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(12) **United States Patent**  
**Mulvihill et al.**

(10) **Patent No.:** **US 9,352,122 B2**  
(45) **Date of Patent:** **May 31, 2016**

(54) **DEVICES FOR CLEARING BLOCKAGES IN SMALL BORE IN-SITU ARTIFICIAL LUMENS**

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(72) Inventors: **Maureen L Mulvihill**, Bellefonte, PA (US); **Jeffrey P Klaus**, State College, PA (US); **Casey A Scruggs**, Middleburg, PA (US)

(73) Assignee: **Actuated Medical, Inc.**, Bellefonte, PA (US)

(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 390 days.

(21) Appl. No.: **13/863,108**

(22) Filed: **Apr. 15, 2013**

(65) **Prior Publication Data**

US 2013/0237930 A1 Sep. 12, 2013

**Related U.S. Application Data**

(63) Continuation-in-part of application No. 13/683,852, filed on Nov. 21, 2012, which is a continuation-in-part of application No. 13/571,104, filed on Aug. 9, 2012, now Pat. No. 8,690,861, which is a continuation of

(Continued)

(51) **Int. Cl.**

**A61M 25/00** (2006.01)  
**A61M 5/00** (2006.01)  
**A61M 31/00** (2006.01)  
**A61M 25/16** (2006.01)  
**A61M 39/02** (2006.01)  
**A61M 27/00** (2006.01)

(52) **U.S. Cl.**

CPC ..... **A61M 25/0082** (2013.01); **A61M 25/00** (2013.01); **A61M 2025/0019** (2013.01)

(58) **Field of Classification Search**

CPC ..... **A61M 5/00**; **A61M 25/00**; **A61M 31/00**; **A61M 25/16**; **A61M 39/02**; **A61M 27/00**; **A61K 9/02**

See application file for complete search history.

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*Primary Examiner* — Tatyana Zalukaeva

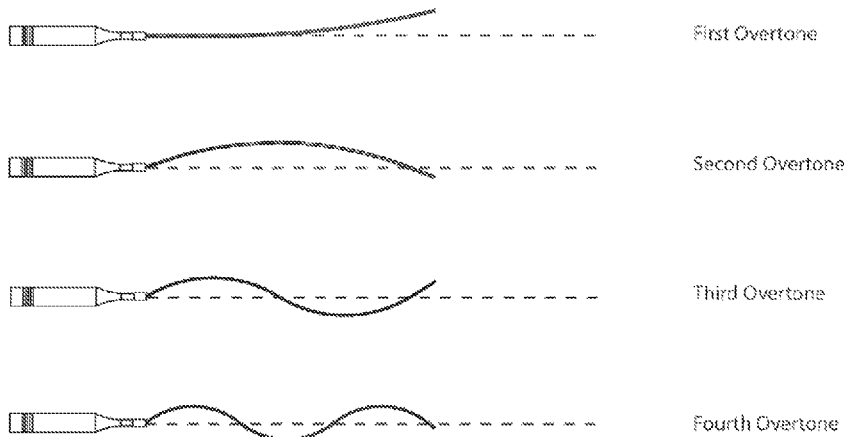
*Assistant Examiner* — Ilya Treyger

(74) *Attorney, Agent, or Firm* — Metz Lewis Brodman Must O'Keefe LLC

(57) **ABSTRACT**

A device for clearing blockages is provided that may have a tube that is slit. The tube may have a lumen. A reciprocating member may be provided and a portion of the reciprocating member may be located within the lumen.

**17 Claims, 63 Drawing Sheets**



**Related U.S. Application Data**

application No. 12/964,252, filed on Dec. 9, 2010, now Pat. No. 8,262,645, which is a continuation-in-part of application No. 12/274,937, filed on Nov. 20, 2008, now abandoned.

- (60) Provisional application No. 61/563,405, filed on Nov. 23, 2011, provisional application No. 61/099,737, filed on Sep. 24, 2008, provisional application No. 60/989,484, filed on Nov. 21, 2007.

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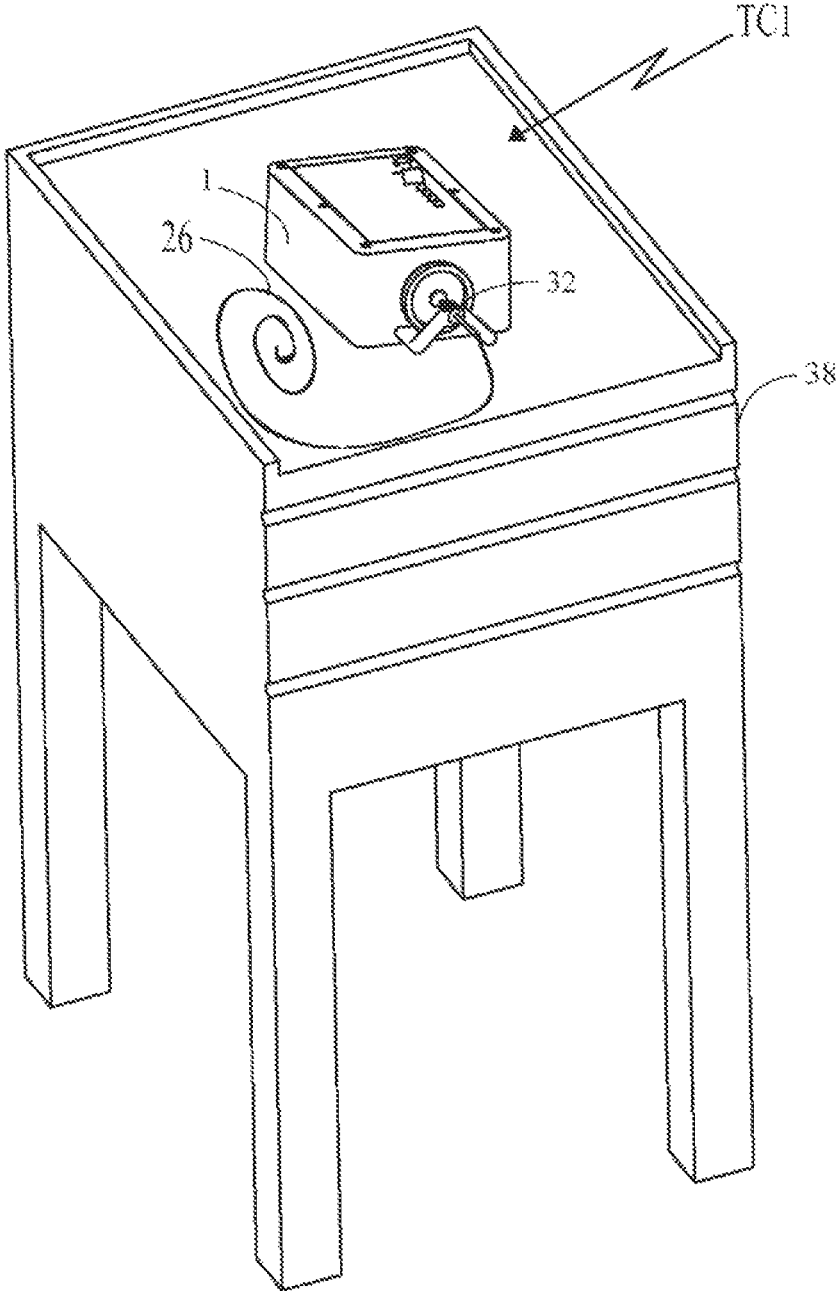


