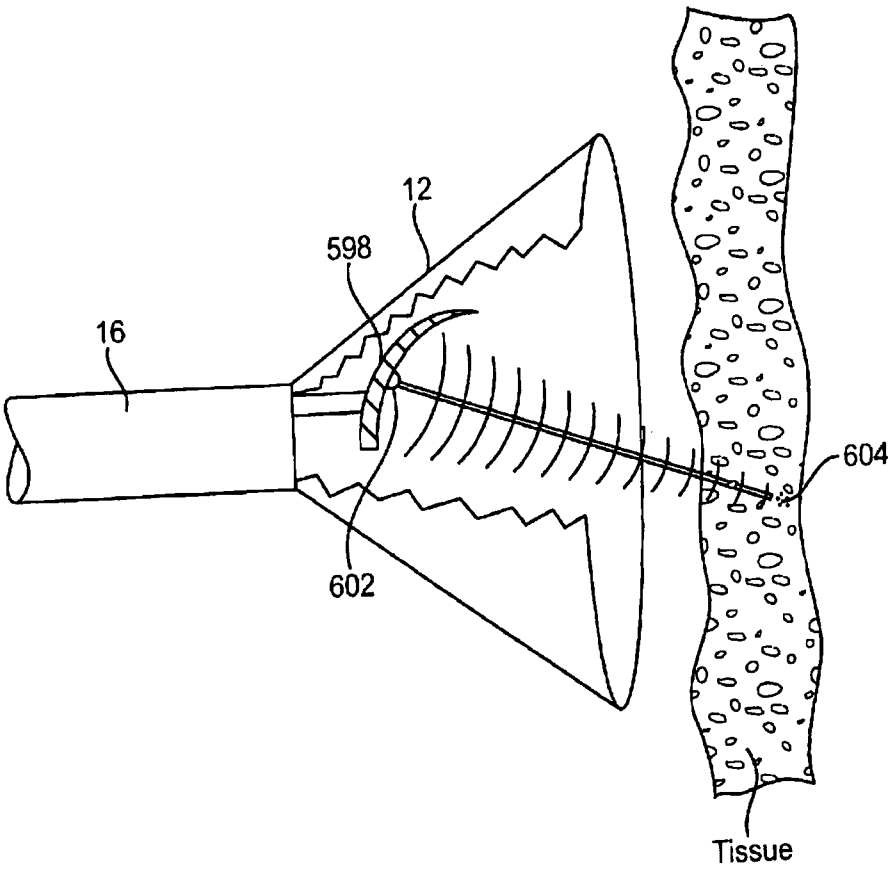

FIG. 33C

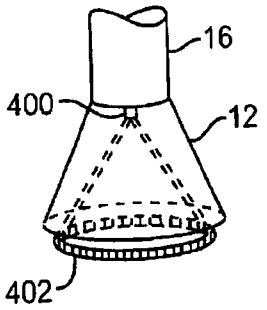

FIG. 34A

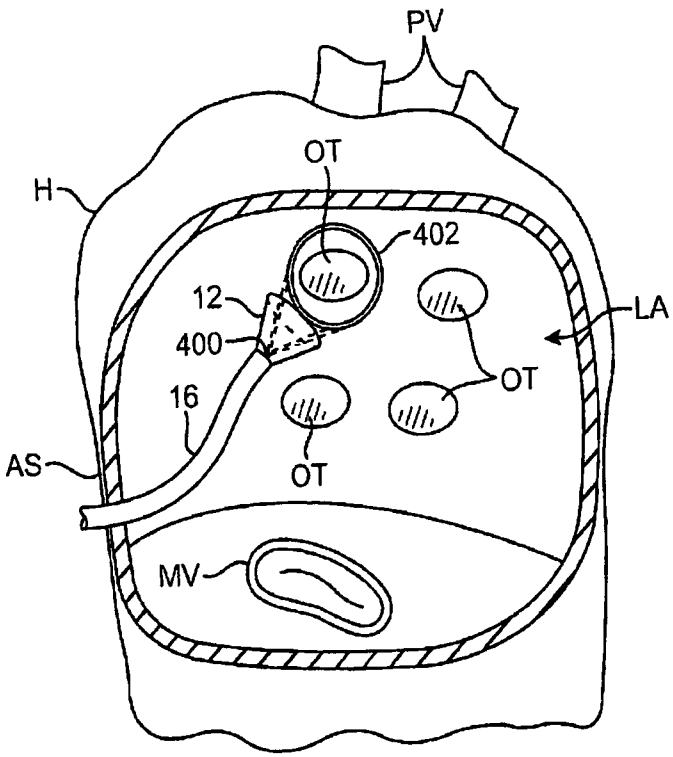

FIG. 34B

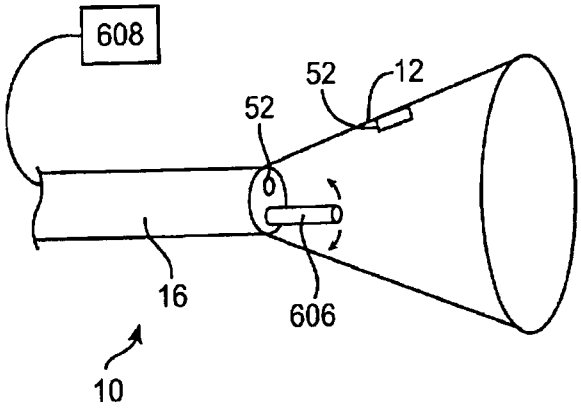

FIG. 34C

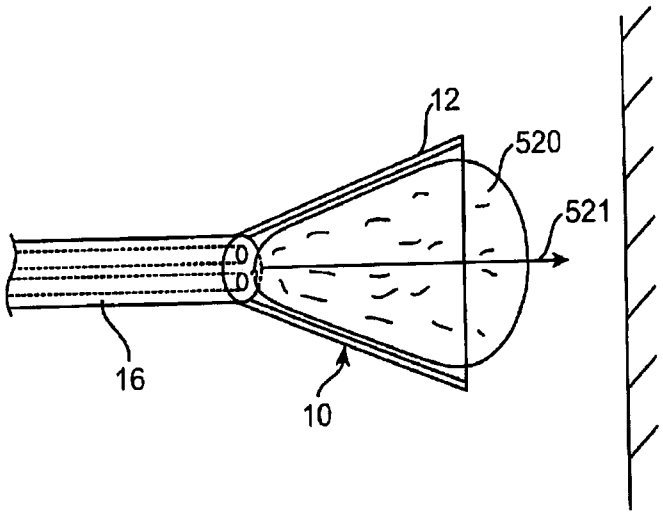

FIG. 34D

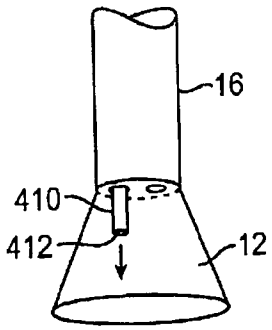

FIG. 35A

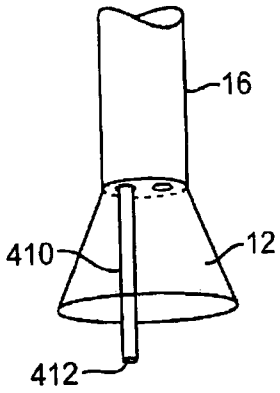

