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(54) ACTIVE SYSTEM FOR IN-SITU CLEARING OF SECRETIONS AND OCCLUSIONS IN TUBES

AKTIVES SYSTEM ZUR IN-SITU-REINIGUNG VON ABLAGERUNGEN UND VERSTOPFUNGEN IN ROHREN

SYSTÈME ACTIF POUR NETTOYAGE IN-SITU DE SECRÉTIONS ET D'OCCLUSIONS DANS DES TUBES

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Description

Related Appl cations

[0001] This application claims the benefit of US Application Serial Number 14/052,278 filed on October 11,2013 and entitled "Active System for In-Situ Clearing of Secretions and Occlusions in Tubes." This application also claims the benefit of United States Patent Application Ser. No. 61/712,437, filed October 11,2012 entitled "Pediatric Endotracheal Tube Clearing System." United States Patent Application Ser. No. 61/712,437.

BACKGROUND OF THE INVENTION

FELDOFTHE INVENTION

[0002] The present invention pertains generally to the field of medical devices, and more specifically to a system for in-situ clearing of secretions in endotracheal tubes and other tubes in the body where secretions or other materials accumulate and negatively impact tube patency.

2. BACKGROUND

[0003] The following is a description of the background of endotracheal tubes (ETTs). It should be understood that the device disclosed herein is not limited to the clearing of ETTs but is applicable to a range of artificial tubes such as indwelling catheters, pigtail catheters, abscess drains, and chest tubes and that ETTs are being discussed simply by way of example. It should also be understood that the device is not limited to secretions but is applicable to a range of accumulating and/or occluding materials such as bbod, clots, and ingrown tissues/membranes.

[0004] Automated mechanical ventilation is often required for patients under anesthesia and for longer-term breathing assistance in compromised patients. Endotracheal tubes are placed in the upper respiratory tract of patients to provide direct airway access when connected to a mechanical ventilator. Annually, 50 million ETTs are sold globally. Patients intubated with ETTs are unable to effectively clear lung secretions, and therefore secretions can accumulate and partially occlude the inside of the ETT. This leads to increased airway resistance and a potentially negative impact on patient health if not remedied. Without proper air humidification, the secretions also potentially become dried, thick, and difficult to remove.

[0005] The most routine method to maintain ETT patency is periodic aspiration with a suction catheter. The suction catheter is designed to be momentarily inserted down the ETT manually while attached to a negative pressure source. There are two general types of suction catheters: open and closed. An open suction catheter requires the patient to be disconnected from the ventilator for the suctioning procedure. A closed suction catheter is enclosed in a sterility sleeve and remains attached to the ventilator circuit the entire time. Suctioning can occur without having to shut off the ventilator or disconnect the patient. Whether open or closed, the general suction procedure remains the same. With one hand stabilizing the proximal end of the ETT, the suction catheter is fed into the ETT with the opposite hand until the end is reached, being careful to not over-insert the catheter beyond the tip of the ETT. While retracting the suction catheter, the negative pressure is applied to suction out secretions accumulated on the inner wall of the ETT. It is generally desired for the entire suction procedure to be performed in 10-15 seconds, or $\leq$ 5 seconds in children to minimize the impact of the suctioning procedure on lung mechanics and respiration. Generally, a patient will require suctioning every 4-6 hours, but the process may be performed with greater regularity if necessary. The procedure is recommended on an as needed basis, not a regular interval, due to the detrimental effect on the patient.

[0006] Attempts to clear the ETT using standard techniques are often ineffective, time-consuming, expensive, and an agonizing experience for the patients, families, and health care providers. Standard methods can also dislodge bacteria-containing particles into the lungs. Ventilator Acquired Pneumonia (VAP) is a major source of infection in hospitals, and is often due to the direct path to the lungs for bacteria from ETT intubation. Standard suctioning has an effect on lung mechanics, including decreased expired tidal volume and lung compliance. Clinical side effects include hypoxia (low oxygen in blood), bradycardia (low heart rate), or atelectasis (collapse of part of the lung). In general, the long term effects of acute changes in lung mechanics or cumulative exposures to short term clinical side effects of suctioning on long term respiratory health is not known. Minimizing the potential negative impacts of the suctioning process on the lungs is desirable.

[0007] Negative effects can be minimized with use of smaller diameter suction catheters, which allow improved airflow during suctioning. With narrow ETTs (such as neonatal or pediatric patients) this is difficult to achieve without severely limiting secretion aspiration effectiveness using standard methods. Such small diameter suction catheters may easily clog, depending on the consistency of the secretions. In addition to airflow considerations, larger suction catheters may be difficult to insert if the catheter diameter to ETT inner diameter ratio is larger than 0.7.

[0008] Occasionally, physiologic saline is first instilled at the inlet to the ETT in an attempt to hydrate and thin the secretions to encourage its removal during the subsequent suctioning procedure, although this point remains controversial. Additional goals of saline instillation may include lubricating and easing the insertion of the catheter itself, and/or elicitation of a cough from the patient to aid secretion removal. The current methods of instilling saline into ETTs are not precise and there is risk of excess fluid entering the lungs and possibly causing dispersion of adherent contaminating material. Reports further suggest saline instillation may cause greater blood oxygen desaturation than suctioning without saline. Despite lack of evidence supporting saline instillation and its potential risks, many clinicians continue the practice.

[0009] When suctioning is unable to restore patency quickly, the only recourse is to replace the ETT, further raising the risk of VAP while also depriving the patient of oxygen until the patient is reintubated and reconnected to the ventilator. The present active device will safely and quickly clear ETTs, while reducing the negative impact the suction procedure has on the lung mechanics of an already compromised patient.

[0010] The present device is also applicable to clearing other types of tubes that may become occluded by secretions or other accumulating or occluding material. For example, pigtail catheters for chest drainage may be cleared in the same way.

BRIEF SUMMARY OF THE INVENTION

[0011] These and other features are described in or are apparent from the following detailed description of various exemplary embodiments.

[0012] It is hereby noted that the term "in situ" is defined as performing an act on an element while the element is being utilized for its commonly known function. For example, per forming the act of clearing bodily fluids from an ETT in situ refers to clearing a clog or blockage in an ETT while the tube is dwelling within the trachea of a living being, human or other.

[0013] The device may be a reusable handset coupled to a disposable clearing catheter that work together to clear secretions from ETis and other tubes in the body more quickly, thoroughly, and with less impact on the patient's lungs or other organs than any current method. The clearing catheter may be designed to operate within a closed system, meaning that the connection to and function of the ventilator is not interrupted when secretion clearing is conducted. Gentle oscillation motion may be applied to the clearing catheter by the handset.

[0014] The clearing catheter may consist of a dual lumen with distal delivery of low volume, continuous irrigation balanced with aspiration -allowing secretions to be broken up and aspirated, without any fluid or debris passing the distal end of the endotracheal tube. Vibration may aid the break-up of tough secretions, allows easier insertion (less hang up in tube), and prevents secretions from getting stuck in the catheter. Implementing the motion applied to the clearing catheter, along with the irrigation and suction, while maintaining the closed system, may require the use of custom connections.

[0015] A method is also disclosed for the in situ clearing of accumulations or occlusions in artificial tubes (e.g., ETTtubes, chesttubes, pigtailtubes, abscess drains)completely or partially disposed within a living being. The method comprises: coupling a first end of a releasably-securable flexible clearing member to a driving mechanism where the driving mechanism remains outside of the living being; and the second working end of the flexible clearing member is disposed inside a closed system in communication with the interior of the artificial tube; and energizing the driving mechanism such that the flexible clearing member experiences repetitive motion and positioning the flexible clearing catheter such that the second working end of the flexible clearing catheter comes into repetitive contact with the accumulation or occlusion for clearing the accumulation or occlusion therein; and wherein the flexible clearing catheter moistens and clears the dried or viscous accumulations or occlusions when positioned within a straight portion or within a curved portion of the artificial tube, with minimal effect on the original function of the artificial tube in the patient.

BRIEF DESCRIPTION OF SEVERAL VIEWS OF THE DRAWINGS

[0016] A full and enabling disclosure of the present invention, including the best mode thereof, directed to one of ordinary skill in the art, is set forth more particularly in the remainder of the specification, which makes reference to the appended Figs. in which:

FIG 1 illustrates arrangement of a standard closed suction catheter system attached to a ventilator circuit of an intubated patient (PRIOR ART).

FIG 1A illustrates the basic components of an active clearing catheter system to remove secretions from ETTs in-situ.

FIG 1B illustrates a close-up view showing the fundamental mechanisms of clearing action at the distal tip of the clearing catheter of the system presented in **FIG 1A.**

FIG 1C illustrates a close-up view showing the fundamental mechanism of clearing action at the distal tip of the clearing catheter with brush tip of the system presented in **FIG 1A.**

FIG 2A illustrates the basic components of an active clearing catheter system to remove secretions from endotracheal tubes in-situ, in which the clearing catheter of the device contains a separate outer sheath which does not undergo repetitive motion.

FIG 2B illustrates a detail view showing the fundamental mechanisms of clearing action of the device in **FIG 2A.**

FIG 3A shows how the clearing catheter is contained in a closed system within the airway tube (handset not attached).

FIG 3B shows a section view of the closed system and its inner components.

FIG 3C shows a detailed section view of the catheter adapter at the proximal end of the clearing catheter demonstrating the separate irrigation and aspiration lumens and connection ports.

FIG 4 illustrates a voice coil motor (VCM) handset, as one driving mechanism for delivering repetitive motion when attached to the clearing catheter via a keyed coupler.

FIG 5 shows the keyed coupler in detail.

FIG 6 shows the use of a dual lumen connector to simplify the fluid connections to the adapter of clearing catheter.

FIG 7 shows the use of an inline dual lumen connector to simplify the fluid and closed system connections of the active system.

FIG 8 shows the integration of a syringe to serve as irrigation source.

FIG 9A illustrates the integration of a novel pump based on an inflatable compliant reservoirto both store irrigation fluid and create pressure to drive the irrigation flow.

FIG 98 shows a detailed section view of the components and lumen boundaries which comprise the compliant reservoir-based pump shown in **FIG 9A.**

FIGS 9C and **90** illustrates the extents of motion of the inflatable compliant reservoir-based pump shown in **FIG9A.**

FIG 10 illustrates the use of a peristaltic pump to provide irrigation flow.

FIG 11 shows a plot illustrating the advantages of the active clearing catheter system over a conventional suction catheter.

[0017] Repeat use of reference characters in the present specification and drawings is intended to represent the same or analogous features or elements of the invention.

REFERENCE LABELS

CC1 Split Lumen Clearing Catheter	34 VCM (voice coil motor) Body
CC2 Sheathed Clearing Catheter	35 Pole Piece
1 Handset	36 Keys
2 Sterility Sleeve	37 Keyway
3 Catheter Adapter	38 Keyed Coupler
4 Power Button	39 Clearing Catheter Port
5 Power Cable	40 Centering Magnet
6a Irrigation Tubing	41 VCM
6b Irrigation Connector	42 Dual Lumen Connector
6c Irrigation Catheter Coupler	43 Male Component
7a Aspiration Tubing	44 Female Component

(continued)

7b Aspiration Connector	45 Inline Dual Lumen Connector
7c Aspiration Catheter Coupler	46 Closed System Adapter
8 Clearing Catheter Coupler	47 Syringe
9 Endotracheal Tube (ETT)	48 Plunger
10 Clearing Catheter	49 Syringe Body
11 Aspiration Lumen	50 Irrigation Port
12 Irrigation Lumen	51 Aspiration Port
13 Oscillation	52 Compliant Reservoir
14 Secretions	53 Compliant Reservoir Adapter
15 Aspiration Flow	54 Magnetic Adapter
16 Irrigation Flow	55 Magnet
17 Bracket	56 Retracted
18 Compliant Wall	57 Extended
19 Bracket Adapter	58 Peristaltic Pump
20 Sheathed Clearing Catheter	59 Pump Tubing
21 Inner Clearing Catheter	60 Fluid Reservoir
21a Inner Clearing Catheter Retracted	61 Pump Housing
21b Inner Clearing Catheter Extended	62 Irrigating Droplets
22 Outer Sheath	63 Syringe Coupling Bracket
23 Patient	64 Clearing Catheter Magnet
24 Ventilator Port	65 IV Pole
25 ETT Port	66 Pressure Data
26 Additional Port	67 Current Embodiment
27 Voice Coil	68 Standard 5 Fr Suction Catheter
28a Magnet Assembly	69 Closed Clearing Catheter System
28b Opposite MagnetAssembly	70 Standard Closed System
29 End Cap	71 Suction Catheter
30 Bearing	72 Suction Valve
31 Shaft	73 Brush
32 Shaft Guides	74 Irrigation Port Valve
33 Handset Housing	75 Irrigation Seal
	76 Irrigation Valve

DETAILED DESCRIPTION OF REPRESENTATIVE EMBODMENTS

[0018] Reference will now be made in detail to embodiments of the invention, one or more examples of which are illustrated in the drawings. Each example is provided by way of explanation of the invention, and not meant as a limitation of the invention. For example, features illustrated or described as part of one embodiment can be used with another embodiment to yield still a third embodiment. It is intended that the present invention include these and other modifications and variations. The preferred embodiments are illustrated in FIGS 1A-11 with the numerals referring to like and corresponding parts.

[0019] The present devices and methods may effectively remove accumulated secretions, blood, clots, or ingrown tissue/membranes from the internal portions of an artificial tube, and preferably an ETT, including pediatric and neonatal ETT. The action of removing accumulated secretions, blood, clots, or ingrown tissue/membranes can also be referred to as a "maintenance action".

[0020] A reusable handset may be provided that is releasably coupled to a disposable clearing catheter that work together to clear secretions from ETTs and other tubes in the body more quickly, thoroughly, and with less impact on the patient's lungs or other organs than any current method. The clearing catheter may be designed *to* operate within a closed system, meaning that the path to and function of the ventilator is not interrupted when secretion clearing is conducted. Gentle oscillatory motion maybe applied to the clearing catheter by the handset.

[0021] In addition, the clearing catheter embodiments themselves as they are described here may work relatively effectively, though less preferably, without being attached to a driving mechanism and without experiencing repetitive

motion. In this case, the advantage over standard suction catheters is the incorporation of multiple lumens, enabling simultaneous irrigation and aspiration.

[0022] The clearing catheter consists of multiple lumens with distal delivery of low volume, continuous irrigation balanced with aspiration in separate lumens -allowing secretions to be broken up and aspirated, without any fluid or debris passing the distal end of the ETT. Vibration aids the break-up of tough secretions, a llows easier insertion (less hang up in tube), and prevents secretions from getting stuck in the catheter. Implementing the motion applied to the clearing catheter, along with the irrigation and suction, while maintaining the closed system, may require, in some instances, the use of custom connections.

[0023] As used herein, the distal direction is the direction toward the patient and away from the health care provider. The proximal direction is toward the health care provider and away from the patient.

[0024] **FIG 1** illustrates the basic setup of an ETT with a standard closed system **70** and a suction catheter **71** installed within.

[0025] The suction catheter **71** is designed to be momentarily inserted down the ETT **9** manually while attached to a negative pressure source. There are two general types of suction catheters: open and closed. An open suction catheter requires the patient to be disconnected from the ventilator for the suctioning procedure. A standard closed system **70** is enclosed in a sterility sleeve **2** and remains attached to the ventilator circuit the entire time. Suctioning can occur without having to shut off the ventilator or disconnect the patient. A slip fitting (not shown) within the clearing catheter coupler **8** enables the catheter to insert into the ETT **9** while a seal is constantly maintained to keep the interior of the sterility sleeve **2,** from inflating/deflating and shunting air away from lungs during ventilation cycle. Whether open or closed, the general suction procedure remains the same. With one hand stabilizing the proximal end of the ETT **9,** the suction catheter **71** is fed into the ETT **9** with the opposite hand until the end is reached, being careful to not over-insert the suction catheter **71** beyond the tip of the ETT **9.** While retracting the suction catheter **71,** the negative pressure is applied to suction out secretions **14** accumulated on the inner wall of the ETT **9.** It is generally desired for the entire suction procedure to be performed in 10-15 seconds, or $\leq$ 5 seconds in children to minimize the impact of the suctioning procedure on lung mechanics and respiration.