FIG. 1

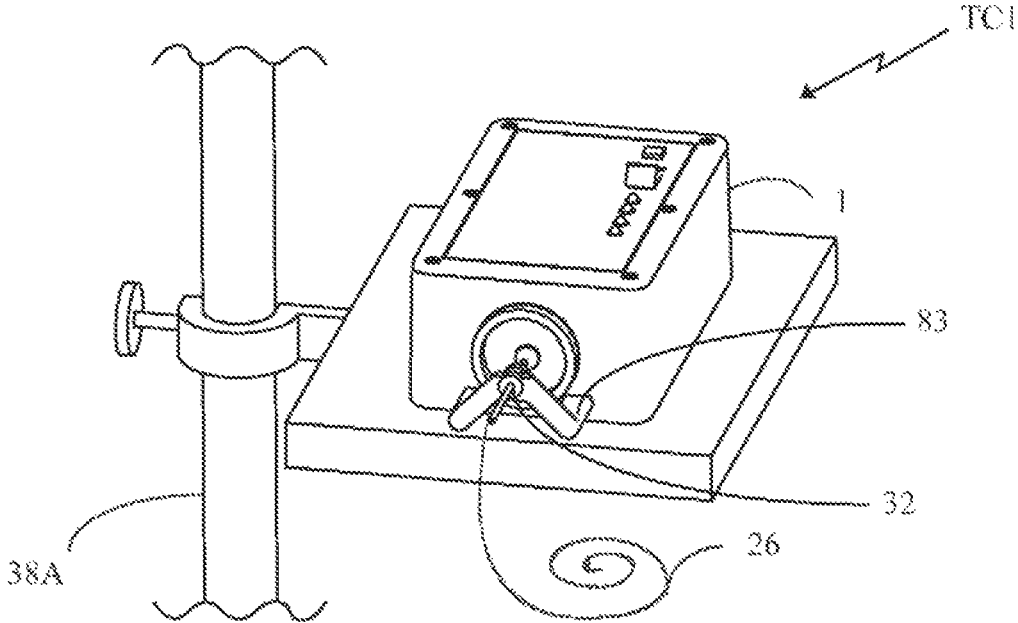


FIG. 1A

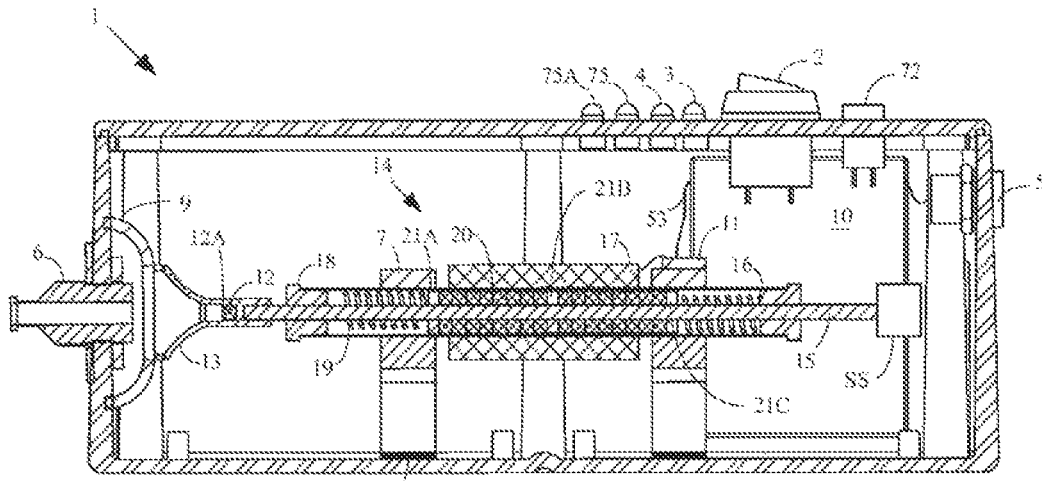


FIG. 2A

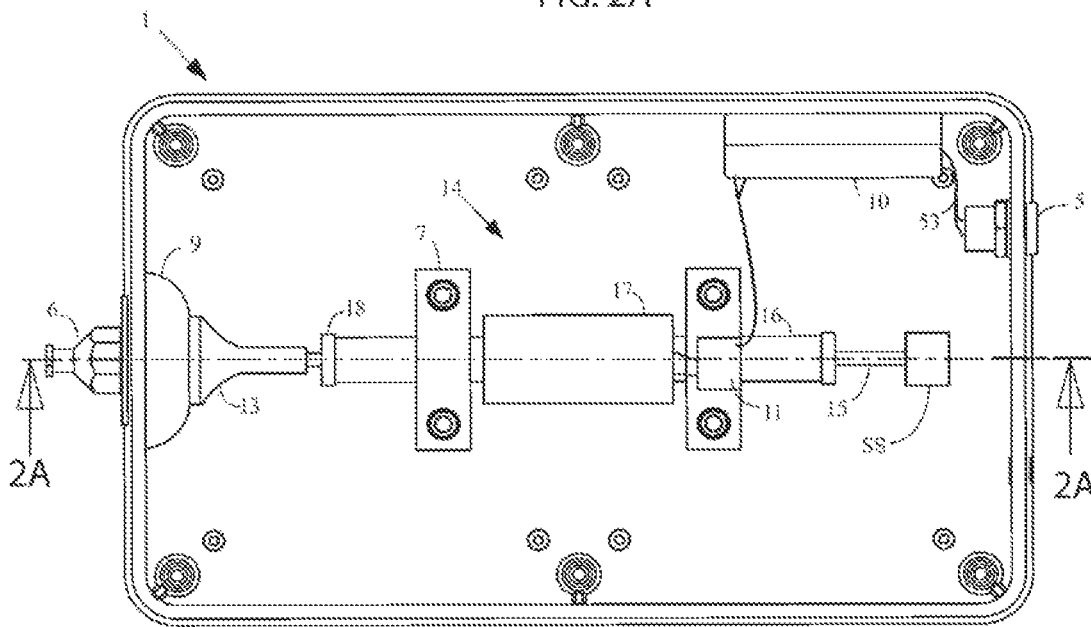


FIG. 2

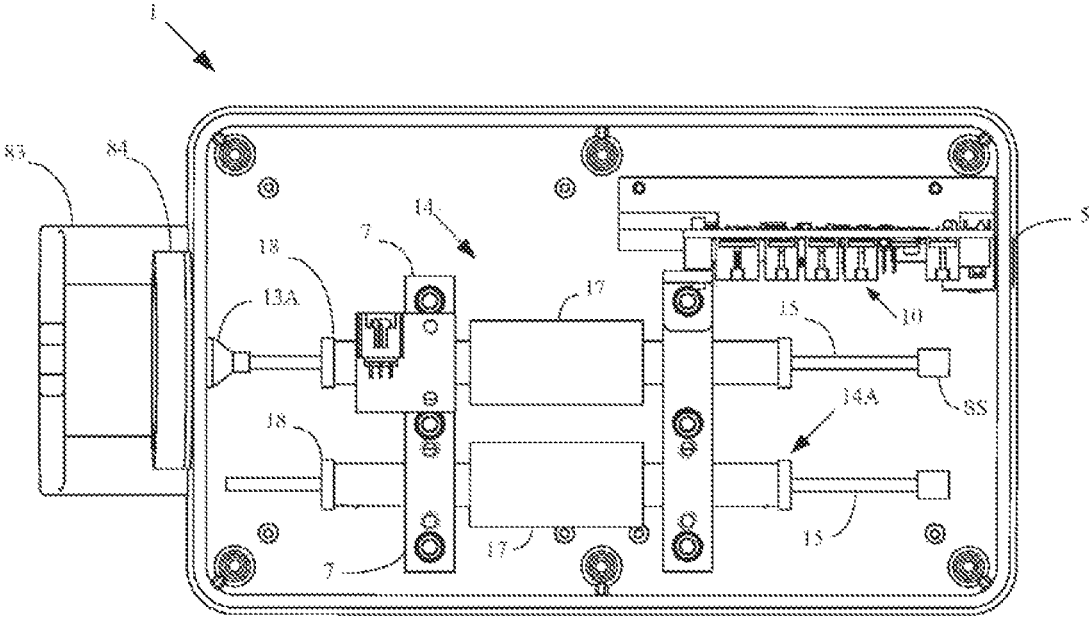


FIG. 28

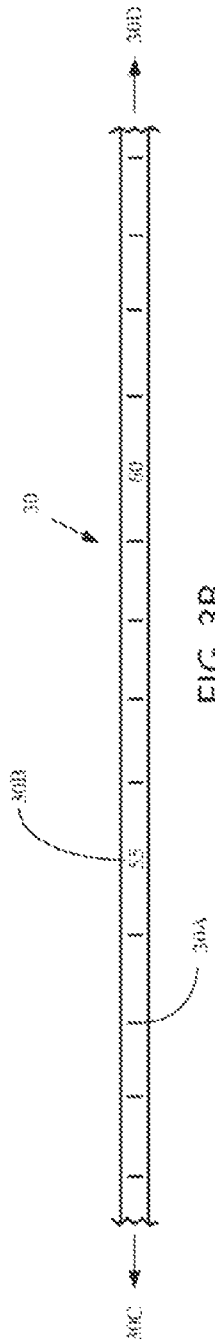


FIG. 3B

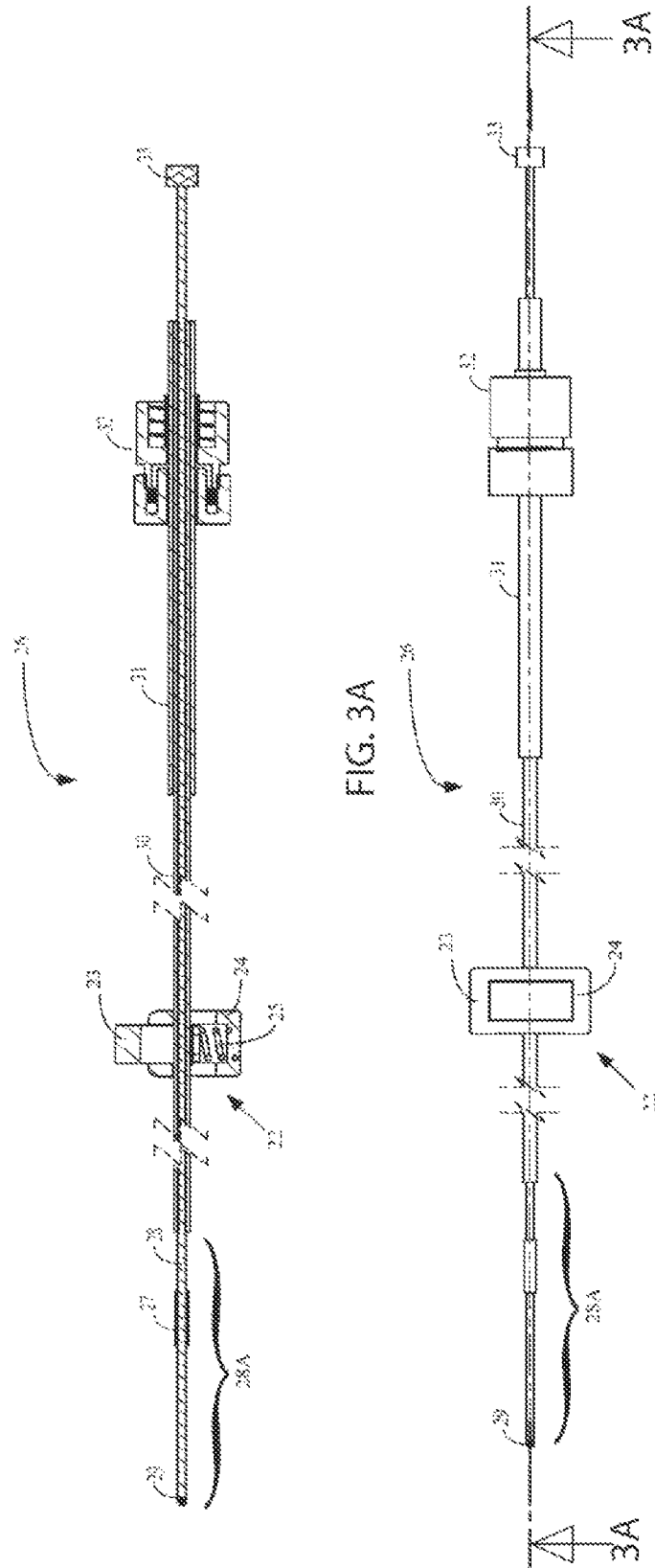


FIG. 3A

FIG. 3

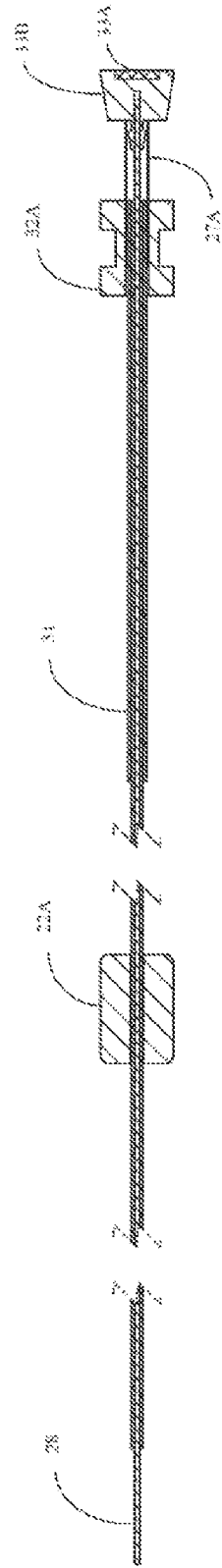


FIG. 3D

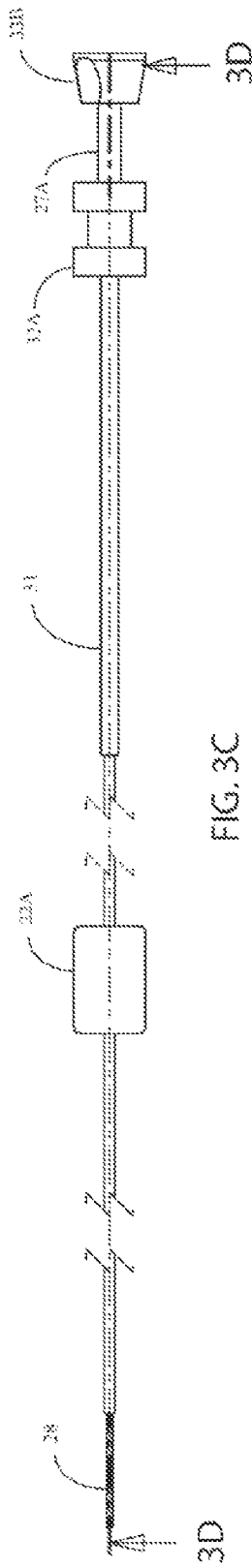


FIG. 3C



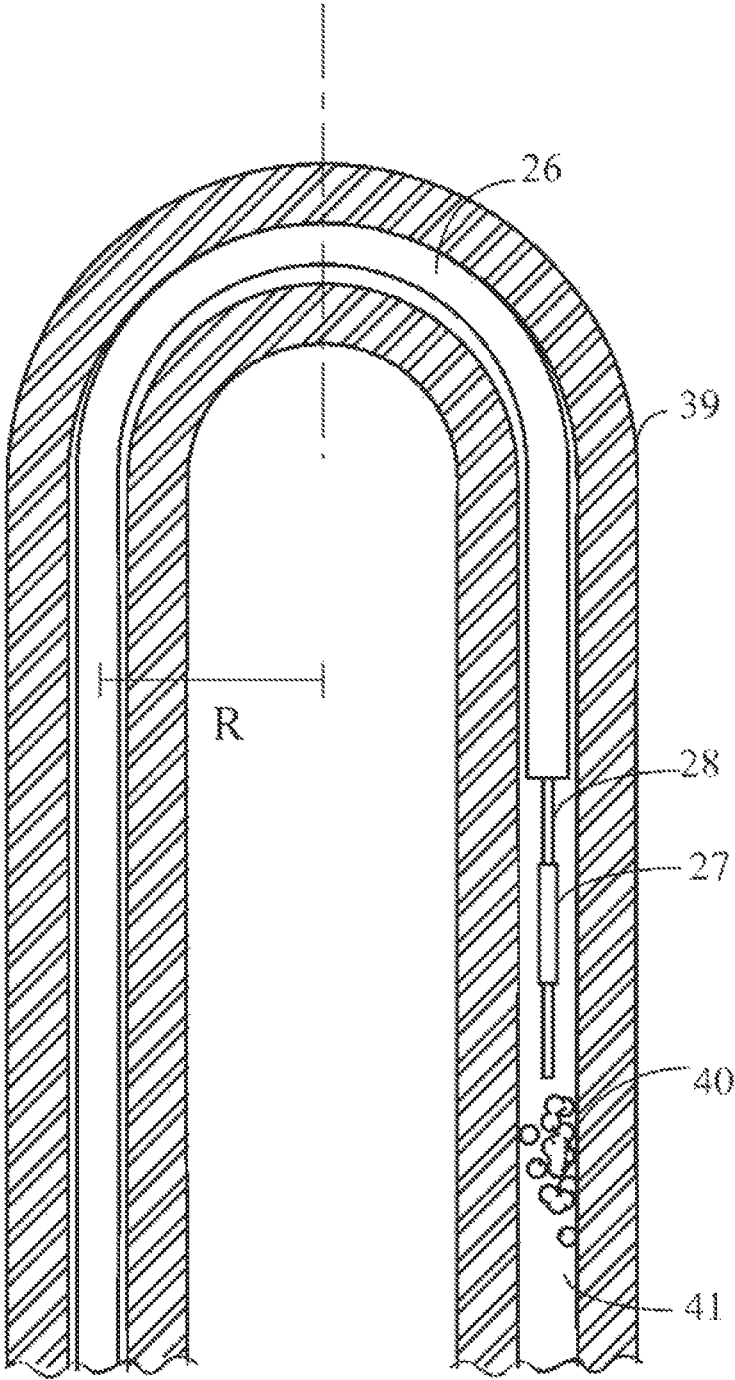


FIG. 4

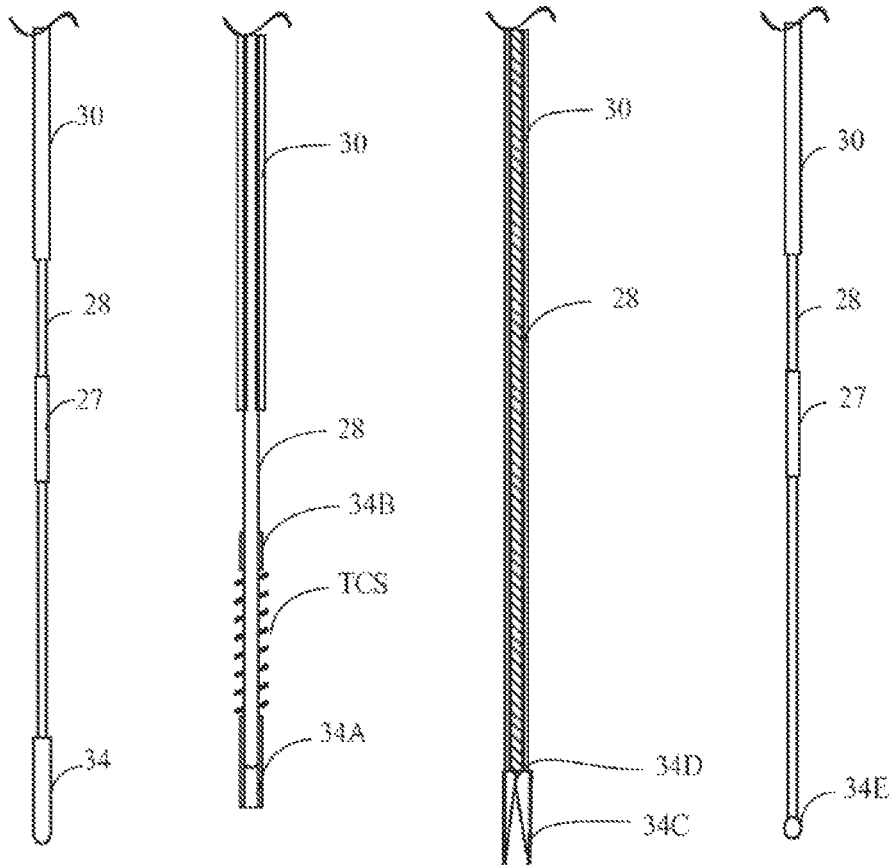


FIG. 5A

FIG. 5B

FIG. 5C

FIG. 5D

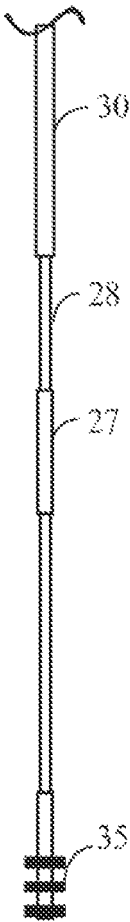


FIG. 6

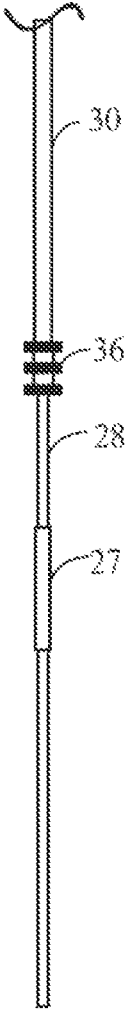


FIG. 7

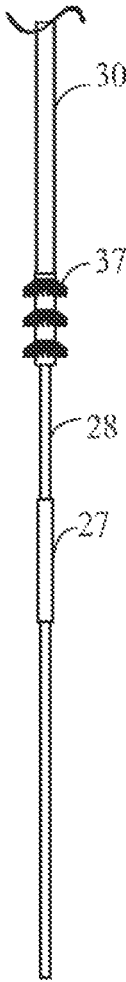
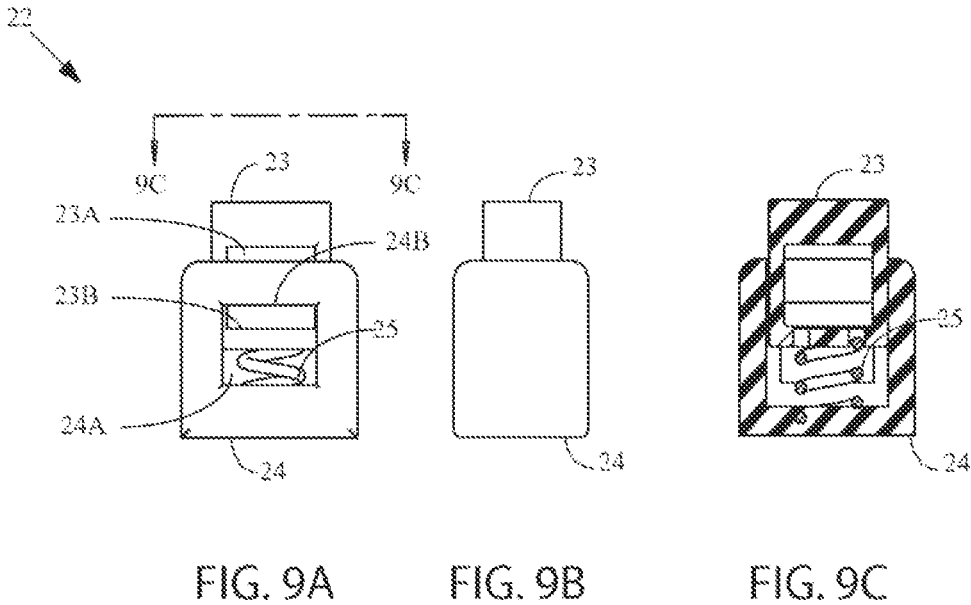


