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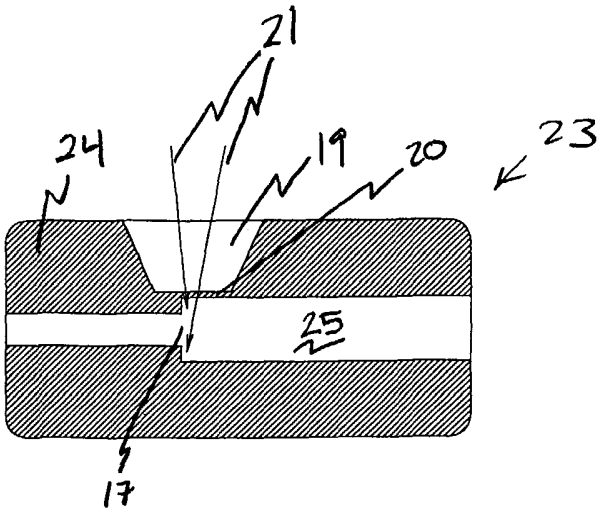
(54) Title: METHOD AND APPARATUS FOR STERILIZING OR DISINFECTING CATHETER COMPONENTS



(57) Abstract: Methods and apparatus for sterilizing or disinfecting using ultraviolet light. One embodiment of the invention is directed to a method for sterilizing or disinfecting at least a portion of an interior surface of a catheter, the interior surface being defined by a wall (24). The method comprises acts of identifying a stagnation zone (17) in the catheter, and transmitting ultraviolet light through the wall (24) at the stagnation zone (17). Another embodiment of the invention is directed to an ultraviolet light-transmissive catheter. The catheter comprises a wall (24) defining an interior of the catheter, and a region (19) of the wall (24) adapted to transmit ultraviolet light.

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METHOD AND APPARATUS FOR STERILIZING OR DISINFECTING CATHETER COMPONENTS

Priority Claim

This application claims the benefit, under 35 U.S.C. §119(e), of the filing date of: U.S. provisional application serial no. 60/298,790 entitled "Method and Apparatus for Disinfecting Catheters and Entrance Sites," filed June 15, 2001; U.S. provisional application serial no. 60/300,803 entitled "Method and Apparatus for Disinfecting Catheters and Entrance Sites," filed June 25, 2001; U.S. provisional application serial no. 60/316,744 entitled "Method and Apparatus for Disinfecting Wound Sites," filed August 31, 2001; and U.S. provisional application serial no. 60/334,722 entitled "Method and Apparatus for Disinfecting Catheter Entrance Sites with a Dressing," filed October 31, 2001; which are incorporated herein by reference.

Field of the Invention

The present invention relates generally to the field of sterilization or disinfection systems and methods.

Background of the Invention

Catheters are used for a variety of purposes including the administration of fluid, nutrients, medications, and blood products to patients. While catheters serve a beneficial purpose, they frequently give rise to harmful infections in the catheterized patient. Some infections arise from microorganisms entering the body at the insertion site of the catheter. Others arise from microorganisms entering the body via the catheter itself. While a catheter is generally sterile when it is first inserted into a patient, it is typical for microorganisms to enter the catheter from the external environment through openings in the catheter. The microorganisms may adhere to the interior surface of the catheter and colonize. An infection may occur in the patient when microorganisms from the catheter are transmitted into the body of the patient via the flow of fluids, including both the backflow and regular flow of fluids, from the catheter into the patient. The risk of infection increases with the length of time that the catheter remains inserted. Catheter

related infections, particularly catheter related blood stream infections, are a serious source of morbidity, mortality, and excess cost in health care settings.

To deter infection, inserted catheters are periodically flushed with a sterile solution such as saline. However, catheters may harbor microbes that are not readily removed by flushing, which will remain adhered. Accordingly, an improved method for sterilization/disinfection of catheters is necessary.

Summary of the Invention

One embodiment of the invention is directed to a method for sterilizing or disinfecting at least a portion of an interior surface of a catheter, the interior surface being defined by a wall. The method comprises acts of identifying a stagnation zone in the catheter, and transmitting ultraviolet light through the wall at the stagnation zone.

Another embodiment of the invention is directed to an ultraviolet light-transmissive catheter, comprising a wall defining an interior of the catheter, and means within the wall for transmitting ultraviolet light through the wall of a catheter to the interior of the catheter.

A further embodiment of the invention is directed to an ultraviolet light-transmissive catheter. The catheter comprises a wall defining an interior of the catheter, and a region of the wall adapted to transmit ultraviolet light.

Another embodiment of the invention is directed to a method for sterilizing or disinfecting a portion of a catheter enclosed within a container. The method comprises an act of transmitting ultraviolet light through the container.

A further embodiment of the invention is directed to a method for sterilizing or disinfecting a portion of a catheter connector coupled to a cap. The method comprising an act of transmitting ultraviolet light through the cap.

Another embodiment of the invention is directed to a method for sterilizing or disinfecting an interior portion of a catheter. The method comprising acts of positioning an ultraviolet light source above a lens component of the catheter, and transmitting light from the ultraviolet light source through the lens and along the interior portion of the catheter.

A further embodiment of the invention is directed to an apparatus for sterilizing or disinfecting an interior portion of catheter using an ultraviolet light source. The apparatus comprises a lens to transmit light from the ultraviolet light source along the portion of the catheter.

Another embodiment of the invention is directed to a method, comprising acts of applying ultraviolet light to a portion of a catheter to sterilize or disinfect the portion of a catheter, and inserting the portion of the catheter into a patient.

Brief Description of the Drawings

Figure 1 illustrates a method for sterilizing or disinfecting a region of a catheter with a light source;

Figure 2 illustrates a conventional configuration for a portion of a catheter connector;

Figures 3A-3B illustrate a first example of a design feature to enhance the UV-transmissivity of a portion of a catheter;

Figure 4 illustrates a first configuration of a connector having enhanced UV-transmissivity in a portion of the connector;

Figure 5 illustrates another configuration of a connector having enhanced UV-transmissivity in a portion of the connector;

Figure 6 illustrates a further configuration of a connector having enhanced UV-transmissivity in a portion of the connector;

Figures 7A-7C and 8A-8C illustrate a first configuration of a sterilization/disinfection unit for sterilizing or disinfecting a region of a catheter;

Figures 9A-9E, 10A-10B, and 11A-11B illustrate another configuration of a sterilization/disinfection for sterilizing or disinfecting a region of a catheter;

Figures 12A-12B illustrate a UV-transmissive container used with the sterilization/disinfection unit of Figures 7A-7C and 8A-8C;

Figures 13A-13C illustrate a first configuration of UV-transmissive cap for use with a portion of a catheter connector;

Figures 14A-14C illustrate another configuration of UV-transmissive cap for use with a portion of a catheter connector;

Figures 15A-15B illustrate a light collector for use with a catheter;

Figure 16 illustrates a block diagram of exemplary circuitry for use with the sterilization/disinfection units of Figures 7-11; and

Figure 17 illustrates a schematic diagram of exemplary circuitry for use in the instantaneous sterilization/disinfection units of Figures 7-11.

Detailed Description

As discussed above, a catheter-related infection may arise when microorganisms within a catheter enter a patient through the backflow or regular flow of fluids into the patient. Microorganisms (e.g., bacteria, virus, fungus, mold, yeast, etc.) may contaminate the catheter via catheter connectors or other ports. The connectors are designed to allow for the connection and disconnection of various external components, e.g., fluid bags, syringes, infusion pumps, etc. When the connectors are disconnected, the internal surfaces in and near the connector may be exposed to external contamination. This contamination may then enter the fluid in the catheter.

Certain regions of catheters are particularly susceptible to adhering and accumulating microbes, which leads to colonization and infection. These regions are susceptible based on design features of the catheter. For example, a diameter change in a catheter may cause fluid to form eddies in the corners formed by the diameter change. The fluid in the corners stagnates, and thus is susceptible to colonization. The same design features that may result in microbial colonization also make conventional sterilization or disinfection of the colonization sites problematic. For example, a sterile saline solution flushed through a catheter will fail to eliminate colonies residing in corners because the saline solution will not adequately access the corners due to the eddies formed. Other typical microbial colonization sites in a catheter may include an interface between catheter components, a crevasse, or a narrow region of a fluid channel. The hub and connector of a catheter often harbor microbes because their design includes many of the features described above that cause microbes to stagnate and colonize.

In view of the foregoing, the present invention relates to improved methods and apparatus for sterilizing catheter components. While prior art attempts have been made at transmitting ultraviolet light through catheter walls to sterilize or disinfect the internal

portions of catheter components, for example as disclosed in U.S. 4,469,835 to Laurin and U.S. 4,475,900 to Popovich et al., these attempts have been insufficient. Accordingly, one aspect of the invention is directed to a method and apparatus for identifying a stagnation zone in a catheter and transmitting ultraviolet light through the wall of the catheter at the stagnation zone. Another aspect of the invention relates to modifications in the design of conventional catheters to increase the transmissivity of certain regions to ultraviolet light.

It should be appreciated that while the terms "sterilize" and "disinfect" are used generally herein, the methods and apparatus described may be used to achieve a desired level (e.g., low or high) of sterilization or disinfection. The sterilization or disinfection may occur by killing microorganisms, inactivating microorganisms (i.e., rendering the microorganisms unable to reproduce), or any combination thereof.

Sterilization or Disinfection of Catheter Components Using Ultraviolet Light

Figure 1 illustrates a method for sterilizing or disinfecting a region of catheter using sterilizing or disinfecting light, in accordance with one embodiment of the invention. Sterilizing or disinfecting light is emitted by one or more light sources 7 and directed to a portion of a catheter 1 with the aid of one or more reflectors 9.

Catheter 1 includes a hub 11 and a male connector portion 3a. A typical catheter system is made up of a number of separate tubing sections linked by connectors and other components. Insertable tubing 4 of catheter 1, proximal to hub 11, is inserted into the body of the patient. Insertable tubing 4 typically has a smaller diameter and is made of a different, bio-compatible, material than other the other tubing of catheter 1. Further, insertable tubing 4 of catheter 1 may contain one or more lumens. Hub 11 may be any junction where insertable tubing 4 is adapted to the external catheter tubing. In a catheter with multiple lumens, this is the location where the lumens of the catheter are split into separate external tubes. Each of the tubes typically terminates at a connector, e.g., male connector portion 3a, a short distance from the hub. Connector 3, including male connector portion 3a and a female connector potion 3b, may be a mechanism for attaching and detaching catheter 1 to/from external catheter equipment. The external catheter equipment may include a needle port, a Y-adapter, a flow adjustment valve, a

drip indicator, or a fluid bag. It should be appreciated that the catheter illustrated in Figure 1 is just one example of a catheter that may be sterilized or disinfected in accordance with the invention.

In Figure 1, UV light is exposed to male connector portion 3a of catheter 1. However, UV light may be exposed to any portion of catheter 1, such as tubing 5, hub 11, or the female connector portion that mates with male connector portion 3a (not shown in Figure 1). Sterilization or disinfection may be performed while catheter 1 is inserted in a patient or while catheter 1 is not inserted. For example, hub 11 or connector 3 of catheter 1 may be sterilized/disinfected while catheter 1 is inserted. On the other hand, a portion of catheter 1 that will be inserted into a patient, such as the tip of the catheter or a portion of tubing 5 that will be disposed at the entrance site of the catheter, may be sterilized/disinfected prior to insertion. In the case where catheter 1 is inserted in the patient, the catheter may be in use (e.g., administering fluids) or not in use during sterilization/disinfection.

During use of catheter 1, sterilization/disinfection may be useful to deter or eliminate colonization of microbes in catheter 1. When catheter 1 is not in use, for example when connector 3 is disconnected to replace an IV fluid bag, sterilization/disinfection may be useful to eliminate the contamination of microbes on exposed portions of catheter 1, such as connector 3. The sterilization/disinfection technique discussed above may be used in addition to or in place of other sterilization/disinfection procedures. For example, chemical treatment of catheter 1, flushing of catheter 1 with a sterile solution, or other techniques for sterilizing or disinfecting catheter 1 or portions thereof may alternatively or additionally be employed.

UV light may be exposed to catheter 1 to sterilize or disinfect the external surfaces of the catheter, the internal surfaces of the catheter, or both. Most polymeric substances such as those used to make catheters and other medical devices are nearly opaque to UV light, even though they may appear transparent or translucent to visible light. Some of these materials may transmit a portion of UV light when used in thin sections, but not when used in thicker sections such as those found in catheter tubing and connectors. However, as will be described in connection with Figures 3-6, catheter 1, or one or more portions thereof, may be constructed to be sufficiently transmissive to UV light.

Light source 7 may be any light source that emits light capable of sterilization or disinfection. For example, light source 7 may be an ultraviolet (UV) light source such as a mercury vapor lamp, a xenon flash lamp, a continuous arc lamp, UV light emitting diodes (LEDs), a UV laser, or any other solid state or non-solid state UV light-emitting device. The lamp may emit narrow spectrum light (e.g., a line spectrum) or broad spectrum light. Broad spectrum light may include, e.g., UVA, UVB, and UVC light, or UV light accompanied by light from another portion of the electromagnetic spectrum. For example, the emission of both UV and visible light from light source 7 may enhance the effectiveness of the light source, as the sensitivity of different microorganisms to light varies with the wavelength of the light. It should be appreciated that though three light sources 7 are illustrated in Figure 1, one, two, or more than three light sources may alternatively be used. Further, while one reflector 9 is shown disposed about each light source 7, two or more reflectors 9 may be includes around a light source 7, or reflector 9 may be eliminated entirely. Reflector 9 may be positioned in any location suitable to direct light from light source 7 towards catheter 1.