[0026] Presently, the new clearing catheter designs (**10** and **20**) may be contained, as with a conventional suction catheter **71,** within a closed clearing catheter system **69.** A handset **1** is releasably connected to the clearing catheters (**10** or **20**) which may apply gentle mechanical action along with irrigation flow and suction.

[0027] **FIG 1A and 2A** illustrates the basic components of the handset **1** and closed clearing catheter system **69** designed to remove secretions **14** (not shown) from endotracheal tubes (ETT) more effectively and with less negative effect on the patient's lungs. The system together consists of a clearing catheter (e.g. **10** or **20**) contained in a closed clearing catheter system **69** and a handset **1** may apply repetitive motion to the clearing catheter (e.g. **10** or **20**) or may not apply repetitive motion to the clearing catheter (e.g. **10** or 20). The handset **1** could also be envisioned as a control box that instead rests on a surface, leaving both hands of the clinician free. The clearing catheter (e.g. **10** or **20**) passes through an attached clearing catheter coupler **8** (i.e. "T", "Y", or straight coupling). Opposite the clearing catheter (e.g. **10** or **20**) is a tube **9,** such as an endotracheal tube (ETT). In the illustrations, an ETT is shown, although the invention is not limited in application to the ETT. A ventilator is attached to the ventilator port **24.** On the additional port **26** of the fitting, if present, a separate device may be attached for other medical treatments. The purpose of the closed system **69** is to maintain sterility and to avoid interfering with the primary function of the **ETT 9** while secretions **14** (not shown) are being cleared from the **ETT 9.**

[0028] As will be discussed in detail later, there are basically two types of tube clearing catheters disclosed herein, both of which are mechanical tube clearers, which benefit from irrigation and aspiration functions. Both approaches may be enclosed within a closed system. Both approaches may apply gentle oscillatory motion or, though less preferably, may not apply gentle oscillatory motion.

[0029] **Clearing Catheter Design 1 (CC1)** uses a dual lumen connected at the proximal end where the handset **1** may provide mechanical oscillation to both lumens. Oscillation may be back and forth repetitive motion along a longitudinal axis of the clearing catheter, driving mechanism or artificial tube.

[0030] **Clearing Catheter Design 2 (CC2)** uses two separate lumens that may experience relative movement in the longitudinal axis. The inner lumen is connected to the handset **1** which may provide mechanical oscillation. Oscillation may be back and forth repetitive motion along a longitudinal axis of the clearing catheter, driving mechanism or artificial tube. The outer lumen in this case is fixed in position by a bracket which is anchored to the outside of the handset **1.** The inner lumen in this case moves freely within the outer lumen, with its distal tip exiting and reentering the distal end of the outer lumen.

Applies to Clearing Catheter Design 1 (Split lumen Clearing Catheter)

[0031] **FIG 1A and 1B** illustrate in more detail the components of the clearing catheter design 1 **CC1** where the clearing catheter **10** may be an oscillating dual lumen or, less preferably, may be a non-oscillating dual lumen. The clearing

catheter **10** passes through an attached clearing catheter coupler **8** (i.e. 'T', "Y", or straight coupling) (shown in **FIG 1A).** Opposite the clearing catheter is a tube **9,** such as an endotracheal tube (ETT). The purpose of the closed system **69** is to avoid interfering with the primary function of the **ETT 9** while secretions **14** (shown **in FIG 18)** are being cleared from the **ETT 9.**

[0032] A multi-port catheter adapter **3** (shown in **FIG 1A** and in cross-sectional view in **FIG 3C)** on the proximal end of the clearing catheter **10** may connect to a handset **1** (shown in **FIG 1A)** via a keyed coupler **38** (shown in **FIG 1A)** which may provide mechanical oscillation **13** (shown in **FIG 18)** in a frequency range of 1-500 Hz, but preferably 50-150 Hz. The oscillations **13** have a stroke length of 0.05-3.0 mm, but preferably 0.25-1.0 mm at the distal tip of the clearing catheter **10.** Compliant tubing, such as silicone, may be used to link the irrigation catheter coupler **6c** to a fluid source via irrigation tube **6a** (shown in **FIG 1A)** as well as link the aspiration catheter coupler **7c** to a suction source via aspiration tubing **7a** (shown in **FIG 1A),** thus permitting both an irrigation flow **16** (shown in **FIG 18)** of fluid, preferably saline,from an irrigation lumen **12** (shown in **FIG 1B)** and aspiration flow **15** (shown in **FIG 1B)** (suction) of the secretions **14** through an aspiration lumen **11** (shown in **FIG 18)** in the clearing catheter **10.** The irrigation and aspiration tubing **(6a** and **7a,** respectively) are sufficiently compliant so as to allow the more rigid catheter adapter **3** (which includes the irrigation catheter coupler 6c and aspiration catheter coupler **7c)** and attached clearing catheter **10** to freely oscillate when handset **1** is actuated, even when distal portion of the tubing (6a and 7a) is anchored to the handset 1 (such as shown in FIG 7). The sterility sleeve 2 (shown in FIG 1A) is composed of relatively thin and flexible material such as plastic which easily folds as the clearing catheter inserts into the tube 9, therefore very little if any vibration is transferred down the distal end of the sterility sleeve 2. As shown in more detail in FIG 18, the mechanical oscillations 13combined with the irrigation flow 16, assist in thinning and breaking up the secretions 14 present in the tube 9, such as an ETT.

[0033] FIG 1C illustrates an alternate embodiment of clearing catheter design 1 CC1, in which a brush 73 is located at the distal end of the clearing catheter 10. The brush 73, being securely connected to the clearing catheter 10, may oscillate 13 with it. The oscillation 13 motion of the brush 73 further assists in breaking up secretions 14 which may be adherent to the inner walls of the ETT 9. This alternative embodiment may also be used without oscillation, thereby using irrigation and aspiration along with the brush to clear secretions 14.

[0034] FIG 6 and FIG 7 refer to methods of making the connections between the clearing stem and the irrigation/aspiration sources. Illustrations are specific to the split lumen clearing catheter design CC1 but the basic connections could be adapted to the sheathed clearing catheter design CC2 (see below) with minor modification. Since the device requires multiple connections, novel methods of simplifying the connections for the operator are of value. As shown in FIG 6, the irrigation tubing 6a which provides irrigation function, connects to the clearing catheter adapter by an irrigation catheter coupler 6c. Similarly, the aspiration tubing 7a which provides aspiration function, also connects at the clearing catheter adapter 3 by an aspiration catheter coupler 7c. The ordering of the irrigation catheter coupler 6c and the aspiration coupler 7c of catheter adapter 3 can be reversed. A dual lumen connector 42 which contains a male component 43 and female component 44 and enable quick connection of both the irrigation tubing 6a and aspiration tubing 7a coming from their source (possibly some distance from the patient or more directly coupled to the handset 1) when the device is to be used in a clearing procedure on the patient. When the handset is activated in FIG 6, the keyed coupler 38, catheter adapter 3 and the attached clearing catheter 10 are mechanically oscillated together. Minimal vibration is transferred to the sterility sleeve 2 (attached to distal end of catheter adapter 3) or the irrigation tubing 6a or aspiration tubing 7a . FIG 7 refers to a similar connector that is placed in-line with the handset 1 and closed system 69. The in-line configuration facilitates the connection of the irrigation 6b and closed system 69 to the handset 1at the same time, minimizing the amount of connections the operator has to make in order to use the device. In FIG 7, the sterility sleeve 2 is connected to a closed system adapter 46, which is part of the female component 44 of the inline dual lumen connector 45. The male component 43 interlocks with the female component 44 of the inline dual lumen connector 45. The male component 43 is connected to the handset 1 in lieu of the catheter adapter 3 on several other configurations. The male component 43 contains ports for irrigation tubing 6a and aspiration tubing 7a, which may be run alongside the handset 1 and terminates in an irrigation connector 6b and an aspiration connector 7b, respectively. Multiple sets of tubing may be used for various functions. The irrigation connector 6b and/or aspiration connector 7b, in this case, may be permanently attached to accessory equipment (i.e., aspiration or irrigation pumps), so that the operator must only make the single connection of the inline dual lumen connector **45** to connect the closed clearing catheter system **69** and its functions. When male component **43** is attached to female component **44** and the handset **1** is activated, both components mechanically oscillate as a single unit along with the clearing catheter **10.** Tubing **6a** and **7a** have sufficient compliance so as to not impede the mechanical oscillation of the inline dual lumen connector **45** or attached clearing catheter **10** during operation.

Applies to Clearing Catheter Design 2 (Sheathed Clearing Catheter)

[0035] **FIG 2A and 2B** illustrate in more detail the components of the sheathed clearing catheter **CC2** which may be an active device to remove secretions **14** (shown in **FIG 2B**) from endotracheal tubes **9,** in which a sheathed clearing

catheter **20** contains an additional non-moving outer sheath **22.** The outer sheath **22** is concentrically disposed with regards to an inner clearing catheter **21** (shown in **FIG 2B**). The outer sheath **22** does not oscillate and is held stationary by a bracket **17** (shown in **FIG 2A**) which is attached to or is integrated into the handset **1** (shown in **FIG 2A**). One benefit of this configuration is that the outer sheath **22** may be lightly gripped without damping the oscillation of the inner catheter **21.** The inner clearing catheter **21** may be single-lumen in order to accommodate aspiration. As shown in more detail in **FIG 2B,** irrigation flow **16** will travel in the space between the outer sheath **22** and the inner clearing catheter **21,** this space being referred to as the irrigation lumen **12.** The clearing catheter can be reversibly attached to handset **1** by pressing bracket adapter **19** into the bracket **17** and connected the compliant reservoir adapter **53** to the magnet adapter **54** which is attached to the keyed coupler **38.** The mechanical oscillations **13** of the compliant reservoir adapter **53** and attached inner clearing catheter **21** combined with the irrigation flow **16,** assist in thinning and breaking up the secretions **14** present in the tube **9.** Once the secretions **14** are thinned or loosened by the irrigation flow **16** and mechanical oscillation **13,** they are removed via aspiration flow **15** through the aspiration lumen **11** in the inner clearing catheter **21.** In an alternative, the irrigation flow **16** may work with the aspiration flow **15** to remove secretions **14** without mechanical oscillations, **13.** The secretions **14** may be, but not limited to, mucus, blood, clots, or ingrown tissue/membranes. Alternatively, the inner clearing catheter **21** may also be of a multi-lumen design in order to accommodate additional functions.

[0036] **FIG 9A** through **FIG 9D** illustrate an embodiment using a compliant reservoir **52** (shown in **FIG 9A** and **B**) to allow delivery of the irrigation fluid down the irrigation lumen **12** (shown in **FIG 2B**) formed between the non-moving outer sheath of **22** and the oscillating inner catheter **21** of the sheathed clearing catheter design **CC2.** In this embodiment shown in full in **FIG 9A** and in detail in **FIG 9B,** the shaft **31** is routed through shaft guides **32** and attaches to keyed coupler **38.** A magnetic adapter **54** and residing magnet **55** interfaces the keyed coupler **38** with clearing catheter magnet **64.** Either magnet **55** or **64** may also be replaced by a magnetically attractive material, such as but not limited to steel. A clearing catheter magnet **64,** which is part of the closed clearing catheter system **69,** makes the connection with the magnet **55** attached to the handset **1.** In order to maintain orientation of the compliant reservoir **52** system and its connections, the magnet **55** and clearing catheter magnet **64,** may incorporate a keyway, interlocking feature, unique shape, and/or specific polarization in order to keep the magnets in a stationary position relative to each other when engaged. The magnetic connection may be replaced with some other releasable mechanical mating connection (e.g. slots, dovetail, or snap). Attached to the clearing catheter magnet **64** is a compliant reservoir adapter **53,** which includes an aspiration port **51.** A compliant reservoir **52** is formed between the compliant reservoir adapter **53** and a bracket adapter **19.** A bracket **17** which attaches to the handset **1** is used to secure the bracket adapter **19** and hold it stationary relative to the oscillating inner clearing catheter **21.** The bracket adapter **19** contains an irrigation port **50** which is used to pressurize the compliant reservoir **52.** Optionally, the irrigation port **50,** may incorporate an irrigation port valve **74** (such as a 1-way or 2-way valve) to allow the compliant reservoir **52** to maintain pressure after filling, for instance with a syringe, disposable ampule, or external pump which is only momentarily connected to fill the compliant reservoir **52.** In addition, there may be a valve, such as a Tuohy-Borst adapter, that controls the inner diameter of the irrigation seal **75** by tightening or loosening of the irrigation valve **76,** thereby reducing or turning off completely the flow of irrigation fluid out of the compliant reservoir **52.** When the compliant reservoir adapter **53** is mechanically oscillated along with the inner clearing catheter **21,** the compliant wall **18** expands outward to accommodate the fluid that is displaced by the compliant reservoir adapter **53.** This produces pressure fluctuation inside the compliant reservoir **52** that may further aid fluid delivery (in addition to the irrigation source and/or the steady-state pressure of the filled compliant reservoir **52).** The movement of the compliant reservoir adapter **53** and ensuing expansion of the compliant wall **18** is shown in **FIG 9C** and **FIG 9D.** When the oscillation is applied through the handset **1,** the compliant reservoir adapter **53** oscillates which causes the compliant wall **18** to expand and contract. **FIG 9C** illustrates the compliant reservoir adapter **53** in the fully retracted **56** position. Here the compliant reservoir **52** pressure is at a minimum and the compliant wall **18** is in its most relaxed state. The inner clearing catheter **21** is also fully retracted **56,** since it oscillates in phase with the compliant reservoir adapter **53. FIG 9D** illustrates the compliant reservoir adapter **53** in the fully extended **57** position. When the compliant reservoir adapter **53** is in the fully extended **57** position the compliant reservoir **52** pressure is at a maximum and the compliant wall **18** is most expanded. The fluctuating pressure increase adds to the steady state pressure of the compliant reservoir **52** (comparable to the initial reservoir filling pressure or the fluid pressure supplied by an external irrigation source) pushes irrigation fluid towards the distal end of the outer sheath **22** in the space between the outer sheath **22** and inner clearing catheter **21.** Due to the flow, irrigating droplets **62** exit the distal end of the outer sheath **22.** The inner clearing catheter **21** is also in a fully extended **57** position at this point. The irrigating droplets **62** that are expelled from the end of the outer sheath **22** assist in clearing secretions **14.**

Applies universally to Clearing Catheter Designs 1 and 2

[0037] Mechanical oscillations **13** of the clearing catheter (**10** or **20**) aids in breaking up and clearing secretions in multiple ways, including but not limited to: agitation and mixing of the secretions with irrigation fluid to decrease viscosity for aspiration and shearing off or scraping of portions of secretions **14** when the tip of the clearing catheter (**10** or 20)

makes direct contact with the secretions **14** (including loosening material adherent with tube wall **9**). Mechanical oscillation **13** of the clearing catheter (**10** or **20**) has other desirable effects, including but not limited to: reduced insertion force with less buckling of the clearing catheter **10** when inserted into the tube **9** (enabling narrower and more flexible clearing catheter design options and ability to insert while pushing with the handset **1,** rather than having to feed the suction catheter **71** into the proximal end of tube **9** with fingers in close proximity to clearing catheter coupler **8** as is commonly practiced). Additionally, mechanical oscillations **13** may produce lateral modes of vibration that tend to re-establish or maintain aspiration flow within clearing catheter, especially when optimal length of clearing catheter (**10** or **20**) is pulled outside of tube **9.** The lateral modes of vibration may also interact with the interior walls of tube **9** to help dislodge and agitate the secretions **14** that are located proximally to the distal tip of the clearing catheter (**10** or **20**). Once the secretions **14** are thinned or loosened by the irrigation flow **16** and mechanical oscillation **13,** they are removed via aspiration flow **15** through an aspiration lumen (**11** or **12**) in the clearing catheter (**10** or **20**). The secretions **14** and other accumulating or occluding materials may be, but not limited to, mucus, blood, clots, or ingrown tissue/membranes. The clearing catheter (**10** or **20**) is of a multi-lumen design in order to accommodate both irrigation and aspiration, delivered locally at the working (distal) end of the clearing catheter (**10 or 20**).

