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(54) **DELIVERY OF BIOLOGICAL COMPOUNDS TO ISCHEMIC AND/OR INFARCTED TISSUE**

(71) Applicant: **Intuitive Surgical Operations, Inc.**, Sunnyvale, CA (US)

(72) Inventors: **Vahid Saadat**, Atherton, CA (US); **Sekhar S. Rao**, Austin, TX (US)

(73) Assignee: **Intuitive Surgical Operations, Inc.**, Sunnyvale, CA (US)

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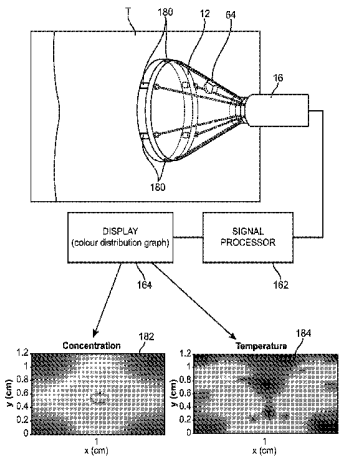
(57) **ABSTRACT**

The delivery of biological compounds to ischemic and/or infarcted tissue are described herein where 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 performing any number of procedures on the tissue for identifying, locating, and/or accessing ischemic and/or infarcted tissue.

18 Claims, 22 Drawing Sheets



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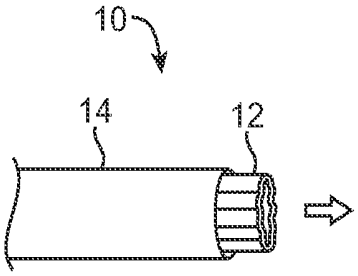


