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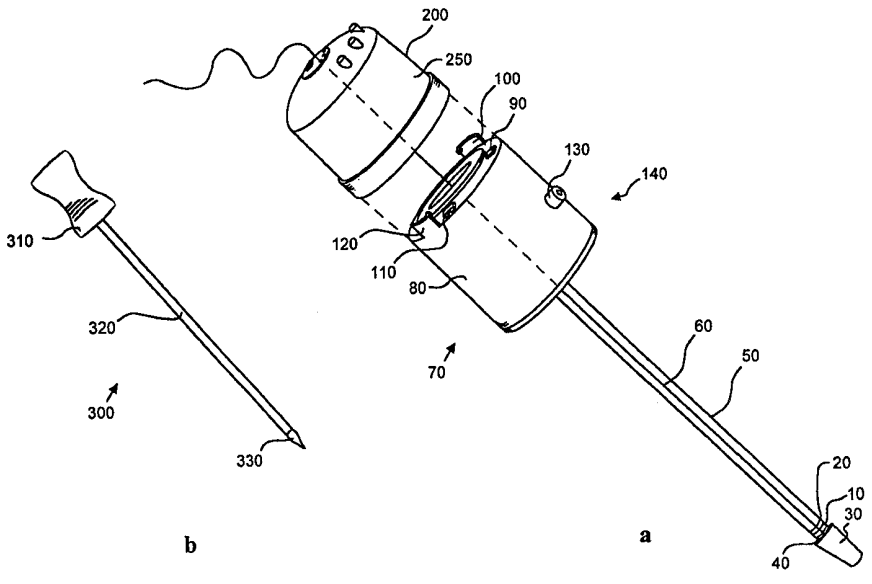

(57) Abstract

The present invention provides systems and methods for reducing the incidence of post-surgical tissue adhesions due to surgical incisions or perforations by applying heat, coolant, and/or sealant to or around the edges of the injured tissues, particularly to those in the peritoneum. One aspect of the invention is RF energy delivery systems (200), and control methods thereof. The RF delivery system is typically arranged to be coupled to a conventional surgical tool such as a trocar (70), and may include a surgical sheet (400), with one or more electrodes (401) for delivering the RF energy to the injured tissue resulting from conventional incisions into the abdominal wall. The treatment dosage of RF heat to the injured tissue may be controlled by monitoring parameters such as treatment time, change in tissue temperature, change in tissue dimension, and change in tissue impedance.

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SYSTEMS AND METHODS FOR REDUCING POST-SURGICAL COMPLICATIONS

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. patent application Serial No. 09/388,363, filed September 1, 1999 and to U.S. patent application Serial No. 09/271,268, filed March 17, 1999.

FIELD OF THE INVENTION

The present invention relates to methods and systems for reducing the incidence of complications that occur following many common surgical procedures. More particularly, the present invention relates to systems for reducing post-surgical complications that occur due to the natural tendency of the human body to form adhesions between injured areas within body cavities.

BACKGROUND

As a result of the healing process that follows abdominal, cardiothoracic, or arthroscopic surgery, complications frequently arise due to the natural tendency of the human body to form adhesions which are connective tissue structures between injured areas within body cavities. Adhesions may form regardless of the nature of surgical procedures, whether done in a so-called minimally invasive fashion using laparoscopy or with a standard technique involving one or more relatively large incisions. These connective tissue bridges may cause various, often serious, complications. Usually the relief of post-surgical complications caused by adhesions requires another surgery. The subsequent surgery is complicated by the adhesions that were formed as a result of the previous surgery. The second surgery, itself, is likely to result in further adhesions and a continuing cycle of additional surgical complications.

One example of a problem that can be caused by adhesions is that following abdominal surgery, loops of intestine may become entangled or twisted about these adhesions. The entanglements may cause partial or total flow obstruction through the bowel, or may compromise the blood flow to and from the bowel. If such a condition is not

relieved rapidly, the bowel dies and shortly thereafter the condition may cause death of the afflicted patient. As another example, adhesions that form in the pelvis after obstetric or gynecologic surgery may cause sterility as well as chronic pain.

Various suggestions have been made to avoid, reduce, or eliminate the formation of adhesions. For instance, standard surgical procedure in the United States often includes the steps of washing powder from surgical gloves prior to surgical operations, using powder-free gloves, and washing body cavities thoroughly prior to closing incisions. Another of the strategies that has been suggested to prevent adhesion formation is to loosely place a non-reactive barrier between an injured peritoneal surface and internal organs. Materials such as Interceed™ and Seprafilm™ and methods as described in U.S. Patent No. 5,791,352 to Reich et al. have been advocated for minimizing adhesions. Also pourable (solidifying liquid gel material) substances have been suggested for preventing adhesion formation. These measures, unfortunately, have had only modest success in reducing the formation of post-surgical adhesions at the surgical locations. Therefore, it would be desirable to provide new and improved methods and apparatus that would eliminate or minimize adhesions.

SUMMARY OF THE PRESENT INVENTION

The present invention provides systems and methods for reducing the incidence of post-surgical tissue adhesions resulting from surgical incisions or perforations. In particular, the present invention is adapted to treat surgical incisions or perforation to the peritoneum of humans and other animals.

During surgery, the tissues could be injured in at least two ways: (1) when punctures are made through peritoneum using a surgical device such as a trocar, and (2) with conventional incisions through the peritoneum. In accordance with the present invention, embodiments of delivery systems are provided to optimize the delivery of various tissue treatments to incisions or punctures.

In one aspect of the invention, a tissue-treatment system is provided to apply RF energy to the edges of tissues (e.g., peritoneal tissues) that have been injured during surgery; the heat thus generated by RF energy minimizes or eliminates the formation of post-surgical adhesions.

In an embodiment of the invention, the system for delivering the RF energy to the injured tissue is provided in conjunction with a trocar system. Electrodes for delivering RF energy to the injured tissue are positioned on the distal portion of the trocar sleeve. Further

embodiments are provided deriving from this delivery system arrangement wherein the RF energy is provided by a separate RF source that is distant from the trocar or wherein the RF energy source is contained within a detachable unit that attaches to the top of a trocar. In the former embodiment, the source of electrical energy for generating RF signal can be an AC power source or a remotely located battery. In the latter embodiment, the detachable unit may contain both a battery as well as the electrical circuitry to provide the RF energy to the electrodes. The batteries may be changed once exhausted, or if the batteries are integral to the detachable unit, the entire unit may be disposed of once the battery is exhausted.

In another embodiment, the system for delivering RF energy to incised peritoneum comprises electrodes embedded into an insulating surgical sheath. The underside of the sheath may have a weakly bonding adhesive layer that allows the sheath to attach to the skin. The adhesive allows the sheath to be placed and attached over the site of an incision before cutting occurs. Within the sheath, a configuration of electrodes is placed in position such that after the surgeon cuts through the sheath, the underlying skin and peritoneum, the electrodes are positioned over the site of incision. Within seconds or minutes of the incision, RF energy is delivered through the electrodes to treat the incised peritoneal tissue.

The RF energy delivery system of the present system offers numerous advantages. First, the system can seal the edges of the injured tissues and/or adjacent lymphatic tissues immediately after the surgery. Accordingly, the release of chemical messengers or adhesion-inducing substances such as growth factors can be avoided, and the post-surgical tissue adhesion can be minimized. The system may also be constructed to be coupled to conventional surgical tools so that the system can apply heat to the injured tissues and seal the edges as the tissues are being incised or perforated. By shortening the time lapse between the incision or perforation of those tissues and the heat treatment thereafter, this arrangement may eliminate, limit or minimize the release of adhesion-inducing substances. Furthermore, the system may also be designed to generate heat by a wide variety of electromagnetic energy sources including, but not limited to, microwave, infrared, ultraviolet, optical (e.g., laser), and mechanical energy (e.g., ultrasound) sources.

Methods are provided for the controlled delivery of optimal dosages of RF induced heat to the tissues. In an aspect of the invention, the change in the impedance of the heated peritoneal tissue can be used to determine the completion of treatment. Circuitry may be employed to measure the tissue impedance using the RF electrodes in order to determine when the tissue impedance has increased to a level where the treatment should be terminated. Another means for determining the end of treatment is by measuring the

temperature of the surrounding tissue using a thermocouple. Once a predetermined temperature is reached, the sensing and control circuitry turns off the RF energy delivery to the electrodes. In another variation, the RF delivery is turned off after a predetermined period has been reached. A further refinement tracks both the temperature of the heated tissue and the duration of the RF energy delivery in order to determine the end of treatment.

In another aspect of the invention, another tissue-treatment system is provided for sufficiently cooling the edges of the injured tissues that have been injured during surgery; the lowered temperature around the surgical site minimizes or eliminates the formation of post-surgical adhesions by inhibiting the release of the above described adhesion-inducing substances from the injured tissues. In one embodiment of this aspect of the invention, the surgical site may be cooled by applying therearound low-boiling point liquid substances such as liquid nitrogen, Freon^{tm} or other endothermic substances known in the art. Methods are also provided for cooling the edges of the surgically injured mammalian tissues.

