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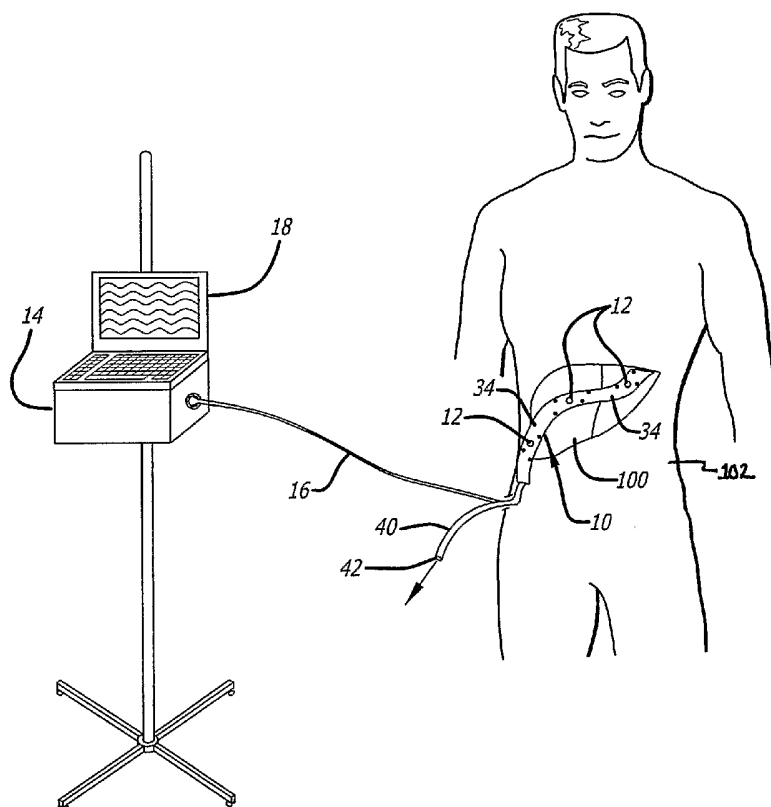
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- (71) Applicant (*for all designated States except US*): **ALFRED E. MANN INSTITUTE FOR BIOMEDICAL ENGINEERING AT THE UNIVERSITY OF SOUTHERN CALIFORNIA** [US/US]; 1042 Downey Way DRB B21, Los Angeles, CA 90089-1112 (US).
- (72) Inventors; and
(75) Inventors/Applicants (*for US only*): **SHEHADA, Ramez, Emile, Necola** [US/US]; 14759 Hardaway Drive, La Mirada, CA 90638 (US). **JABBOUR, Nicolas** [US/US]; 534 Vallombrosa Drive, Pasadena, CA 91107 (US).
- (74) Agents: **BROWN, Marc, E.** et al.; McDermott, Will & Emery, 2049 Century Park East, Suite 3400, Los Angeles, CA 90067 (US).
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[Continued on next page]

(54) Title: SURGICAL DRAIN WITH SENSORS FOR MONITORING INTERNAL TISSUE CONDITION AND FOR MONITORING FLUID IN LUMEN



(57) Abstract: The present invention is directed to devices and methods of using a surgical drain, and more particularly to a surgical drain having at least one sensor for monitoring and/or recording the condition of the anatomical site or fluid emitted from the site where the surgical drain is placed. The invention may also include modifications of the surgical drain to improve stabilization or immobilization in the proximity of the anatomical site to be monitored.



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SURGICAL DRAIN WITH SENSORS FOR MONITORING INTERNAL TISSUE CONDITION AND FOR MONITORING FLUID IN LUMEN

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Patent Applications 60/445,714 filed February 7, 2003 and 60/453,009 filed March 6, 2003, and incorporates the contents in their entirety.

BACKGROUND OF THE INVENTION

[0002] Field of Invention

[0003] The present invention is directed to devices and methods of using a surgical drain to monitor internal tissue condition, and more particularly to a surgical drain having at least one sensor for monitoring the condition of a tissue proximate to the surgical drain.

[0004] Description of Related Art

[0005] It is desirable for a physician to know the condition of tissues or organs (hereafter referred to interchangeably) within the patient's body particularly after trauma or surgical manipulation. Since such tissues may reside under the skin or within a body cavity, a physician must invasively inspect the tissue (such as by surgery, including laparoscopy), or use indirect measures to assess an organ's condition (such as radiological, blood testing and patient accounts of sensations of illness or pain). However, these methods can be disadvantageous. An invasive examination may cause discomfort and risk of infection to the patient, and the information obtained either through direct inspection or indirectly via blood or radiological analysis, may be relevant only to the time at which the procedure is performed, and examination may render only indirect information about the physiological condition of the organ.

[0006] Monitoring of organ function can be important after surgeries such as organ transplantation, resection, cryosurgery and alcohol injection. Surgical complications, such as vascular complications, may disrupt adequate oxygen circulation to the tissue, which is critical to organ function and survival. Following liver surgery, for example, a physician may draw patient blood to determine the condition of the organ by measuring liver enzymes (such as transaminases) and

clotting factors (such as prothrombin). Unfortunately, these blood tests reflect liver condition only at the time the blood sample is drawn, and changes in these laboratory values can often be detected only after significant organ damage has already occurred, permitting a limited opportunity for intervention by the physician to improve the condition of the organ or find a replacement organ in case of transplantation for the patient.

[0007] Other methodologies have been used to assess internal tissue conditions. For example, (1) imaging and Doppler techniques, (2) optical techniques, and (3) thermodilution have been used to measure tissue oxygenation and/or perfusion. However, these techniques can be difficult to successfully apply to continuous monitoring of organ condition, and may provide only qualitative or indirect information regarding a condition, and/or may provide information about only a small segment of an organ.

[0008] Imaging and Doppler Methods. Angiography may be used for determining the location and extent of blood flow abnormalities in major hepatic vessels, such as hepatic artery or portal vein stenoses and thromboses. Similarly, Doppler sonography may be used for the evaluation of blood flow in the hepatic artery and the portal vein. These methods can lack the sensitivity and the resolution necessary for assessing hepatic microcirculation. Contrast sonography has been applied for qualitative assessment of blood perfusion in the microvasculature, but its potential for quantitative measurement is still unclear. Although sonography can be performed at bedside, it is neither sensitive nor specific, and does not indicate the actual tissue oxygenation. It is usually used as a screening for the more invasive angiography. Angiography is still a preferred clinical standard in determining vessel patency for any organ such as blood flow abnormalities in major hepatic vessels, such as hepatic artery or portal vein and may visualize stenosis or thrombosis in these and other vascular structure. This test however is invasive and requires the injection of contrast material with its side effect of allergic reaction, kidney failure and fluid overload. The test cannot be performed at bedside (as in Doppler Ultrasonography) and requires moving critical ill patient to the radiology suite, and the side effects are also higher in these sick patients.

[0009] Other imaging methods, such as Spiral Computer Tomography (CT), three-dimensional magnetic resonance, angiography and radionuclide scintigraphy using Technetium 99m sulfur colloid may be used to assess blood flow to organs such as the liver following liver transplantation. However, these methods may not be sufficiently sensitive to obviate angiographic assessment, as described above. Further, these methods can also be limited in their ability to measure blood perfusion in microvasculature of the tissue. Although blood may be circulating to large vessels, it is oxygenation and perfusion at the capillary level, which often maintains the health of the entirety of the organ. By the time larger vessels are visibly impaired, the organ may have already undergone significant tissue damage. Further, these methods may be invasive in requiring the infusion of dye to which patients may react. Finally, for each dye injection, the organ condition may be assessed for a given interval. If further monitoring is needed, additional dye injection and repeated imaging may be required.

[0010] Laser Doppler flowmetry (LDF) has been used to measure blood flow in the hepatic microcirculation, but may not be able to provide information about the tissue oxygenation or blood content. LDF is also limited in its application due to the short depth of penetration and the large spatiotemporal variations of the signal obtained. Therefore, this technique may not reflect information regarding a broad geography of the tissue, and large variations may occur in recordings from different areas, in spite of tissue conditions being similar between the regions.

[0011] Thermodilution. Thermodilution technology has also been used for monitoring tissue perfusion. One example is the Bowman perfusion monitor, which uses an invasive catheter probe to measure hepatic perfusion. The probe may be inserted into the liver and a thermistor in its tip may be heated to remain slightly above tissue temperature. The local perfusion may be estimated from the power used in heating the thermistor to few degrees above tissue temperature to induce local dilation of the blood vessels. This can lead to a false perfusion measurement that is higher than the actual perfusion away from the probe. The latter source of error may not be corrected by calibration because the degree of vasodilation per temperature rise may vary between patients and may depend on many factors including administered drugs.

[0012] Thermodilution techniques may also be disadvantageous at least in requiring the insertion of catheter probes into an organ, which can become impractical when multiple probes are to be used.

[0013] Perfusion detection techniques such as LDF and thermodilution have an additional common inherent limitation. These methods may not measure tissue oxygenation, which is more relevant than perfusion in determining tissue viability. Perfused tissue can still suffer ischemia, oxygen deprivation, depending on the oxygen demand by the tissue versus its availability in the blood. For example, the liver has a dual blood supply from the hepatic artery and the portal vein. The blood flowing from the portal vein into the liver carries much less oxygen to the hepatic tissue than that from the hepatic artery. An occlusion of the hepatic artery would not cause a significant drop the hepatic perfusion, however, it would cause a drastic drop in the oxygenation. Hence, monitoring the hepatic perfusion only would be a misleading measure of ischemia. Further, this critical demand-availability balance can be easily disturbed due to immunogenic and/or drug reactions, therefore monitoring of oxygenation levels is important in monitoring tissue condition.

[0014] Optical Methods. Conventional optical techniques for the detection of tissue ischemia include fluorescence and transmission methods. Ischemia leads to anaerobic respiration and the accumulation of the reduced nicotinamide coenzyme NADH. The concentration of NADH may be detected optically because it is autofluorescent and has peak excitation and emission wavelengths at about 340 nm and 470 nm, respectively. Therefore, the fluorometric properties of NADH can be used to monitor and quantify this marker of ischemia.

[0015] However, this technique may not have been applied clinically due to several concerns. First, the fluorescence of NADH can be strongly modulated by the optical absorption of tissue hemoglobin, and the absorption of hemoglobin varies with its state of oxygenation, which can complicate the analysis of the data. These modulations can mask the actual intensity of NADH fluorescence thereby causing inaccuracies in the evaluation of ischemia. Further, this method may be disadvantageous at least in that repeated exposure of the tissue to ultraviolet light results in photobleaching of the tissue. Therefore, it may not be possible to continuously monitor the same position on the organ for a prolonged period of time

(i.e., more than 24 hours). Finally, the above method is only an indirect evaluation of tissue ischemia, as it relies on monitoring abnormalities in the concentration of NADH and may result from other conditions such as generalized sepsis or hypotension.

[0016] Optical transmission methods involve the use of visible and/or near-infrared radiation to measure the absorbance of blood in a tissue bed and determine the oxygen saturation of hemoglobin. A common transmission technique is pulse oximetry where red and infrared light from light emitting diodes is transmitted through the tissue, usually a finger or ear lobe, and detected by a photodiode. The oxygen saturation of hemoglobin can be estimated by measuring its optical absorption at predetermined wavelengths that allow the maximum distinction between oxyhemoglobin and deoxyhemoglobin. Researchers have used lasers to illuminate one side of the kidney and detected the transmitted light on the opposite side using a photomultiplier. For example, Maarek et al., SPIE, *Advances in Laser and Light Spectroscopy to Diagnose Cancer and Other Disease*, 2135:157-165, 1994. A major disadvantage of such techniques is the invasive nature of the procedure to place a tissue sample between the light source and the detector for a single measurement.

[0017] Intra-abdominal pressure following major surgery or trauma (such as a car accident, gun shot wounds, combat, or earthquake injuries) may rise to extremely high levels due to tissue edema secondary to the injury, especially following multiple blood transfusions, severe shock or inflammatory responses.

[0018] An increase in pressure may lead to severe organ dysfunction, such as kidney failure and acute respiratory failure due to lung compression through the diaphragm. The increased pressure in the abdomen may also lead to a decrease in the venous returns to the heart, therefore, affecting the cardiac output and the perfusion to all organs/tissues leading to a decrease in oxygen delivery.

[0019] Early detection of critical intra-abdominal pressure may be corrected by several interventions, including sedating the patient or opening of the abdomen. Prompt restoration of proper intra-abdominal pressure can reverse the consequences described above. However, once a critical point is reached, organs may suddenly fail, which may be irreversible in certain conditions and lead to rapid deterioration of multiple organs and potentially death.

[0020] A current method of monitoring intra-abdominal pressure following major surgery or trauma relies on indirect measurement of intra-organ pressure such as the bladder or the stomach pressure. These methods require direct operator intervention and are done only intermittently at a specific timing, such as every 1 to 4 hours, or if the patient shows signs of deterioration.

[0021] Current methods of measuring abdominal pressure may carry significant errors due to direct personal intervention, lack of reproducibility and challenges related to the injury itself. For example, a large hematoma or pelvic fracture may affect the bladder pressure directly without relation to the overall intra-abdominal pressure.

[0022] As discussed above, each of these methods has significant technical disadvantages to monitoring tissue condition. Further, each of these methods can also be cumbersome and expensive for bedside operation due to the size of the apparatus and cost associated with staff administering these methods, and unsuitable for continuous monitoring of tissue conditions.

[0023] Therefore, it is desirable to have a device and methods to aid physicians in predicting problems and complications associated with internal trauma or surgery. It is desirable to have a device which is positionable and removable with relatively minimal effort, minimally invasive and causes minimal discomfort for the patient, provides continuous current information about tissue or organ condition, provides direct information about tissue or organ condition, and/or provides feedback on the effects of interventions, such as medications or other procedures to improve tissue or organ condition.

BRIEF SUMMARY OF INVENTION

[0024] In one embodiment of the invention, a surgical drain may be used for postoperative monitoring of the condition of a tissue and/or organ, generally or a transplanted organ, more specifically.

[0025] In one embodiment of the invention, a surgical drain may be used to provide continuous intraoperative and/or postoperative information on the physiological condition of a tissue including perfusion and/or oxygenation.

[0026] In one embodiment, a surgical drain may be configured for ease of application by a physician, as well as ease of removal when monitoring is no longer required.

[0027] These, as well as other objects, features and benefits will now become clear from a review of the following detailed description of illustrative embodiments and the accompanying drawings.

BRIEF DESCRIPTION OF DRAWINGS

[0028] FIG. 1A is a schematic diagram of one embodiment of a surgical drain in use having at least one sensor; FIG. 1B is a schematic diagram depicting one embodiment of a surgical drain; FIG. 1C is a schematic diagram of one embodiment of the surgical drain in use having a plurality of sensors.

[0029] FIGS. 2A & B are each schematic diagrams each of one embodiment of the invention.

[0030] FIGS. 3A-F are schematic diagrams depicting views of embodiments of the surgical drain according to the invention. FIGS. 3A-F are bottom views of embodiments of a surgical drain; FIGS. 3D & E are end views of embodiments of a surgical drain.

[0031] FIGS. 4A & B are schematic diagrams each of a side view of one embodiment of a surgical drain.

[0032] FIGS. 5A & B are schematic diagrams of a top and bottom plan view of one embodiment of a surgical drain, respectively; FIG. 5C is a schematic diagram depicting a cross-sectional view of one embodiment of a surgical drain.

[0033] FIG. 6A is a schematic diagram of a side view of one embodiment of a surgical drain; FIG. 6B is a schematic diagram depicting a cross-sectional view at A-A of the embodiment shown in 6A.

[0034] FIG. 7 is a schematic diagram of one embodiment of a surgical drain in use.

[0035] FIGS. 8A & B are a schematic diagrams each of an alternate embodiment of a multifiber connector.

[0036] FIG. 9 is a schematic diagram of one embodiment of a surgical drain with wireless connectivity.

[0037] FIG. 10 is a flow diagram of one embodiment of a monitoring system of the invention.

[0038] FIG. 11 is a schematic diagram of one embodiment of a multiplexer circuit.

[0039] FIGS. 12A -D are schematic diagrams each depicting one embodiment of a display.

[0040] FIGS. 13A & B and 13E & F are schematic diagrams of cross-sectional views of embodiments of surgical drains having an inflatable chamber. FIGS. 13C & D are schematic depictions of side views of one embodiment a surgical drain having an inflatable chamber and inflation devices. Fig. 13G is a graphic representation of reflectance intensities received from the sensing system.

[0041] FIG. 14A is a schematic depiction of a bottom view and FIG. 14B is a schematic depiction of a side view of one embodiment of a surgical drain having protrusions thereon.

[0042] FIGS. 15A-F are schematic diagrams of embodiments of surgical drains modified to improve stability of the drain relative to the tissue monitored.

[0043] FIG. 16 is a modified distal end of a fiber collecting or receiving energy of one embodiment of a surgical drain.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0044] FIG. 1A is a schematic diagram depicting one embodiment of a surgical drain in use having at least one sensor. As shown in FIG. 1A, the device may include a surgical drain 10 configured for implantation within the patient's body proximate to a tissue and/or organ 100 of interest having at least one sensor or receiver 12.

[0045] The surgical drain 10 may include one or a plurality of sensors 12 in communication with a monitor 14, such as via a data cable 16. The monitor 14 may also include a display 18 configured to depict information obtained from the sensor 12. The surgical drain 10 may be in communication with a tube 40 having a conduit lumen 42, such that the fluids passing from the body in the drain lumen 32 may be transported out of the body 102 via the conduit lumen 42. The tube 40 may be formed integrally or as separate piece attached to the surgical drain 10.

[0046] FIG. 1B is a schematic diagram depicting one embodiment of a surgical drain 10. As shown in FIG. 1B, the surgical drain 10 may have a drain length 20, extending from the drain distal end 22 to the drain proximal end 24. The surgical drain 10 may have an outer surface 26 and a drain inner surface 28 and a drain wall 30 extending from the drain outer surface 26 to the drain inner surface 28. The drain wall 30 may be in any cross-sectional shape, such as rectangular, round, oval. The surgical drain 10 may include a drain lumen 32 extending the drain length 20, and the drain lumen 32 may be open or closed at the drain distal end 22. The surgical drain 10 may include at least one or a plurality of drain holes 34 extending through at least one location on the drain wall 30. The surgical drain 10 may include approximately a drain upper surface 36, and a drain lower surface 38, and may include drain holes 34 on the drain upper surface 36 and/or lower surface 38.

[0047] A surgical drain 10 may be in the form of an elongated conduit and a flexible drain wall 30, having a substantially flat cross section having at least one internal rib 128 as shown in FIG. 5C) within the drain lumen 32, and a pattern of drain holes 34 along at least a portion of the drain length 20, such as along at least half of the drain length or along the entire drain length 20. The conduit may be in the form of a linear conduit or any shape, including but not limited to circular, square or triangular form.

[0048] An internal rib 128 may act to prevent the drain wall 30 from collapsing into the drain lumen 32 even when the surgical drain 10 is subject to a very high vacuum and/or strong lateral compression forces due to body movements of the patient and the healing process at the drainage site. An internal rib 128 may also wipe back and forth across the opposite drain wall 30 to keep the conduit lumen 32 and drain holes 34 clear when the drain walls 30 are moved laterally relative to one another. An internal rib may extend partially into the drain lumen (as in FIG. 5C) or across the entire lumen (as in FIG. 6B), for example.

[0049] The surgical drain 10 may be made of any material suitable for implantation within the body 102. The material may be selected so as to be minimally allergenic, for example. A surgical drain 10 which may be used in this invention may include a standard surgical drain. By way of example, the surgical drain 10 may be of a biocompatible silicone, latex rubber, polyvinyl chloride (PVC)

or teflon of any color, and may be entirely or partially transparent. This may be advantageous in that transmitting and receiving elements may be positioned within the drain wall. In one embodiment, the optical fibers 44 may transmit light to a fiber distal aperture proximal to the surgical drain 10 and irradiate a tissue 100, and a second optical fiber distal aperture may collect the returned light via an optically transparent window in the drain wall 30.

[0050] FIG. 1C is a schematic diagram depicting one embodiment of a surgical drain 10 in use having a plurality of sensors 12. The surgical drain 10 may include electrical transmitters and/or sensors, and/or fiberoptic transmitters and/or sensors. A corresponding wire or fiber from each sensor 12 may run along the drain length 20 and exit the surgical drain 10 as a data cable and/or multi-fiber bundle 16 that couples the sensor 12 to a monitoring system 14. Examples of connectors 62 which may be used to couple the sensor to the monitoring system are described with reference to FIGS. 8A & B below.

[0051] FIGS. 2A & B are schematic diagrams of each of one embodiment of the invention. The surgical drain 10 may include at least one or a plurality of sensors 12. As shown in FIG. 2A, the surgical drain 10 may include a plurality of sensors 12 spaced along the drain length 20 to permit the monitoring of different locations of a tissue 100 A, B & C to be monitored. As shown in FIG. 2B, the surgical drain 10 may have a plurality of drain branches 10a/b to accommodate monitoring larger wounds, tissue beds or tissues 100. Finally, in one embodiment, a plurality of separate surgical drains 10 may be used to monitor a single organ or a plurality of organs 100 at the same time.

[0052] The surgical drain may include a sensing system configured to sense a physiological property of a tissue 100 proximate to a surgical drain 10. In some embodiments, the sensing system may include sensors 12 which are positioned proximate to the surgical drain 10 and tissue. In some embodiments, transmitting elements 48 and receiving elements 12 may be configured to deliver energy and receive energy, for transmission to another portion of the sensing system to sense a physiological property of a tissue. The energy may include, but is not limited to, light, heat and ultrasound. It is to be understood that sensor 12 may refer to either a sensor, such as an electrical sensor, or a receiving element such as a fiberoptic proximate to the surgical drain 10. The sensors 12 may be positioned proximate to

a tissue 100 for which monitoring is desired, and the sensors 12 may be configured to receive and/or detect parameters regarding the condition of the tissue 100, fluid proximate to the tissue or flowing into the surgical drain 10 therefrom. The surgical drain 10 may include at least one sensor 12 in contact with the surgical drain 10. For example, the sensor 12 may be on the drain outer wall surface 26, drain inner wall surface 28 or within the drain wall 30. The drain wall 30 may be modified to include a groove 46 to accommodate the sensors 12, transmitter 48 and/or wires/fibers 44 extending therefrom.

[0053] The sensor 12 may be situated such that at least a portion of the sensor 12 is in contact with the monitored tissue 100 or in proximity to the tissue 100, or in contact with interstitial fluids therefrom so as to probe the condition of the adjacent tissue.

[0054] A sensor 12 may be configured to detect physiological parameters, which permit the measurement of tissue oxygenation, perfusion, haemoglobin content, color, temperature, pressure, pH, respiratory coenzymes (such as NADH), local exogenous drug levels, mechanical properties (such as turgidity) and biochemical composition of the fluid within the surgical drain (such as hemoglobin, puss, bile, intestinal contents, etc.).

[0055] By way of example, pH sensors 12 may be used to detect changes in ion concentration in fluids surrounding a tissue 100 or within a drain lumen 32. For examples of pH sensors that may be useful in this invention, see U.S. Patent 5,916,171 to Mayviski, herein incorporated by reference.

[0056] In one embodiment, a temperature sensing system may be used to detect the temperature of a tissue 100. For example, a fiberoptic thermometer may be used. The fiberoptic may transmit an excitation light pulse to the fiber distal end in proximity to a tissue 100, causing it to fluoresce. The fiber distal end may include a nonconductive phosphor tip. The fluorescent signal may be transmitted back to a photodetector by the same fiber. The fluorescent decay time may be measured by a multipoint digital integration decay curve, used to correlate the decay curve with a temperature value.