FIG. 1A

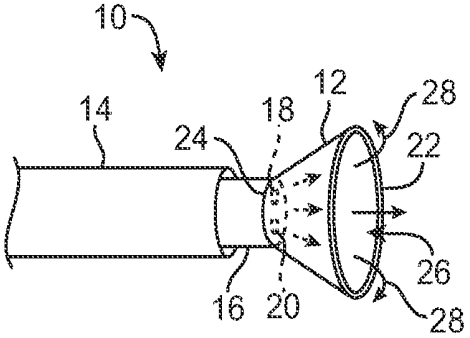


FIG. 1B

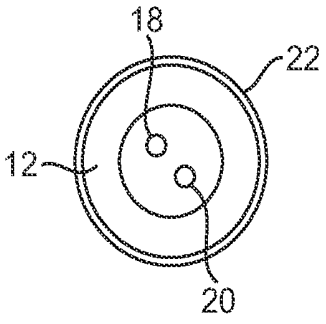


FIG. 1C

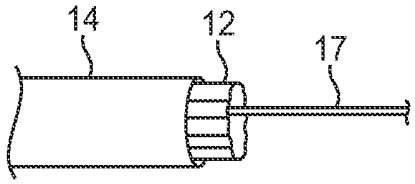


FIG. 1D

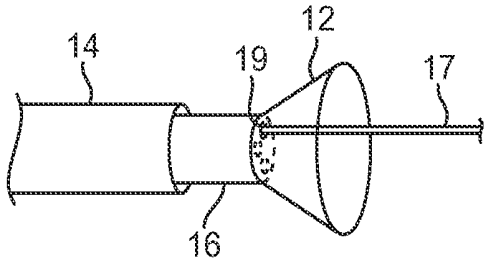


FIG. 1E

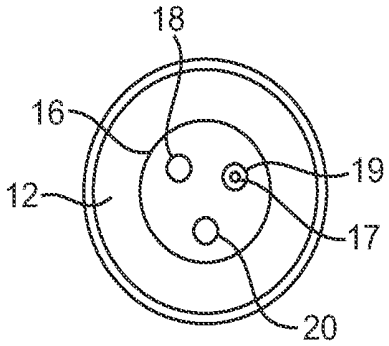


FIG. 1F

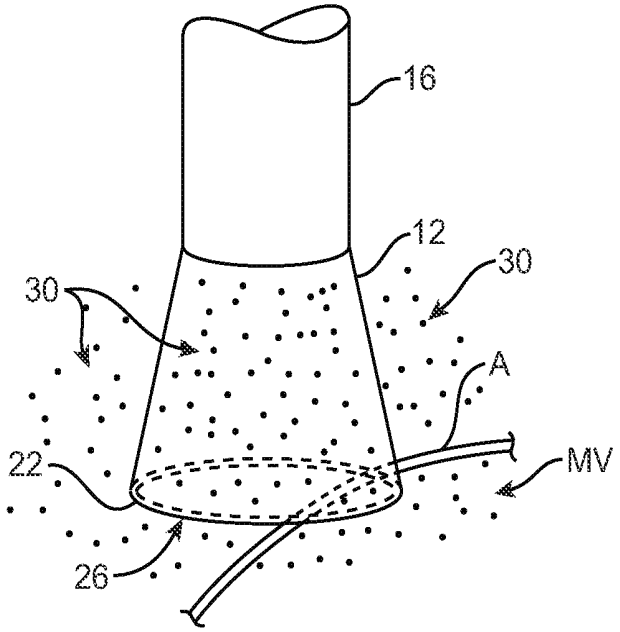


FIG. 2A

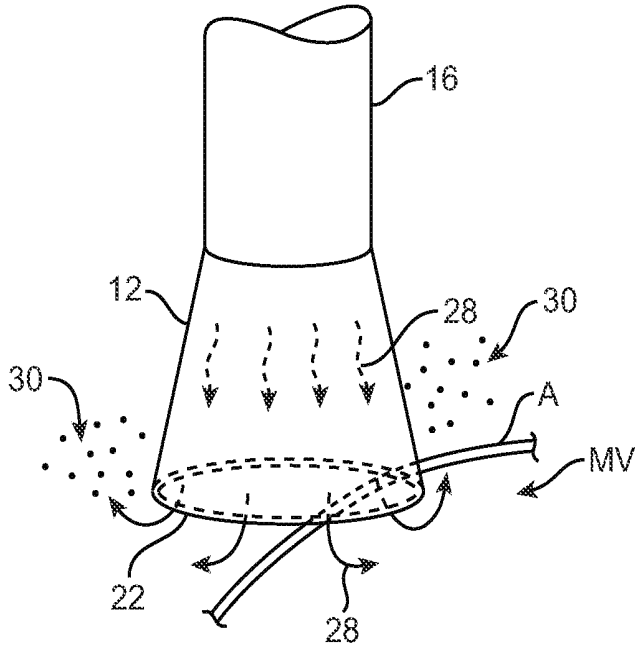


FIG. 2B

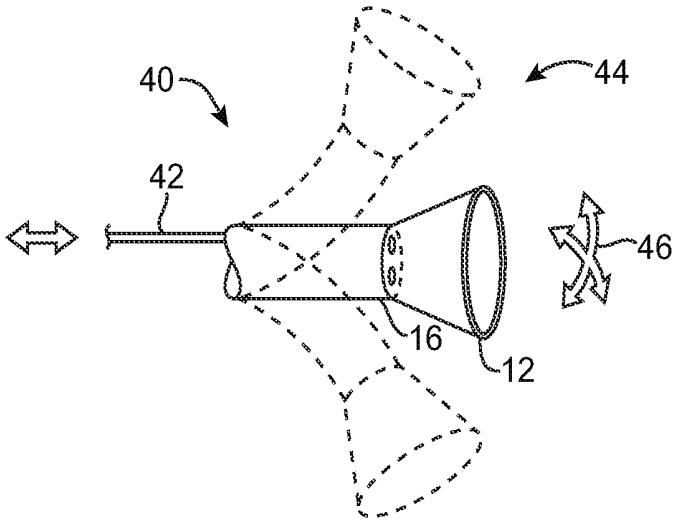


FIG. 3A

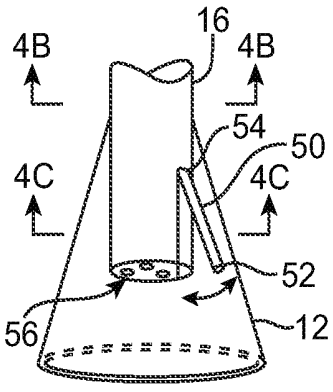


FIG. 4A

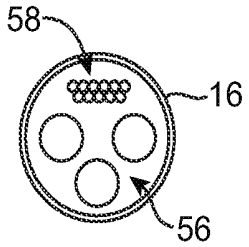