FIG. 35B

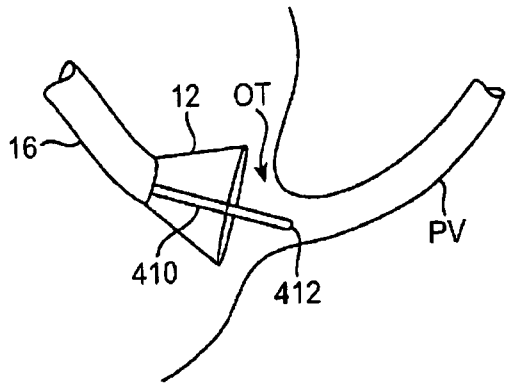

FIG. 35C

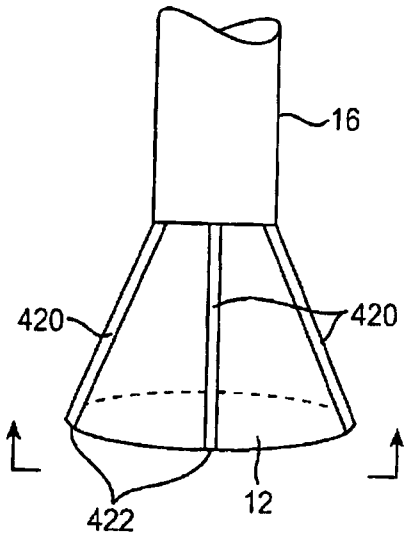

FIG. 36A

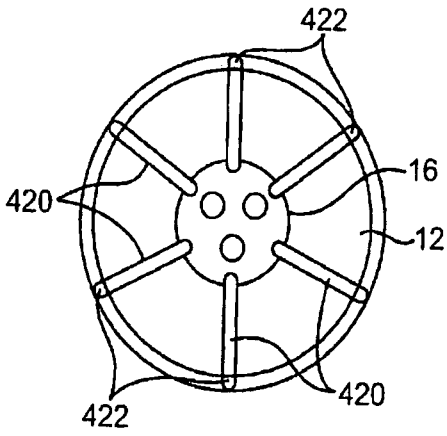

FIG. 36B

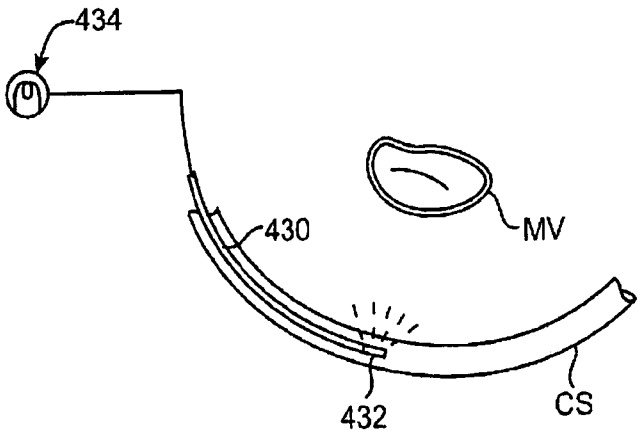

FIG. 37A

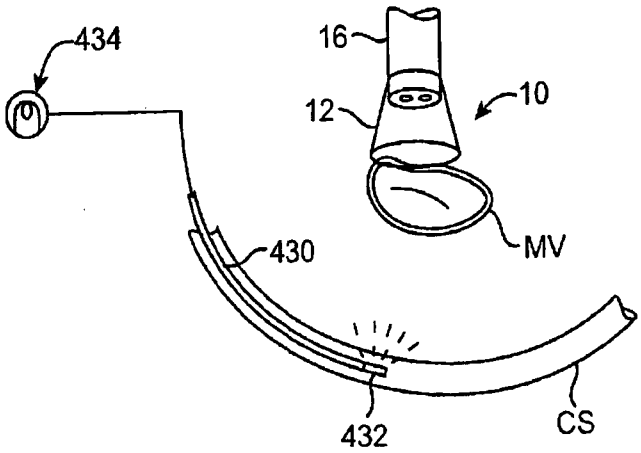

FIG. 37B

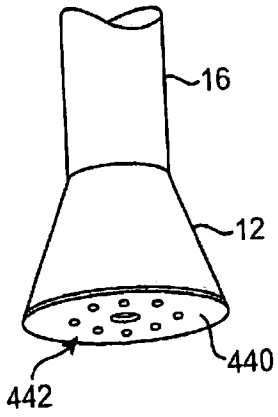

FIG. 38A