[0038] When clearing secretions **14** from an ETT **9** using the present invention, the irrigation and aspiration applied at the distal tip of the clearing catheter **10** or **20** must be balanced in order to prevent irrigation fluid from entering or collecting in the lungs. The balancing of irrigation and aspiration at the distal tip of the clearing catheter **10** or **20** may be used with or without oscillation **13.** Considerations for balancing irrigation and aspiration may include, but are not limited to, cross sectional area ratio of the lumens, fluid flow rate, and fluid velocity. Cross sectional area ratio is defined as the area of the aspiration lumen divided by the area of the irrigation lumen. Ideal cross sectional area ratios may range from 2:1 to 25:1, but more preferably from 10:1 to 20:1. Fluid flow rates are necessary to consider, since the fluid flow rate of the aspiration must be equal to the irrigation flow rate plus the desired flow rate of secretion removal. A factor of safety may also be incorporated into the flow rate design in order to increase confidence that all irrigation fluid is aspirated. As an additional effect to balance, aspiration flow rate cannot be too great, as it would reduce the pressure in the patient's lungs. Fluid velocity must be considered, since it largely predicts the strength of the irrigation and aspiration flows. Aspiration flow must be of higher velocity than the irrigation flow, so that the irrigation flow does not exit the effective area of aspiration. The strength of the aspiration flow must be greater than that of the irrigation flow. While each independent factor is important to consider, interactions between the factors must also be considered for different applications.

[0039] **FIG 3A** through **FIG 3C** illustrate how the closed clearing catheter system **69** (shown in **FIG 3A** and **3B**) is implemented with regards to the patient **23** (shown in **FIG 3A**), in both embodiments, **CC1** and **CC2,** though specifically a closed clearing catheter system **69** and associated catheter adapter **3** (shown in **FIG 3A** and **3B**) for **CC1** is shown. The patient's **23** ETT **9** (shown in FIG **3A** and **3B**) is connected to the endotracheal tube port **25** (shown in **FIG 3A** and **3B**) on a clearing catheter coupler **8** (shown in **FIG 3A** and **3B**) which may have multiple ports, including but not limited to a ventilator port **24** (shown in **FIG 3A** and **3B**), a clearing catheter port **39** (shown in **FIG 3A** and **3B**), and an additional port **26** (shown in **FIG 3A** and **3B**). The additional port **26** may be capped, used for a separate function, such as to wean the patient **23** off of assisted breathing, or not be present at all. The closed clearing catheter system **69** is attached to the clearing catheter port **39.** Also, within clearing catheter port **39** there may be a seal (not shown), such as a slip fitting or possibly an adjustable valve such as a Tuohy-Borst adapter, for preventing the interior of the sterility sleeve **2** (shown in **FIG 3A** and **3B**) from ventilating, particularly when a clearing catheter **10** or sheathed clearing catheter **20** is not inserted into the ETT **9** to clear secretions, but retracted and resting near patient's bedside while still connected to clearing catheter coupler **8,** the purpose of this being to prevent air from shunting away from patient and into sterility sleeve **2** while being ventilated. A clearing catheter **10** or sheathed clearing catheter **20** is concentrically disposed on the inner bore of the clearing catheter port **39.** A sterility sleeve **2** is concentrically disposed with regards to both the clearing catheter port **39** and clearing catheter **10** or **20,** and seals exterior contaminants from entering the closed clearing catheter system **69.** A catheter adapter **3** on the proximal end of the closed clearing catheter system **69** is connected to the sterility sleeve **2** and maintains the closed clearing catheter system **69** seal. Part of the catheter adapter **3** is an aspiration catheter coupler **7c** and irrigation catheter coupler **6c** which couples aspiration tubing **7a** and irrigation tubing **6a,** respectively. This tubing may extend to aspiration/irrigation sources or terminate in a connection, such as the irrigation connector **6b** which can be secured to a source. For detail of lumen paths within the catheter adapter **3,** see **FIG 3C.**

[0040] Referring to **FIG 4,** a handset **1** attaches to the clearing catheter **10** or **20** (not shown) via the catheter adapter **3** or magnet adapter 54, respectively (not shown). Inside the handset **1** is a voice coil motor (VCM) **41** which provides the oscillation energy which may be applied to the clearing catheter **10** or the sheathed clearing catheter **20.** The VCM **41** provides the driving mechanism and consists of a cylindrical VCM body **34,** with an embedded voice coil **27** disposed concentrically within. A magnet assembly **28a,** adjacent to an opposing magnet assembly **28b** with a pole piece **35** separating the two assemblies are fastened concentrically upon a displaceable shaft **31.** Centering magnets **40** are attached to bearings **30,** made from a low friction material such as but not limited to PTFE or Acetal, at the extreme ends of the VCM body **34.** End caps **29** are present at each end to secure the entire assembly. The centering magnets **40** are magnets disposed in opposite polarization to the magnet assembly **28a** and opposite magnet assembly **28b,** and

prevent collisions with the bearings **30** and end caps **29** while the shaft **31** is oscillating. The shaft **31** is routed through the distal end of the handset housing **33.** Shaft guides **32** within the handset housing **33** maintain concentricity of the oscillating shaft **31.** The shaft guides **32** may be integrated into the handset housing **33** design itself or may be inserts made of a specific low-friction material, such as but not limited to PTFE or Acetal. The distal end of the shaft **31** is connected to a keyed coupler **38,** which attaches to the catheter adapter **3** on the clearing catheter **10** or the magnet adapter **54** of the sheathed clearing catheter **20** (not shown). A power cable **5** is routed through the proximal end of the handset housing **33,** providing alternating current electrical energy to the voice coil **27.** A power button **4** is pressed by the operator to control ON/OFF function of the handset **1.** In order to keep the shaft **31** of the VCM **41** from rotating during operation, **FIG 5** illustrates a keyed coupler **38** with integrated keys **36,** which slide within a keyway **37,** which is integrated into the handset housing **33.** The keys **36** and keyway **37** keep the shaft **31** from freely rotating when oscillating. Although shown as employing a VCM **41,** it is to be understood that in accordance with other exemplary embodiments that the handset **1** may use various types of motors or components to create the vibratory motion.

[0041] FIG 8 and FIG 10 illustrate methods for the integration of accessory equipment which faciltate the function of, but not limited to, aspiration or irrigation to CC1 and CC2. The integration of a syringe 47 is shown in FG 8. The syringe 47 attaches to irrigation tubing 6a via an irrigation connector 6b to the closed clearing catheter system 69. The irrigation catheter coupler 6c couples the irrigation tubing 6a to the irrigation lumen 12 (not shown) in the clearing catheter 10 (not shown) or sheathed clearing catheter 20 (not shown). The syringe 47 is coupled to the handset 1 via a syringe coupling bracket 63 which attaches to the syringe body 49. Flow is controlled by applying pressure to the plunger 48 either by manual or automatic means. Automatic means may be, but not limited to, mechanical syringe pumps utilizing a pre-loaded spring or an electric motor/actuator which advances the plunger 48 within the syringe body 49, creating pressure and flow through the irrigation tubing 6a.

[0042] FIG 10 illustrates the use of a peristaltic pump 58 to provide irrigation flow to the closed clearing catheter system 69. Fluid, such as saline, is held in a fluid reservoir 60. Pump tubing 59 attaches from the fluid reservoir 60 and passes through a pump housing 61. The pump housing 61 on a peristaltic pump 58 facilitates the easy replacement of pump tubing 59, eliminating contamination of the pump between uses, and the use of disposable fluid reservoirs 60 and pump tubing 59. After passing through the pump housing 61, the pump tubing 59 is routed into the closed clearing catheter system 69 as irrigation tubing 6a via an irrigation catheter coupler 6c.

[0043] FG 11 illustrates the advantages to the patient from using the current embodiment 67 versus a standard 5 Fr suction catheter 68. A plot of pressure data 66 versus time is shown for both the current embodiment 67 and a standard 5 Fr suction catheter 68. The data was taken in a constant volume varying only the device used to clear the ETT. The pressure drop is significantly smaller in the current embodiment 67 than the standard 5 Fr suction catheter 68. Since the volumes of both experiments were held constant, the flow rate due to pressure drop is also proportional, showing that the present embodiment has less of an effect on the patient since less airflow is being taken from the lungs.

[0044] Additional lumens may be added whose functions may include, but are not limited to, a lumen for delivery of supplemental air and/or oxygen, sensing capability, or sampling functions. The lumen delivering supplemental air assists in replacing lost airway capacity due to the presence of the clearing catheter in the tube. Sensing functions may include, but are not limited to, oxygen content measurement or lung flow rate measurements. Sampling functions may include, but are not limited to, taking samples of air or secretions for composition or bacterial analysis.

Claims

1. A device (CC1) for removing materials from an artificial tube (9), comprising a clearing catheter (10) having an aspiration lumen (11) and an irrigation lumen (12) a driving mechanism (1) configured to apply repetitive motion to the clearing catheter (10) to move the clearing catheter (10) and the aspiration lumen (11) and the irrigation lumen (12) of the clearing catheter (10), **characterized in that** the device further comprises a dual lumen connector (42; 45) in fluid communication with said aspiration lumen (11) and said irrigation lumen (12), said dual lumen connector (42; 45) having releasably attachable male (43) and female (44) components interconnecting said aspiration lumen (11) and irrigation lumen (12) respectively with aspiration tubing (7a) and irrigation tubing (6a).

2. The device (CC1) as set forth in claim 1, further comprising a handset (1) that has a handset housing (33) that carries the driving mechanism (1), wherein the driving mechanism (1) has a shaft (31) that reciprocates in a longitudinal direction; and a keyed coupler (38) that is keyed to the handset housing (33), wherein a distal end of the shaft (31) is located at the keyed coupler (38), and wherein the keyed coupler (38) prevents the shaft (31) from freely rotating during reciprocation of the shaft (31).

3. The device (CC1) as set forth in either claim 1 or claim 2, further comprising a clearing catheter coupler (8) connecting the tube (9) and the clearing catheter (10), wherein the tube (9), the clearing catheter coupler (8), the clearing

catheter (10) and the driving mechanism (1) collectively define a closed system (69).

4. The device (CC1) as set forth in any one of the preceding claims, wherein the driving mechanism (1) is at least one of a voice coil motor (41), a piezoelectric actuator, a pneumatic actuator, and a direct current motor.

5. The device (CC1) as set forth in any one of the preceding claims, further comprising a brush (73) located at a distal end of the clearing catheter (10, 20).

6. The device (CC1) as set forth in any one of the preceding claims, wherein said clearing catheter (1) has an interior space divided such that said aspiration lumen (11) and irrigation lumen (12) are parallel to each other.

7. The device (CC1) as set forth in any one of the preceding claims, further comprising a first coupler (7c) connecting said aspiration lumen (11) and a first portion of aspiration tubing (7a), a second coupler (6c) connecting said irrigation lumen (12) and a first portion of irrigation tubing (6a), wherein said male component (43) of said dual lumen connector (42) receives said first portions of said irrigation tubing (6a) and said aspiration tubing (7a), and wherein said female component (44) of said dual lumen connector (42) receives second portions of said irrigation tubing (6a) and said aspiration tubing (7a).

8. The device (CC1) as set forth in any one of the preceding claims, wherein said female component (44) of said dual lumen connector (42) receives said aspiration lumen (11) and said irrigation lumen (12), and said male component (43) of said dual lumen connector (42) receives aspiration tubing (7a) and irrigation tubing (6a).

9. The device (CC1) as set forth in any one of the preceding claims, further comprising a handset (1) having a handset housing (33), wherein said male component (43) of said dual lumen connector (42) attaches to said handset housing (33) and said female component (44) of said dual lumen connector (42) attaches to said clearing catheter (10).

Patentansprüche

1. Vorrichtung (CC1) zum Entfernen von Stoffen aus einem künstlichen Tubus (9), die Folgendes aufweist: einen Reinigungskatheter (10) mit einem Aspirationslumen (11) und einem Spülungslumen (12), einen Antriebsmechanismus (1), der zum Anwenden einer sich wiederholenden Bewegung auf den Reinigungskatheter (10) zum Bewegen des Reinigungskatheters (10) und des Aspirationslumens (11) und des Spülungslumens (12) des Reinigungskatheters (10) gestaltet ist, **dadurch gekennzeichnet, dass** die Vorrichtung ferner einen Doppellumenverbinder (42; 45) aufweist, der mit dem genannten Aspirationslumen (11) und dem genannten Spülungslumen (12) in Fluidverbindung ist, wobei der genannte Doppellumenverbinder (42; 45) auslösbar anbringbare männliche (43) und weibliche (44) Komponenten hat, die das genannte Aspirationslumen (11) und das genannte Spülungslumen (12) mit Aspirationstubusmaterial (7a) bzw. Spülungstubusmaterial (6a) verbinden.

2. Vorrichtung (CC1) nach Anspruch 1, die ferner ein Handgerät (1), das ein Handgerätgehäuse (33) hat, das den Antriebsmechanismus (1) trägt, wobei der Antriebsmechanismus (1) eine Welle (31) hat, die sich in einer Längsrichtung hin- und herbewegt; und eine kodierte Kupplung (38), die mit dem Handgerätgehäuse (33) kodiert ist, aufweist, wobei sich ein distales Ende der Welle (31) an der kodierten Kupplung (38) befindet und wobei die kodierte Kupplung (38) die Welle (31) daran hindert, sich während der Hin- und Herbewegung der Welle (31) frei zu drehen.

3. Vorrichtung (CC1) nach Anspruch 1 oder Anspruch 2, die ferner eine Reinigungskatheterkupplung (8) aufweist, die den Tubus (9) und den Reinigungskatheter (10) verbindet, wobei der Tubus (9), die Reinigungskatheterkupplung (9), der Reinigungskatheter (10) und der Antriebsmechanismus (1) zusammen ein geschlossenes System (69) definieren.

4. Vorrichtung (CC1) nach einem der vorhergehenden Ansprüche, wobei der Antriebsmechanismus (1) wenigstens einer ist von:

einem Schwingspulenmotor (41), einem piezoelektrischen Aktor,
einem Pneumatik-Aktor und einem Gleichstrommotor.

5. Vorrichtung (CC1) nach einem der vorhergehenden Ansprüche, die ferner eine Bürste (73) aufweist, die sich an einem distalen Ende des Reinigungskatheters (10, 20) befindet.

6. Vorrichtung (CC1) nach einem der vorhergehenden Ansprüche, wobei der genannte Reinigungskatheter (1) einen Innenraum hat, der so unterteilt ist, dass das genannte Aspirationslumen (11) und das genannte Spülungslumen (12) parallel zueinander sind.