FIG. 4B

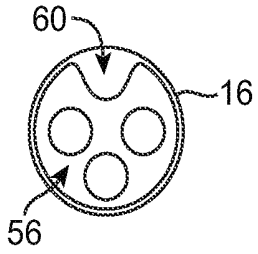


FIG. 4C

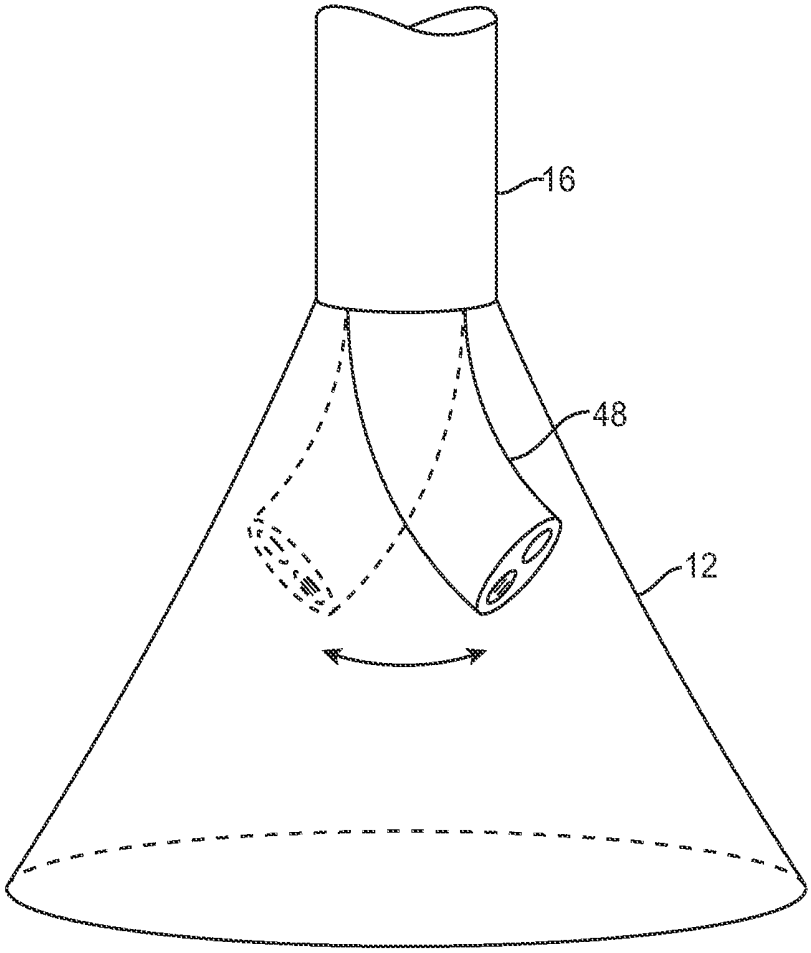


FIG. 3B

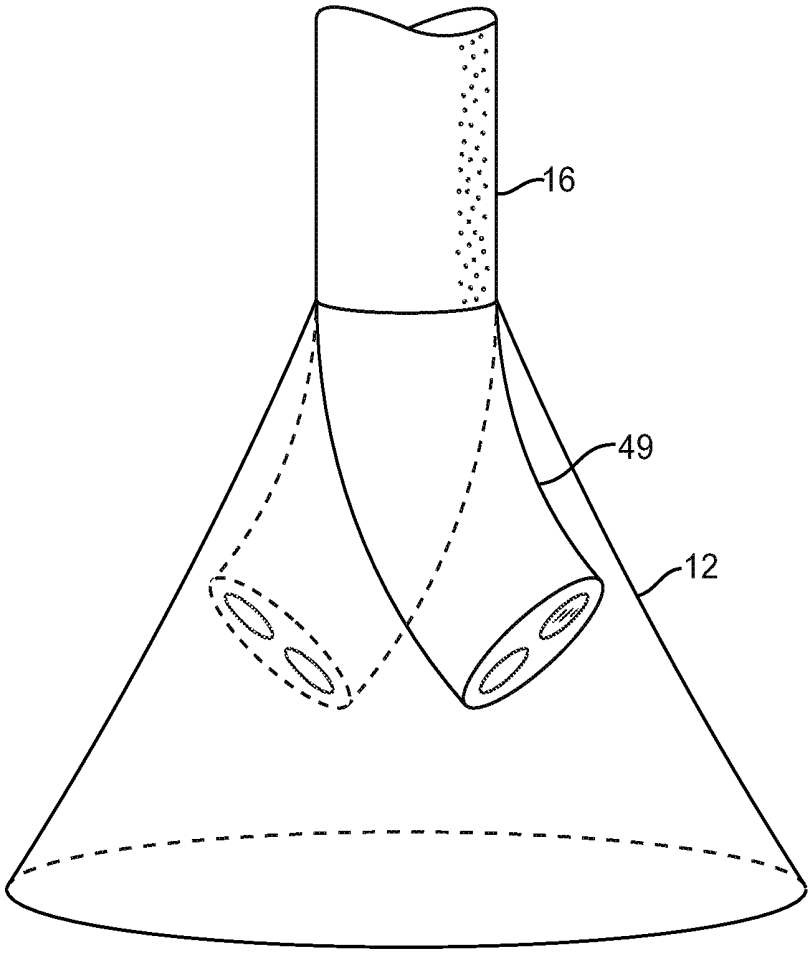


FIG. 3C

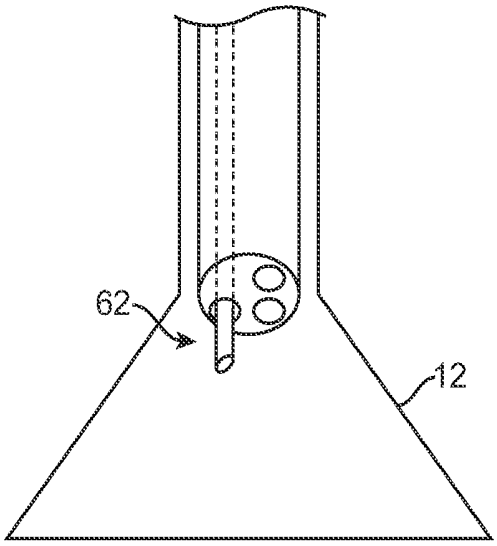


FIG. 5A

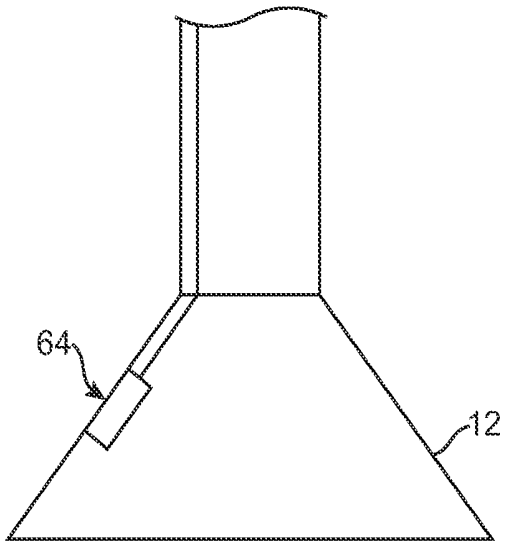


FIG. 5B

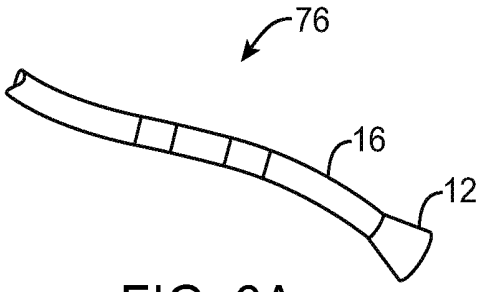


FIG. 6A

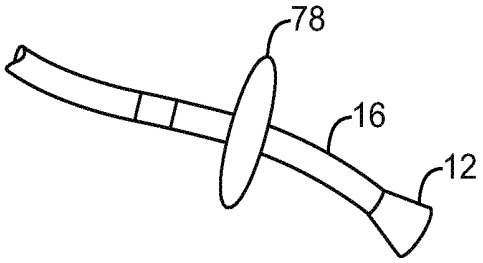


FIG. 6B

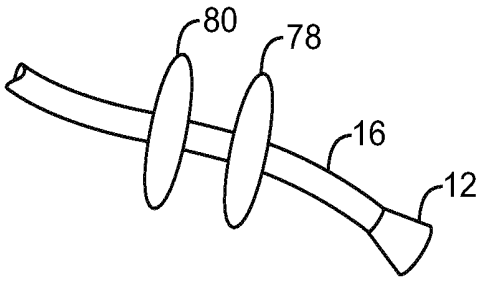


FIG. 6C

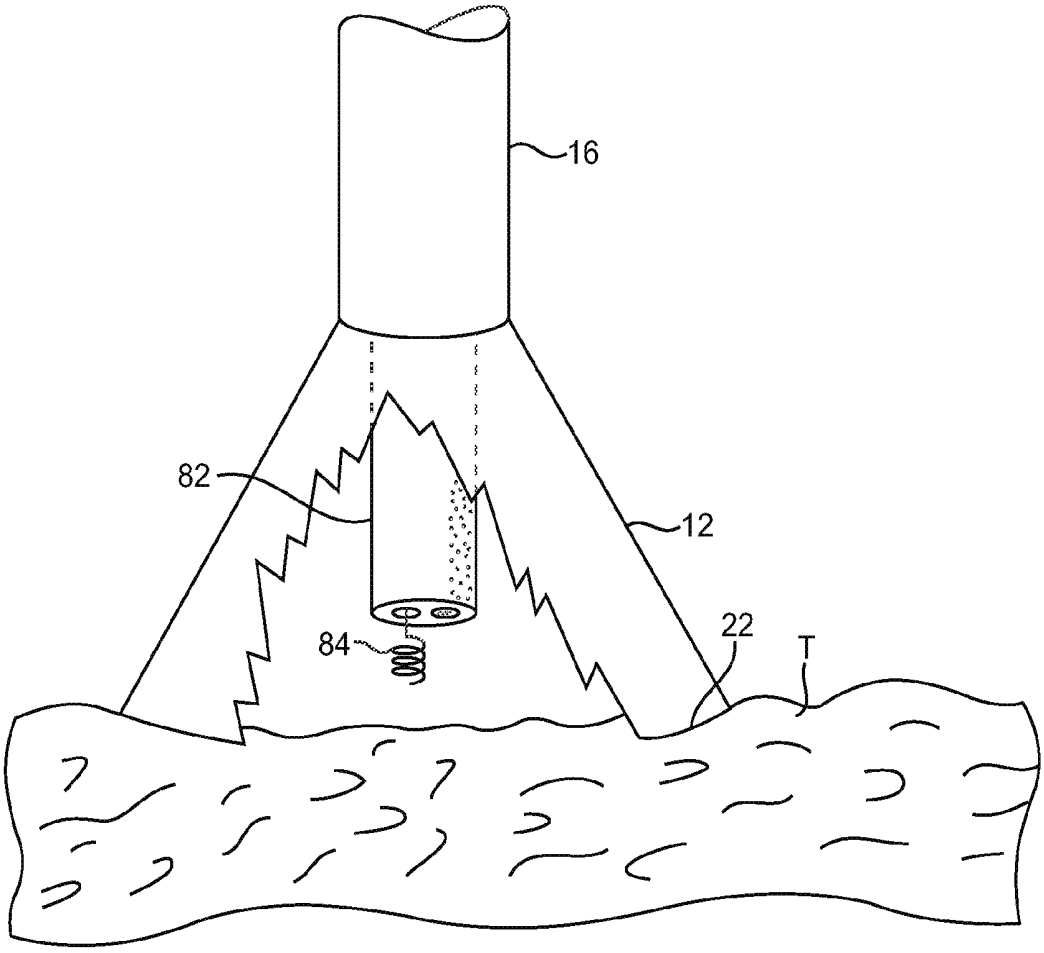


FIG. 7A

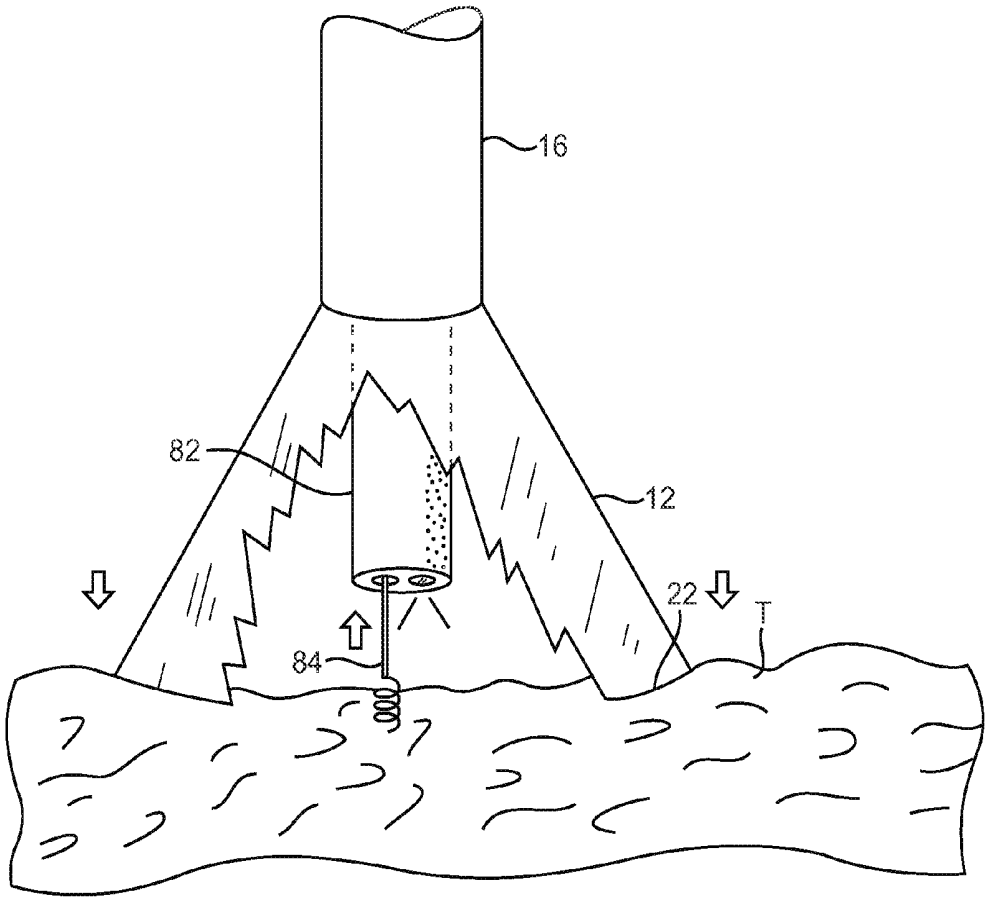