In yet another aspect of the invention, yet another tissue-treatment system is arranged to seal the edges of surgically injured mammalian tissues; the sealant applied around the injured tissues minimizes or eliminates the formation of post-surgical adhesions by blocking the release of above described adhesion-inducing substances from the injured tissues. In general, biocompatible barrier material may be used as the sealant. Examples of such sealants may include, but not limited to, cyanoacrylate liquid, polyvinyl resins, polylactate glycolides, polycaprolactones, poly oxyethylenes, and other similar pharmaceuticals known in the art. Biological materials such as proteins like collagen, gelatin, elastin, albumins, and their mixtures may also be used as the sealant. Methods are provided for sealing the edges of the surgically injured mammalian tissues as well.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A shows a perspective view of the two-part trocar-based RF energy delivery system having a top detachable RF unit and a trocar sleeve which has a bipolar electrode arrangement, in accordance with the present invention;

Fig. 1B shows a perspective view of the obturator (puncturing tool) that is inserted into the trocar sleeve and functions as an assembly for puncturing the abdominal wall;

Fig. 2 shows a more detailed top perspective view of the detachable RF unit of Fig. 1A that fits over the trocar unit, in accordance with the present invention;

Fig. 3 shows a perspective view of the trocar based RF energy delivery system having a top detachable RF unit and a trocar sleeve which has a monopolar electrode arrangement, in accordance with the present invention;

Fig. 4 shows the trocar based RF energy delivery system with an external power supply and a remotely located RF unit, in accordance with the present invention;

Fig. 5 shows a cross-sectional view of a monopolar trocar based RF heat delivery system with an external power supply and a remotely located RF unit, in accordance with the present invention;

Fig. 6 shows an uncut array of electrodes on a sheet, which sheet is used in RF treatment of surgical incisions, in accordance with the present invention;

Fig. 7 shows a cross-sectional view of the electrode array sheet at A-A, after the surgeon has cut the sheet, and folded the sheet under the skin, in accordance with the present invention;

Fig. 8 is a generalized block diagram of one embodiment of an RF delivery system showing the feedback system with a temperature sensor;

Fig. 9 is a perspective view of a coolant delivery system in accordance with the present invention; and

Fig. 10 is a perspective view of a sealant delivery system in accordance with the present invention; and

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The following description provides preferred embodiments of tissue-treatment systems for treating cut edges of tissues and methods for determining and controlling the extent of various tissue treatments for optimization thereof. There are two types of common surgical injuries to the tissues, in particular to the peritoneum and pleura: (1) punctures produced by trocars during laparoscopic surgery and (2) incisions made during laparotomies (open surgery).

In one aspect of the invention, a tissue-treatment system may be arranged to apply energy (e.g., RF energy) along the edges of surgically injured mammalian tissues (e.g., peritoneal tissues)so as to minimize or eliminate the formation of post-surgical adhesions by inhibiting the release of adhesion-inducing substances such as growth factors, transforming growth factors, and TGF-β from the injured tissues and/or adjacent lymphatic tissues.

Figs. 1A-B illustrates a trocar compatible RF energy delivery system using a bipolar electrode configuration. This system is used for laparoscopies, laparotomies and other minimally invasive surgery that require punctures through the peritoneum. In accordance with a preferred embodiment of the invention, this system comprises three separable components. One part is detachable RF unit 200. A second part is trocar sleeve 70 which connects to RF unit 200 using attachment means known in the art. And a third part is puncturing unit 300, called an obturator, which inserts into trocar sleeve 70. The means of attachment to lock detachable unit 200 with trocar sleeve 70 is provided by latches 100 and 120. Other means of attachment known to those skilled in the art may also be used. For example, a thread and screw pair, or clasps are but a few of the possible means of attachment. But generally, the means of attachment is preferably of a design which allows the surgeon to quickly lock and release the connections since reduction of surgical time is of the essence.

Fig. 1A shows trocar sleeve 70, which has a cylindrical top portion 80 and lower rod-like sleeve portion 50. The top portion has protruding latches 100 and 120. The rod-like sleeve portion is elongated to permit insertion into the body cavity, whereas the top portion has an enlarged diameter to permit manipulation of the trocar sleeve assembly. The trocar sleeve is hollow along its entire length including top portion 80 and rod-like portion 50. The rod-like portion ends at lip 40 formed by conical portion 30 at the distal end of the trocar. The presence of the lip helps position the sleeve relative to the peritoneum so that when the trocar is gently pulled out, the lip catches the edge of the peritoneum. First electrode 10 is close to the lip in order to be positioned near the injured peritoneum. Once conical portion 30 of the trocar has been inserted past the peritoneum, lip 40 prevents the sleeve from being pulled out of the abdominal wall during routine procedures such as inserting or removing laparoscopic instruments through the trocar.

As shown in Fig. 1A, electrodes 10 and 20 are mounted in a bipolar arrangement around the distal portion of the trocar sleeve near lip 40. The electrodes are preferably shaped as rings and are made of conductive materials such as stainless steel. The electrodes may be made of platinum, platinum-iridium, aluminum, carbon or other typical, body-compatible electrode materials. The two electrodes are shaped and mounted to fully encircle the sleeve and are spaced about a millimeter apart from each other. First electrode 10 is slightly smaller in width, and hence in surface area, than second electrode 20. The first electrode shown has a width preferably between about 0.5 to 3 millimeters and has a

spacing of between about 0.5 to 5.0 millimeters. More preferably, the spacing between the electrodes should be between about 0.5 to 3.0 millimeters.

One or more thermocouples (not shown) can be optionally mounted to the distal end of the sleeve, preferably beneath second electrode 20, to measure the instantaneous tissue temperature at that site. The temperature measurements thus obtained may be used to control the delivery of heat to the target tissue.

Additionally, the rod-like portion 50 contains conducting wires connecting electrical contacts 110 and 90 with electrodes 10 and 20. Conducting wire 60 is shown on the outside of sleeve 50 and connects active electrode 10 with electrical contact 110. Wire 60 can also be placed within the wall of the sleeve or on the inside surface of the sleeve wall. Another conducting wire (not shown) connects the second, return electrode 20 with electrical contact 90. Another conducting wire (not shown) may be placed on the inside or outside surface of the sleeve wall or within the wall itself to connect a thermocouple that is located approximately at the location of electrode 10, but positioned directly beneath it.

Trocar sleeve top portion 80 has standard luer valve 130 with opening 140. The opening is used to inflate the cavity as known in the art in preparation for viewing with laparoscopy or for inserting therapeutic fluids such as antibiotics after the surgery.

As shown in Fig. 1A, the detachable unit 200 is made of a housing which encloses various circuitry. As in the system of Fig. 1A, the detachable unit is fully self-contained and includes a battery within the housing. Since a battery is used, the unit may be used more than a single lifetime of the battery by replacing the battery. Alternatively, the unit may be designed to be thrown away after the single battery is exhausted. The advantage of such design is that the unit can be made relatively inexpensively since it is only to be used once, and the unit does not need to be re-sterilized after its use. Alternatively, the unit may be constructed more robustly to last multiple battery cycles and to accept sterilization.

The detachable unit also contains an RF circuit to transmit energy through at least a pair of electrical contacts (not shown) on the underside of the housing 250 of detachable unit 200. The two contacts are preferably small rectangular pieces of conductive material which are complementary to electrical contacts 90 and 110, located on the trocar top portion 80. The two contacts on the underside of detachable unit 200 are positioned such that when the detachable unit 200 is locked with latches 100 and 120 to the trocar top portion 80, there is electrical communication between the two contacts in the detachable unit with complementary contacts 90 and 110. Moreover, once the detachable unit is locked to the

trocar top portion, there is also electrical communication between the RF circuitry residing in detachable unit 200 and the electrodes 10 and 20.

Fig. 2 shows a perspective top view of the housing 250 of the detachable unit 200 with greater detail. There is a push button 210 for turning the RF circuitry on in order to deliver RF energy to the electrodes located on the trocar sleeve. There are three indicator lights 220, 230 and 240, which indicate, respectively, that the treatment is finished, that the treatment is in progress, and that the circuitry is ready to initiate delivery of the RF energy. The top portion of the housing is made of materials known in the art such as plastic.

As shown in Fig. 1B, the third part of the system is an obturator 300 having a top cap 310 and a rod 320. The distal end of the rod 320 ends in a sharp tip 330. The rod 320 fits inside the trocar 70 and the tip 330 passes the conical portion 30 when inserted. Once mated, the cap portion 310 should be locked to trocar top portion 80 and the puncture unit tip 330 should be just exposed through the distal end of the conical portion 30. The materials to make the puncturing unit are standard. The cap 310 may be of sterilizable plastic and rod 320 a metal, such as stainless steel or aluminum, although alternatively, it may be made of other materials such as medical grade plastics.

The foregoing RF energy delivery system is used in operation according to the following steps. The target skin area in the abdominal wall is prepared using the usual procedures in preparation for surgery such as shaving the skin and applying a topical antibacterial solution. Under sterile conditions, rod 320 is inserted into trocar 70 such that tip 330 is exposed. The assembly then is used to puncture a hole through the prepared abdominal skin and through the peritoneum. The assembly is withdrawn slowly until trocar lip 40 abuts against the edge of the peritoneum. The puncturing unit 300 is disengaged and withdrawn from the trocar 70. As soon as practical, within a few minutes of elapsed time, detachable unit 200 is twisted and locked onto the trocar top portion 80. When Ready Light 240 lights up on detachable unit 200, indicating a proper connection between the detachable unit and the trocar as well as between tissue and electrode, the Start Button may be pushed. The In Progress Light will light up for a duration of time during the RF energy delivery to the electrodes. After a predetermined dosage of energy has been applied, the Finished Light will automatically come on indicating the treatment has been completed.

While RF energy can be applied to the edges of the surgical incision or perforation of the peritoneum at any time while the incision or perforation is still open, the above procedure is preferably accomplished within the first few seconds to a few minutes after creating the surgical intrusion. More preferably, the treatment should be accomplished

within 30 seconds. After the Finished Light turns on, the detachable unit is disengaged from the trocar. The surgeon proceeds with the laparoscopy or laparotomy or other tasks using the trocar. Optionally, the surgeon repeats the RF treatment procedure subsequent to completion of the task for additional tissue treatment.