Light may be generated by light source 7 in one or more flashes. If multiple flashes are generated, the flashes may be applied at specified intervals that may occur, for example, one or more times per day. A flash lamp or other non-continuous lamp may be used to generate light in one or more flashes. The lamp may be a high intensity source of sterilizing or disinfecting light where the sterilization dosage may be applied in less than a few minutes or seconds. The energy of a single flash may be sufficient to deliver a sterilizing or disinfecting dosage, e.g., greater than 10 mJ/cm^2 of UVC, to all surfaces to be sterilized or disinfected.

Light may alternatively be generated by light source 7 as continuous radiation over a period of time. To generate continuous radiation, a lower intensity source capable of emitting sterilizing or disinfecting light continuously over a period of time may be used. The intensity of the light emitted by light source 7 may be adjusted for use on different materials and catheter components. Alternatively, sterilization or disinfection operations may be performed once a day or a few times a day, and a continuous light source may be turned on for long enough to perform a complete sterilization or disinfection operation for each instance. The timing for each operation may be

preformed by a standard timer or with a light sensor that measures light exposure and turns the continuous light source off when a desired dosage is reached.

A catheter that is sterilized or disinfected in accordance with the invention may include any or all of the illustrated and described components of catheter 1. As described herein, a catheter may include any conduit through which fluids pass into or out of the body, such as a standard injection needle, a blood sample needle, or a cannula. The catheter need not pass through an opening in the skin; instead the catheter may pass through a natural opening, as is the case with Foley catheters or other urinary catheters.

Catheter Features to Enhance Ultraviolet Light Transmissivity

Figure 2 illustrates a typical configuration of male connector portion 3a, which is one example of a catheter component. Male connector portion 3a includes a tubing retaining cap 13. Tubing retaining cap 13 secures tubing 5 to male connector portion 3a. The interface between male connector portion 3a and tubing 5 creates a diameter transition 17 of a fluid channel 25 in catheter 1. The interface also creates a crevasse 15 at the junction between tubing 5 and male connector portion 3a.

Diameter transition 17 and crevasse 15 create stagnation zones where the fluid flow through fluid channel 25 is decreased or where eddies form. Thus, the fluid at diameter transition 17 and crevasse 15 does not move as rapidly along catheter 1 as it does at other portions of fluid channel 25. As discussed previously, the stagnation of fluid may result in the increased accumulation of microbes, as microbes tend to adhere to the surface of catheter 1 in regions of decreased fluid rate. Colonies of microorganisms, which lead to infection, can then form. Other examples of features of catheters that may create stagnation zones, and hence infection, are an interface between catheter components, a notch in the wall of the catheter, and a narrow region of a fluid channel. However, any location where the passage of fluid is slowed or stopped, may be considered a stagnation zone in accordance with the invention. Components that typically include one or more of these features (in addition to male connector portion 3a) are, for example, a hub, a drip indicator, a pinch valve, an infusion pump, a needle pump, a Y-adapter, and a female connector portion of the catheter.

Conventional catheter components and tubing are not designed to be transmissive to UV light. Thus, the method described in connection with Figure 1 will be less effective on conventional catheters. However, the components and tubing of catheter 1 may be designed to be sufficiently UV-transmissive. One way to design catheter components and tubing to be UV-transmissive is to decrease the thickness of the UV-attenuating material of the wall so that it transmits a sufficient percentage of the UV light applied. Another way to design catheter components and tubing to be UV-transmissive is to fabricate these portions entirely or partially from materials having a higher UV transmissivity.

Figures 3A and 3B illustrate one example of a design feature to increase the UV-transmissivity of a catheter component 23. In this configuration, catheter component 23 includes three recesses 19 in a wall 24 of the component. Recesses 19 are adjacent to diameter transition 17, which represents a stagnation zone. Recesses 19 are designed to provide sufficient UV light transmission through wall 24 in a region 20 below each recess. A UV-transmissivity of 20% or lower may be sufficient for sterilization/disinfection in some circumstances. Regions 20 in wall 24 may, for example, be formed from polyethylene, polycarbonate, acrylic, polyurethane, Teflon, or PVC, which are typical materials for wall 24. Regions 20 may also be fabricated by adding UV-transmissive particles to the material of wall 24. The addition of UV-transmissive particles to the existing material of wall 24 improves the transmissivity of wall 24. Alternatively, regions 20 may be formed of a continuous UV-transmissive material such as quartz, fused silica, UV-transmissive glass, or ceramic. These continuous materials may be integrated into the material of wall 24.

Recesses 19 may be positioned so the light passing through the recesses will be directed at one or more stagnation zones and/or any other locations that are susceptible to microbial colonization. Figures 3A and 3B illustrate recesses 19 positioned around the periphery of diameter transition 17, which is a stagnation zone. Light rays 21 enter recesses 19 from a UV light source and penetrate regions 20 in wall 24. The inner surface of fluid channel 25 is thereby exposed to a sterilizing/disinfecting dose of UV light. UV light transmitted through a single

region 20 will illuminate, and thus sterilize/disinfect, both the portion of the inner surface of fluid channel 25 on the portion of wall 24 adjacent to region 20, as well as the portion of wall 24 directly across from region 20, on the other side of fluid channel 25.

Figures 3A and 3B illustrate three recesses 19, however, one, two, four, or more recesses 19 may alternatively be used. Further, recesses 19 need not be positioned symmetrically. The regions of wall 24 that separate each recess 19 provide structural strength for component 23. However, these regions may be omitted, such that a continuous ring-shaped recess is formed around an inner circumference surrounding fluid channel 25. More than one continuous ring-shaped recess may be included in parallel. Any of recesses 19 described above may also be filled with a UV-transmissive material to enhance the structural integrity of component 23.

The side walls of recesses 19 are shown angled outward to provide a larger acceptance angle for light rays 19 entering each recess. The side walls may be coated with a UV-reflective material to enhance the efficiency of light transmission to fluid channel 25, although such a coating is not necessary for effective UV transmission. If regions 20 are formed of a continuous UV-transmissive material, such as UV-transmissive glass, the outer surface of the material may be shaped to form a convex lens to increase the acceptance angle of the light and direct more UV light into fluid channel 25.

Diameter transition 17 represents an exemplary stagnation zone in catheter component 23. It should be appreciated that the design features described above and in further configurations may be used to increase the transmission of UV light to any type of stagnation zone, as described above, or any other location on catheter 1. Catheter component 23 may be any portion of catheter 1, including a portion of connector 3, hub 11, a needle port, or a Y-adapter.

Figures 4-6 illustrate various configurations of connector 3 of catheter 1 having enhanced UV-transmissivity in one or more portions of the connector. For example, connector 3 of Figure 4 includes at least one recess 19, while connector 3 in each of Figures 5 and 6 includes other design features to increase the transmission of UV light to fluid channel 25. Figures 4-6 illustrate a cross-sectional view of connector 3, which includes at least three possible stagnation zones: (1) an abrupt diameter change 29 created by the interface between male connector portion 3a and female connector portion

3b, and (2) crevasse 15a created by the interface between tubing 5 and male connector portion 3a, and (3) crevasse 15b created by the interface between tubing 5 and male connector portion 3b. Stagnation is minimized at a region 27 in male connector portion 3b because the diameter change in that region is designed to be gradual. Where possible, it is preferable to reduce the magnitude of diameter changes or crevasses in fluid channel 25, or otherwise facilitate the flow of fluid therethrough, to reduce stagnation.

In Figures 4-6, connector 3 and tubing 5 include features to increase the transmission of UV light to a region including crevasses 15a and 15b. While the magnitude of the stagnation at crevasses 15a and 15b may be reduced by more closely matching the size of fluid channel 25 in male connector portion 3a/female connector portion 3b and tubing 5, it cannot be eliminated in a connector of this configuration. Thus, stagnation of fluid will result in this area. UV light may be applied through to a region including crevasses 15a and/or 15b to expose the inner surface of fluid channel 25, at the region including crevasse 15a and/or 15b, to sterilizing or disinfecting light.

Connector 3 has been designed so that crevasses 15a and 15b occur outside of tubing retaining caps 13. Thus, UV light does not need to pass through tubing retaining caps 13, which comprises a thick material and is therefore highly attenuating to UV light. Designing connector 3 such that crevasses 15a and 15b occur outside of connector 3 allows UV light to reach the crevasses 15a and 15b through the wall of tubing 5, if tubing 5 is properly designed. The material of tubing 5 may be chosen or modified to provide sufficient transmission of UV light. For example, the thickness of tubing 5 may be chosen to be small, and therefore more UV-transmissive, and/or the material of tube 5 may be chosen to be UV-transmissive. The UV-transmissivity of tubing 5 may also be increased via the inclusion of UV-transmissive additives in tubing 5.

Figure 4 illustrates a first configuration of connector 3 designed to increase the transmission of UV light to the region including diameter change 29. While the magnitude of diameter change 29 may be reduced by more closely matching the size of fluid channel 25 in male connector portion 3a and female connector portion 3b, it cannot be eliminated in a connector of this configuration. Thus, some stagnation of fluid will result. In Figure 4, male connector portion 3a includes at least one recess 19 positioned to increase the transmission of UV light to a region including diameter change 29. As discussed in connection with Figure 3, UV light may be applied through region 20 below

recess 19 to expose the inner surface of fluid channel 25, at the region including diameter change 29, to sterilizing or disinfecting light. UV light may be applied using one or more light sources, and may be applied to one or more regions 20. The region including diameter change 29 may be sterilized/disinfected while male connector portion 3a and female connector portion 3b are coupled, or by disconnecting male and female connector portions 3a and 3b and applying UV light to each of connector portions 3a and 3b separately. In the case where male connector portion 3a and female connector portion 3b are coupled, the region including diameter change 29 may be sterilized/disinfected while connector 3 is in use by a patient or not in use.

Figure 5 illustrates another configuration of connector 3 designed to increase the transmission of UV light to the region including diameter change 29. Wall 24 in male connector portion 3a includes one or more voids 31, which are similar to recesses 19, except that void 31 is open on a side of male connector 3a rather than on the circumferential surface of male connector 3a. Thus, void 31 is bounded on one side by a region 30 of wall 24 that is parallel to region 20. Void 31 serves a similar function to recess 19 in that it reduces the cross-sectional area of wall 24 of male connector portion 3a, and thereby enhances UV transmission. UV light may be applied to one or more regions 30, such that UV light travels through void 31 and region 20 to expose the inner surface of fluid channel 25, and sterilize or disinfect the region including the diameter change 29. As discussed above, the region including diameter change 29 may be sterilized/disinfected while male connector portion 3a and female connector portion 3b are coupled and in use, coupled and not in use, or disconnected.

Figure 6 illustrates a further configuration of connector 3 designed to increase the transmission of UV light to the region including diameter change 29. Wall 24 in male connector portion 3a includes UV-transmissive material 33 to increase the overall UV-transmissivity of wall 24. Some examples of possible UV-transmissive material 33 are quartz, fused silica, UV transparent glass, ceramic, UV enhanced acrylic, polycarbonate, polyethylene, or Teflon. Polymers designed for UV transmission, such as UV enhanced acrylic or polycarbonate, have some transparency to UVC down to wavelengths in the 280 nm range. For some applications this is sufficient, particularly where a broadband sterilizing light source, such as a xenon flash lamp, is used to generate UV light.

Material 33 may be transmissive to the entire UV spectrum or a portion thereof,

e.g., UVC. In one example, material 33 may be in particle form, such as small beads, powder, or short fibers (i.e., rovings). When in particle form, material 33 may be distributed continuously throughout the circumference or entirety of male connector portion 3a or only in certain regions. While material 33 is shown as particles in Figure 6, larger elements of UV-transmissive material may also be used. For example, the entirety of male connector portion 3a, connector 3, or catheter 1 may be formed of a UV-transmissive material.

UV light may be applied to one or more portions of wall 24 that include UV-transmissive material 33, such that UV light travels through material 33 and/or wall 24 and exposes the inner surface of fluid channel 25. In this way, UV light may be exposed to the region including diameter change 29, which is sterilized or disinfected by a sufficient dose of UV light. As discussed above, the region including diameter change 29 may be sterilized/disinfected while male connector portion 3a and female connector portion 3b are coupled and in use, coupled and not in use, or disconnected.

The features and configurations described above are exemplary only. Any combination of described features may be included in a catheter to increase its UV-transmissivity, in accordance with the invention. Further, those skilled in the art will readily see many possible variations on the specific physical configuration described that can be used to perform the function of this invention. Other techniques for enhancing the UV-transmissivity of a catheter to sufficient levels or allowing UV light to expose regions of the catheter where microbial colonization is possible may be alternatively or additionally be included.

Apparatus for Sterilization or Disinfection of Catheter Components

Figures 7A-7C and 8A-8C illustrate a first configuration of a sterilization/disinfection unit, in accordance with one embodiment of the invention. A housing 35 of a sterilization/disinfection unit 34 includes a sterilization/disinfection chamber 39, defined vertically by upper surface 39a and lower surface 39b. A light source 7 and reflector 9 are disposed at the rear of sterilization chamber 39, although they may be alternatively disposed at upper surface 39, lower surface 39b, or another location in or near sterilization chamber 39. Reflector 9, disposed about light source 7, directs

light emitted by light source 7 to all surfaces of the portion of catheter 1 within sterilization/disinfection chamber 39. Further, upper surface 39a and lower surface 39b may include a reflective coating to further aid in directing light to the portion of catheter 1 within sterilization/disinfection chamber 39.