FIG. 7B

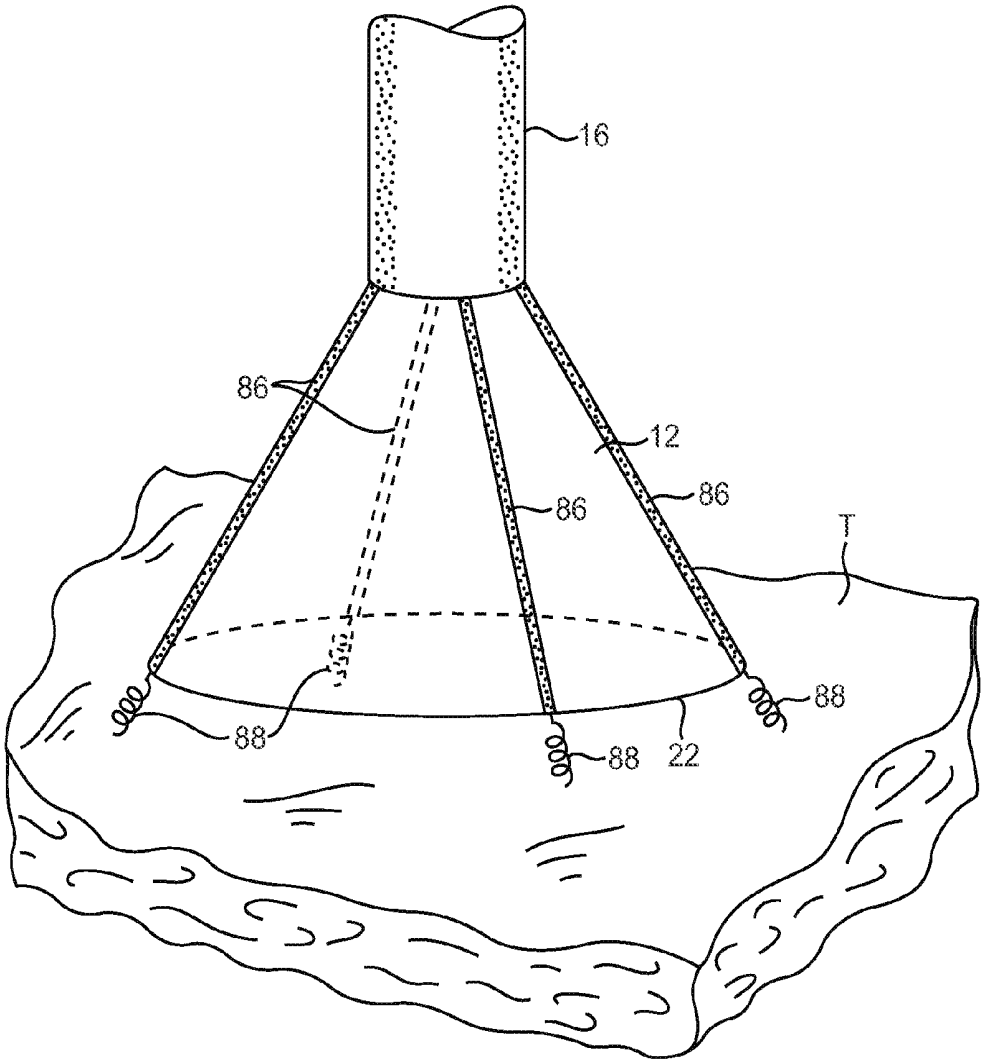


FIG. 7C

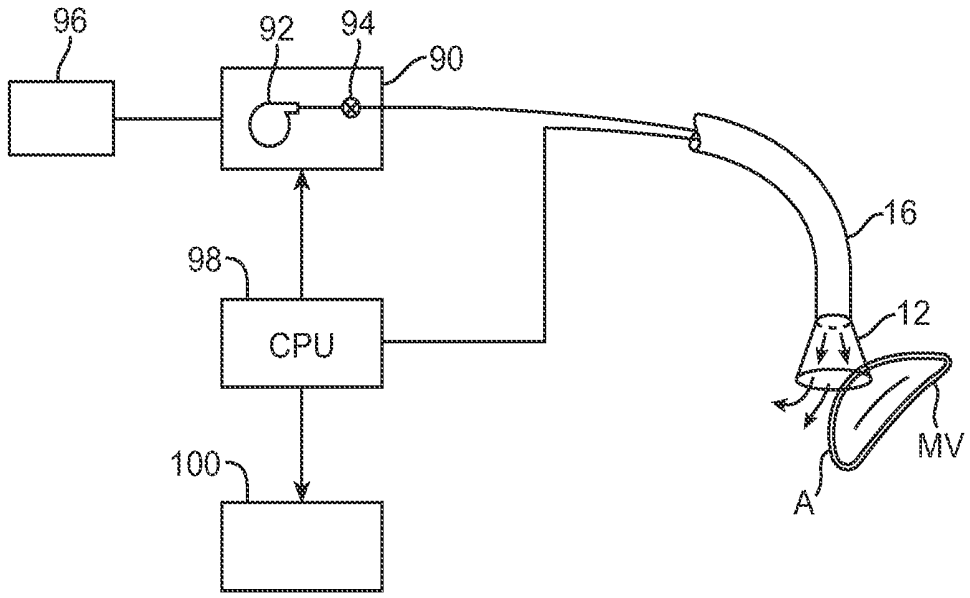


FIG. 8A

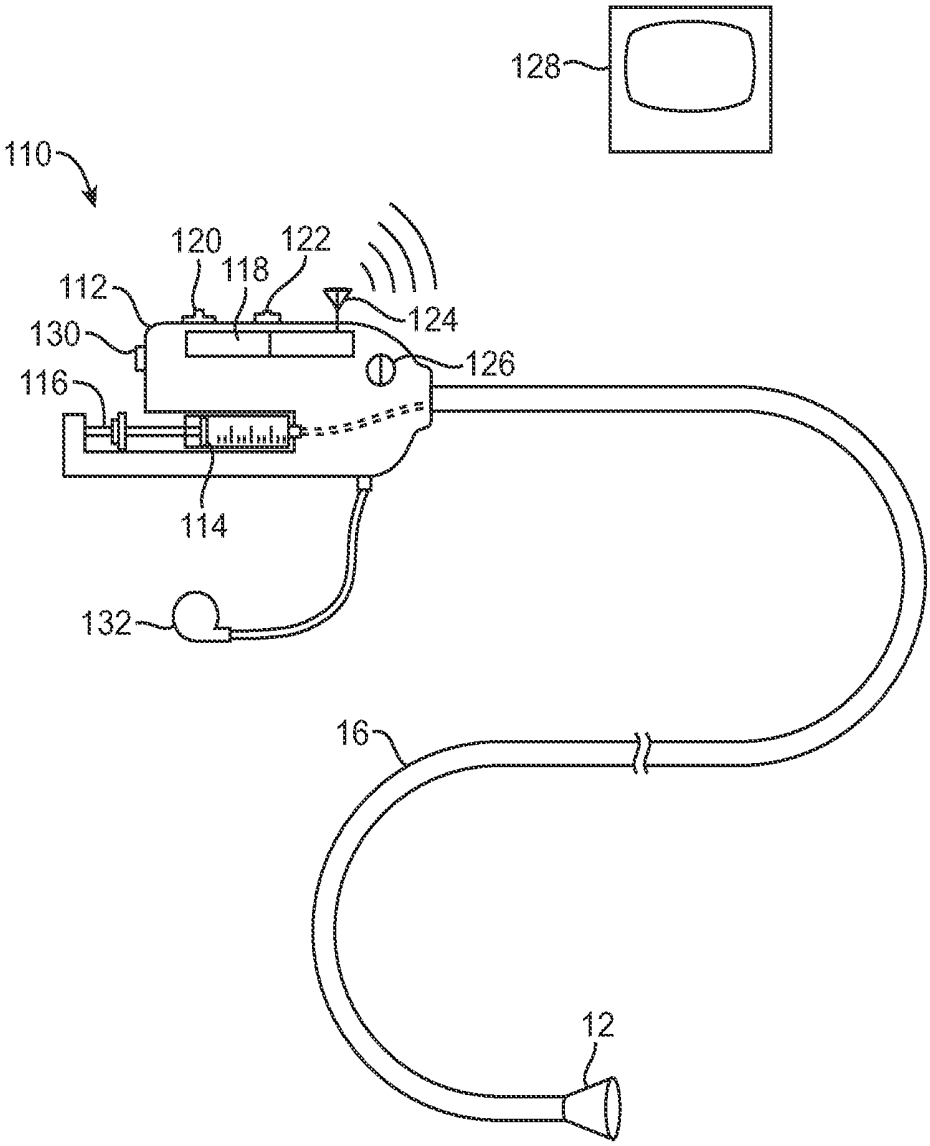


FIG. 8B

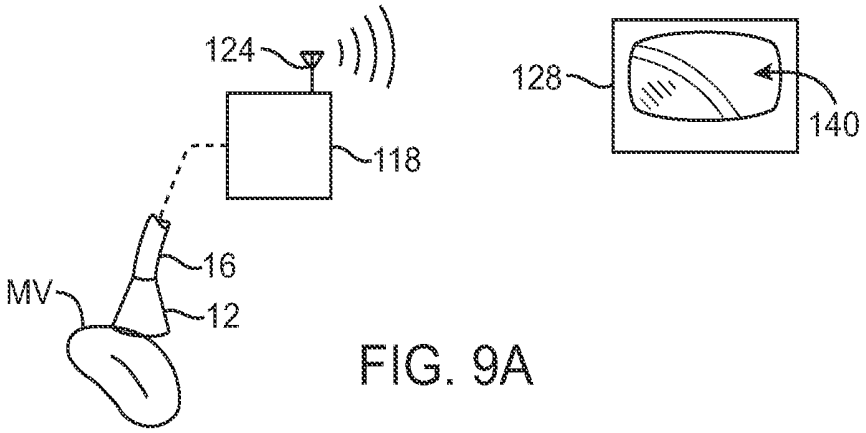


FIG. 9A

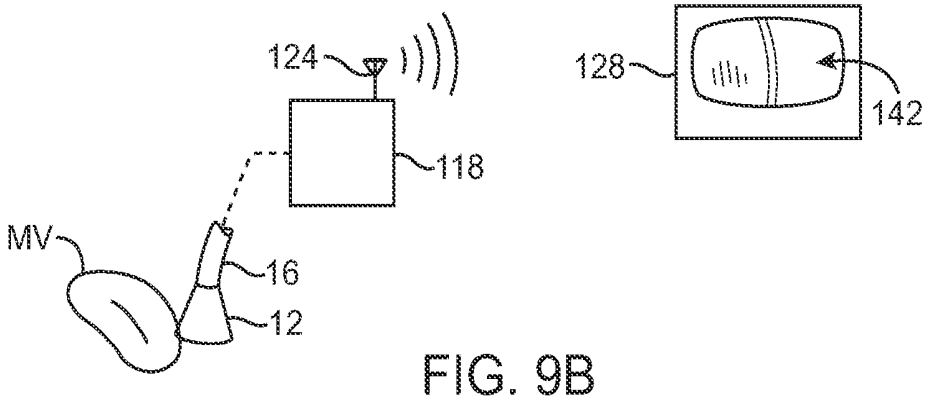


FIG. 9B

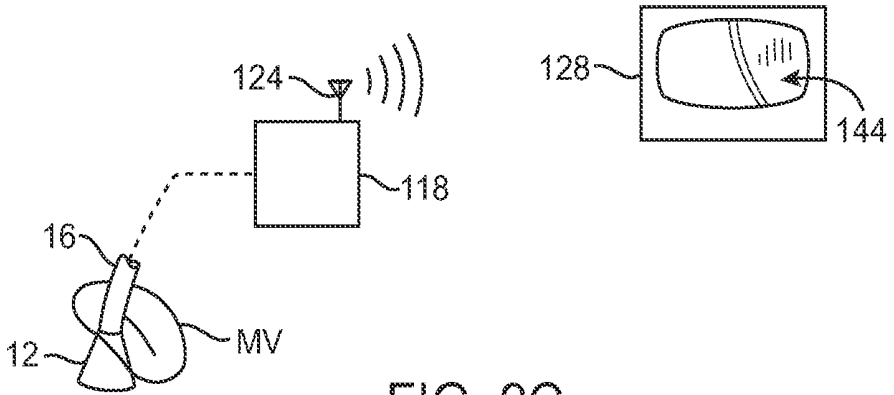


FIG. 9C

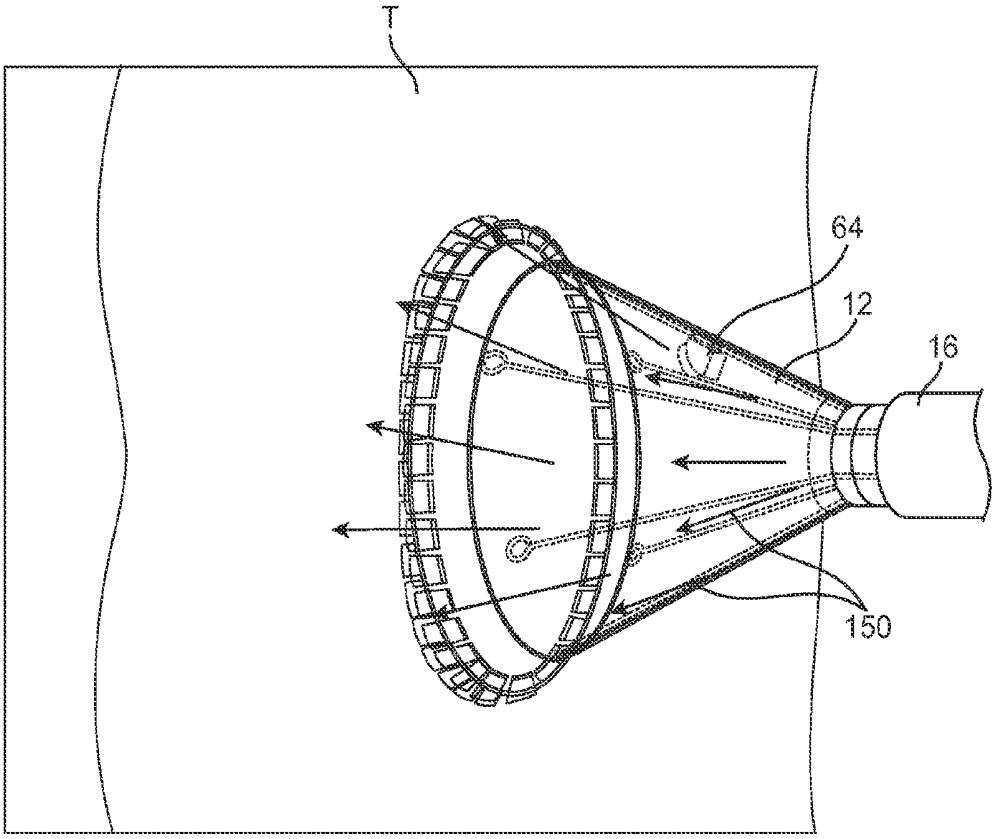


FIG. 10

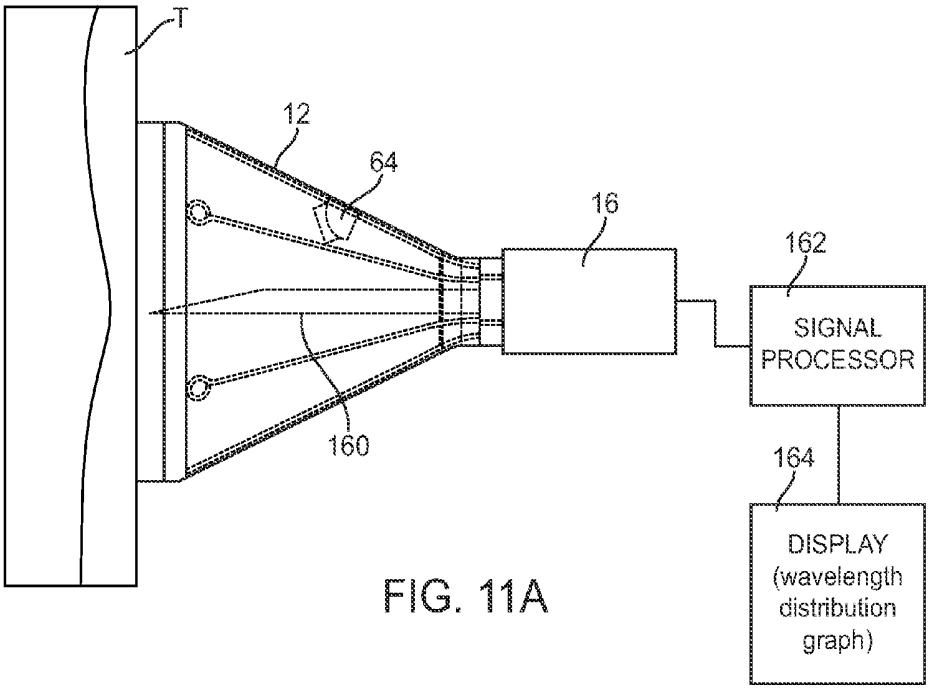


FIG. 11A

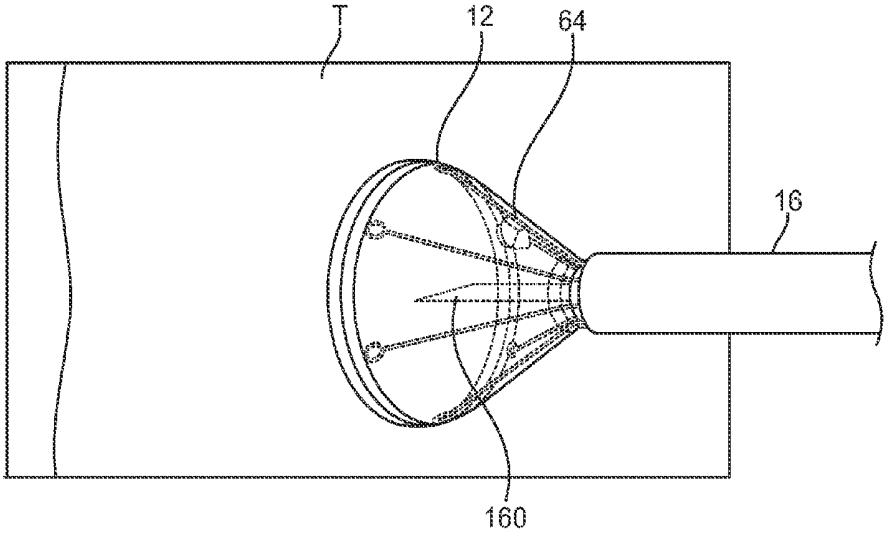
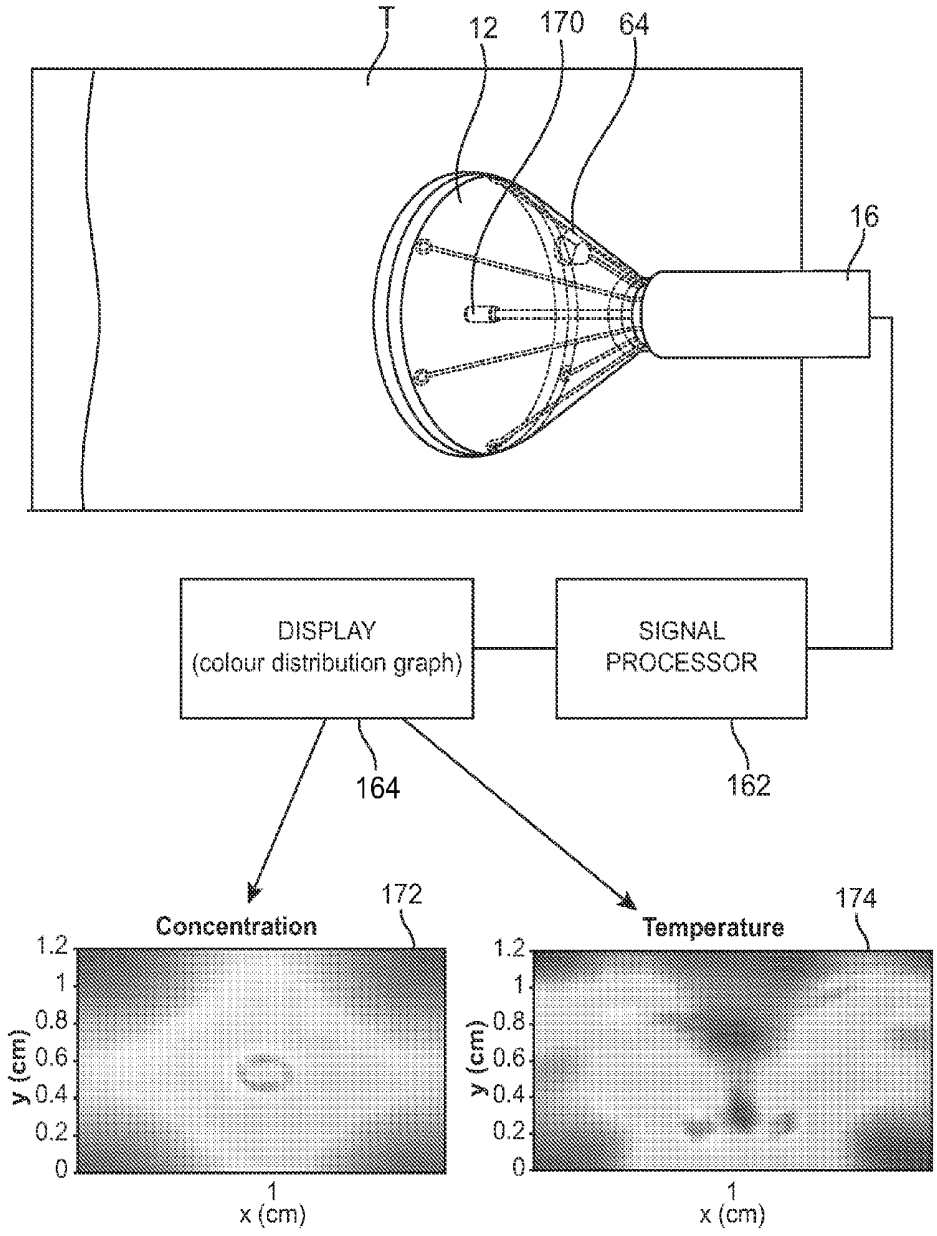