[0057] In one embodiment, a pressure sensing system may be used to detect the pressure within a body cavity, such as the abdominal cavity. For example, a fiberoptic pressure sensor may be used, and may include a pressure sensing

element such as an optical interferometer at a distal tip of a fiber, and interferometric integration may be used to sense and monitor pressure over time. For examples of integration methods, see U.S. Patent Nos. 5,392,117 and 5,202,949, herein incorporated by reference.

[0058] FIGS. 3A-F are schematic diagrams depicting views of embodiments of the surgical drain according to the invention. FIG. 3A depicts a bottom view of one embodiment of a surgical drain 10 including at least one sensor 12 proximate to the drain lower surface 38. The surgical drain 10 may further include at least one transmitter 48 for delivering energy, such as light, including white light, to the monitored tissue 100, in the proximity of the at least one sensor 12. The surgical drain 10 may further include a plurality of pairs of transmitters 48 and sensors 12 located along the surgical drain length 20 so as to detect information from different regions of the organ 100, as shown in FIG. 1C, for example.

[0059] By way of example, as shown in FIG. 3A, a sensor 12 in proximity to a transmitter 48 may be used to collect derived energy, including the reflectance or diffuse reflectance from, or transmitted energy through the tissue 100 monitored.

[0060] FIG. 3B depicts a bottom view of one embodiment of a surgical drain 10 including at least one sensor 12 positioned in a groove 46 formed in the surgical drain wall 30. The surgical drain 10 may further include a transmitting element 48, and/or at least one or a plurality of drain holes 34 along the drain length 20.

[0061] FIG. 3C depicts a bottom view of one embodiment of a surgical drain 10 including at least two sensors 12a/b, spaced at a distance from a transmitter 48 on the drain lower surface 38. In one embodiment, the configuration may be used such that at least one transmitter 48 transmits energy and the sensors 12a/b receive derivative energy to detect different physiological parameters of the tissue 100, such as perfusion, oxygenation and temperature. The configuration may be used to measure the same parameter, and may permit the measurement of energy attenuation over distance between the transmitter 48 and the sensors 12a/b.

[0062] FIG. 3D depicts an end view of one embodiment of a surgical drain 10 including at least one sensor 12 positioned within the drain wall 30. This configuration may allow the positioning of longer sensors in the drain wall and may avoid the need for thicker drain walls. In addition, this configuration may allow a farther placement of a sensor 12 from a transmitter 48 to avoid saturation. This

may be a particularly useful arrangement when using high output (e.g., luminance) transmitters for deeper range detection. Positioning of sensors 12 in different areas of the drain wall 30 may permit the collection of information from a variety of tissue locations 100. Information from each location may be compared to obtain differential parameter measures.

[0063] FIG. 3E depicts one embodiment of the surgical drain 10 which may include at least a pair, including a transmitting element 48 and a sensor 12 positioned at different positions of the drain wall 30, such as within approximately opposite sides of the drain lumen 32. In one embodiment, the transmitting element 48/sensor 12 pair may act as an *in situ* spectrophotometer to detect substances within the drain lumen 32 between the transmitting element 48/sensor 12. Variation of the composition of fluid along sequential pairs of sensors 12 along the drain length 20 may yield information about the source or condition of the fluid. For example, the wavelength dependent attenuation of transmitted radiation by the fluid flowing in the drain lumen may be used to determine whether blood, puss, bile, intestinal contents, and/or a mixture of all are present, according to standard spectrophotometric techniques. The contents of the drain lumen may be indicative of the condition, including the healing progress of the tissue.

[0064] FIG. 3F depicts one embodiment of the surgical drain 10, which may include at least one sensor 12 positioned at least partly within the drain lumen 32. In one embodiment, the sensor 12 may act to detect the composition or the mechanical properties of fluid flowing in the surgical drain lumen 32.

[0065] FIG. 4A is a schematic diagram depicting a side view of one embodiment of a surgical drain 10, which may include a sensor 12 embedded in the drain wall 30 and a transmitting element 48 to be inserted into the organ 100. The sensor 12 and transmitting element 48 may be fiberoptic or electrical, and the distal ends of each may be oriented such that energy emitted from the transmitting element 48 may be substantially received by the sensor 12. For example, as shown in FIG. 4A the sensor distal end 12 may terminate at a perpendicular to the surgical drain outer surface 26 and the transmitting element distal end 48 may be angled such that the sensor receives energy emitted from the transmitting element 48 distal end. In one embodiment, the distal end of the sensor 12 and the transmitting element 48 may be coaxially aligned. In one embodiment, the surgical drain 10 may include a

transmitting element 48 embedded in the drain wall 30, and a sensor 12 to be inserted into the organ 100. In one embodiment, a housing 50 with a housing lumen 52 may be opposed to or encompass the transmitting element 48 or sensor 12 that is being inserted into the organ 100 to provide structural support. The housing 50 with a housing lumen 52 may be a hollow needle made of a biologically compatible material. The housing 50 may advantageously serve as an anchor to attach and/or immobilize the surgical drain 10 relative to an organ 100.

[0066] FIG. 4B is a schematic diagram depicting a side view of one embodiment of the invention, which may include optical transmission sensors composed of two needle shaped fiber optics 12/48 for insertion into a monitored tissue 100. For example, as shown in FIG. 4B the transmitting element distal end 48 and sensor distal end 12 may be angled such that the sensor 12 receives radiation emitted from the transmitting element 48. In one embodiment, the transmitting element 48 and sensor 12 may each be opposed to or encompassed by a housing 50 with a housing lumen 52 to provide structural support. The housing 50 with a housing lumen 52 may be a hollow needle made of a biologically compatible material. The housing 50 can advantageously serve as an anchor to attach and immobilize the drain 10 on the organ 100.

[0067] As shown in FIG. 16, in one embodiment, to enable a fiber to irradiate energy at about 90 degrees, the fiber distal end may be polished at about a 42-degree angle (α) to its axis. Further, glass ferrule caps may be placed over the polished end. In use, the light may be reflected on the polished end, and be emitted at about 90 degrees to the fiber axis 132.

[0068] In one embodiment, a fiber collecting or receiving energy may be prepared using a similar process.

[0069] In these configurations, for example, light emitted from a transmitting element 48 may be transmitted through a tissue thickness 54 to a sensor 12. Using standard transmission, reflection and/or fluorescence spectroscopy techniques, the transmitted light may be used to measure physiological information including, but not limited to tissue oxygenation, perfusion, coloration, and drug concentration.

[0070] FIGS. 5A & B are schematic diagrams depicting a top and bottom plan view of one embodiment of a surgical drain 10. Optical fibers and/or the lead wires 44 that may connect the sensors 12 and the transmitters 48 may be evenly

distributed along the drain surface lengthwise to prevent the mechanical twisting of the drain wall 30. This may be advantageous at least to maximize contact between the sensors 12 and the tissue 100.

[0071] FIG. 5C is a schematic diagram depicting a cross-sectional view of one embodiment of a surgical drain 10. In one embodiment of the invention, the surgical drain 10 may include at least one pair of sensors 12 a/b positioned approximately on opposite sides of the drain wall 30. The surgical drain 10 may also include a plurality of pairs of sensors 12a/b, 12 c/d, 12 e/f positioned at different locations along the drain length to detect information from different positions along the drain length 20, such as shown in FIG. 6A.

[0072] FIG. 6A is a schematic diagram of a side view of one embodiment of a surgical drain; and FIG. 6B is a schematic diagram depicting a cross-sectional view of one embodiment of a surgical drain. In one embodiment of the invention, the surgical drain 10 may include at least one pair of sensors 12a/b positioned proximate to different surfaces of the surgical drain 10. The surgical drain 10 may also include a plurality of pairs of sensors 12a/b, 12c/d, 12e/f positioned at different locations along the surgical drain length to detect information from different positions along the drain length 20.

[0073] As shown in FIG. 6B, in one embodiment, the surgical drain 10 may have a drain width 56 of about 15 mm, and a drain height 58 of about 6 mm, a drain length 20 of about 200 mm, a drain hole diameter 34 of about 1.5 mm, and a drain lumen height and width of about 4 mm. The surgical drain 10 may include a plurality of lumens 32; and fibers/wires 44 to and/or from the transmitting elements 48 and/or sensors 12 may be oriented within the surgical drain 10, such as in an internal rib 128. In one embodiment, a sensor 12 may be embedded in the drain wall 30. This may be advantageous at least in facilitating the use of additional modifications to drain wall 30 or outer surface 26, such as stabilization devices and mechanisms for increasing contact between tissue and sensors, described below.

[0074] FIG. 7 is a schematic diagram depicting one embodiment of a drain in use. In one embodiment, sensors 12 may be placed on opposite sides or proximate to sides of the surgical drain 10 such that the sensor pairs 12a/b may be used to acquire differential measurements between different organs/tissues positioned in the proximity of sensors pair 12a/b. For example, as shown FIG. 7 a

surgical drain 10 may be positioned, such that the drain lower surface 38 is proximate to an organ to be monitored 100, and the drain upper surface 36 is proximate to an adjacent tissue. Therefore, sensor pairs 12a/b may be positioned to measure a parameter differentially between the monitored organ 100 and the adjacent tissue. These differential measurements may improve the accuracy of the measurements/diagnosis, such as in monitoring for complications in hepatic perfusion. For example, a lower than normal oxygenation of the liver may not be indicative of problems in the hepatic perfusion because the oxygenation of the whole body may be lower than normal due to respiratory and/or circulatory problems. However, if the oxygenation levels of the liver are lower than normal while the adjacent tissues are at normal oxygenation levels, then this is a real indication of reduced hepatic perfusion.

[0075] Any type of sensors (such as oxygenation, perfusion, pH, temperature, color) may be used in a differential mode measurement, such as described above. The sensor 12 type used may be selected so as to maximize the detection of the desired physiological parameter, maximize biological compatibility with the patient's tissues or other components of the device, and to minimize any risk of electrocution or the like.

[0076] In one embodiment, the device may be configured to detect the color of an organ 100. The surgical drain 10 may use a single fiber, or may include at least one transmitting element 48 and at least one sensor 12. The transmitting element 48 may be a fiberoptic 44 having a distal end configured to deliver light from a light source to the organ 100. The light may be reflected from, diffusely reflected from or transmitted through at least a portion of the organ 100 in the proximity of the transmitting element distal end 48. The sensor 12 may be a fiberoptic 44 having a distal end configured to collect light having a spectral pattern reflected, diffusely reflected or transmitted through the organ 100, and transmit the spectral pattern to a photodetector or processing system 80. The color may be extracted from a wavelength spectrum using standard wavelength to RGB conversion techniques.

[0077] The oxygenation of an organ may be determined by measuring the oxygenation of the hemoglobin within a tissue. The spectral characteristics of hemoglobin are dependent on its state of oxygenation. The oxygenation of the

organ 100 may be determined by measuring the spectral characteristics of hemoglobin using a similar sensor 12, as described above.

[0078] The monitoring system 14 may include a processing system 80 for converting the spectral pattern information to a color, which may be presented to a physician on a display 18. The processing system 80 may also convert the spectral pattern information to a color index number, which may be presented to a physician on a display 18. The system may also include data of normal colors and color indexes for automatic or manual comparison so that a tissue abnormality may be noted.

[0079] Determining the physiological conditions, such as color and/or color index of the tissue, may be advantageous at least in that the physician may determine from the color of the tissue the general health of the tissue, including whether the tissue is adequately oxygenated and/or jaundiced. Further, the monitoring function is advantageous in that it may be continuous or at intervals selected. Further, the monitoring function is advantageous in that it may be minimally invasive and does not require opening the patient to assess the tissue condition.

[0080] In one embodiment, diffuse reflection may be used to determine the oxygenation level of at least a portion of an organ 100. This method may be advantageous at least in that information about the internal portion of the organ 100 may be obtained, without penetrating the surface of the tissue with a sensor 12 or a transmitting element 48.

[0081] In one embodiment, the device may be configured to detect the temperature of the monitored organ 100. In one embodiment, the device may include a fiberoptic temperature sensor as described above in proximity to the surgical drain 10. The temperature sensor 12 may transmit the light for information processing. A processing system 80 may convert the phosphorescence decay-time to a temperature value which may be presented to a physician on a display 18. The system may also include data of normal temperatures for automatic or manual comparison so that an abnormality may be noted. Determining the temperature of the organ 100 is advantageous at least in that the physician can determine from the temperature the general health of the tissue including whether the tissue is being properly perfused after transplant as improperly perfused tissues may decrease in temperature, for example. A temperature sensor 12 may be of any type other than

fiberoptic including thermistors, thermocouples and resistance temperature detectors (RTD's), for example.

[0082] The system may acquire simultaneous differential measurements from along the drain length or between the different tissues between which the surgical drain 10 is positioned. Measurement of a given parameter simultaneously from adjacent normal organs/tissues (e.g., abdominal wall) and from the organ/tissue of interest suffering problems (e.g., the liver) can provide a control or reference value. This control or reference value can be used as a comparison factor to improve the accuracy of the parameter measured from the organ/tissue of interest 100.

[0083] In one embodiment, the device may be configured to detect the respiratory coenzyme NADH levels from the monitored organ 100. Fluorescence spectroscopy may be used to measure the fluorescence of NADH which has a peak emission at 470-nm and to detect its concentration in the tissue 100.

[0084] In one embodiment, the device may be configured to detect concentrations of exogenous drugs within the tissue 100 or fluid in the drain lumen 32. For example, drugs (such as chemotherapeutic agents) may auto-fluoresce or may be coupled with a fluorescing tag having a selected peak emission, which may be detected by fluorescence spectroscopic methods.

[0085] In one embodiment, the device may be configured to detect pressure. In one embodiment, the surgical drain 10 may include fiberoptic pressure sensors as described above.

[0086] The surgical drain 10 may include at least one or a plurality of sensors 12 in communication with a monitoring system 14, such as via a data cable 16, such as shown in FIG. 1A. Wires and/or fibers 44 may be bundled together towards the surgical drain 10 proximal end and exit the surgical drain 10 within a sheath.

[0087] In one embodiment, the surgical drain 10 may include optical fibers 44a/b and a multifiber connector 62 may be an optical fiberoptic connector, which joins each fiber 44a to a complementary fiber 44b in the monitoring system 14 to establish optical continuity. FIG. 8A is a schematic depicting a side view of one embodiment of an optical connector 62 that may be constructed to minimize the distance between the apertures of the corresponding optical fibers 44a/b. The region where the fiber apertures meet may be filled with an index-matching substance 64, such as optical gel to optimize the optical continuity between the

corresponding fibers 44a/b. The optical gel may fill the air gap between corresponding optical fibers and hence improve light transmission by decreasing the back reflection that may occur at an air interface due to mismatch in the refractive index. The connector 62 may be configured so as to have a complementary shape to a receptor 66. The connector 62 and receptor 66 may include complementary locking members 68a/b to maximize the meeting of the apertures of the corresponding optical fibers and prevent inadvertent separation between the components.

[0088] FIG. 8B is a schematic depiction of one embodiment of a multifiber connector 62, which may be used in a surgical drain 10 including light sources 60. In one embodiment, at least one light emitting diode (LED) may be used as a light source 60, such as when low power consumption is desirable. The LED may be of the white, multi-wavelength, or monochromatic type. An LED-block 70, such as shown in FIG. 8, may be used to couple at least one LED to a transmitting element 48, such as an excitation optical fiber 44 and hence minimize light losses at the multifiber optical connector 62. In one embodiment, electrical connectors 72 may be used to drive LEDs 60 in a LED-block 70, while the optical connectors 74 may be used to guide the collected optical signals from sensors 12 to a monitoring system 14.

[0089] FIG. 9 is a schematic diagram depicting one embodiment of a surgical drain with sensors and wireless connectivity. In one embodiment, the device may include a monitor 14 in communication with the sensors 12 of the surgical drain 10. The monitor 12 may be directly affixed to the end of the surgical drain 10 and/or tube 40, and may utilize an antenna 78 to receive command signals to activate transmitting elements 48 and/or transmit data obtained from the sensors 12 to a receiver 76. If the monitoring system 14 includes an antenna 78, the antenna 78 may be positioned such that it runs longitudinally along the drain tube 40.

[0090] In one embodiment of the invention, the device may comprise a surgical drain 10 in communication with a monitoring system 14 that may include a processing system 80, a display 18, device(s) to drive the frequency and/or magnitude of signals to transmitting elements (such as a lamp multiplexer 82) and/or receive and detect information from sensors 12 and/or a device to record information from a sensor 12 associated with the surgical drain 10 over time. The

monitoring system 14 may be configured so as to continuously obtain information regarding the condition of the organ or obtain information only at preselected intervals or on demand from a physician. In one embodiment of the invention, the monitoring system may include a recorder 108. The recorder 108 may store acquired information for later retrieval and review. The recorder may be a hard disk of a processor or computer. Extended history (e.g., 7 days) of a given physiological parameter may be stored and later retrieved from the recorder, and displayed if desired. The processor 80 may include signal-processing algorithms to automatically detect and alarm for abnormalities. In one embodiment, the system may include an alarm which may be triggered when an abnormality is detected in a physiological parameter is detected (relative to pre-set values) or when inadequate contact of sensors to make a measurement. The system may include a manual preset of the alarm threshold.

[0091] In one embodiment of the invention, the processing system 80 may process the reflectance intensities received from the sensing system at about 540, 580 and 640 nm to determine if a reflectance sensor 12 is in optimal contact with an organ 100. Figure 13G shows one example of the reflectance spectrum of white light from the surface of a deoxygenated liver. Spectrum 200 may result from a reflectance sensor that is in good contact with the surface of the organ 100. Spectra 210, 220 and 230 may result from a sensor 12 that is not in contact with the organ 100. The processing system may activate a pump 118 upon detection of a spectrum representing poor sensing system contact such as 210, 220 and 230 or the like. The processing system 80 may further control a pump 118 to incrementally pump a fluid (e.g., saline) volume into the inflatable chambers 114 while measuring changes in the spectrum after each pumped volume. The filling of the inflatable chambers 114 may push the sensor 12 closer towards the organ 100. The processing system 80 may stop this contact ensure sequence upon the measurement of a spectrum representing optimal sensor contact with the organ 100, such as about spectrum 200, or the like. A pressure sensor 120 may monitor the pressure output from the pump 118 and provide real-time feedback information to the pump 118 and the processing system 80 to avoid excessive pressure that may rupture the inflatable chamber 114. The processing system 80 may memorize

the volume pumped into the inflatable chamber 114, so that it can be withdrawn later or repeated at a later time.

[0092] The system may be configured to permit a physician to be able to review previously recorded data simultaneously while the monitor 14 is recording. The system may include a search feature, such that a physician may display the data segments where selected physiological information occurs, such as periods where abnormalities were detected (e.g., hypoxia or ischemia). The system may also include an alarm feature, selectable by the user so that the system may alert the user if an abnormality is detected. A display 18 may include a touch-screen graphic user interface 112. For example, the graphic user interface 112 may permit a user to select options, including but not limited to history review of the information detected for a selected parameter, review of abnormal conditions, select alarm option, freeze screen option, trace display option, sample interval selection, display mode. In one embodiment, the physician may select an interval at which measurements are obtained from the tissue. This interval may vary, for example from about 1 to 60 minutes, such as about 5 minutes.

[0093] FIG. 10 is a schematic depiction of one embodiment of a monitoring system 14. In one embodiment of the invention, the monitoring system 14 may include a processor 80, a display 18, a fiberoptic thermometer and a spectroscopic system. The spectroscopic system may include a spectrograph and a multiplexed light source, which may be used to measure parameters such as the tissue perfusion, oxygenation and color. The spectrograph, lamp multiplexer 82 and/or thermometer may be connected to a processor 80, such as by computer interface such as universal serial data bus (USB), digital input/output interface card (DIO), analog to digital converter (A/D), and/or RS232 serial port.

[0094] In one embodiment, a spectrometer 88 may be used to monitor physiological parameters at a plurality of locations of the organ 100 corresponding to the sensors 12 positioned at various positions along the drain length 20.

[0095] FIG. 11 is a schematic depiction of one embodiment of a lamp multiplexing configuration 82. An excitation optical fiber 44a may transmit light from a lamp 60 to a tissue 100, while a collection optical fiber 44b may collect light reflected from, diffusely reflected from or transmitted through the tissue 100. The system may be configured such that light is emitted from one lamp 60a for

transition via an excitation optical fiber 44a terminating at a first position (A) of the organ 100 for a selected duration of time, at which time no other lamp (such as 60b or 60c) emits light at a second (B) or third (C) position of the organ 100 (as shown in FIG. 2A). A counter 90 may be controlled by two signal lines (i.e., clock and rest) to multiplex the spectral acquisition from different locations relative to a tissue. In one embodiment, a plurality of optical collection fibers 44b may connect to the spectrometer 88, while each of the excitation optical fibers 44a may receive light from a separate lamp 60a-c, respectively. Hence, the spectrometer 88 may measure the spectrum of the light received via any of the plurality of collection fibers 44b at a selected time. In use, a sensor 12 may be in the dark (i.e., inside the body) and cross talk minimized between sensors 12, such as by positioning the sensors at a suitable distance from one another along the drain length 20.

[0096] With respect to the lamp 60, an optical filter 92 may be used to remove undesired wavelength bands such as those in the ultraviolet region. A lens 94 may be used to focus light emitted by a lamp 60 into the proximal aperture of the optical fiber 44a. An adjustable iris (not shown) may be used to limit the light intensity to the desired levels. A voltage regulator 96 may be used to supply a constant voltage to the lamp 60 and hence maintain constant irradiation levels. The processor 80 or a separate drive may control the light on/off via its interface with the multiplexer 82.

[0097] In one embodiment, a measured spectrum of the light (such as diffusely reflected) may be corrected for distortions caused by the dark current, ambient light and/or spectral response of the system. The spectra measured by a spectrometer 88 may be processed by the processor 80 according to the known methods of diffuse reflectance spectroscopy (or transmission spectroscopy methods if applicable) for the measurement of the concentrations of oxygenated and deoxygenated hemoglobin in an organ 100. The spectral classification methods may include peak ratios, artificial neural networks (ANN), multiple linear regression (MLR), principal component regression (PCR), and partial least squares techniques (PLS).

[0098] In one embodiment, standard methods for converting wavelength to visual red, green, blue ("RGB") may be used to regenerate a color corresponding to the spectra collected from the organ 100 for visualization on a display 18 of the monitoring system 14. The wavelength to color transformation formula and the

color display algorithm values may be calibrated using colorimetry techniques to ensure that the displayed color is visually similar to the actual color of the organ 100.

[0099] In one embodiment, spectral information obtained regarding the organ 100 may be converted to a color index, such as a number for visualization on a display 18 of the monitoring system 14. A numerical color index may be displayed to provide the physician with a quantitative color evaluation of the organ 100. This may be advantageous at least in diagnosing tissue conditions, which affect the color of the organ 100, such as jaundice and ischemia.