A cover 41 of sterilization/disinfection unit 34 forms a clamshell configuration with a base 40 of housing 35. Cover 41 is coupled to base 40 via hinge 45, and may be opened by pressing on a lever 43 coupled to cover 41. The clam-shell configuration allows for easy placement of a portion of catheter 1 into, or removal of the portion of catheter 1 from, sterilization/disinfection chamber 39. A light seal 37 is disposed on the rim of cover 41 and the rim of base 40. When the clamshell formed by cover 41 and base 40 is in a closed configuration, light seal 37 on each rim interfaces to form a substantially light-tight seal of sterilization/disinfection chamber 39.

Light seal 37 may be formed from a complaint material. For example, light seal 37 may be formed from a convoluted and/or foamed opaque elastomeric material such as neoprene, natural rubber, silicone rubber, or a thermoplastic elastomer (TPE). The use of a compliant material allows a substantially light-tight chamber to be formed when a component of catheter 1 is placed across light seal 37. For example, light seal 37 may conform to hub 11, connector 3, or tubing 5, as shown in Figures 7-8. Thus, the compliance of light seal 37 allows portions of catheter 1 to be placed in sterilization/disinfection unit 34 for sterilization/disinfection without disassembling catheter 1 (e.g., disconnecting male and female connector components 3a and 3b of connector 3). However, catheter 1 may be disconnected from external catheter equipment at connector 3 to allow hub 11 and male connector portion 3a of catheter 1 to fit inside sterilization/disinfection unit 34, within the confines of light seal 37, during sterilization or disinfection.

In the example of Figures 7A-7C, two male connector components 3a are enclosed within housing 35, along with tubing 5 of the dual-lumen catheter. In the example of Figures 8A-8C, female connector components 3b are also included such that two connectors 3, each having male connector component 3a coupled to female connector component 3b, are enclosed within housing 35 along with tubing 5. Advantageously, in the example of Figures 8A-8C, catheter 1 may be in use (e.g., administering fluids) during sterilization/disinfection. UV light may be applied at an

intensity sufficient to sterilize/disinfect the external surfaces of the catheter components contained within sterilization/disinfection chamber 39, or at an intensity sufficient to sterilize/disinfect both the internal and external surfaces of the catheter components.

In one example, light source 7 may be adapted to generate one or more light flashes. To generate light flashes, light source 7 may be a xenon flash lamp, and may be made with an envelope of quartz, fused silica, or UV transparent glass to maximize the output of UV light in the flash. Light source 7 may be driven with a high current density, e.g., 3,000 to 6,000 amps/cm^2, and a short flash duration, e.g., less than 200 microseconds for a small flash unit, for maximum UVC light production. The energy required by light source 7 to generate a flash sufficient for sterilization or disinfection is determined by the amount of area to be illuminated, the minimum sterilizing light dosage desired, the uniformity of the illumination, and the spectrum of light source 7. For example, a flash light source made from UV glass used to illuminate 25 square centimeters (about 4 square inches) produces a UVC energy intensity of about 20 mJ/cm^2 and a total flash input energy of about 20 joules. A flash light source may generate greater than 10 mJ/cm^2 of UVC for disinfection, and greater than 30 mJ/cm^2 of UVC for higher level sterilization. A higher intensity may be required to sterilize or disinfect the internal surfaces of the portion of catheter 1 in sterilization chamber 39. Light source 7 may also generate UVA, UVB, infrared, and/or visible light. In some applications, it is desirable to limit the amount of UVA, UVB, visible, infrared light, and/or portions of the UVC spectrum emitted. In this case, an optical filter may be incorporated into the light source envelope to absorb or block undesired wavelengths.

In another example, light source 7 may be a continuous light source used to generate light at a lower intensity and over a longer period of time. Because a lower intensity of UV light is required for a continuous light source, a standard germicidal mercury vapor lamp may be used. These lamps produce most of their energy at a wavelength of approximately 253.7 nanometers, in the middle of the UVC sterilizing band. With a mercury vapor lamp, several minutes or more may be required for sterilization or disinfection. Mercury vapor lamps produce a small amount of energy at UV wavelengths outside of the UVC band, as well as energy in the visible spectrum. The intensity of UVA and UVB light produced by these lamps is low and typically does

not present a hazard for others nearby at the dosage level required for periodic sterilizations or low-level, long-term, continuous sterilization.

Sterilization/disinfection unit 34 may contain a safety interlock to prevent accidental activation of light source 7 when the sterilization/chamber 39 is not sealed, i.e., when light seal 37 is not substantially complete. The safety interlock may be an optical device such as a photodetector to detect the presence of light and prevent light source 7 from triggering unless the sterilization/disinfection chamber 39 contains substantially no light. Alternatively, a mechanical sensor may be included in housing 25 to detect contact between cover 41 and base 40, or the light seals 37 thereof.

Figures 9-11 illustrate another configuration of a sterilization/disinfection unit, in accordance with one embodiment of the invention. A housing 53 of sterilization/disinfection unit 47 includes light source 7 and reflector 9 to aid in directing light emitted by light source 7. Light source 7 may have any of the configurations described in connection with Figures 7-8, and may be operated in any of the described modes.

Sterilization/disinfection unit 47 includes a circuit board 44 enclosed within housing 53. Circuit board 44 may include a capacitor 54 for storing a charge used by light source 7, where light source 7 is a flash lamp, to generate a flash. Circuit board 44 may also include circuitry to charge capacitor 54 and control the charging and flashing. Circuit board 44 is coupled to a power source, and safety interlock circuitry to prevent accidental triggering at inappropriate times. The circuitry required to charge the capacitor and trigger the flash may be the same as that used in typical photographic flash units, which is well known in the industry. One example of circuitry that may be included on circuit board 44 will be discussed in connection with Figures 16 and 17.

Housing 53 includes a power switch 50 to initiate the charging of capacitor 54. Power switch 46 may be a simple on-off power switch or pushbutton to control the power to circuit board 44 to charge capacitor 54. Power switch 46 is coupled to a power source, which is shown as batteries 52 in Figures 9A, 9B, and 9E. Batteries advantageously allow sterilization/disinfection unit 47 to be portable and hand-held. Further, the power requirement for a typical sterilization/disinfection unit is such that several hundred of more sterilization/disinfection operations may be performed using a single set of batteries. However, external power from an AC power source may also be

used. Housing 53 also includes a trigger switch 50 to control activation of light source 7 when safety interlock actuators, when present, are activated. Power switch 46 and/or trigger switch 50 may be manipulated manually (e.g., by pressing a button), or may be coupled to one or more safety interlock actuators 36 in light seal 37a to trigger upon depression of light seal 37a. The inclusion of power switch 46 and trigger switch 50 enhances the safety of instantaneous sterilization/disinfection unit 16a and reduces its power consumption. However, either of power switch 46 and trigger switch 50 may be eliminated, as they are not necessary to the operation of the unit.

A UV dosage control mechanism may also be included to vary the intensity of the UV light generated by light source 7. The UV dosage control may be continuously variable or variable in discrete steps determined by a switch. The sterilizing light output is controlled by altering the energy stored in capacitor 54 by changing the voltage to which capacitor 54 is charged, or by switching one or more capacitors into the circuit to change the total capacitance value.

A ready indicator 56, such as a light emitting diode (LED) may be included on the external surface of housing 53 to alert an operator when the charging of capacitor 54 is complete, and hence when a flash may be generated by light source 7. A second indicator (not shown), or a color change or flashing of a light of indicator 56, may be included to alert an operator that safety interlock actuators 36 have been activated, and hence that sterilization/disinfection unit 47 may be operated. A third indicator (not shown), or a change in color or flashing of other indicators, may be used to indicate that a successful flash has occurred.

A light seal 37a is disposed around an opening 26 in sterilization/disinfection unit 47. When light seal 37a is pressed against an object, it creates a substantially light-tight chamber to contain the light emitted by light source 7 and prevent injury or discomfort to the user or others nearby. Thus, the light emitted by light source 7 is substantially confined to housing 53. As shown in Figures 10-11, sterilization/disinfection unit 47 may interface with a sterilizing/disinfecting attachment 48 to form a sterilization/disinfection chamber 55. Sterilization/disinfection chamber 55 is formed by placing light seal 37a of sterilization/disinfection unit 47 against light seal 37b of sterilizing/disinfecting attachment 48.

Sterilizing/disinfecting attachment 48 includes a base 49 coupled to light seal 37b and two reflectors 51. Although two reflectors 51 are shown, one, three, or more reflectors may alternatively be included. Reflectors 51 may also be eliminated entirely, as a reflective surface may be included on base 49 of sterilization/disinfection chamber 55 in addition to or instead of other reflectors 51. The reflectors and reflective surfaces of sterilization/disinfection unit 47 and/or sterilizing/disinfecting attachment 48 direct light rays 21 emitted by light source 7 to the portion of catheter 1 in sterilization/disinfection chamber 55.

Light seals 37a and 37b may be formed from a complaint material so as to allow a substantially light-tight chamber to be formed when a component of catheter 1 is placed across light seals 37a and 37b. Thus, the compliance of light seal 37a and 37b allows portions of catheter 1 to be placed in sterilization/disinfection unit 34 for sterilization/disinfection without disassembling catheter 1 (e.g., disconnecting male and female connector components 3a and 3b of connector 3).

In the example of Figures 10A and 10B, two male connector components 3a are enclosed within sterilization/disinfection chamber 55, along with tubing 5 of the dual-lumen catheter. In the example of Figures 11A and 11B, female connector components 3b are also included such that two connectors 3, each having male connector component 3a coupled to female connector component 3b, are enclosed within sterilization/disinfection chamber 55 along with tubing 5. Advantageously, in the example of Figures 11A and 11B, catheter 1 may optionally be in use during sterilization/disinfection.

Although sterilization/disinfection unit 47 is shown used with sterilizing/disinfecting attachment 48 in Figures 10-11, it may alternatively be used alone or with other devices in related applications. For example, sterilization/disinfection unit 47 may be used in connection with the apparatus of Figures 15A-15B, which will be subsequently described.

Catheter Attachments for the Sterilization or Disinfection of Catheter Components

Figures 12A-12B illustrate the sterilization/disinfection unit 34 of Figures 7A-7C and 8A-8C used with a container 57, in accordance with one embodiment of the

invention. Male connector portion 3a of catheter 1 is enclosed in a container 57 within sterilization/disinfection unit 34, as shown in Figure 12A. Light rays 21 emitted by light source 7 are directed at container 57, optionally with the aid of reflector 9 or reflective surfaces within sterilization/disinfection chamber 39.

In Figures 12A-12B, container 57 has a bag configuration. An adhesive strip may be used on one or more edges of container 57 to allow container 57 to be positioned over the connector and sealed. The adhesive strip may be used to seal container 57 against tubing 5 to maintain an air-tight or substantially air-tight enclosure around male connector portion 3a. While container 57 is shown in a bag configuration in Figures 12A-12B, container 57 may alternatively be a box, a coating, a wrapper, or another type of container suitable for enclosing a portion of a catheter 1.

Container 57 is transmissive to at least a portion of the UV light spectrum, e.g., UVC light. Thus, UV light rays 21 transmitted through container 57 sterilize or disinfect male connector portion 3a within container 57 when applied at an appropriate dosage. Further, UV light rays 21 may sterilize or disinfect the interior and/or exterior of container 57 itself. Container 57 may be substantially or fully air-tight to maintain a sterile environment within the container after sterilization/disinfection. Thus, container 57 may be useful where an enclosed device, e.g., male connector portion 3a, will not be used for a period of time after sterilization/disinfection. Container 57 may also be useful to contain fluid which may be present in male connector portion 3a of tubing 4, and prevent contamination of sterilization/disinfection unit 34 with fluid.

Container 57 may be fabricated from a number of different UV-transmissive materials. For example, container 57 may be made of a thin film of UV-transmissive polymer, such as polyethylene. A thin film of polyethylene (a common material used for medical applications) with a thickness of .002 inches (.05 mm) transmits up to 80% of the sterilizing light emitted by a xenon flash lamp having a wavelength in the range of 220 to 310 nm. Even films up to .01 inches (.25 mm) thick can transmit over 50% of the sterilizing light. The dosage of sterilizing/disinfecting light emitted by sterilization/disinfection unit 34 may be selected to deliver at least the minimum required dose of sterilizing light to male connector portion 3a, or another portion of catheter 1 within container 57.

Figures 13A-13C and 14A-14C illustrate another configuration of a cover that may be used with a component of catheter 1, such as male connector portion 3a and female connector portion 3b as shown in Figures 13A-C and 14A-C, respectively. A female cap 59 is shown coupled to male connector portion 3a in Figure 13A, while a male cap 61 is shown coupled to female connector portion 3b in Figure 14A. Female cap 59 and male cap 61 may contain fluid within male connector portion 3a and female connector portion 3b, respectively, during sterilization/disinfection. Further, female cap 59 and male cap 61 may form a substantially air-tight seal with male or female connector portions 3a and 3b, and thereby maintain a sterile interior of the connector portions following sterilization/disinfection.

Figures 13A, 13B, and 13C illustrate male connector portion 3a coupled to female cap 59, a side view of female cap 59, and a bottom up view of female cap 59. As shown, female cap 59 includes threading to mate with threading on male connector portion 3a. Thus, according to one example, female cap 59 may be placed over male connector portion 3a and may be screwed in to form a seal with male connector portion 3a. Female cap 59 may alternatively be snapped on, slid over, or otherwise attached to form a seal with male connector portion 3a.