7. Vorrichtung (CC1) nach einem der vorhergehenden Ansprüche, die ferner Folgendes aufweist: eine erste Kupplung (7c), die das genannte Aspirationslumen (11) und einen ersten Teil des Aspirationstubusmaterials (7a) verbindet, eine zweite Kupplung (6c), die das genannte Spülungslumen (12) und einen ersten Teil des Spülungstubusmaterials (6a) verbindet, wobei die genannte männliche Komponente (43) des genannten Doppellumenverbinders (42) den genannten ersten Teil des genannten Spülungstubusmaterials (6a) und des genannten Aspirationstubusmaterials (7a) aufnimmt und wobei die genannte weibliche Komponente (44) des genannten Doppellumenverbinders (42) den zweiten Teil des genannten Spülungstubusmaterials (6a) und des genannten Aspirationstubusmaterials (7a) aufnimmt.

8. Vorrichtung (CC1) nach einem der vorhergehenden Ansprüche, wobei die genannte weibliche Komponente (44) des genannten Doppellumenverbinders (42) das genannte Aspirationslumen (11) und das genannte Spülungslumen (12) aufnimmt und die genannte männliche Komponente (43) des genannten Doppellumenverbinders (42) Aspirationstubusmaterial (7a) und Spülungstubusmaterial (6a) aufnimmt.

9. Vorrichtung (CC1) nach einem der vorhergehenden Ansprüche, die ferner ein Handgerät (1) mit einem Handgerätgehäuse (33) aufweist, wobei die genannte männliche Komponente (43) des genannten Doppellumenverbinders (42) an dem genannten Handgerätgehäuse (33) angebracht ist und die genannte weibliche Komponente (44) des genannten Doppellumenverbinders (42) an dem genannten Reinigungskatheter (10) angebracht ist.

Revendications

1. Dispositif (CC1) destiné à éliminer des substances dans un tube artificiel (9), comprenant un cathéter d'aspiration (10) présentant une lumière d'aspiration (11) et une lumière d'irrigation (12) un mécanisme d'entraînement (1) configuré pour appliquer un mouvement répétitif au cathéter d'aspiration (10) afin de déplacer le cathéter d'aspiration (10) ainsi que la lumière d'aspiration (11) et la lumière d'irrigation (12) du cathéter d'aspiration (10), **caractérisé en ce que** le dispositif comprend en outre un connecteur à double lumière (42 ; 45) en communication fluidique avec ladite lumière d'aspiration (11) et ladite lumière d'irrigation (12), ledit connecteur à double lumière (42; 45) présentant des composants mâle (43) et femelle (44) pouvant être attachés de manière amovible qui interconnectent ladite lumière d'aspiration (11) et ladite lumière d'irrigation (12) respectivement à un tube d'aspiration (7a) et à un tube d'irrigation (6a).

2. Dispositif (CC1) selon la revendication 1, comprenant en outre un combiné (1) présentant un boîtier de combiné (33) renfermant le mécanisme d'entraînement (1), dans lequel le mécanisme d'entraînement (1) présente un arbre (31) qui se déplace en va-et-vient dans un sens longitudinal ; et un coupleur claveté (38) qui est claveté au boîtier de combiné (33), dans lequel une extrémité distale de l'arbre (31) est située au niveau du coupleur claveté (38), et dans lequel le coupleur claveté (38) empêche l'arbre (31) de tourner librement durant le déplacement en va-et-vient de l'arbre (31).

3. Dispositif (CC1) selon la revendication 1 ou la revendication 2, comprenant en outre un coupleur de cathéter d'aspiration (8) qui connecte le tube (9) et le cathéter d'aspiration (10), le tube (9), le coupleur de cathéter d'aspiration (8), le cathéter d'aspiration (10) et le mécanisme d'entraînement (1) définissant collectivement un système fermé (69).

4. Dispositif (CC1) selon l'une quelconque des revendications précédentes, dans lequel le mécanisme d'entraînement (1) est au moins un d'un moteur à bobine acoustique (41), d'un actionneur piézo-électrique, d'un actionneur pneumatique et d'un moteur à courant continu.

5. Dispositif (CC1) selon l'une quelconque des revendications précédentes, comprenant en outre une brosse (73) située à une extrémité distale du cathéter d'aspiration (10, 20).

6. Dispositif (CC1) selon l'une quelconque des revendications précédentes, dans lequel ledit cathéter d'aspiration (1) présente un espace intérieur divisé de telle sorte que lesdites lumière d'aspiration (11) et lumière d'irrigation (12) soit parallèles l'une à l'autre.

7. Dispositif (CC1) selon l'une quelconque des revendications précédentes, comprenant en outre un premier coupleur (7c) qui connecte ladite lumière d'aspiration (11) et une première partie du tube d'aspiration (7a), un second coupleur (6c) qui connecte ladite lumière d'irrigation (12) et une première partie du tube d'irrigation (6a), dans lequel ledit composant mâle (43) dudit connecteur à double lumière (42) reçoit lesdites premières parties dudit tube d'irrigation (6a) et dudit tube d'aspiration (7a), et dans lequel ledit composant femelle (44) dudit connecteur à double lumière (42) reçoit des secondes parties dudit tube d'irrigation (6a) et dudit tube d'aspiration (7a).

8. Dispositif (CC1) selon l'une quelconque des revendications précédentes, dans lequel ledit composant femelle (44) dudit connecteur à double lumière (42) reçoit ladite lumière d'aspiration (11) et ladite lumière d'irrigation (12), et ledit composant mâle (43) dudit connecteur à double lumière (42) reçoit le tube d'aspiration (7a) et le tube d'irrigation (6a).

9. Dispositif (CC1) selon l'une quelconque des revendications précédentes, comprenant en outre un combiné (1) présentant un boîtier de combiné (33), dans lequel ledit composant mâle (43) dudit connecteur à double lumière (42) s'attache audit boîtier de combiné (33) et ledit composant femelle (44) dudit connecteur à double lumière (42) s'attache audit cathéter d'aspiration (10).