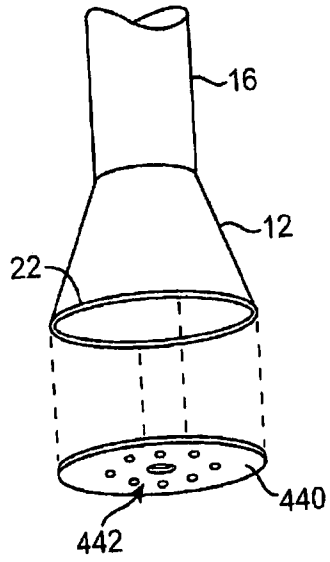

FIG. 38B

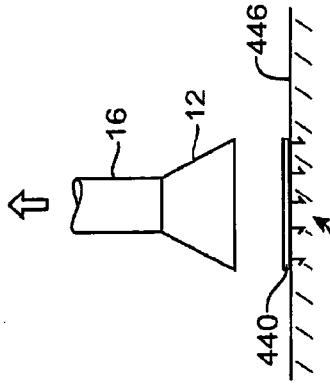

FIG. 39C

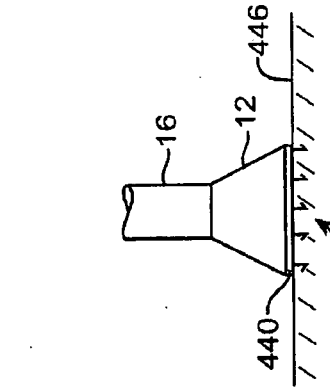

FIG. 39B

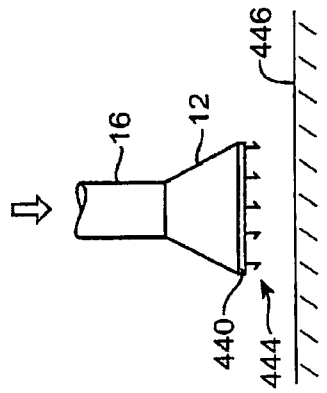

FIG. 39A

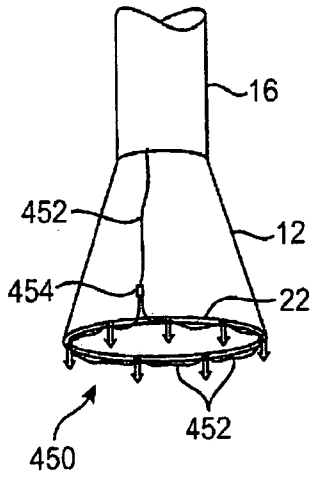

FIG. 40A

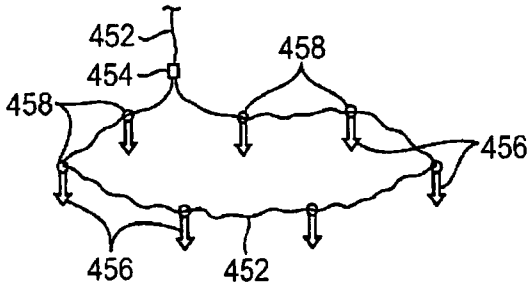

FIG. 40B

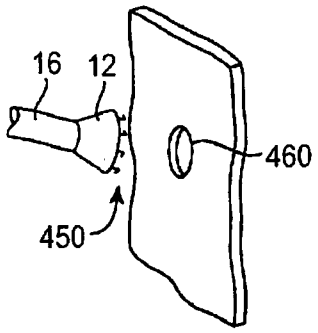