Similarly, Figures 14A, 14B, and 14C illustrate female connector portion 3b coupled to male cap 61, a side view of male cap 61, and a bottom up view of male cap 61. As shown, male cap 61 includes threading to mate with threading on female connector portion 3b. Thus, according to one example, male cap 61 may be placed within the opening of female connector portion 3b and may be screwed in to form a seal with female connector portion 3b. Male cap 61 may alternatively be snapped into, slid into, or otherwise attached to form a seal with female connector portion 3b.

Female cap 59 and male cap 61 are transmissive to at least a portion of the UV light spectrum, e.g., UVC light. A number of different UV-transmissive materials may be used to fabricate female cap 59 and male cap 61, such as polyethylene, Teflon, UV-transmissive glass, ceramic, quartz, or fused silica. Alternatively, caps 59 and 61 may be fabricated from a UV-attenuating material that is enhanced by adding UV-transmissive material. Because water and aqueous solutions are generally UV-transmissive, fluid present in the connector portions 3a and 3b will generally not disturb the ability to sterilize or disinfect the interior surfaces of connector portion 3a and 3b using UV light.

Figures 15A and 15B illustrate another apparatus that may be used to sterilize/disinfect an interior and/or exterior portion of catheter 1 while catheter 1 is in use, although the apparatus may also be used when catheter 1 is not in use. Figure 15A illustrates an apparatus including tubing 5 configured to include a light collector 55 coupled to tubing 5, and a tube stabilizing component 63. Light collector 65 permits light to enter tubing 5 and optionally directs light rays 21 at a particular angle into tubing 4. Tube stabilizing component 63 holds tubing 5 such that light collector 65 may receive light from light source 7.

Figure 15B illustrates tubing 5 of catheter 1 inserted at an entrance site 71 in tissue 67. Light source 7 and reflector 9 are positioned above light collector 65. Light source may be a flash light source, a continuous light source, or any other type of light source described herein. A sterilization/disinfection unit, such as sterilization/disinfection unit 47 described in connection with Figures 9-11, may be used to provide light source 7 and/or reflector 9. The upper surface of tube stabilizing component 63 may be shaped in a smooth arch to provide a better light seal with sterilization/disinfection unit 47.

Light collector 65 may direct UV light through the liquid in the catheter 1. Many liquids are UV-transmissive, so light entering light collector 65 may be transmitted through the liquid in catheter 1 and into the patient. Light collector 65 may be a lens formed as a thin domed structure, and may be UV-transmissive. The domed structure of light collector 65, together with the liquid in catheter 1, may create a condensing lens that directs the light from light source 7 down catheter 1.

If the material of catheter 1 is chosen to have a lower index of refraction than the aqueous solution in catheter 1, as is the case with Teflon, catheter 1 will form a liquid light pipe. Thus, similar to an optical fiber, catheter 1 will conduct UV light down a length of the catheter. Roughness of the internal wall of catheter 1 will cause the UV light to exit through the wall of catheter 1, which may expose the exterior of tubing 5 and adjacent tissue 67 to a sterilizing/disinfecting dose of UV light. A biofilm caused by bacteria or other microorganisms in the catheter will increase the amount of light exiting catheter 1 in the areas where sterilization/disinfection is most beneficial (i.e., where biofilm coats catheter 1). If the material of catheter 1 does not have the correct index of refraction to form a light pipe, some reflection of light will still occur due to the

difference in index of refraction between catheter 1 and the fluid therein. Thus, some amount of light will be directed down catheter 1.

Alternatively, light collector 65 may be connected to a fiber optic device that is capable of transmitting UV light down catheter 1. The fiber optic device may be made from quartz, fused silica, or UV transparent glass, for example, so that it is transmissive to UV light. The optical fiber may be integrated into catheter 1, or may be a separate attachment placed inside catheter 1. A lumen may be provided in catheter 1 to accommodate the optical fiber. For maximum efficiency, light collector 65 may be fabricated as an integral part of the fiber optic device. The surface texture and material of the optical fiber determine the amount of light that is emitted along its length. The properties of the optical fiber can be controlled to provide sterilizing or disinfecting UV light along the desired length of catheter 1. Applying UV light at regular intervals to the interior of catheter 1 during use may prevent the buildup of the biofilm in catheter 1, which has traditionally been a problem with long-term catheters. Alternatively, light may be directed at the tip of catheter 1 may prevent infection at the tip.

Tube stabilizing component 63 is disposed on skin 69, and may be coupled to skin 69 by an attachment mechanism. For example, tube stabilizing component 63 may be attached to skin 69 using an adhesive or may be sutured to the skin using holes in tabs 73. A UV-transmissive bandage may be included over the apparatus including light collector 65, tubing 5, and tube stabilizing component 63 to protect entrance site 71, if desired.

Tube stabilizing component 63 may be the hub of catheter 1, as shown in Figure 15B, or may be an additional component. Thus, tube stabilizing component 63 may be an existing portion of catheter 1 or a component added to catheter 1. A reflective surface 75 may be included on tube stabilizing component 63 to direct light emitted by light source 7 to entrance site 71 to sterilize or disinfect the interior or exterior of tubing 5 at entrance site 71. Further reflective surface 75 may direct light emitted by light source 7 to tissue 67 and/or skin 69 at entrance site 71. Reflective surface 75 may be sloped and/or mirrored. Although a curved mirror is shown in Figure 15A, one or more planar mirrors or refractive optics, such as a cylindrical lens made of a UV transparent material, may be used to direct the light from light source 7 entrance site 71.

Electrical Configuration of Sterilization/Disinfection Units

According to one embodiment of the invention, electrical circuitry associated with a flash lamp of a sterilization/disinfection unit may be implemented as shown by electrical circuit 76 in Figure 16. Electrical circuit 76 may be used in a sterilization/disinfection unit according to any of the embodiments described above. Electrical circuit 76 uses a high voltage power supply 103 that contains a capacitor to store the energy necessary to power a flash lamp 95. A power source 71, which may be an AC line or a battery, typically supplies a voltage in the range of 200V to 1000V depending characteristics of the flash lamp used, although the voltage supplied may be smaller than 200V or greater than 1000V. Small linear flash lamps typically operate with voltages of 200V to 500V; small short-arc flash lamps may require 1000V or more. The voltage is selected based on the flash lamp specifications: the total energy desired per flash and the maximum flash current desired. A higher voltage will provide a higher flash current for the same energy, resulting in a greater percentage of the flash light output in the ultraviolet spectrum. The energy per flash is determined by Equation 1:

$$E = 1/2\ CV^2 \qquad [1]$$

where E is the energy per flash in Joules, C is the value of the energy storage capacitor in Farads and V is the voltage in volts. For a sterilizer/disinfector application, the selected voltage should be as high as possible so that the flash lamp produces the greatest amount of ultraviolet light. The value of the capacitor is then chosen to provide the desired amount of energy per flash. The energy required by the flash to perform the sterilization/disinfection is determined by the amount of area to be illuminated, the minimum sterilizing light dosage desired, the uniformity of the illumination, and the spectrum of flash lamp 95. For example, a flash lamp made from UV glass used to illuminate 25 square centimeters (about 4 square inches) produces a UVC energy intensity of about 20 mJ/cm2 with a total flash input energy of about 20 joules.

The sterilizer/disinfector circuitry also includes a flash lamp trigger 105 which is very similar to the trigger circuit in a camera flash. The flash lamp trigger provides a very high voltage pulse, typically in the range of 4 kV to 15 kV depending on the specifications of the flash lamp, to initiate the flash. According to one embodiment of the sterilizer/disinfector, a charge storage capacitor is kept charged to the appropriate

voltage whenever the unit is powered on. Safety interlock switch 99 may prevent triggering of flash lamp 95 when a light seal is incomplete. Thus, flash lamp trigger 105 may be initiated when a trigger switch and a safety interlock switch 99 have been activated. Alternatively, either trigger switch (e.g., a pushbutton) or safety interlock switch 99 (e.g., mechanical actuators) may individually initiate flash lamp trigger 105.

Figure 17 shows one example of a typical battery powered xenon flash lamp driver circuit with trigger circuitry for activating flash lamp 95. Circuits of this nature are commonly used in camera flash units. For simplicity, the diagram does not show the details of an AC power supply or user indicators. A power transistor 77 and its related components form a low voltage oscillator, typically in the range of 15 to 20 kHz. Current from a high voltage transformer 79 passes through a high voltage diode 81 and charges an energy storage capacitor 83 to a voltage that will drive flash lamp 95. A resistor 85 charges a trigger capacitor 87 to the flash lamp voltage. When a diac 92 and a safety interlock switch 93 are turned-on, trigger capacitor 87 is discharged through a trigger transformer 89 which creates a very high voltage pulse to a trigger electrode 91 on flash lamp 95 This causes flash lamp 95 to flash using the stored energy in energy storage capacitor 83. Diac 93 may be turned-on only when safety interlock switch 93 is activated, signifying that the light seal is appropriately complete for sterilization/disinfection.

It should be appreciated that the above-described circuitry is merely intended to illustrate one possible implementation, and many such circuits are possible and known in the art. For example, there exists in the art many circuits for driving flash lamps that may be suitably applied to the sterilizers/disinfectors described herein. Thus, the invention is not limited in this respect.

UV Exposure Indicators for Catheter Components

Any of the catheter components described herein (e.g., hub 11, connector 3, tubing 5) may be fabricated from or include color-changing materials that change color when exposed to UV light. Further, any of the catheter attachments described herein (e.g., container 57, female cap 59, male cap 61, tube stabilizing component 63) may be fabricated from or include color-changing materials that change color when exposed to

UV light. Polymeric materials that exhibit this property may be made by including photochromic or fluorescent additives that change color or emit light after exposure to UV light. This color change may provide a positive indication that a disinfection/sterilization operation has successfully occurred, and/or that a catheter component or attachment was properly positioned in a sterilization/disinfection unit. Alternatively, the color-changing material may change color or emit light when exposed to light from another portion of the spectrum. A color change resulting from light from another portion of the spectrum may still provide an indication of UV light exposure if the proportion of UV light to the light from the other portion of the spectrum is known.

Photochromic or fluorescent inks or dyes may also be included on, or printed on, the catheter components or attachments. Since color-changing inks or dyes absorb UV light, it may be desirable to print such inks or dyes in a pattern that does not interfere with the UV transmission to stagnation zones and/or colonization sites. For example, color-changing material may be applied as an array of lines, dots, or another discontinuous pattern, to allow the UV light to sterilize or disinfect the areas between the color-changing material. The pattern may indicate the area of exposure of the component to UV light while leaving most of the catheter component uncovered by the light absorbing ink or dye. The dyes may also be printed in a pattern that includes operator information, manufacturer identification, etc.

Having described several embodiments of the invention in detail, various modifications and improvements will readily occur to those skilled in the art. Such modifications and improvements are intended to be within the spirit and scope of the invention. Accordingly, the foregoing description is by way of example only, and is not intended as limiting. The invention is limited only as defined by the following claims and equivalents thereto.

What is claimed is:

Claims

1. A method for sterilizing or disinfecting at least a portion of an interior surface of a catheter, the interior surface being defined by a wall, the method comprising acts of:

identifying a stagnation zone in the catheter; and

transmitting ultraviolet light through the wall at the stagnation zone.

2. The method of claim 1, wherein the stagnation zone includes a change in diameter of the wall.

3. The method of claim 1, wherein the stagnation zone includes a crevasse in the wall.

4. The method of claim 1, wherein the at least a portion of the interior surface of the catheter includes at least a portion an interior surface of a connector defined by a wall, and wherein the act of transmitting includes transmitting ultraviolet light through the wall of the at least a portion of the connector.

5. The method of claim 4, wherein the connector has male and female components, and wherein act of transmitting includes transmitting ultraviolet light through the wall of the at least a portion of the connector while the male and female components are coupled.

6. The method of claim 4, wherein the connector has male and female components, and wherein the method further comprises an act of:

coupling a terminal cap to one of the male and female components; and

wherein that act of transmitting includes sterilizing or disinfecting the one of the male and female components using ultraviolet light while the one of the male and female components is coupled to the terminal cap.

7. The method of claim 1, wherein the at least a portion of the interior surface of the catheter includes at least a portion of the interior surface of a hub defined by a wall,

and wherein the act of transmitting includes transmitting ultraviolet light through the wall of the at least a portion of the hub.

8. The method of claim 1, further comprising an act of:

detecting an exposure of the wall to ultraviolet light based on a color change of the wall.

9. An ultraviolet light-transmissive catheter, comprising:

a wall defining an interior of the catheter; and

means within the wall for transmitting ultraviolet light through the wall of a catheter to the interior of the catheter.

10. The ultraviolet light-transmissive catheter of claim 9, wherein the means for within the wall for transmitting ultraviolet light includes a recess in the wall.

11. The ultraviolet light-transmissive catheter of claim 9, wherein the means within the wall for transmitting ultraviolet light includes a void in the wall.

12. The ultraviolet light-transmissive catheter of claim 9, wherein the means in the wall for transmitting ultraviolet light includes ultraviolet light-transmissive material infused in the wall.

13. An ultraviolet light-transmissive catheter, comprising:

a wall defining an interior of the catheter; and

a region of the wall adapted to transmit ultraviolet light.

14. The catheter of claim 13, wherein the region of the wall includes recess.

15. The catheter of claim 13, wherein the region of the wall includes a void.

16. The catheter of claim 13, wherein the region of the wall is infused with ultraviolet light-transmissive material.

17. The catheter of claim 16, wherein the region of the wall further includes a recess.

18. The catheter of claim 16, wherein the region of the wall further includes a void.

19. The catheter of claim 16, wherein at least a portion of the wall includes a color-changing material to indicate an exposure to ultraviolet light.