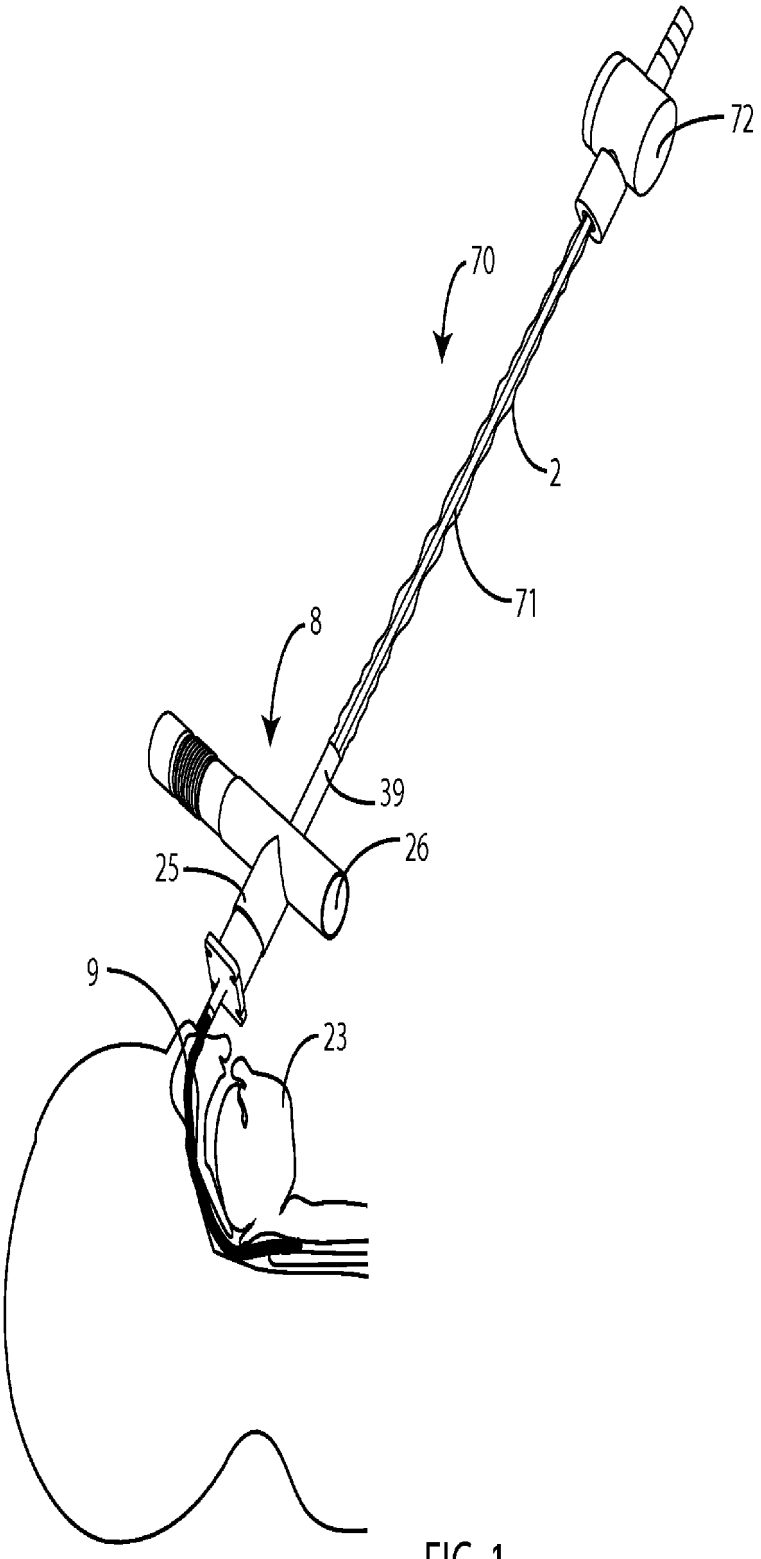


FIG. 1
PRIOR ART

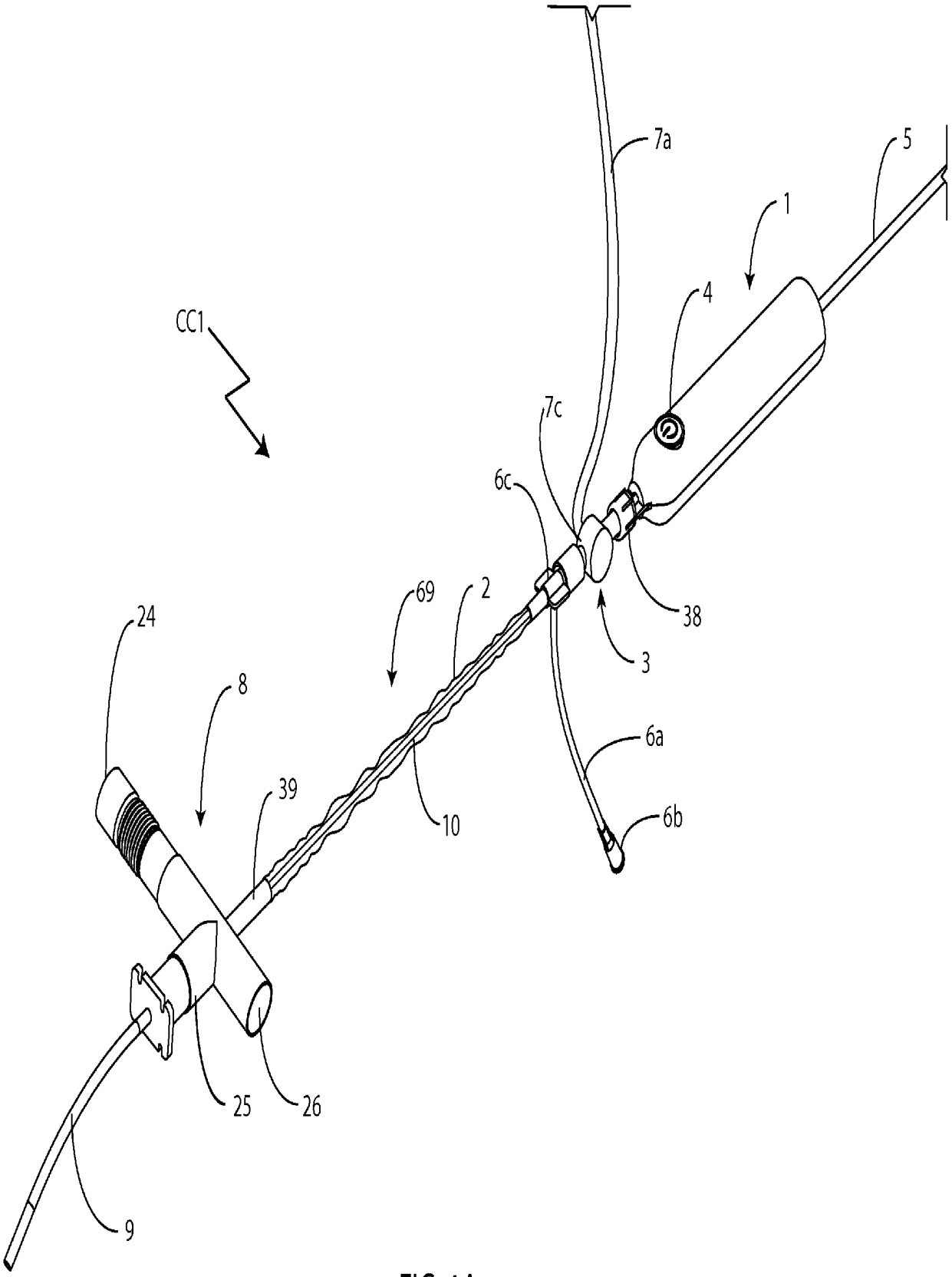


FIG. 1A

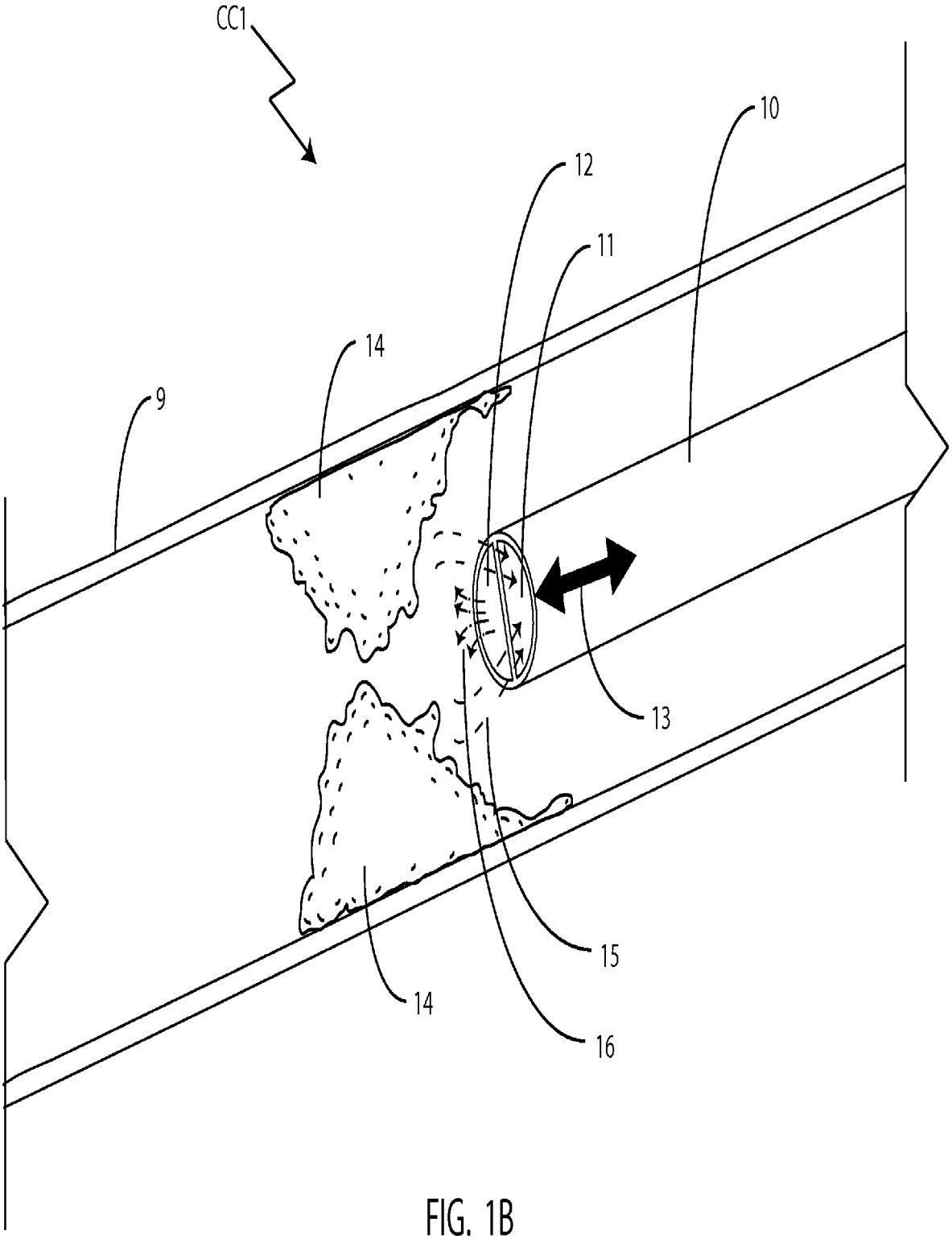


FIG. 1B

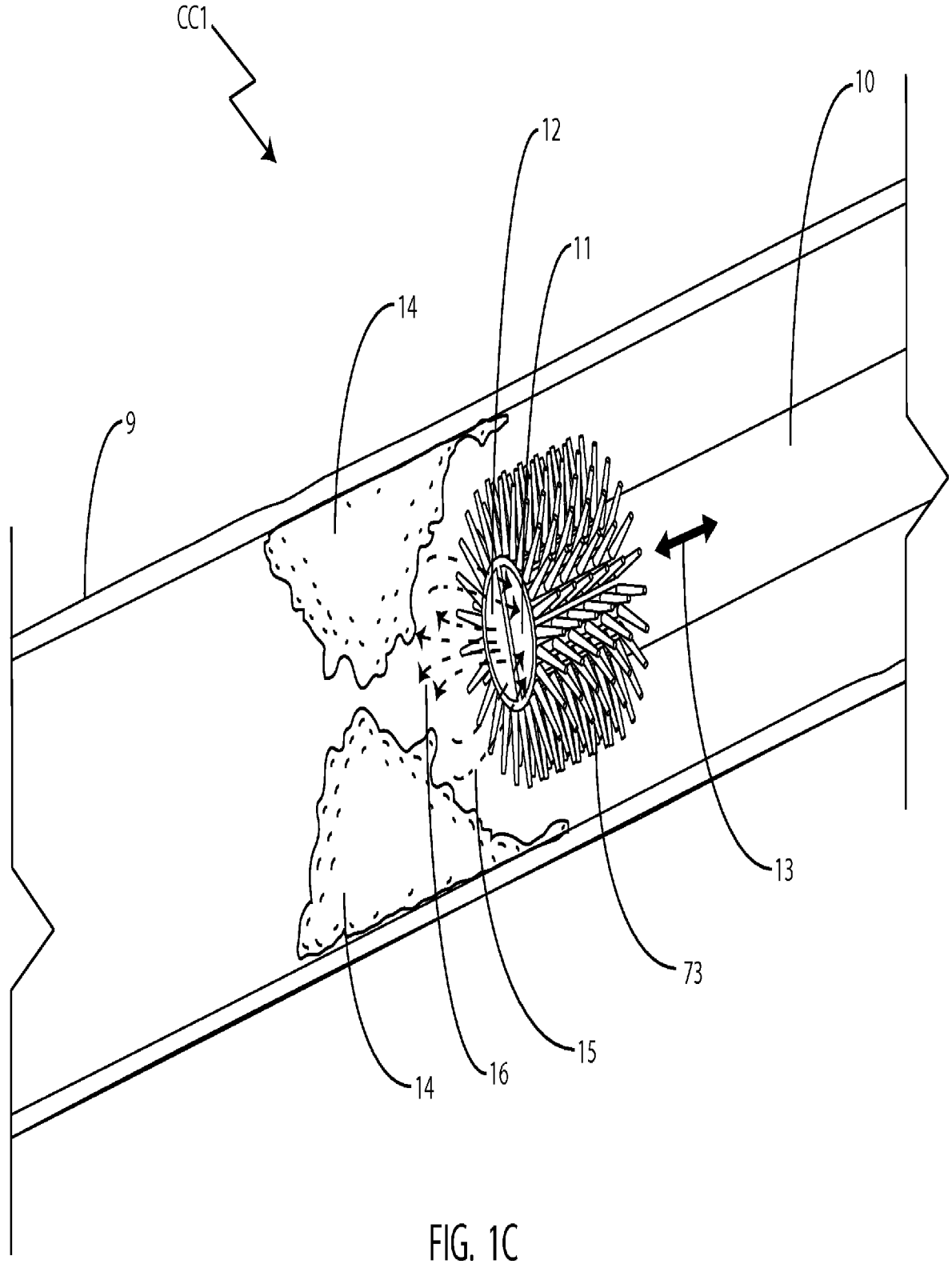


FIG. 1C

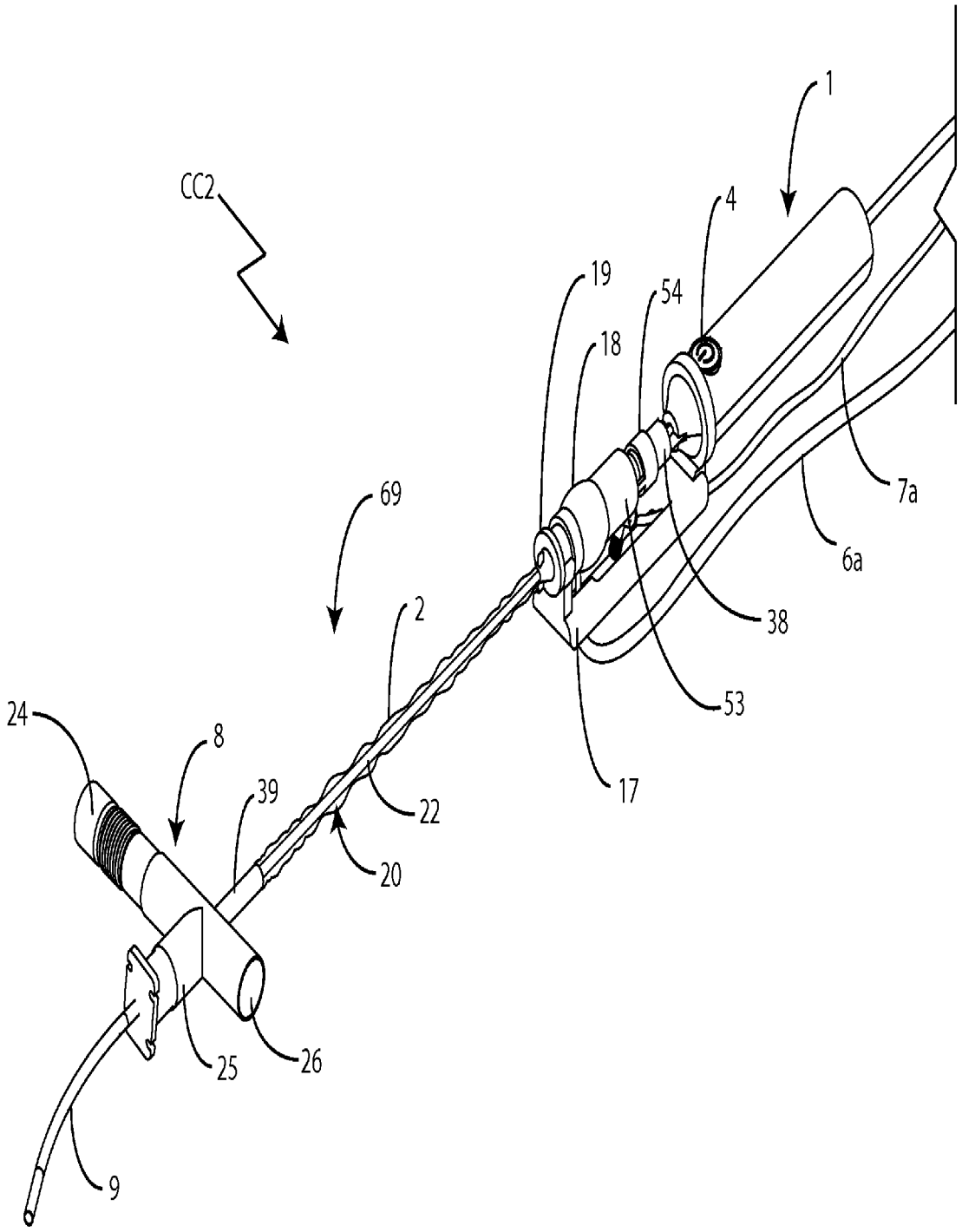
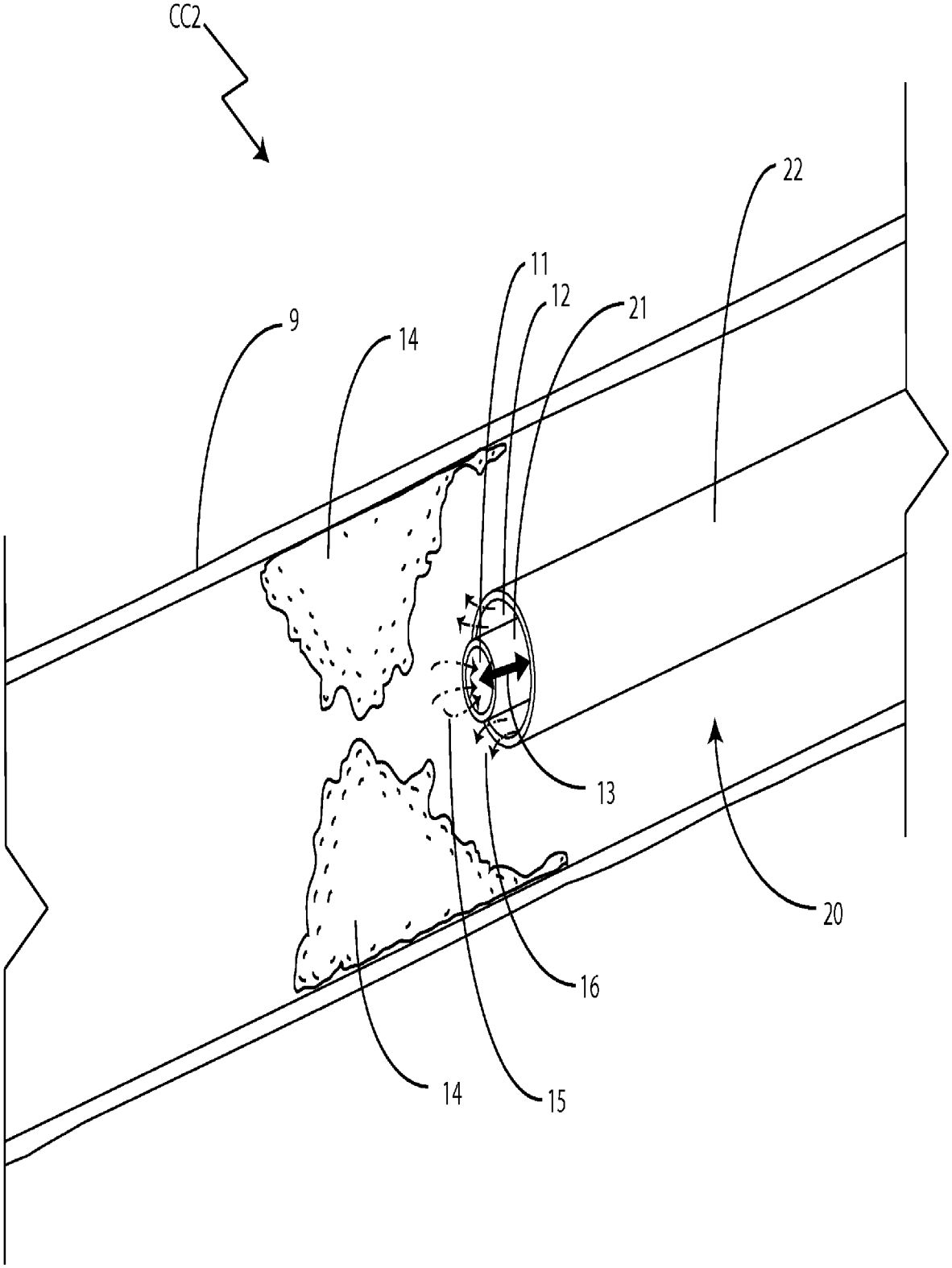


FIG. 2A



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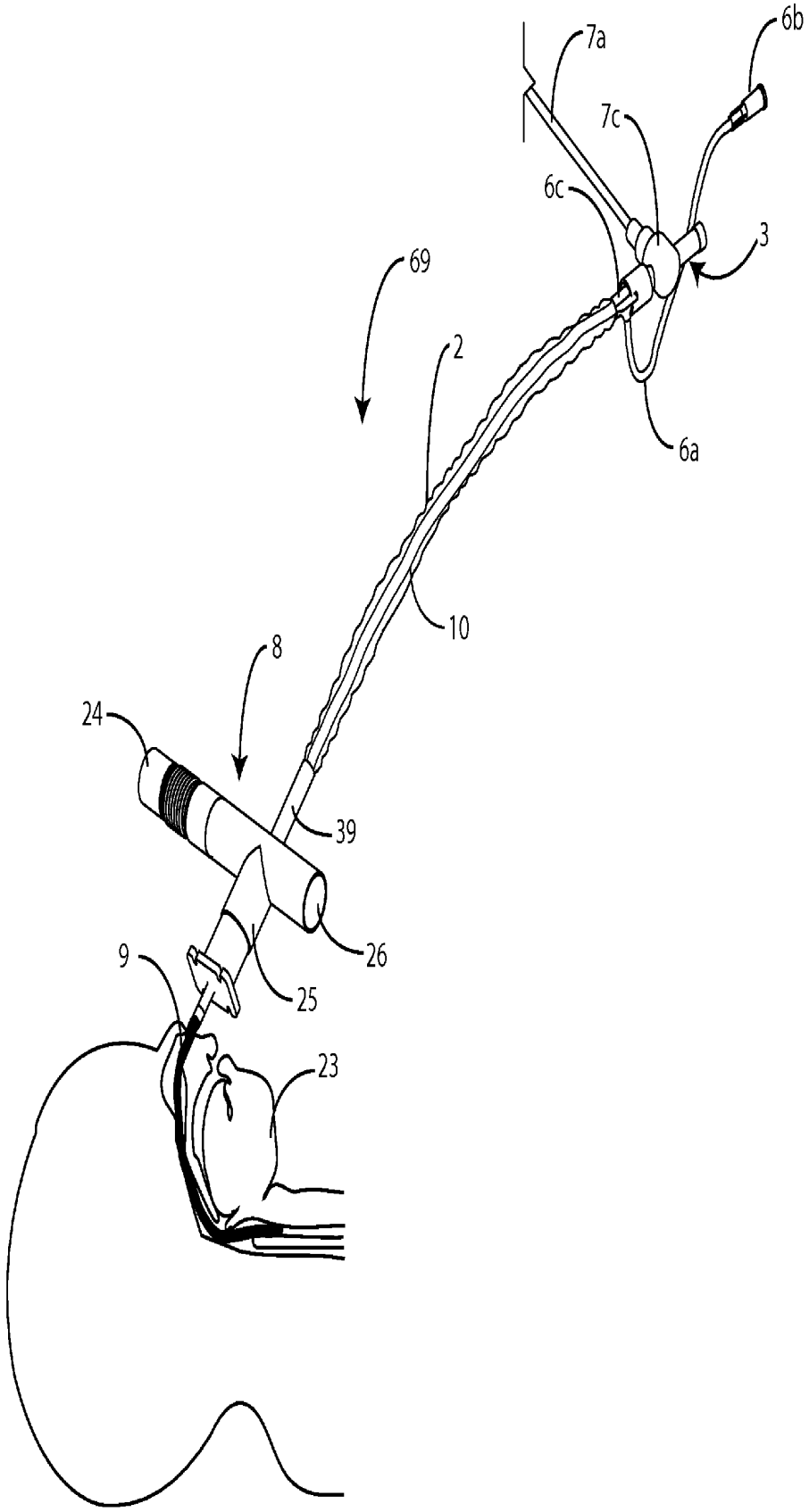