The system embodiment of Fig. 1A provides a bipolar electrode arrangement and a fully self-contained detachable unit 200 which contains the RF circuitry, control circuitry, and battery power source. There are other workable variations of this system. For example, instead of a bipolar electrode configuration, a monopolar electrode configuration may be employed. Instead of a self-contained detachable unit containing the power source, control circuitry, and RF circuitry, any one or all of these elements may be located outside the detachable unit.

Fig. 3 illustrates an alternative embodiment of the present invention system using a monopolar electrode configuration. Here, there is only one electrode 10 which is the active, heat-inducing electrode. Return electrode 25 has a large surface area and is placed somewhere on the body generally using a conductive gel. The impedance presented by the body-to-return-electrode interface should be orders of magnitude smaller than presented by the body-to-active-electrode interface.

Fig. 4 illustrates another variation of a bipolar electrode configuration having an external box 310 containing the control circuitry, the RF circuitry and power derived from an AC-wall outlet source 330. Detachable unit 300 has status lights but minimal circuitry. Conductor cord 320 has multiple conductors and may be disconnected from the external box 310 and from detachable unit 300. This allows detachable unit 300 and conductor cord 320 to be cleaned and sterilized using known sterilization methods such as autoclaving, ethylene oxide gas sterilization, irradiation, etc.

Fig. 5 is a schematic cross-sectional view of a system inserted into the abdomen which is similar to the configuration of Fig. 4 in that all circuitry is external to the detachable unit. The difference is that the system in Fig. 5 is a monopolar, not bipolar, electrode configuration.

Incisions are the second type of common surgical injury to the peritoneum. These produce wounds that are larger than with laparoscopic surgery. Nonetheless, the method of inhibiting adhesion formation using application of RF induced heat can also be employed to treat the wound edges during open chest or open abdominal surgery.

Fig. 6 illustrates the device used to treat injured incised tissue in conjunction with such open surgery in order to inhibit post-surgical adhesions. Heating sheet 400 is made

from an insulating material, for example, a medical grade plastic Mylar®, Lexan®, PET, plexiglass, etc. Multiple pairs of electrodes 401 are imprinted on nonconductive sheet 402. The multiple electrodes are connected by conductors 403. Each pair of electrodes 401 when connected by conductor 403 can act as a bipolar electrode arrangement. Non-conductive sheet 402 can be cut using conventional instruments such as a scissors or scalpel. Conductors 403 connect to electrodes 401 such that these electrodes can be energized when conductors 403 are connected to an appropriate source of energy.

During open surgery, the adhesion prevention electrode array sheet is used as follows. Before an incision is made into the target, sheet 400 is placed on the skin of the patient at the site where the incision will be made. The surgeon cuts the sheet at the incision lines 420 and 430, then the skin underneath, and then the underlying tissue. Next, the cut edge 420 of the sheet 400 is folded such that the cut peritoneal surface is covered by the cut edge of the sheet.

Fig. 7 shows the sheet after it has been cut and folded over the skin and peritoneum. One row of electrodes will contact the skin surface and the other row of electrodes will be tucked underneath contacting the peritoneum. Next, RF energy is activated and transmitted through a conductor 403, and to set of electrodes 401. When the treatment is completed, the next set of electrodes 405 is activated until the entire injured peritoneal surface is treated.

Another aspect of the present invention are systems to measure and control the dosage of RF energy applied to tissue. In one embodiment, the change in tissue impedance may be used as a parameter to determine the treatment completion. Instantaneous impedance of the tissue may be determined by using the same set of RF electrodes used to apply the RF energy to injured tissue. The impedance may be determined using known methods dependent on whether the energy source is a constant voltage or constant current source. If a constant voltage source is used, the change in current pulse may be used to determine the impedance. Similarly, if a constant current source is used, the change in voltage over the duration of the test pulse may be used to calculate the impedance. When a predetermined tissue resistance is reached, for example, as a percentage of the initial tissue resistance, the RF generator is turned off.

A more sophisticated version using impedance measurements measures the total energy dissipated into the tissue over time. The instantaneous impedance values may be measured to calculate instantaneous power and total cumulative energy dissipated into the tissue. When the target cumulative energy is reached, the RF generator is turned off. Such

energy calculation is well known in the art, in particular in the cardiac pacing industry, for measuring cardiac lead impedance and energy consumption.

In another embodiment the temperature of the treated tissue may be monitored using a temperature measuring device such as a thermocouple. When the tissue is heated to a certain temperature, for example, between 65 to 100°C, the RF generator is turned off.

In yet another embodiment treatment time elapsed may be used as a parameter. When the treatment duration reaches a predetermined level, the RF generator is turned off.

In yet another embodiment, in accordance with the present invention, a combination of both time and temperature are used to regulate the amount of RF energy used to reduce the incidence of post-surgical connective tissue adhesions. Achieving a set temperature and maintaining the target tissue at that set temperature for a predetermined period results in minimal adhesions. Temperatures between about 65 to 100°C and treatment times ranging from 5 to 25 seconds provide beneficial results.

The system could be battery operated and be constructed of disposable materials. Alternatively, the system may be contained in an external box with an RF generator, thermometer circuitry, clock and feedback loop to control temperature and to end the treatment. In a preferred embodiment the thermocouple is attached to a delivery system structure near the active electrode providing RF energy. The energy supplied is determined by a pre-set temperature level and this level may be maintained for a predetermined duration through a temperature feedback loop.

As depicted in Fig. 2 the control indicator system comprises a Start Button and three lights. The Ready Light is illuminated when the system has completed a successful check to ensure appropriate tissue contact. When the user presses the Start Button, the In Progress Light glows indicating that RF energy is being supplied to the electrodes. During this time, the RF generator heats the tissue to a pre-set temperature, which is measured by the thermocouple, and maintains that temperature until an internal timer turns the generator off. Once the generator is turned off, the Finished Light illuminates indicating that the treatment is over. Other signals such as audio signals could be used instead of or in addition to lights to indicate progress of the treatment.

Fig. 8 is a generalized block diagram of one embodiment of an RF delivery system. Section 500 contains circuitry for an RF generator, a current and voltage sense means, a microcontroller and a battery. Section 500 contains starting means 520, which may be a start button 210 as shown in Fig. 2. Section 500 also has indicator means 510 which may be an array of lights, 220, 230, 240 as shown in Fig. 2. Alternatively, the indicator means

may be various distinct audio signals. Section 600 represents the delivery structure such as the trocar sleeve 70 or a non-conductive sheet 400 which contains the electrodes. Section 600 contains two electrodes 10 and 20 providing a bipolar electrode configuration. Section 600 also contains a temperature sensor, for example, a thermocouple.

The voltage and current sensing means provides instantaneous voltage and current as well as tissue temperature values to the microcontroller. If the tissue temperature does not exceed a predetermined value, the microcontroller increases the energy level delivered by the RF generator. If the tissue temperature exceeds a predetermined value, the microcontroller decreases the energy level delivered by the RF generator. The RF energy delivered to the tissue is thus continuously altered within this feedback loop to maintain a predetermined tissue temperature.

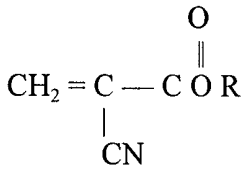
In another aspect of the invention, a tissue-treatment system may be arranged to lower the temperature along the edges of surgically injured tissues so as to minimize or eliminate the formation of post-surgical adhesions by inhibiting the release of adhesion-inducing substances such as growth factors, transforming growth factors, and TGF-β from the injured tissues and/or adjacent lymphatic tissues. Fig. 9 is a perspective view of one embodiment of such coolant delivery system in accordance with the present invention. The coolant delivery system 700 includes a chamber 701 for storing coolant therein, an applicator 702 for applying the coolant around the injured tissues, and a fluid pathway 703 for providing fluid communication between the chamber 701 and the applicator 702. Similar to the RF-energy delivery system described in Figs. 1 through 8, the coolant delivery system 700 may also be arranged to be fixedly or detachably coupled to the conventional surgical tools such as a trocar. In the embodiment shown in Fig. 9, the applicator 702 and a portion of the fluid pathway 703 are fixedly coupled to the trocar. Any liquid, gas or fluid medium may be used as the coolant. Examples of such coolants may include, but not limited to, low-boiling point liquid substances such as liquid nitrogen, Freon™ and other endothermic or heat-absorbing substances known in the art. The coolant delivery system may also include a sensor 705 for monitoring a change in physical and/or chemical parameter or property of the tissues and a controller (not shown) for engaging or disengaging the cooling procedure depending on whether the change in the tissue properties reaches a pre-determined level.

In operation, the storage 701 of the coolant delivery system 700 is filled with the coolant kept at low temperature. The coolant delivery system 700 is detachably or fixedly coupled to a conventional surgical tool so that a tip 704 of the applicator of the system can

be disposed adjacent to a cutting element of the surgical tool. The tissues are lacerated or perforated by the surgical tool and the applicator 702 applies the coolant around the injured tissues and/or lymphatic cells disposed therearound. The sensor 705 of the system 700 may monitor temperature around the surgical site, dimension of the injured cells (e.g., shrinkage due to deformed collagen), hydration, thermal/electrical conductivity or resistivity, concentration of the adhesion-inducing substances described hereinabove, and/or other physical or chemical properties indicative of the changed properties of the injured tissues attributed to the lowered temperature therearound. The sensor 705 may be arranged to monitor one or more of the above described parameters or properties constantly or at pre-determined time intervals. When the change in the tissue property reaches a pre-determined level, the controller stops the delivery of the coolant to the injured tissues and disengages the cooling operation. In another embodiment, the coolant may be kept in the chamber 701 at room temperature and delivered toward the applicator 702. In this embodiment, the coolant delivery system 700 includes a conventional cooling device (not shown) along or at the applicator 702 or the fluid pathway 703 so as to instantaneously lower temperature of the coolant passing therethrough. After the surgery, the coolant may be carefully removed from the surgical site and the injured tissues are sutured back together. It is appreciated, however, that the injured tissues may also be sutured with the coolant disposed thereon when the coolant is biocompatible and does not adversely affect the healing process.