[00100] A display 18 may show information, for example in a graphical, numerical or color form to a physician of user-selected physiological parameters including, but not limited to, tissue oxygenation, perfusion, temperature, coloration, pH and pressure. FIGS. 12A-E are schematic diagrams depicting one embodiment of a display 18. In FIG. 12A, for example, the display 18 may include a screen showing at least one selected parameter for each sensor position on the organ 100 (such as "1," "2" or "3") over a selected time. In this example, oxygenation levels are shown graphically over time, and corresponding patches of color are depicted on a graphical symbol of the selected organ relative to the position of each sensor 12 along the organ 100. The color patch may be depicted as an annulus surrounding the sensor number from which the color is detected. In FIG. 12B, for example, the display 18 may include a screen showing a plurality of different parameters for a single sensor position upon the organ 100 over a selected time. In this example, oxygenation, perfusion and temperature levels are shown graphically over time, and the corresponding patch of color is depicted on a graphical symbol of the selected organ relative to the sensor 12 (e.g., "2") for which the information is being displayed. The color patch may be depicted as an annulus surrounding the sensor number from which the color is detected. A screen indicator may mark the sensor number from which the displayed oxygenation, perfusion and temperature values were collected. The operator may select to display the parameters set of any sensor by simply clicking on the symbol of that sensor on the touch screen.

[00101] The physiological parameter detected by each sensor 12 (such as perfusion or oxygenation of the tissue at the location of each sensor) may be visualized on a display 18 as percentage of predetermined normal values. For

example, the display 18 shown in FIG. 12C displays the oxygenation traces of five sensors along the drain length 20 relative to a normal value.

[00102] FIG. 12C is a schematic depiction of one embodiment of a display 18. A physician may select to display at least one of selected physiological parameters such as tissue perfusion, oxygenation, color or temperature at each trace representative of each sensors, as shown in FIG. 12C. The display may also indicate if a sensor is not operating to collect information (such as in trace "4"). The display may include a user input such as "Sensor Ensure" button which when activated employs the "sensor contact ensurance system" shown in FIG. 13, if needed. The user may select this feature to ensure that all sensors are in good contact with tissue 100, where and when needed.

[00103] FIG. 12D is a schematic depiction of one embodiment of a display 18. In one embodiment, the physician may select to display different physiological parameters measured at each sensor location, as shown in FIG. 12D. The display 18 may be configured such that multiple screen windows may be opened to display different sensor locations at the same time.

[00104] FIG. 12E is a schematic depiction of one embodiment of a display 18. As shown in FIG. 12 E, measured parameters include: blood content, abdominal secretions and bile. These parameters may be measured optically using standard spectrophotometric techniques. Other optical and electrical sensors may be used to measure the pH and the concentration of ions in the drained fluid, for example.

[00105] As depicted in this example, the surgical drain has three optical sensors distributed along the drain length 20 for detecting fluid within the lumen at each of the locations. Using the "Display-Mode" slide button, a user may select to display all the parameters at a given sensor location or a single parameter for all sensors. The concentration of each of the measured parameters may be determined and displayed as a percentage of the fluid mixture.

[00106] The display 18 may include a movable drain-shaped screen cursor that may be freely oriented on a graphical symbol of the human abdomen to show the physician the actual drain orientation inside the body. The drain-shaped cursor may be manually oriented upon the application of the drain.

[00107] In one embodiment, it may be desirable configure the surgical drain 10 to maximize the contact between a sensor 12 and the organ 100. This may be

advantageous at least in improving the accuracy of measurements obtained from the organ 100.

[00108] FIGS. 13A & B are schematic diagrams depicting cross-sectional views of one embodiment of a surgical drain 10. FIGS. 13B & C are schematic depictions of side views of a surgical drain 10. In one embodiment, the surgical drain 10 may include at least one inflatable chamber 114, such as balloons within the body of the surgical drain 10. The surgical drain 10 may further include a channel 116 in communication with the interior of the inflatable chamber 114. In one embodiment, a pump 118 may be in communication with the channel 116 and the interior of the inflatable chamber 114. The pump 118 may include a pressure sensor 120 in communication with the inflatable chamber 114 may be used to control the inflation process so that the sensor 12 comes in optimal contact with the organ 100. In one embodiment, the inflatable chamber 114 may be positioned on the surgical drain upper surface 36 approximately opposite a sensor 12 proximate to drain lower surface 38. The inflatable chamber 114 may be expanded by inflation, such as with saline, air or the like such that the inflatable chamber 114 would bulge out and create a force (F) against the adjacent tissue, as shown in FIG. 13C. This force may generate a reaction force (R) that may press the sensor 12 on the drain lower surface 38 against the organ 100.

[00109] The inflatable chamber 114 may be left continuously inflated throughout the monitoring period, or temporarily inflated when the sensors 12 are acquiring measurements. The processor 80 may analyze the average intensity and/or spectral features of the reflected light measured at the sensor to determine if the sensor 12 is in optimal contact with the organ 100.

[00110] FIGS. 13 E & F are schematic diagrams of a cross-sectional view of an alternative embodiment of a surgical drain including an inflatable compartment 114. The inflatable compartment 114 may be positioned within a central portion of the drain 10, such as within an internal rib 128. Upon inflation, forces may press the drain upper surface 36 and lower surface 38 against tissue 100, thereby improving sensor 12 contact.

[00111] FIGS. 14A & B are schematic depictions of a bottom view and a side view of one embodiment of a surgical drain 10. In one embodiment, sensors 12 may be positioned within or upon protrusions 122 which extend from the drain outer surface

26. The protrusions 122 may be integral to the drain body 10 or attached thereto. The protrusions 122 may be made of a transparent material. This configuration may be advantageous in increasing the pressure with which the sensors contact an organ 100.

[00112] In use, a surgical drain 10 may be placed within a body cavity proximate to a site of trauma or surgery. The surgical drain 10 may permit the fluid caused by tissue edema, for example, to be drained from the site. To position a surgical drain 10, a physician may, for example, create an incision through which the surgical drain may be implanted. Alternatively, if the patient has been opened for surgery, the drain may be positioned proximate to the surgical site and the body closed around it. The surgical drain 10 may be positioned upon an organ or between tissues of interest, and may be positioned such that sensors 12 contact different regions of a tissue until monitoring is no longer needed, at which time the drain may be pulled out of the body. In one embodiment of the invention, one or more surgical drains 10 may be placed on/in/proximate to an organ 100 to monitor its condition and removed when monitoring is no longer desired, such as at the end of the postoperative monitoring period.

[00113] In some embodiments, it may be desirable to stabilize the position of the drain 10 relative to the tissue, such that the sensors 12 have improved contact with the tissue 100 and/or to increase the likelihood that measurements taken over time will be of the same or similar portion of the tissue 100. Therefore, in some embodiments, the surgical drain 10 may be modified to stabilize its position relative to a monitored organ 100.

[00114] The surgical drain 10 may be actively attracted to the surrounding organs/tissue by the continuous negative pressure (suction) in its lumen 32. The negative pressure may also draw wound fluids from the surgical drain 10. External suction may be actively applied to a tube 40 in communication with a surgical drain 10.

[00115] FIGS. 15A & B are schematics depicting a plan view and a side view of a surgical drain 10. In one embodiment, the surgical drain 10 may include at least one anchor 124 configured for insertion into a tissue 100 to stabilize the position of the surgical drain 10 within the body. The anchor 124 may be integral to the surgical drain 10 or may be fabricated separately from the surgical drain 10 and

connected thereto. The anchor 124 may be in the form of a biologically compatible needle, which may include a beveled distal end for insertion into a tissue 100. The direction of the insertion into a tissue 100 may be opposite to the pullout direction of the surgical drain 10 for smoother removal from the patient.

[00116] FIG. 15C is a schematic depicting a plan view of a surgical drain 10. The anchor 124 may be in the form of a loop 124 extending from the surgical drain outer surface 26. In use, a surgeon may utilize the loop as a suture point to attach the surgical drain 10 to a tissue, such as with a resorbable suture.

[00117] FIG. 15D is a schematic depicting a bottom view of a surgical drain 10. The anchor 124 may be in the form of biocompatible adhesive 124, such as medical grade pressure sensitive adhesive, or fibrin glue for adhering the surgical drain 10 to the surface of the organ 100.

[00118] FIGS. 15E & F are schematics depicting a bottom view and a side view of a surgical drain 10, respectively. The anchor 128 may be in the form of a flap 136 which extends from the drain outer surface 26. The flap 136 may be integral to the drain wall 30 or formed separately and attached thereto. The flap may be formed of the same material as the drain wall 30. The material may be selected so as to permit flexibility of the flap 136 as it is positioned relative to the tissue 100 or as it is removed from the body 102. The flap may further include a leading edge 130, which may be reinforced to provide a greater thickness at the leading edge 130 than at the remainder of the flap 136. The shape of the flap may be selected so as to enhance the stabilization of the drain 10 relative to the organ 100, and may prevent rotation of the drain 10. The flaps may assume any other shape including square, circular and rectangular. The flaps 136 may also include a layer of adhesive for adhering the flap to a tissue. The flaps 136 may also include sensors 12, if desired.

[00119] In one embodiment, there may be flap wings 136 on both sides to stabilize the surgical drain 10 on the surface of the tissue 100. The flap wings may increase the surface area of the drain 10 at the sensor location 12 and hence improve its passive adhesion to the moist surface of an organ. The flaps 136 may be preferably rectangular in shape with their apex pointing in the pullout direction of the drain 10 for smoother removal from the patient. The flaps 136 may have edges

130 that are reinforced against tearing by a thicker silicone layer or by an embedded thread or wire that is continuous into the drain wall 30.

[00120] Anchors 124 may be advantageous at least in preventing the surgical drain 10 from moving relative to the organ 100 during use. Further, the anchor 124 may also hold the sensor 12 on the surgical drain outer surface 26 against the surface of the tissue of interest 100. The form of the anchor 124 may be selected to minimize damage to the tissue or organ to which the surgical drain 10 is attached. Further, the anchor may be selected to maximize the stability of the connection between the surgical drain and the target organ, yet minimize the effort and damage caused during surgical drain removal.

[00121] In one embodiment, a surgical drain 10 may be placed in the proximity of an organ which has been transplanted, such as a liver, kidney, such that the drain length 20 is positioned longitudinally over the organ 100. This embodiment may be advantageous at least in allowing a physician to monitor the condition of the transplanted organ from the time of surgery through recovery to determine the condition of the organ 100. A physician may use information about the condition of the organ to decide if any further intervention, such as drug treatment (such as antibiotics or immunosuppressants) or retransplantation may be required. This method of monitoring may be advantageous at least in that it may minimize procedures to inspect the organ, enabling detection of organ dysfunction at an early stage, which may allow therapeutic intervention prior to reversible damage, increase implant survival, decrease mortality rate (from infection, organ rejection), decrease the number of organs used for retransplantation, and the additional risk and cost of retransplantation.

[00122] While the specification describes particular embodiments of the present invention, those of ordinary skill can devise variations of the present invention without departing from the inventive concept. For example, it will be understood that the invention may also comprise any combination of the embodiments described.

[00123] Although now having described certain embodiments of methods and devices of a surgical drain, it is to be understood that the concepts implicit in these embodiments may be used in other embodiments as well. In short, the protection of this application is limited solely to the claims that now follow.

WE CLAIM:

1. A surgical drain comprising:
 - an elongated conduit configured to be implanted in and to drain fluid from a body cavity, the elongated conduit including a first surface located on an outer side of the elongated conduit and a second surface located on an outer side of the elongated conduit that is substantially opposite of the first surface;
 - a first sensing system configured to sense a physiological property of tissue proximate to the first surface; and
 - a second sensing system configured to sense the same physiological property of tissue proximate to the second surface.
2. The surgical drain of claim 1, wherein the physiological property is selected from the group comprising: temperature, oxygenation, perfusion, pH, NADH levels, biochemical composition, drug concentrations, turgidity or pressure.
3. The surgical drain of claim 1, further including at least one transmitting element configured to deliver energy to the tissue proximate to the first and second surface.
4. The surgical drain of claim 1, comprising a third sensing system configured to sense a second physiological property of tissue proximate to the conduit that is different from the physiological property sensed by the first and second sensing systems.
5. The surgical drain of claim 1, wherein the conduit includes a drain portion configured to rest against a substantial length of tissue within the body cavity and a plurality of drain holes spaced along substantially the entire length of the drain portion.
6. The surgical drain of claim 1, wherein at least portions of the first and second sensing systems are embedded within the conduit behind material that is optically transparent.
7. The surgical drain of claim 1, further including a processing system in communication with the first and second sensing systems configured to compare a

difference between the physiological property sensed by the first and second sensing systems.

8. The surgical drain of claim 7, wherein the sensing systems sense temperature and wherein the processing system is configured to compare the difference between the temperatures sensed by the first and second sensing systems.

9. The surgical drain of claim 1, further including a display configured to depict data corresponding to the physiological property sensed by the first or second sensing systems.

10. The surgical drain of claim 1, wherein the conduit includes a third surface located on an outer side of the conduit and a fourth surface located on an outer side of the conduit that is substantially opposite of the third surface and further including:

a third sensing system configured to sense the same physiological property of tissue proximate to the third surface; and

a fourth sensing system configured to sense the same physiological property of tissue proximate to the fourth surface.

11. The surgical drain of claim 10, further including a processing system configured to compare a difference between the physiological property sensed by the first and third sensing systems.

12. The surgical drain of claim 1, wherein the first and second sensing systems include optical fibers.

13. The surgical drain of claim 1, wherein the first sensing system includes a component that is affixed to the conduit.

14. The surgical drain of claim 1, wherein the component is embedded in the conduit.

15. The surgical drain of claim 1, wherein the component includes a sensor.

16. The surgical drain of claim 1, wherein the component includes an optical fiber.

17. A surgical drain comprising:

an elongated conduit configured to be implanted in and to drain fluid from a body cavity, the elongated conduit including a first surface located on an outer side of the elongated conduit;

a drain portion configured to rest against a substantial length of tissue within the body cavity;

a plurality of drain holes spaced along substantially the entire length of the drain portion; and

a first sensing system configured to sense a physiological property of tissue proximate to the first surface, the first sensing system including a component that is affixed to the conduit.

18. The surgical drain of claim 17, wherein the component is embedded in the conduit.

19. The surgical drain of claim 17, wherein the component includes a sensor.

20. The surgical drain of claim 17, wherein the component includes an optical fiber.

21. The surgical drain of claim 17, wherein the physiological property sensed is selected from the group comprising: temperature, oxygenation, perfusion, pH, NADH levels, biochemical composition, drug concentration, turgidity or pressure.

22. The surgical drain of claim 17, wherein the first sensing system detects the level of oxygenation of the tissue.

23. The surgical drain of claim 17, wherein the sensing system detects the hemoglobin content in the tissue.

24. The surgical drain of claim 17, further including a transmitting element configured to deliver energy to the tissue proximate to the first surface.

25. The surgical drain of claim 17, comprising a second sensing system configured to detect a physiological property in tissue proximate to the conduit that is different from the physiological property sensed by the first sensing system.

26. The surgical drain of claim 17, wherein the first sensing system is embedded within the conduit behind material that is optically transparent.

27. The surgical drain of claim 17, further including a display configured to depict data corresponding to the physiological property sensed by the first sensing system.

28. The surgical drain of claim 17, wherein the conduit includes a second surface located on an outer side of the conduit and, further including a second sensing system configured to sense the same physiological property of tissue proximate to the second surface.

29. The surgical drain of claim 28, further including a processing system in communication with the first and second sensing system configured compares a difference between the physiological property sensed by the first and second sensing systems.

30. A surgical drain system comprising:

- an elongated conduit configured to be implanted in and to drain fluid from a body cavity, the elongated conduit including a first surface located on an outer side of the elongated conduit and a second surface located on an outer side of the elongated conduit;

- a first sensing system configured to sense a physiological property of tissue proximate to the first outer surface;

- a second sensing system configured to sense the same physiological property of tissue proximate to the second outer surface; and

- a processing system in communication with the first and second sensing system that compares a difference between the physiological property sensed by the first and second sensing systems.

31. A surgical drain comprising:

- an elongated conduit configured to be implanted in and to drain fluid from a body cavity;

- a first transmitting system configured to deliver spectral energy to tissue proximate to the conduit; and

- a first sensing system configured to detect spectral energy from the tissue proximate to the conduit.

32. The surgical drain of claim 31, further including a second sensing system configured to sense a physiological property from the tissue proximate to the conduit.

33. The surgical drain of claim 32, wherein the physiological property is selected from the group comprising: oxygenation, perfusion, temperature, pH, NADH levels, biochemical composition, drug concentration, turgidity or pressure.

34. The surgical drain of claim 31, wherein the conduit includes a drain portion configured to rest against a substantial length of tissue within the body cavity and a plurality of drain holes spaced along substantially the entire length of the drain portion.

35. The surgical drain of claim 31, wherein the transmitting element and a portion of the first sensing system are embedded within the conduit behind optically transparent material.

36. The surgical drain of claim 31, further including a display configured to depict data corresponding to the spectral energy detected by the first sensing system.

37. The surgical drain of claim 36, wherein the display is configured to display a color corresponding to the spectral energy detected.

38. The surgical drain of claim 36, wherein the display is configured to display a numerical value corresponding to the spectral energy.

39. The surgical drain of claim 31, further including:

a second transmitting system configured to deliver spectral energy to a different tissue proximate to the conduit; and

a second sensing system configured to detect spectral energy from the different tissue proximate to the conduit.

40. The surgical drain of claim 39, further including a processing system in communication with the first and second sensing systems that compares a difference between the spectral energy sensed by the first and second sensing systems.

41. The surgical drain of claim 31, further including:

a second transmitting system configured to deliver spectral energy to a different location of the same tissue than the first transmitting system;
and

a second sensing system configured to detect spectral energy from the different location of the same tissue.

42. The surgical drain of claim 41, further including a processing system in communication with the first and second sensing systems that compares a difference between the spectral energy sensed by the first and second sensing systems.

43. The surgical drain of claim 31, wherein the first sensing system includes a component that is affixed to the conduit.

44. The surgical drain of claim 31, wherein the component is embedded in the conduit.

45. The surgical drain of claim 31, wherein the component includes a sensor.

46. The surgical drain of claim 31, wherein the component includes an optical fiber.

47. A system comprising:

an elongated conduit configured to be implanted in and to drain fluid from a body cavity, the elongated conduit including a first outer surface and a second surface;

a first sensing system configured to detect spectral energy from tissue proximate to the first outer surface;

a processing system in communication with the first sensing system configured to determine a color value based on the spectral energy; and

a display configured to depict a color representative of tissue proximate to the first outer surface.

48. The system of claim 47, further comprising:

a second sensing system configured to detect spectral energy from tissue proximate to the second outer surface;

a processing system in communication with the second sensing system configured to determine a color value based on the spectral energy; and

a display configured to depict a color representative of the tissue proximate to the second outer surface.

49. The system of claim 48, wherein the processing system is configured to compare a difference between the spectral energy detected by the first sensing system and the second sensing system.

50. The system of claim 47, further including third sensing system configured to sense a physiological parameter different than the first sensing system.

51. The system of claim 50, wherein the physiological property is selected from the group comprising: temperature, pH, NADH levels, biochemical composition, drug concentration, turgidity or pressure.

52. The system of claim 47, further comprising a transmitting element configured to deliver energy to the tissue proximate to the first surface.

53. The system of claim 47, wherein at least portions of the first sensing system and transmitting element are embedded within the conduit behind optically transparent material.

54. The surgical drain of claim 47, wherein the conduit includes a drain portion configured to rest against a substantial length of tissue within the body cavity and comprising a plurality of drain holes spaced along substantially the entire length of the drain portion.

55. The surgical drain of claim 47, wherein the first sensing system includes a component that is affixed to the conduit.

56. The surgical drain of claim 47, wherein the component is embedded in the conduit.

57. The surgical drain of claim 47, wherein the component includes a sensor.

58. The surgical drain of claim 47, wherein the component includes an optical fiber.

59. A system comprising:

an elongated conduit configured to be implanted in and to drain fluid from a body cavity, the elongated conduit including a first outer surface and a second outer surface;

a first sensing system configured to detect spectral energy from tissue proximate to the first outer surface;

a processing system in communication with the first sensing system configured to determine a numerical color value; and

a display configured to depict a numerical color value representative of tissue proximate to the first outer surface.

60. The system of claim 59, further comprising:

a second sensing system configured to detect spectral energy from tissue proximate to the second outer surface;

a processing system in communication with the second sensing system configured to determine a numerical color value based on the spectral energy; and

a display configured to depict a numerical color value representative of the tissue proximate to the second outer surface.

61. The system of claim 59, wherein the processing system is configured to compare a difference between the spectral energy detected by the first sensing system and the second sensing system.

62. The system of claim 59, further including third sensing system configured to sense a physiological parameter different than the first sensing system.

63. The system of claim 62, wherein the physiological property is selected from the group comprising: temperature, pH, NADH levels, biochemical composition, drug concentration, turgidity or pressure.

64. The system of claim 59, further comprising a transmitting element configured to deliver energy to the tissue proximate to the first surface.

65. The system of claim 59, wherein at least portions of the first sensing system and transmitting element are embedded within the conduit behind optically transparent material.

66. The surgical drain of claim 59, wherein the conduit includes a drain portion configured to rest against a substantial length of tissue within the body cavity and comprising a plurality of drain holes spaced along substantially the entire length of the drain portion.

67. The surgical drain of claim 59, wherein the first sensing system includes a component that is affixed to the conduit.

68. The surgical drain of claim 59, wherein the component is embedded in the conduit.

69. The surgical drain of claim 59, wherein the component includes a sensor.

70. The surgical drain of claim 59, wherein the component includes an optical fiber.

71. A surgical drain comprising:

an elongated conduit configured to be implanted in and to drain fluid from a body cavity, the elongated circuit including a first surface and a second surface;

a first optical fiber having a first optical fiber distal end configured for insertion in tissue proximate to the first surface and configured to deliver energy to the tissue; and

a second optical fiber having a second optical fiber distal end configured to receive energy from tissue proximate to the first surface.

72. The surgical drain of claim 71, wherein the first optical fiber distal end has an axis that is substantially parallel to the second fiberoptic distal end.

73. The surgical drain of claim 71, wherein the second optical fiber distal end is configured for insertion in the tissue.

74. The surgical drain of claim 71, wherein the elongated conduit further comprises at least one housing extending from the conduit, wherein the housing supports the first optical fiber distal end for insertion into the tissue.

75. The surgical drain of claim 71, comprising a sensing system configured to sense a different physiological property of the tissue.

76. The system of claim 71, wherein the physiological property is selected from the group comprising: oxygenation, perfusion, temperature, pH, NADH levels, biochemical composition, drug concentration, turgidity or pressure.

77. The surgical drain of claim 71, wherein the conduit includes a drain portion configured to rest against a substantial length of tissue within the body cavity and a plurality of drain holes spaced along substantially the entire length of the drain portion.

78. The surgical drain of claim 71, wherein at least the second optical fiber distal tip is embedded within the conduit behind material that is optically transparent.

79. The surgical drain of claim 71, further comprising a display configured to depict information corresponding to the energy received by the second optical fiber distal end.

80. The surgical drain of claim 71, further comprising:

a third optical fiber having a third optical fiber distal end configured for insertion in tissue proximate to the second surface and configured to deliver energy to the tissue; and

a fourth optical fiber having a fourth optical fiber distal end configured to receive energy emitted from the third optical fiber distal end.

81. The system of claim 71, further including a processing system in communication with the second and fourth optical fibers configured to compare a difference between the energy received by the second and fourth fibers.

82. The surgical drain of claim 71, wherein the first sensing system includes a component that is affixed to the conduit.

83. The surgical drain of claim 71, wherein the component is embedded in the conduit.

84. The surgical drain of claim 71, wherein the component includes a sensor.

85. The surgical drain of claim 71, wherein the component includes an optical fiber.

86. A surgical drain comprising:

an elongated conduit configured to be implanted in and to drain fluid from a body cavity; and

a first sensing system configured to sense a physiological property of a substance within the drain lumen.