FIG. 41A

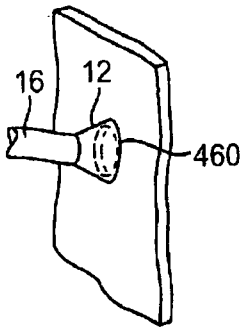

FIG. 41B

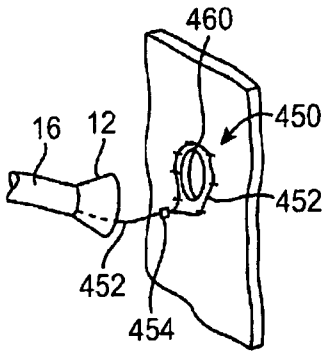

FIG. 41C

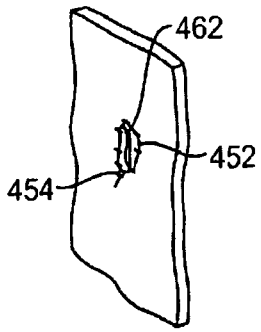

FIG. 41D

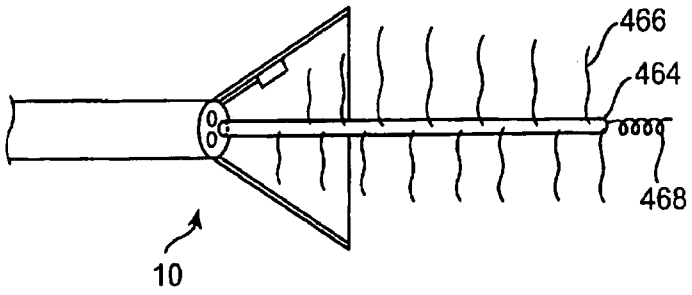

FIG. 41E

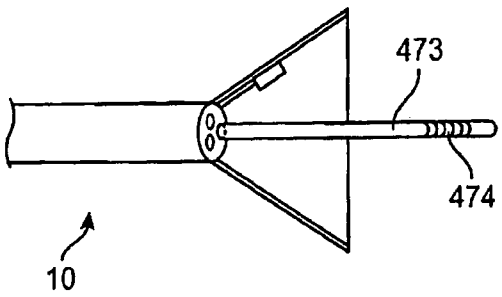

FIG. 41F

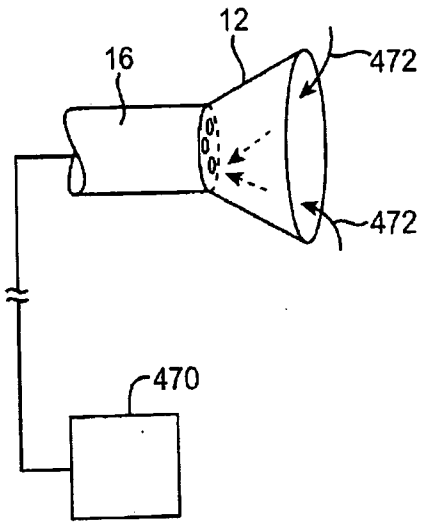

FIG. 42