In yet another aspect of the invention, another tissue-treatment system may be provided to seal the edges of surgically injured tissues so as to minimize or eliminate the formation of post-surgical adhesions by sealing the edges of the injured tissues and blocking the release of the adhesion-inducing substances described hereinabove. Fig. 10 is a perspective view of a sealant delivery system in accordance with the present invention. In general, the sealant delivery system 800 may be arranged to include a chamber 801 for storing the sealant therein, an applicator 802 for applying the sealant around the injured cells, and a fluid pathway 803 providing fluid communication between the chamber 801 and the applicator 802. Similar to the RF energy delivery system in Figs. 1 through 8 and the coolant delivery system 700 in the previous paragraphs, the sealant delivery system 800 may also be configured to be fixedly or detachably coupled to the conventional surgical tools such as a trocar. Any non-solid medium may be used as the sealant as long as it can mechanically block the release of the adhesion-inducing substances from the injured tissues and/or lymphatic tissues adjacent thereto. A typical example of such coolant is

cyanoacrylate or its derivatives which have the following basic structures where R is an alkyl or other suitable substituent.



Such cyanoacrylates are disclosed in U.S. Patent Nos. 3,527,224, 3,591,676, 3,667,472, 3,995,641, 4,035,334, and 4,650,826 which are incorporated herein by reference in their entirety. It is appreciated that the cyanoacrylate composition can optionally include formaldehyde scavenger compounds such as those described by Leung, et al. in U.S. Patent No. 5,328,687, which is also incorporated herein by reference in its entirety. The use of such scavengers has been suggested as enhancing internal *in vivo* applications of cyanoacrylates by, e.g., reducing inflammation associated therewith. Other examples of the sealants may include, but not be limited to, biocompatible barrier materials such as cyanoacrylate liquid, polyvinyl resins, polylactate glycolides, polycaprolactones, poly oxyethylenes, and other similar pharmaceuticals known in the art. Biological materials such as protein, collagen, gelatin, albumin, albuntin, elastin, and their mixture may also be used as the sealant. The sealant delivery system 800 may also include a sensor 805 for monitoring a change in physical and/or chemical parameter or property of the tissues and a controller (not shown) for engaging or disengaging the sealant delivery procedure depending on whether the change in the tissue parameters or properties reaches a pre-determined level.

In operation, the storage 801 of the sealant delivery system 800 is filled with the sealant. The sealant delivery system 800 is detachably or fixedly coupled to a conventional surgical tool so that a tip 804 of the applicator 802 of the system 800 can be disposed adjacent to a cutting element of the surgical tool. The tissues are lacerated or perforated by the surgical tool and the applicator 802 applies the sealant around the injured tissues and/or lymphatic cells adjacent thereto. The sensor 805 may be arranged to monitor concentration of the adhesion-inducing substances described hereinabove constantly or at pre-determined time intervals. When the change in the tissue property reaches a pre-determined level, the controller (not shown) stops the delivery of the coolant to the injured tissues and disengages the cooling operation. In the alternative, the controller may also be arranged to engage the

delivery operation upon detecting presence of such adhesion-inducing substances around the surgical site. After the surgery, the sealant is carefully removed from the injured tissues which are sutured thereafter. It is also appreciated that the tissues may be sutured without removing the sealant therefrom when the coolant is biocompatible and does not adversely affect the healing process.

The following examples summarize results of animal studies which indicate that the control parameters such as change in tissue impedance, change in tissue temperature, and time of treatment may be used to determine when the treatment cycle should be ended.

EXAMPLE 1

Using Impedance Change as the Indicator of Treatment Completion

A study was conducted using rabbits to determine the effects of applying RF energy to the impedance of the peritoneal tissue and whether impedance may be used to indicate treatment completion. For the RF energy treated group (n=3), an incision was made about the midline on the dorsal surface of the rabbit. A single trocar was introduced into the abdomen of each animal. Using a monopolar assembly, RF energy was applied to the peritoneum until the measured tissue impedance was above three times the initial impedance. To mimic a surgical procedure that would be performed laparoscopically, a cotton swab was used to roughen the serosa of the small bowel. The incisions were sutured with a bioabsorbable suture material. One week later, the treated and control animals were sacrificed and a necropsy performed. The same procedure was performed on four control animals except that no RF energy was applied to their peritoneums.

None of the three animals that were treated with RF energy formed adhesions. But three of the four control animals did form adhesions. One had mild adhesions to the abdominal wall, while two had extensive, highly vascularized adhesions to the bladder, bowel and abdominal wall. Impedance may, therefore, be used as a treatment completion indicator.

EXAMPLE 2

Using Temperature as the Indicator of Treatment Completion

A rabbit study was conducted to determine the effects of monitoring tissue temperature to control the amount of RF energy applied to the peritoneal tissue and the

effect on the incidence of post-operative adhesions. A small midline incision was made on the dorsal surface of each of the three treated rabbits. Immediately after a trocar was inserted into the incision, RF energy was applied to the injured tissue until the tissue temperature reached a set trigger point of 100°C; a monopolar assembly was used. After each animal's serosa of the small bowel was roughened using cotton swabs, the incision was sutured. One week later, the animals were sacrificed and the incidence of adhesions to the port site and organs was determined. Two of the three animals showed no signs of adhesions while the third had grade 2 adhesions (rated 0 to 5 with 5 being the worst).

EXAMPLE 3

Using Time as the Indicator of Treatment Completion

Rabbits were used to determine the effects of using time to control the amount of RF energy applied to the peritoneal tissue and the effect on the incidence of post-operative surgical adhesions. Two small incisions were made on either side of the dorsal midline surface of the rabbit's body (n=2). One trocar was inserted into each incision, and RF energy was applied for 60 seconds. The rest of the procedure is as described in Example 2. One week later, the animals were sacrificed and the extent of adhesion formation at the port site and to the organs was assessed. One animal exhibited no adhesions to either of the port sites or to any of the abdominal organs. The other animal had no adhesions to one port site but at the other port site, there was herniation of the small bowel, accompanied by a grade 2 adhesion.

EXAMPLE 4

Using a Combination of Temperature and Time as the Indicator of Treatment Completion: Rabbit Study

A rabbit study was conducted to determine the effects of applying RF energy on the incidence of connective tissue adhesion formation following perforation of the peritoneum. After the rabbits were anesthetized, two trocars were inserted into the abdomen of each rabbit. RF energy was applied through each trocar hole immediately after insertion maintaining the temperature at 75°C for a duration of either 5, 10, or 15 seconds. The serosa of each animal was roughened using cotton swabs before the holes were closed. One week after the RF treatment, the rabbits were sacrificed and examined for adhesions to the

abdominal cavity. The rabbits had no adhesions to either the trocar site or to any peripheral sites. Evaluating the blanching of tissue caused by the RF treatment, it was concluded that applying RF energy for 10 seconds was an appropriate treatment duration.

EXAMPLE 5

Using a Combination of Temperature and Time as the Indicator of Treatment Completion: Pig Study

The above study was also conducted in pigs in order to determine the effects of RF energy to the peritoneum on the incidence of adhesion formation. In these studies the standard treatment duration was 75°C for 10 seconds. Four trocars, three 5mm and one 12mm in length, were inserted into a pig's abdominal wall. Upon insertion of each trocar, RF energy was immediately applied to the edges of the perforated peritoneum. The animal's serosa was roughened using sterile cotton gauze before the entry sites were closed. Viewing through a second-look laparoscopy one week later, no adhesions were found in either the trocar sites, the peripheral abdominal wall sites, or the animal's small bowel.

A control study was conducted by performing the same procedure on another pig for which the two trocar holes were not treated with RF. One week later, observed during a second-look laparoscopy, there were highly vascularized adhesions to one of the trocar entry sites connecting the abdominal wall to the internal organs.

It will now be readily apparent to those skilled in the art that various modifications may be made to the systems and methods disclosed herein utilizing RF heating to reduce post-surgical adhesions without departing from the spirit and scope of the invention. For example, the systems and methods of the present invention may be applied to, used with, and/or coupled to conventional surgical devices and tools other than the trocar. In addition, the systems and methods of the present invention may also be applied to minimize or eliminate the formation of post-surgical adhesions in various mammalian injured tissues, e.g., chest tissues, abdominal tissues, extremity tissues, and the like. Furthermore, the systems and methods of the present invention may also be applied to large surgical incisions as well as smaller laparoscopic incisions.

The scope of the invention shall not be limited to the embodiments described in the specification but shall instead be defined by all variations and equivalents as embraced by the appended claims.

What is claimed is:

1. A system for treating a cut edge of a tissue in surgery comprising:

at least one member configured and dimensioned to have a treatment surface which may be disposed adjacent to the cut edge of the tissue;

at least a treatment element disposed on said treatment surface and positioned to be in communication with the cut edge when said treatment surface is positioned adjacent to the cut edge of the tissue; and

a treatment source communicating with the treatment element to apply treatment to the cut edge of the tissue in a controlled manner to reduce post-surgical complications.

2. The system according to claim 1 wherein said treatment source contains sealant, said treatment element is a sealant applicator configured to deliver said sealant therethrough, and said treatment is application of said sealant to the cut edge of the tissue.

3. The system according to claim 1 wherein said treatment source contains coolant, said treatment element is a coolant applicator configured to deliver said coolant therethrough, and said treatment is application of said coolant to the cut edge of the tissue.

4. The system according to claim 1 wherein said treatment source is an energy source, said treatment element is a first electrode, and said treatment is application of energy to the cut edge of the tissue.