87. The surgical drain of claim 86 configured to drain blood, puss, bile or intestinal contents.

88. The surgical drain of claim 86, comprising a second sensing system configured to sense a different physiological property than the first sensing system.

89. The surgical drain of claim 86, wherein the physiological property is selected from the group comprising: oxygenation, perfusion, temperature, pH, NADH levels, biochemical composition, drug concentration, turgidity or pressure.

90. The surgical drain of claim 86, wherein the conduit includes a drain portion configured to rest against a substantial length of tissue within the body cavity and a plurality of drain holes spaces along substantially the entire length of the drain portion.

91. The surgical drain of claim 86, comprising a display in communication with the first sensing system, wherein the display is configured to depict data corresponding to the physiological property sensed by the first sensing system.

92. A surgical drain comprising:

an elongated conduit configured to be implanted in and to drain fluid from a body cavity, the elongated conduit including a lumen having a first position and a second position located within the lumen;

a first transmitting element configured to deliver energy to the lumen proximate to the first position; and

a first sensing system configured to receive energy proximate to the lumen second position.

93. The surgical drain of claim 92, wherein the first transmitting element and first sensing system are embedded within the conduit behind material that is optically transparent.

94. The surgical drain of claim 92, wherein the first position and second position are located on substantially opposite sides of the drain lumen.

95. The surgical drain of claim 92, wherein the lumen includes a third position and a fourth position, further comprising:

a second transmitting element configured to deliver energy to the lumen proximate to the third position; and

a second sensing system configured to receive energy proximate to the lumen fourth position.

96. The surgical drain of claim 95, further comprising a processing system in communication with the first and second sensing systems configured to compare a difference between the energy detected by the first and second sensing systems.

97. The surgical drain of claim 95, comprising a third sensing system configured to sense a different physiological property than the first sensing system.

98. The surgical drain of claim 95, wherein the physiological property is selected from the group comprising: oxygenation, perfusion, temperature, pH, NADH levels, biochemical composition, drug concentration, turgidity or pressure.

99. The surgical drain of claim 95, wherein the conduit includes a drain portion configured to rest against a substantial length of tissue within the body cavity and a plurality of drain holes spaced along substantially the entire length of the drain portion.

100. The surgical drain of claim 95, comprising a display in communication with the third sensing system, wherein the display is configured to depict data corresponding to the physiological property sensed by the third sensing system.

101. A surgical drain comprising:

an elongated conduit configured to be implanted in and to drain fluid from a body cavity, the elongated conduit including a first and a second surface on an outer side of the elongated conduit;

a first sensing system configured to sense a physiological property of tissue proximate to the first surface; and

a first inflatable compartment associated with the elongated conduit.

102. The surgical drain of claim 101, wherein the first inflatable compartment is proximate to the second surface.

103. The surgical drain of claim 101, wherein the first inflatable compartment is within the elongated conduit.

104. The surgical drain of claim 101, wherein the first sensing system and first inflatable compartment are positioned at about the same position along a drain length.

105. The surgical drain of claim 101, wherein the physiological property is selected from the group comprising: oxygenation, perfusion, temperature, pH, NADH levels, biochemical composition, drug concentration, turgidity or pressure.

106. The surgical drain of claim 101, comprising a second sensing system configured to sense a different physiological property than the first sensing system.

107. The surgical drain of claim 101, wherein the conduit includes a drain portion configured to rest against a substantial length of tissue within the body cavity and a plurality of drain holes spaced along substantially the entire length of the drain portion.

108. The surgical drain of claim 101, further including a display configured to depict data corresponding to the physiological property sensed by the first sensing system.

109. The surgical drain of claim 101, further comprising a pump in communication with an interior portion of the inflatable compartment.

110. The surgical drain of claim 101, further comprising a pressure monitor in communication with the interior portion of the inflatable chamber.

111. The surgical drain of claim 101, wherein the surgical drain further includes an anchor configured to stabilize the position of the surgical drain relative to tissue in the body cavity.

112. The surgical drain of claim 101, wherein the surgical drain further includes a projection extending from the outer side, wherein the projection is configured for insertion into tissue in the body cavity.

113. The surgical drain of claim 101, wherein the surgical drain further includes a first loop extending from the outer side.

114. The surgical drain of claim 101, wherein the surgical drain further includes adhesive on at least a portion of the outer side.

115. The surgical drain of claim 101, wherein the surgical drain further includes a flap extending from the outer side.

116. A surgical drain comprising:

an elongated conduit configured to be implanted in and to drain fluid from a body cavity, the elongated conduit including a first surface located on an outer side of the elongated conduit and a second surface located on an outer side of the elongated conduit;

a projection extending from the first surface; and

a first sensing system configured to sense a physiological property of the tissue proximate the first surface.

117. The surgical drain of claim 116, wherein the surgical drain further comprises an inflatable compartment proximate to the second surface.

118. The surgical drain of claim 101, wherein the surgical drain comprises transparent material.

119. The surgical drain of claim 117, wherein the first inflatable compartment is proximate to the second surface.

120. The surgical drain of claim 117, wherein the first inflatable compartment is within the elongated conduit.

121. The surgical drain of claim 117, wherein the first sensing system and first inflatable compartment are positioned at about the same position along a drain length.

122. The surgical drain of claim 116, wherein the physiological property is selected from the group comprising: oxygenation, perfusion, temperature, pH, NADH levels, biochemical composition, drug concentration, turgidity or pressure.

123. The surgical drain of claim 116, comprising a second sensing system configured to sense a different physiological property than the first sensing system.

124. The surgical drain of claim 116, wherein the conduit includes a drain portion configured to rest against a substantial length of tissue within the body

cavity and a plurality of drain holes spaced along substantially the entire length of the drain portion.

125. The surgical drain of claim 116, further including a display configured to depict data corresponding to the physiological property sensed by the first sensing system.

126. The surgical drain of claim 117, further comprising a pump in communication with an interior portion of the inflatable compartment.

127. The surgical drain of claim 117, further comprising a pressure monitor in communication with the interior portion of the inflatable chamber.

128. The surgical drain of claim 116, wherein the surgical drain further includes an anchor configured to stabilize the position of the surgical drain relative to tissue in the body cavity.

129. The surgical drain of claim 116, wherein the surgical drain further includes a projection extending from the outer side, wherein the projection is configured for insertion into tissue in the body cavity.

130. The surgical drain of claim 116, wherein the surgical drain further includes a first loop extending from the outer side.

131. The surgical drain of claim 116, wherein the surgical drain further includes adhesive on at least a portion of the outer side.

132. The surgical drain of claim 116, wherein the surgical drain further includes a flap extending from the outer side.

133. A surgical drain comprising:

an elongated conduit configured to be implanted in and to drain fluid from a body cavity; and

at least one anchor configured to stabilize the elongated conduit with respect to a tissue in the body cavity.

134. The surgical drain of claim 133, further comprising a first sensing system configured to sense a physiological property of a tissue proximate to the elongated conduit.

135. The surgical drain of claim 133, wherein the physiological property is selected from the group comprising: oxygenation, perfusion, temperature, pH, NADH levels, biochemical composition, drug concentration, turgidity or pressure.

136. The surgical drain of claim 133, further including a display configured to depict data corresponding to the physiological property sensed by the first sensing system.

137. The surgical drain of claim 133, comprising a second sensing system configured to sense a different physiological property than the first sensing system.

138. The surgical drain of claim 133, wherein the conduit includes a drain portion configured to rest against a substantial length of tissue within the body cavity and a plurality of drain holes spaced along substantially the entire length of the drain portion.

139. The surgical drain of claim 133, wherein the surgical drain further comprises an inflatable compartment.

140. The surgical drain of claim 133, further comprising a pump in communication with an interior portion of the inflatable compartment.

141. The surgical drain of claim 133, further comprising a pressure monitor in communication with the interior portion of the inflatable chamber.

142. The surgical drain of claim 133, wherein surgical drain comprises transparent material.

143. A surgical drain comprising:

an elongated conduit configured to be implanted in and to drain fluid from a body cavity, the elongated conduit including an outer side and a projection extending from the drain outer surface configured for insertion into tissue in the body cavity.

144. The surgical drain of claim 143, further comprising a first sensing system configured to sense a physiological property of a tissue proximate to the elongated conduit.

145. The surgical drain of claim 143, wherein the physiological property is selected from the group comprising: oxygenation, perfusion, temperature, pH, NADH levels, biochemical composition, drug concentration, turgidity or pressure.

146. The surgical drain of claim 143, further including a display configured to depict data corresponding to the physiological property sensed by the first sensing system.

147. The surgical drain of claim 143, comprising a second sensing system configured to sense a different physiological property than the first sensing system.

148. The surgical drain of claim 143, wherein the conduit includes a drain portion configured to rest against a substantial length of tissue within the body cavity and a plurality of drain holes spaced along substantially the entire length of the drain portion.

149. The surgical drain of claim 143, wherein the surgical drain further comprises an inflatable compartment.

150. The surgical drain of claim 143, further comprising a pump in communication with an interior portion of the inflatable compartment.

151. The surgical drain of claim 143, further comprising a pressure monitor in communication with the interior portion of the inflatable chamber.

152. The surgical drain of claim 143, wherein surgical drain comprises transparent material.

153. A surgical drain comprising:

an elongated conduit configured to be implanted in and to drain fluid from a body cavity, the elongated conduit including an outer side and a first loop extending from the drain outer side.

154. The surgical drain of claim 153, further comprising a first sensing system configured to sense a physiological property of a tissue proximate to the elongated conduit.

155. The surgical drain of claim 153, wherein the physiological property is selected from the group comprising: oxygenation, perfusion, temperature, pH, NADH levels, biochemical composition, drug concentration, turgidity or pressure.

156. The surgical drain of claim 153, further including a display configured to depict data corresponding to the physiological property sensed by the first sensing system.

157. The surgical drain of claim 153, comprising a second sensing system configured to sense a different physiological property than the first sensing system.

158. The surgical drain of claim 153, wherein the conduit includes a drain portion configured to rest against a substantial length of tissue within the body cavity and a plurality of drain holes spaced along substantially the entire length of the drain portion.

159. The surgical drain of claim 153, wherein the surgical drain further comprises an inflatable compartment.

160. The surgical drain of claim 153, further comprising a pump in communication with an interior portion of the inflatable compartment.

161. The surgical drain of claim 153, further comprising a pressure monitor in communication with the interior portion of the inflatable chamber.

162. The surgical drain of claim 153, wherein surgical drain comprises transparent material.

163. A surgical drain comprising:

an elongated conduit configured to be implanted in and to drain fluid from a body cavity, the elongated conduit including an outer side and adhesive on at least a portion of the outer side.

164. The surgical drain of claim 163, wherein the adhesive is a pressure sensitive adhesive or fibrin glue.

165. The surgical drain of claim 163, wherein at least the adhesive comprises transparent material.

166. The surgical drain of claim 163, further comprising a first sensing system configured to sense a physiological property of a tissue proximate to the elongated conduit.

167. The surgical drain of claim 163, wherein the physiological property is selected from the group comprising: oxygenation, perfusion, temperature, pH, NADH levels, biochemical composition, drug concentration, turgidity or pressure.

168. The surgical drain of claim 163, further including a display configured to depict data corresponding to the physiological property sensed by the first sensing system.

169. The surgical drain of claim 163, comprising a second sensing system configured to sense a different physiological property than the first sensing system.

170. The surgical drain of claim 163, wherein the conduit includes a drain portion configured to rest against a substantial length of tissue within the body cavity and a plurality of drain holes spaced along substantially the entire length of the drain portion.

171. The surgical drain of claim 163, wherein the surgical drain further comprises an inflatable compartment.

172. The surgical drain of claim 163, further comprising a pump in communication with an interior portion of the inflatable compartment.

173. The surgical drain of claim 163, further comprising a pressure monitor in communication with the interior portion of the inflatable chamber.

174. The surgical drain of claim 163, wherein surgical drain comprises transparent material.

175. A surgical drain comprising:

an elongated conduit configured to be implanted in and to drain fluid from a body cavity, the elongated conduit including an outer side and a flap extending from the outer side.

176. The surgical drain of claim 175, wherein the flap further has a first edge, wherein the first edge has a thickness greater the thickness of the flap.

177. The surgical drain of claim 175 having a sensing system for detecting a physiological property of tissue proximate to the flap.

178. The surgical drain of claim 175, further having adhesive on at least a portion of the outer side or flap.

179. The surgical drain of claim 175, further comprising a first sensing system configured to sense a physiological property of a tissue proximate to the elongated conduit.

180. The surgical drain of claim 175, wherein the physiological property is selected from the group comprising: oxygenation, perfusion, temperature, pH, NADH levels, biochemical composition, drug concentration, turgidity or pressure.

181. The surgical drain of claim 175, further including a display configured to depict data corresponding to the physiological property sensed by the first sensing system.

182. The surgical drain of claim 175, comprising a second sensing system configured to sense a different physiological property than the first sensing system.

183. The surgical drain of claim 175, wherein the conduit includes a drain portion configured to rest against a substantial length of tissue within the body cavity and a plurality of drain holes spaced along substantially the entire length of the drain portion.

184. The surgical drain of claim 175, wherein the surgical drain further comprises an inflatable compartment.

185. The surgical drain of claim 175, further comprising a pump in communication with an interior portion of the inflatable compartment.

186. The surgical drain of claim 175, further comprising a pressure monitor in communication with the interior portion of the inflatable chamber.

187. The surgical drain of claim 175, wherein surgical drain comprises transparent material.

188. A surgical drain comprising:

an elongated conduit configured to be implanted in and to drain fluid from a body cavity, wherein at least a portion of the elongated conduit comprises an optically transparent material; and

a first sensing system configured to sense a physiological property of any substance proximate to the elongated conduit.

189. The surgical drain of claim 188, wherein the physiological property is selected from the group comprising: temperature, oxygenation, perfusion, pH, NADH levels, biochemical composition, drug concentrations, turgidity or pressure.

190. The surgical drain of claim 188, wherein the conduit includes a drain portion configured to rest against a substantial length of tissue within the body

cavity and a plurality of drain holes spaced along substantially the entire length of the drain portion.

191. The surgical drain of claim 188, wherein at least portions of the first and second sensing systems are embedded within the conduit behind material that is optically transparent.

192. The surgical drain of claim 188, further including a display configured to depict data corresponding to the physiological property sensed by the first or second sensing systems.

193. The surgical drain of claim 188, wherein the first sensing system includes a component that is affixed to the conduit.

194. The surgical drain of claim 188, wherein the component is embedded in the conduit.

195. The surgical drain of claim 188, wherein the component includes a sensor.

196. The surgical drain of claim 188, wherein the component includes an optical fiber.

197. The surgical drain of claim 188, wherein the surgical drain further includes an anchor configured to stabilize the position of the surgical drain relative to tissue in the body cavity.

198. The surgical drain of claim 188, wherein the surgical drain further includes a projection extending from the outer side, wherein the projection is configured for insertion into tissue in the body cavity.

199. The surgical drain of claim 188, wherein the surgical drain further includes a first loop extending from the outer side.

200. The surgical drain of claim 188, wherein the surgical drain further includes adhesive on at least a portion of the outer side.

201. The surgical drain of claim 188, wherein the surgical drain further includes a flap extending from the outer side.

202. The surgical drain of claim 188, further comprising a first inflatable compartment associated with the elongated circuit.

203. A method of utilizing a surgical drain to monitor the condition of a tissue in a body cavity, comprising:

implanting a surgical drain within a body cavity in proximity to a tissue to be monitored, wherein the surgical drain includes a first sensing system configured to sense a physiological property of the tissue;

receiving information from the first sensing system regarding a physiological property of the tissue;

monitoring the information received from the first sensing system to evaluate the condition of the tissue over time.

204. The method of claim 203, wherein the tissue condition monitored is selected from the group comprising: perfusion, oxygenation, temperature, pH, NADH level, drug concentration, turgidity and pressure.

205. The method of claim 203, comprising transmitting energy to a tissue, and receiving energy from a tissue with the first sensing system.

206. The method of claim 203, comprising transmitting energy through a tissue, and receiving energy from a tissue with the first sensing system.

207. The method of claim 203, further including processing the information received from the first sensing system.

208. The method of claim 203, further including displaying information received from the first sensing system.

209. The method of claim 203, comprising detecting a lack of receipt of information from the first sensing system.

210. The method of claim 203, comprising detecting a lack of contact between a sensor of a sensing system and the tissue.

211. The method of claim 203, comprising inflating an inflatable chamber associated with the surgical drain to decrease distance between the tissue and the surgical drain.

212. The method of claim 203, comprising applying suction to a lumen within the surgical drain to decrease distance between the tissue and the surgical drain.

213. The method of claim 203, wherein implanting the surgical drain comprises anchoring the surgical drain to a tissue within the body cavity.

214. The method of claim 203, further comprising removing the surgical drain when monitoring is not desired.

215. A method of utilizing a surgical drain to monitor the condition of a tissue comprising:

implanting a surgical drain within a body cavity in proximity to tissue to be monitored, wherein the surgical drain includes a first sensing system and a second sensing system configured to sense a physiological property of the tissue;

receiving information from the first and second sensing systems regarding the physiological property of the tissue;

monitoring the information received from the first and second sensing systems to evaluate the condition of the tissue over time.

216. The method of claim 215, comprising processing information from the first and second sensing systems to compare a difference in information sensed by the first and second sensing systems.

217. The method of claim 215, comprising processing information from the first and second sensing systems to compare a difference in information received from the first and second sensing systems from different regions along the same tissue.

218. The method of claim 215, comprising processing information from the first and second sensing systems to compare a difference in information received from the first and second sensing systems from different tissues.

219. A method of utilizing a surgical drain to monitor substances in a drain lumen comprising:

implanting a surgical drain having a surgical drain lumen within a body cavity in proximity to a tissue to be monitored, wherein the surgical drain includes a first sensing system configured to sense a physiological property of a substance within a drain lumen;

receiving information from the first sensing system regarding a substance within the drain lumen;

monitoring the information received from the sensing system to evaluate the condition of the tissue over time.

220. The method of claim 219, comprising transmitting energy within the drain lumen and receiving energy with the first sensing system.

221. The method of claim 219, further including processing the information received from the first sensing system.

222. The method of claim 219, further including displaying information received from the first sensing system.

223. The method of claim 219, wherein implanting the surgical drain comprises anchoring the surgical drain to a tissue within the body cavity.

224. A method of utilizing a surgical drain to monitor substances in the drain lumen comprising:

- implanting a surgical drain within a body cavity in proximity to tissue to be monitored, wherein the surgical drain includes a first and a second sensing system configured to sense a physiological property of a substance within the drain lumen;

- receiving information from the first and second sensing systems regarding substances in the drain lumen;

- monitoring the information received from the first and second sensing systems to evaluate the condition of the tissue over time.

225. The method of claim 224, comprising processing information from the first and second sensing systems to compare a difference in information received from the first and second sensing systems.

226. The method of claim 224, comprising processing information from the first and second sensing systems to compare a difference in information received from the first and second sensing systems proximate to different positions along the drain lumen.

227. A surgical drain comprising:

- a conduit that is bifurcated into at least two elongated conduits to be implanted in and to drain fluid from a body cavity,

the first elongated conduit including a first surface located on an outer side of the conduit and a second surface located on an outer side of the conduit that is substantially opposite of the first surface;

the second elongated conduit including a third surface located on an outer side of the conduit and a fourth surface located on an outer side of the conduit that is substantially opposite of the first surface;

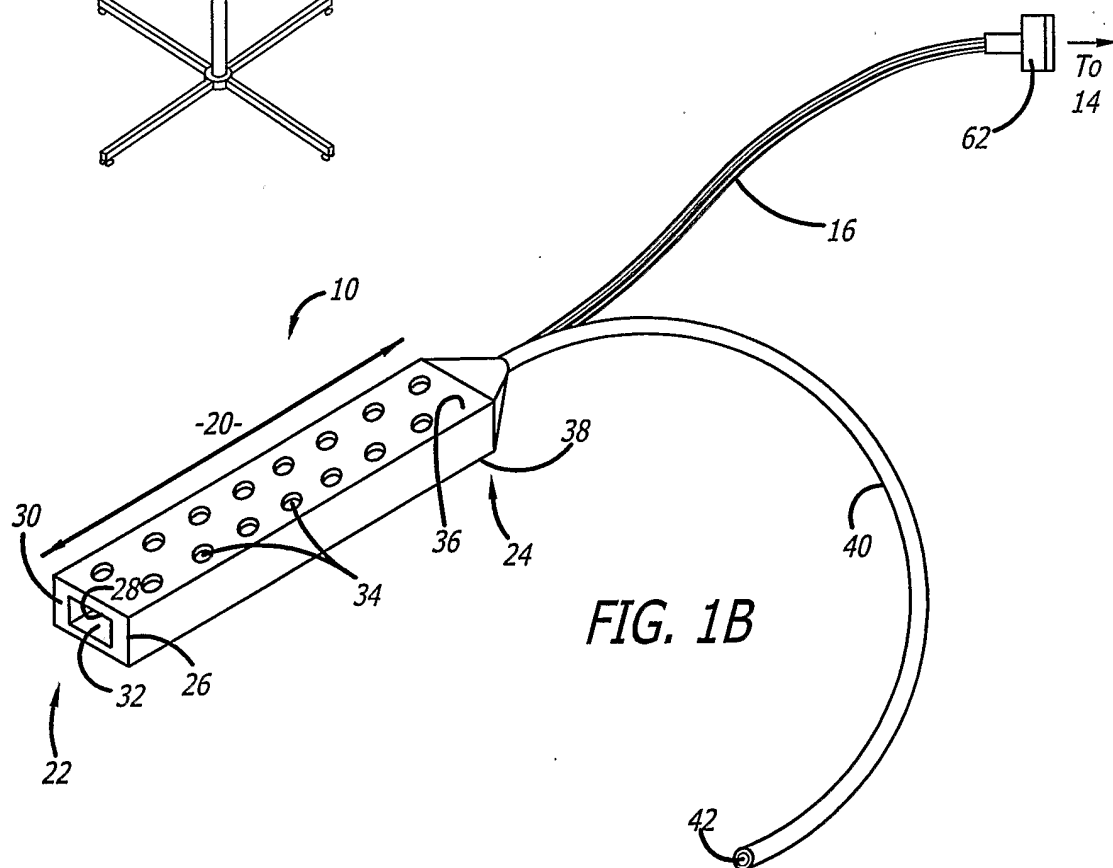
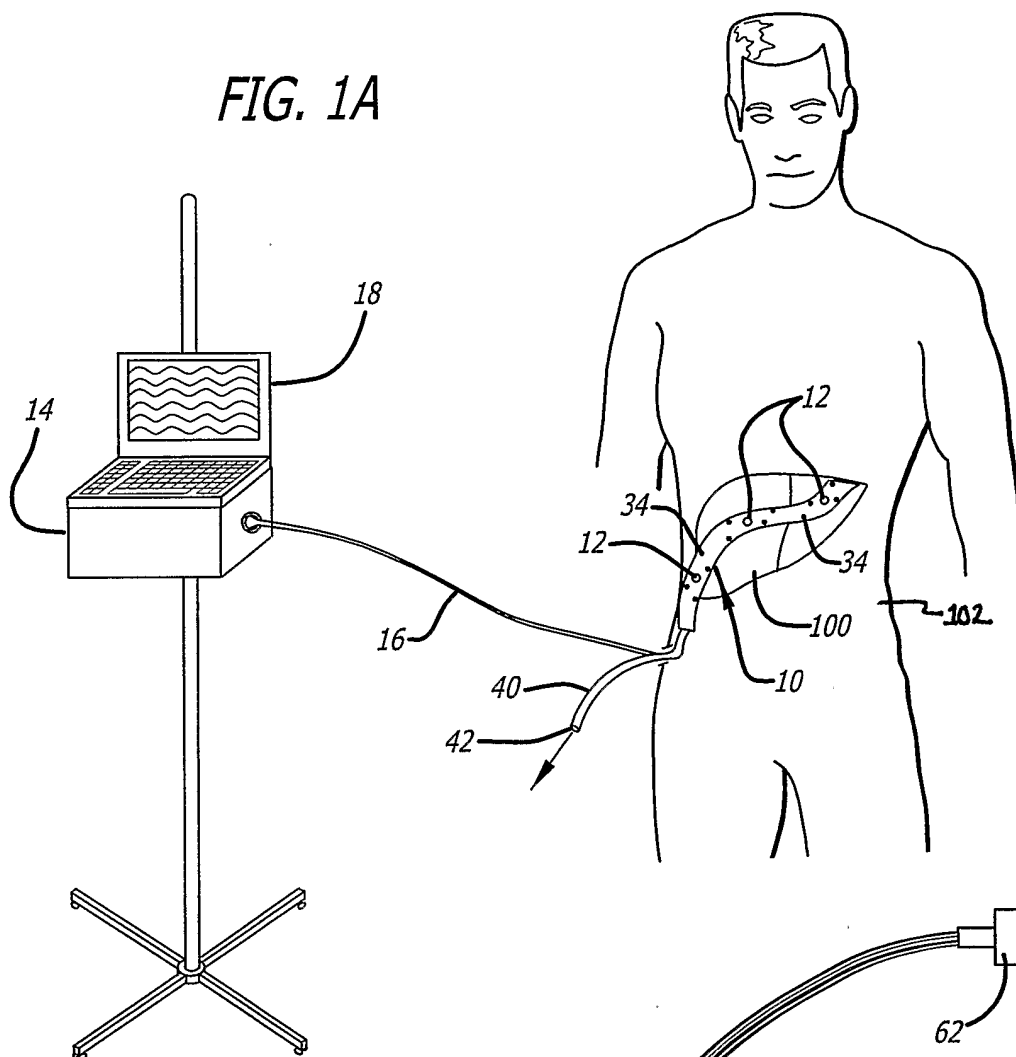
a first sensing system configured to sense a physiological property of tissue proximate to the first surface; and

a second sensing system configured to sense a physiological property of tissue proximate to the second surface; and

a third sensing system configured to sense a physiological property of tissue proximate to the third surface; and

a fourth sensing system configured to sense a physiological property of tissue proximate to the fourth surface.