FIG. 3A

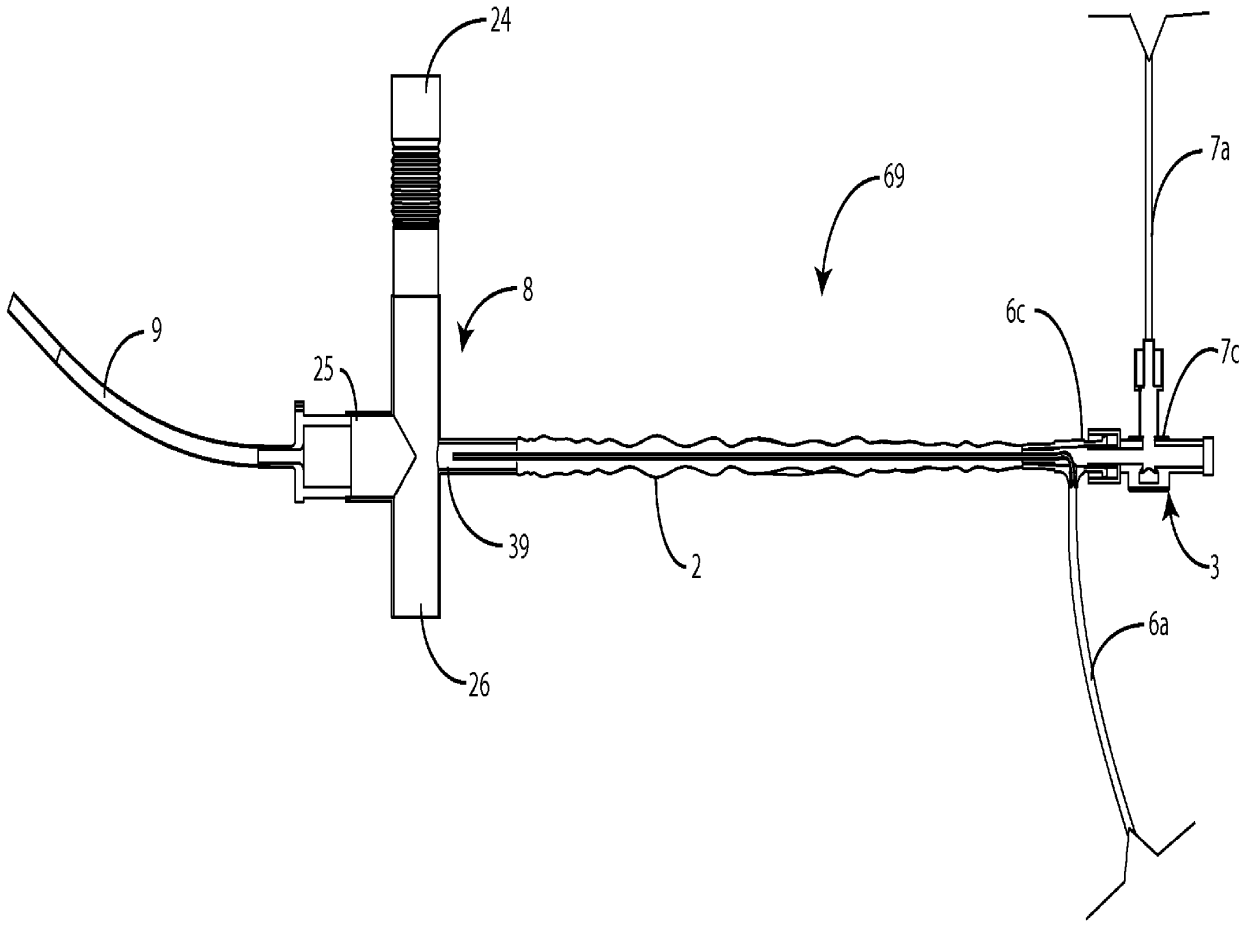


FIG. 3B

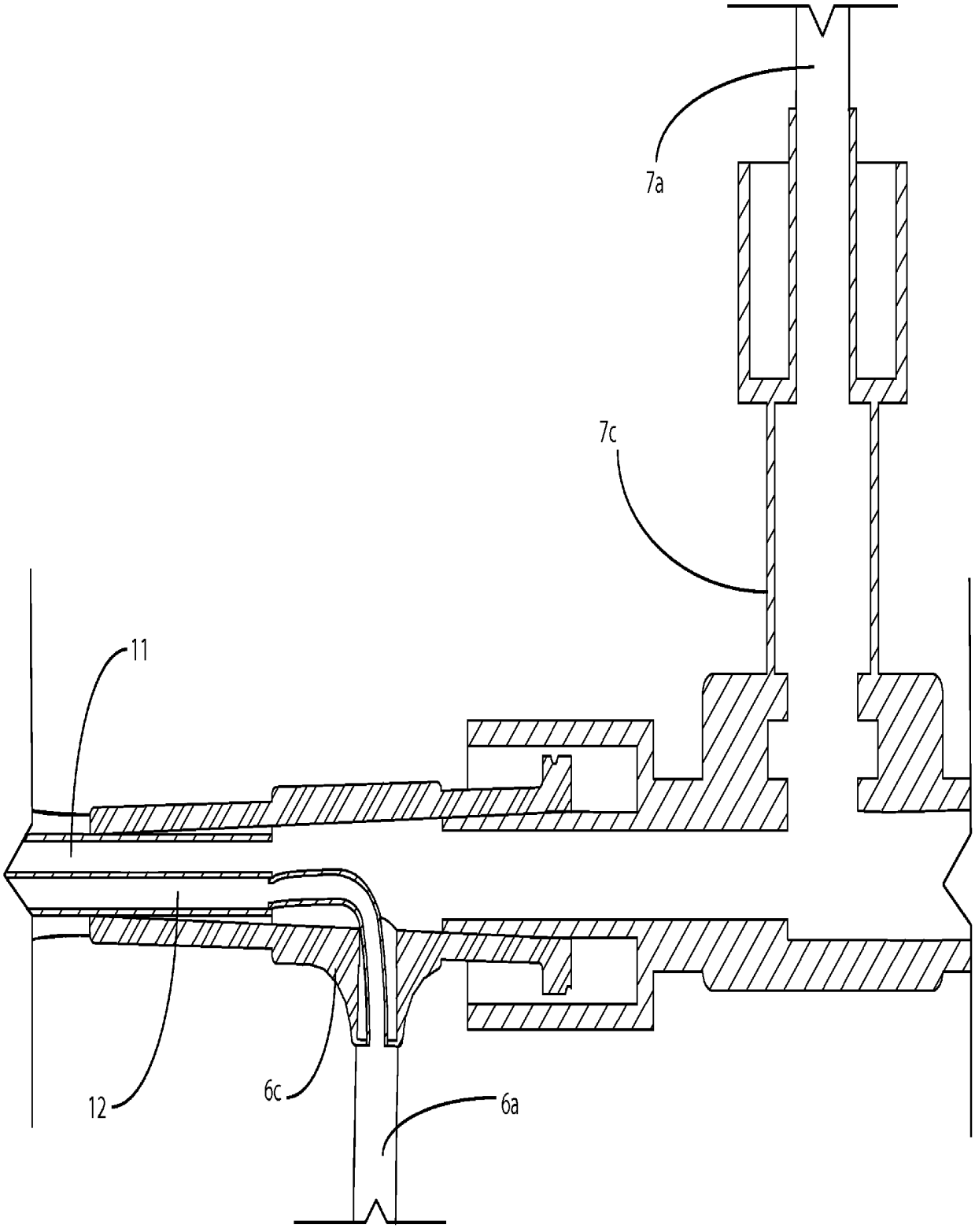


FIG. 3C

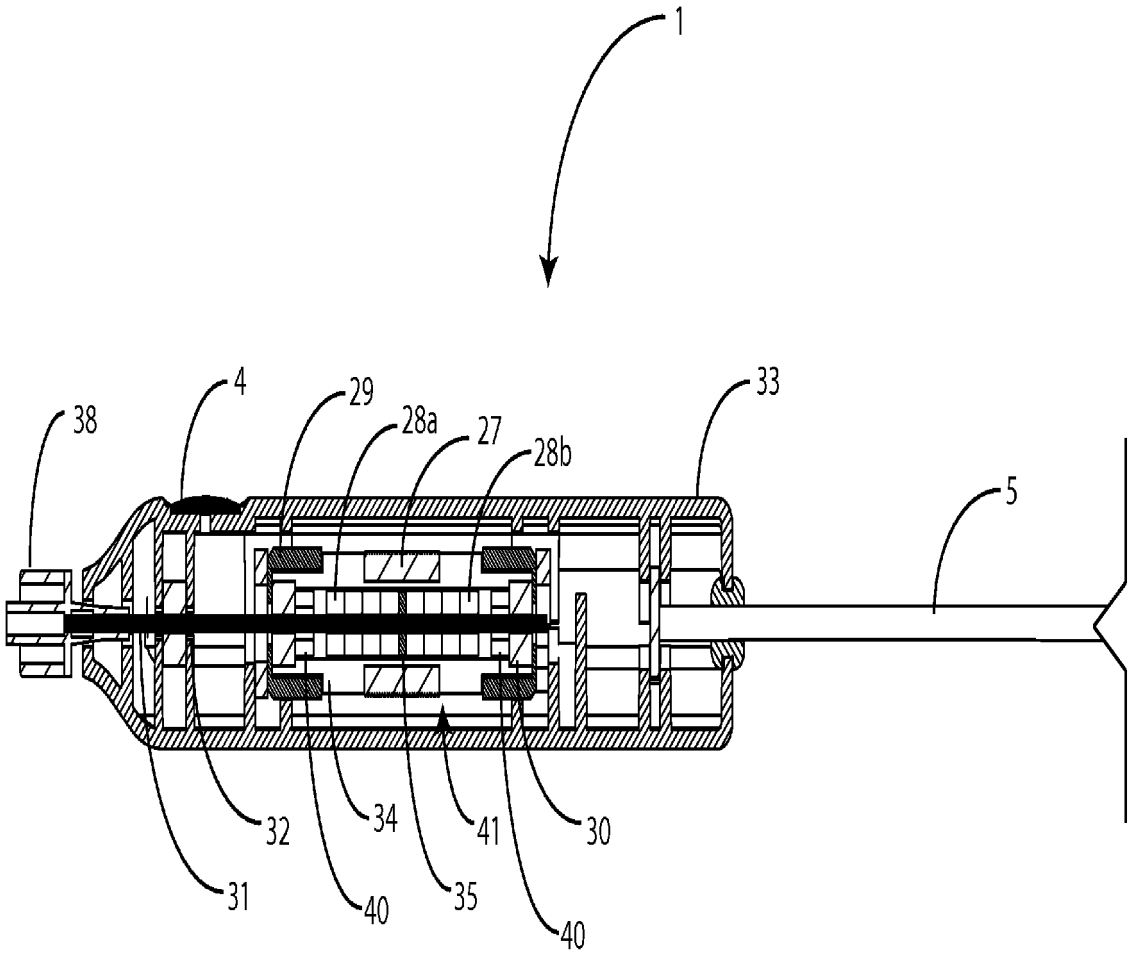


FIG. 4

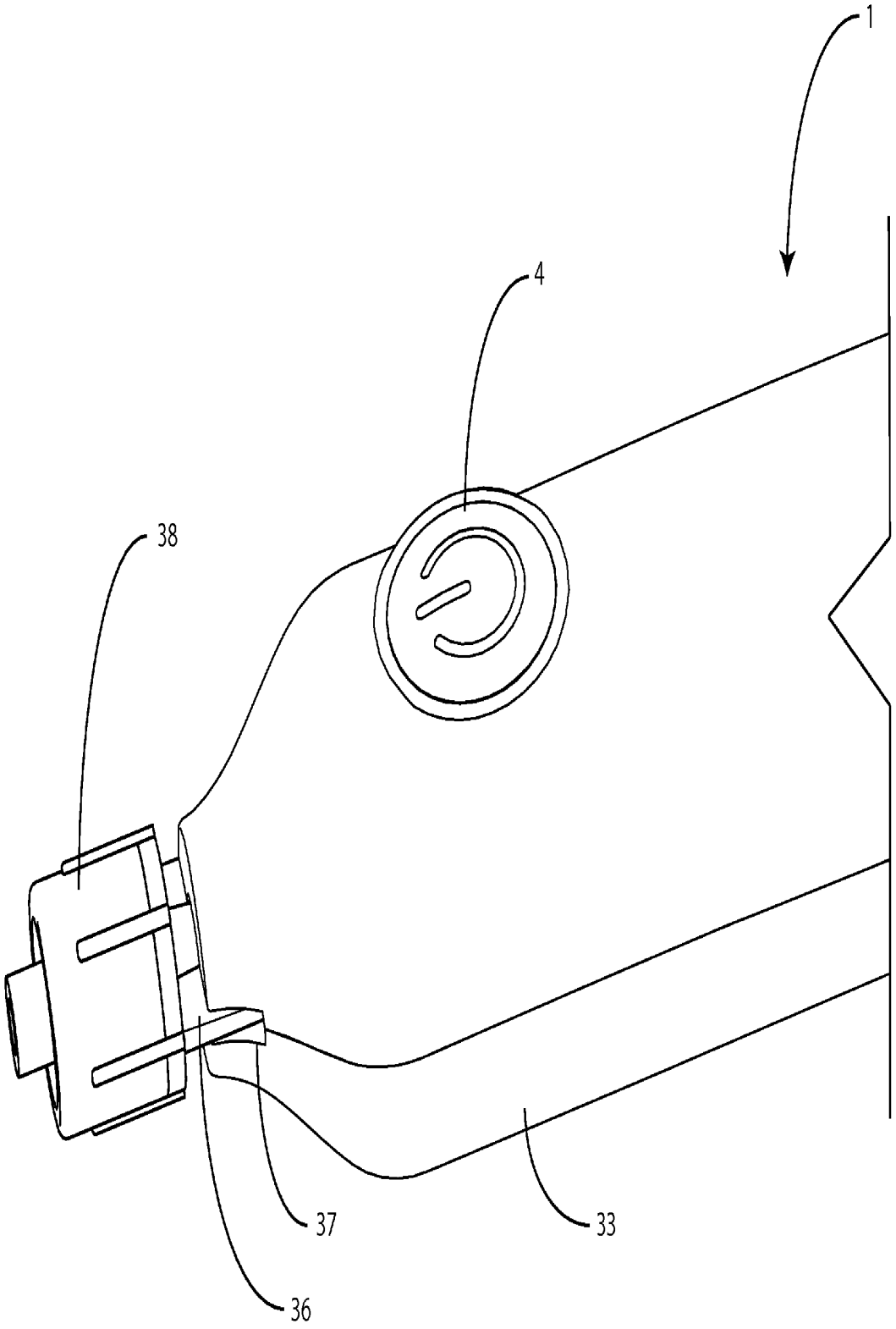


FIG. 5

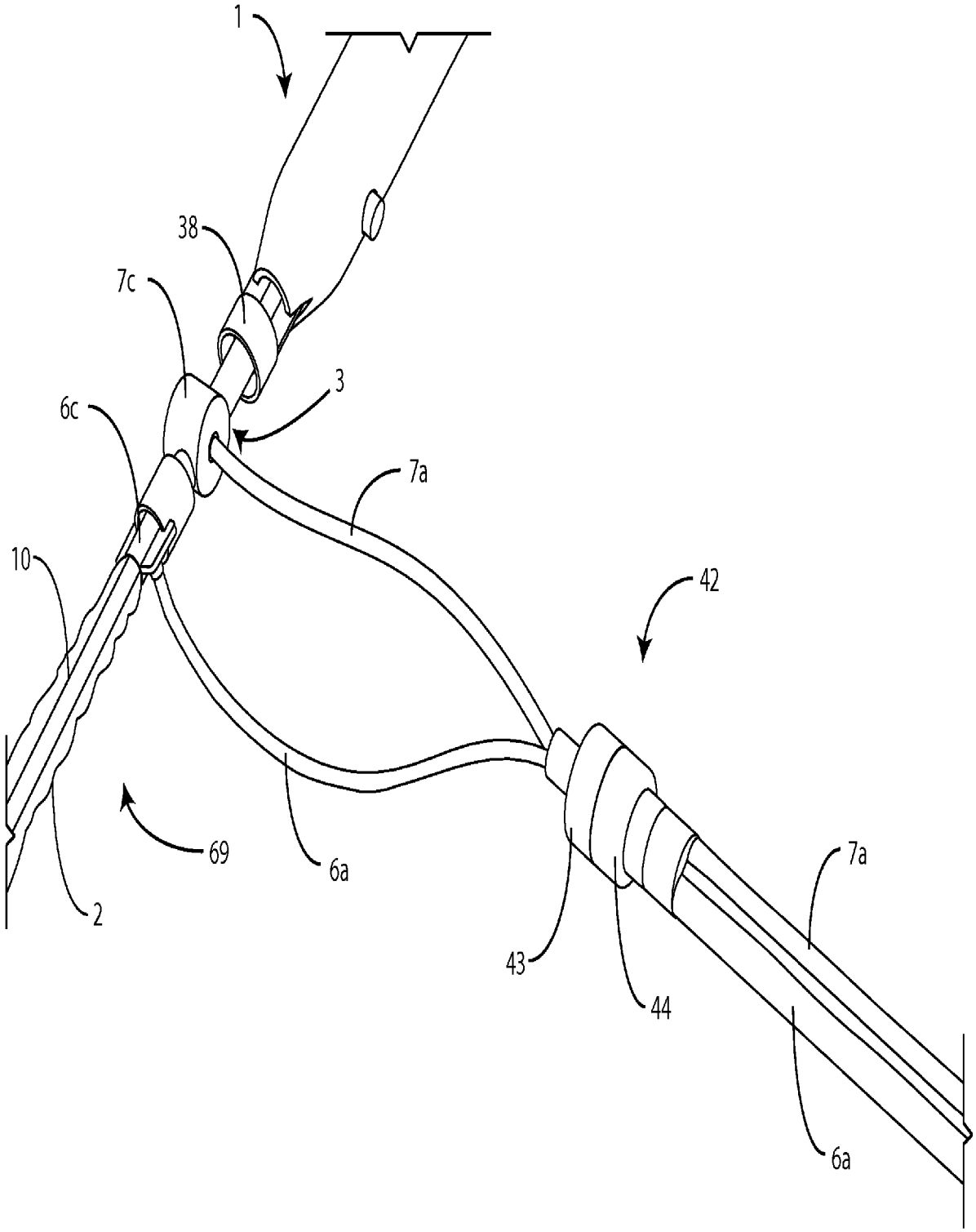


FIG. 6

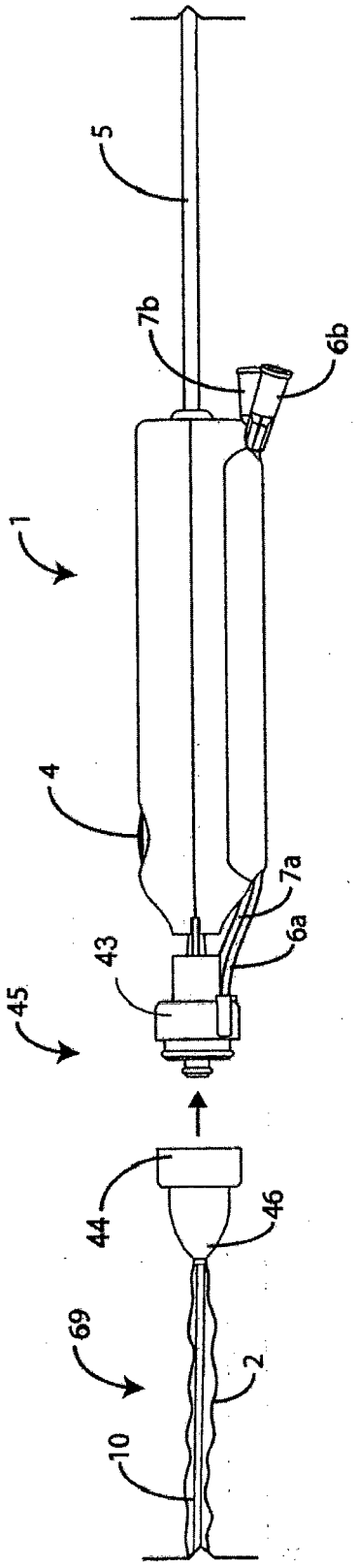


FIG. 7

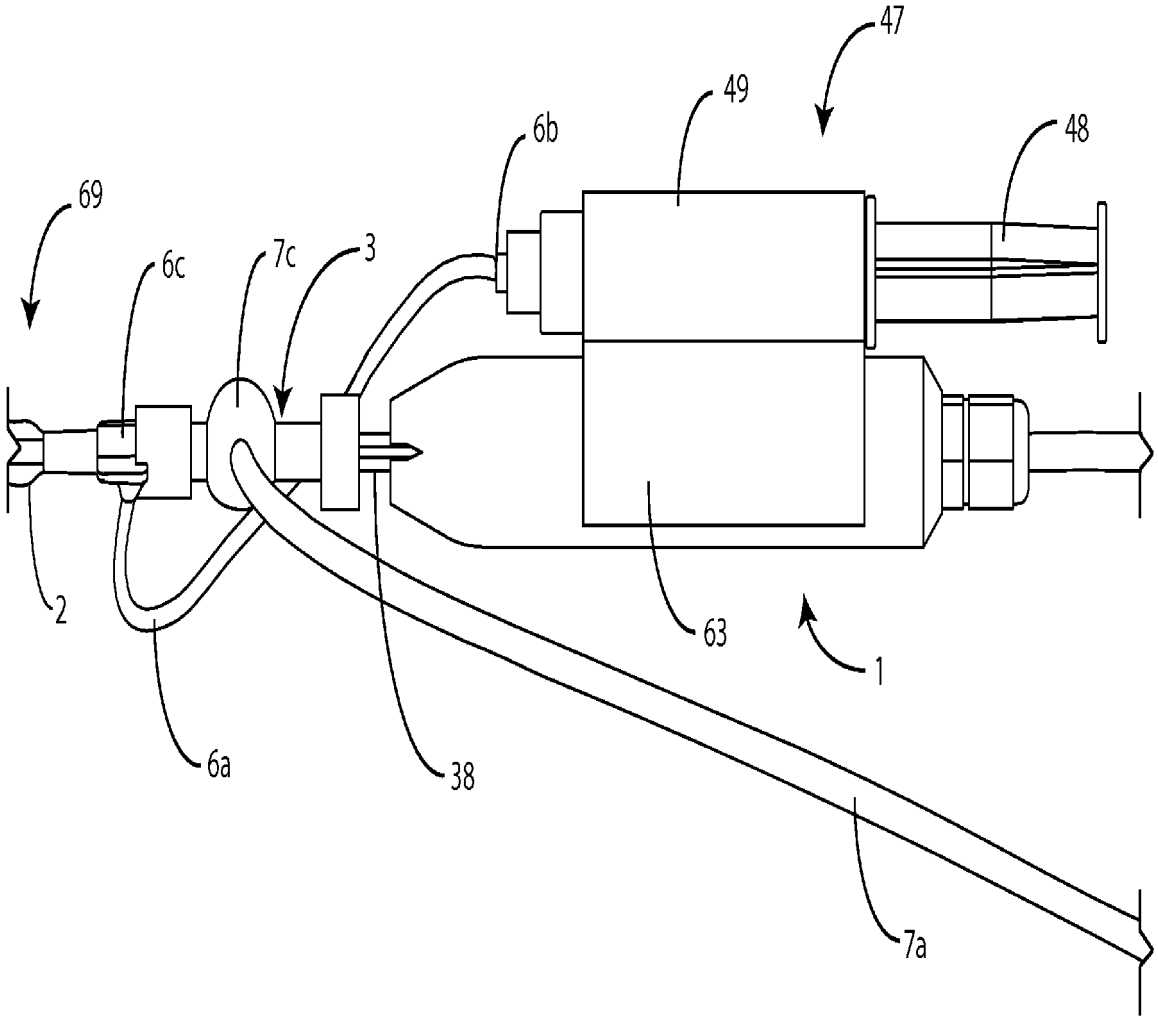


FIG. 8

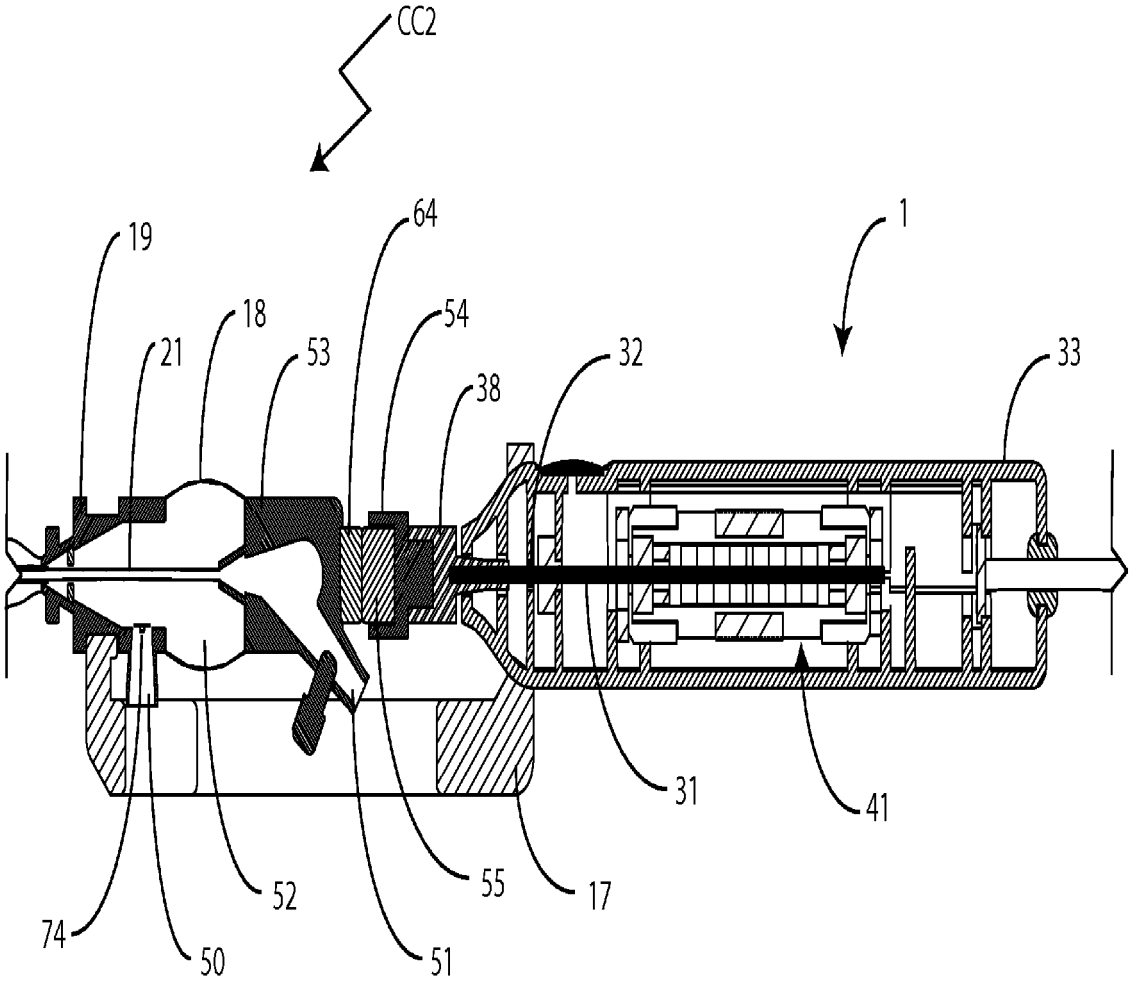


FIG. 9A