5. The system according to claim 4 wherein said energy source contains RF energy.

6. The system according to claim 4 wherein said member is a trocar sleeve having a hollow channel.

7. The system according to claim 4 wherein said member is a non-conductive sheet.

8. The system according to claim 6 further comprising a detachable unit containing and producing RF energy.

9. The system according to claim 8 wherein said detachable unit has a first electrical contact and said sleeve has a second electrical contact,

whereby RF energy is transmitted from said detachable unit to said electrode located on said sleeve when said first and second electrical contacts are in electrical communication.

10. The system according to claim 9 wherein said detachable unit further comprises:

an attachment means used to lock and unlock said detachable unit to said sleeve.

11. The system according to claim 10 wherein said attachment means are protruding latches that lock and unlock said detachable unit to said sleeve by twisting said detachable unit, relative to the position of said sleeve, in one direction and in the opposite direction, respectively.

12. The system according to claim 4 or 9 further comprising:
a timer; and
means for shutting off the delivery of RF energy through said first electrode.

13. The system according to claim 4 or 9 further comprising:
an impedance measurement device; and
means for shutting off the delivery of RF energy through said first electrode.

14. The system according to claim 4 or 9 further comprising:
a first apparatus for measuring temperature; and
means for shutting off the delivery of RF energy through said first electrode.

15. The system according to claim 4 or 9 further comprising:
a timer;
a second apparatus for measuring temperature; and

means for shutting off the delivery of RF energy through said first electrode.

16. The system according to claim 14 or 15 wherein said apparatus for measuring temperature is a thermocouple attached to said sleeve.

17. The system according to claim 16, wherein said thermocouple is disposed adjacent to said first electrode.

18. The system according to claim 9 further comprising:
means to measure impedance using said first electrode;
means to calculate instantaneous total energy dissipated into the tissue; and
means for shutting off the delivery of RF energy through said first electrode once a predetermined amount of energy is delivered.

19. The system according to claim 6 wherein said sleeve has a second electrode providing a bipolar electrode configuration.

20. The system according to claim 19 wherein said second electrode is a second ring electrode and said first electrode is a first ring electrode.

21. The system according to claim 20 wherein the spacing between said first and second ring electrodes is between 0.5 and 3.0 millimeters.

22. The system according to claim 21 wherein said first ring electrode has a width between about 0.5 and 3.0 millimeters; said second ring electrode has a width of between about 0.5 and 3.0 millimeters; and the width of said first electrode is substantially smaller than the width of said second electrode.

23. The system according to claim 6 wherein said trocar sleeve comprises:
a hollow conical section disposed at a distal end of said trocar sleeve, said conical section having an end having a larger diameter portion and a distal end having a smaller diameter portion;
a hollow, rod-like sleeve portion; and

a hollow cylindrical portion having a substantially larger diameter than said rod-like sleeve portion;

wherein said conical section connecting its larger diameter portion to one end of said rod-like portion; said cylindrical portion connects to the other end of said rod-like portion to form a channel through an entire length of a trocar; a protruding lip formed between said rod-like portion and said conical portion; and said first electrode is positioned close to said protruding lip.

24. The system according to claim 23 further comprising:
a return electrode that is not attached to the trocar.

25. The system according to claim 23 wherein said sheet does not include any return electrodes.

26. The system according to claim 7 wherein said sheet has multiple electrodes positioned thereon so that when said sheet is cut, said multiple electrodes are in close proximity to the cut edge of the tissue.

27. The system according to claim 7 wherein said sheet is an insulating material having one adhesive side.

28. The system according to claim 8 wherein said detachable unit comprises:
a first means for starting RF treatment;
a second means for indicating sufficient electrode contact with tissue;
a third means for indicating that RF treatment is ongoing; and
a fourth means for indicating that RF treatment has been completed.

29. The system according to claim 28 wherein said first means is a push button, and said second, third, and fourth means are each a light-generating element.

30. The system according to claim 28 wherein said first means is a push button, and said second, third, and fourth means are each a sound-generating element.

31. A method for treating a tissue during surgery by a tissue-treatment system comprising the steps of:

cutting the tissue to form a cut edge thereof; and

applying treatment to at least a portion of the cut edge to an extent sufficient to reduce post-surgical adhesion.

32. The method according to claim 31 wherein said treatment step comprises the step of sealing at least a portion of the cut edge.

33. The method according to claim 31 wherein said treatment step comprises the step of cooling at least a portion of the cut edge.

34. The method according to claim 31 wherein said treatment step comprises the step of applying a controlled dosage of energy to at least a portion of the cut edge.

35. The method according to claim 34 wherein said system comprises at least one electrode and wherein said applying step comprises the step of delivering RF energy through said electrode.

36. The method according to claim 34 wherein said applying step further comprises the steps of:

measuring at least one parameter which is indicative of completion of said treatment; and

shutting off delivery of energy after said parameter reaches a pre-set value.

37. The method according to claim 36 wherein said measuring step comprises the step of monitoring tissue impedance.

38. The method according to claim 36 wherein said measuring step comprises the step of monitoring duration of energy application.

39. The method according to claim 36 wherein said measuring step comprises the step of monitoring tissue temperature.

40. The method according to claim 36 wherein said measuring step comprises the step of monitoring both tissue temperature and duration of energy application.

41. The method according to claim 39 or 40 wherein said monitoring step comprises the steps of:

disposing a thermocouple in close proximity to the tissue; and

measuring temperature of the tissue.

42. The method according to claim 36 wherein said measuring step comprises the steps of:

monitoring impedance using an electrode; and

calculating instantaneous total energy dissipated into the tissue.

43. The method according to claim 31 further comprising the steps of:

placing an obturator within a trocar sleeve to form an assembly;

using said assembly to puncture an abdominal wall;

withdrawing said obturator from said trocar sleeve;

placing a detachable unit over an exposed portion of said trocar sleeve to provide electrical contact between said detachable unit and said sleeve;

providing RF energy from said detachable unit to an electrode located on said trocar sleeve to heat the tissue.

detaching said detachable unit; and

performing a surgical function through said trocar sleeve.

44. The method according to claim 31 further comprising the steps of:

placing a surgical sheet having a plurality of electrodes embedded therein over a surgical site, said electrodes providing electrical communication through at least one side of said sheet;

cutting through said sheet and the tissue thereunder to form an incision;

folding said surgical sheet in a manner to position said of electrodes adjacent to the incision; and

applying RF energy through said electrode to heat the tissue.