FIG. 1A



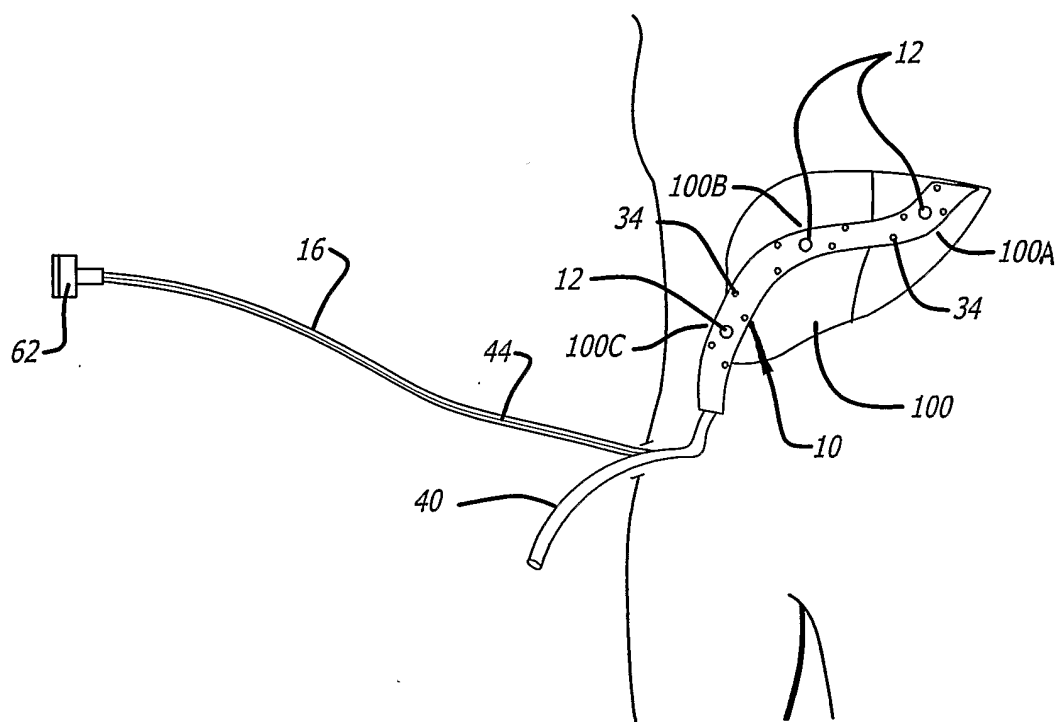


FIG. 1C

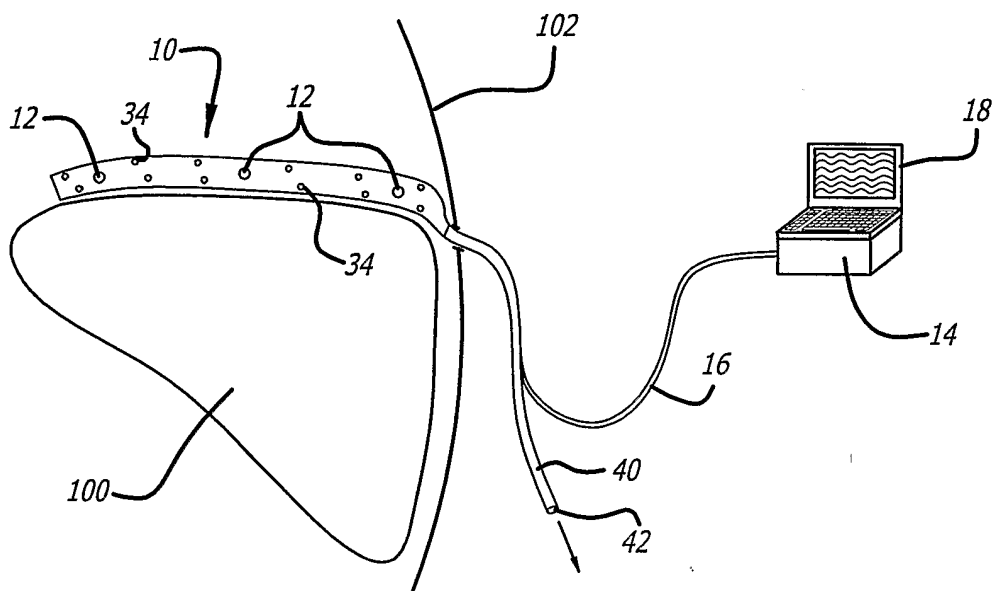


FIG. 2A

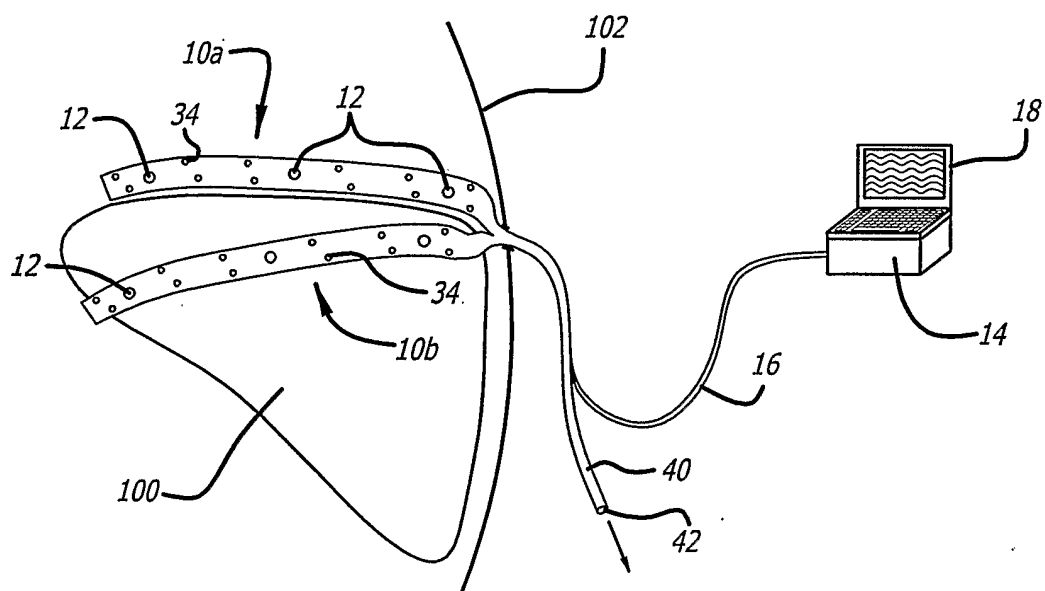


FIG. 2B

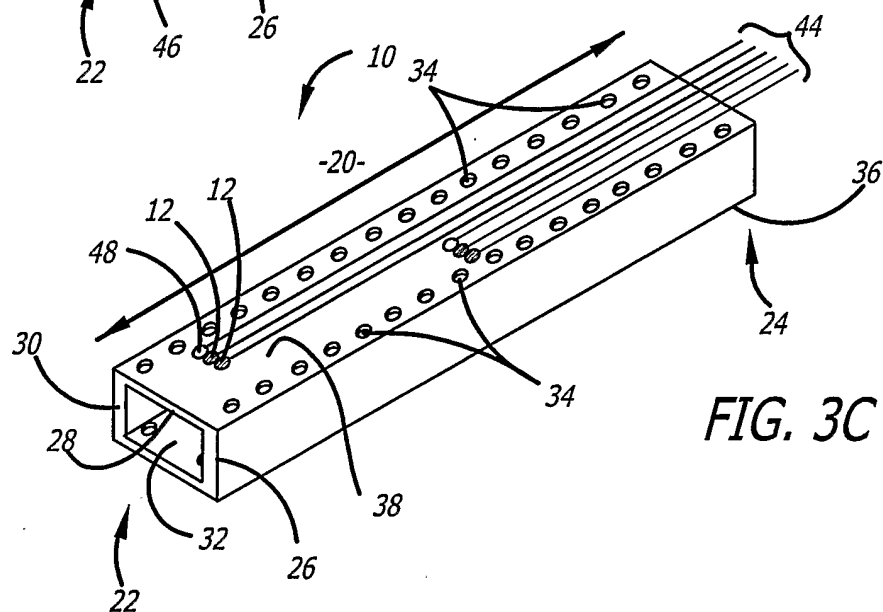
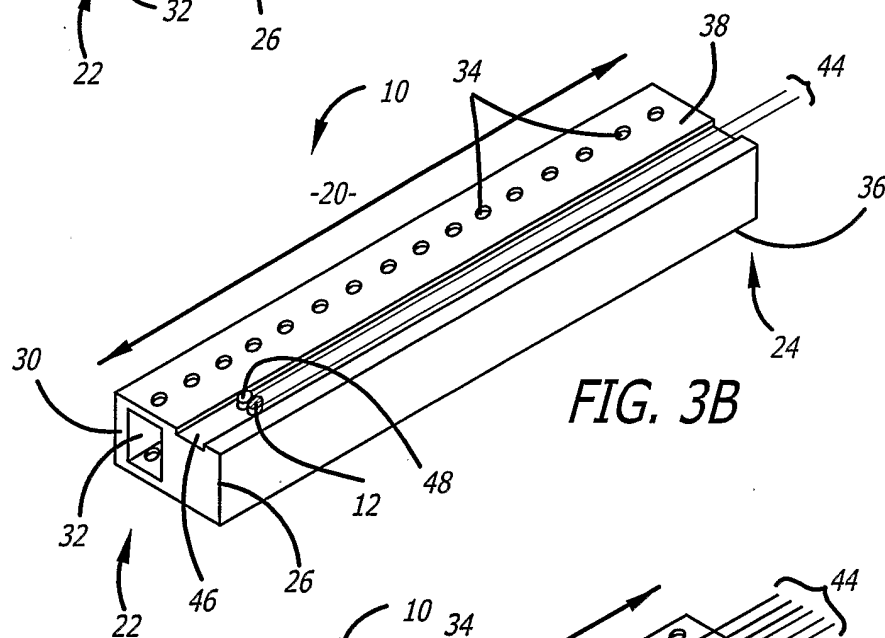
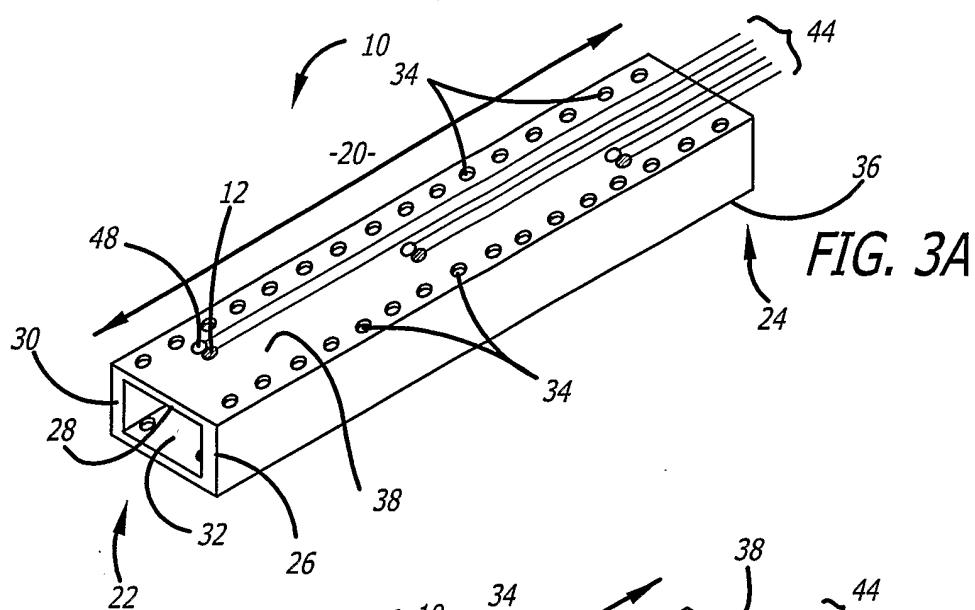