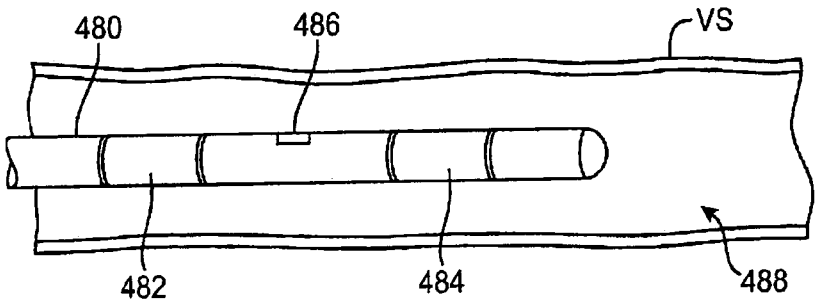

FIG. 43A

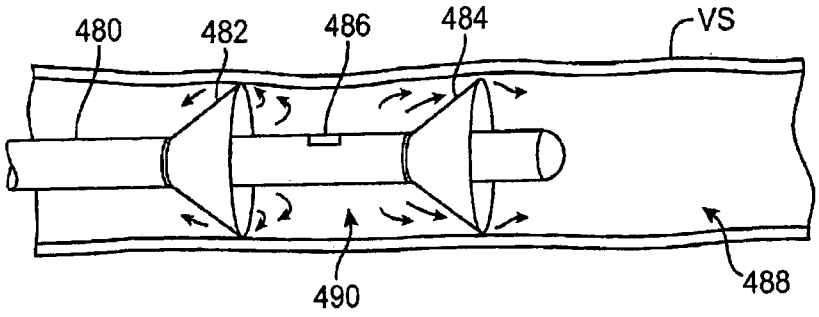

FIG. 43B

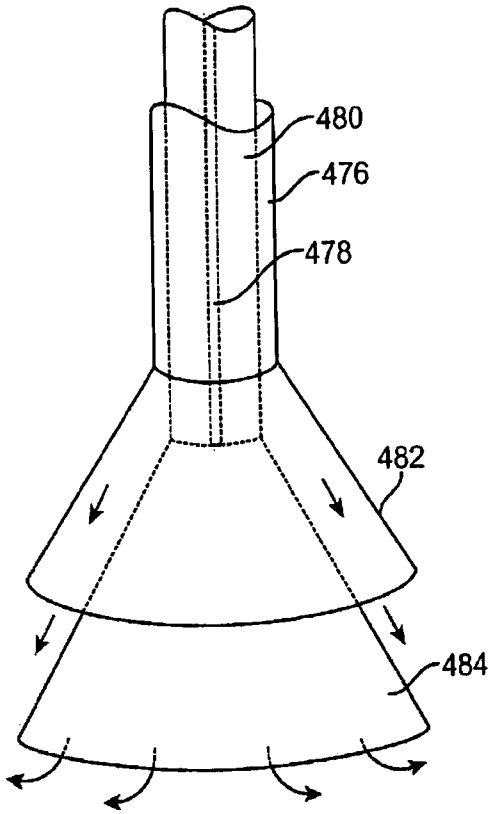

FIG. 43C

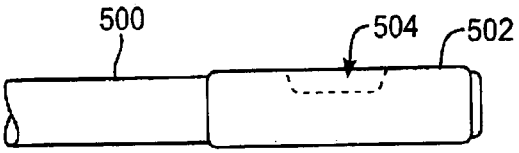

FIG. 44A

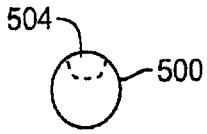

FIG. 44B

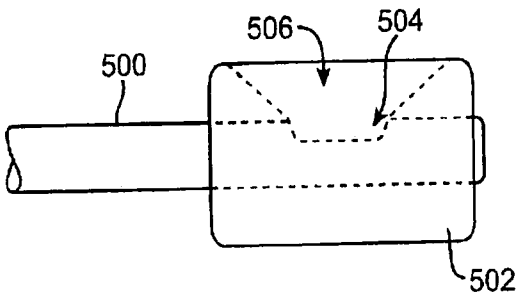

FIG. 45A

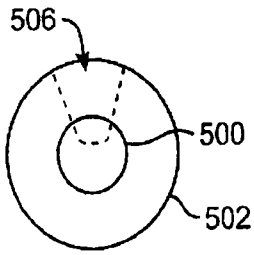