FIG. 8



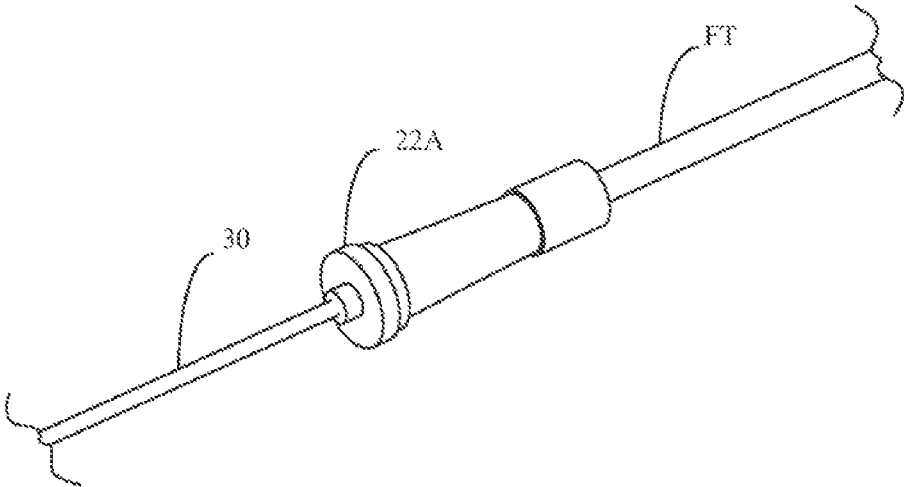


FIG. 9D

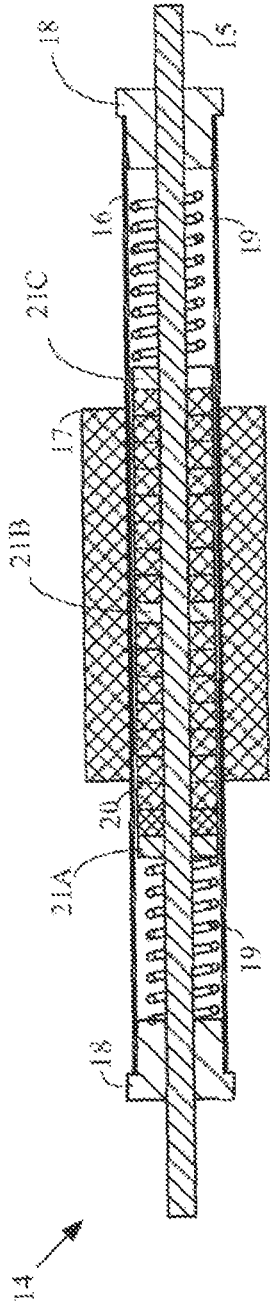


FIG. 10A

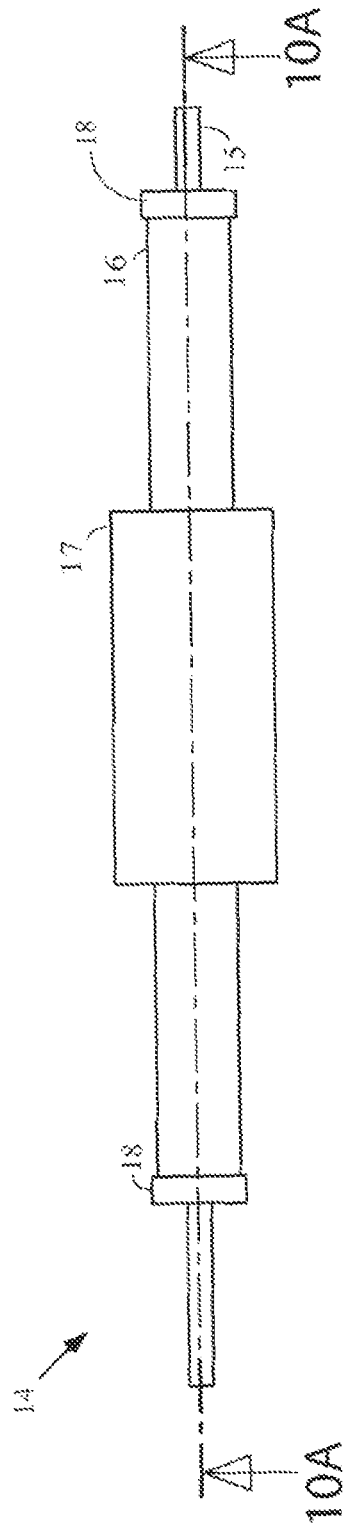


FIG. 10

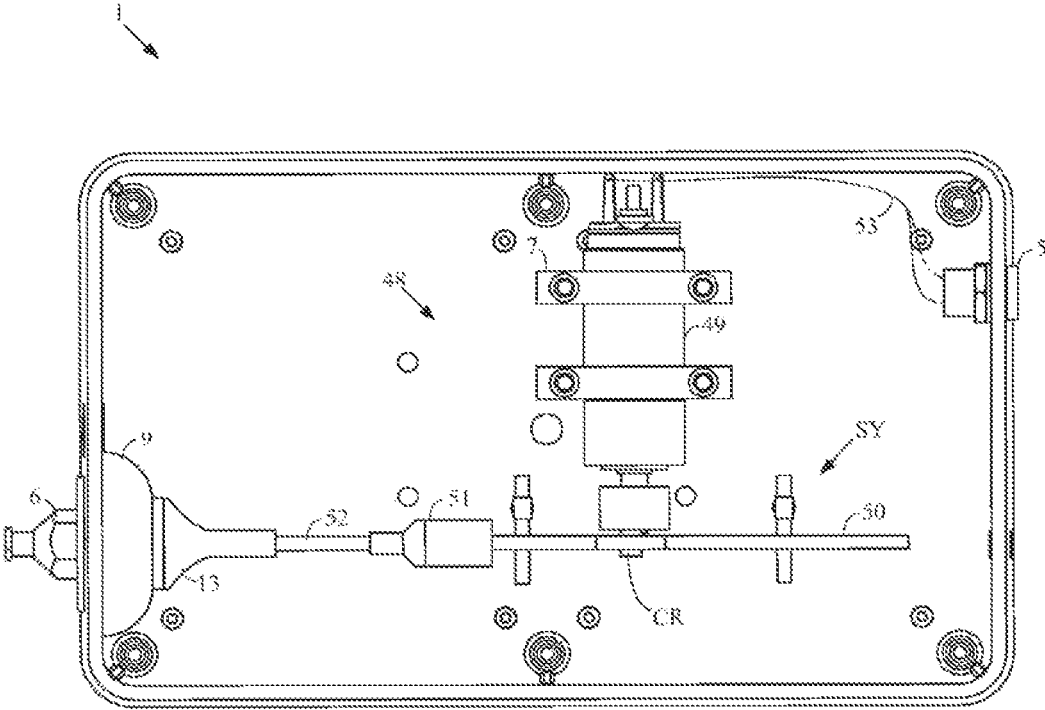


FIG. 11

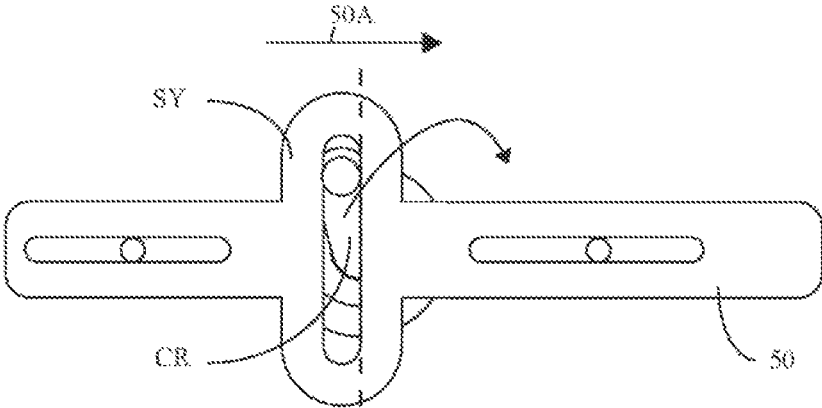


FIG. 11A

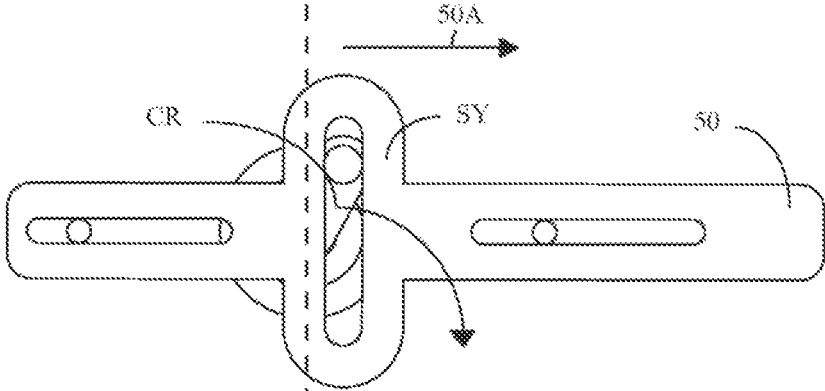


FIG. 11B

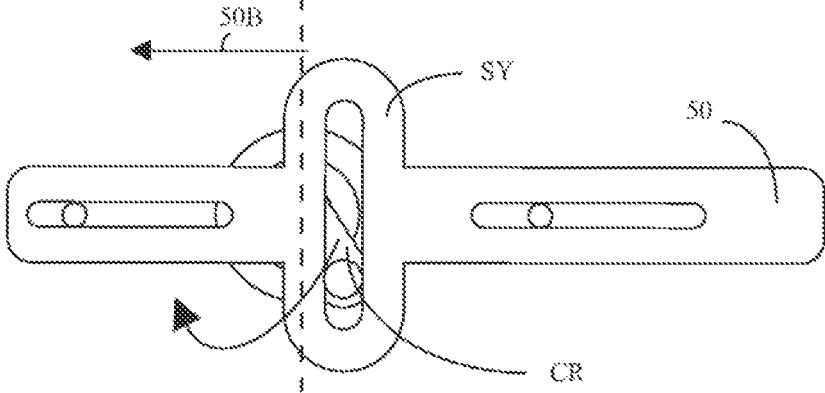


FIG. 11C



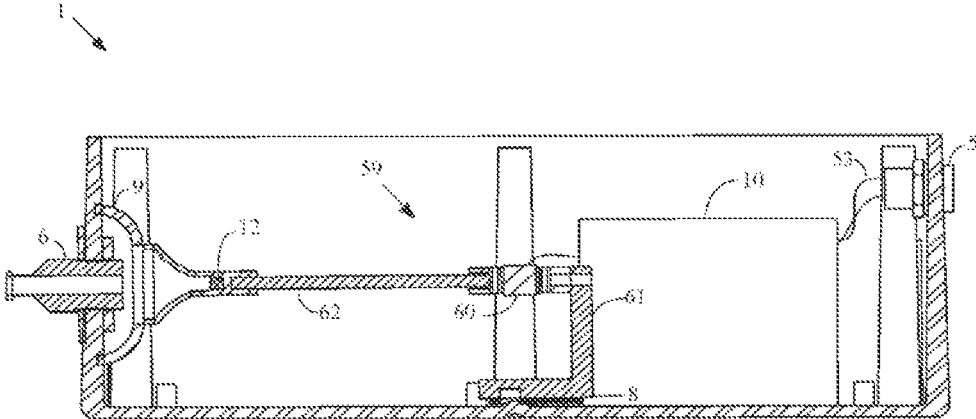


FIG. 12A

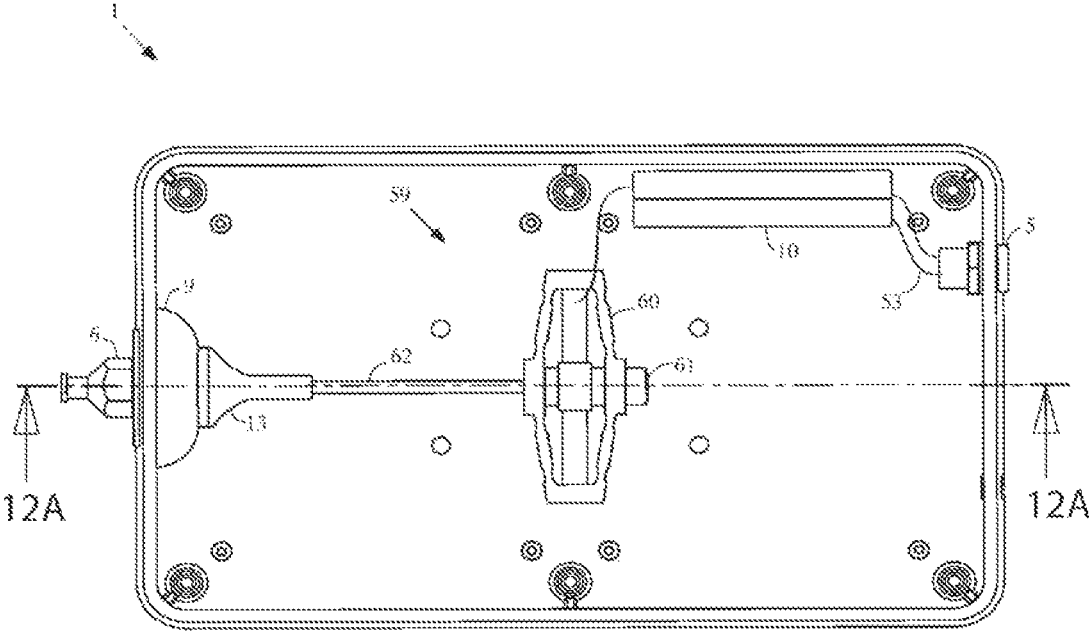


FIG. 12

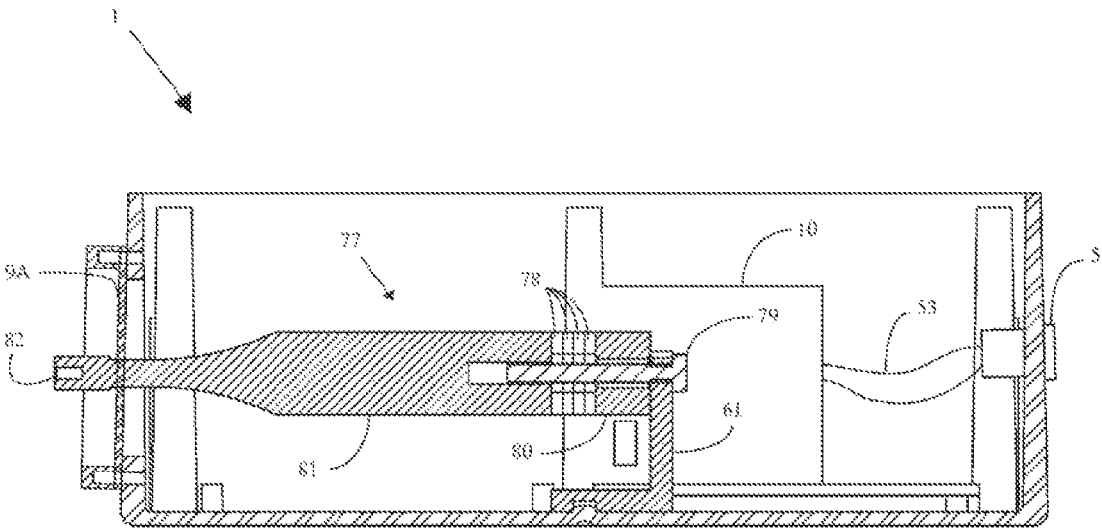


FIG. 12B

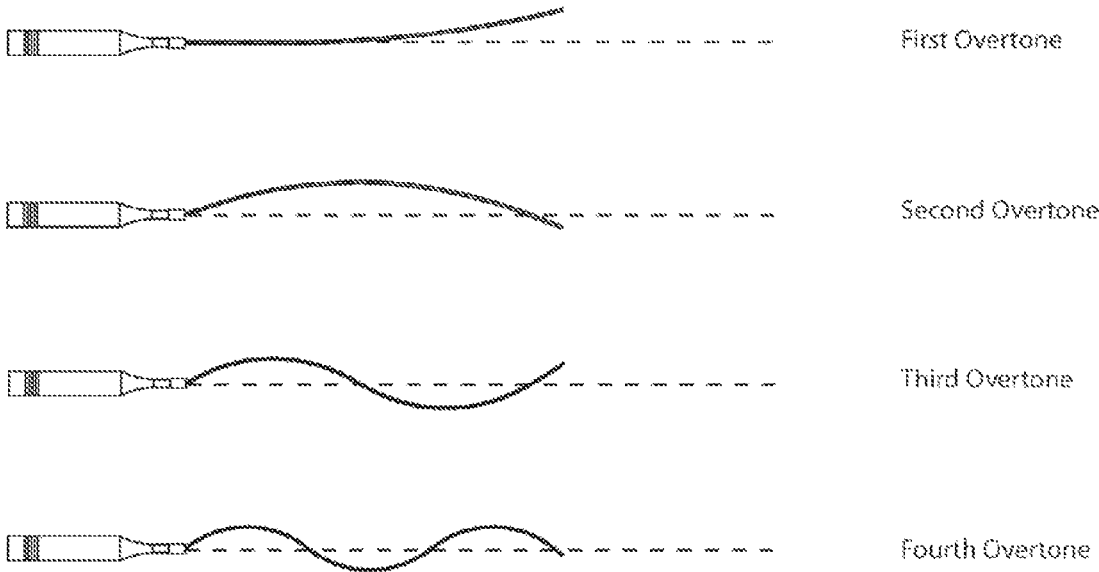


FIG. 12C