20. A method for sterilizing or disinfecting a portion of a catheter enclosed within a container, comprising an act of:

transmitting ultraviolet light through the container.

21. The method of claim 20, wherein the container is a substantially air-tight container.

22. A method for sterilizing or disinfecting a portion of a catheter connector coupled to a cap, comprising an act of:

transmitting ultraviolet light through the cap.

23. A method for sterilizing or disinfecting an interior portion of a catheter, comprising acts of:

positioning an ultraviolet light source above a lens component of the catheter; and

transmitting light from the ultraviolet light source through the lens and along the interior portion of the catheter.

24. An apparatus for sterilizing or disinfecting an interior portion of catheter using an ultraviolet light source, comprising:

a lens to transmit light from the ultraviolet light source along the portion of the catheter.

25. The apparatus of claim 24, wherein the lens is fixed to the catheter.

26. A method, comprising acts of:

applying ultraviolet light to a portion of a catheter to sterilize or disinfect the portion of a catheter; and

inserting the portion of the catheter into a patient.

27. The method of claim 26, wherein the act of applying includes applying ultraviolet light to an interior portion of the catheter.

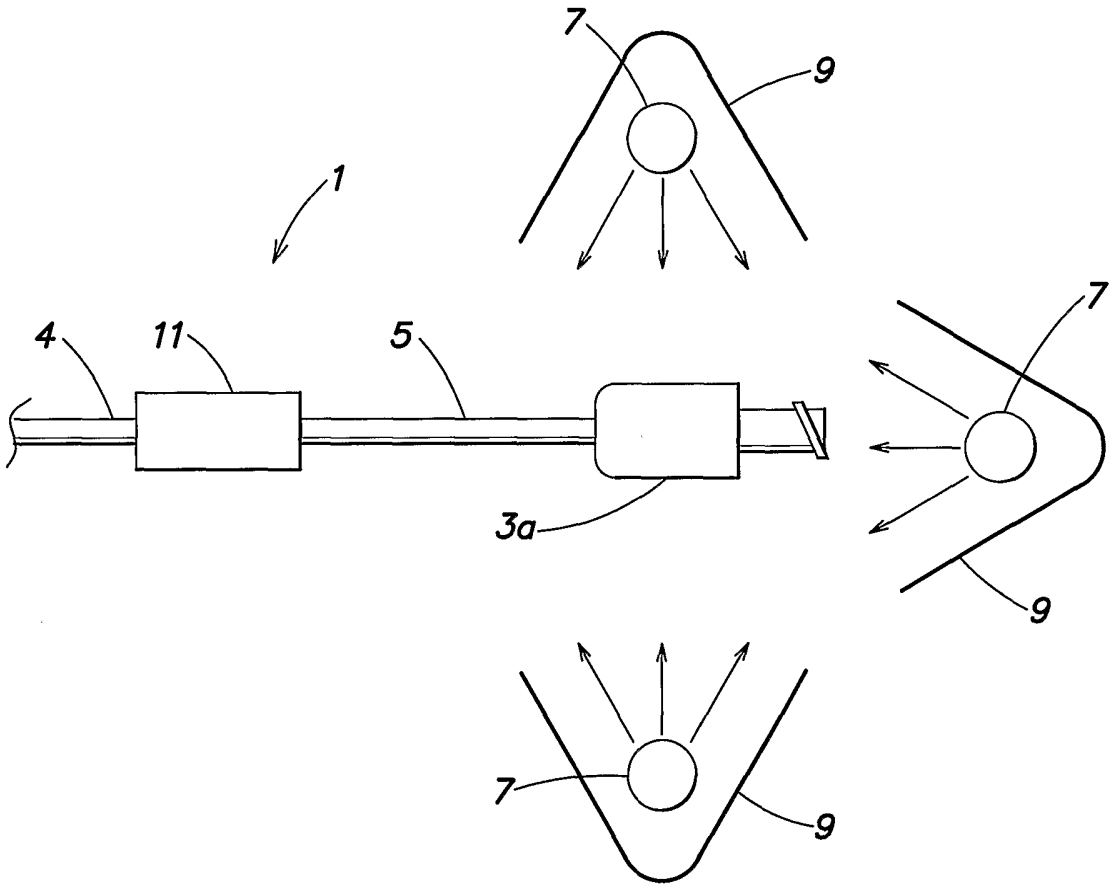

FIG. 1

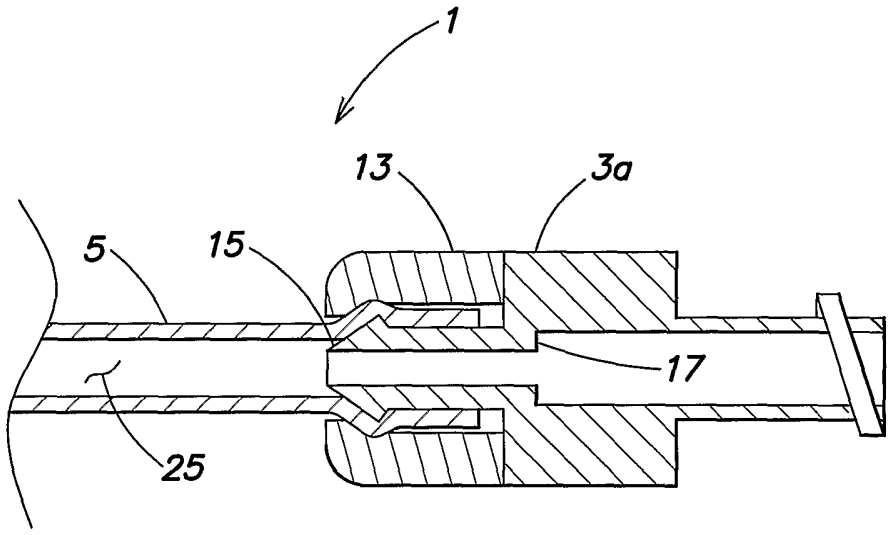

FIG. 2
(PRIOR ART)