FIG. 11B


T
12
170
64
16
DISPLAY
(colour distribution graph)
SIGNAL
PROCESSOR
164
162
172
Concentration
174
Temperature
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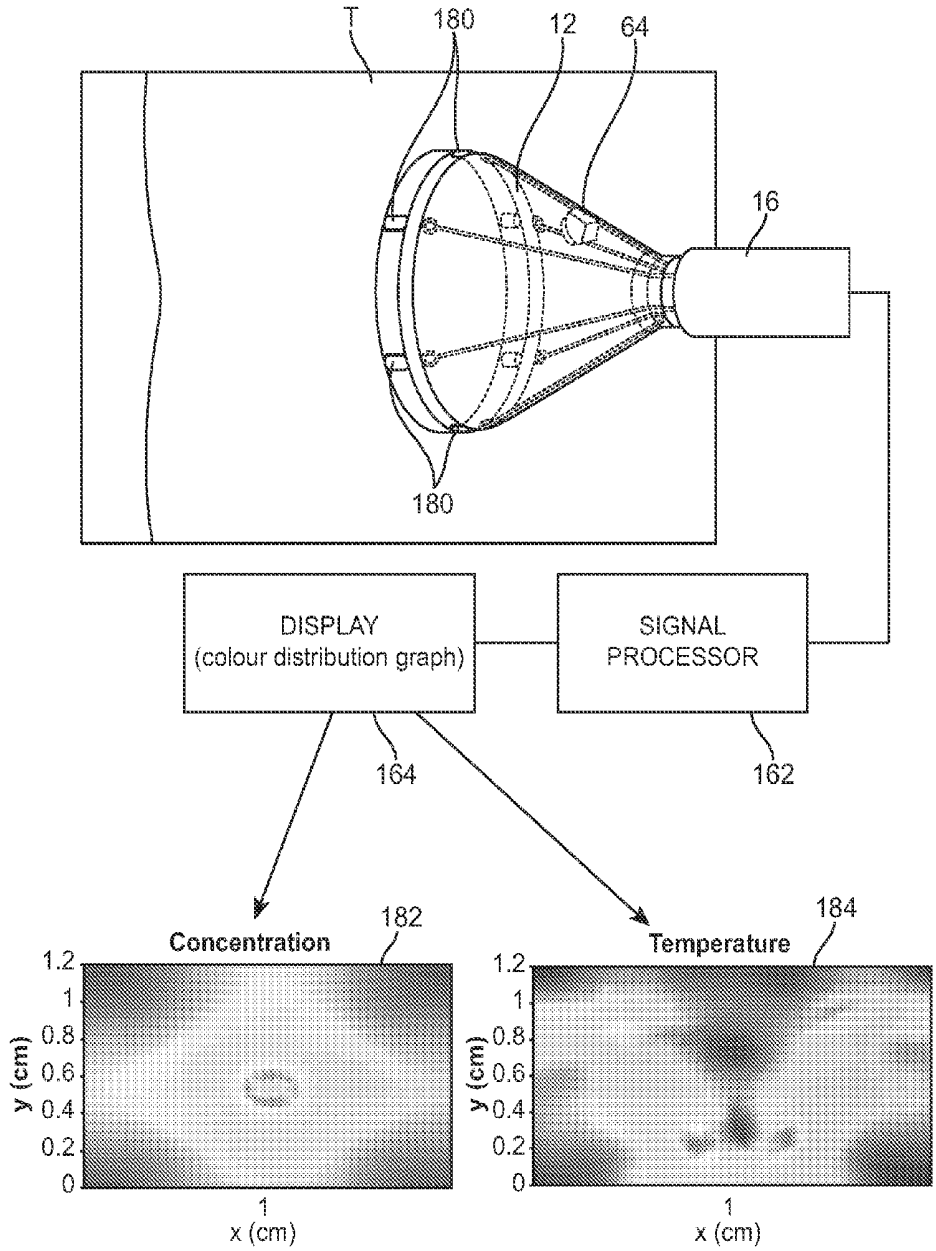
1
0.8
0.6
0.4
0.2
0
y (cm)
1
x (cm)

FIG. 12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64
16
180
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(colour distribution graph)
SIGNAL
PROCESSOR
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162
182
Concentration
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x (cm)