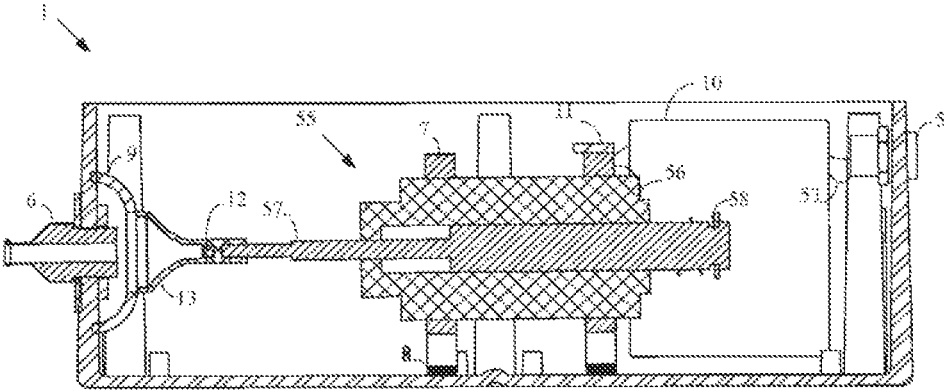


FIG. 13A

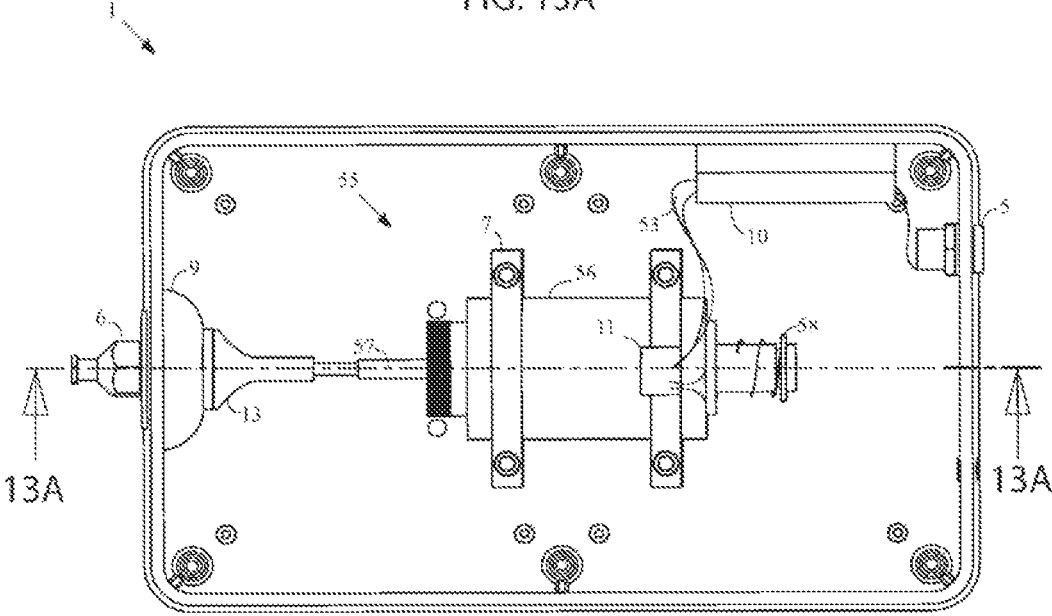


FIG. 13



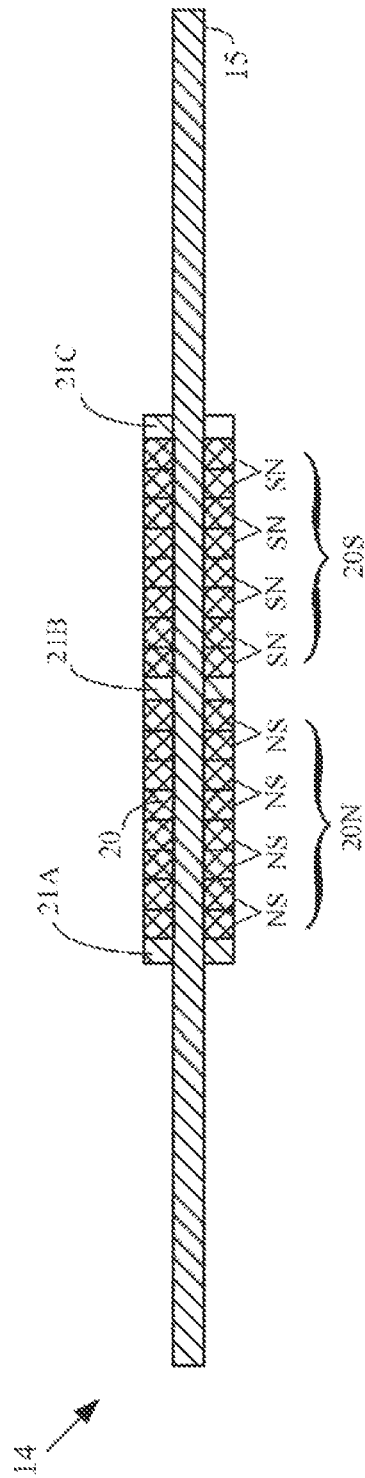


FIG. 15

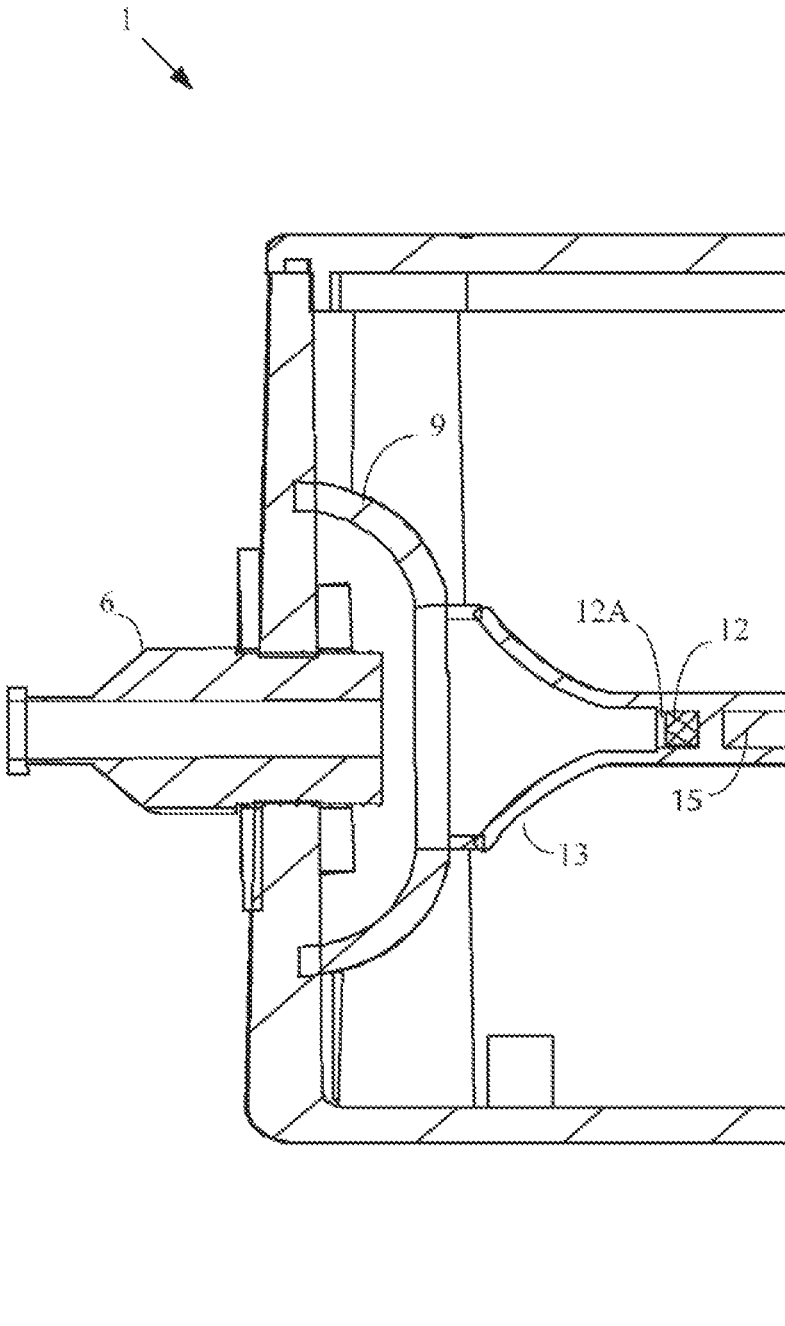


FIG. 16A

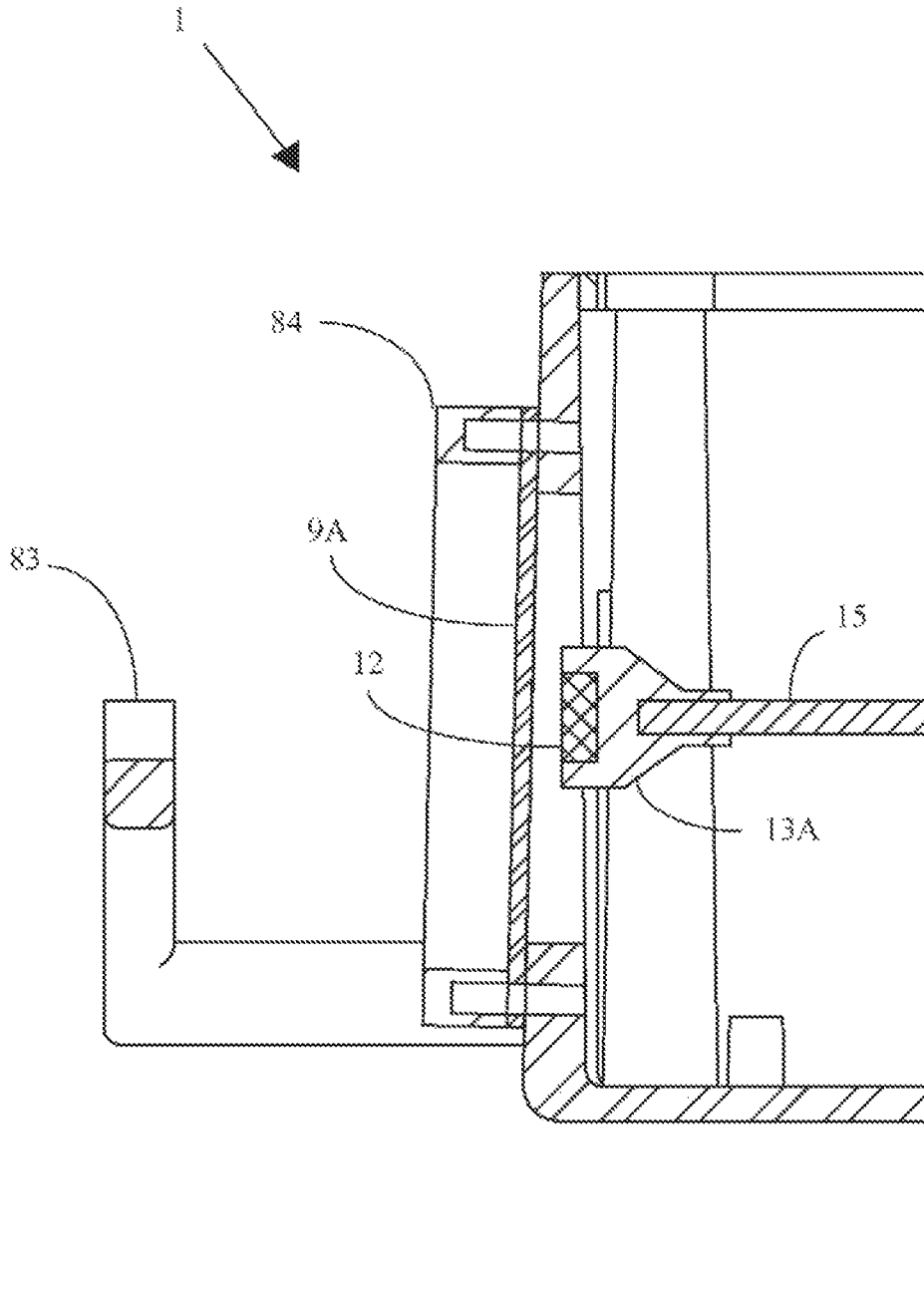


FIG. 16B



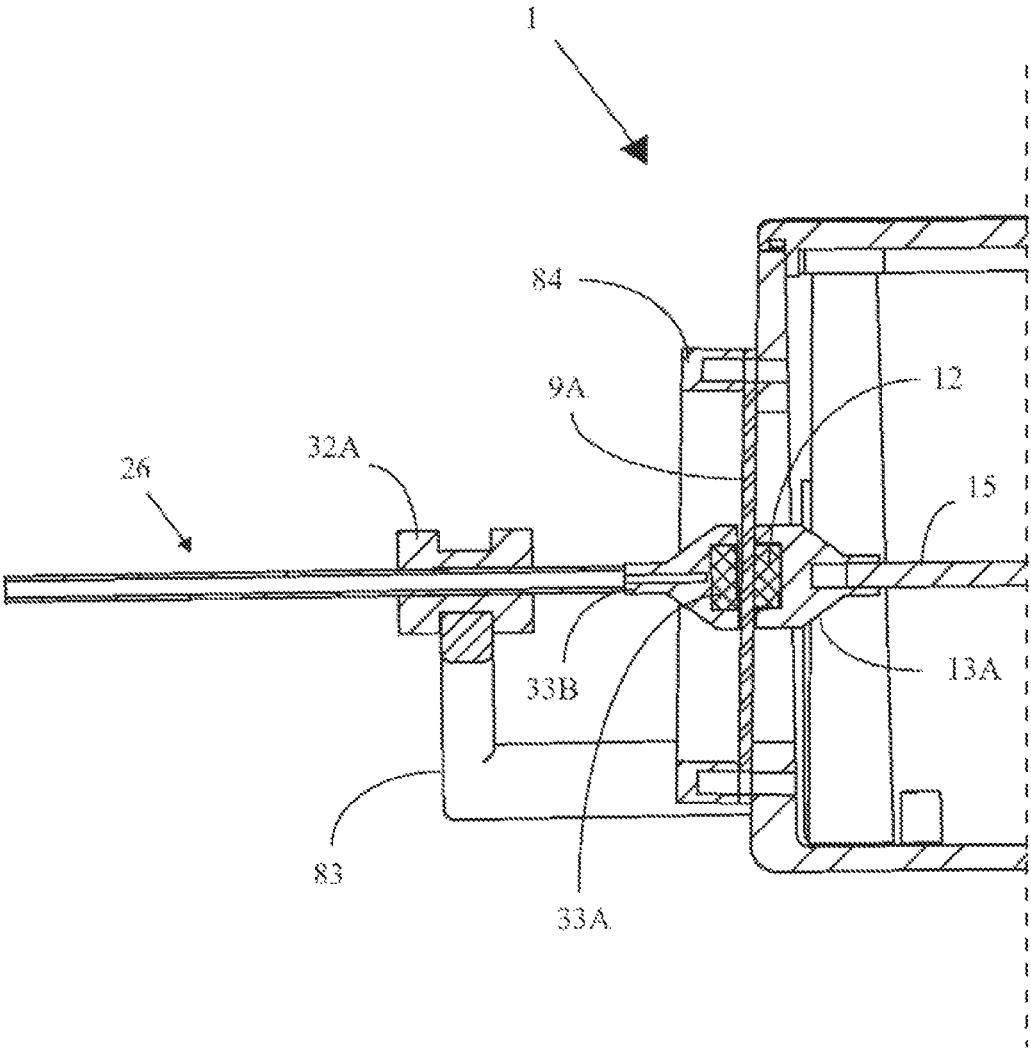


FIG. 16C



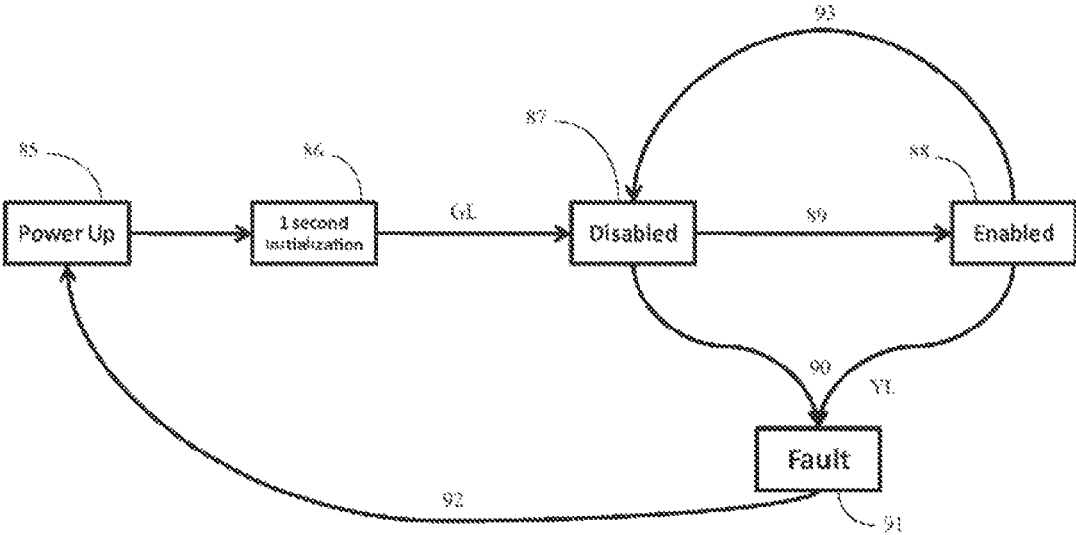


FIG. 17B

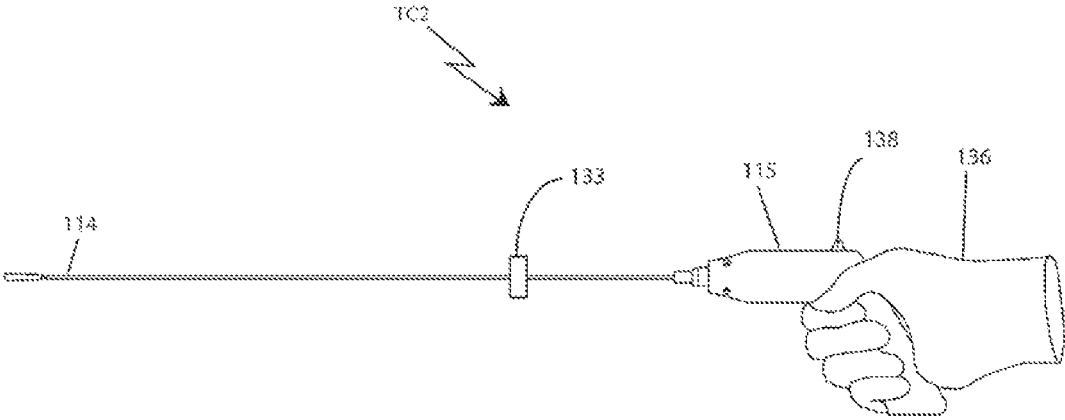


FIG. 18A

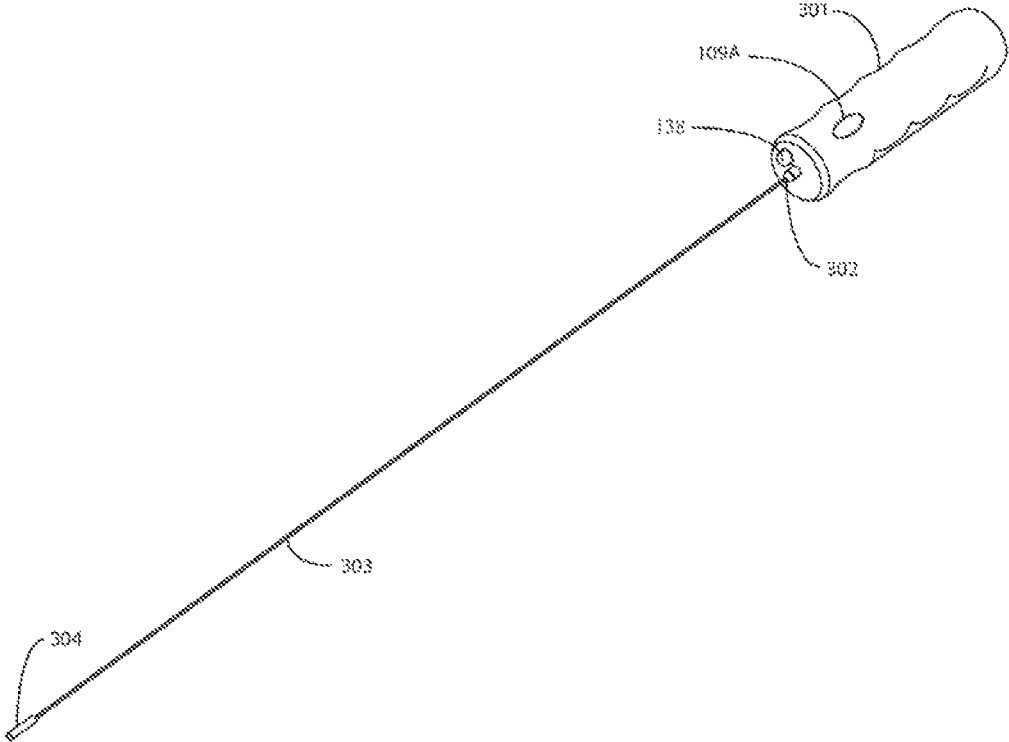


FIG. 18B

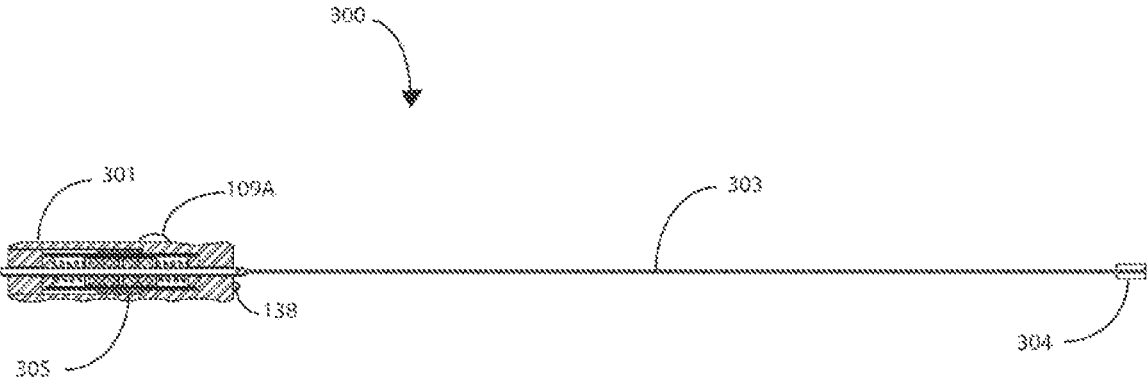


FIG. 18C

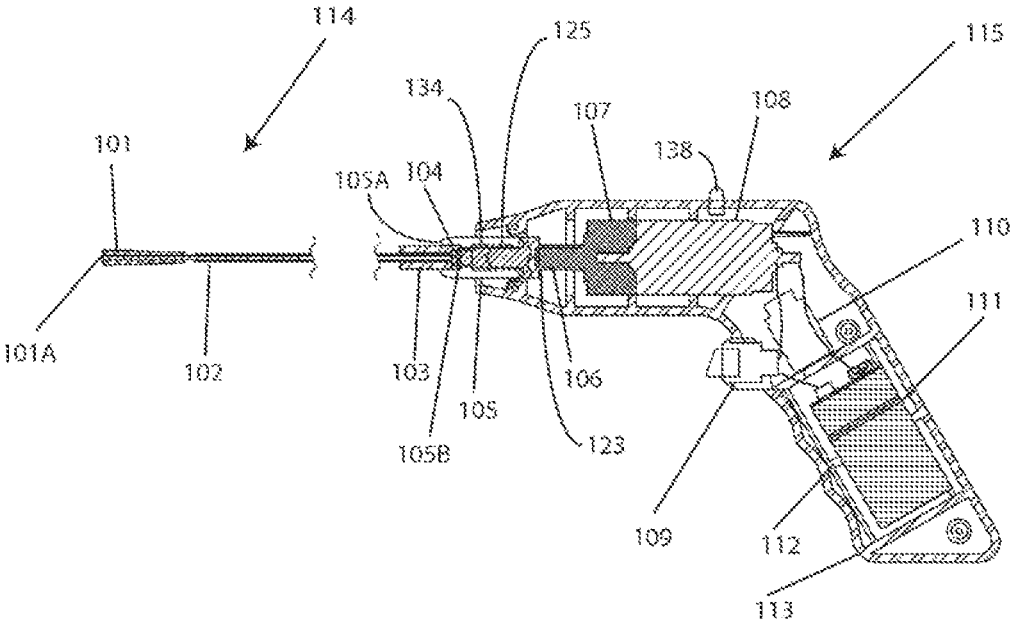


FIG. 19