FIG. 3D

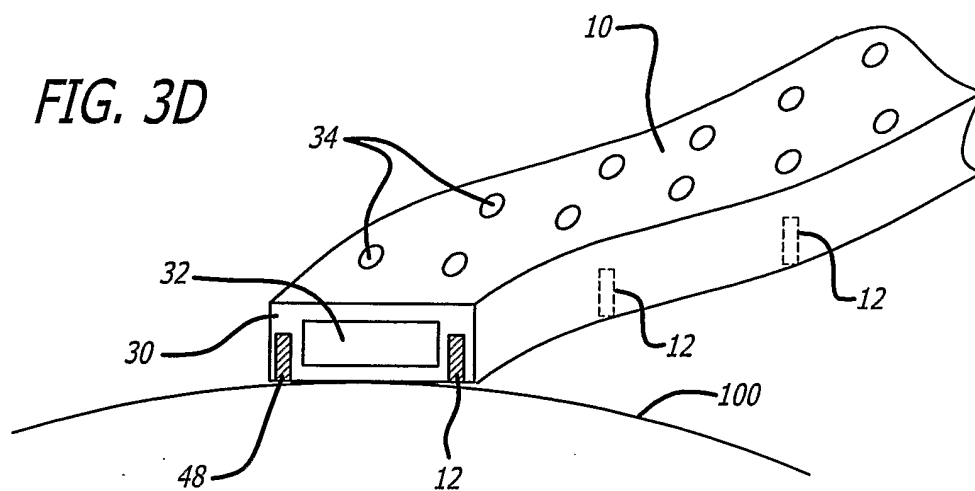


FIG. 3E

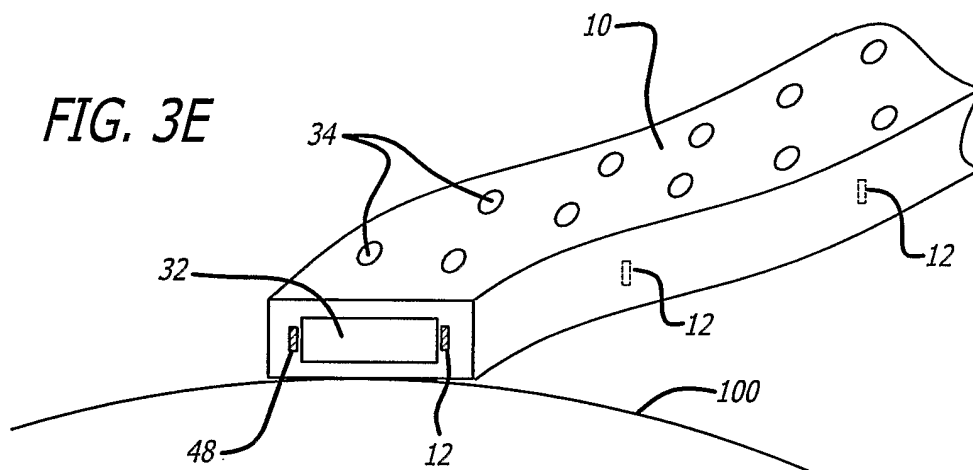


FIG. 3F

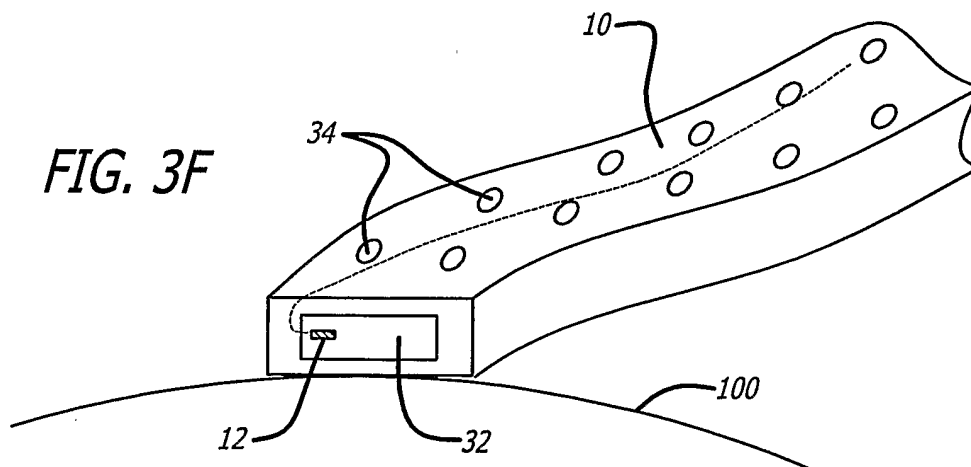


FIG. 4A

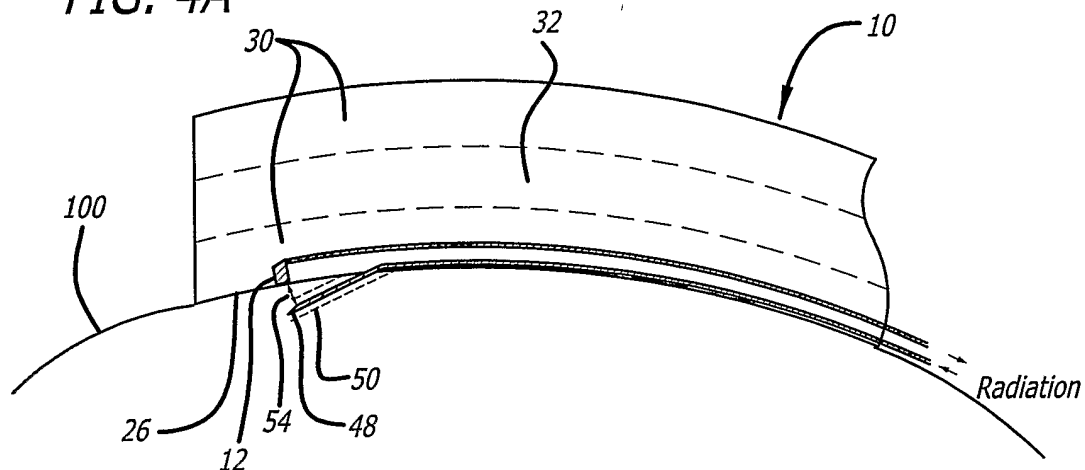


FIG. 4B

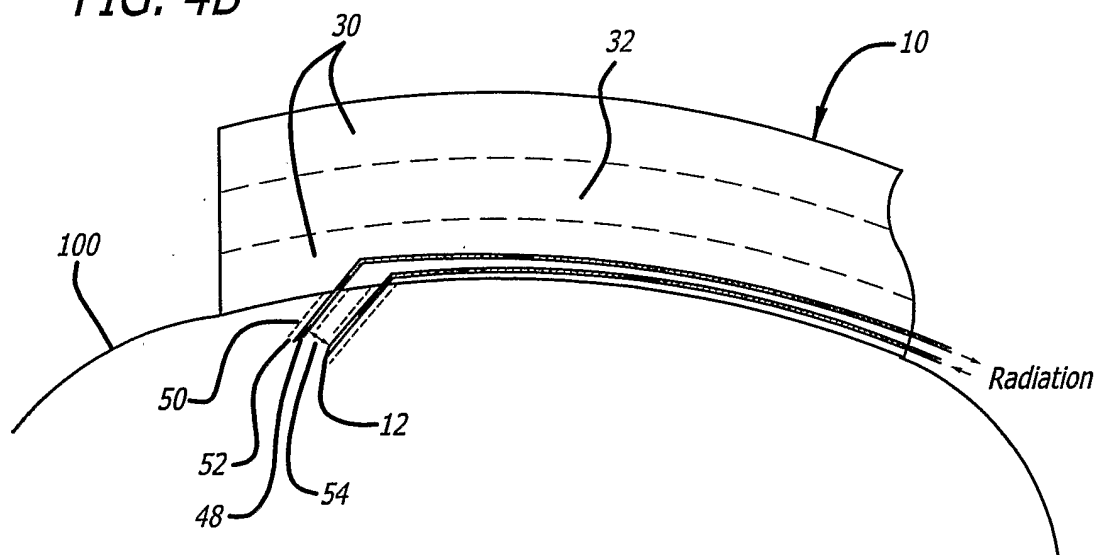


FIG. 5A

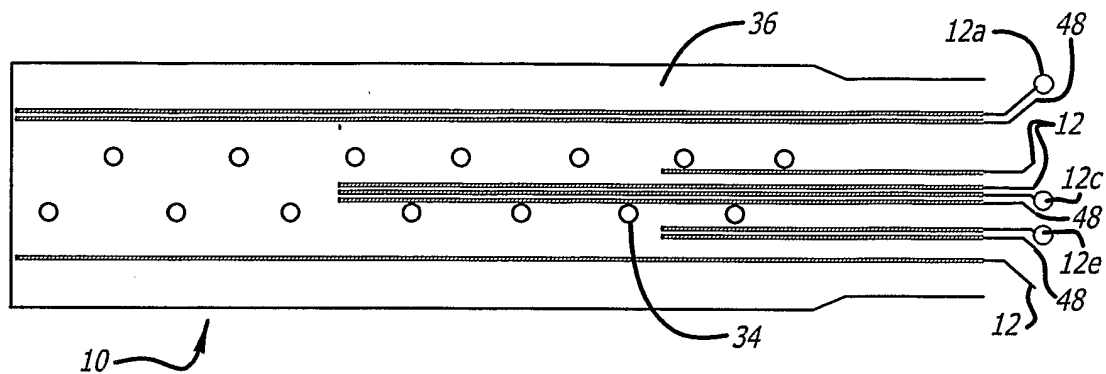


FIG. 5B

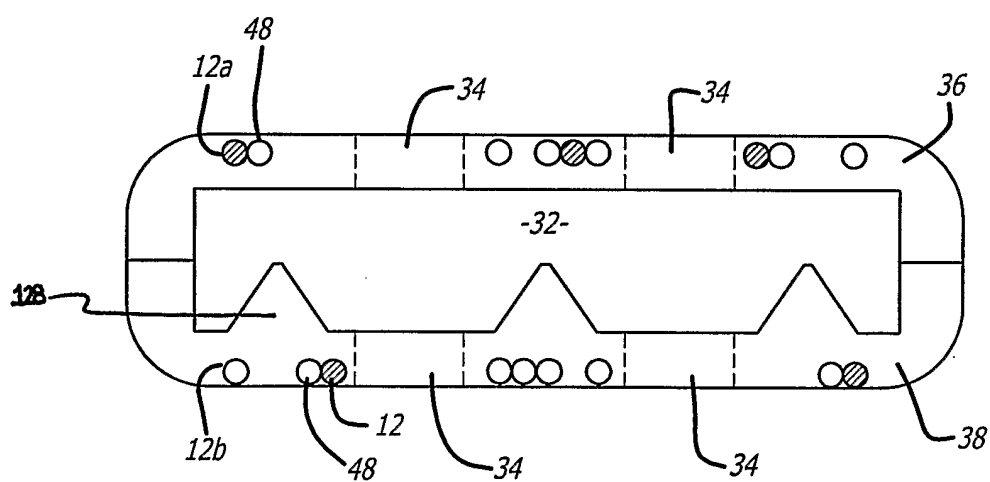
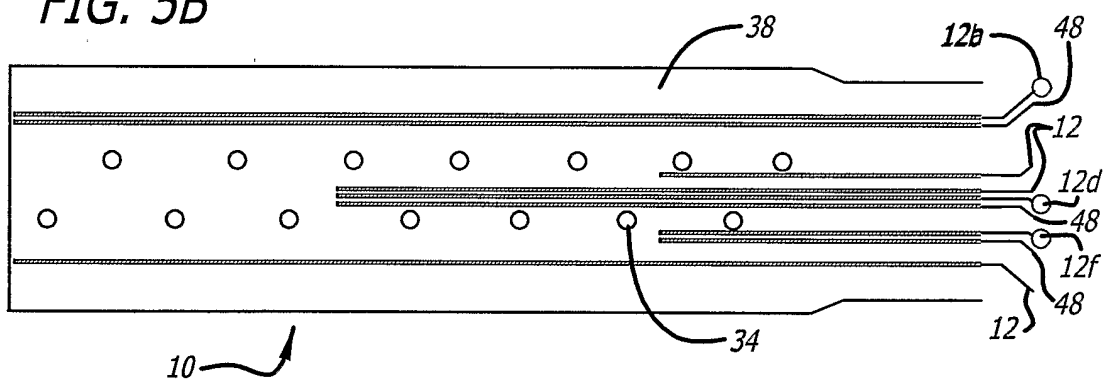
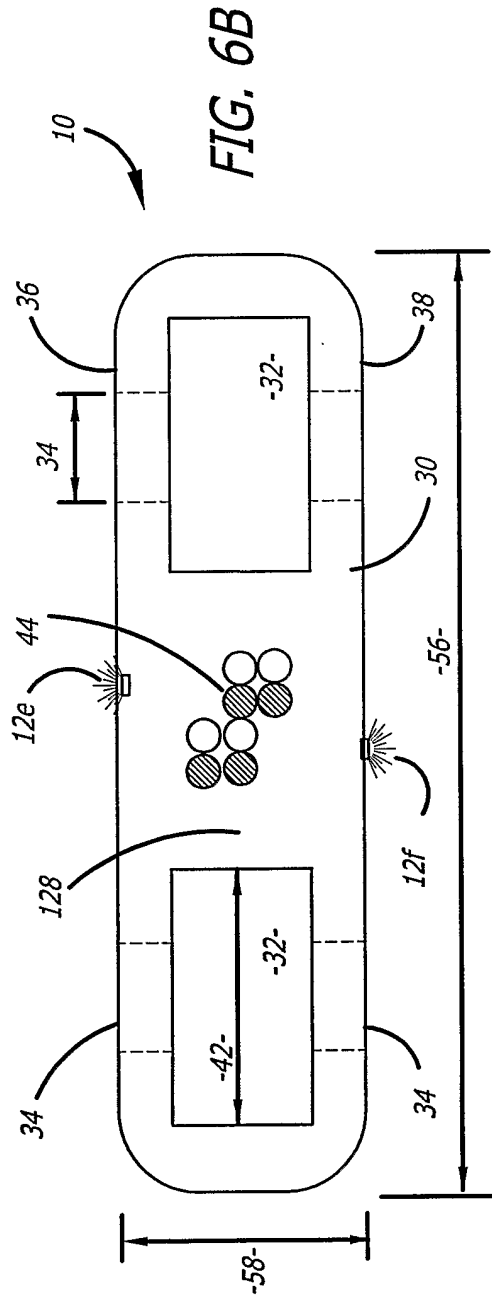
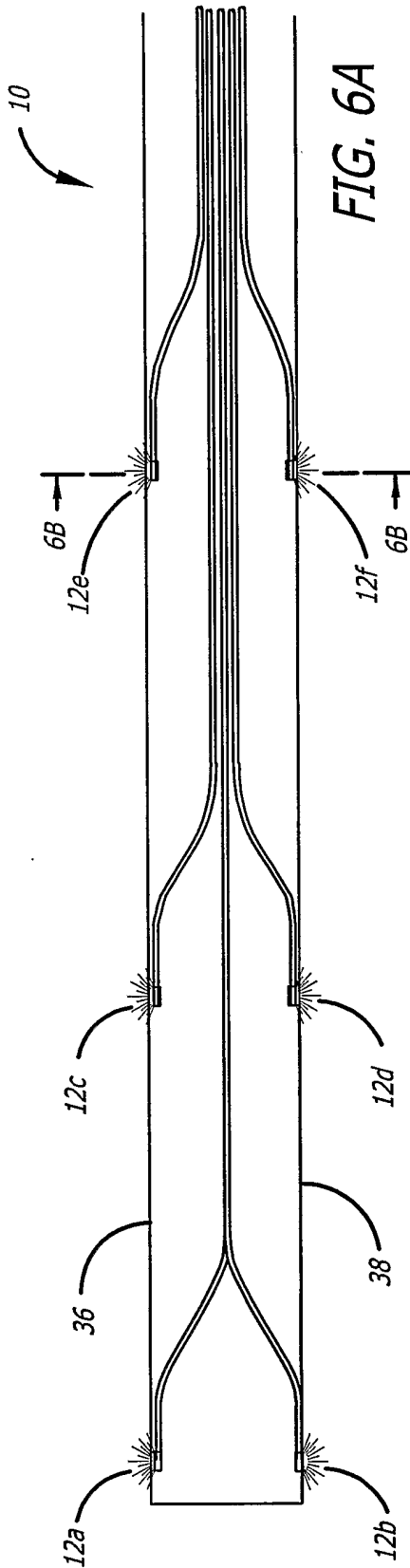
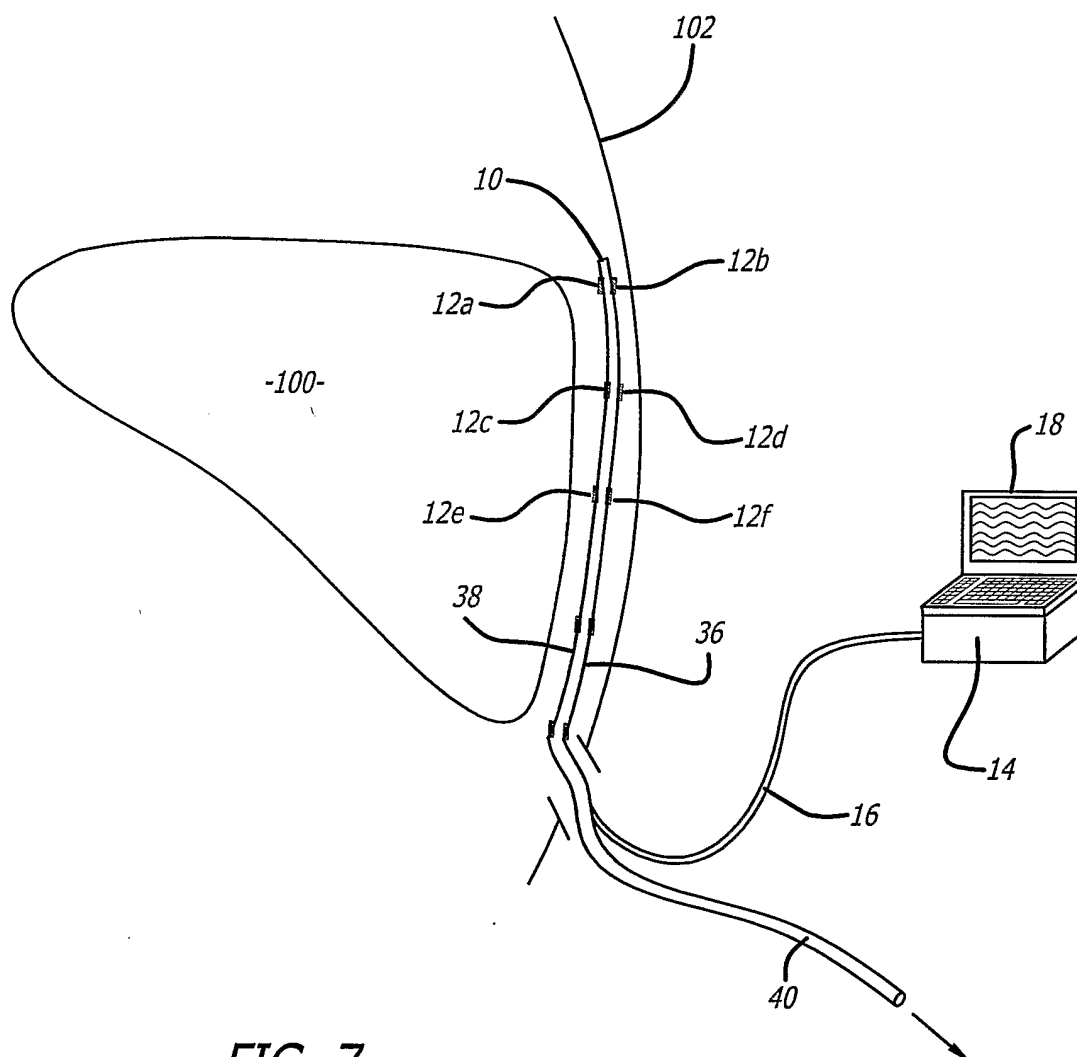


FIG. 5C



**FIG. 7**

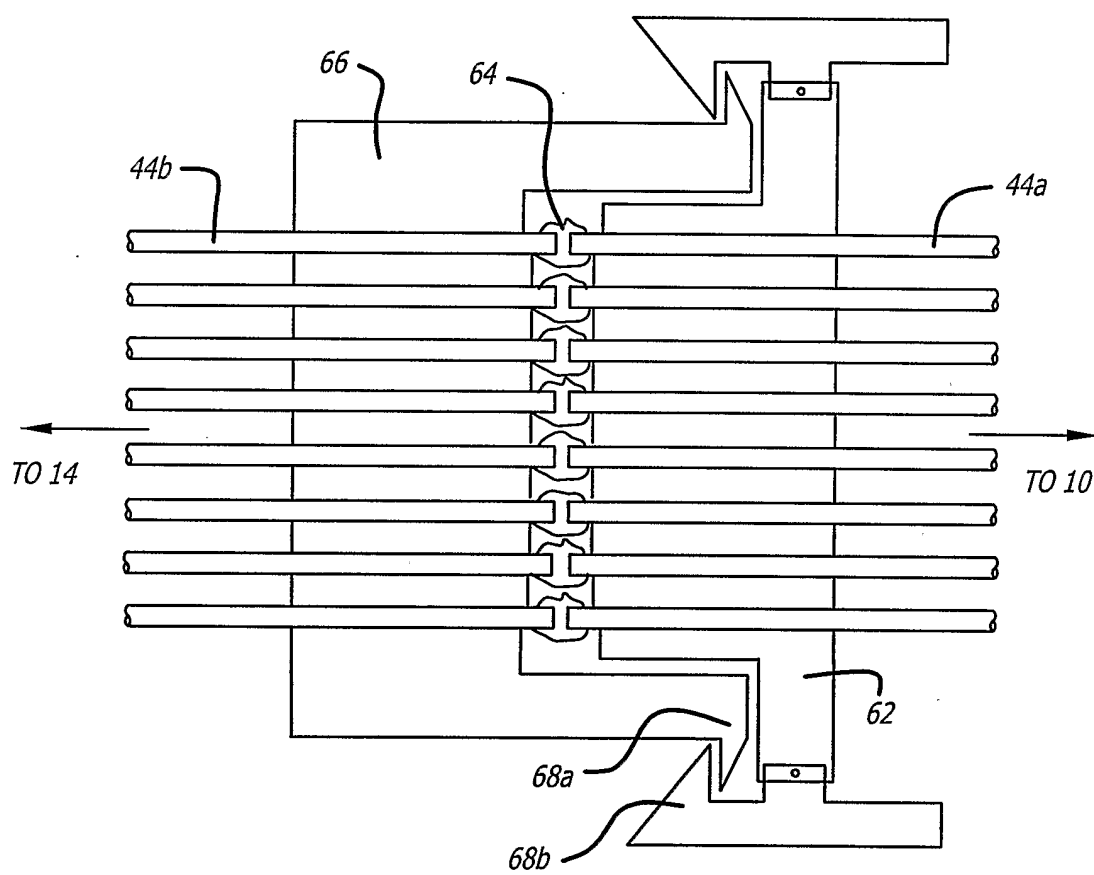


FIG. 8A

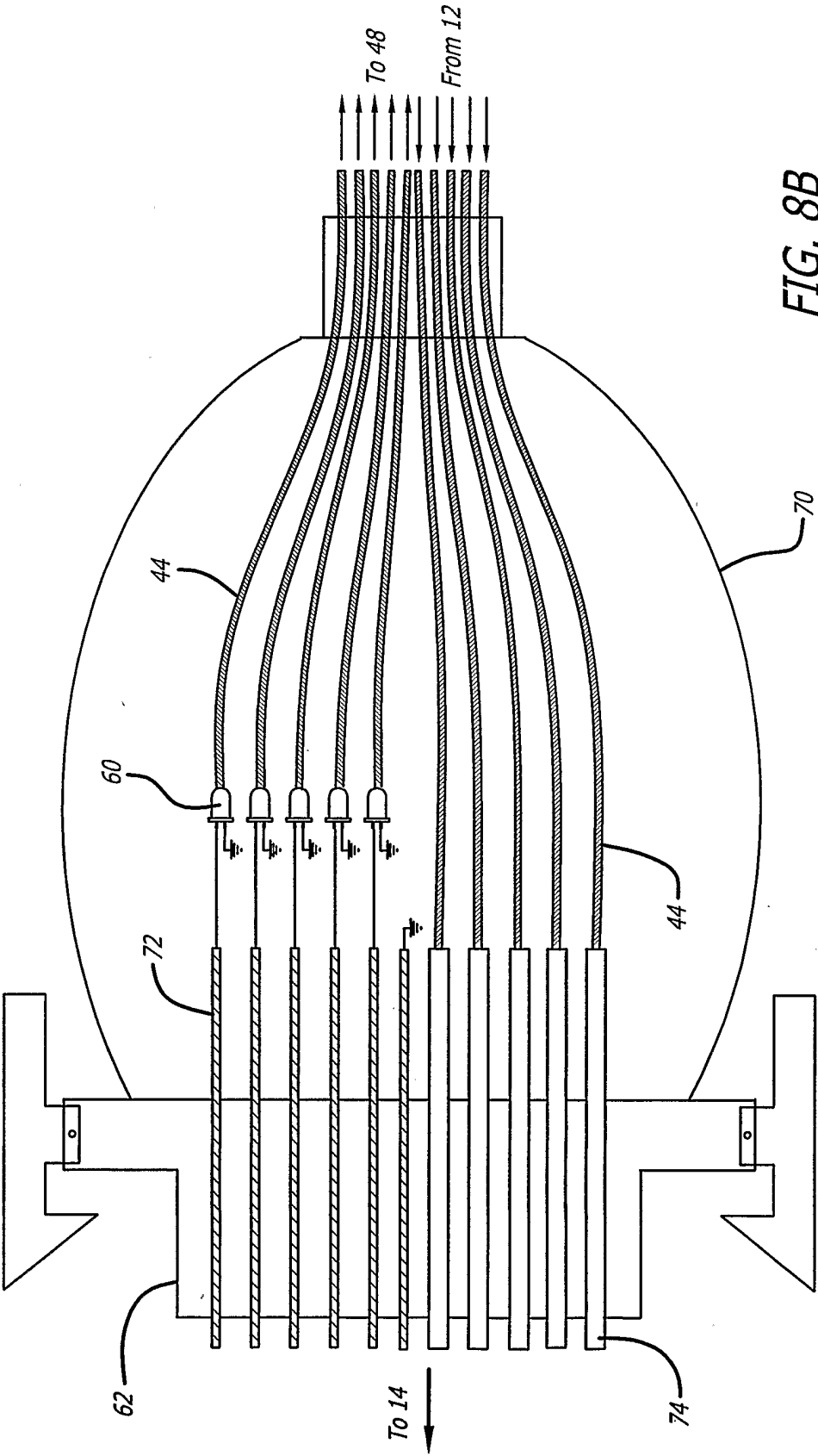
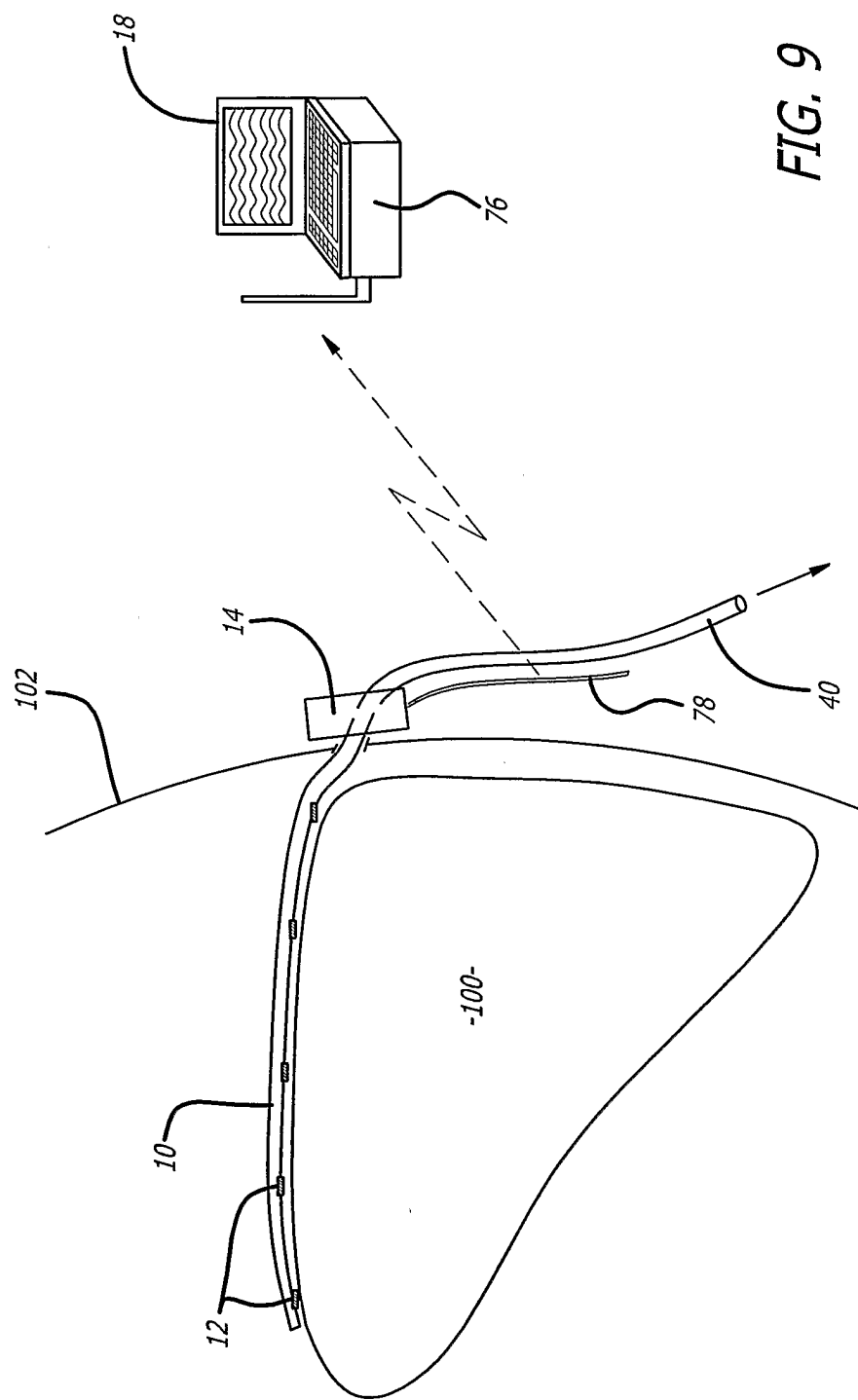