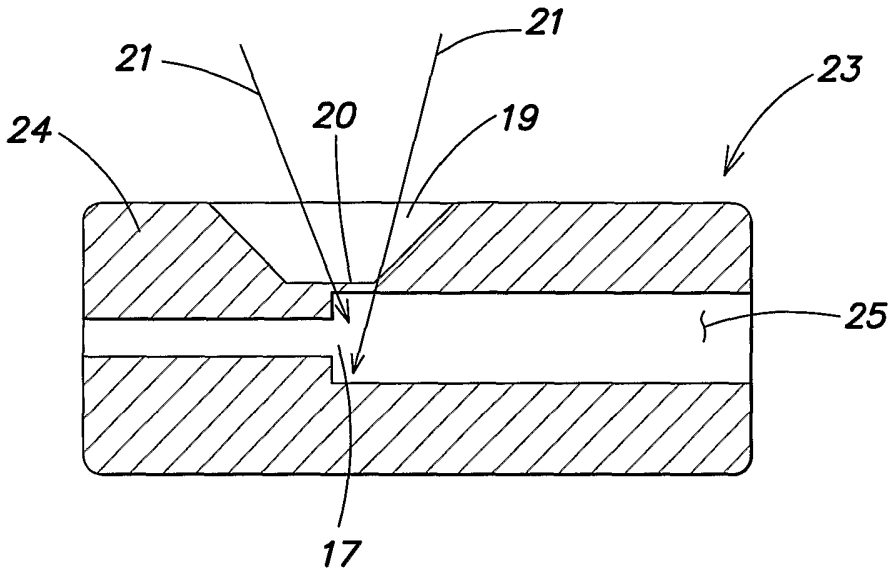

FIG. 3A

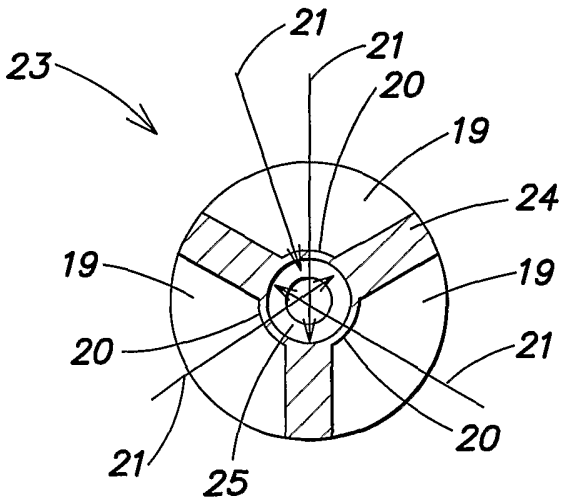

FIG. 3B

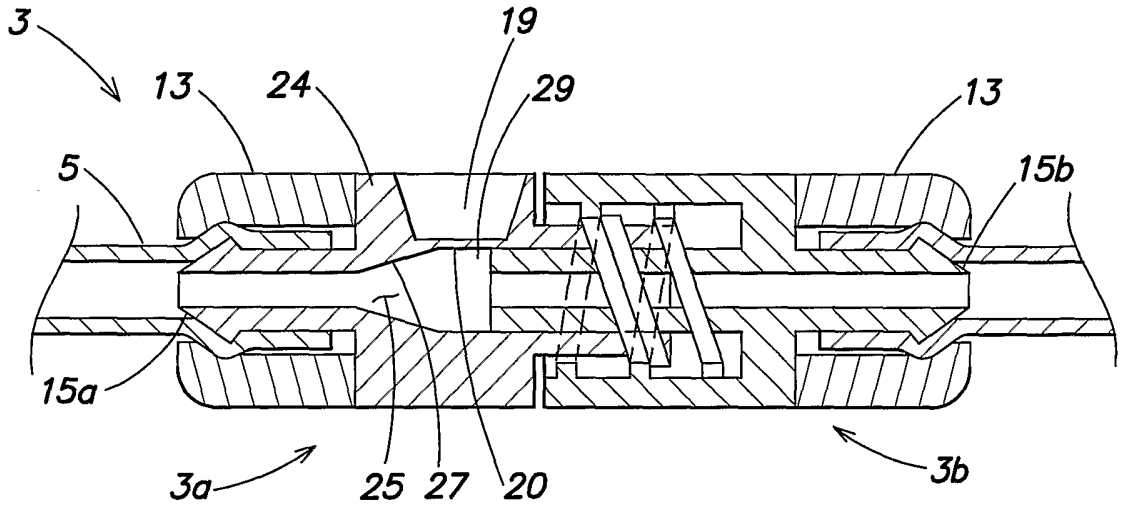

FIG. 4

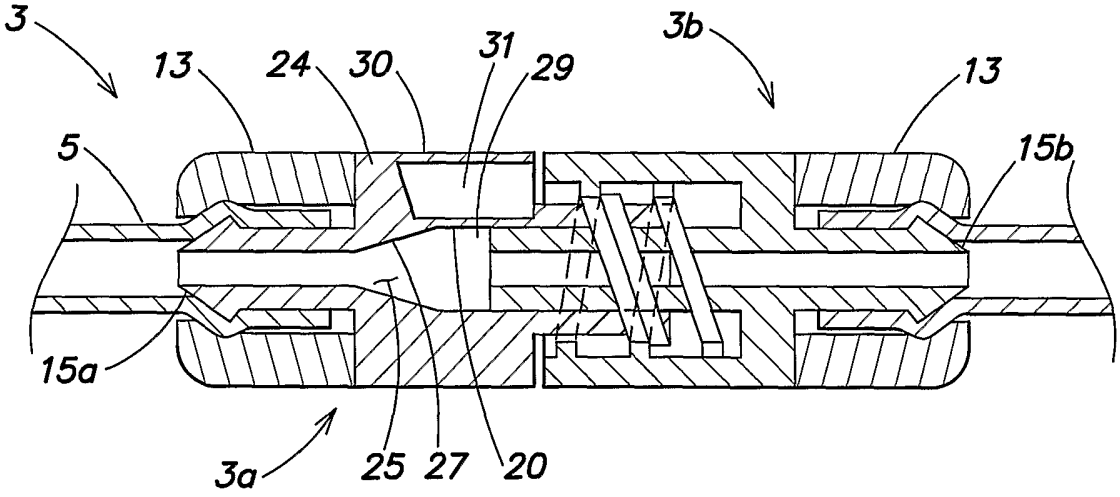

FIG. 5

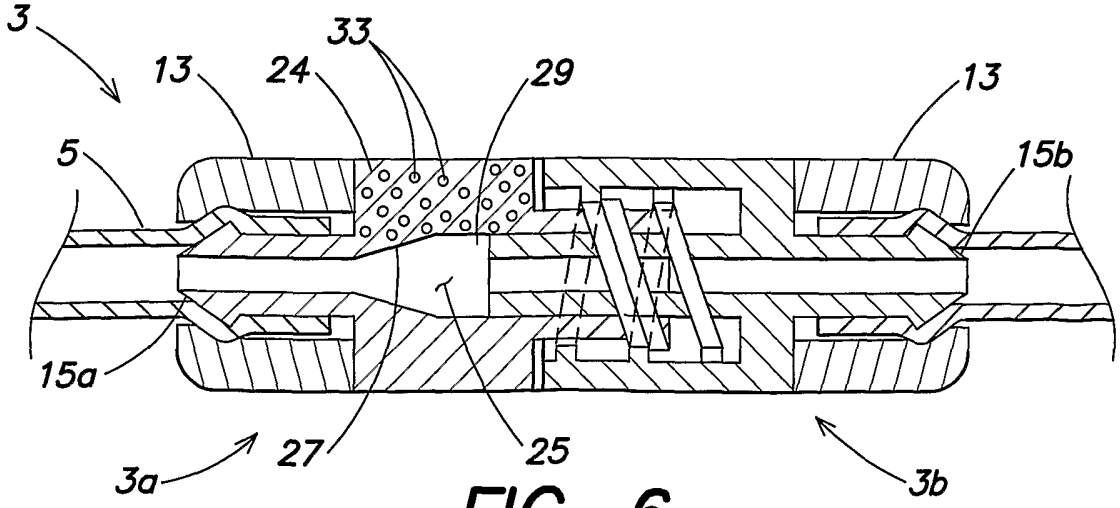

FIG. 6

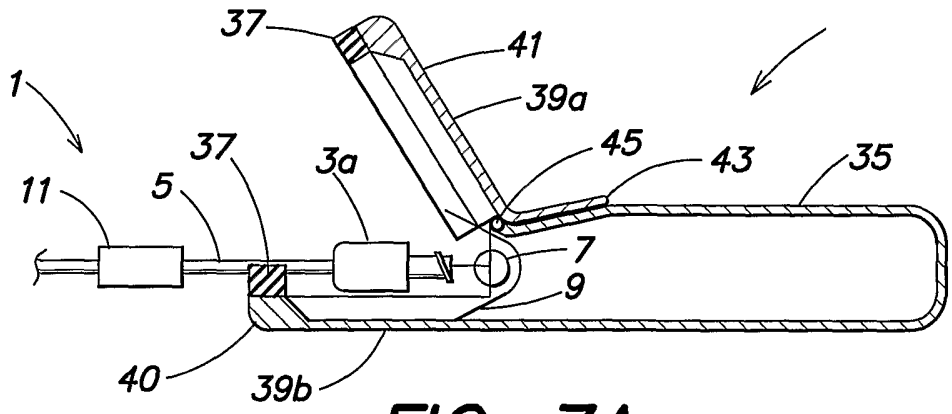

FIG. 7A

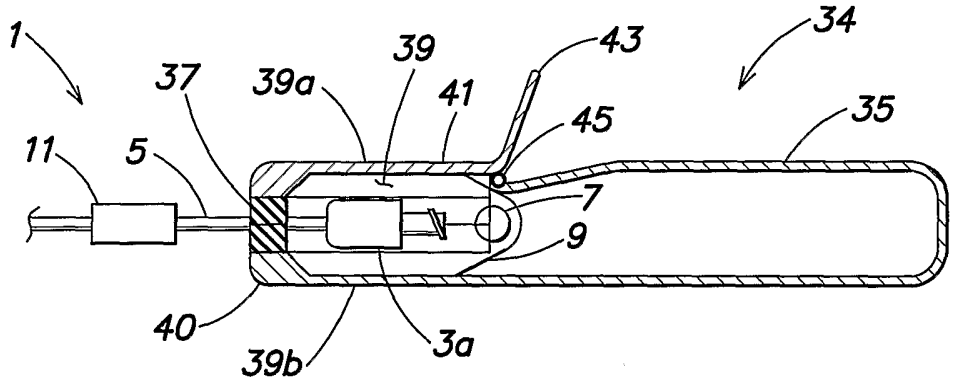

FIG. 7B

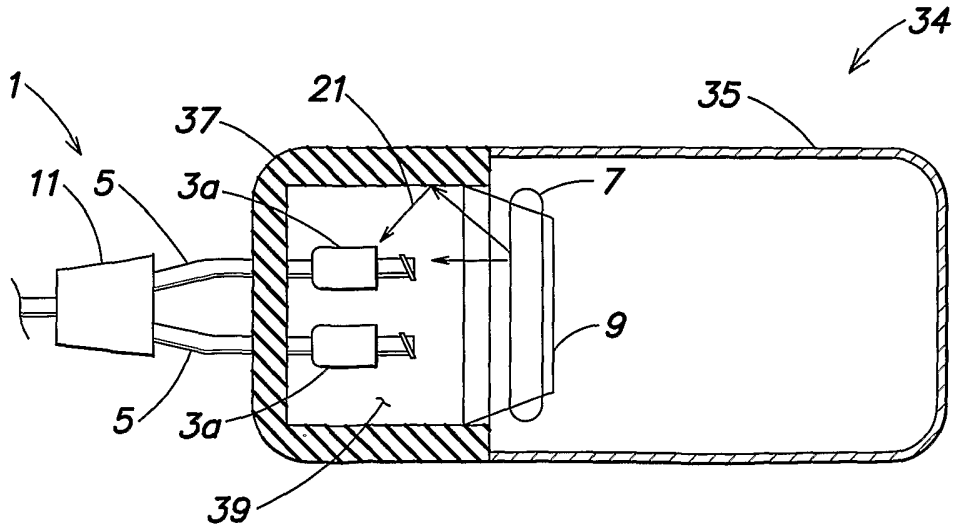

FIG. 7C

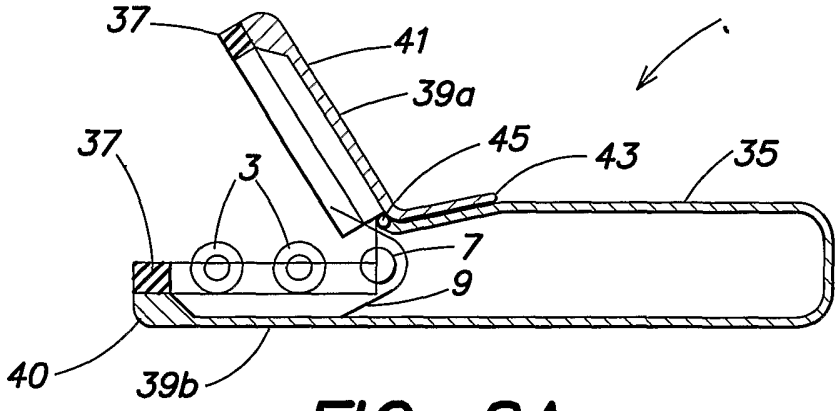

FIG. 8A

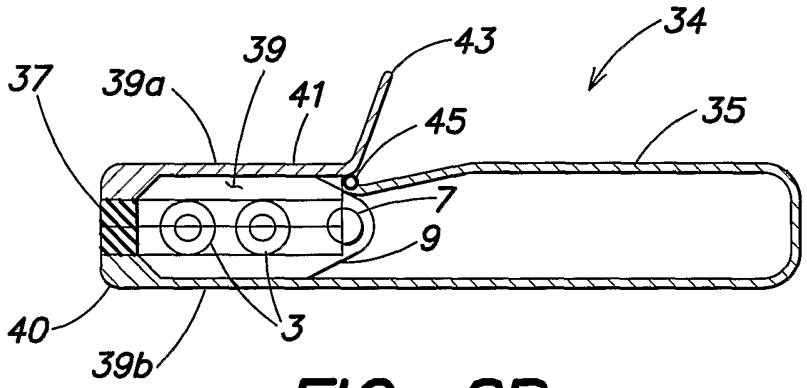

FIG. 8B

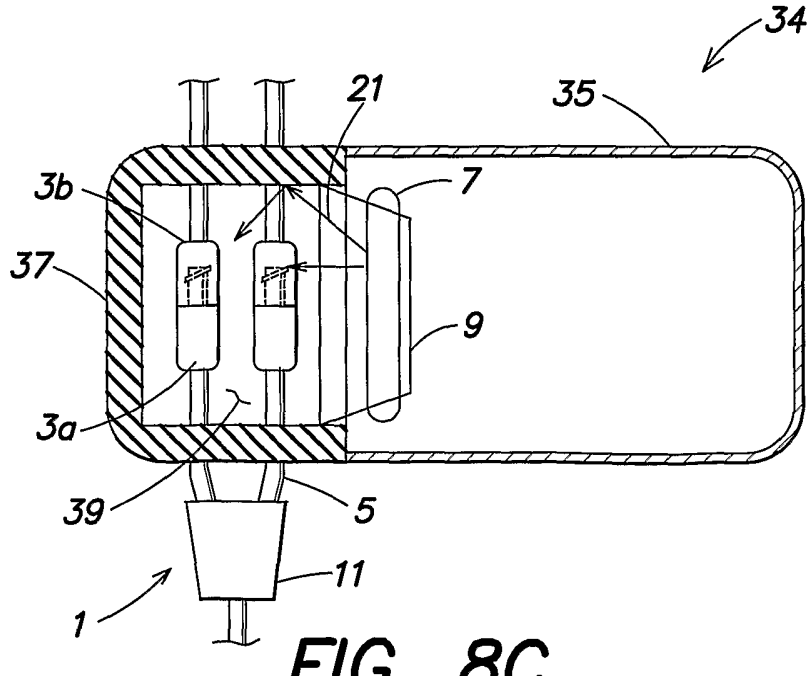

FIG. 8C

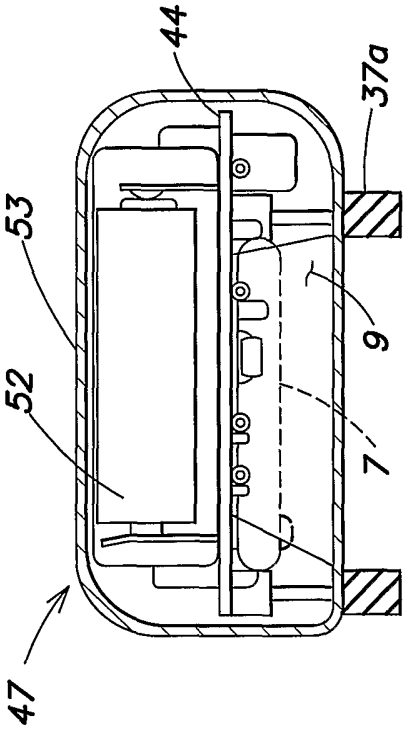

FIG. 9B

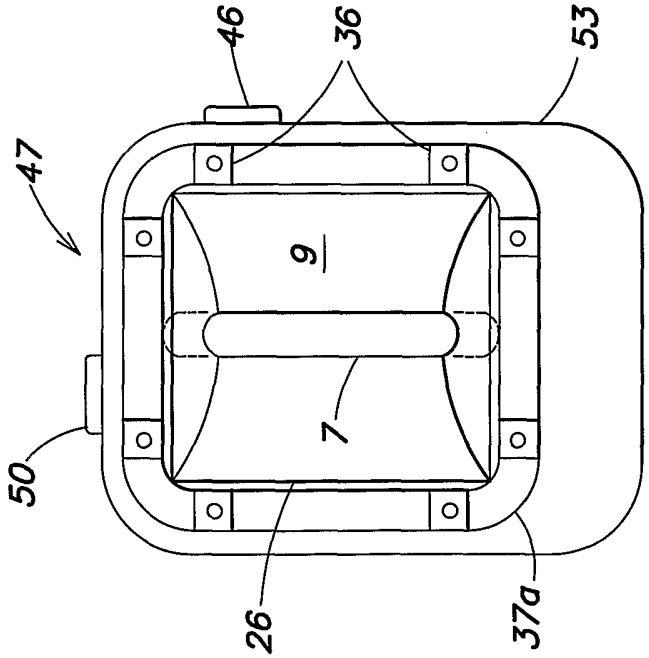

FIG. 9C

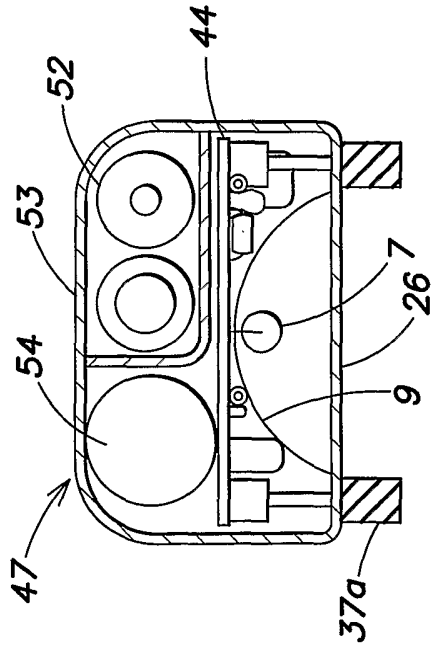

FIG. 9A

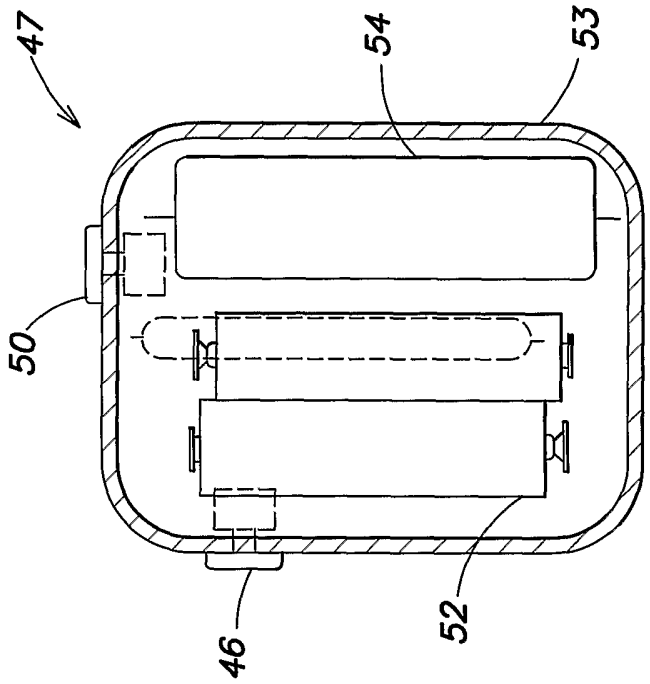

FIG. 9E

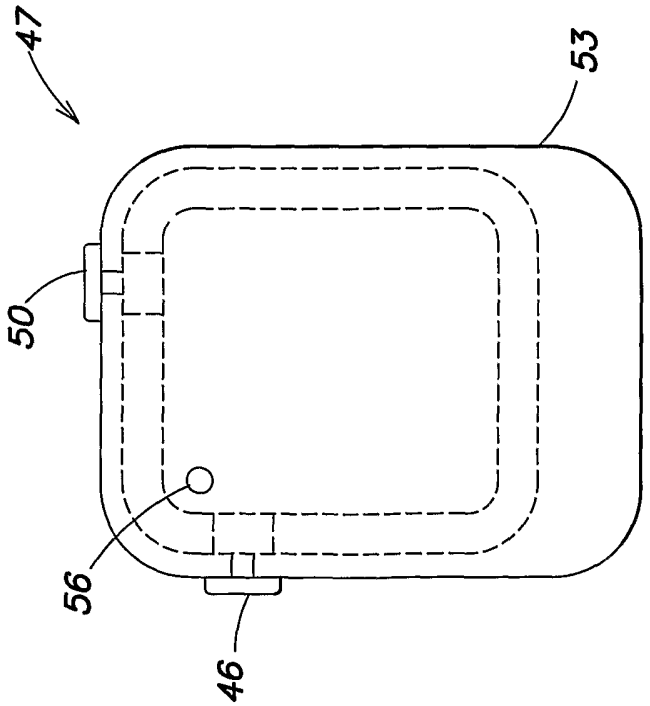

FIG. 9D

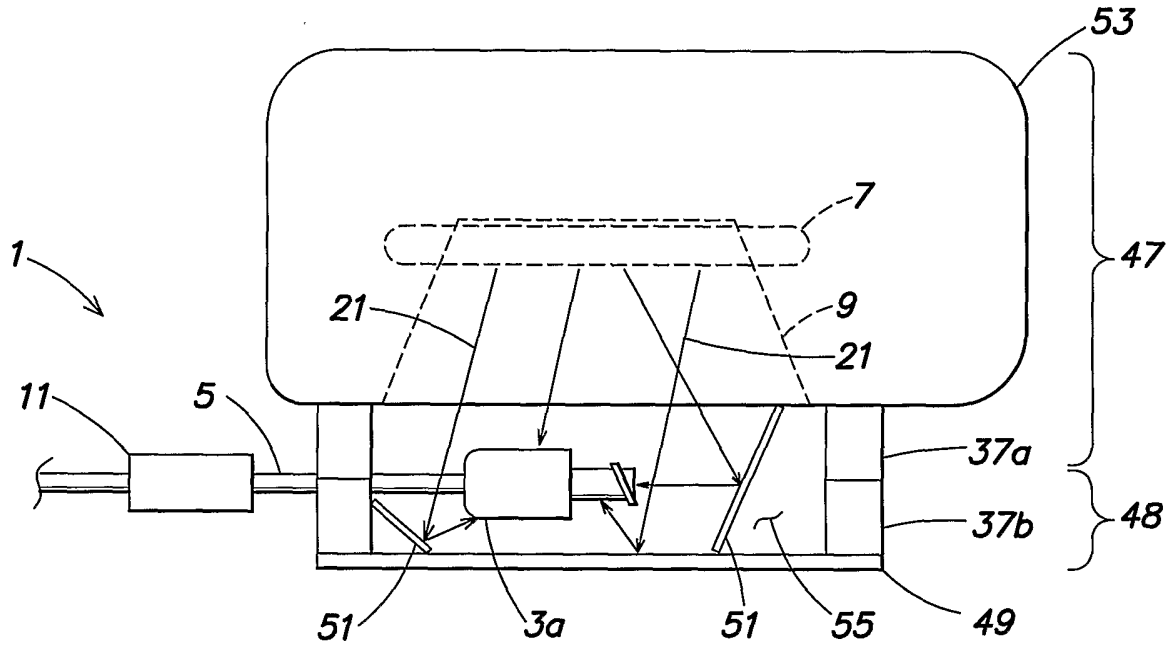

FIG. 10A

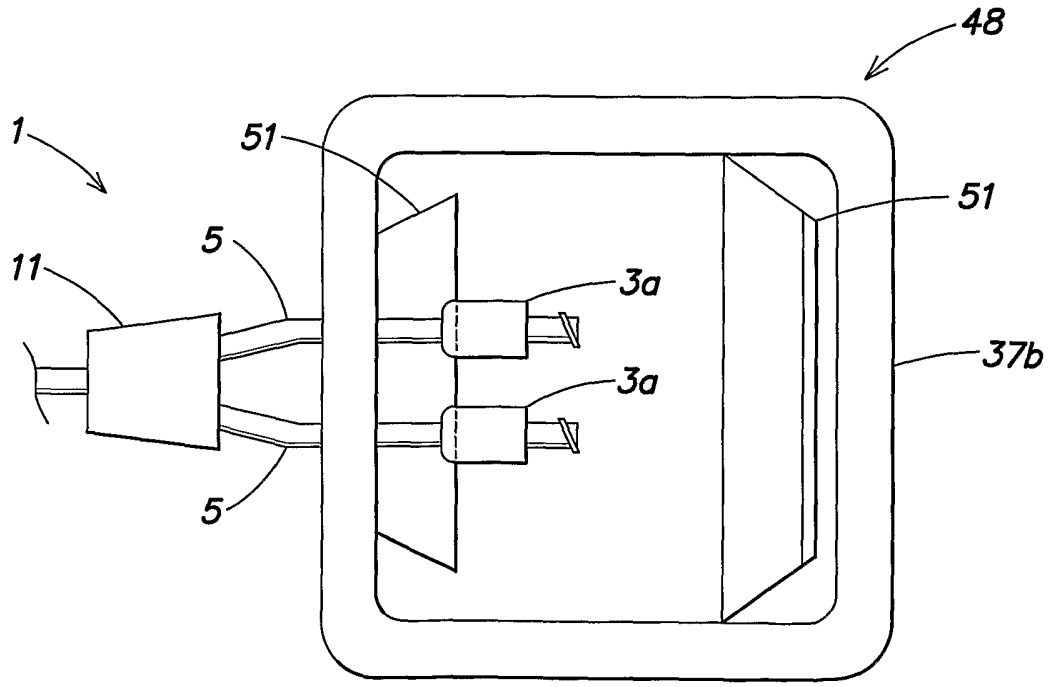

FIG. 10B

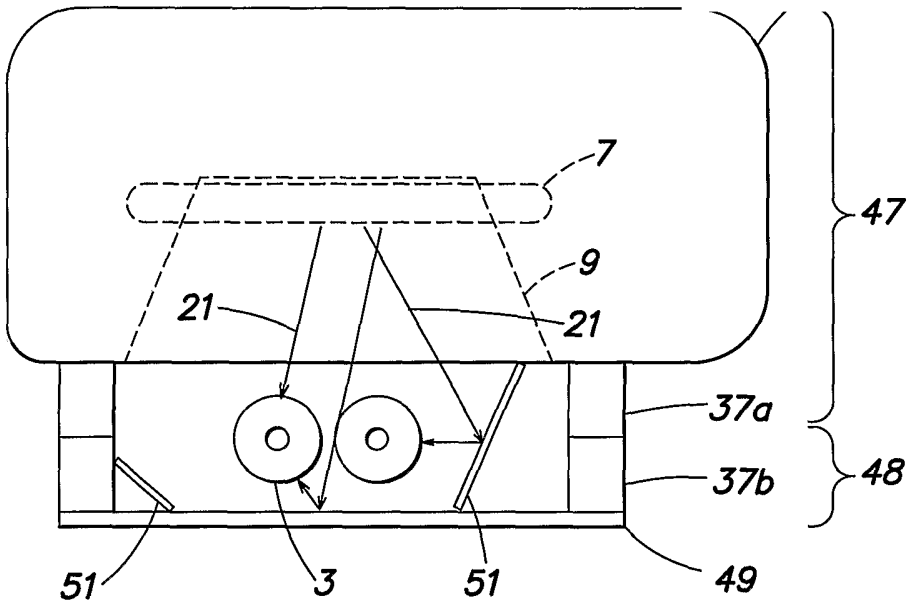

FIG. 11A

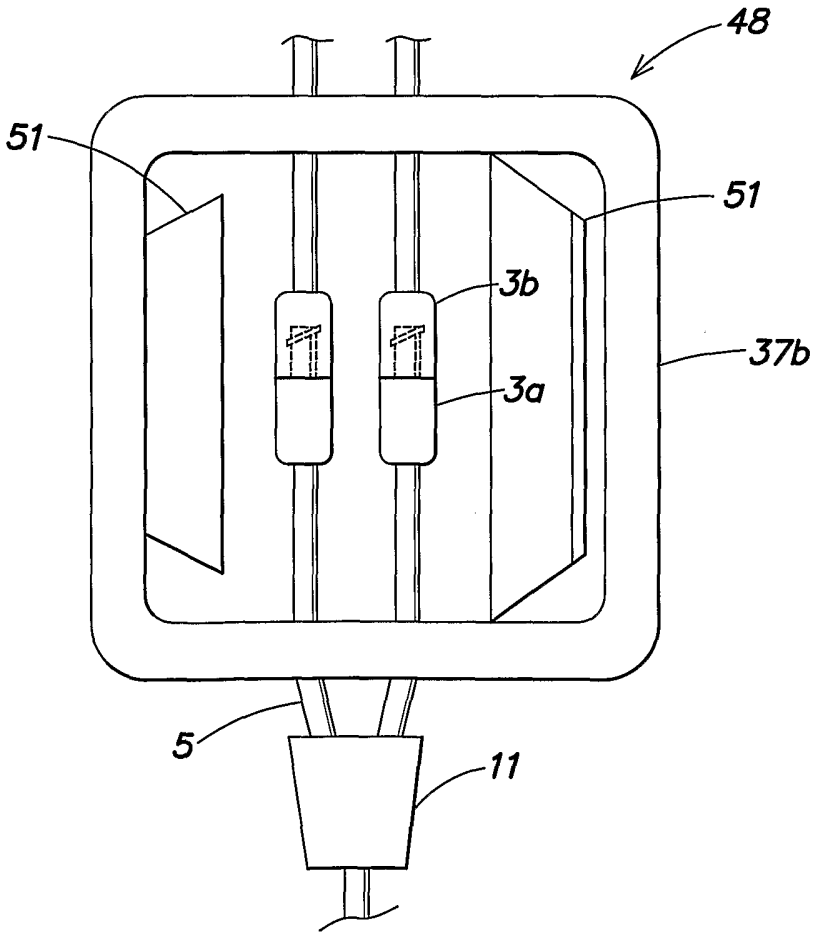

FIG. 11B

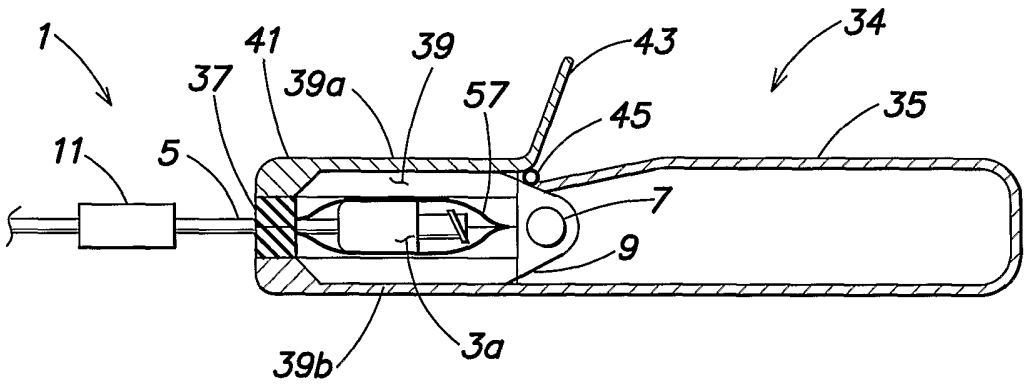

FIG. 12A

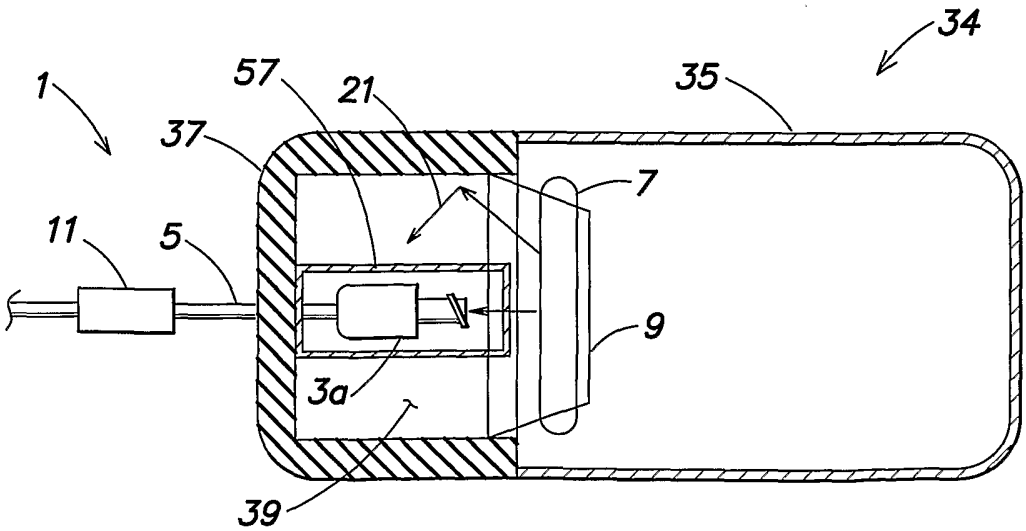

FIG. 12B

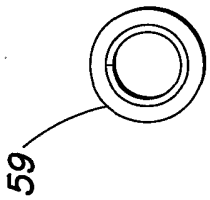