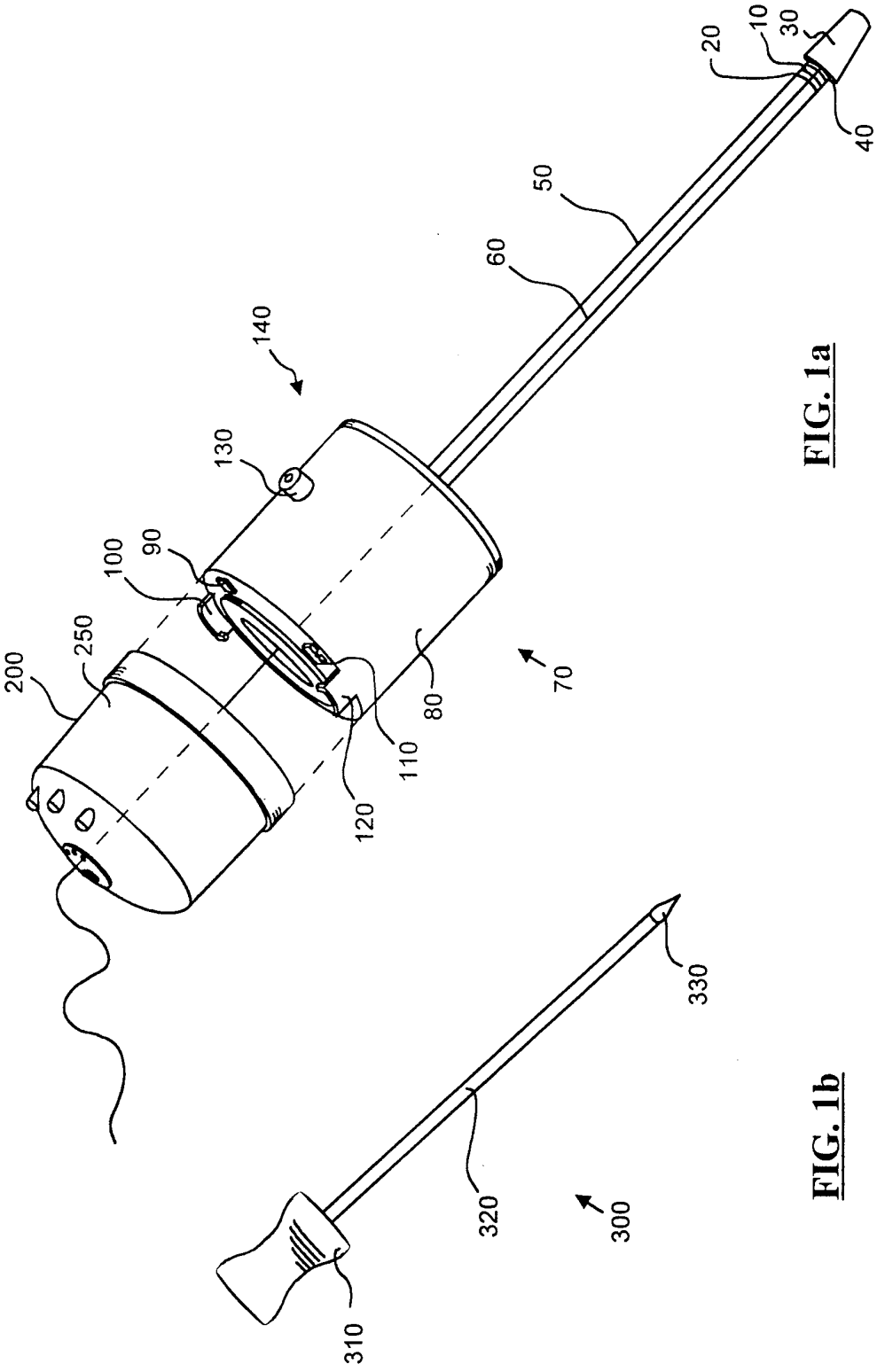

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FIG. 1a

FIG. 1b

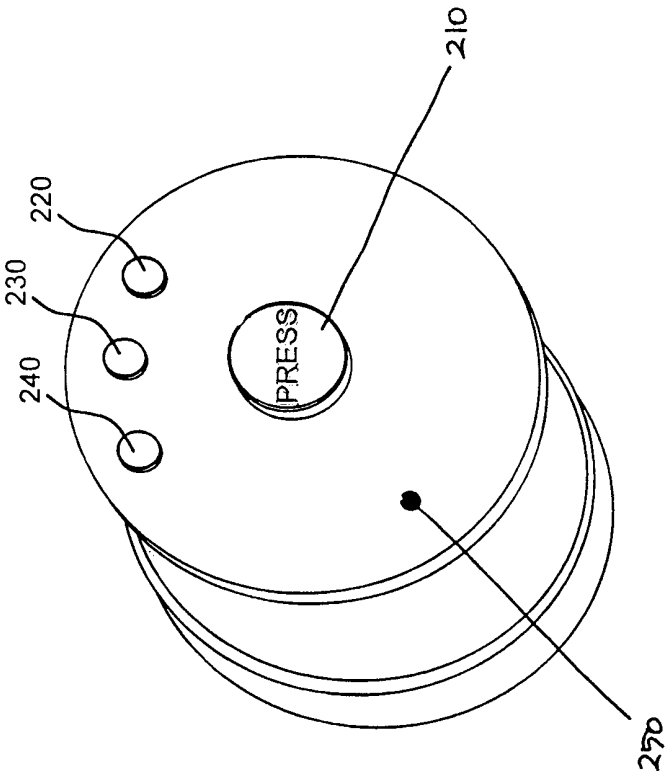
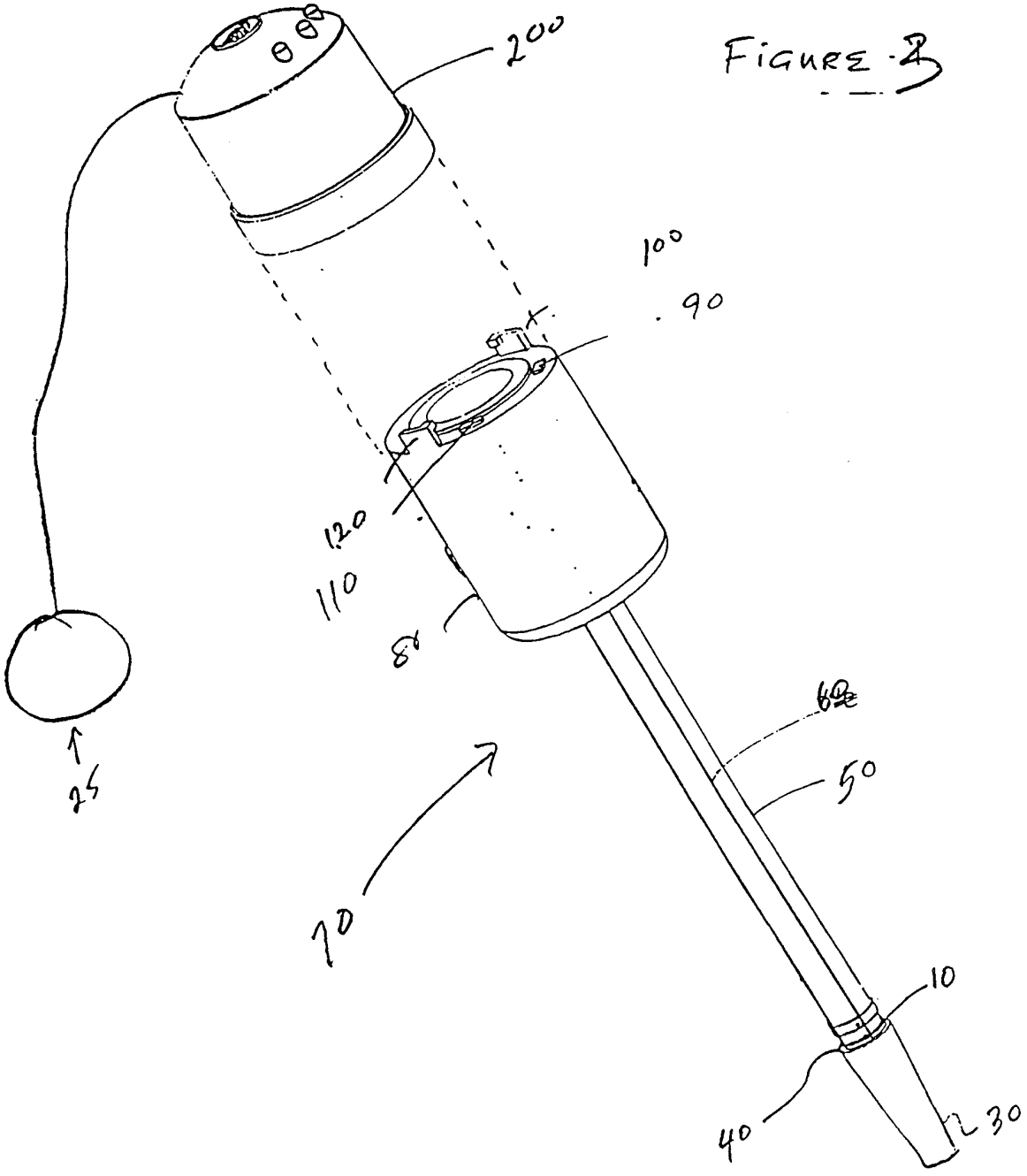