FIG. 13

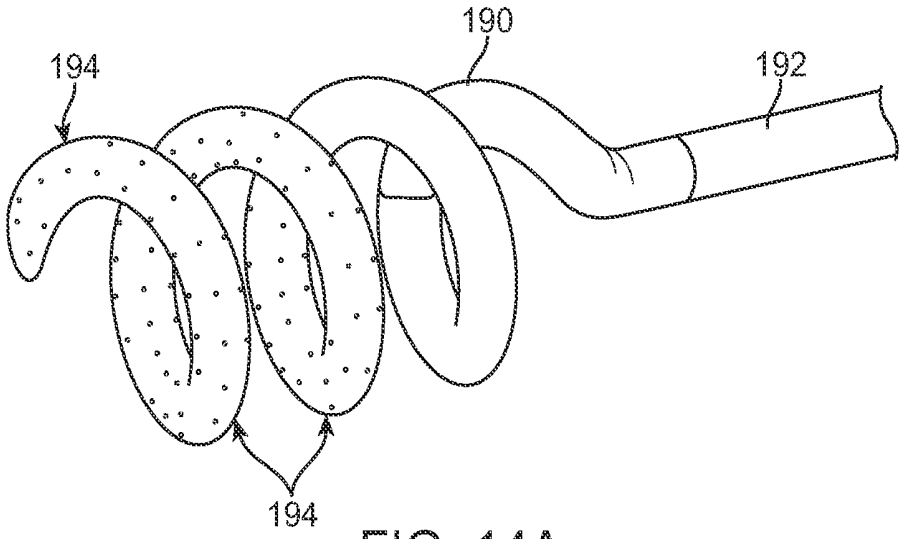

FIG. 14A

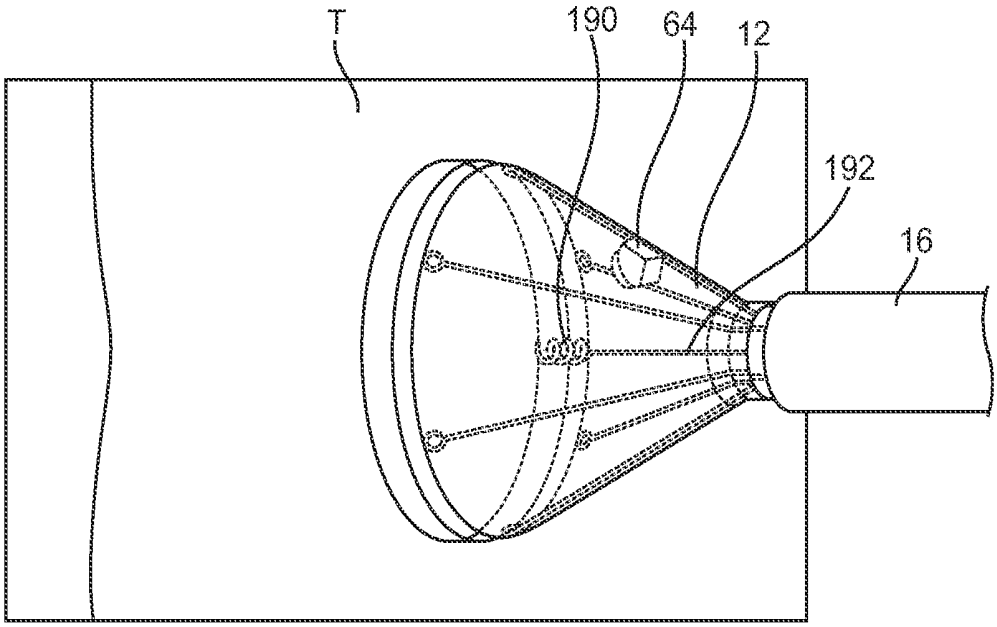

FIG. 14B

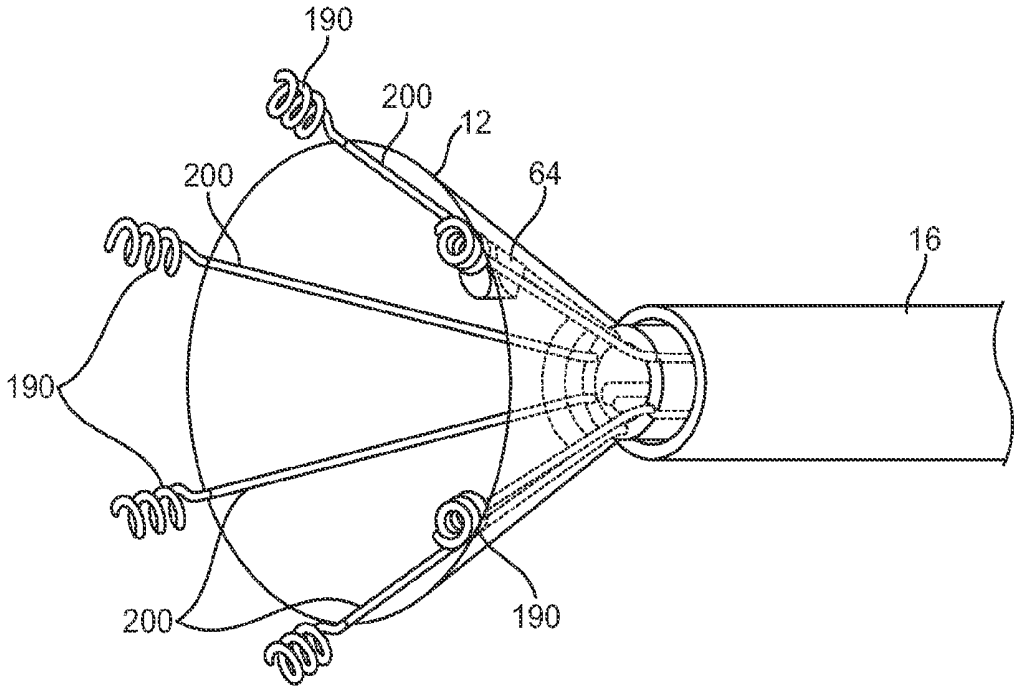

FIG. 15

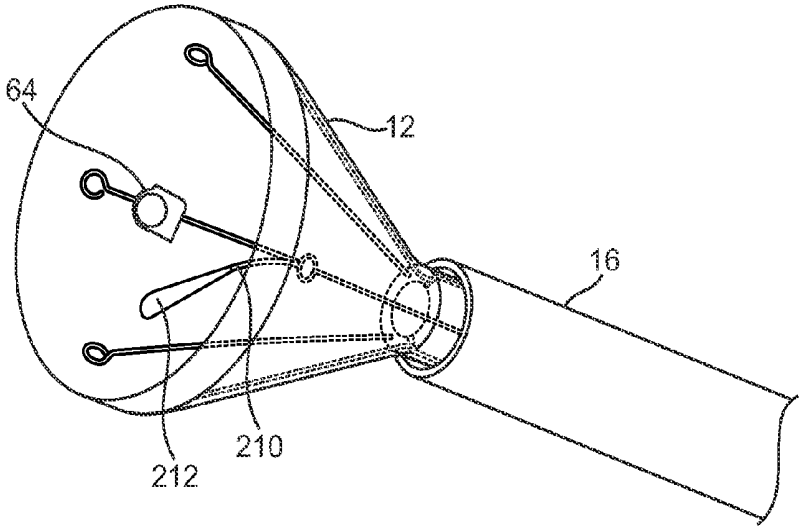

FIG. 16A

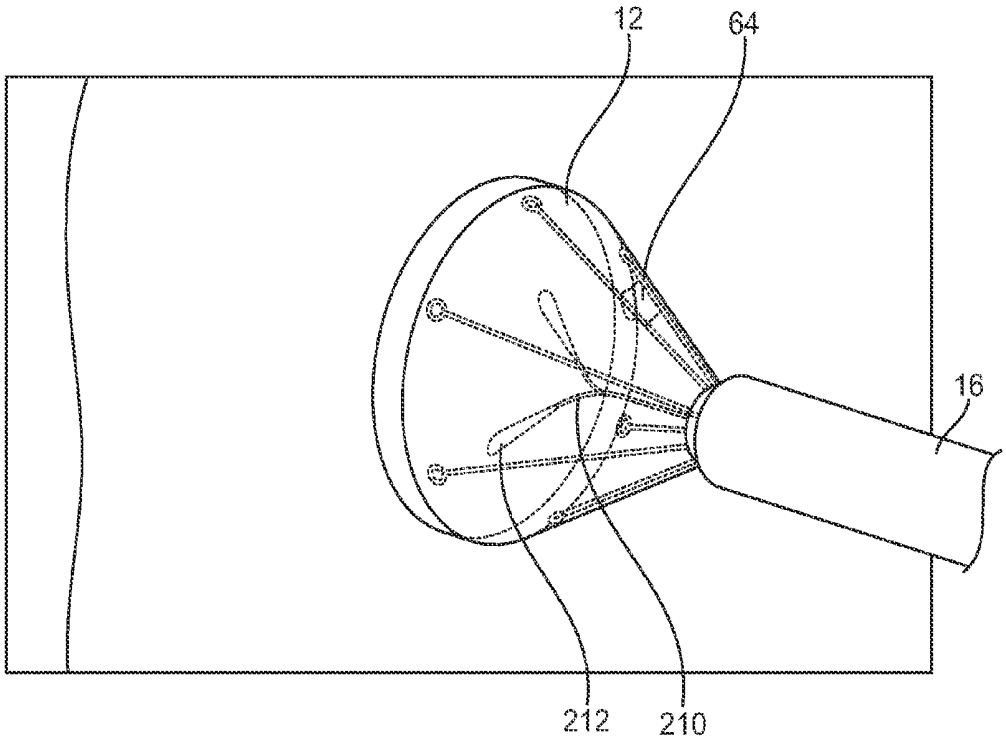

FIG. 16B

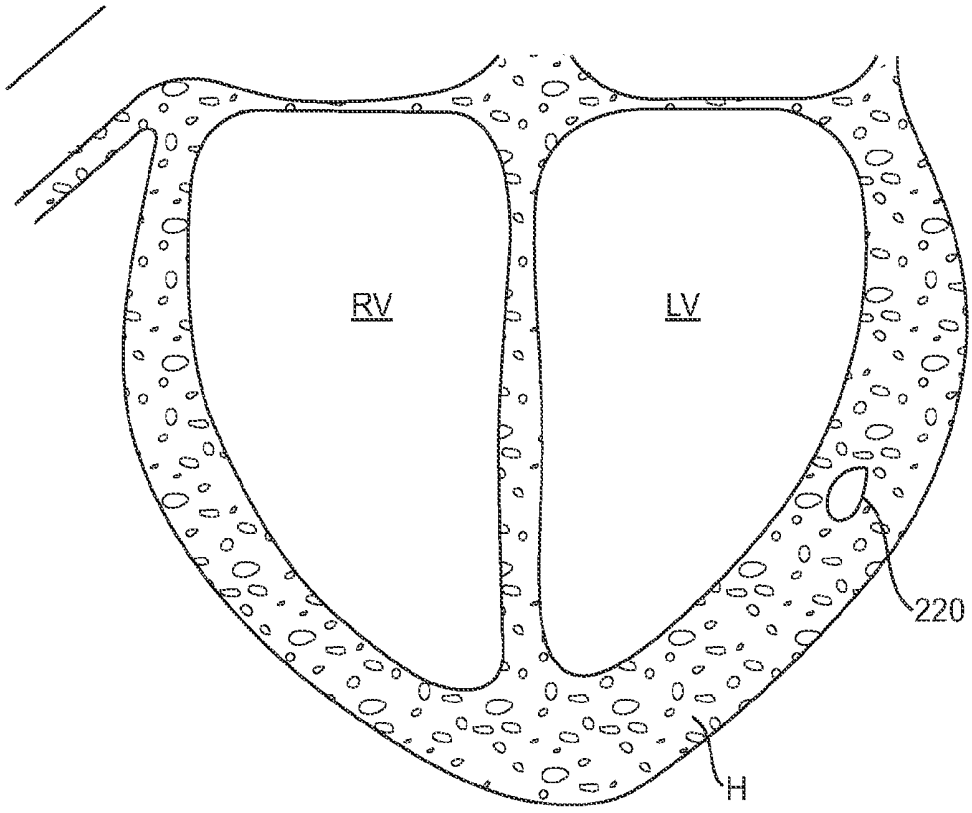

FIG. 17

DELIVERY OF BIOLOGICAL COMPOUNDS TO ISCHEMIC AND/OR INFARCTED TISSUE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 13/365,914, filed Feb. 3, 2012 which is a continuation of U.S. patent application Ser. No. 11/828,267, filed Jul. 25, 2007, which claims the benefit of U.S. Provisional Application No. 60/821,117 filed Aug. 1, 2006. U.S. patent application Ser. No. 11/828,267 is a continuation-in-part of U.S. patent application Ser. No. 11/259,498 (now U.S. Pat. No. 7,860,555), which claims the benefit of U.S. Provisional Application No. 60/649,246, filed on Feb. 2, 2005. Each of the above listed applications is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

The present invention relates generally to medical devices used for accessing, visualizing, and/or treating regions of tissue within a body. More particularly, the present invention relates to methods and apparatus for locating and accessing ischemic and/or infracted tissue and for treating the tissue by delivering biologically active compounds within a patient heart.

BACKGROUND OF THE INVENTION

Conventional devices for accessing and 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.

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.

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 balloons 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.

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.

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.

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 of the tissue to diagnose pathologies or to perform some form of therapy on it.

Thus, a tissue imaging system which is able to provide real-time in vivo access to and images of tissue regions within body lumens such as the heart through opaque media such as blood and which also provide instruments for therapeutic procedures upon the visualized tissue are desirable.

SUMMARY OF THE INVENTION

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.

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. 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

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 pumped continuously or intermittently to allow for image capture by an optional processor which may be in communication with the assembly.

One particular application for the tissue visualization system includes utilizing the system for detecting the presence and/or location of ischemic and/or infarcted tissue by visual inspection and/or measurement of one or more parameter of the tissue. Any number of physiologic parameters can be utilized to obtain measurements of the visualized tissue to detect the certain parameters, e.g., partial pressure values of oxygen (PO2) and carbon dioxide (PCO2); temperature differences between tissue regions; biomarkers indicative of injured tissue; electrical current and/or electrical potential differences through the tissue; variations in tissue surface hardness and deflection between tissue regions; etc.

Once the injured tissue region has been identified, a number of treatments may be utilized for injecting or infusing bioactive agents into or upon the tissue. Accordingly, a number of systems and methods for utilizing instruments to locate and/or access ischemic and/or infarcted tissue and to treat the tissue by delivering biologically active compounds may be utilized.

BRIEF DESCRIPTION OF THE DRAWING

FIG. **1**A shows a side view of one variation of a tissue imaging apparatus during deployment from a sheath or delivery catheter.

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

FIG. **1**C shows an end view of a deployed imaging apparatus.

FIGS. **1**D to **1**F show the apparatus of FIGS. **1**A to **1**C with an additional lumen, e.g., for passage of a guidewire therethrough.

FIGS. **2**A and **2**B 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.

FIG. **3**A shows an articulatable imaging assembly which may be manipulated via push-pull wires or by computer control.

FIGS. **3**B and **3**C 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.

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

FIGS. **5**A and **5**B show examples of various visualization imagers which may be utilized within or along the imaging hood.

FIGS. **6**A to **6**C illustrate deployment catheters having one or more optional inflatable balloons or anchors for stabilizing the device during a procedure.

FIGS. **7**A and **7**B 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.

FIG. **7**C 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.

FIG. **8**A shows an illustrative example of one variation of how a tissue imager may be utilized with an imaging device.

FIG. **8**B shows a further illustration of a hand-held variation of the fluid delivery and tissue manipulation system.