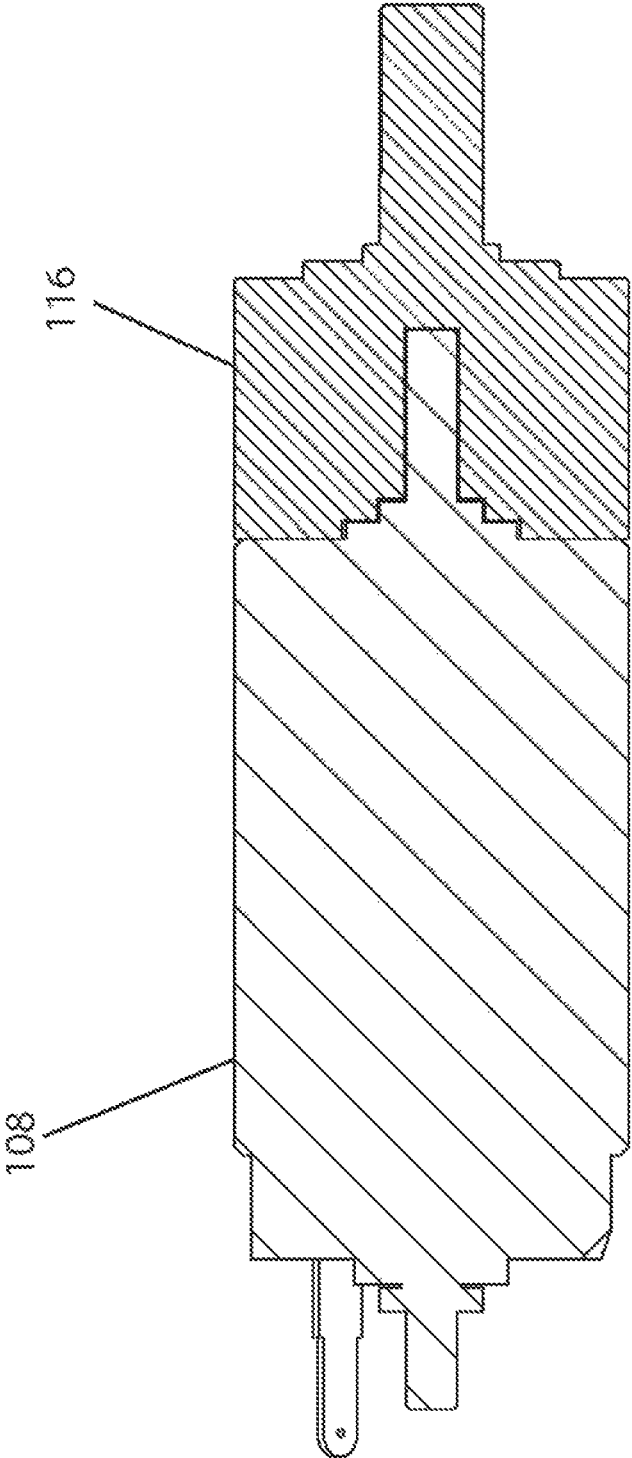


FIG. 20



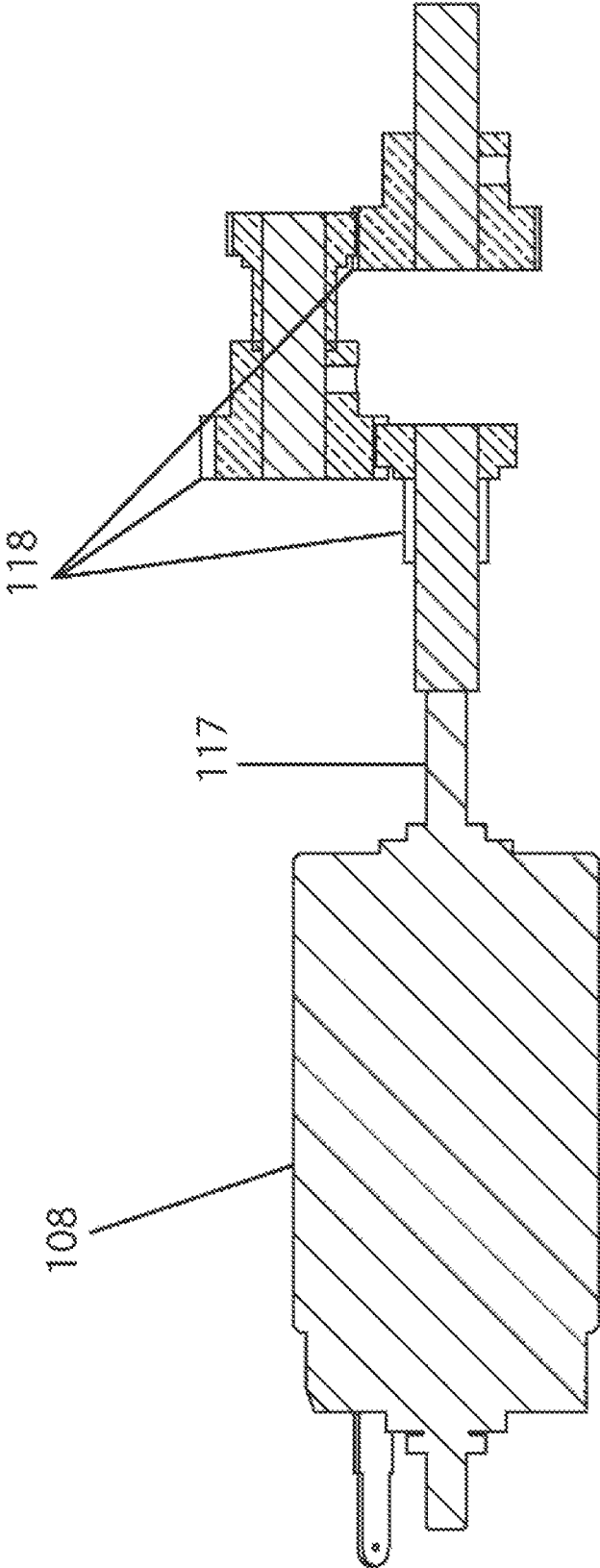


FIG. 21

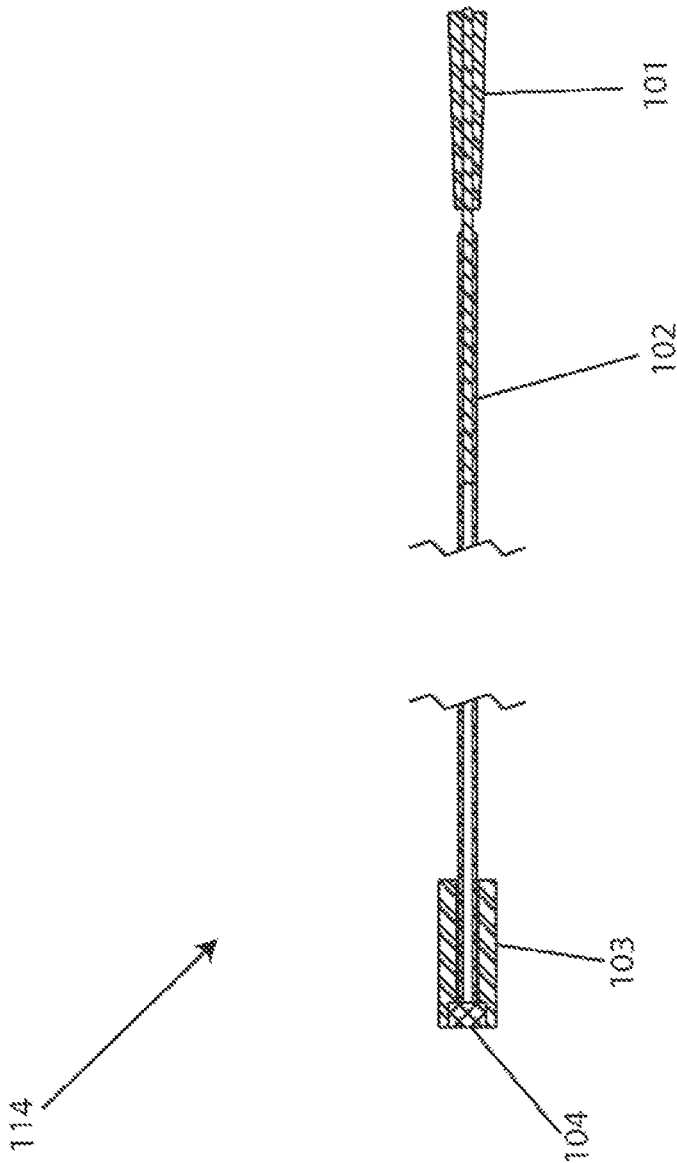


FIG. 22

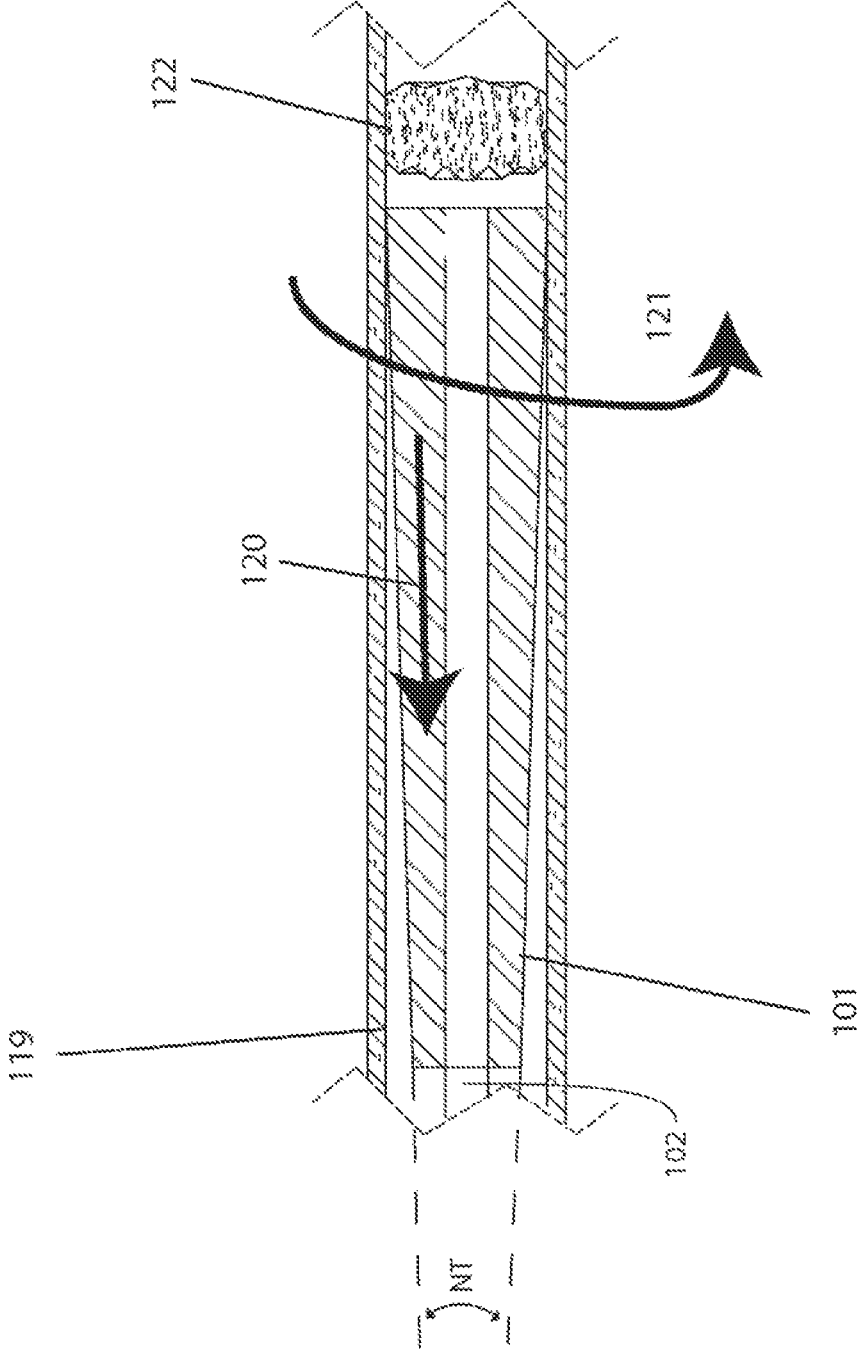


FIG. 23

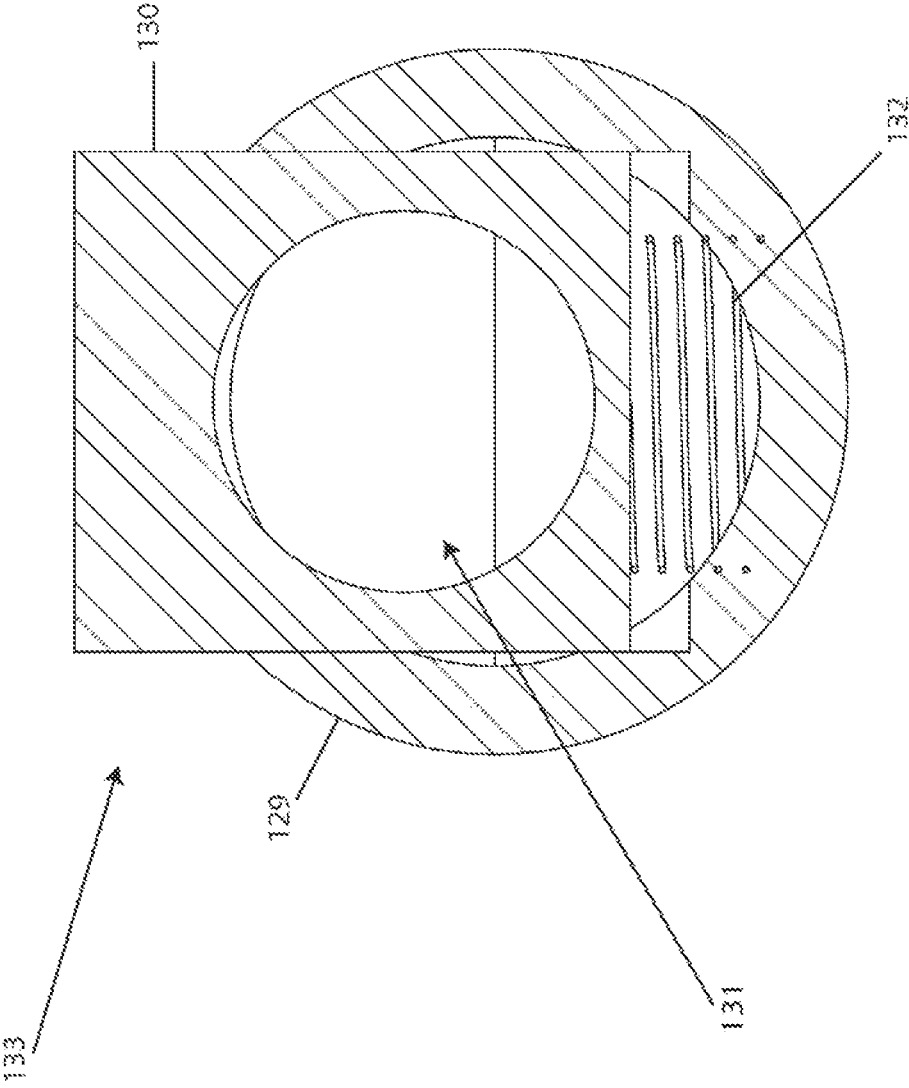


FIG. 24

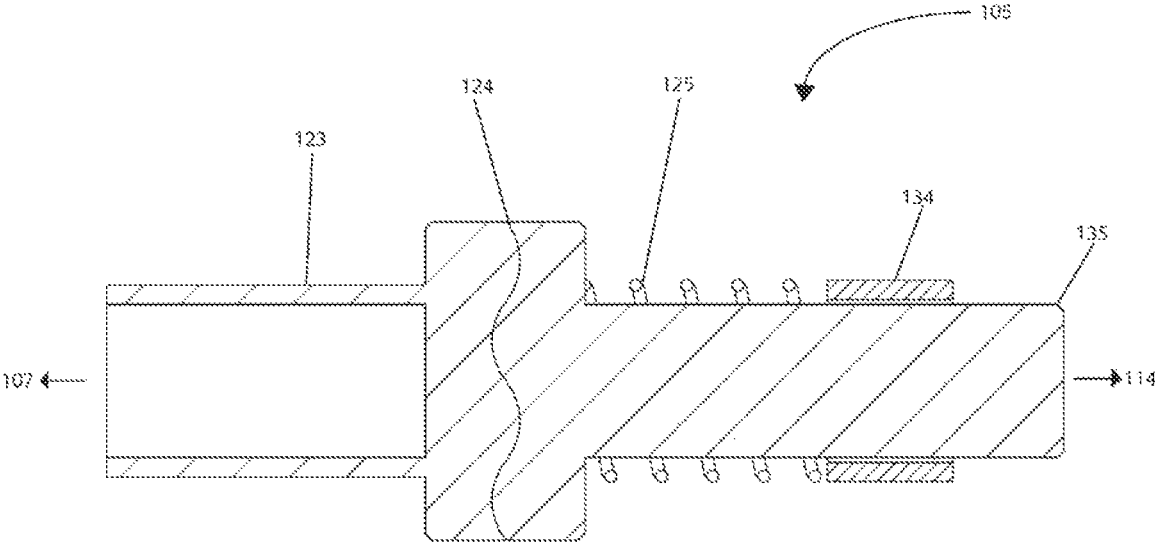


FIG. 25

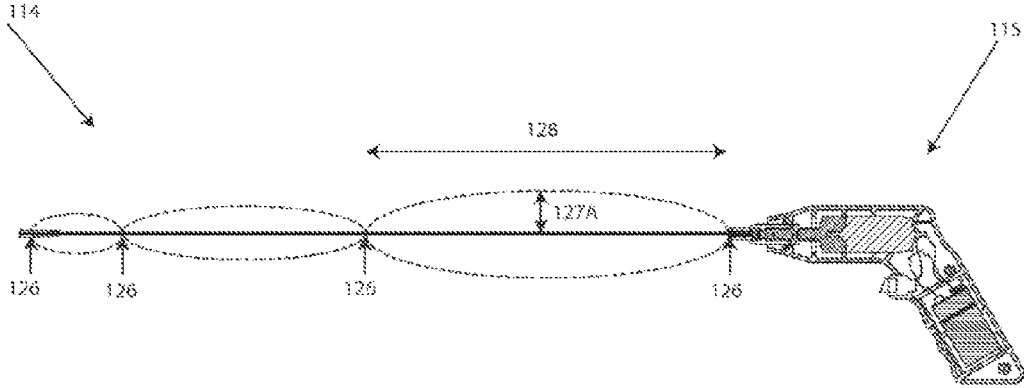


FIG. 26

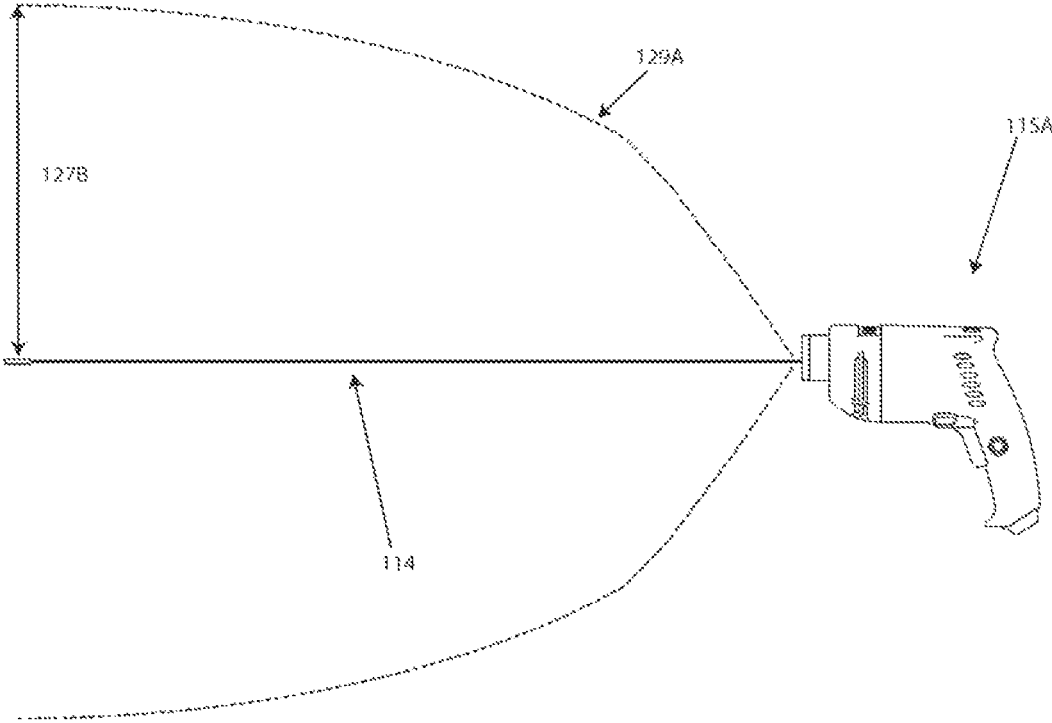


FIG. 27

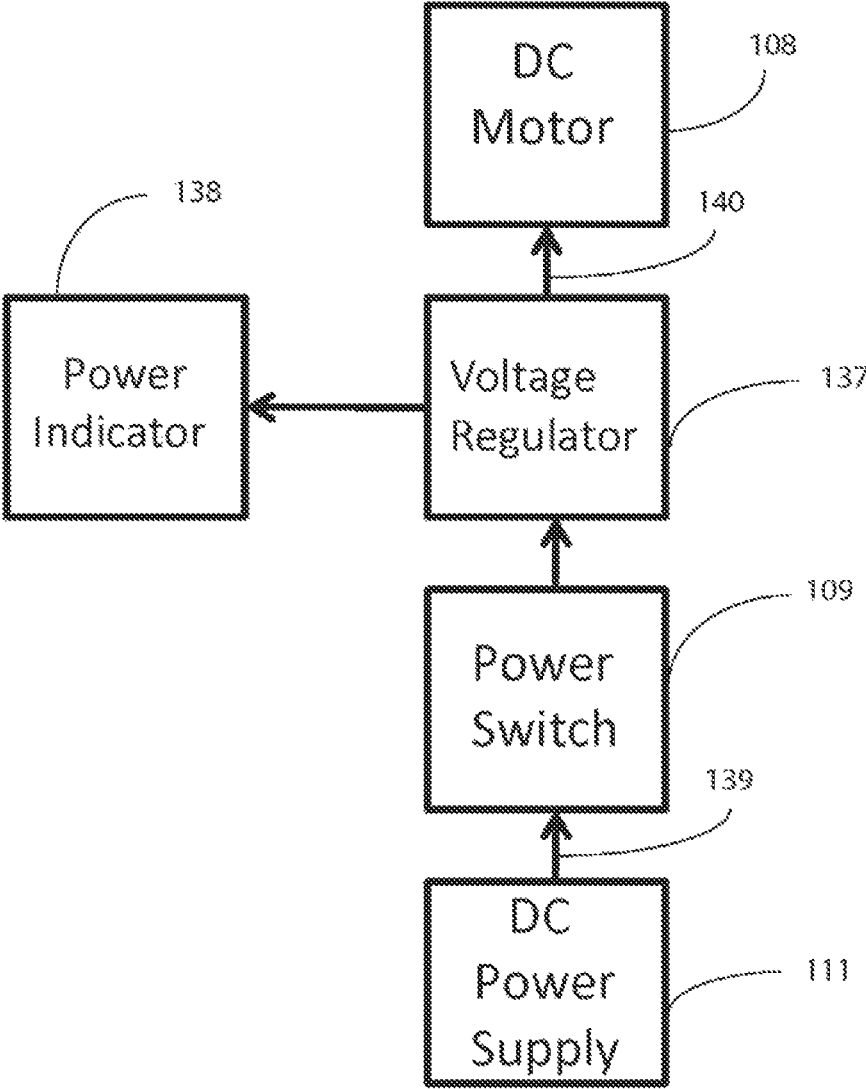


FIG. 28



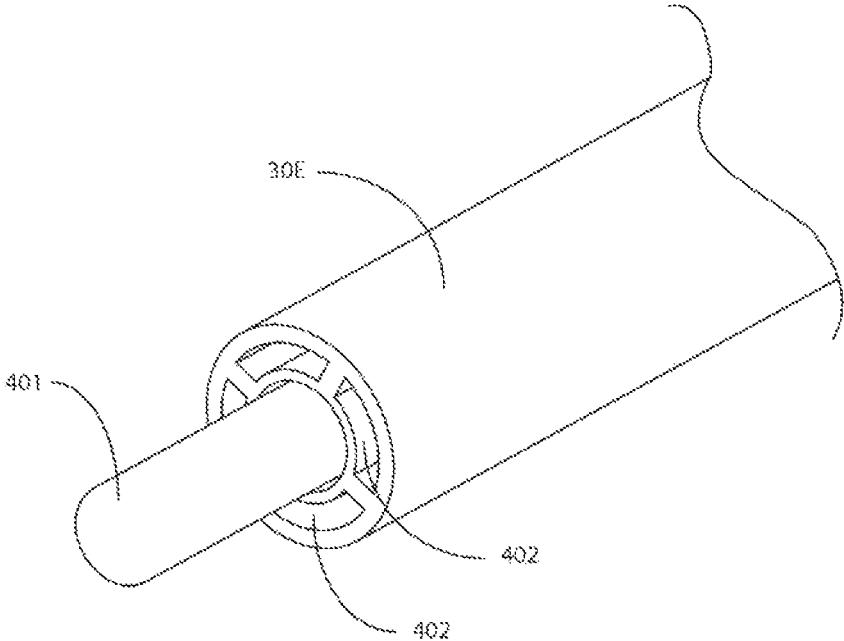


FIG. 29

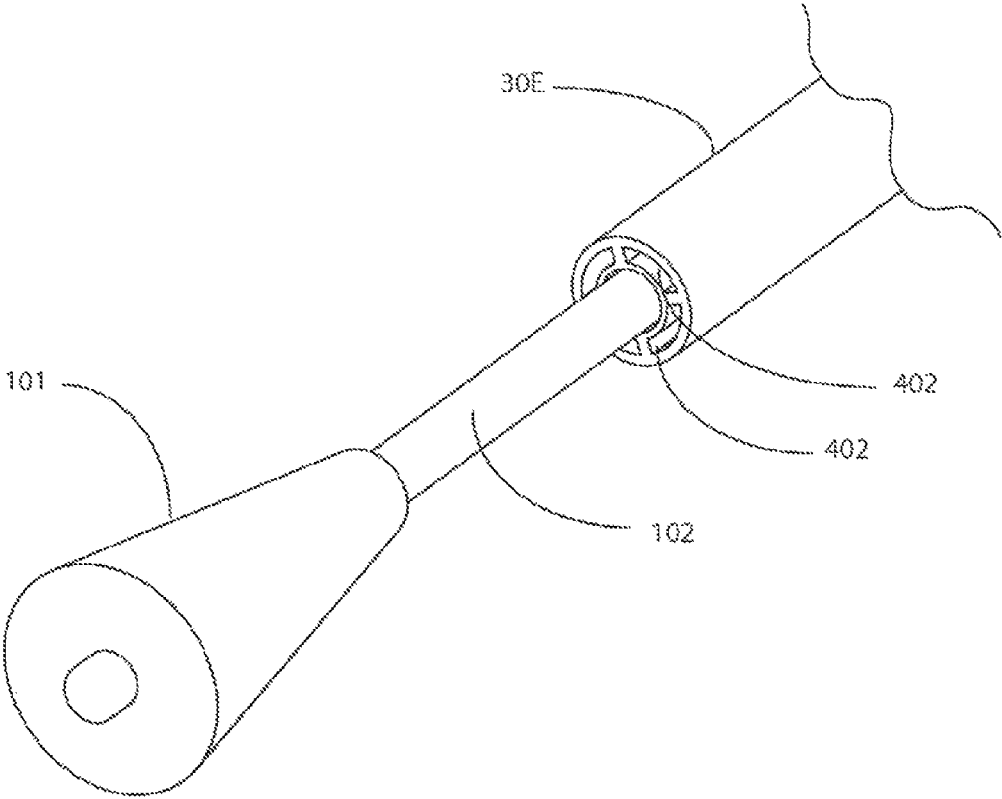


FIG. 29A

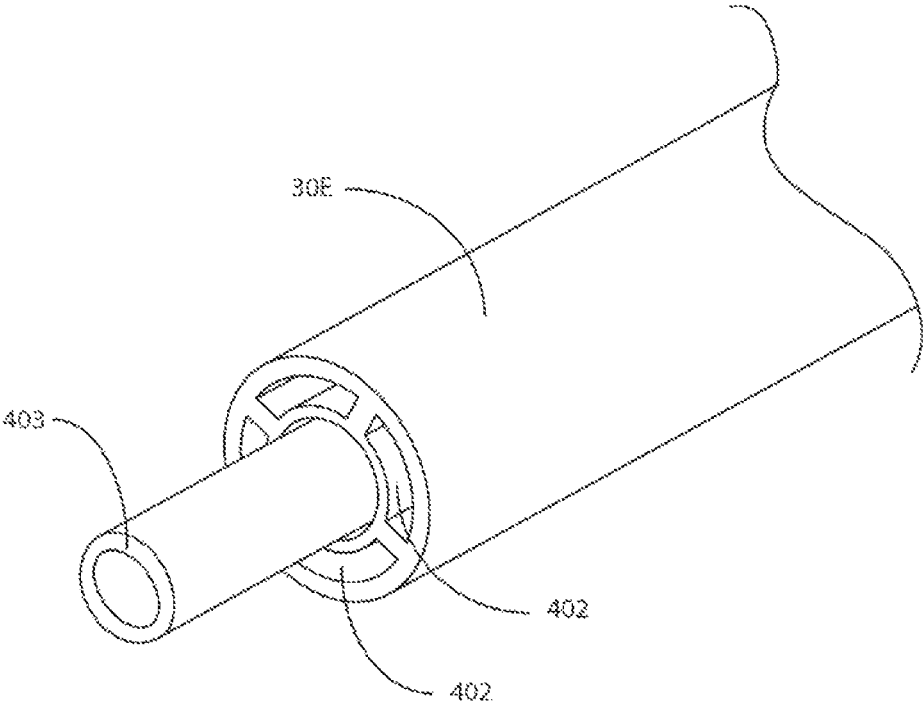