FIG. 2

FIGURE 3



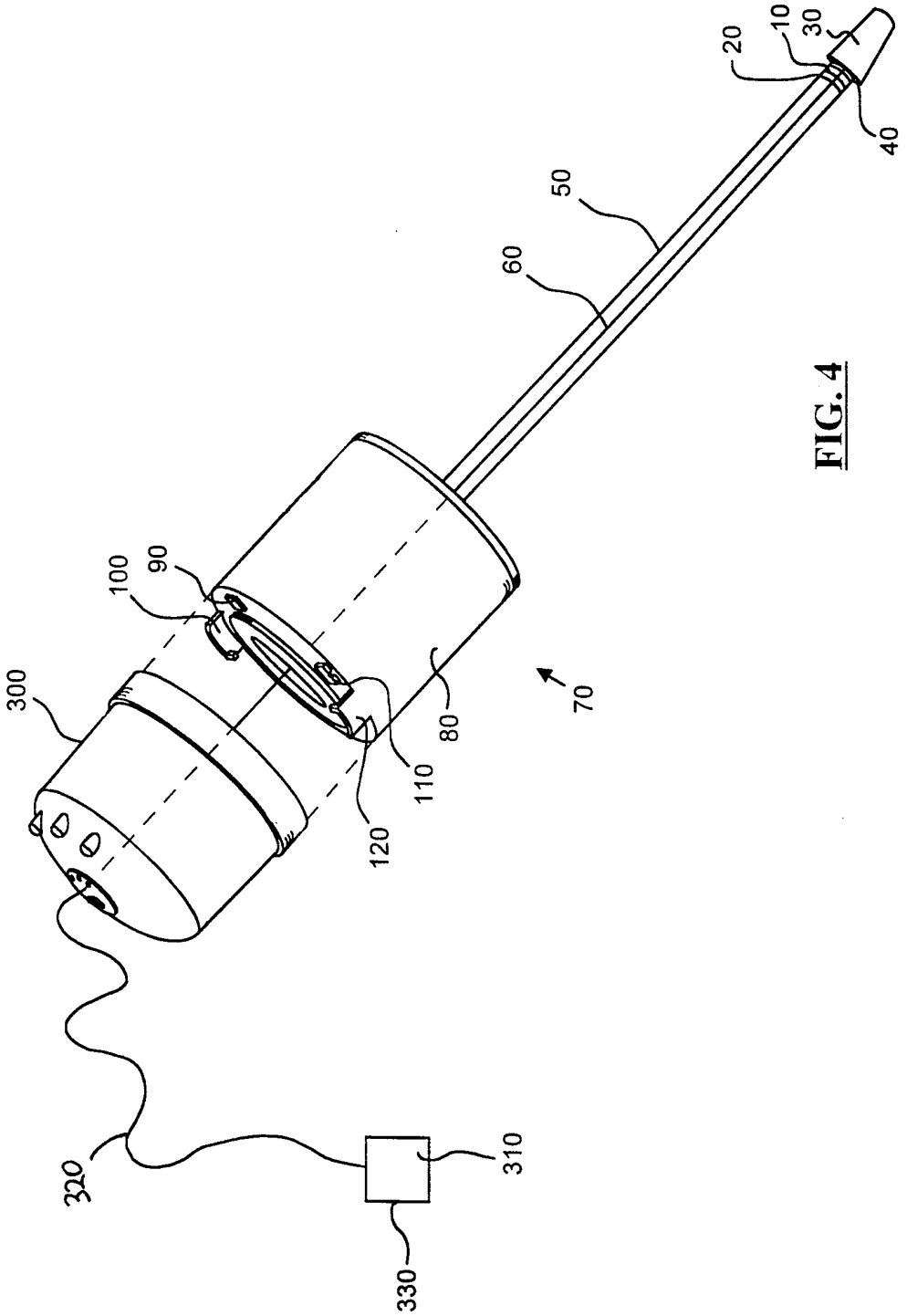


FIG. 4

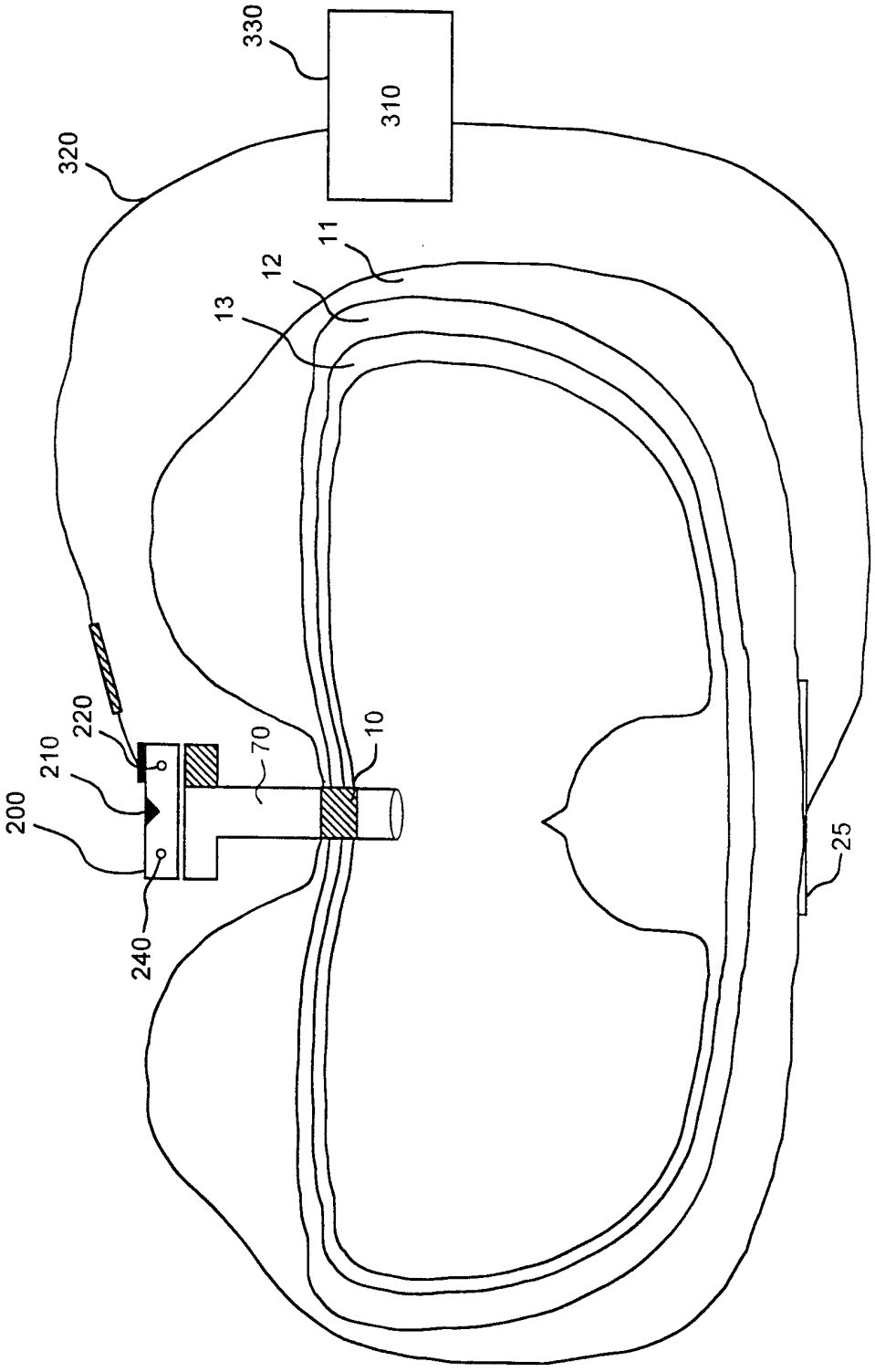


FIG. 5

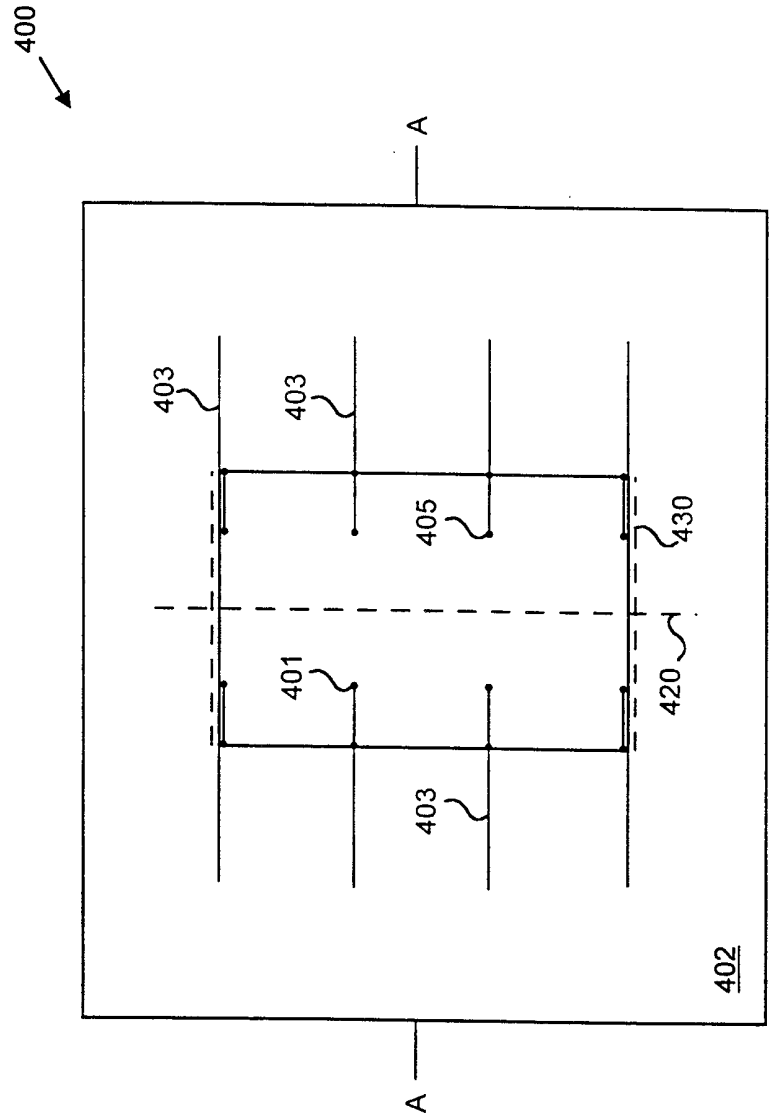


FIG. 6

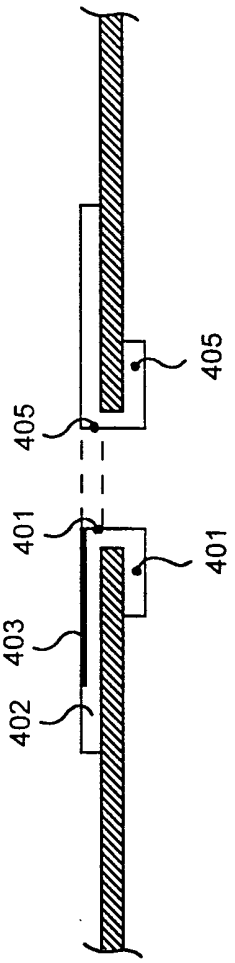


FIG. 7

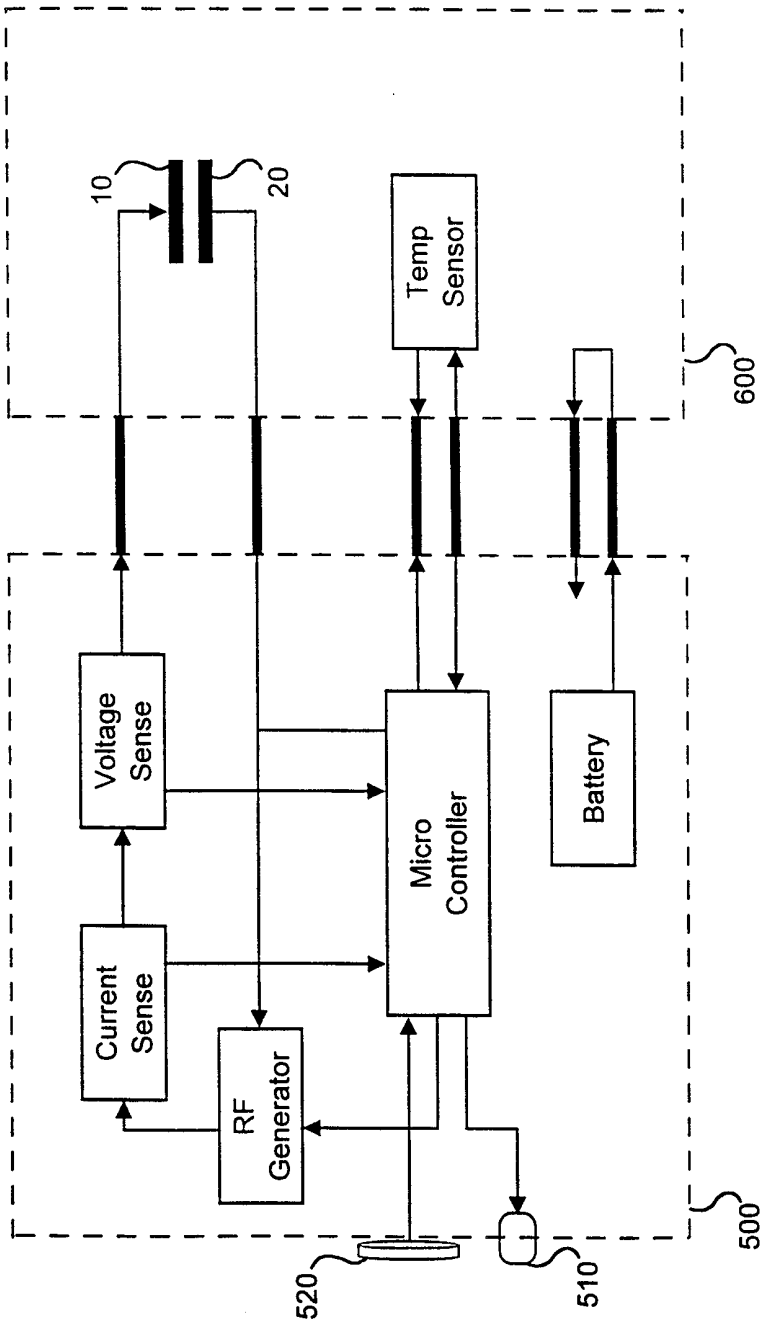

10
20
Temp Sensor
600
Voltage Sense
Micro Controller
Battery
Current Sense
RF Generator
500
520
510