FIGS. **9**A to **9**C illustrate an example of capturing several images of the tissue at multiple regions.

FIG. **10** shows a perspective view of the tissue visualization catheter visualizing the underlying tissue for the presence of ischemic and/or infarcted tissue.

FIGS. **11**A and **11**B show side and perspective views, respectively, of a variation of the tissue visualization catheter having a needle catheter for injecting a fluorescent dye into the underlying tissue to determine whether ischemic and/or infarcted tissue is present.

FIG. **12** shows a perspective view of a variation of the tissue visualization catheter having a single probe configured to obtain measurements of a variety of physiologic parameters for determining the presence and/or location of ischemic and/or infarcted tissue.

FIG. **13** shows a perspective view of another variation of the tissue visualization catheter having a multi-probe configuration to obtain measurements of a variety of physiologic parameters for determining presence and location of ischemic and/or infarcted tissue.

FIG. **14**A shows a perspective view of a helical needle having a plurality of holes or openings along a surface of the needle body for delivery of bioactive substances into tissue

FIG. **14**B shows a perspective view of the helical delivery needle to be advanced into the underlying tissue while under direct visualization.

FIG. **15** shows a perspective view of another variation of the visualization catheter having multiple helical delivery needles positioned circumferentially around a periphery of the hood.

FIGS. **16**A and **16**B illustrate perspective views of another variation where a laser probe, e.g., an optical fiber bundle coupled to a laser generator, may be inserted through the work channel of the tissue visualization catheter and activated for ablation treatment prior to delivery of bioactive substances into the ablated tissue.

FIG. **17** shows a cross sectional view of the heart illustrating the implantation of a deposited delivery of a bioactive substance, e.g., in the anterolateral myocardium of the left ventricle.

DETAILED DESCRIPTION OF THE INVENTION

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. Details of tissue imaging and manipulation systems and methods which may be utilized with apparatus and methods described herein are described in U.S. patent application Ser. No. 11/259,498 filed Oct. 25, 2005 (U.S. Pat. Pub. No. 2006/0184048 A1), which is incorporated herein by reference in its entirety.

One variation of a tissue access and imaging apparatus is shown in the detail perspective views of FIGS. **1**A to **1**C. As shown in FIG. **1**A, 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 replacement, trans-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.

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 or may form a non-inflatable barrier or membrane, as shown in FIG. **1**B. 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, Del.), 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.

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 even greater, as practicable) a diameter of deployment catheter **16**. FIG. **1**C shows an end view of the imaging hood **12** in its deployed configuration. Also shown are the contact lip or edge **22** and fluid delivery lumen **18** and imaging lumen **20**.

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. **1**D to **1**F. 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.

In operation, after imaging hood **12** has been deployed, as in FIG. **1**B, 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.

As seen in the example of FIGS. **2**A and **2**B, deployment catheter **16** may be manipulated to position deployed imaging hood **12** against or near the underlying tissue region of interest to 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 hood **12** and within open area **26** defined within imaging hood **12**, as seen in FIG. **2**A, 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. **2**B.

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.

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. **3**A, 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.

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 working lumens, may be delivered through the deployment catheter **16** and into imaging hood **12**. With a distal portion of articulatable delivery catheter **48** within imaging hood **12**, the clear displacing fluid may be pumped through delivery catheter **48** or deployment catheter **16** to clear the field within imaging hood **12**. As shown in FIG. **3**B, 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**.

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. **3**C. 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**.

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. **4**A. 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**.

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. **4**B, 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 imagers may be wirelessly coupled to a receiver for the wireless transmission of images. Additional optical 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 **50** may 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. **4**C. 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. **4**A. Other configurations for support member **50** for off-axis visualization may be utilized, as desired.

FIG. **5**A shows a partial cross-sectional view of an example where one or more optical fiber bundles **62** may be positioned within the catheter and within imaging hood **12** to provide direct in-line imaging of the open area within hood **12**. FIG. **5**B shows another example where an imaging element **64** (e.g., CCD or CMOS electronic imager) may be placed along an interior surface of imaging hood **12** to provide imaging of the open area such that the imaging element **64** is off-axis relative to a longitudinal axis of the hood **12**. The off-axis position of element **64** may provide for direct visualization and uninhibited access by instruments from the catheter to the underlying tissue during treatment.

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. **6**A. 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. **6**B shows a first balloon **78** inflated while FIG. **6**C 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 deployment catheter **16**.

To further stabilize a position of the imaging hood **12** relative to a tissue surface to be imaged, various anchoring mechanisms may be optionally employed for 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. **7**A, and into imaging hood **12**.

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. **7**B, 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.

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**.

In another variation where the tool delivery catheter **82** may be omitted entirely to temporarily anchor imaging hood **12**, FIG. **7**C 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 having helical tissue engaging devices **88** positioned within. When an expanded imaging hood **12** 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 torqued 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.

An illustrative example is shown in FIG. **8**A 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.

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.

FIG. **8**B 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 assembly **112** and fluidly coupled to handle assembly **112** via one or more tubes. The fluid flow rate and other mechanisms may be metered by the electronic controller **118**.

Deployment of imaging hood **12** may be actuated by a hood deployment 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, Wash.), RF, etc., for viewing on a monitor **128** or for recording for later viewing.

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**.

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. **9**A to **9**C 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. **9**A.

The deployment catheter **16** may be then repositioned to an adjacent portion of mitral valve MV, as shown in FIG. **9**B, 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. **9**C, 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.

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**.

Detail examples and descriptions of a visualization catheter device and system which may be utilized herein are shown and described in further detail in U.S. patent application Ser. No. 11/259,498 filed Oct. 25, 2005, which has been incorporated herein above in its entirety.

One particular application for the tissue visualization system includes utilizing the system for detecting the presence and/or location of ischemic and/or infarcted tissue by visual inspection and/or measurement of one or more parameter of the tissue. Any number of physiologic parameters can be utilized to obtain measurements of the visualized tissue to detect the certain parameters, e.g., partial pressure values of oxygen (PO2) and carbon dioxide (PCO2); temperature differences between tissue regions; biomarkers indicative of injured tissue; electrical current and/or electrical potential differences through the tissue; variations in tissue surface hardness and deflection between tissue regions; etc.

One method for detecting the ischemic and/or infarcted tissue is by visual inspection alone. As shown in the perspective view of FIG. **10**, with hood **12** placed over a tissue region T to be inspected, transparent displacement fluid **150** may be infused into the hood **12** and the underlying tissue may be visually inspected via imaging element **64**. In determining the presence and/or location of the affected tissue, the user may directly visualize the tissue surface via the visualization catheter and ascertain, e.g., the colors, intensities, and patterns of appearance. Accordingly, regions of healthy and diseased tissue may be identified. Such physical parameters are generally known to one of skill in the art as indicated in various clinical-pathologic correlation studies.

Another method for detecting certain tissue conditions may incorporate the use of fluorescent compounds injected into the tissue being visually inspected to enhance any contrasts in the tissue appearance. As shown in the respective side and perspective views of FIGS. **11**A and **11**B, with hood **12** placed against the tissue region T to be inspected and the hood open area purged of blood, hollow piercing needle **160** may be advanced through deployment catheter **16** and into the underlying tissue T to penetrate at least partially into the tissue to directly administer a fluorescent chemical dye, e.g., indocyanin green. Alternatively, piercing needle **160** may be advanced against the tissue surface and simply drip the fluorescent dye onto or over the tissue surface. In yet another alternative, the fluorescent chemical dye may be systemically administered to the patient via an intravenous route. When the fluorescent dye has been absorbed by the tissue region T to be inspected, the tissue may exhibit a visual appearance which is indicative of certain physiological characteristics. For instance, the dyed tissue region may exhibit different patterns of variously fluorescing regions of tissue which may be indicative of tissue health, e.g., healthy, perfused tissue; ischemic tissue; infarcted tissue, necrotic tissue, etc.

The intensity and pattern of fluorescence may be observed directly by the user without image processing. Alternatively, imaging element **64** (which may be optionally filtered) may be in communication with signal processor **162** which may take the images and process them for analysis of the emitted wavelength distribution. The emitted wavelength distribution may be correlated to determine the physiologic characteristics of the tissue and the resulting image may be displayed upon a monitor **164** for user evaluation.

Another variation for determining tissue condition may include the use of a sensor probe **170** advanced into contact against the tissue surface T while under visualization from imaging element **64**, as shown in FIG. **12**. Sensor probe **170** may be used to measure physiologic data such as local tissue concentrations of the partial pressure values of oxygen (PO2) and/or carbon dioxide (PCO2) within the tissue region T. This data may be analyzed by processor **162** to extrapolate the locations of tissue having relatively higher PO2 values and/or lower PCO2 values which are indicative of well-perfused (and healthy) tissue. Conversely, regions with relatively lower PO2 and/or higher PCO2 values may indicate poorly-perfused and presumably ischemic and/or infarcted tissue. The measured concentration values of PO2 and/or PCO2 may be processed **162** for visual representation **164** to and evaluation by the user, as illustrated by the concentration profile **172** as measured by probe **170**.

Aside from PO2 and PCO2 concentration measurement, sensor probe **170** may be additionally or alternatively configured to detect tissue temperature values as well. From local measured tissue temperatures as well as from the known temperature of the local perfusate, the user may extrapolate regions of the tissue T having relatively higher temperature values, which may be indicative of tissue having higher perfusion and metabolic activity (and presumably increased viability). Conversely, regions of tissue with relatively lower temperature values may be indicative of tissue having lower perfusion and metabolic activity (and presumably lowered viability), thus possibly indicating ischemic and/or infarcted tissue regions. The temperature measurements may also be processed **162** for visual representation **164**, as illustrated by the temperature profile **174** as measured by probe **170**.

FIG. **13** illustrates a perspective view of a variation of hood **12** having one or more sensor probes **180** which are located circumferentially about the periphery of hood **12**. Several sensor probes **180** may be uniformly (or non-uniformly) placed around the hood **12** circumference such that when hood **12** contacts the tissue region T to be inspected, multiple measurements or a greater region of the tissue may be interrogated. Each of the sensor probes **180** may be configured for measuring PO2/PCO2 and/or temperature as well. Moreover, the measured data may be processed **162** to generate a concentration profile **182** and/or temperature profile **184**, as above.

The sensor probe(s) in FIG. **12** and/or FIG. **13** may also be configured to detect other tissue parameters besides concentration and temperature. For instance, yet another variation includes utilizing the sensor probes for detecting the presence of certain biomarkers which are typically indicative of tissue injury, and presumably the presence of ischemic and/or infarcted tissue. In such a variation, one or more biochemical sensor probe(s) may be utilized to measure the presence of certain chemical substances. Typically, damaged tissues release unique chemical substances. In the case of myocardial tissue, damaged cardiac muscles release troponin T, I, and C; creatine phosphokinase; MB fraction (CKMB); myoglobin;

and lactate dehydrogenase (LDH). By quantitatively measuring the concentrations of one or more of these biochemical markers, processor **162** may be used to map the location and degree of injury within the tissue.