FIG. 29B

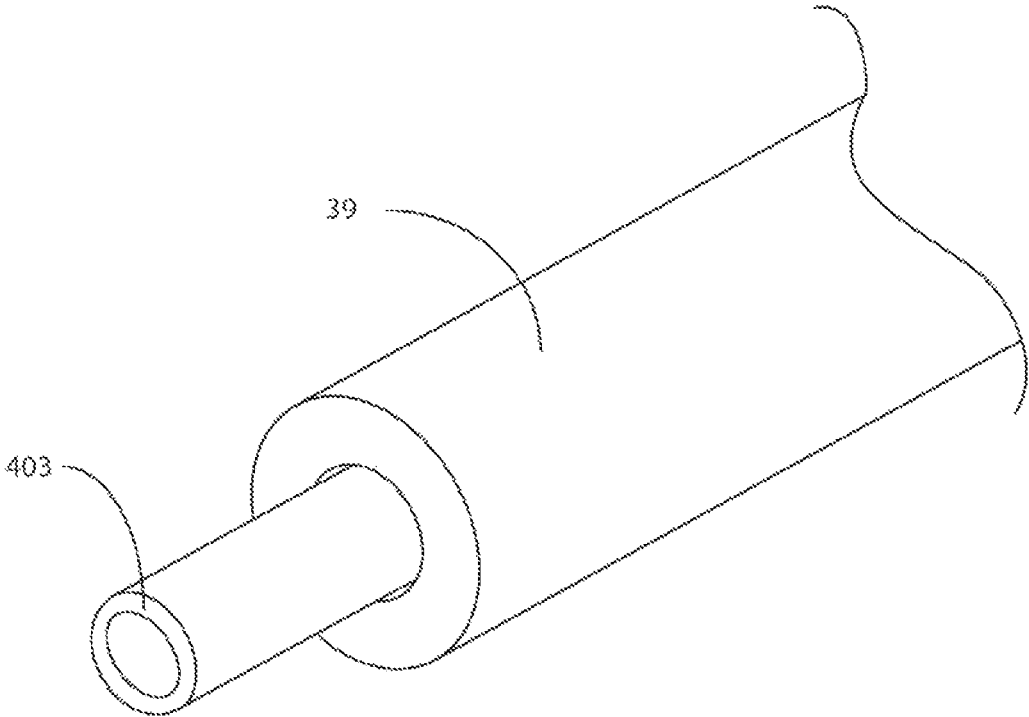


FIG. 29C

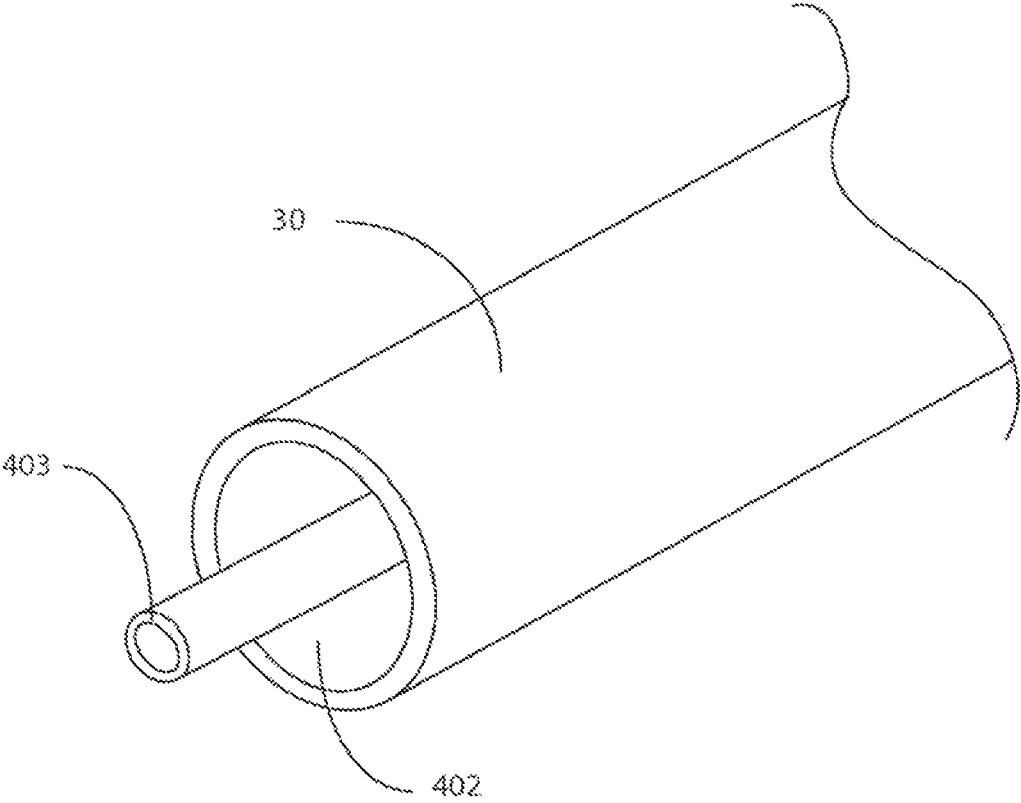


FIG. 29D

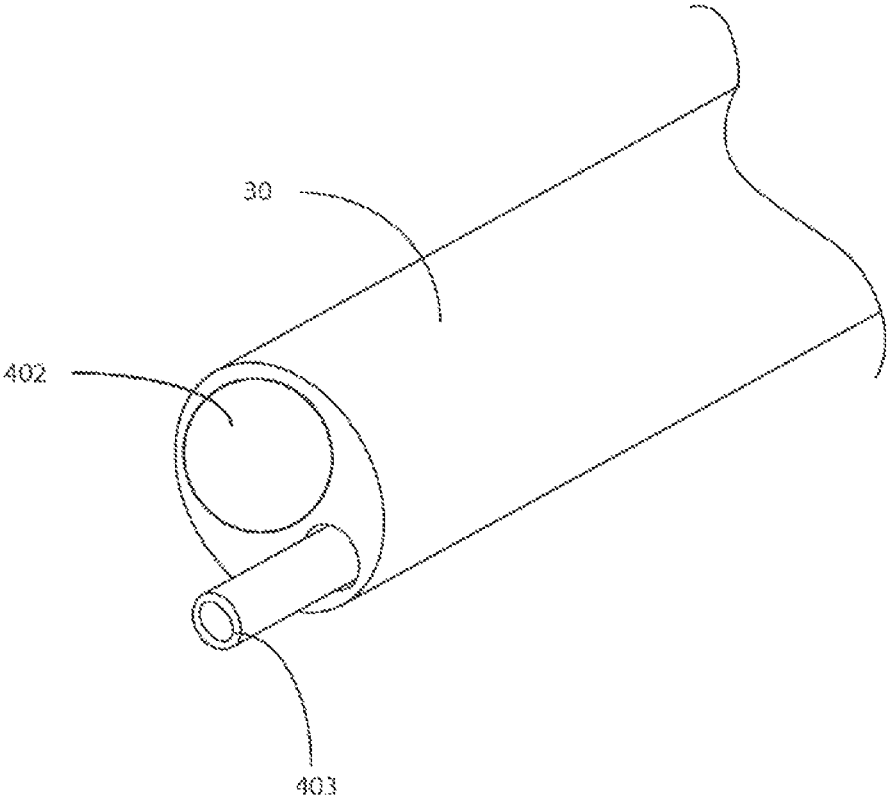


FIG. 29E

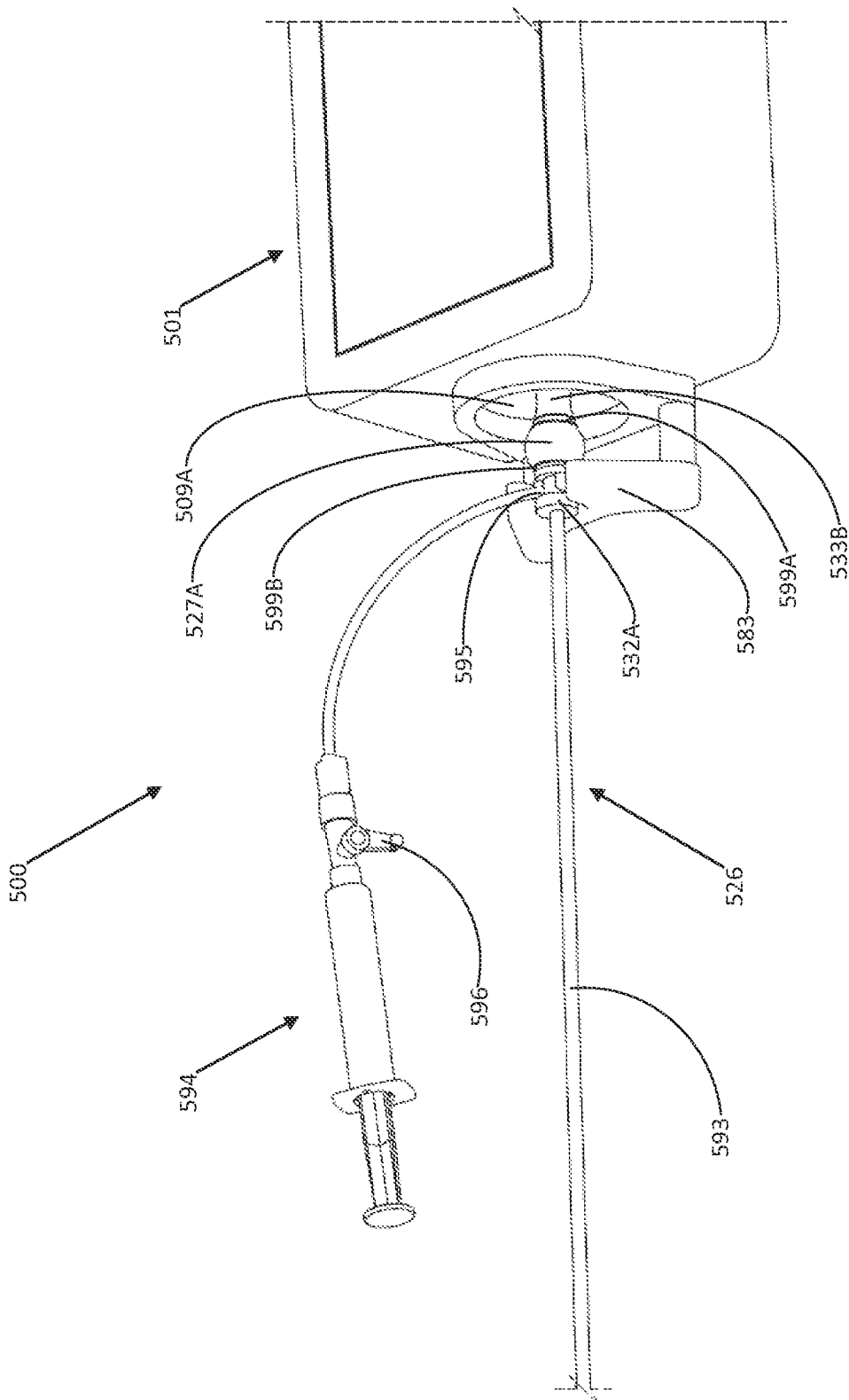


FIG. 30

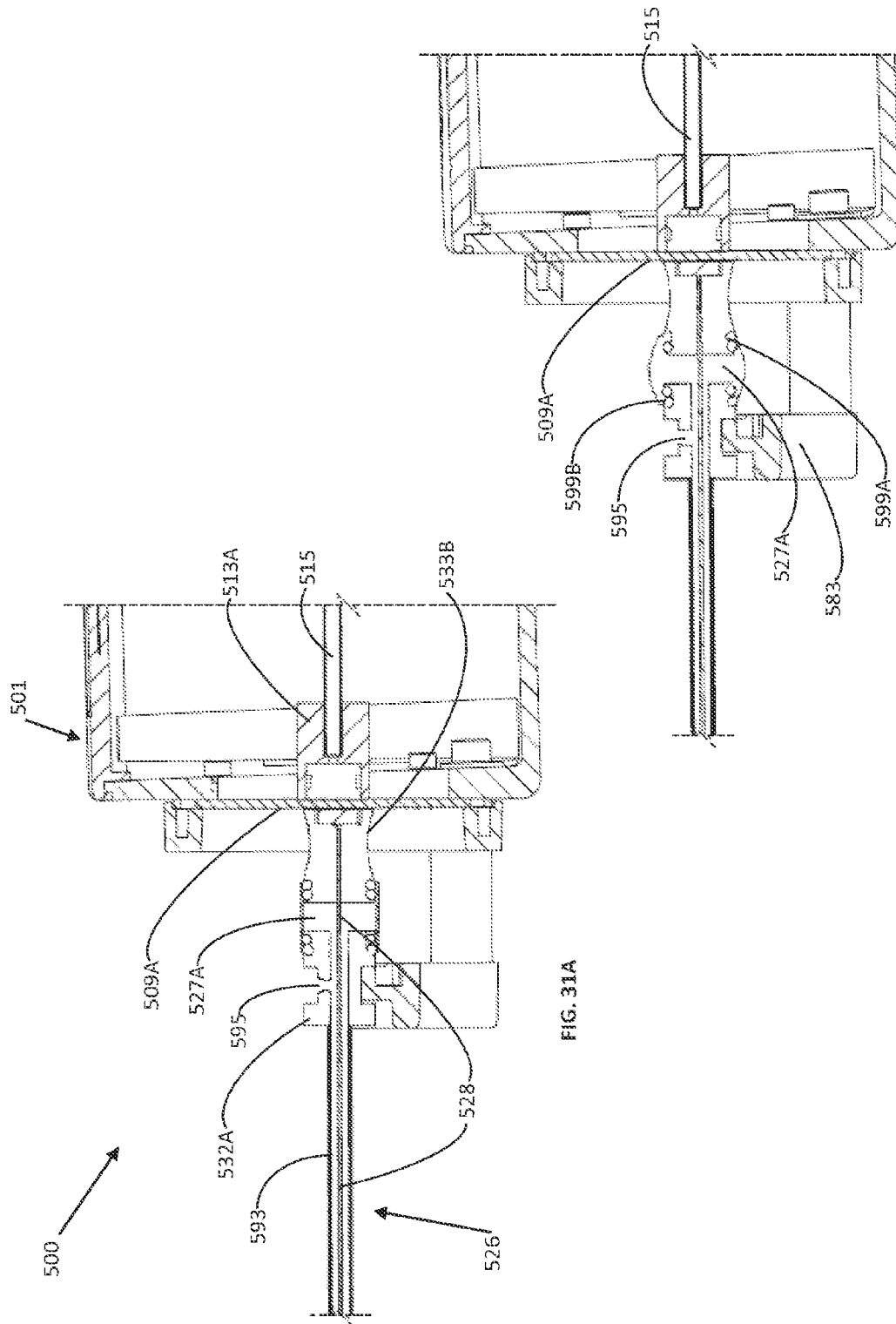


FIG. 31B



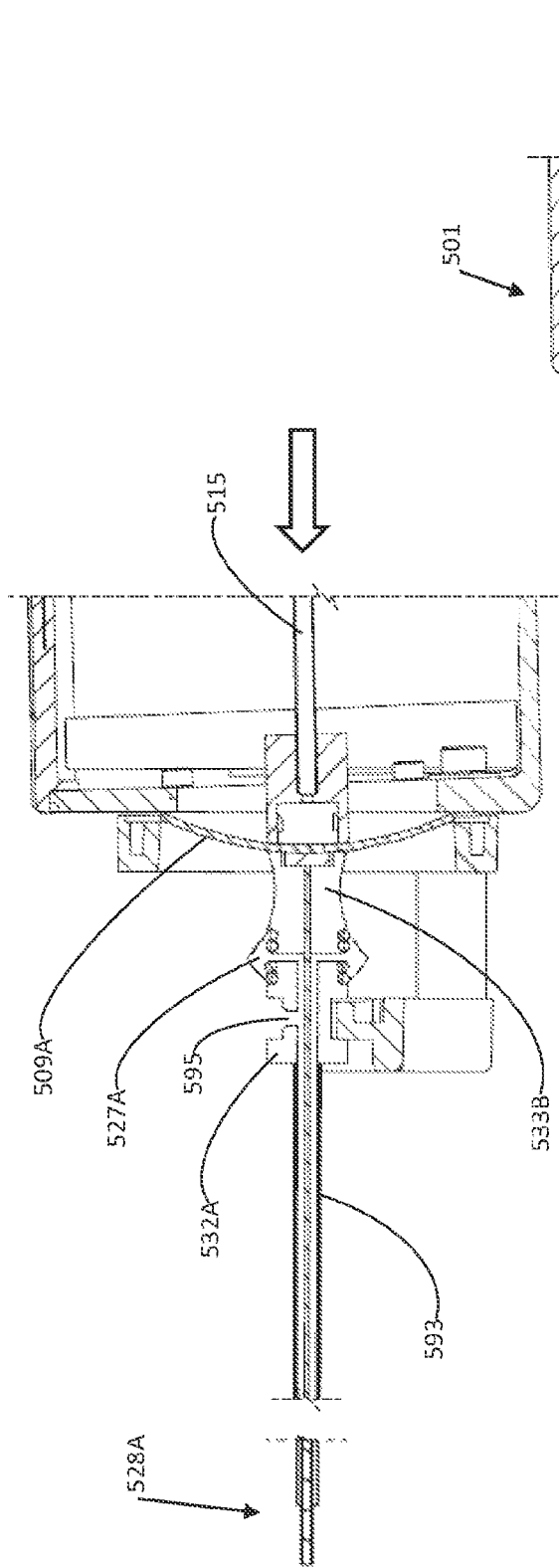


FIG. 31C

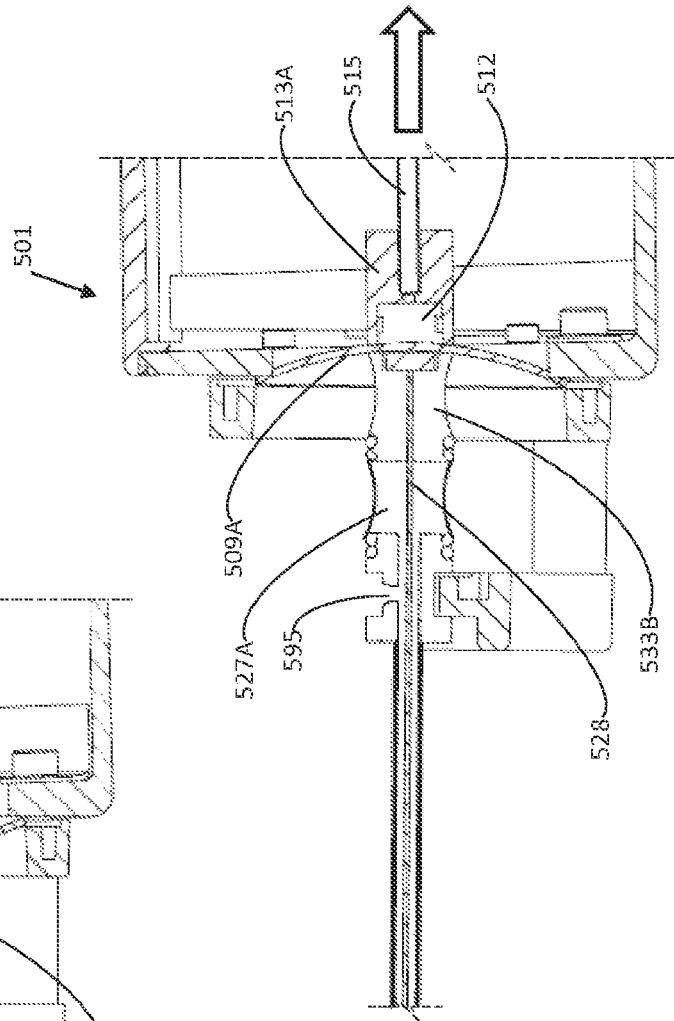


FIG. 31D

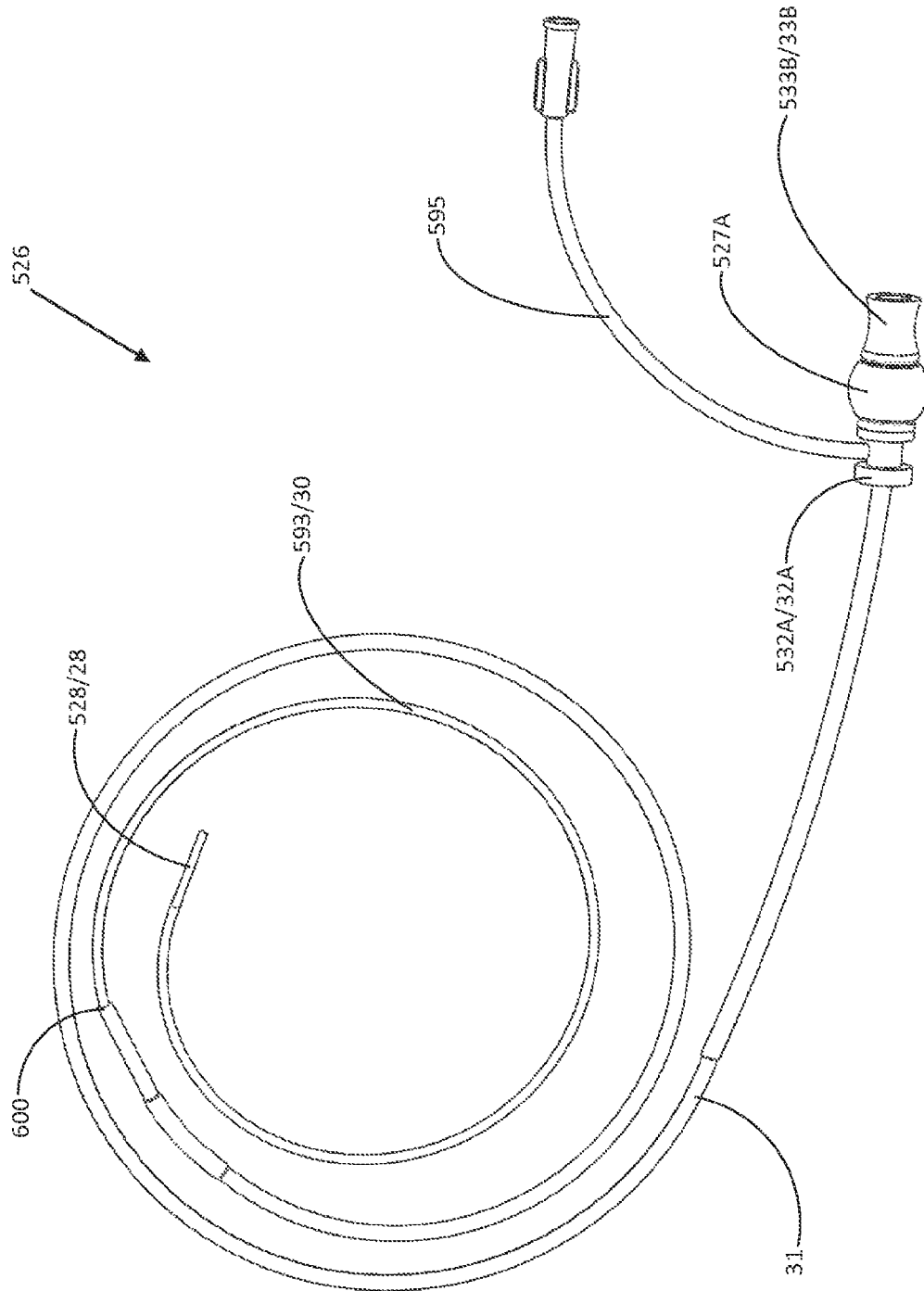
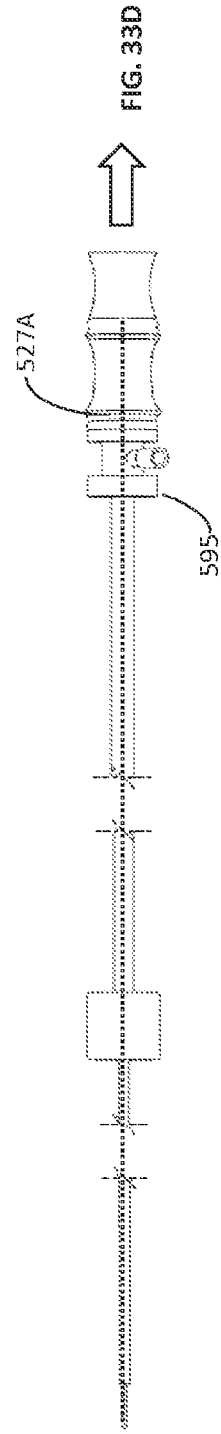
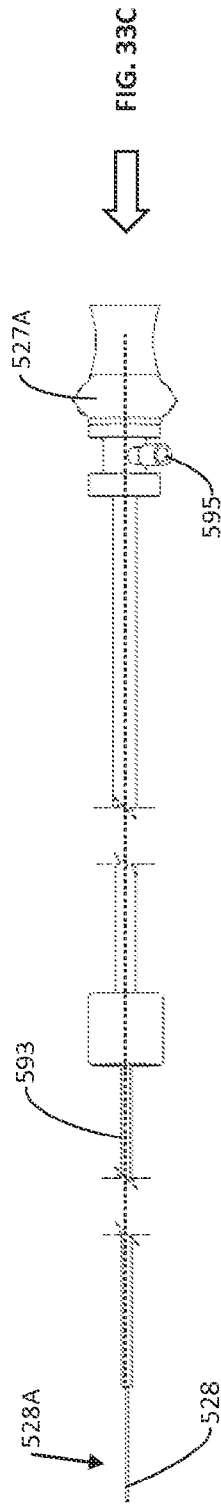
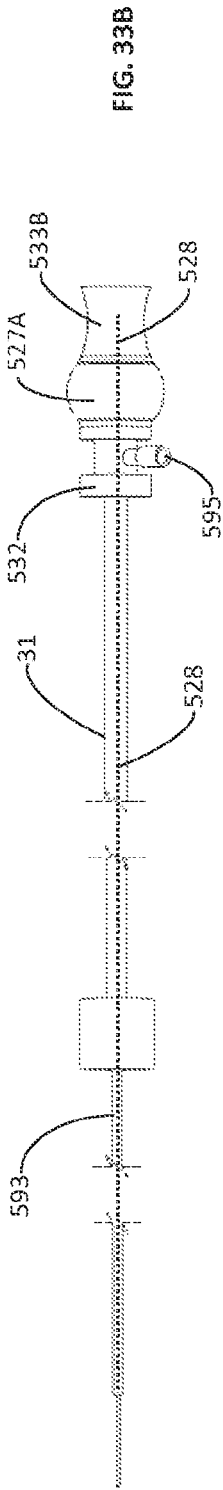
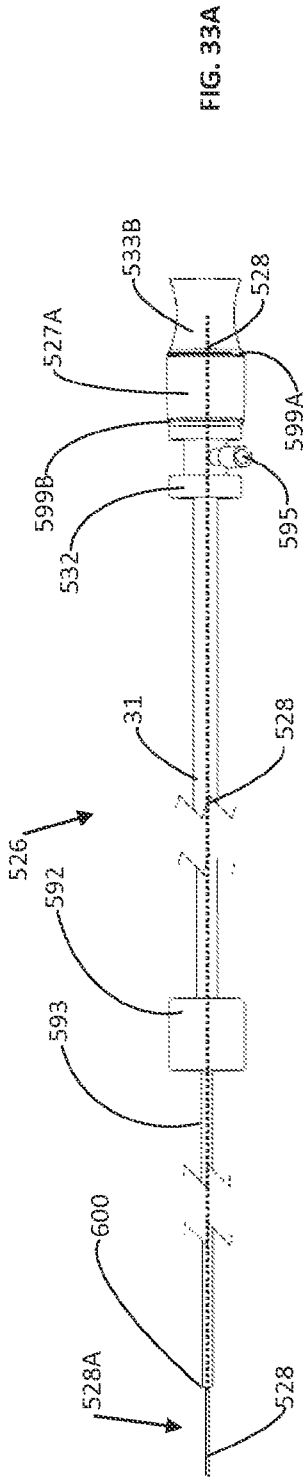