FIG. 8

FIGURE 9

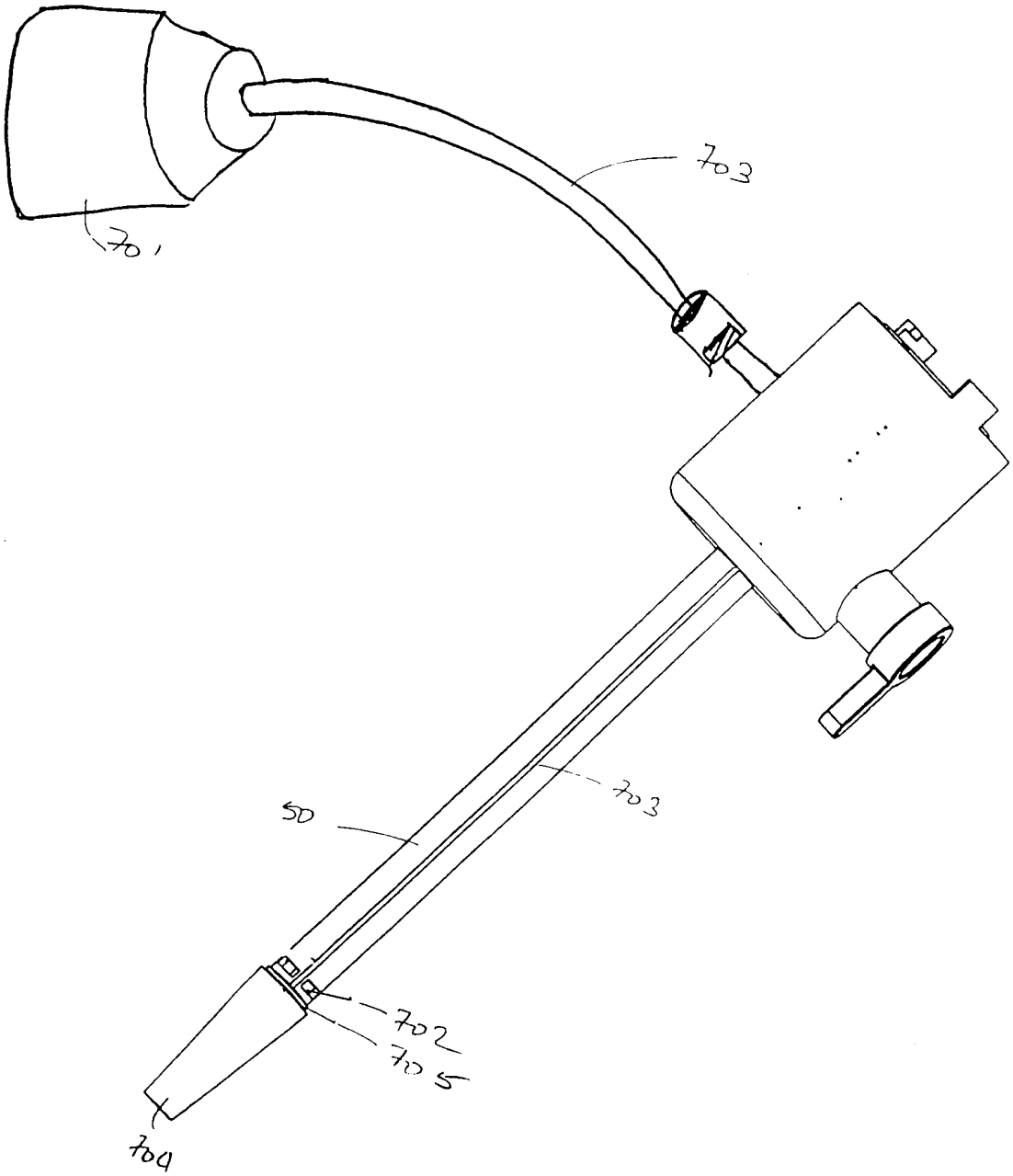
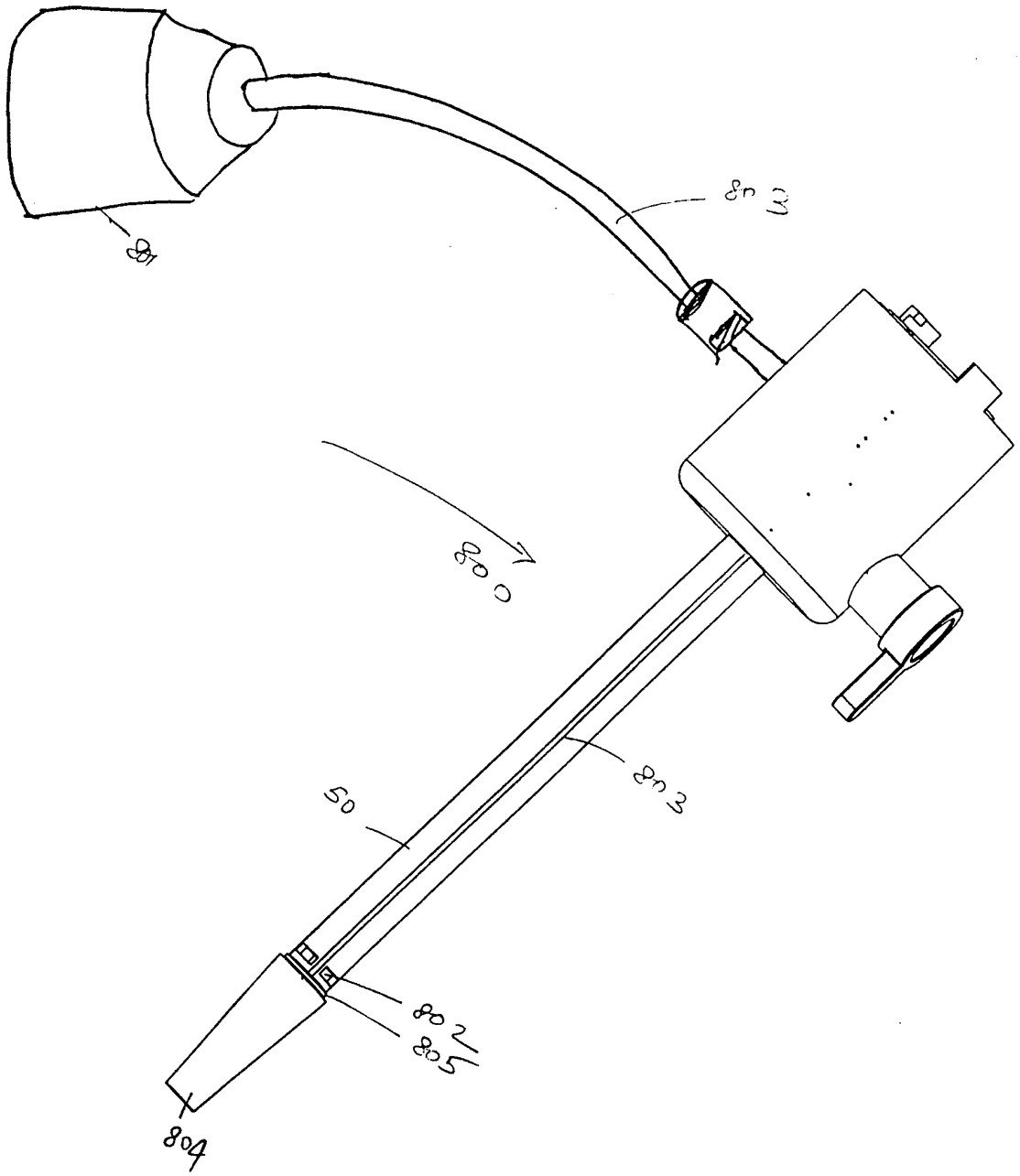


FIGURE 10



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/06949

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) :A61B 18/04
US CL :606/34
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/20-23, 32, 34, 37-41, 45-50

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,779,699 A (LIPSON) 14 July 1998, entire document.	1, 4, 30 --- 31, 34-44
X --- Y	US 5,846,235 A (PASRICHA et al.) 08 December 1998, entire document.	3 --- 33
X --- Y	US 5,711,958 A (COHN et al.) 27 January 1998, entire document.	2 --- 32

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 10 MAY 2000	Date of mailing of the international search report 26 JUL 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer ROSILAND KEARNEY Telephone No. (703) 308-2711

Form PCT/ISA/210 (second sheet) (July 1998) ★