FIG. 8B



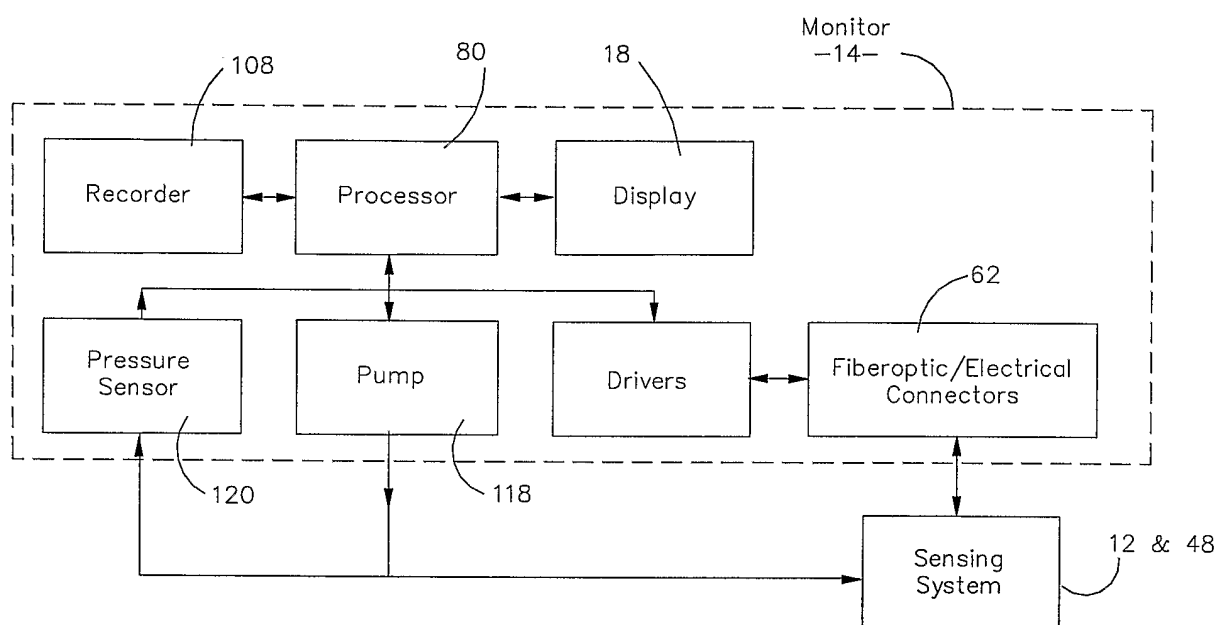


FIG. 10

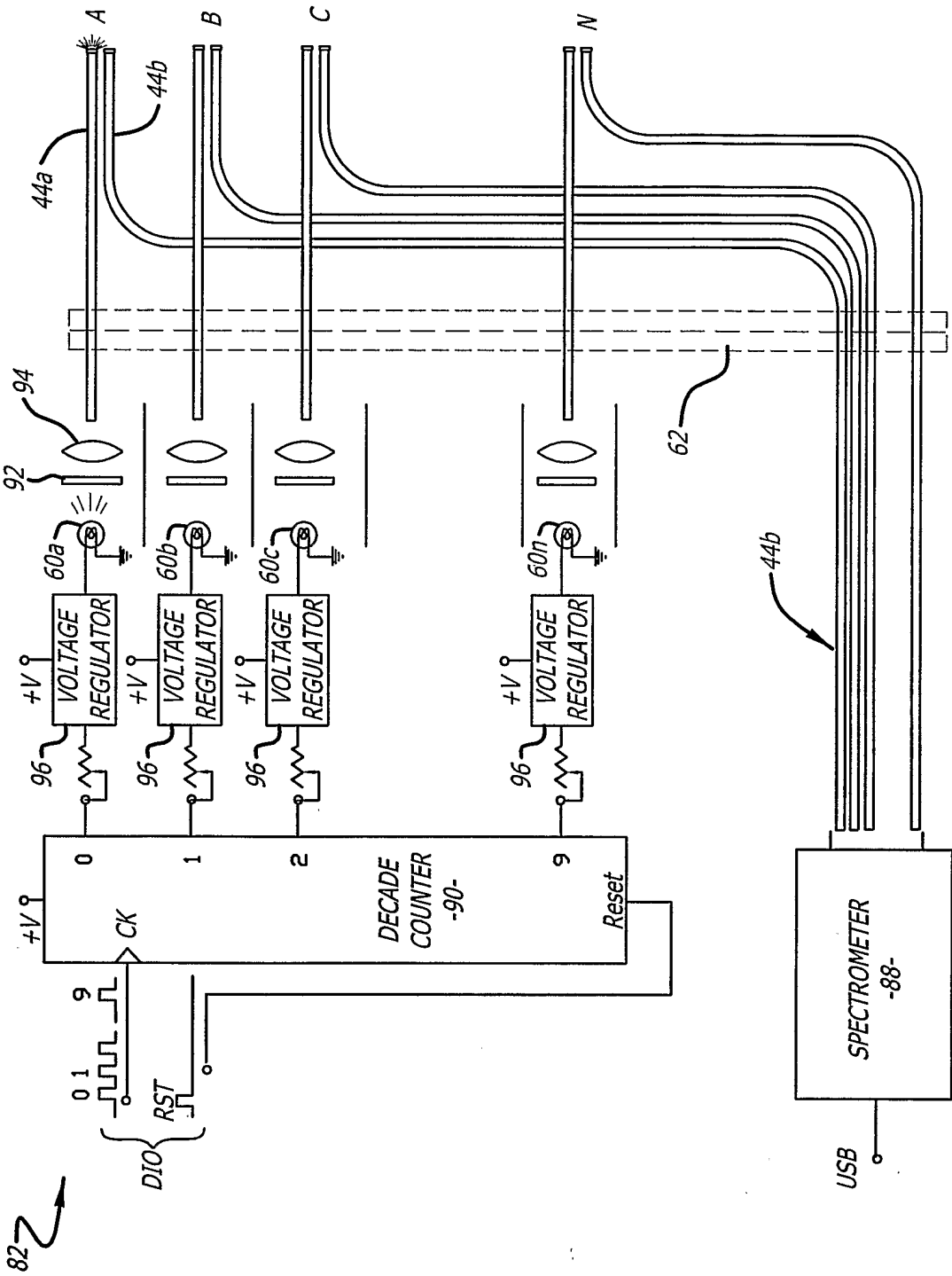


FIG. 11

FIG. 12A

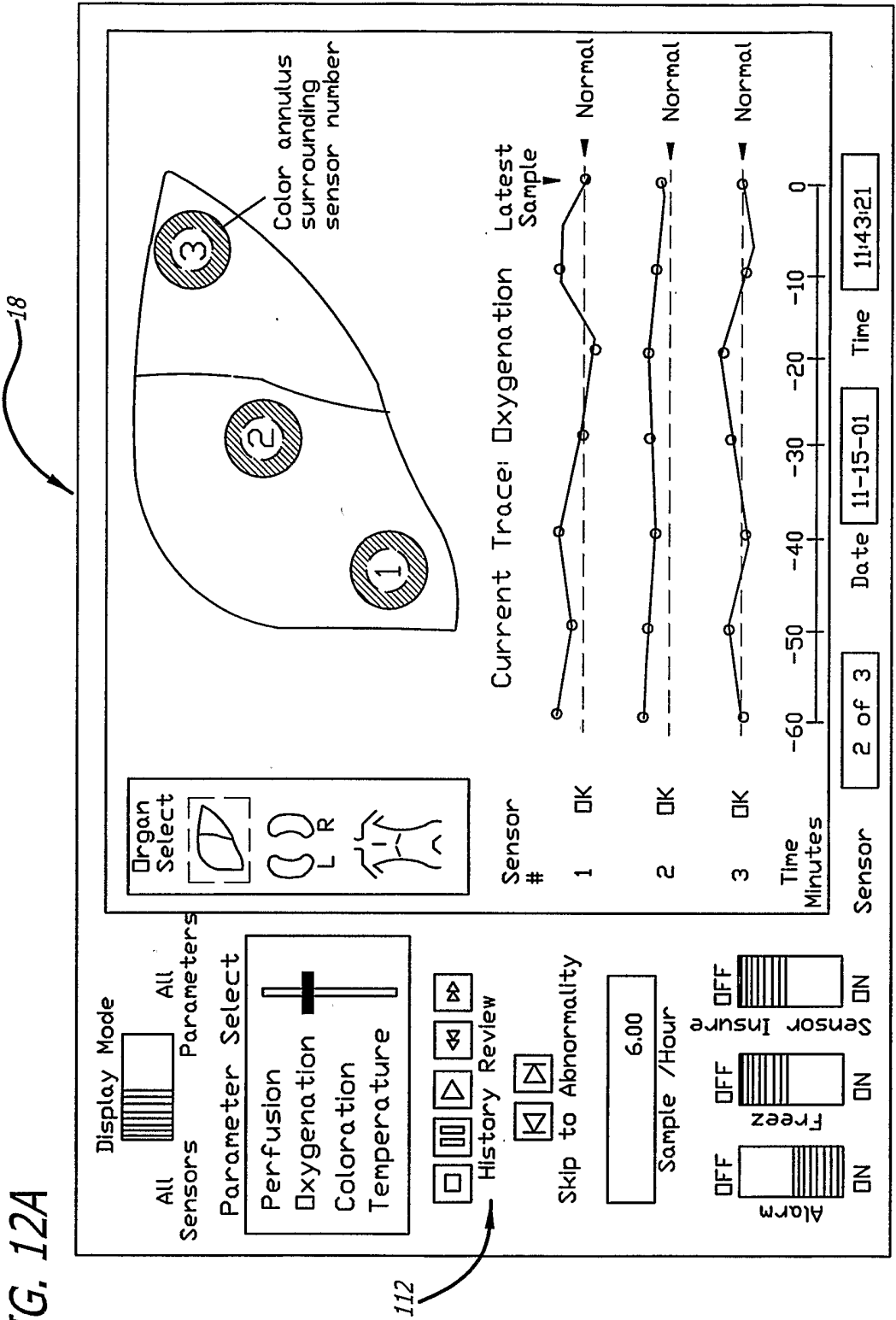


FIG. 12B

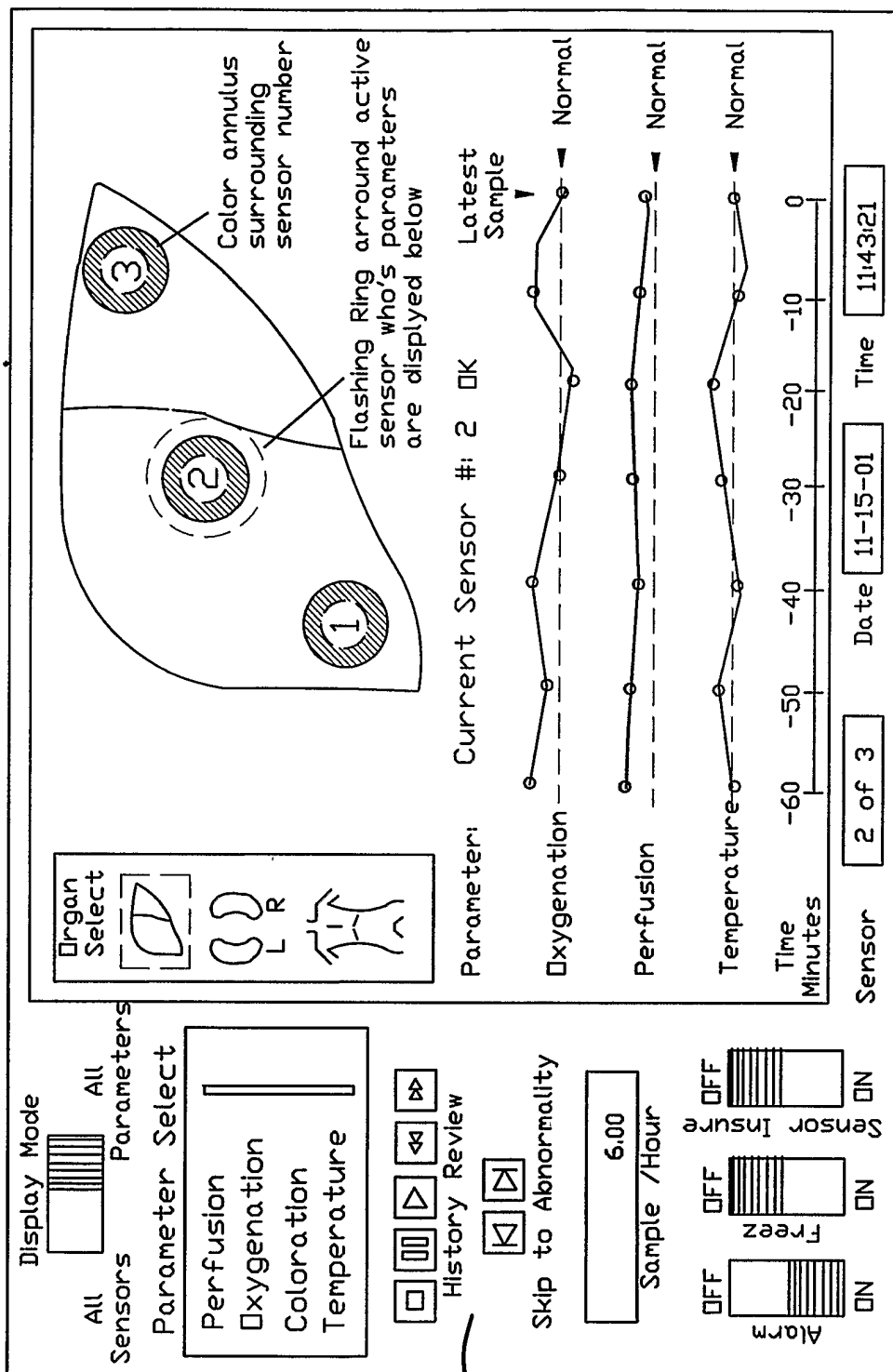


FIG. 12C

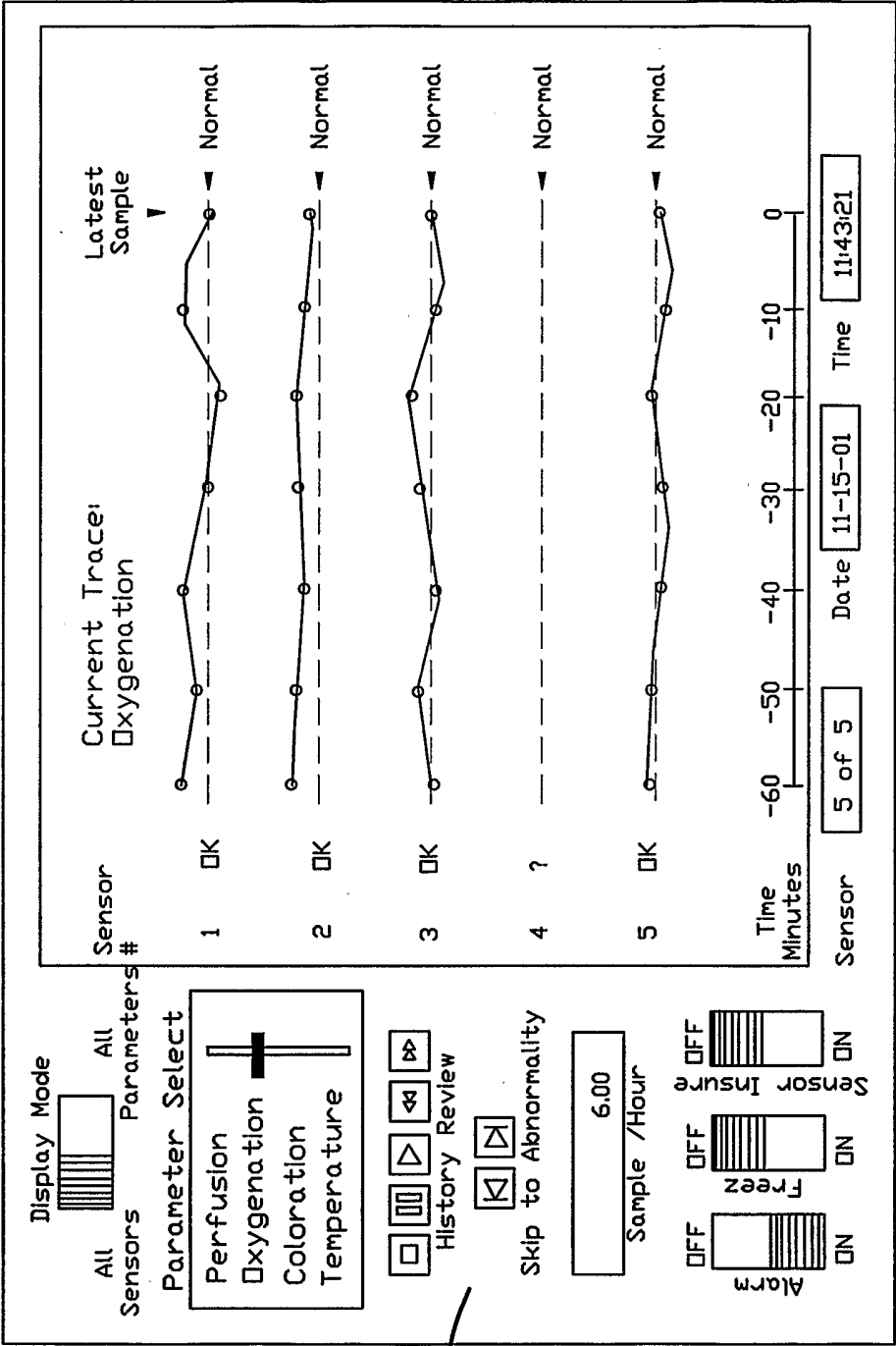


FIG. 12D

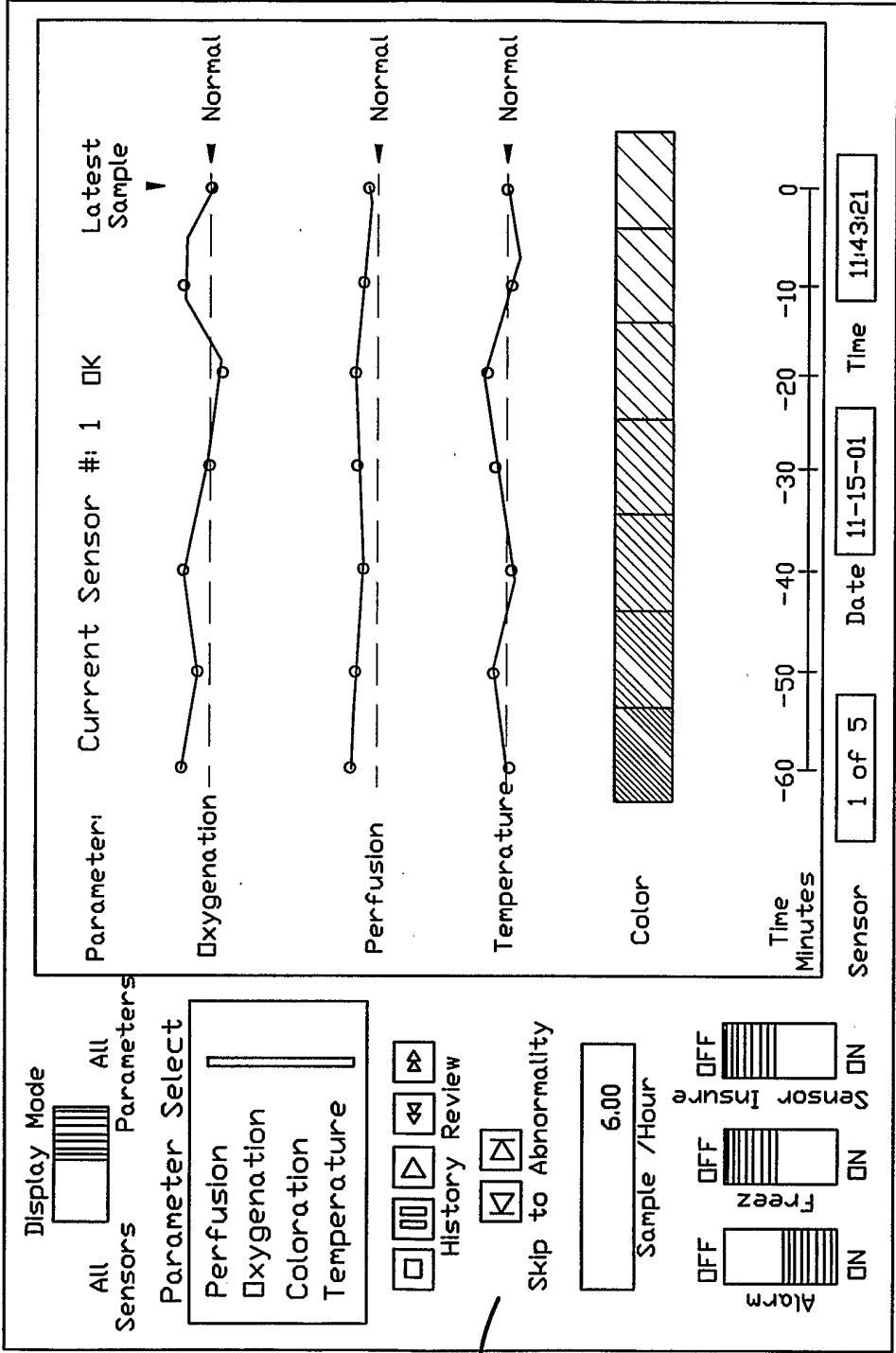
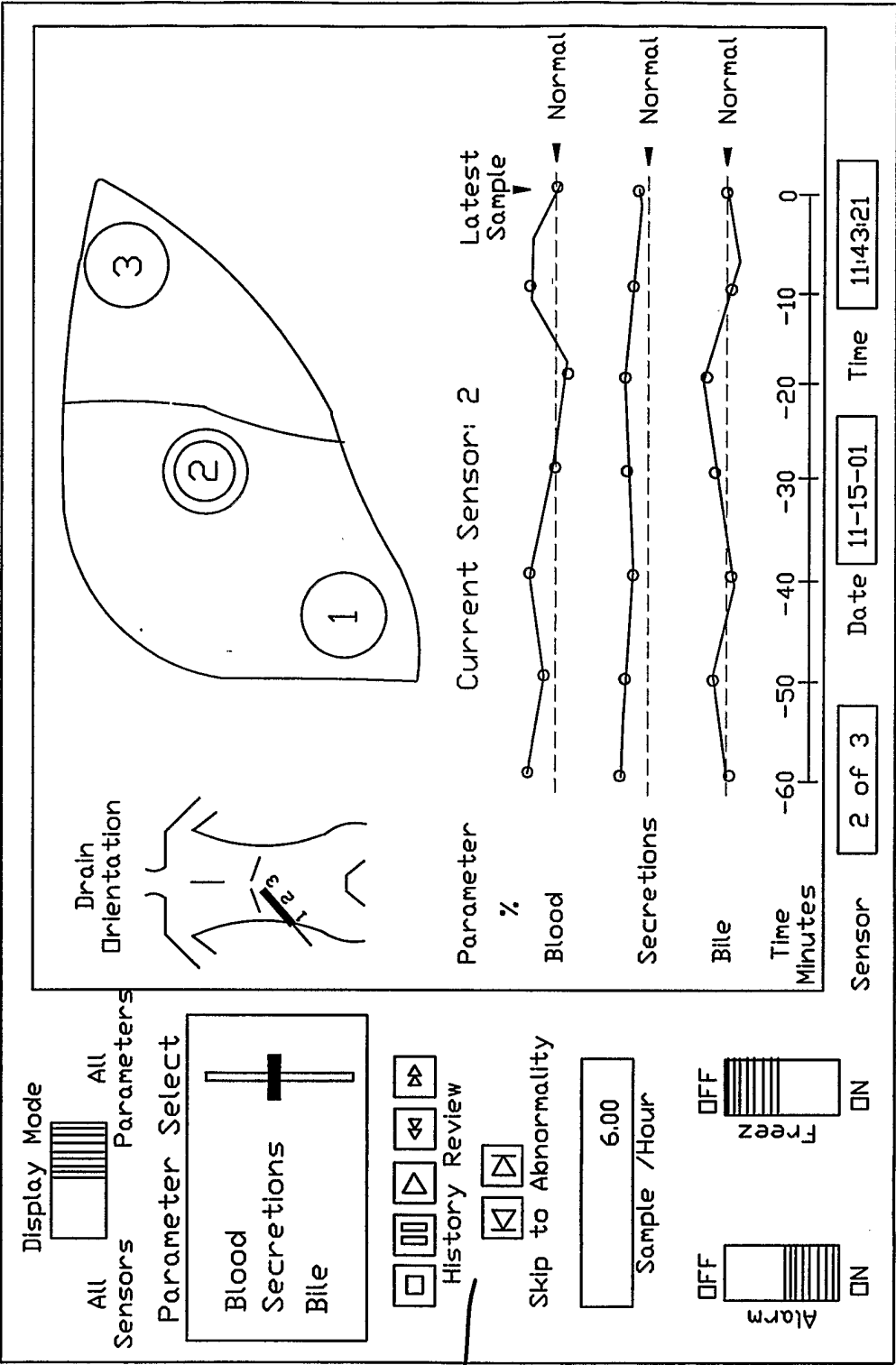
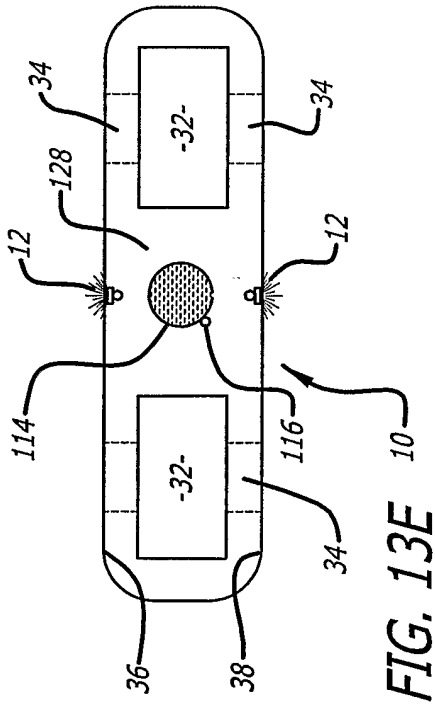
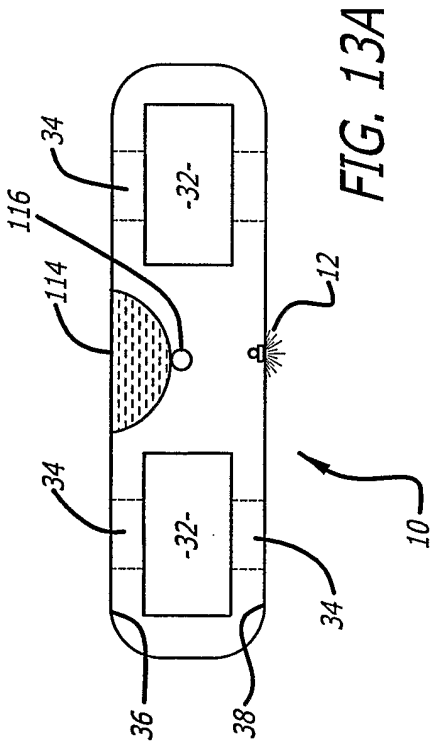
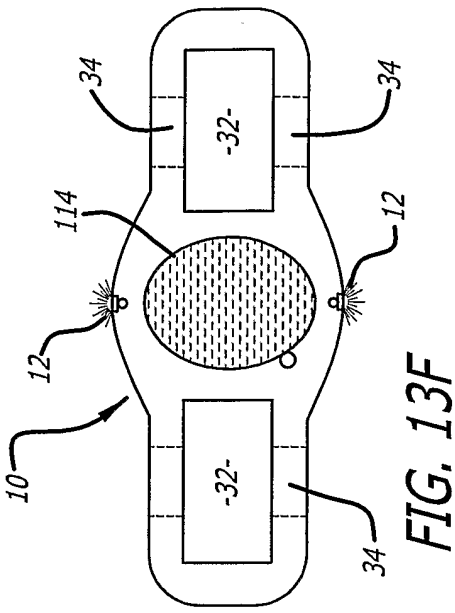
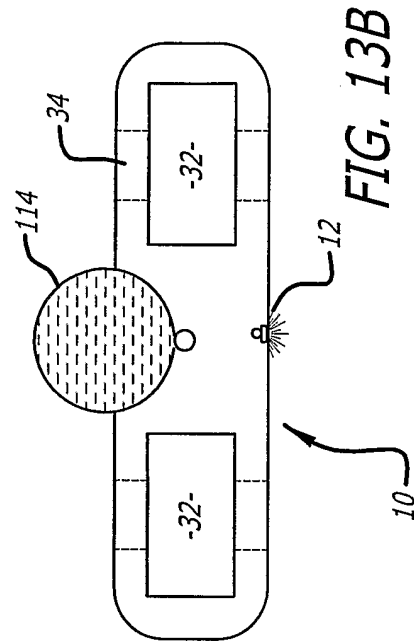