FIG. 32



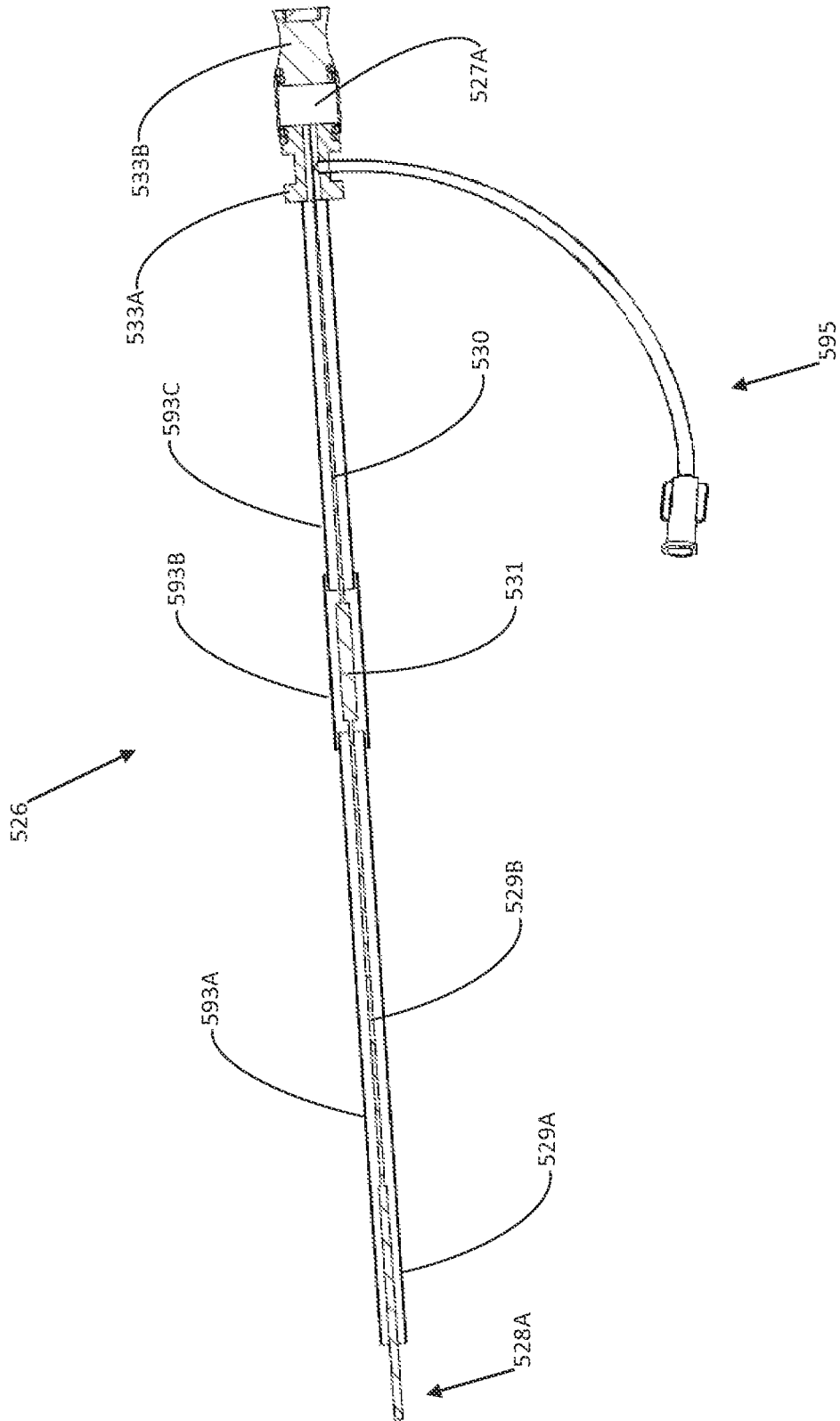


FIG. 34

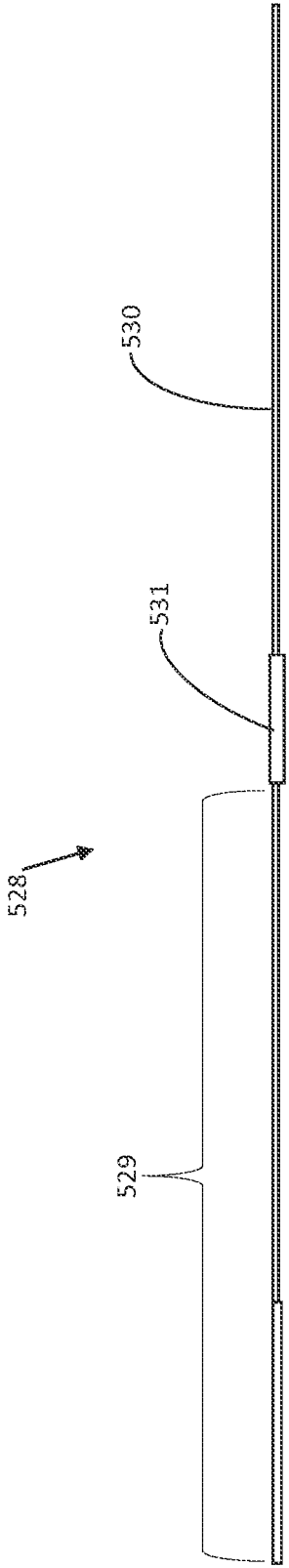


FIG. 35A

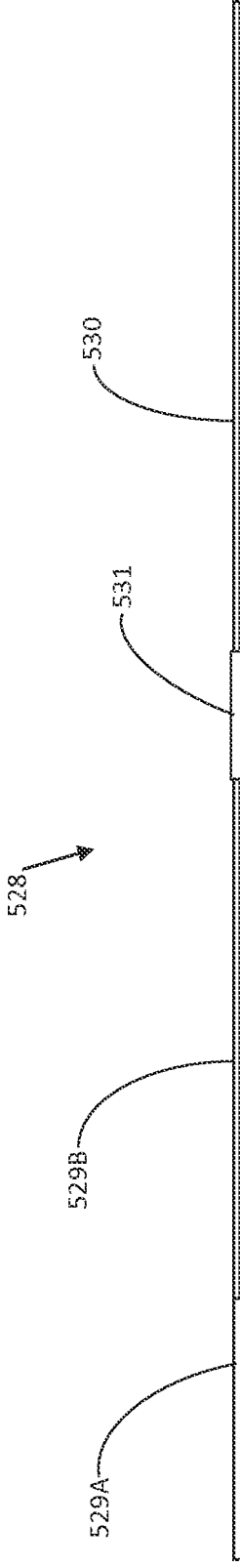


FIG. 35B

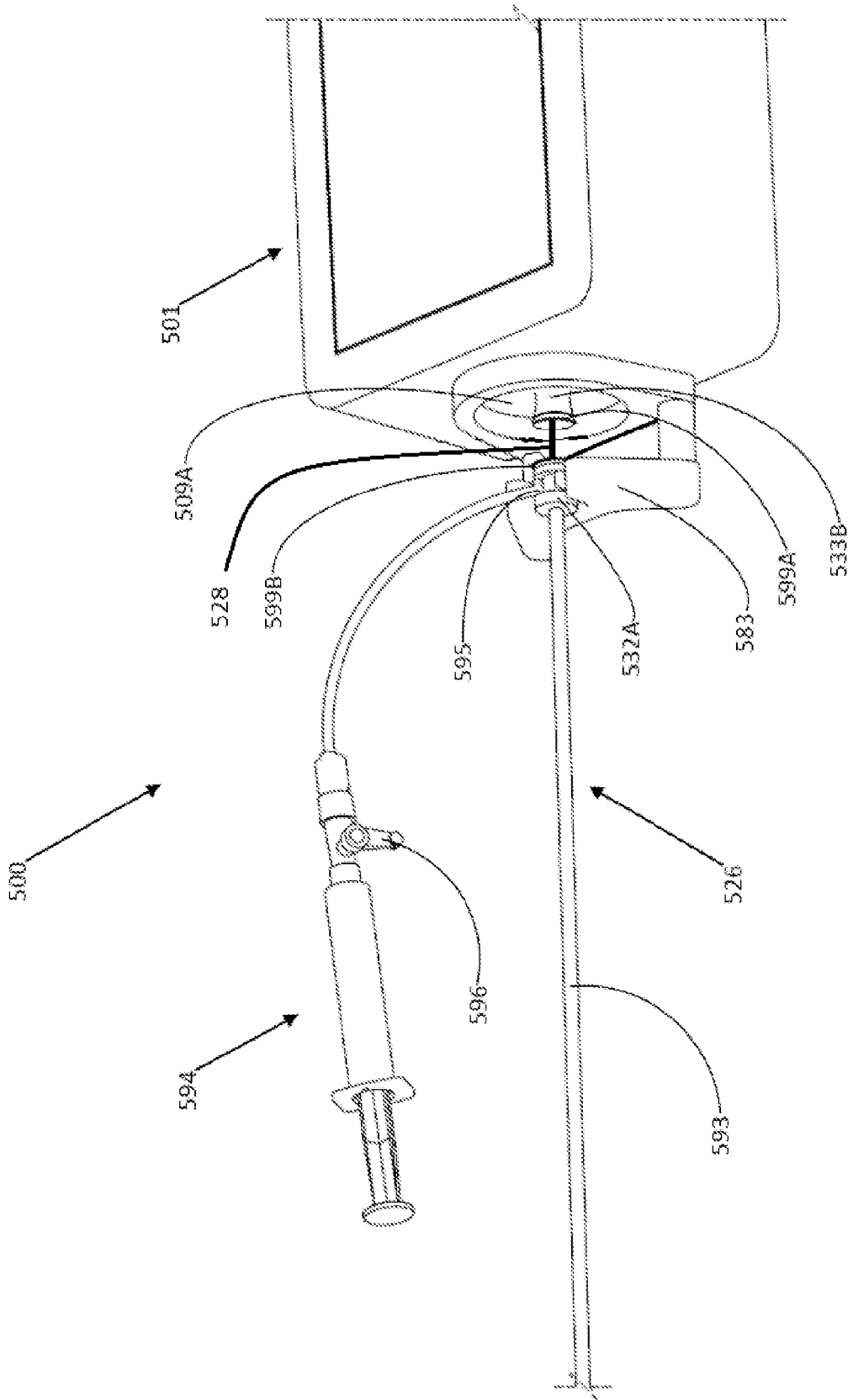


FIG. 36



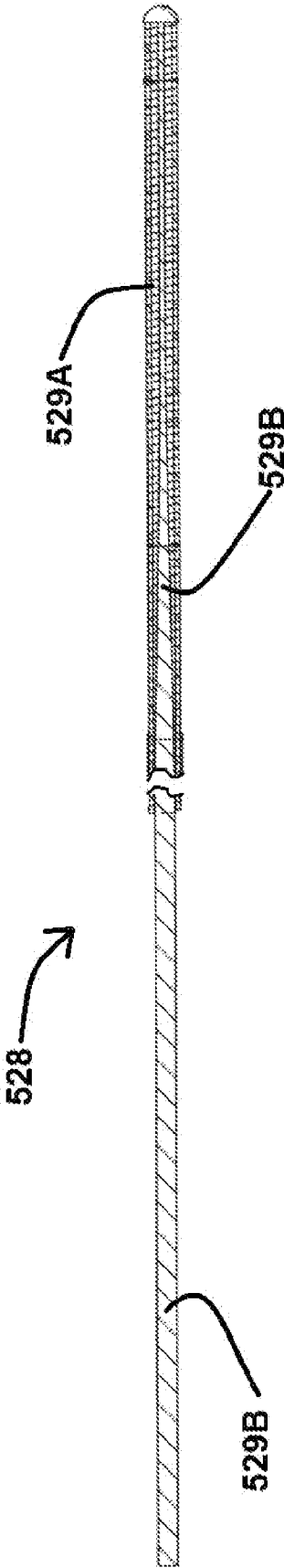


FIG. 38



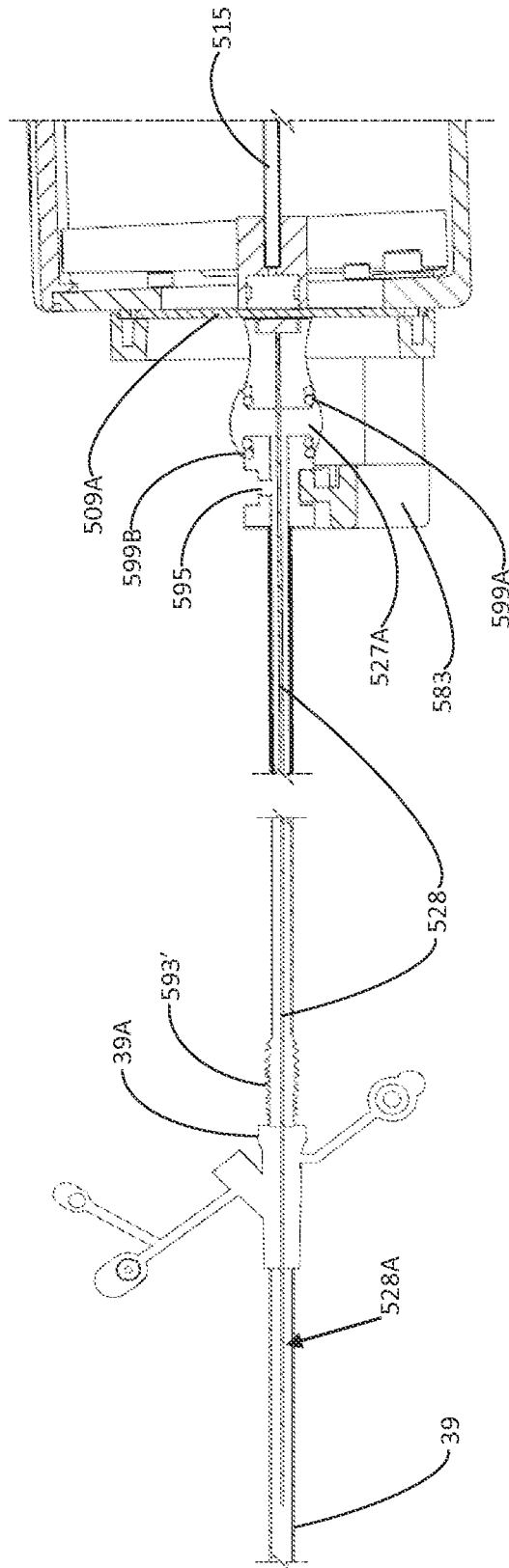


FIG. 39

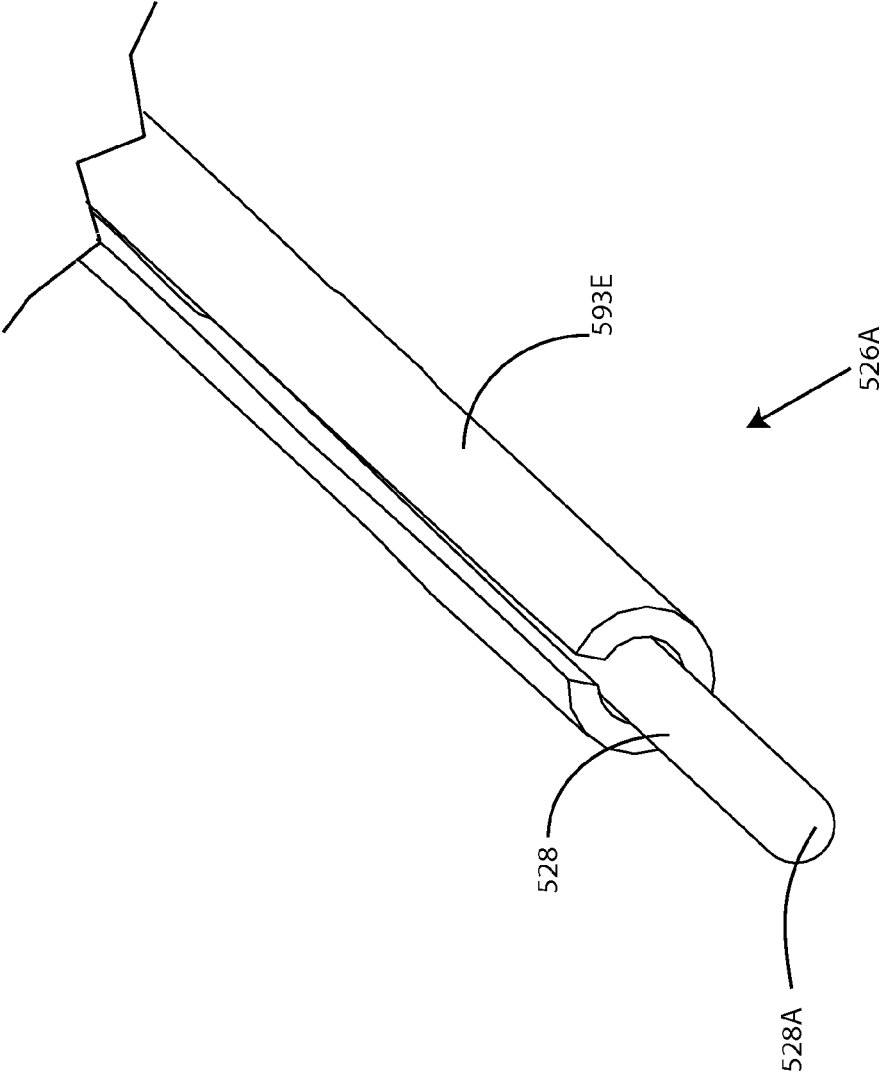


FIG. 40

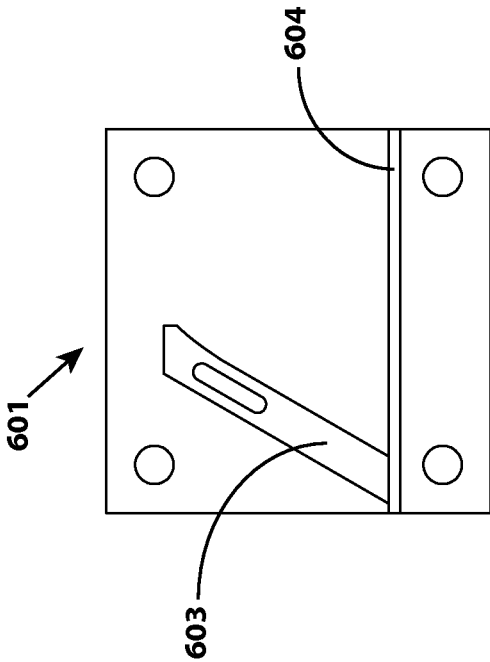


FIG. 41A

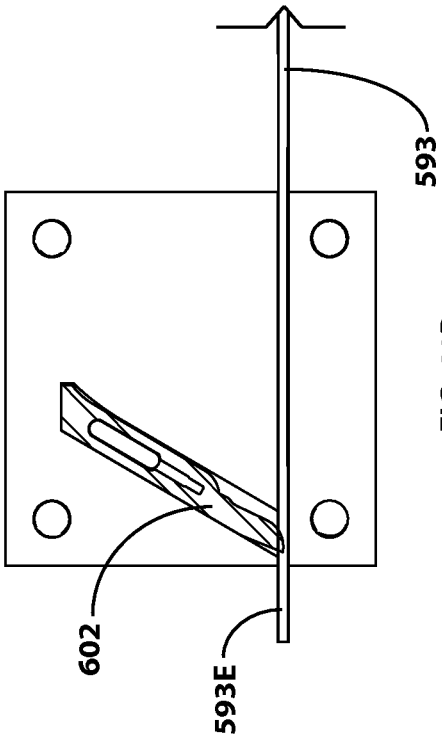


FIG. 41B

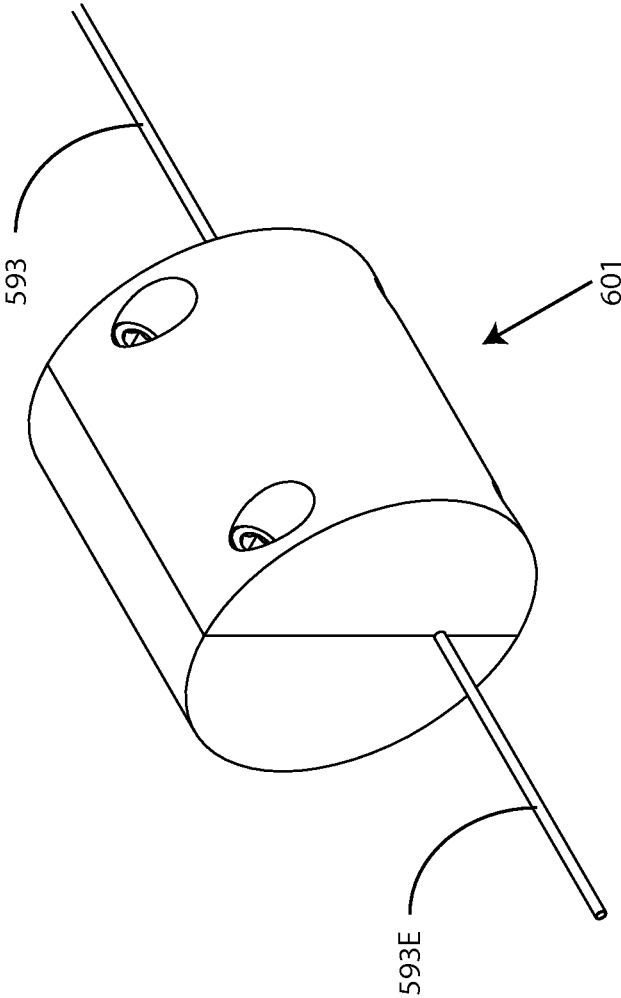
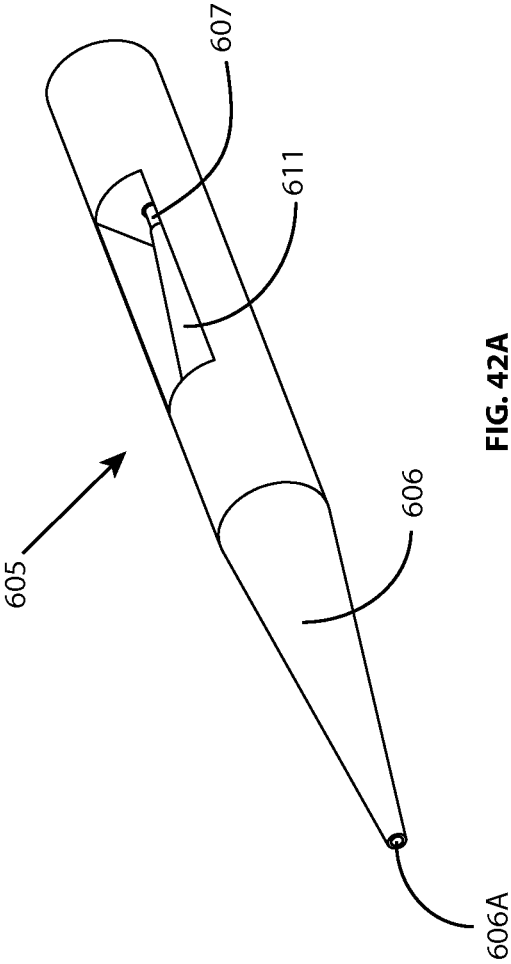


FIG. 41C



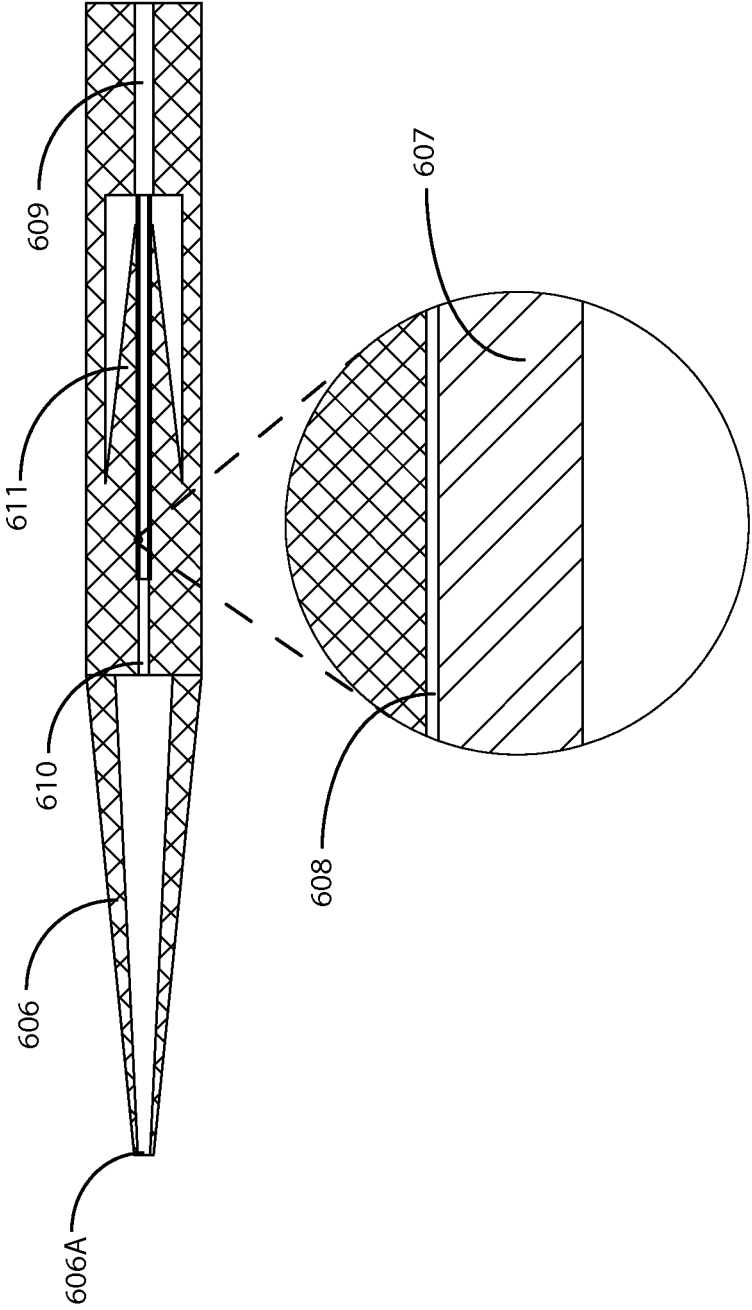


FIG. 42B

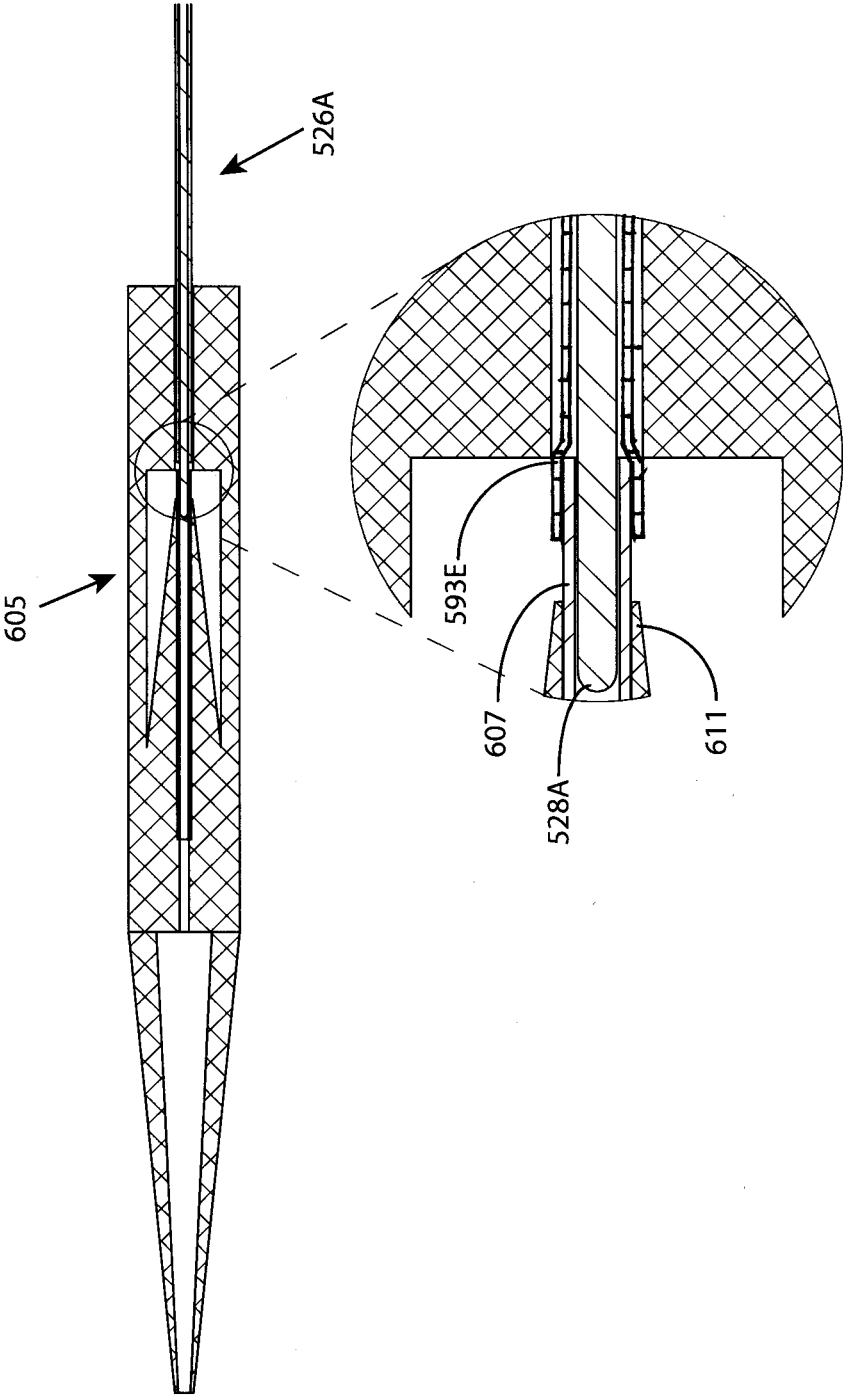


FIG. 43A

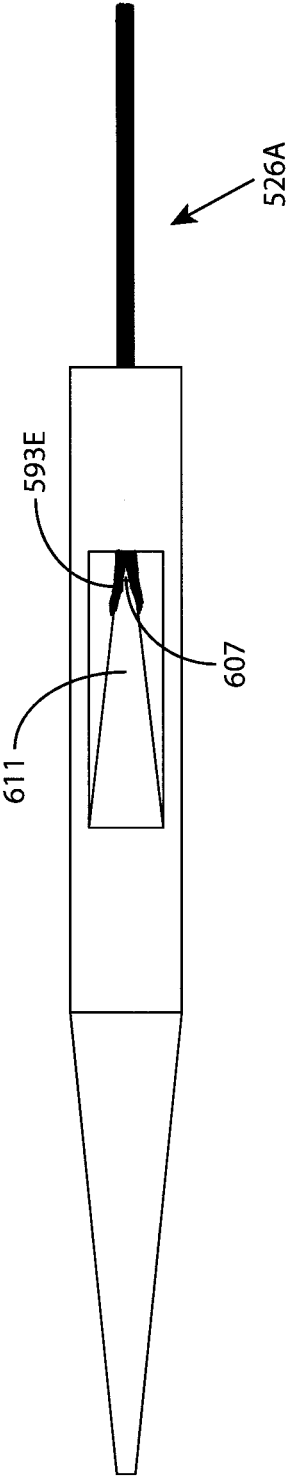


FIG. 43B



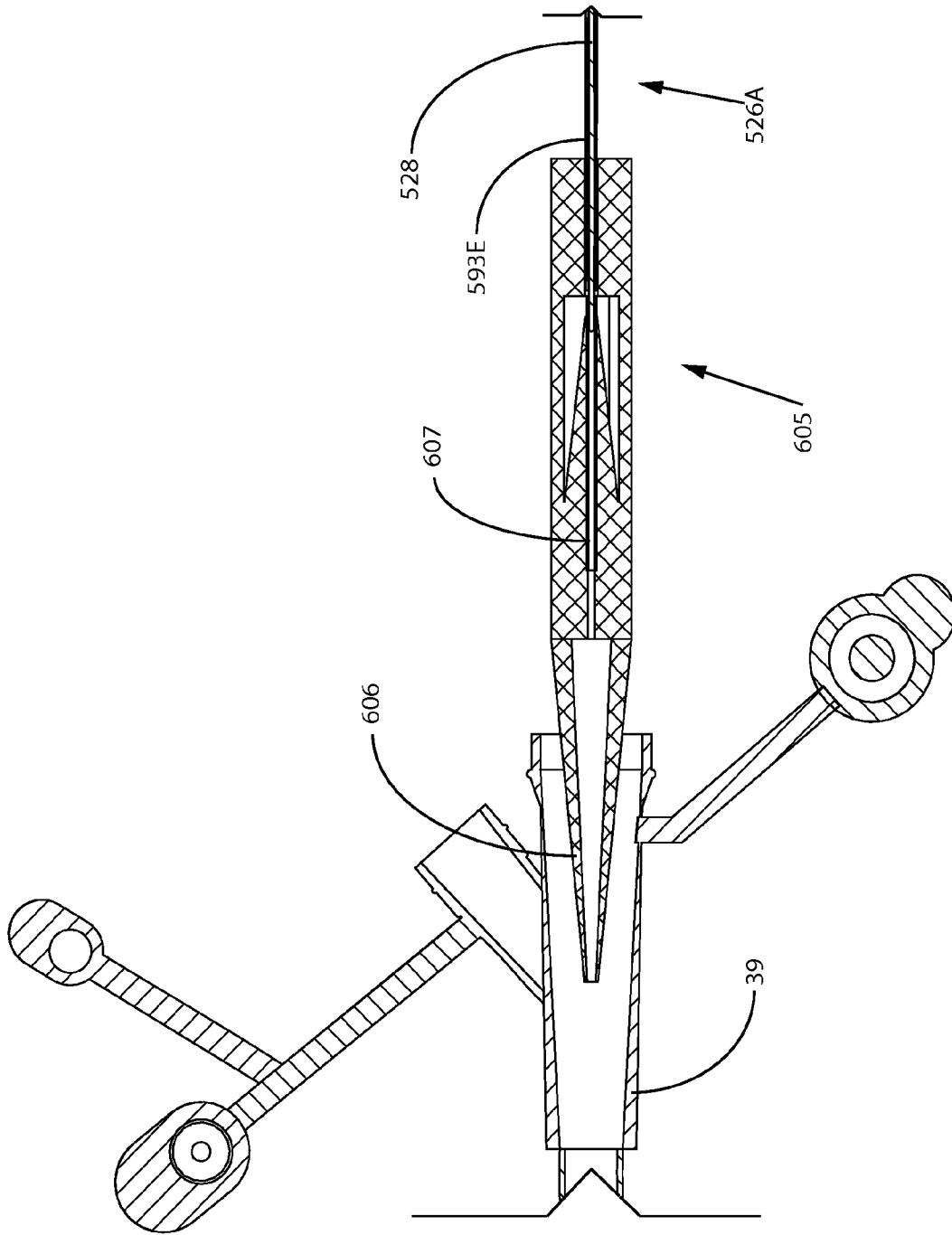


FIG. 44

**DEVICES FOR CLEARING BLOCKAGES IN  
SMALL BORE IN-SITU ARTIFICIAL  
LUMENS**

CROSS-REFERENCE TO RELATED  
APPLICATIONS

The present application is a Continuation-In-Part of U.S. patent application Ser. No. 13/683,852 filed on Nov. 21, 2012 and entitled DEVICES AND METHODS FOR CLEARING OCCLUSIONS AND FOR PROVIDING IRRIGATION IN IN-SITU ARTIFICIAL AND NATURAL LUMENS and claims the benefit of this application under 35 U.S.C. § 120 and incorporates the entire contents of this application herein in their entirety for all purposes. U.S. patent application Ser. No. 13/683,852 claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application Ser. No. 61/563,405 filed on Nov. 23, 2011 entitled DEVICES AND METHODS FOR CLEARING OCCLUSIONS AND FOR PROVIDING IRRIGATION IN IN-SITU ARTIFICIAL AND NATURAL LUMENS and is also a Continuation-in-Part application and claims the benefit under 35 U.S.C. § 120 of U.S. patent application Ser. No. 13/571,104 filed on Aug. 9, 2012 entitled DEVICES FOR CLEARING BLOCKAGES IN IN-SITU ARTIFICIAL LUMENS which in turn is a continuation of U.S. patent application Ser. No. 12/964,252 filed on Dec. 9, 2010 entitled DEVICES FOR CLEARING BLOCKAGES IN IN-SITU ARTIFICIAL LUMENS, which issued as U.S. Pat. No. 8,262,645 on Sep. 11, 2012, which in turn is a Continuation-in-Part and claims the benefit under 35 U.S.C. § 120 of U.S. patent application Ser. No. 12/274,937 filed on Nov. 20, 2008 entitled FEEDING TUBE CLEANER, now abandoned, and which in turn claims the benefit under 35 U.S.C. 119(e) of U.S. Provisional Patent Application No. 60/989,484, filed on Nov. 21, 2007 entitled FEEDING TUBE CLEANER and of U.S. Provisional Patent Application No. 61/099,737 filed on Sep. 24, 2008 entitled DEVICE FOR CLEARING BLOCKAGES IN FEEDING TUBES, and all of whose entire disclosures are incorporated by reference herein.

STATEMENT REGARDING FEDERALLY  
SPONSORED RESEARCH OR DEVELOPMENT

This invention was made with government support under grant number HD065365 awarded by the National Institutes of Health and grant numbers 0810029 and 0923861 awarded by the National Science Foundation and grant number W81XWH-11-2-0099 awarded by the ARMY/MRMC. The government has certain rights in the invention.

BACKGROUND OF THE INVENTION

1. Field of Invention

The present invention generally pertains to cleaning or clearing devices and methods of using such devices for the in-situ clearing of artificial lumens within a living being including the in-situ clearing of feeding tubes.

2. Description of Related Art

The following is a description of the background of feeding tubes. It should be understood that the device and method of the present invention is not limited to the clearing of feeding tubes but is applicable to a range of artificial lumens such as indwelling catheters and that feeding tubes are being discussed simply by way of example.

A feeding tube is a medical device used to provide nutrition to patients who cannot obtain nutrition by swallowing. The

state of being fed by a feeding tube is called enteral feeding or tube feeding. Placement may be temporary for the treatment of acute conditions or lifelong in the case of chronic disabilities. Varieties of feeding tubes are used in medical practice and are usually made of polyurethane or silicone.

A gastric feeding tube, or “G-tube”, is a tube inserted through a small incision in the abdomen into the stomach and is used for long-term enteral nutrition. The most common type is the percutaneous endoscopic gastrostomy (PEG) tube. Feeding tubes may also be of the nasogastric type commonly called “NG-tube”, which are introduced through the nose, down the esophagus and into the stomach in a procedure called Nasogastric intubation. PEG-tubes on the other hand are placed endoscopically: the patient is sedated, and an endoscope is passed through the mouth and esophagus into the stomach. The position of the endoscope can be visualized on the outside of the patient’s abdomen because it contains a powerful light source. A needle is inserted through the abdomen, visualized within the stomach by the endoscope, and a suture passed through the needle is grasped by the endoscope and pulled up through the esophagus. The suture is then tied to the end of the PEG-tube that is to be external, and pulled back down through the esophagus, stomach, and out through the abdominal wall. The tube is kept within the stomach either by a balloon on its tip (which can be inflated or deflated) or by a retention dome which is wider than the tract of the tube. In the case of NG-tubes, once they are passed through the patient’s nostril, a clinician must be careful not to accidentally slip the end of the tube into the patient’s lungs. Additionally, upon placing the NG-tube in the patient’s gastric system, for example the stomach, it is common for the tubes to slip as the primary securing means is to tape the tube to the patient immediately outside the nostril. Clinicians may pass nutrients to the patient’s stomach or remove fluids from the patient via the lumen or NG-tube.

Approximately 410,000 PEG-tubes and 5 million NG-tubes are placed each year in the U.S. A down-side of the life-sustaining feeding tube is that they can become clogged. Based on a 35% clogging rate, US civilian medical facilities, treat over 1.7 million NG clogs and 140k PEG clogs annually.

Numerous conditions that may necessitate enteral nutrition over long periods of time include but are not limited to traumatic injury or elderly illness such as Alzheimer’s, Parkinson’s, or Cancer. When long-term enteral access is needed, gastronomy- (G), jejunostomy- (J) or gastrojejunal- (GJ) tubes are often surgically inserted. J- and GJ-tubes are employed when gastric complications are present and improved nutrient uptake is necessary. Therefore, the J-tube distal end is positioned in the bowels. Reported clogging rates of GJ and J-tubes have been as high as 35% mainly due to the small bore, considerable length, and convoluted geometries of the tubes once placed. As the discussion below suggests, standard nursing protocols to clear tube occlusions are time consuming at best and are often unsuccessful. GJ- and J-tubes are especially challenging due to the curvature associated with placement.

When a patient’s enteral feeding tube becomes clogged, the process of clearing it can be time-consuming and expensive, especially if the tube must be replaced. Additionally, a clog can interrupt the patient’s supply of nutrients and cause him discomfort. Many nursing policies recommend flushing feeding tubes with water every four to six hours, and before and after administering medications or checking gastric residuals. Even with these policies, the rate of feeding tube occlusion is approximately 12.5%. Small-bore tubes are even more prone to clogging than are large-bore tubes, and clogging of these tubes has been shown to be a major cause of

feeding downtime. A patient with an occluded tube may miss several hours of feeding and receiving nutrients before the tube is unclogged or replaced. This concern, along with patients' discomfort and the expense incurred by having to replace tubes that could not be unclogged, identifies problems to be corrected by the present invention.

Over time, feeding tubes become brittle and need to be replaced. A major cause of this is the accumulation of fungus inside the feeding tube. Standard feeding tube maintenance is to "flush" feeding tubes with water; however, this does not remove debris and fungus from the inner walls. Once a tube clogs, it is prone to reclogging.

Medications are the number one reason for tubes getting clogged. Certain medications, such as Metamucil or liquid pain reliever, build up on the inner walls of the tube and promote clogging. Other medications need to be crushed and mixed with water. If these medications are not adequately flushed or crushed finely, they will clog the tube. Older patients receive an average of 8-11 medications regularly throughout the day. Due to medical restrictions on fluid intake, or if the care-giver is rushed, an adequate flush may not occur. A clogged tube can leave an already compromised patient without medication or nutrition for hours, or even days, and is extremely frustrating to both the patient and the caregiver.

Patients with long-term feeding tubes are generally cared for at home or in a long term nursing facility. Advancements in technology and home nursing have allowed the utilization of home enteral nutrition to dramatically increase over the last few decades. While this is certainly positive, the down side is that when a feeding tube becomes clogged such that it cannot be unclogged with conventional methods, the patient must be transported to a specialty hospital to have the tube surgically removed and replaced. For persons recovering in rural areas, this could be even more problematic as an extensive car ride—several hours—may be necessary to reach the specialty hospital. This disruption is a time consuming, expensive, and agonizing experience for the patient and family members. Numerous hours without nutrients and medication could have significant adverse effects on recovery of wounded soldiers, elderly and chronically ill patients.