FIG. 45C

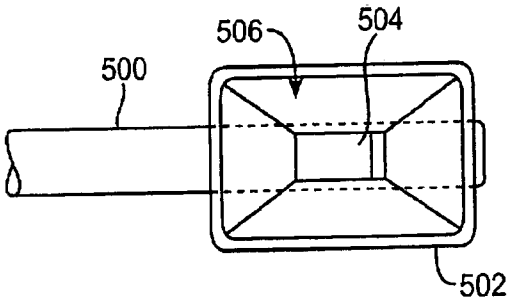

FIG. 45B

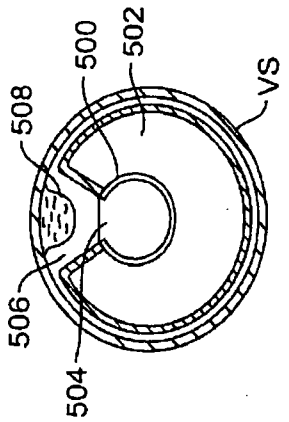

FIG. 46B

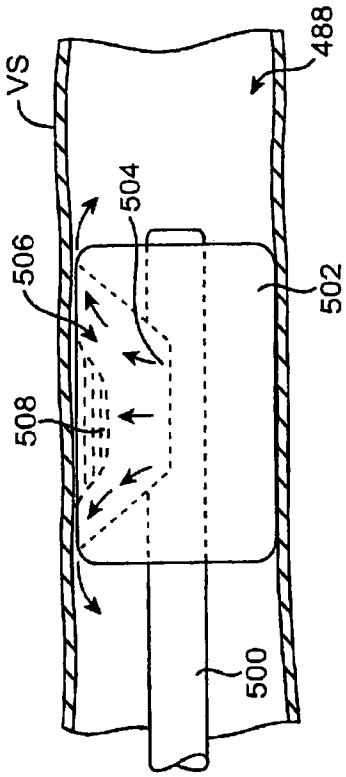

FIG. 46A

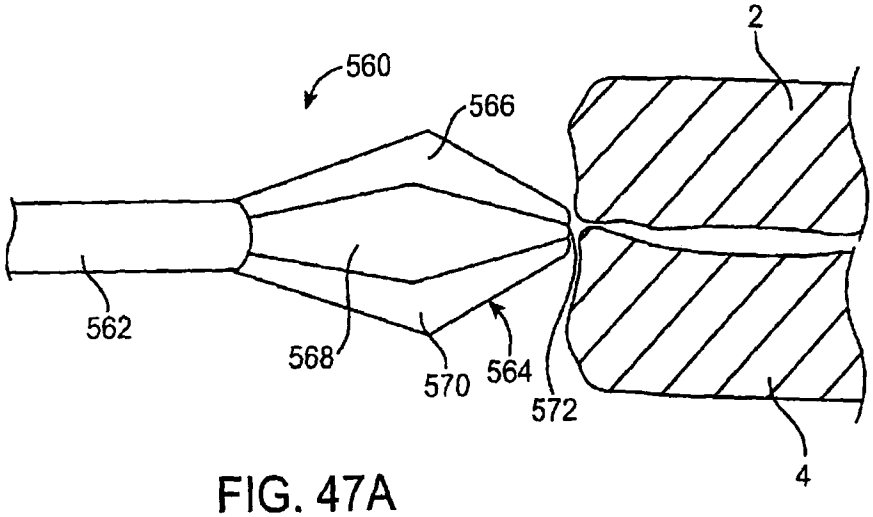

FIG. 47A

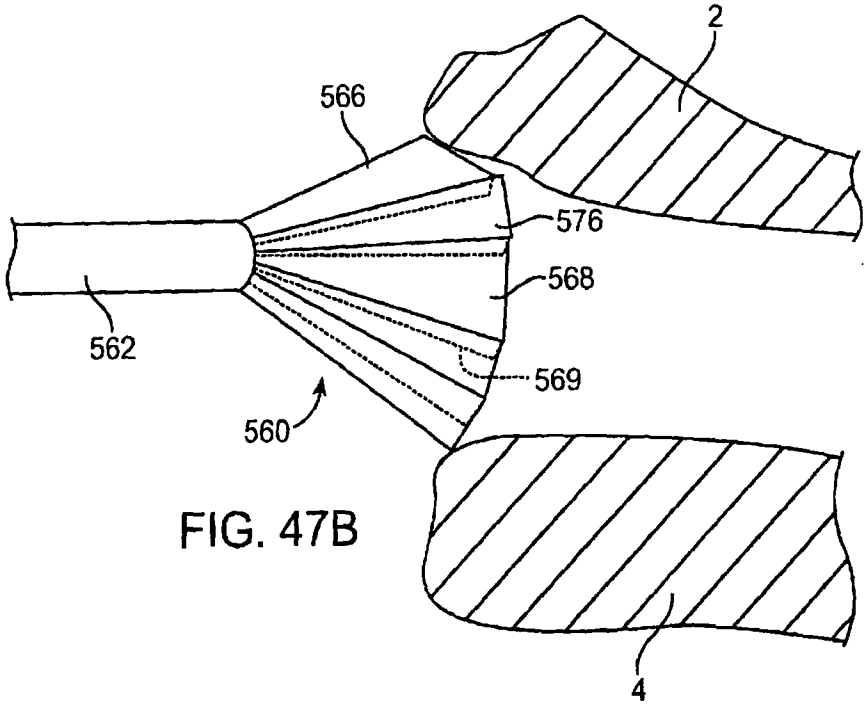

FIG. 47B

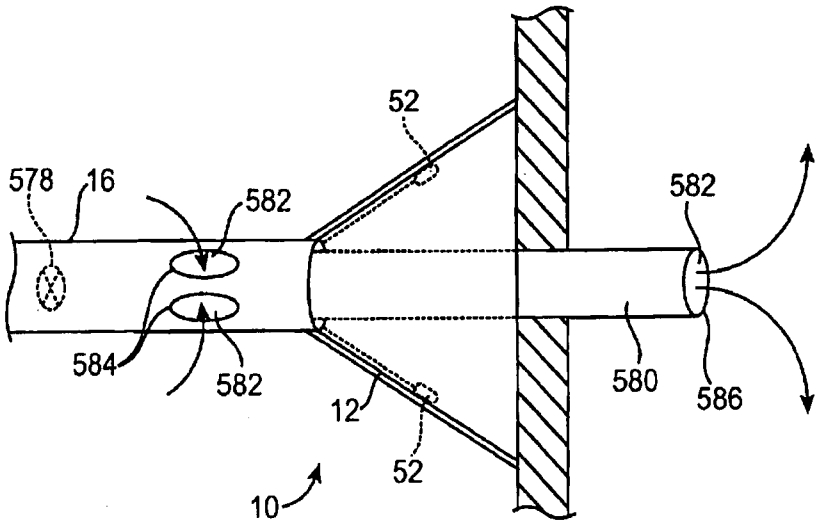

FIG. 48A