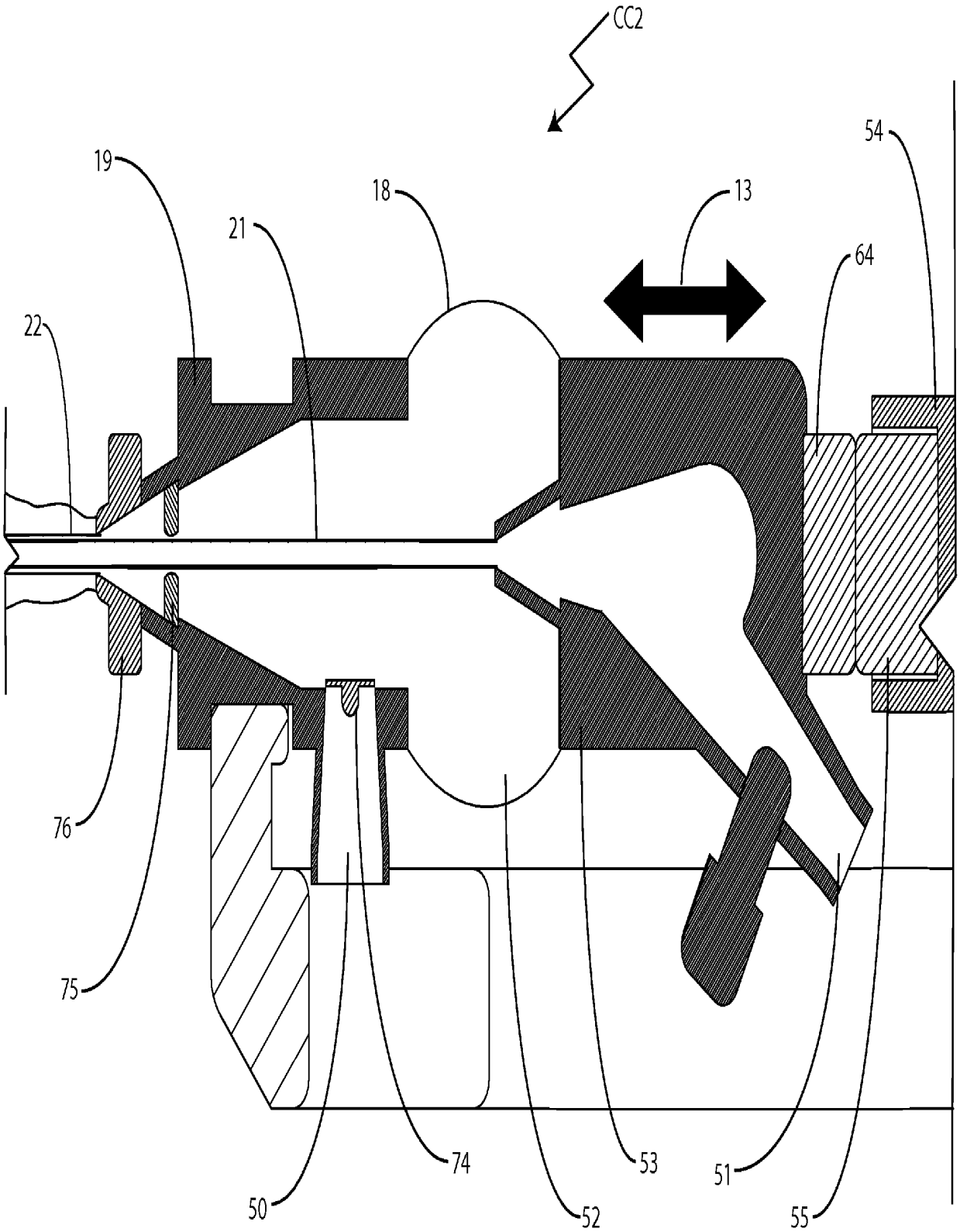
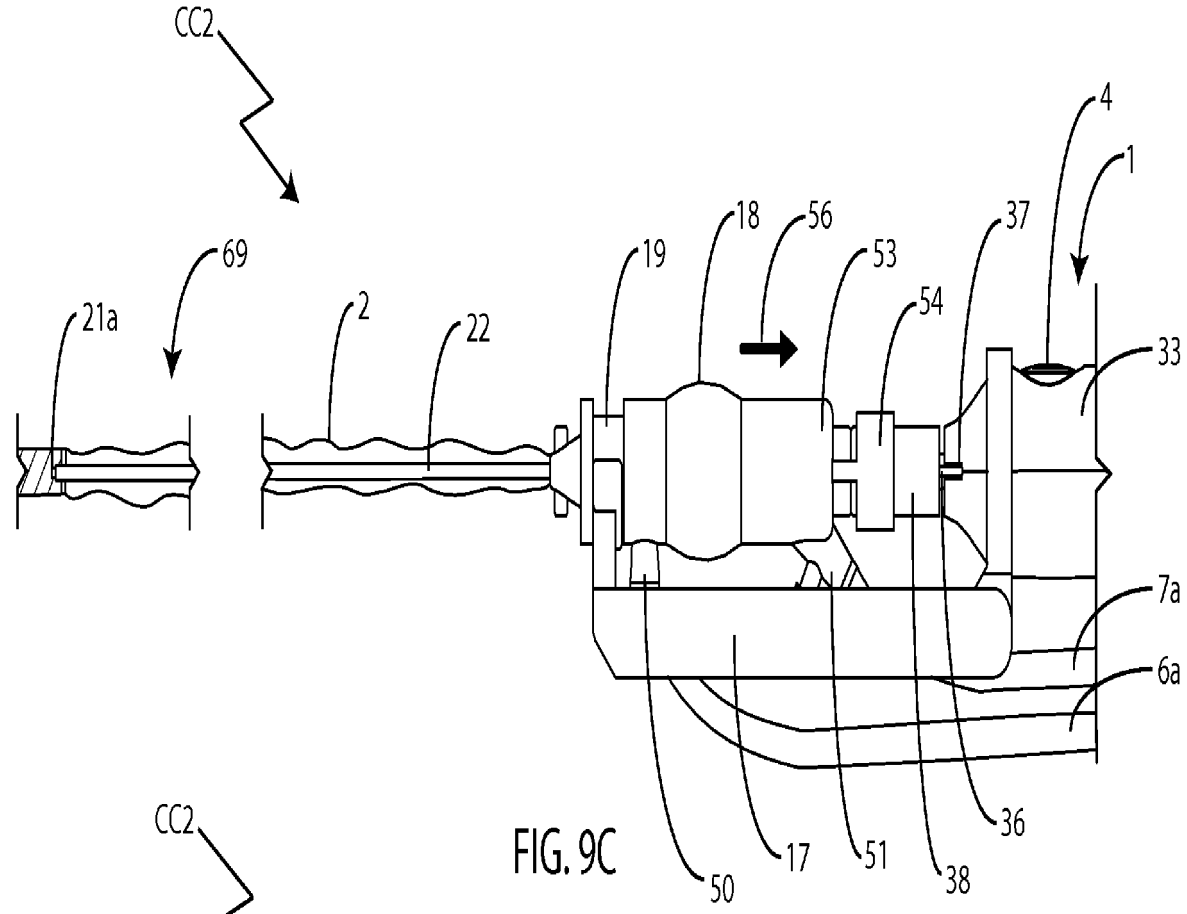


FIG. 9B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69
21a
2
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19
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54
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4
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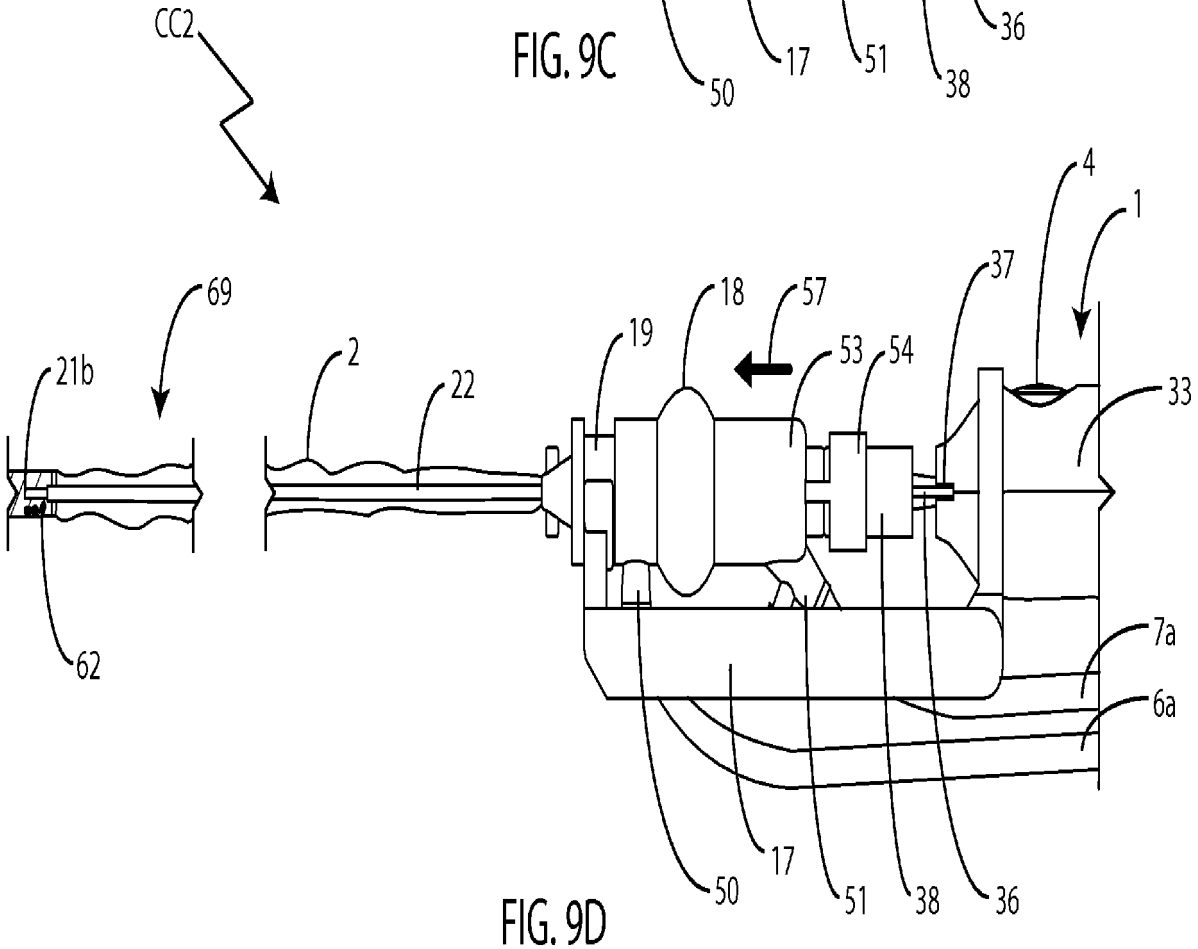
33
7a
6a
50
17
51
38