FIG. 13C

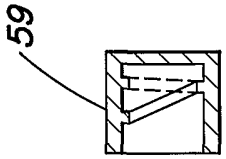

FIG. 13B

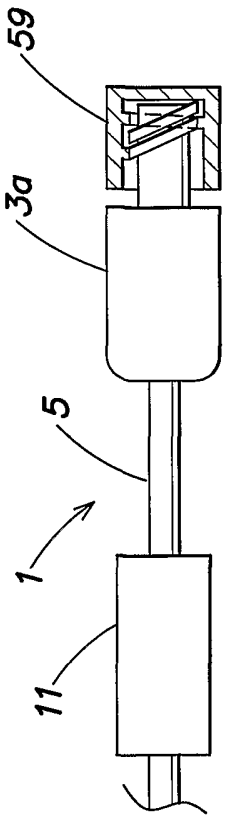

FIG. 13A

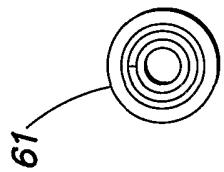

FIG. 14

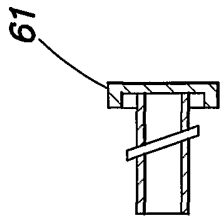

FIG. 14B

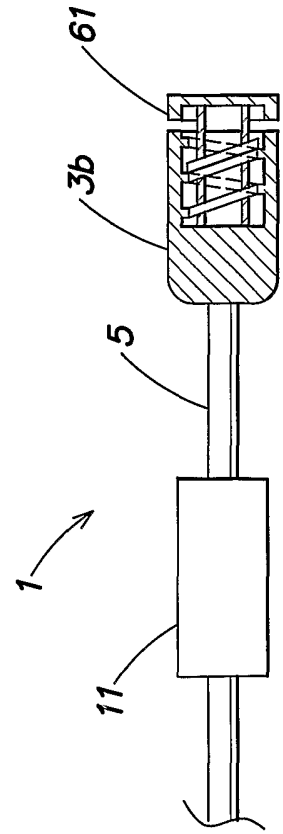

FIG. 14A

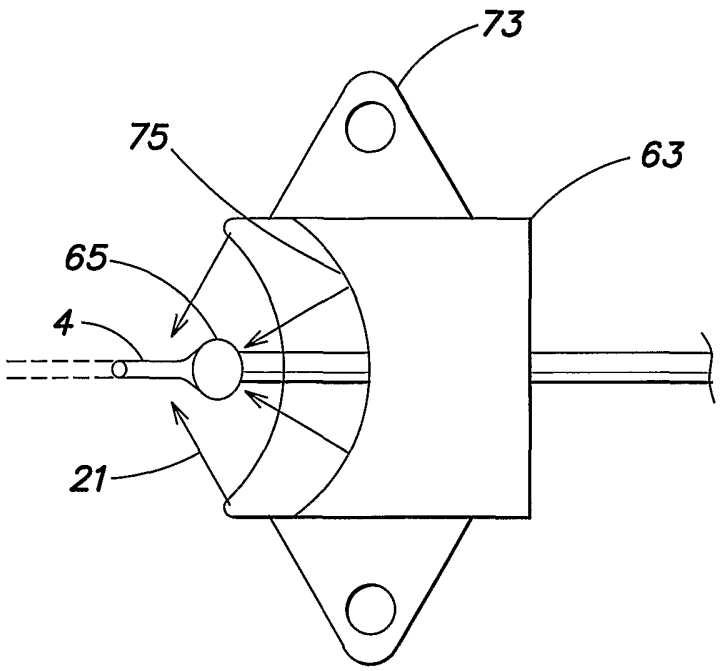

FIG. 15A

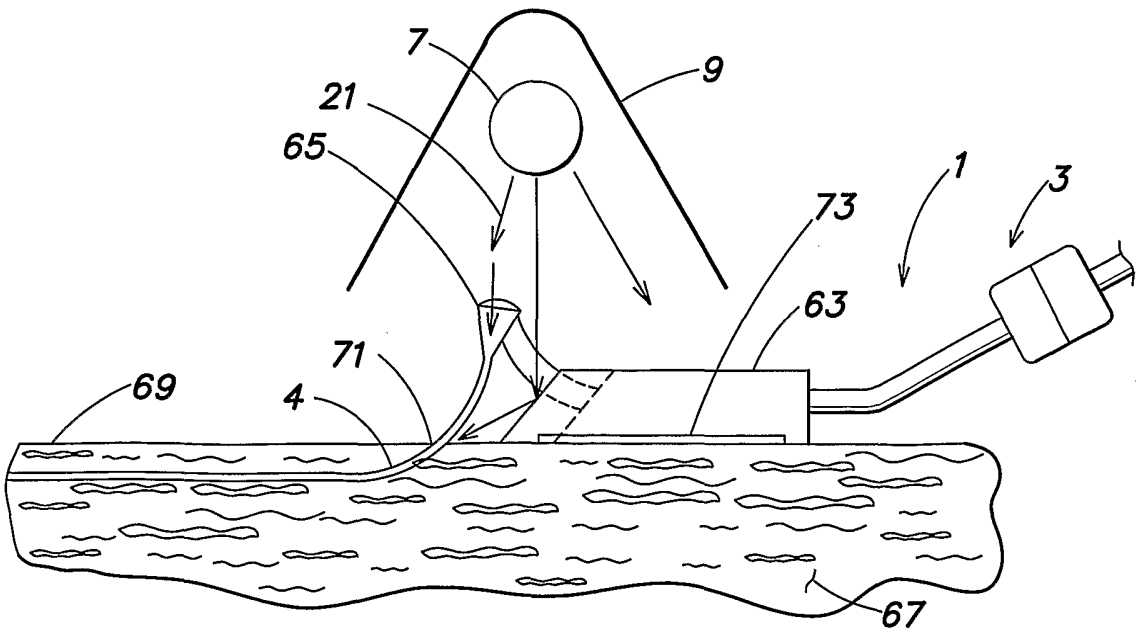

FIG. 15B

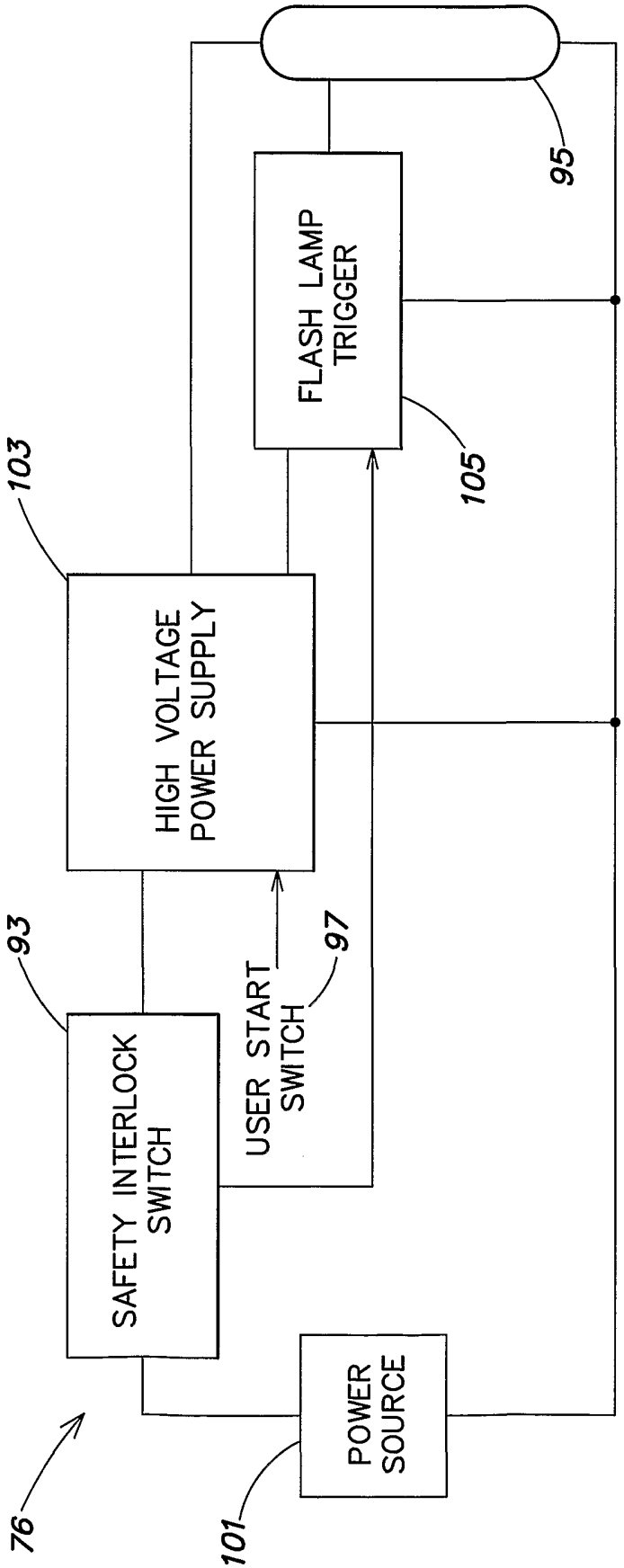
95
FLASH LAMP TRIGGER
105
103
HIGH VOLTAGE POWER SUPPLY
93
USER START SWITCH
97
SAFETY INTERLOCK SWITCH
POWER SOURCE
76
101

FIG. 16

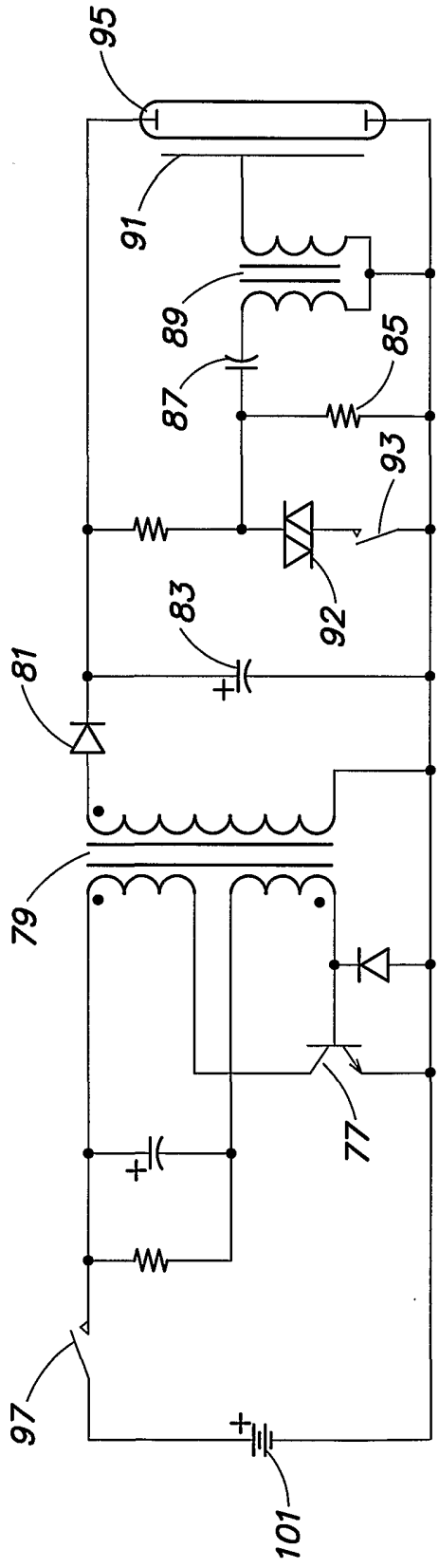

FIG. 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/19099

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61L 2/00
US CL : 422/24, 22; 250/455.11; 604/15, 21, 267

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. : 422/24, 22; 250/455.11; 604/15, 21, 267

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)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,193,544 A (JAFFE) 16 March 1993 (16.03.1993), see entire document.	1-27
Y	US 5,260,020 A (WILK et al) 09 November 1993 (09.11.1993), see entire document.	1-27
Y	US 5,637,877 A (SINOFSKY) 10 June 1997 (10.06.1997), see entire document.	1-27
Y	US 5,695,482 A (KALDANY) 09 December 1997 (09.12.1997), see entire document.	1-27
y	US 5,240,675 A (WILK et al) 31 August 1993 (21.08.1993), see entire document.	1-27
Y	US 5,855,203 A (MATTER) 05 January 1999 (05.01.1999), see entire document.	1-27

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

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"E" earlier application or patent published on or after the international filing date

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"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

"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

"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

"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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 September 2002 (27.09.2002)	05 NOV 2002
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 Krisanne M. Thornton Telephone No. 703-308-0661

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

INTERNATIONAL SEARCH REPORT

PCT/US02/19099

Continuation of B. FIELDS SEARCHED Item 3:
EAST
sterilize, disinfect, catheter, uv or ultraviolet