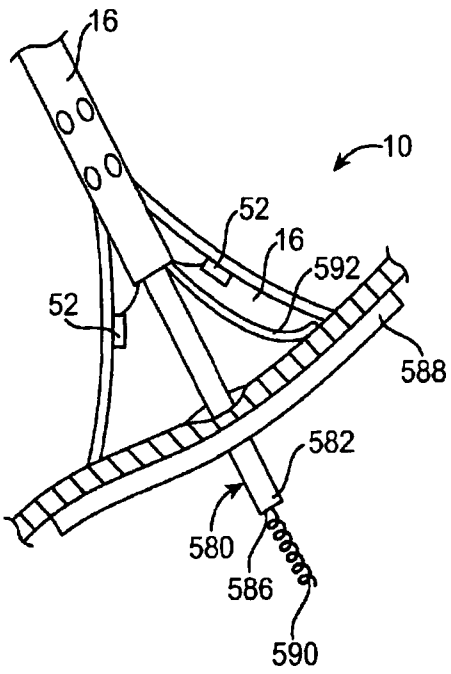

FIG. 48C

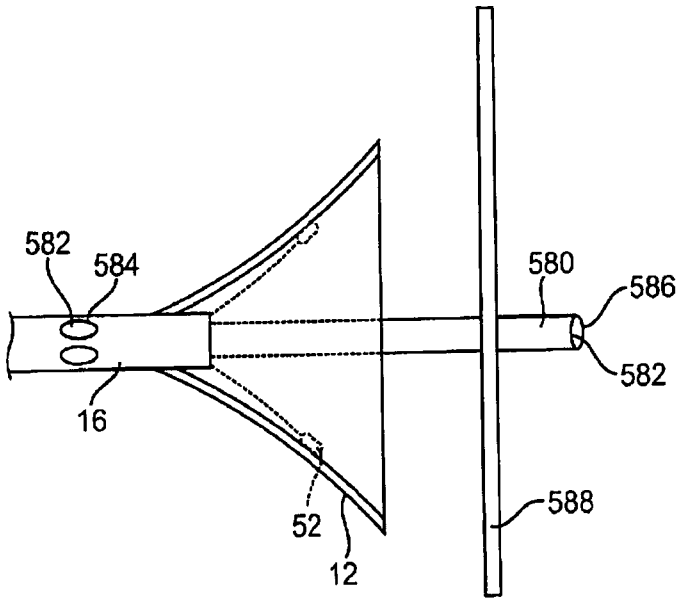

FIG. 48B

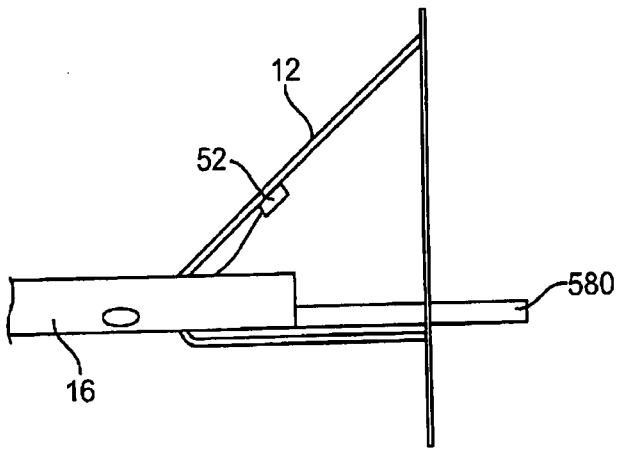

FIG. 48D

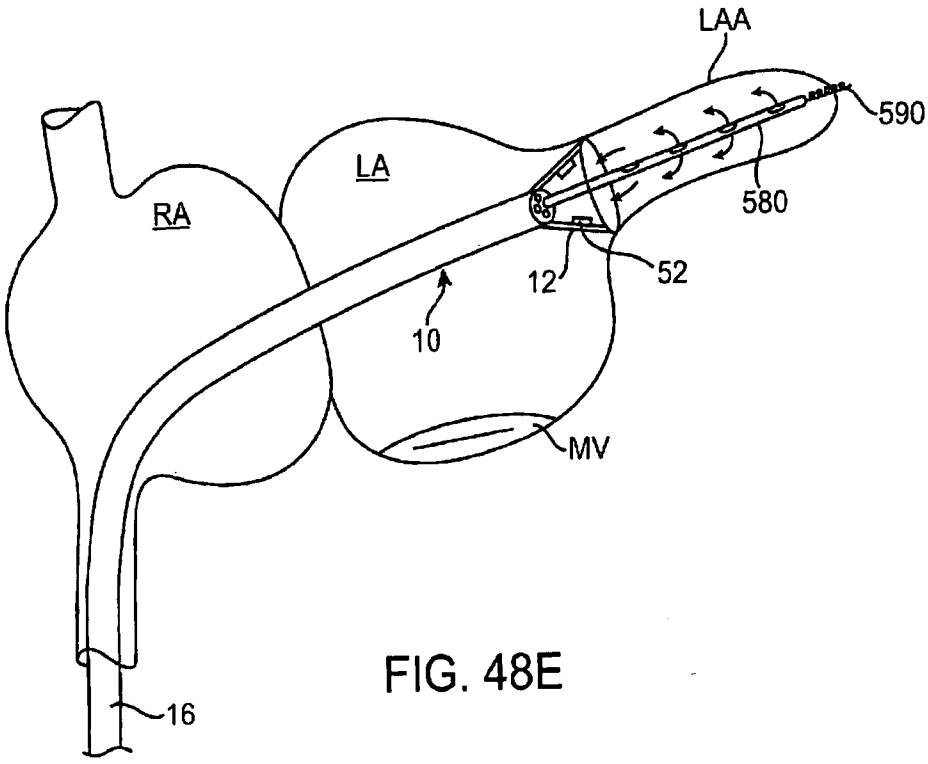

FIG. 48E

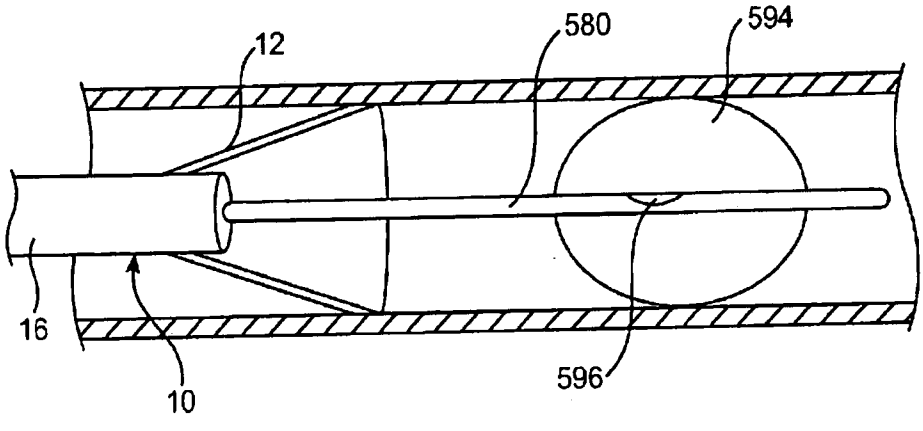

FIG. 48F

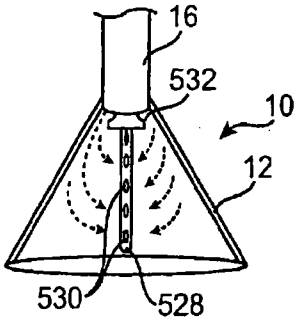

FIG. 49A

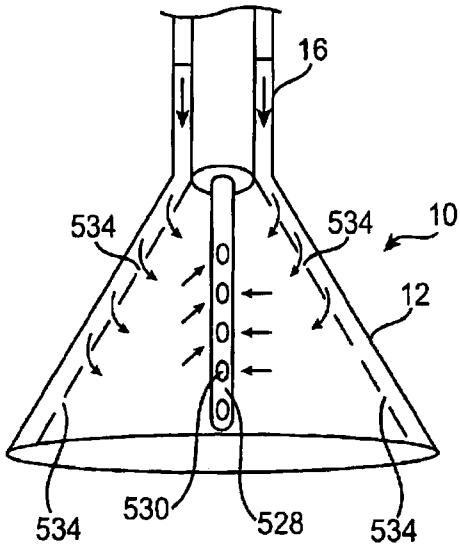