In yet another variation of FIG. **12** and/or FIG. **13**, sensor probe(s) may be configured to measure electrical current in the interrogated tissue region T. The pathologic physiologic changes induced by ischemia and infarction may be evident in the current level measured within injured tissue. For example, several weeks after myocardial tissue experiences infarction, the cardiac muscle undergoes liquefactive necrosis, remodeling, and ultimately scar formation. Scar tissue, comprised primarily of fibroblasts and collagen, demonstrates diminished electrical conductivity secondary to increased impedance (relative to healthy myocardium). By electrically sampling levels of tissue impedance at several points across the region of interest, one may generate a map delineating regions of tissue ischemia, infarct in evolution, acute infarct, subacute infarct, and old infarct (scar).

In another variation of FIG. **12** and/or FIG. **13**, sensor probe(s) may be configured to measure electrical potential differences in the interrogated tissue region T. As such, one or more electrical probe(s) or electrodes may be utilized for measurement of electrical potential difference. The presence of pathologic physiologic changes induced by ischemia and/or infarction may be evidenced in the voltages measured, e.g., via an electrocardiogram (ECG) within injured tissues. An ECG is a graphical representation of cardiac electrical activity depicting voltage (ordinate) as a function of time (abcissa). ECG measurements have long been utilized to diagnose cardiac pathology including ischemia (S-T segment elevation) and infarction (S-T segment depression, Q waves). Presumably, intracardiac voltage measurements may demonstrate findings correlating to traditional transcutaneous ECG data. By mapping voltage differences throughout the tissue of interest, one may generate a map delineating regions of tissue ischemia, acute infarct, subacute infarct, and old infarct.

In yet another variation of FIG. **12** and/or FIG. **13**, sensor probe(s) may be configured to detect tissue hardness and deflection differences in the interrogated tissue region T. As such, one or more probe(s) may be configured as pressure-sensitive probes for measuring hardness (e.g., Rockwell, Vickers, durometer type, etc.) or force required to produce a given deflection in the tissue of interest. Several weeks after infarction, myocardial tissue becomes weakened secondary to coagulative necrosis. In fact, the patient may be at risk for ventricular rupture. After several more weeks, the necrotic tissue is replaced with fibroblasts (scar tissue) which, although non-contractile, provides relatively stable structural support for the moving ventricle. It is theorized that the complete but unscarred infarct may demonstrate increased compliance and decreased hardness relative to normal myocardial tissue. Similarly, the healed (scarred) old infarct is thought to demonstrate decreased compliance and increased hardness relative to normal myocardial tissue. By acquiring multiple measurements from the tissue surface of interest, a map delineating the hardness and extrapolated infarct ages and locations may be generated.

Once a region of ischemic and/or infarcted tissue has been identified using any of the modalities described above, the injured tissue may be repaired or improved, in one variation, by administering one or more bioactive substances into the affected tissue. One method for treating the injured tissue may utilize a hollow needle, such as piercing needle **160** shown above in FIG. **11**A, advanced into the tissue through hood **12** while under direct visualization. Another variation may utilize helical delivery needle **190**, as shown in the perspective view of FIG. **14**A. A hollow helical delivery needle **190** may be positioned upon elongate member **192** and it may also define a plurality of openings **194** along its surface through which one or more bioactive substances may be infused. In use, as shown in the perspective view of FIG. **14**B, once the tissue region T of interest is identified, the helical delivery needle **190** may be gently twisted and advanced into the tissue. Once partially or fully embedded, bioactive chemicals may be infused within the tissue via the openings **194** in the needle **190**. In another variation, rather than utilizing a single helical delivery needle, multiple delivery needles **190** may be positioned to extend along support struts/elongate members **200** along hood **12** and extend distally past the hood **12** for advancement into the underlying tissue, as shown in the perspective view of FIG. **15**.

In yet another alternative for treating tissue regions identified as potentially ischemic and/or infarcted, a laser catheter may be utilized while under direct visualization of the tissue region of interest. FIGS. **16**A and **16**B illustrate perspective views where a laser probe or fiber **210**, e.g., an optical fiber bundle coupled to a laser generator, may be inserted through the work channel of the tissue visualization catheter. When actuated, laser energy **212** may be channeled through probe **210** and applied to the underlying tissue at different angles to form a variety of lesion patterns. Further examples of laser or ablation probes are described in detail in U.S. patent application Ser. No. 11/775,819 filed Jul. 10, 2007, which is incorporated herein by reference in its entirety.

As the laser energy **212** is highly focused with intense energy to precisely ablate small quantities of tissue, the laser probe **210** may be used to perforate the tissue surface and/or deeper layers. Various bioactive chemicals may then be infused through hood **12** or through a catheter and directly into the tissue via the perforations. Alternatively, the tissue may be perforated during or after the various bioactive chemicals have been infused into the tissue. In yet another alternative, the tissue may be simply revascularized with the laser treatment and the infusion of bioactive chemicals may be omitted entirely, if so desired.

In yet another variation, a bioactive substance may be implanted into or near the injured tissue region. As shown in the partial cross-sectional view of the heart H, a bioactive substance **220** may be delivered and deposited directly into the tissue wall, e.g., in the anterolateral myocardium of the left ventricle, as shown in FIG. **17**. The bioactive substance **220** may be delivered utilizing any number of delivery devices through hood **12** while under direct visualization, e.g., via a needle as described above. As shown, the deposited administration of a bioactive substance **220** within the tissue of interest may or may not be encapsulated for controlled release over time.

In treating the tissue with bioactive substances, any number of suitable materials may be delivered utilizing the devices and methods herein. For instance, bioactive substances for healing and/or regenerating functional tissue may include the use of stem cells, which are protean cells from which other specialized cell lines are formed. Most damaged tissues undergo a natural process of death, resorption, and scar formation. If the stem cells, e.g., from a patient's bone marrow, can be identified and isolated these may be transplanted into the damaged tissue of interest. Ideally, the specific stem cell line responsible for generating the tissue of interest is identified and transplanted. Preclinical studies have established that implantation of bone marrow mononuclear into ischemic limbs increased collateral vessel formation. Direct myocardial injection of, e.g., bone marrow cells, into the infarct border zone produced improved LV function and infarct tis-

sue perfusion (Tse, et al. Lancet 2003, Jan. 4; 361 (9357): 47-9), which is incorporated herein by reference in its entirety. It follows that by utilizing any of the previously described devices for direct visualization to identify the location of damaged tissue (e.g. infracted myocardium) and any of the delivery systems to deposit the bioactive substances, one may deliver bone marrow cells (e.g. vascular progenitor cells) to stimulate angiogenesis for improved tissue perfusion and function as well as new intrinsic tissue formation (e.g. myogenesis).

Another example of a bioactive substance which may be infused into the identified injured tissue may include biologic substances which promote angiogenesis and subsequently improve local tissue perfusion and function. Vascular endothelial growth factor (VEGF) is an angiogenic factor regulating vascular endothelial cell migration, proliferation, and permeability. Fibroblast growth factor (FGF) induces microvascular endothelial cell growth and neovascularization. Similarly, pro-angiogenic cytokines including tumor necrosis factor alpha (TNF) and interleukin 8 (IL8), as well as the peptides SIKVAV (derived from laminin 1) and neuropeptide Y (NPY) have been shown to demonstrate similar effects.

Aside from administering bioactive agents, chemical irritants may also be delivered to tissue utilizing any of the methods and systems described herein to promote angiogenesis and improved tissue perfusion and function.

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.

What is claimed is:

1. A method of identifying a tissue region of interest for treatment, comprising:

expanding a non-inflatable fluid barrier, defining an open area which is in fluid communication with an environment external to the fluid barrier and projecting distally from a deployment catheter, against the tissue region of interest;

urging a transparent fluid into the open area such that an opaque fluid is displaced therefrom;

visualizing the tissue region of interest through the transparent fluid; and

assessing at least one parameter of the tissue region.

2. The method of claim **1** further comprising intravascularly advancing the deployment catheter prior to expanding.

3. The method of claim **1** wherein expanding comprises self-expanding the fluid barrier from a low-profile delivery configuration into an expanded deployed configuration.

4. The method of claim **1** wherein urging a transparent fluid comprises pumping the transparent fluid into the open area through a fluid delivery lumen defined through the deployment catheter.

5. The method of claim **4** wherein pumping the transparent fluid comprises urging saline, plasma, water, or perfluorinated liquid into the open area such that blood is displaced.

6. The method of claim **1** wherein visualizing comprises imaging the tissue region via an imaging element positioned within or adjacent to the expanded fluid barrier.

7. The method of claim **1** wherein assessing comprises visually inspecting the tissue region for indications of ischemic or infarcted regions of tissue.

8. The method of claim **1** wherein assessing comprises measuring a partial pressure of oxygen or carbon dioxide present in the tissue region.

9. The method of claim **1** wherein assessing comprises measuring a temperature of the tissue region.

10. The method of claim **1** wherein assessing comprises measuring for a presence of a biomarker indicative of tissue injury.

11. The method of claim **10** wherein the biomarker is selected from the group consisting of troponin T, troponin I, troponin C; creatine phosphokinase, MB fraction (CKMB), myoglobin, lactate dehydrogenase (LDH), and combinations thereof.

12. The method of claim **1** wherein assessing comprises detecting differences in electrical current or electrical potential in the tissue region.

13. The method of claim **1** wherein assessing comprises measuring relative tissue hardness or deflection over the tissue region.

14. The method of claim **1** further comprising identifying injured tissue based upon an assessment of the at least one parameter.

15. The method of claim **14** further comprising treating the injured tissue with a bioactive agent.

16. The method of claim **15** further comprising injecting or infusing the bioactive agent upon or into the injured tissue.

17. The method of claim **15** wherein the bioactive agent is selected from the group consisting of stem cells, vascular endothelial growth factor, fibroblast growth factor, pro-angiogenic cytokines, tumor necrosis factor alpha, interleukin 8, SIKVAV, and neuropeptide Y.

18. The method of claim **14** further comprising ablating the tissue region of interest based upon the assessment.

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专利名称(译)	将生物化合物递送至缺血和/或梗塞组织		
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申请(专利权)人(译)	Intuitive Surgical公司运营，INC.		
当前申请(专利权)人(译)	Intuitive Surgical公司运营，INC.		
[标]发明人	SAADAT VAHID RAO SEKHAR S		
发明人	SAADAT, VAHID RAO, SEKHAR S.		
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摘要(译)

本文描述了生物化合物向缺血和/或梗塞组织的递送，其中这样的系统可包括展开导管和可展开成扩张构型的附接成像罩。在使用中，成像罩靠着或邻近待成像的组织区域放置在体腔中，该体腔通常填充有不透明的体液，例如血液。可以将半透明或透明的流体（例如盐水）泵送到成像罩中，直到流体置换任何血液，从而通过展开导管中的成像元件留下待清晰的组织区域。另外，任何数量的治疗工具也可以通过展开导管并进入成像罩，用于在组织上执行任何数量的程序，以识别，定位和/或接近缺血和/或梗塞组织。