36

FIG. 9C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21b
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38
36

FIG. 9D

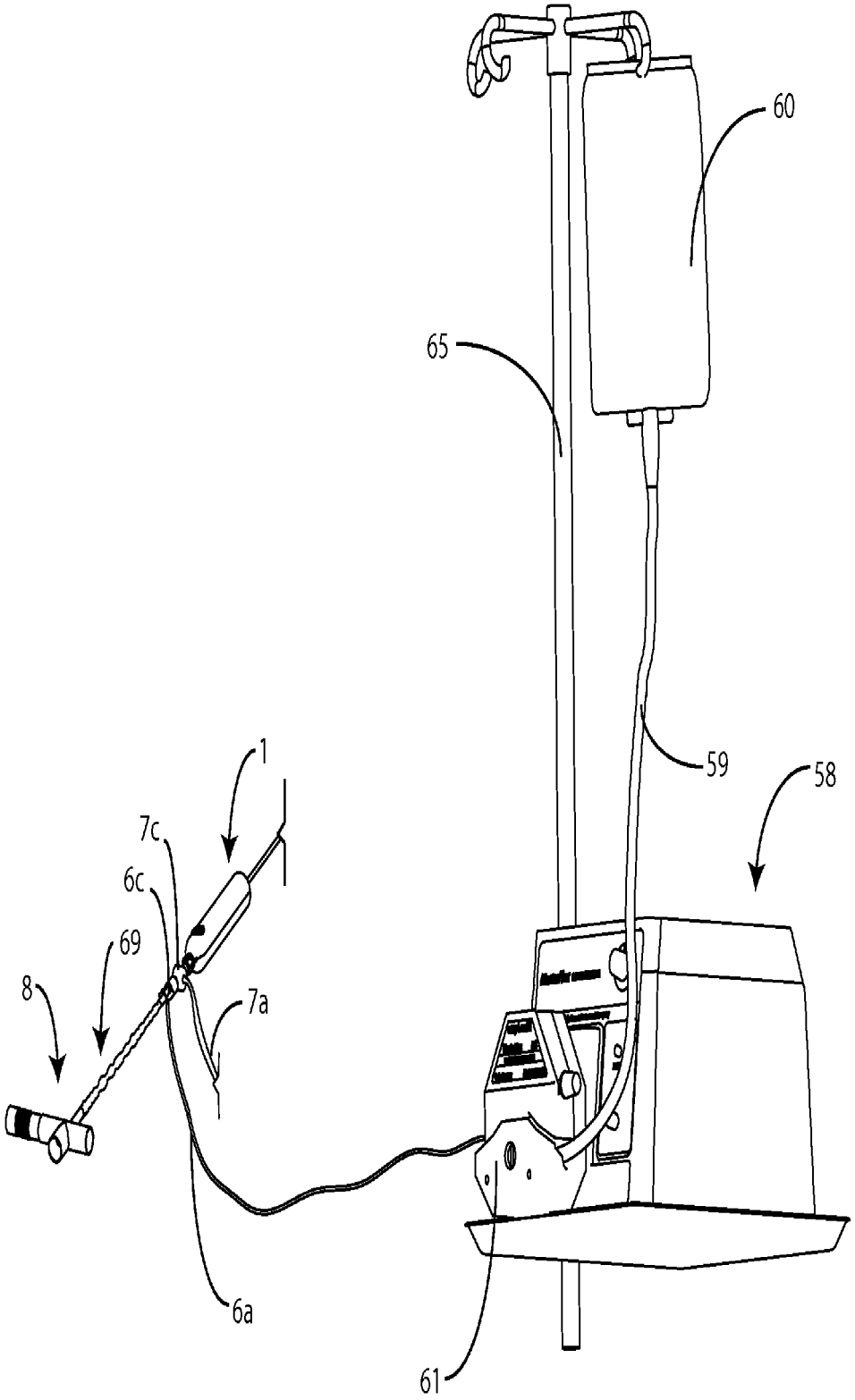

FIG. 10

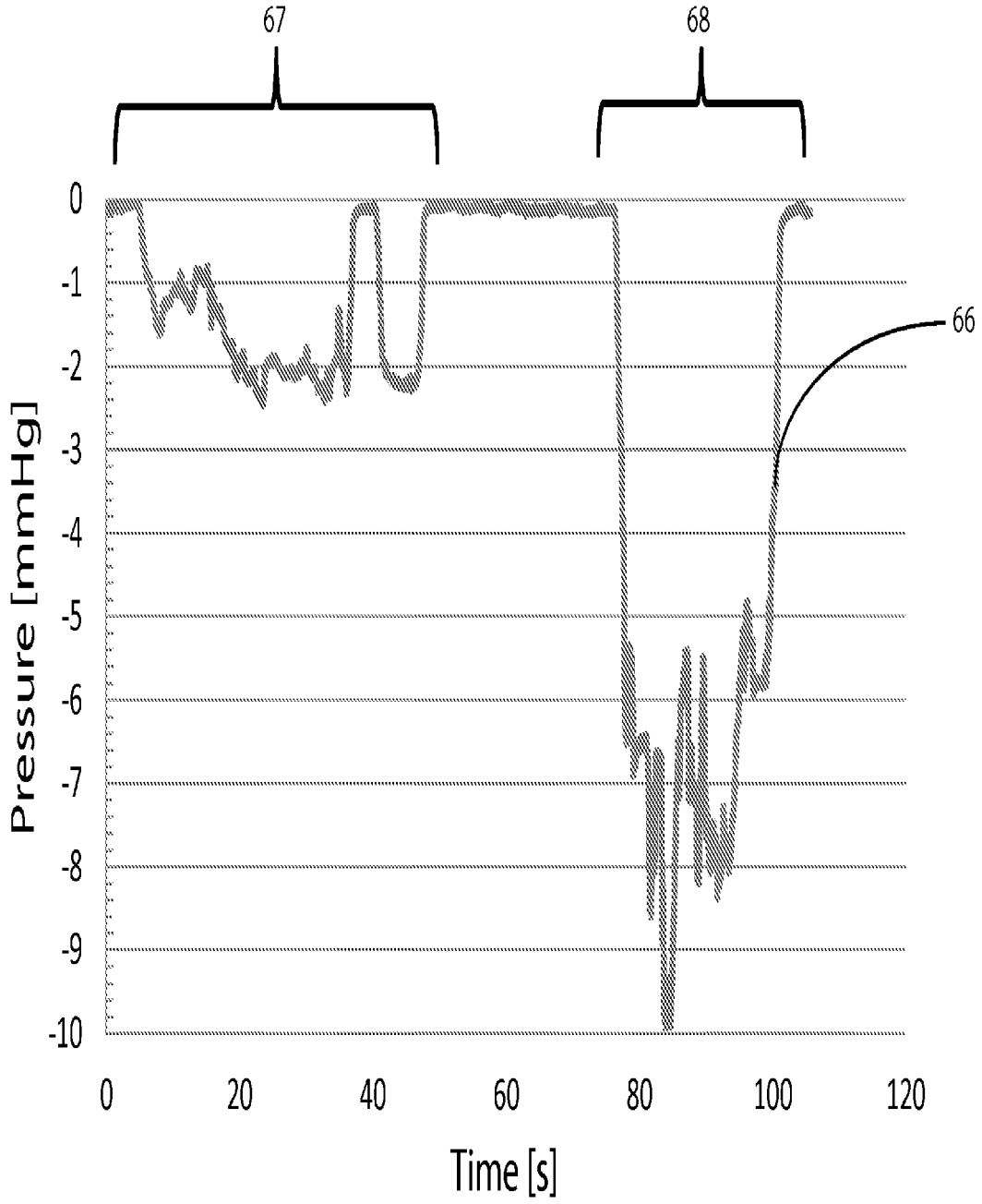
67
68
66
0
-1
-2
-3
-4
-5
-6
-7
-8
-9
-10
Pressure [mmHg]
0
20
40
60
80
100
120
Time [s]

FIG. 11

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 14052278 B **[0001]**
- US 61712437 B **[0001]**