FIG. 49B

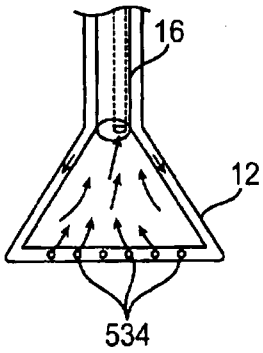

FIG. 49C

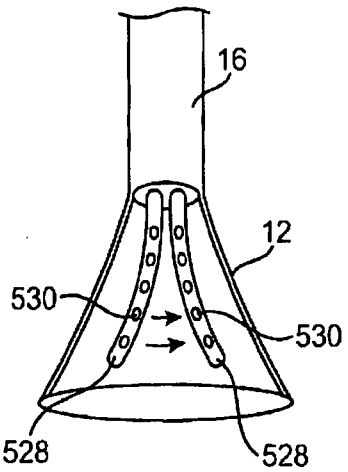

FIG. 49E

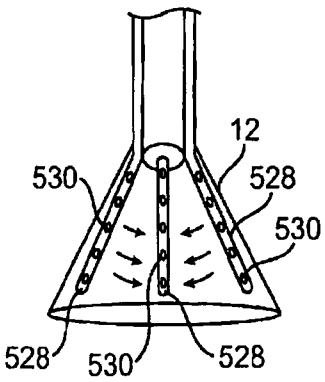

FIG. 49D

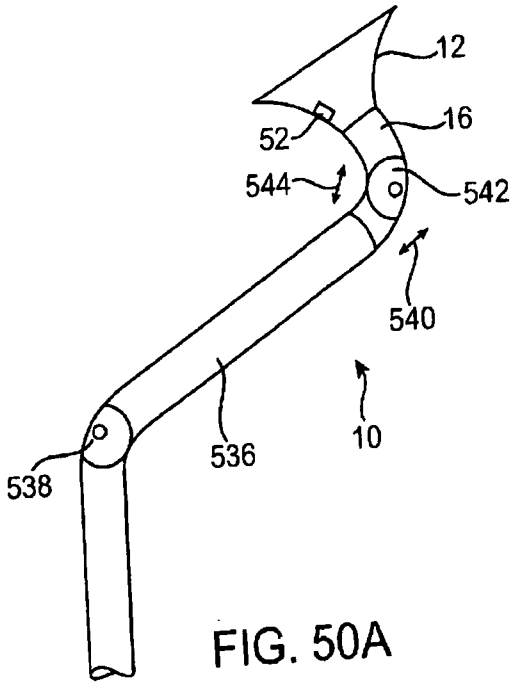

FIG. 50A

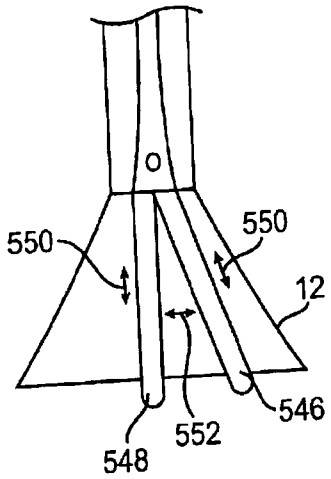

FIG. 50B

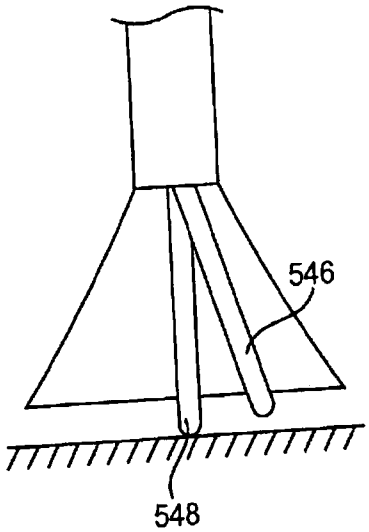

FIG. 50C