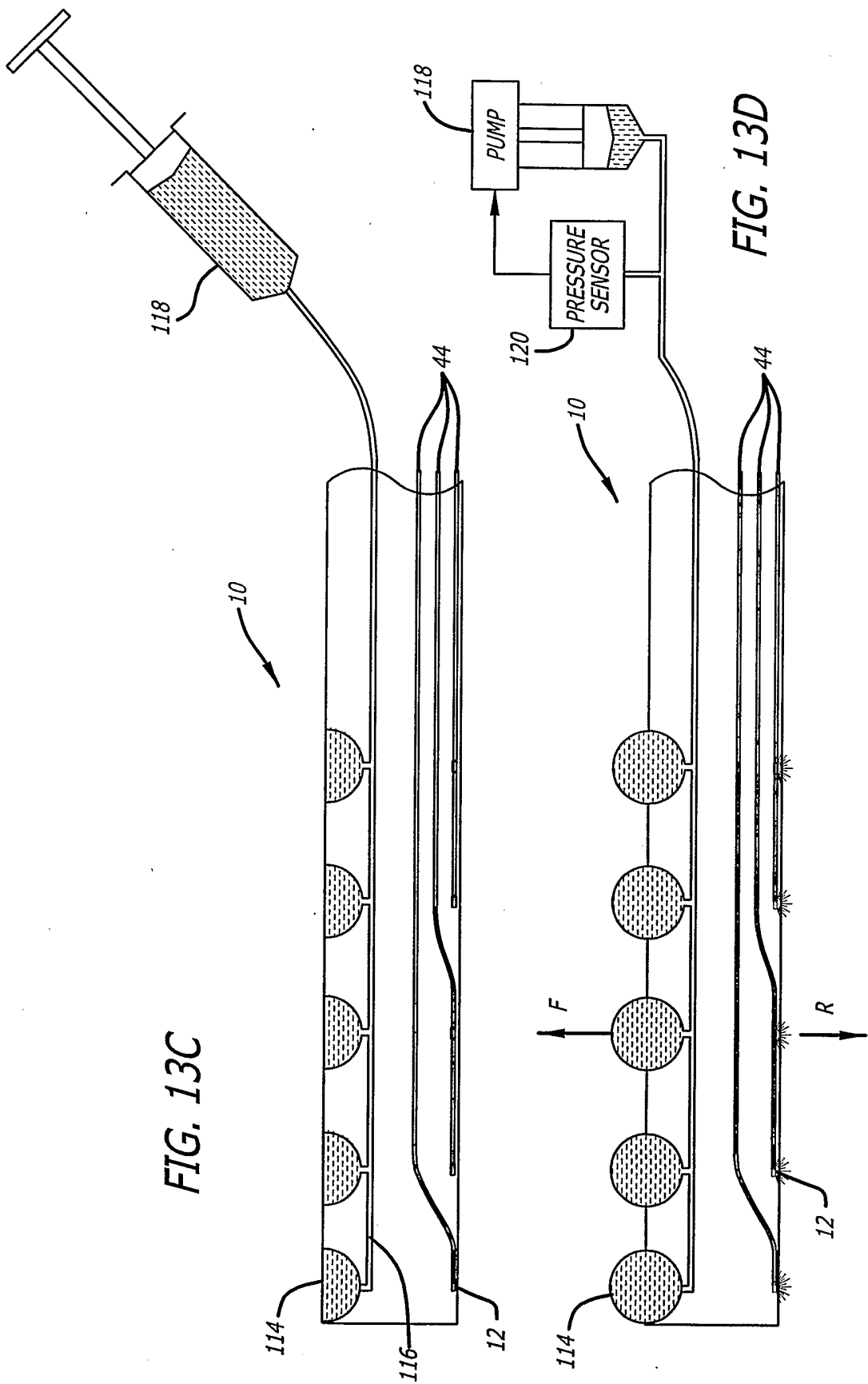


FIG. 12E







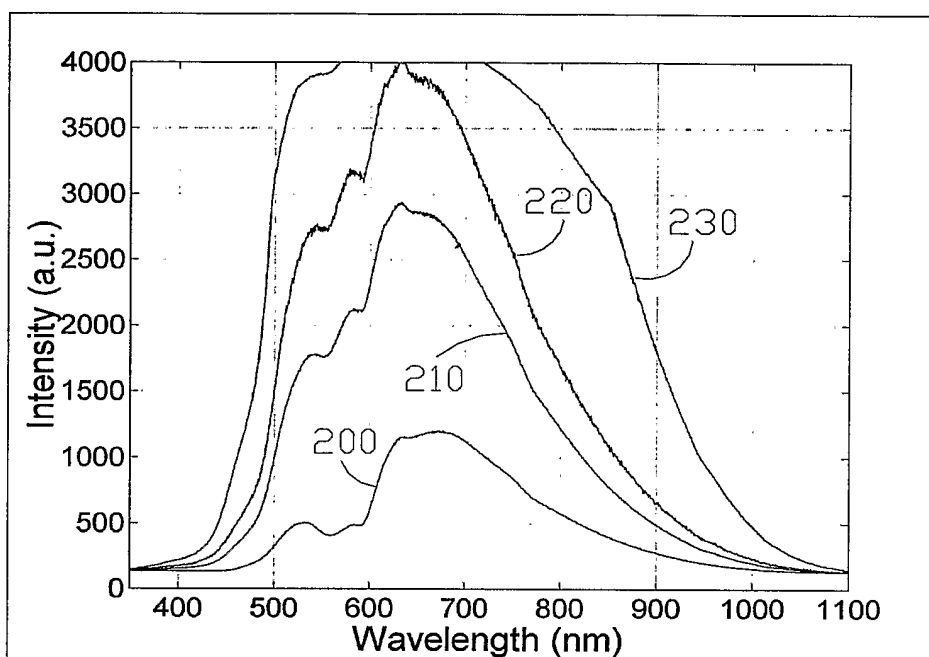
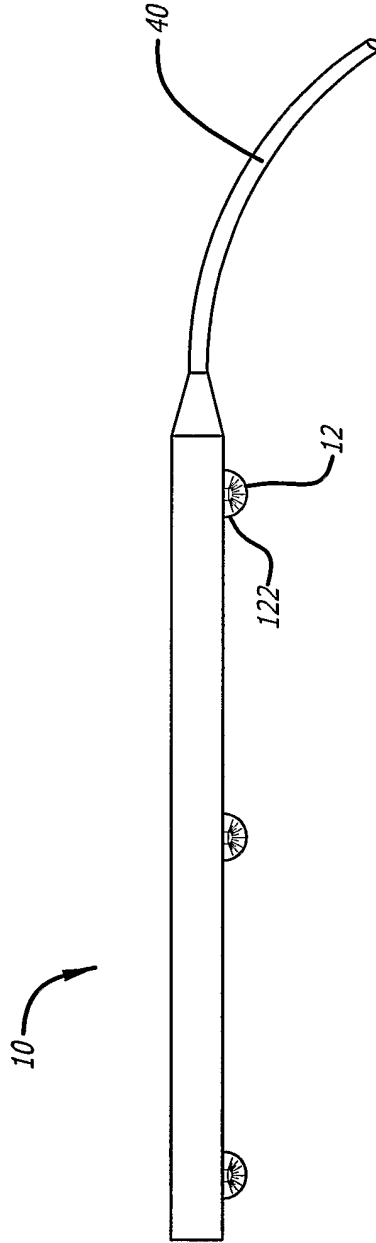
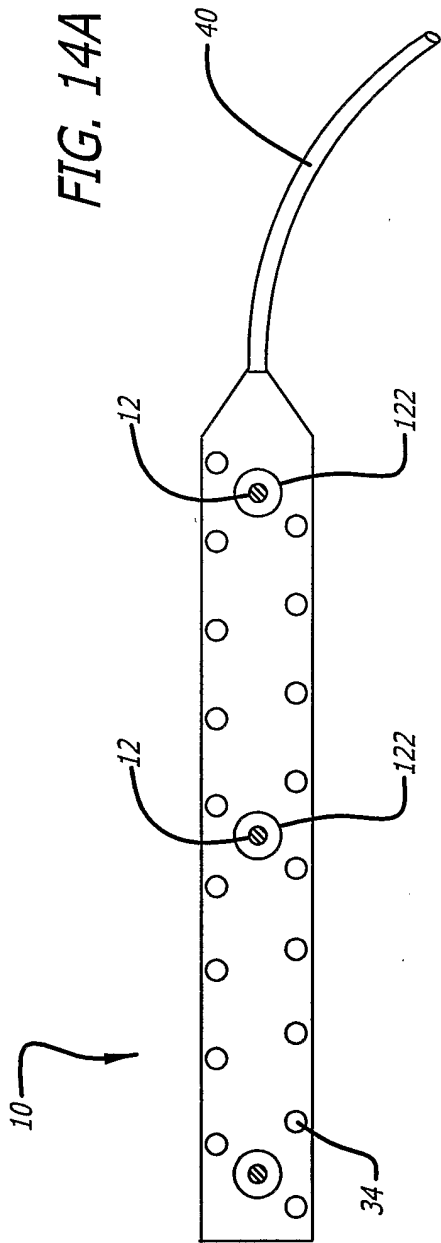


FIG. 13G



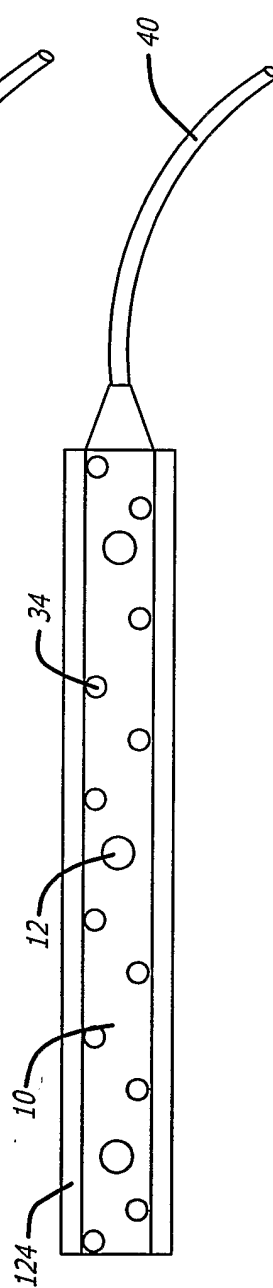
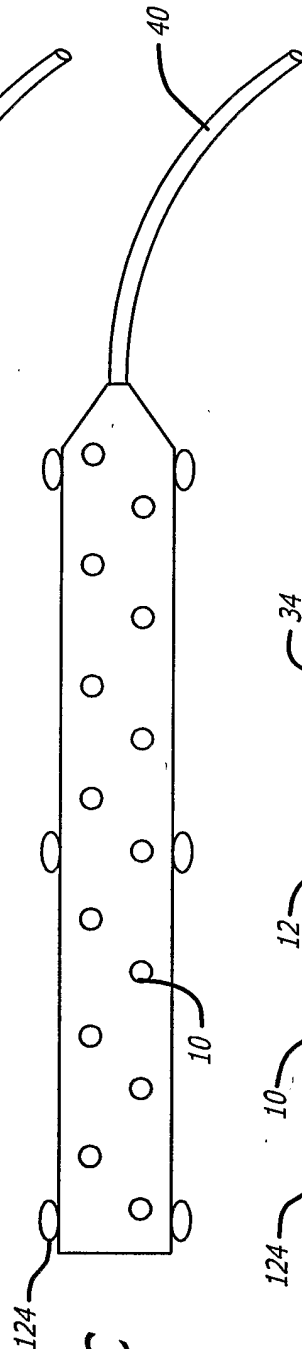
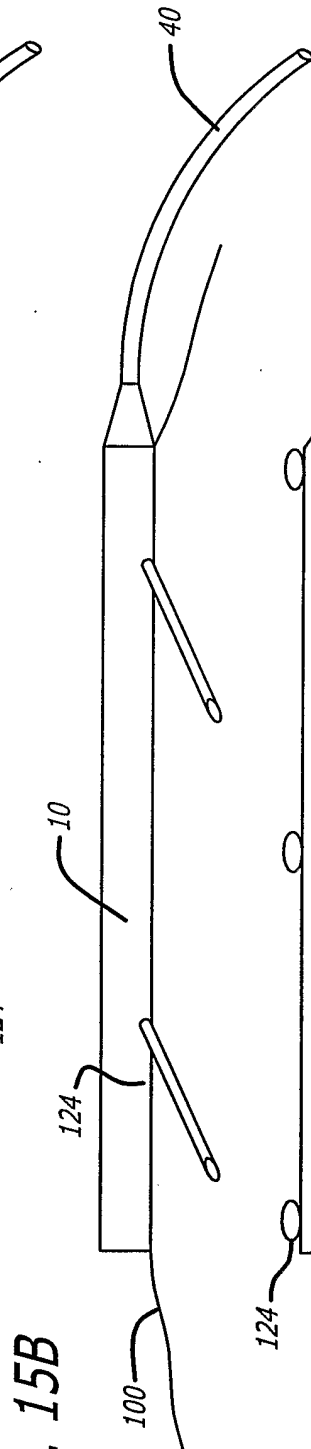
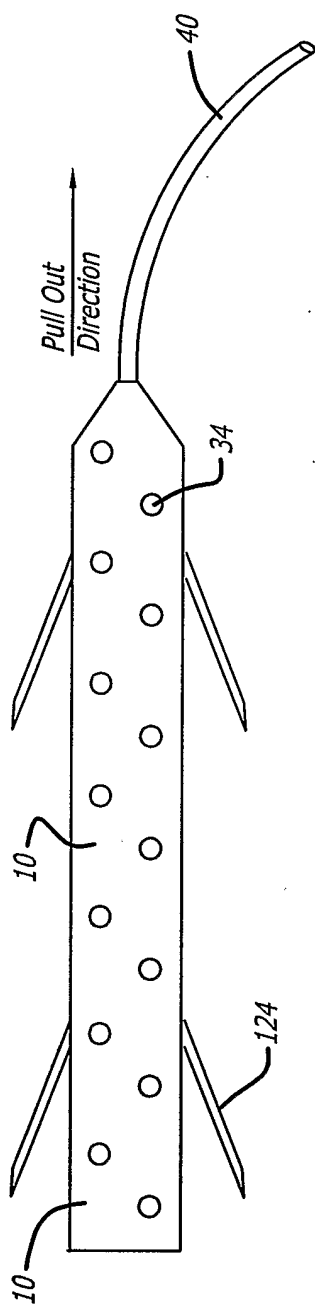


FIG. 15E

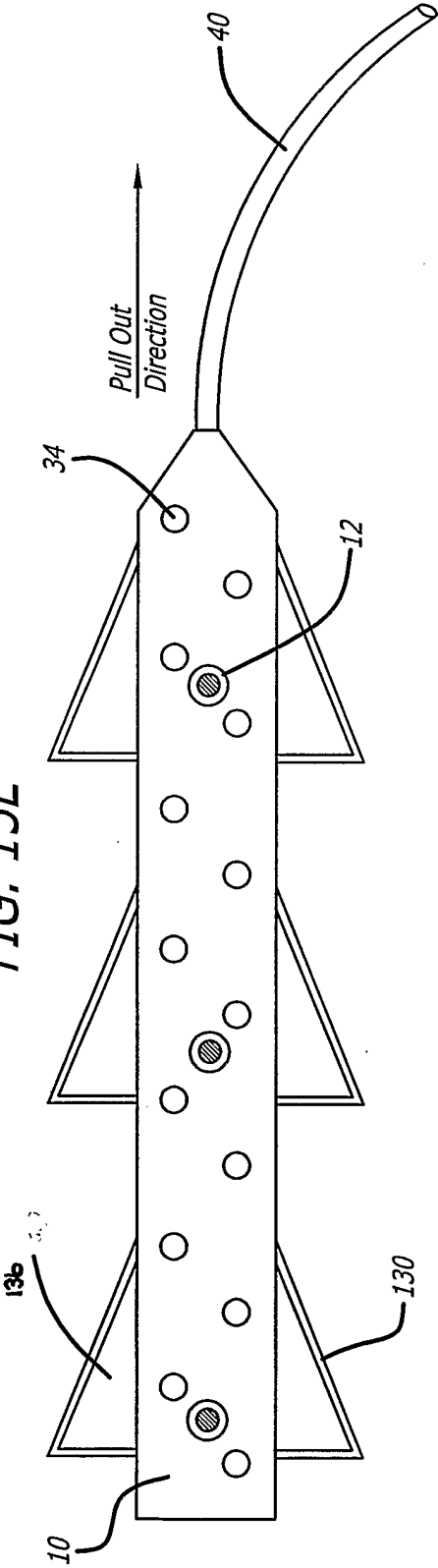
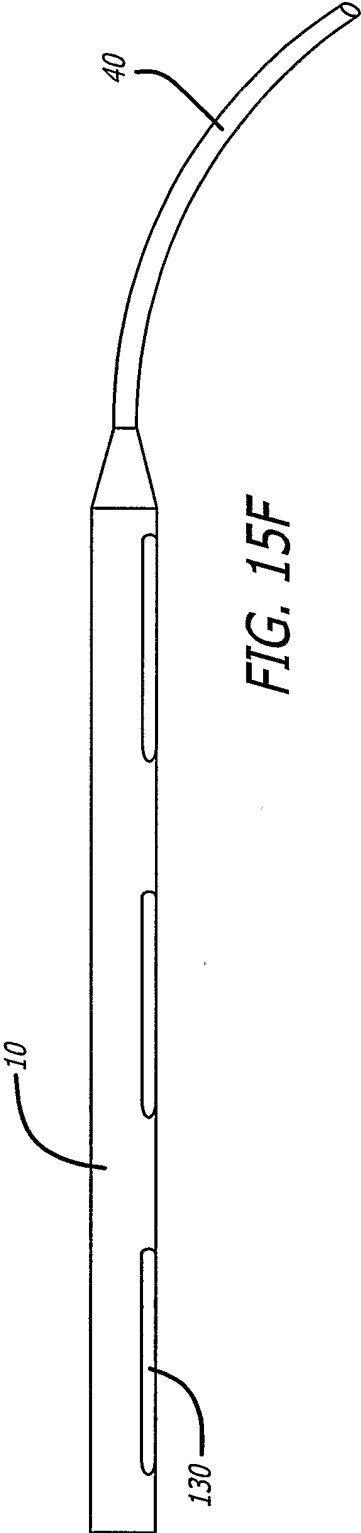


FIG. 15F



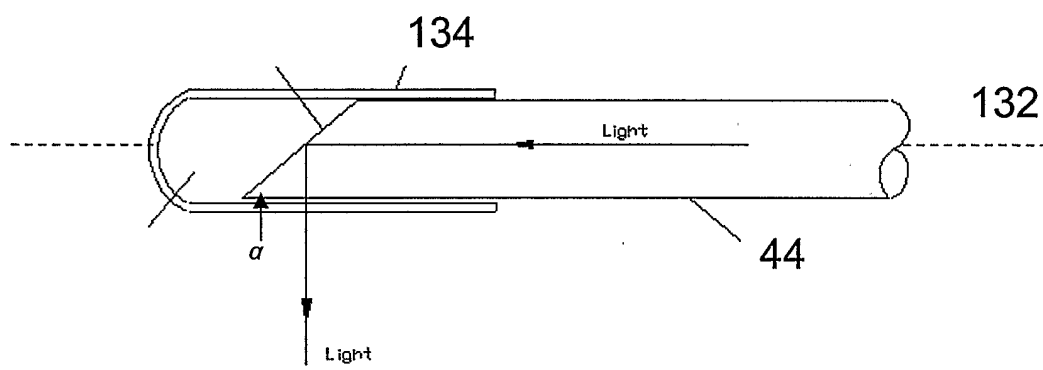


FIG. 16