One product which claims the ability to assist in restoring feeding tubes by degrading the clogged matter is the CLOG ZAPPER™ available through CORPAK® MedSystems of Wheeling, Ill. and is disclosed in part in U.S. Pat. No. 5,424, 299 (Monte). This product relies on a chemical solution being injected into an enteral feeding tube to clear remnant food from the tube and decontaminate the tube. The chemical solution mixture comprises maltodextrin, cellulase, alpha-amylase, potassium sorbate, papain, ascorbic acid, disodium phosphate, sodium lauryl sulfate, disodium EDTA, and citric acid. While the solution provides some assistance in degrading the clogged matter, some patients may be allergic to at least one of these ingredients and the system for introducing the chemical solution is not always successful.

The current state of science includes three approaches to remove a clog: (1) syringe flush, (2) chemical and enzymatic treatment, and (3) mechanical devices.

#### Syringe Flush

The most recommended approach is to use a 'flushing syringe'. The first step is to insert the syringe into the tube and pull back on the plunger to attempt to dislodge the clog. If not successful, warm water is placed into the tube and pressure, alternating with syringe suction, is performed. This may need to be repeated for up to 30 or more minutes. However, this may not always be done with enough efficiency or regularity and a high percentage of tubes remain clogged.

#### Chemical and Enzymatic Treatment

Chemical approaches to clog removal involve a nurse flushing the tube with a variety of reported substances, such as enzymes, meat tenderizer, soda, and fruit juices. More recently developed chemical approaches include using a dose of pancrelipase (Viokase®) and sodium bicarbonate mixed with water. The Clog Zapper uses a syringe filled with an unclogging powder with a variety of ingredients. Product directions state to allow the solution to set for an hour before flushing the tube. The InTRO-ReDUCER is a catheter that allows the solution to be introduced directly at the clog site, which has been reported to be more effective than introducing the solution at the external end of the feeding tube. Chemical approaches to clog removal are not effective. Enzymes are limited to breaking down medication and have no effect on medications. Patients can also be allergic to the ingredients in the chemical approaches, or adversely affected by the high sodium content.

#### Mechanical Devices

Mechanical devices to remove clogs are also available. Tiny brushes on wires can be used to break up the clog, but have been reported to pack the material in some clogs even more densely. The Enteral Feeding Tube DeClogger® by Bionix is a plastic, flexible rod with a spiral tip on the end. The DeClogger can be twisted to break through or pull out obstructions. Even when successful, these approaches can take up to 30 minutes to several hours per patient, do not leave the tube walls clear, and do not progress through tortuous paths well. Moreover, the DeClogger is only available for use in Tubes that are 14 French and larger.

What is needed is an apparatus capable of mechanically breaking up the clogged material from the sidewalls and inner portions of indwelling artificial tubes and catheters, and especially enteral feeding tubes. In addition, a regular maintenance schedule is preferred for using the apparatus to clean the walls of the tube. This regular maintenance cleans the tube walls of debris while stopping potential nucleation sites in which new clogs can grow from.

All references cited herein are incorporated herein by reference in their entireties.

#### BRIEF SUMMARY OF THE INVENTION

These and other features of this invention are described in, or are apparent from, the following detailed description of various exemplary embodiments of this invention.

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, performing the act of clearing a clog or blockage from a feeding tube in situ refers to cleaning or clearing a clog or blockage in a feeding tube while the feeding tube is connected to the digestive system of a being, human or other.

It should be understood that it is the Applicant's belief that where the clearing member of the embodiments disclosed herein utilizes a brush or brush function along any portion of the clearing member that makes any entry into the artificial lumen, the clearing member also cleans that interior portion of the artificial lumen.

A device is disclosed for the in situ clearing of blockages in artificial tubes (e.g., feeding tubes, including pediatric feeding tubes, PEG-tubes, NG-tubes, GJ-tubes, NJ-tubes, etc.) completely or partially disposed within a living being. The device comprises: a controller that remains outside of the living being, and wherein the controller comprises an actuator (e.g., voice coil motor; DC motor; piezoelectric actuator such as amplified piezoelectric actuators and Langevin transduc-

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ers; solenoid motor; pneumatic motor, etc.) for generating repetitive motion (e.g., reciprocating, rotating, etc.); a clearing member having a first end that is releasably coupled to the actuator and having a second working end that is insertable into an opening in the artificial tube; wherein the second working end has a portion that comes into repetitive contact with a blockage in the artificial tube for clearing the blockage therein, wherein the clearing member comprises a flexible material that permits the clearing member to make repetitive contact with the blockage while the clearing member is positioned within a straight portion or within a curved portion of the artificial tube.

A method is also disclosed for the in situ clearing of blockages in artificial tubes (e.g., feeding tubes, including pediatric feeding tubes, PEG-tubes, NG-tubes, GJ-tubes, NJ-tubes, etc.) completely or partially disposed within a living being. The method comprises: coupling a first end of a releasably-securable flexible clearing member to a controller and wherein the controller remains outside of the living being; inserting a second working end of the flexible clearing member into an opening in the artificial tube; energizing the controller such that the flexible clearing member experiences repetitive motion (e.g., reciprocating, rotating, etc.) and positioning the flexible clearing member such that the second working end of the flexible clearing member comes into repetitive contact with the blockage for clearing the blockage therein; and wherein the flexible clearing member clears the blockage when positioned within a straight portion or within a curved portion of the artificial tube.

In another embodiment, an occlusion clearing device includes a controller comprising at least one actuator for generating repetitive motion and a stem coupled to the at least one actuator. The stem can include a deformable reservoir, a port in fluidic communication with an internal volume of the deformable reservoir, a conduit member in fluidic communication with the deformable reservoir, and a reciprocating member disposed in the volume of the deformable reservoir and configured to accept the repetitive motion.

In yet another embodiment, a method of delivering fluid is disclosed. The method includes energizing at least one actuator to provide reciprocating motion to a deformable reservoir coupled thereto, the reciprocating motion of the actuator causing the deformable reservoir to be compressed, expanded, or both. Additionally, the method includes providing a flowable medium stored in the deformable reservoir through a distal end of a conduit which is in fluid communication with the reservoir. The method also includes providing the reciprocating motion of the at least one actuator to a reciprocating member that extends through an inner volume of the deformable reservoir, is also slidably disposed in the conduit, and is also coupled to the actuator.

In an additional embodiment, a method of delivering fluid is disclosed. The method includes energizing at least one actuator to provide reciprocating motion to a reciprocating member slidably disposed within a conduit. The method also includes providing a flowable medium through a distal end of the conduit, the flowable medium flowing through a volume defined by a space between the reciprocating member and a hollow portion of the conduit. Such space may be coaxial with same reciprocating member.

#### BRIEF DESCRIPTION OF SEVERAL VIEWS OF THE DRAWINGS

Exemplary embodiments of this invention will be described with reference to the accompanying figures.

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FIG. 1 is an isometric view of the control box and clearing stem of the present invention resting on a table;

FIG. 1A is an isometric view of the control box and clearing stem of the present invention disposed on another device support (e.g., a pole cart, bed, etc.), shown in partial, adjacent the patient;

FIG. 2 is a top plan view of another control box with the lid removed;

FIG. 2A is a cross-sectional view of the control box taken along line 2A-2A of FIG. 2;

FIG. 2B is a top plan view of an alternate embodiment of the control box of FIGS. 1 and 1A with the lid removed;

FIG. 3 is a side view of the clearing stem of the present invention;

FIG. 3A is a cross-sectional view of the clearing stem taken along line 3A-3A of FIG. 3;

FIG. 3B is a partial view of the sheath depicting both integer and periodic length markings;

FIG. 3C is a side view of an alternate clearing stem that is the preferred embodiment of the present invention;

FIG. 3D is a cross-sectional view of the alternate clearing stem of FIG. 3C taken along line 3D-3D of FIG. 3C;

FIG. 4 is top plan view shown in cross-section depicting the clearing stem inserted within an artificial lumen in a living being showing the clearing stem clearing a blockage and depicting the stem's radius of curvature;

FIG. 5A is a partial view of the clearing stem whose distal end includes a plastic clearing tip on the distal end of the wire;

FIG. 5B is a partial cross-sectional view of the clearing stem whose distal end includes an alternative hollow cylindrical clearing tip on the distal end of the wire including a tip compression spring (TCS);

FIG. 5C is a partial cross-sectional view of the clearing stem whose distal end includes an alternative clearing tip on the distal end of the wire including a gripping or chopping mechanism;

FIG. 5D is a partial view of the clearing stem whose distal end includes an alternative clearing tip on the distal end of the wire includes a welded ball;

FIG. 6 is a partial view of the clearing stem whose distal end includes a brush mounted on the wire tip;

FIG. 7 is a partial view of the clearing stem whose distal end includes a brush mounted on the distal end of the sheath;

FIG. 8 is a partial view of the clearing stem whose distal end includes a brush mounted on the distal end of the sheath with bristles swept toward the extreme distal end of the stem;

FIG. 9A is a top view of the tube depth-control collar;

FIG. 9B is a side view of the tube depth-control collar;

FIG. 9C is a cross-sectional view of the depth-control collar taken along line 9C-9C of FIG. 9A;

FIG. 9D is a partial isometric view of a fixed tube depth-control collar with the clearing stem inserted into a feeding tube;

FIG. 10 is a plan view of an exemplary voice coil motor (VCM) for use in the present invention;

FIG. 10A is a cross-sectional view of the VCM taken along line 10A-10A of FIG. 10;

FIG. 11 is a top plan view of another exemplary motor of the present invention with the lid removed and depicting a DC motor that drives a scotch yoke;

FIGS. 11A-11C depict a sequence of the scotch yoke operation of FIG. 11;

FIG. 12 is a top plan view of another exemplary motor of the present invention with the lid removed and depicting an amplified piezoelectric actuator (APA);

FIG. 12A is a cross-sectional view of the APA control motor taken along line 12A-12A of FIG. 12;

FIG. 12B is a cross-sectional view of Langevin transducer control motor;

FIG. 12C is a functional diagram depicting the first four overtones of clearing stem motion introduced by the Langevin transducer;

FIG. 13 is a top plan view of another exemplary motor of the present invention with the lid removed and depicting a solenoid;

FIG. 13A is a cross-sectional view of the solenoid motor taken along line 13A-13A of FIG. 13;

FIG. 14 is a top plan view of another exemplary motor of the present invention with the lid removed and depicting a pneumatic actuator;

FIG. 14A is a cross-sectional view of the control motor taken along line 14A-14A of FIG. 14;

FIG. 15 is a cross-sectional view of the magnetic pattern used in the VCM showing driving members having opposite pole directions;

FIG. 16A is a partial end view of the drive side of the control box depicting a sealing diaphragm;

FIG. 16B is a partial end view of the drive side of the control box depicting an alternative clearing stem coupling and sealing diaphragm configuration;

FIG. 16C is a partial end view of the drive side of the control box of FIG. 16 showing the clearing stem being engaged with the control box of FIG. 16B;

FIG. 17A is a block diagram of the control box electronics for the reciprocating tube clearer (TC1) configuration;

FIG. 17B is an operational flow diagram of the microprocessor of the control box electronics of FIG. 17A;

FIG. 18A depicts a hand-held version of the present invention showing the handset being gripped by the operator and including a tube depth control-collar on the clearing member;

FIG. 18B depicts an alternative hand-held version of the present invention;

FIG. 18C is a side view of the alternative hand-held version showing the hand grip in cross-section;

FIG. 19 is a cross-sectional view of the hand-held version of FIG. 18A;

FIG. 20 is a cross-sectional view of the DC motor using a planetary gear train configuration;

FIG. 21 is a cross-sectional view of the DC motor using a compound gear train configuration;

FIG. 22 is an enlarged cross-sectional view of the clearing member and its components;

FIG. 23 is an enlarged cross-sectional view of the distal end of the clearing member which uses a helical design;

FIG. 24 is an enlarged cross-sectional view of the push-button actuated tube depth-control collar;

FIG. 25 is an enlarged cross-sectional view of a torque-limiter that is designed to slip once a certain applied torque is exceeded;

FIG. 26 is a cross-sectional view of the hand-held version of the present invention depicting the multi-nodal harmonics while the clearing member is spinning;

FIG. 27 is a cross-sectional view of a prior-art hand-held device that generates rotatable motion depicting undesired operation with only a nodal point at the proximal end of the clearing stem;

FIG. 28 is a block diagram of the control box electronics for the rotating tube clearer (TC2) configuration;

FIG. 29 is a partial isometric view of the distal end of the sheath of the tube clearers TC1 and TC2 showing aspiration/irrigation ports;

FIG. 29A is a partial isometric view of the distal end of the sheath of the tube clearers TC1 and TC2 showing aspiration/irrigation ports;

FIG. 29B is a partial isometric view of the distal end of the sheath showing a lumen or wire that is hollow;

FIG. 29C is a partial isometric view of the clearing stem using only a hollow lumen or a wire only, without a sheath, effectively using the indwelling lumen as the sheath;

FIG. 29D is a partial isometric view of the distal end of the sheath of the tube clearers TC1 and TC2 showing a very narrow hollow wire allowing aspiration/irrigation along sides of wire; and

FIG. 29E is a partial isometric view of the distal end of the sheath of the tube clearers TC1 and TC2 showing a small sheath channel for a very narrow hollow wire and a larger channel for aspiration/irrigation.

FIG. 30 illustrates an embodiment of a device for clearing occlusions which provides irrigation, and includes a stem coupled to a controller that further includes an actuator;

FIG. 31A is a cross-sectional illustration of the device of FIG. 30 showing a proximal end of a stem magnetically coupled to the actuator, with the deformable reservoir shown undisturbed;

FIG. 31B is a cross-sectional illustration of the embodiment of FIG. 31A with the deformable reservoir shown filled with a flowable medium, for example, a fluid or a gas;

FIG. 31C is a cross-sectional illustration of the embodiment of FIG. 31B with the deformable reservoir being compressed on a downstroke of the actuator (the force/motion of the downstroke indicated by the left-pointing arrow);

FIG. 31D is a cross-sectional illustration of the embodiment of FIG. 31A with the deformable reservoir being stretched on an upstroke of the actuator (the force/motion of the upstroke indicated by the right-pointing arrow);

FIG. 32 is a side view showing a stem used in the device of, for example, FIG. 30 with its deformable reservoir in fluidic communication with a conduit and a port;

FIG. 33A is a view of an embodiment of a stem, including a port, conduit, reciprocating member and deformable reservoir;

FIG. 33B is a view of the stem of FIG. 33A with the deformable reservoir filled with flowable medium;

FIG. 33C is a view of the stem of FIG. 33B upon providing the deformable reservoir with a compressive force provided by the downstroke of an actuator (force/motion indicated by left-pointing arrow; actuator not shown) to which it is coupled, such that upon being compressed by a sufficient amount, a pressure is created so that the flowable medium flows through the conduit, for example, between reciprocating member slidably disposed therein and an inner diameter thereof so as to flow out of an open distal end of the conduit;

FIG. 33D illustrates the stem of FIG. 33C upon providing the deformable reservoir with a tensile force by an upstroke of an actuator (force/motion indicated by the right-pointing arrow; actuator not shown), to which it is coupled such that upon being stretched, a vacuum forms of a sufficient amount to allow flowable medium to flow into the deformable reservoir from an external source (not shown) to replenish the fluid expelled during the stroke shown in FIG. 33C;

FIG. 34 is a cross sectional view of an embodiment of a stem;

FIGS. 35A-B are cross sectional views of an embodiment of a reciprocating member;

FIG. 36 illustrates an embodiment of a device for clearing occlusions which provides irrigation, and includes a stem coupled to a controller that further includes an actuator;

FIG. 37A is a cross-sectional illustration of the device of FIG. 36 showing a proximal end of a stem, such as a pre-filled

stem or a stem in fluidic communication with a fluid medium source, magnetically coupled to the actuator, without a deformable reservoir;

FIG. 37B is a cross-sectional illustration of the embodiment of FIG. 37A with the reciprocating member being reciprocated on a downstroke of the actuator (the force/motion of the downstroke indicated by the left-pointing arrow);

FIG. 37C is a cross-sectional illustration of the embodiment of FIG. 37A with the deformable reservoir being stretched on an upstroke of the actuator (the force/motion of the upstroke indicated by the right-pointing arrow); and

FIG. 38 is a cross sectional view of an embodiment of a stem.

FIG. 39 is a cross sectional view of an embodiment of a stem.

FIG. 40 is an isometric view illustrating the concept of the split conduit.

FIG. 41A is a section view of the conduit cutter showing scalpel channel and conduit channel.

FIG. 41B is a section view of the conduit cutter with a scalpel blade inserted and a conduit being passed through it.

FIG. 41C is an isometric view illustrating the process of creating a split conduit by using the conduit cutter.

FIG. 42A is an isometric view of the conduit splitter.

FIG. 42B is a section view of the conduit splitter with a magnified view of the interior of the conduit splitter to show more detail of the hypodermic tubing and its corresponding channel.

FIG. 43A is a section view of the conduit splitter with a magnified view of the split stem passing through it.

FIG. 43B is a top view of the conduit splitter as the split conduit is spread out over the conical conduit guide.

FIG. 44 is a section view of an artificial tube with the conduit splitter inserted into it.

#### DETAILED DESCRIPTION OF THE INVENTION

The preferred embodiments of this present invention are illustrated in FIGS. 1-29E with the numerals referring to like and corresponding parts.

The present inventions are portable devices, as well as methods for such devices, for effectively removing, moving or breaking up a clog from the internal portions of an artificial tube or catheter, enteral tube, and preferably a feeding tube, including pediatric feeding tubes. The action of removing clogs and clearing artificial tubes can also be referred to as a "maintenance action".

As will be discussed in detail later, there are basically two types of tube clearers (TC) disclosed herein, both of which are mechanical tube clearers. The first type of tube clearer TC1 includes several embodiments that generate reciprocating motion of a clearing member for removing, moving or otherwise breaking up a clog in the artificial tube. This tube clearer TC1 is preferred for use in nasogastric (NG) feeding tubes, although it should be understood that TC1 is not limited for only clearing NG feeding tubes. FIGS. 1-17B, 29, 29B, 29C, 29D and 29E are directed to TC1.

The second type of tube clearer TC2 involves the generation of rotational motion of a clearing member for removing, moving or otherwise breaking up a clog. This tube clearer TC2 is preferred for use in percutaneous endoscopic gastric (PEG) feeding tubes, although it should be understood that TC2 is not limited for only clearing PEG feeding tubes. FIGS. 5A, 5D, 18A-28, and 29A-29D are directed to TC2.

Both types of tube clearers TC1 and TC2 are unique to feeding tube clearing and overcome major obstacles in critical and long-term care medicine by clearing clogged feeding

tubes quickly and efficiently. As will be discussed in detail later, the tube clearer TC1 and TC2 can remove a clog much faster (e.g., in less than 6 minutes) and at a much greater success rate than other currently-available clearing methodologies/devices, while at the same time, resulting in cleaner tube walls. Existing methodologies/devices simply do not work at all, do not clear the clogs properly, or they take a considerable time to do so.

In both tube clearers TC1 and TC2, an activation unit or controller remains external to the artificial tube and therefore the patient. The activation unit or controller delivers energy to a clearing stem (also referred to as a "clearing member") which is inserted into the artificial tube and whereby the clearing stem destroys the clog (e.g., clogs of food and/or ground medication, etc.) and cleans the tube walls. As a result, the activation units in these clearers TC1 and TC2 are reusable devices and the clearing stems are disposable. The clearing stems of TC1 and TC2 operate in narrow tube diameters, through several radial curves sufficient to reach, e.g., the bowel. Thus, the tube clearers TC1 and TC2 clear safely and with greater efficiency for NG-, PEG-, GJ- and NJ-tubes. Both tube clearers TC1 and TC2 require no complicated set up, e.g., no tuning is required.

#### Reciprocating Tube Clearer TC1

As shown in FIG. 1, the tube clearer TC1 comprises an activation unit (also referred to as the "control box" or "controller") 1 which remains external to the artificial tube 39 (see FIG. 4) being cleared, and therefore is also external to the patient (not shown). The activation unit 1 delivers energy to a clearing stem 26 which clears as it moves through the tube inner lumen 41 of the indwelling artificial tube 39, destroying the clog 40 and clearing the walls of the artificial tube 39, viz., the tube inner lumen 41 walls. Where feeding tubes are being cleared by the tube clearer TC1, the tube clearer TC1 breaks up clogs of food and ground medication in a short time (e.g., less than 6 minutes). The reusable control box 1 includes a motor which drives (actuates) the disposable clearing stem 26. The control box 1 is positioned and releasably secured onto a table, tray, or nursing cart 38, such as shown in FIG. 1. Alternatively, the control box 1 can be positioned on a pole cart 38A (see FIG. 1A), or bed rail or any other type of support that is adjacent, or which can be moved adjacent to the patient or living being.

As shown most clearly by way of example in FIG. 3A, the clearing stem 26 comprises a wire 28 running concentrically through a sheath 30. The wire 28 protrudes from the end of the sheath 30 and is actuated while the sheath 30 remains stationary and is secured to a non-moving portion of the control box 1. The motion at the wire tip 29 clears the occlusion or clog 40.

#### Control Box 1

As shown in FIGS. 2-2B, the control box 1 comprises a motor 14, drive electronics 10, electrical connectors, wiring, and clearing stem connectors. The control box 1 is preferably constructed of polymer, although metallic, rubber, or a combination of all three materials may be used. The preferred polymer is flame-retardant ABS plastic, although other polymers such as polyurethane, polypropylene, and nylon, but not limited to such, may be used for, among other things, their lightweight composition and structural integrity. Metals such as aluminum, titanium, steel, brass in sheet or machined form may also be used, especially where certain motor technologies (e.g., amplified piezoelectric actuators (APAs)) are used; to maintain efficiency of APAs, the non-moving portion of them needs to be effectively clamped or else too much deflection on the side that should be clamped will greatly reduce the APAs' efficiency; a metal control box provides sufficient

rigidity to properly clamp. The control box **1** has a releasable securing mechanism such as rubber feet, mechanically actuated suction cup, screws, rubber stops, or magnetic feet, etc. that facilitates its use on a table or nursing cart. As such, the control box **1** remains portable but is stationary during use. The motor **14** drives a motor shaft **15** that generates the reciprocating motion.

It should be understood that FIG. 2B depicts the preferred control box **1** because it comprises a novel clearing stem-control box interface, as will be discussed in detail later with regard to FIGS. 16B-16C. FIG. 2B also depicts, by way of example only, the use of a counter balance mechanism **14A** to counteract vibration caused by the reciprocation of an actuating motor **14**, as will also be discussed later.

In another embodiment, the electronic circuit and components for example power indicator **3**, fault indicator **4**, enable switch **72** can be incorporated into a membrane switch such as XYMOX Technologies, Inc. Model No. 54894. Clearing Stem/Member and Connectors

The clearing stem **26** comprises a sheath **30** which is fed into the clogged artificial tube. The preferred sheath material is polytetrafluoroethylene (PTFE) although other tube materials may also be used such as, but not limited to, nylon, polyvinyl chloride (PVC), polyurethane, polyethylene, polypropylene, fluoropolymer, Viton, Hytrel. As mentioned previously, within the sheath **30** is a wire **28**, which is attached to the motor **14**. The motor **14** supplies reciprocating (also referred to as "oscillating") motion to the wire **28**, causing the wire **28** and its wire tip **29** to reciprocate back and forth. As can be seen most clearly in FIGS. 3-3A, the wire **28** protrudes beyond the end of the sheath **30**, and into the clog **40** (FIG. 4) which causes the disruption of the clog **40**. The length of the wire protrusion **28A** beyond the end of the sheath **30** strongly impacts the effectiveness of the clearing. In addition, the roundness of the wire tip **29** strongly impacts the ease of insertion of the clearing stem **26** into the artificial tube **39**.

The clearing stem **26** may comprise a length of 60 cm to 250 cm, but preferably 180-220 cm, and most preferably, 203 cm. In addition, the wire **28** may comprise a flexible wire most preferably stainless steel twisted wire, but could also be helical wrapped wire or a flexible stainless steel wire encased in a polymer wrapping, such as shrink wrap. The wire **28** protrudes from the end of the sheath a distance of 0 to 13 cm, but preferably 1 to 5 cm and most preferably 2.54 cm. The clearing stem **26** releasably secures to the control box **1** via a Luer clearing stem connector **6**.

It should be noted that that, alternatively, the wire **28** may be hollow to enable other features such as irrigation or aspiration of the artificial lumen, as will be discussed later.

FIGS. 3-3A depict the clearing stem **26** which uses a magnetic-based and Luer lock connection to the control box motor **14**, a stem stiffener **31** at a proximal end of the clearing stem **26**, the amount that the wire tip **29** extends beyond the sheath **30** (referred to as the "protrusion" or "wire protrusion") **28A**, a wire stop **27**, and tube depth-control collar **22**.

In particular, the proximal end of the clearing stem **26** comprises a clearing stem magnet **33** and a Luer clearing stem fitting **32** (FIGS. 3-3A). The control box **1** includes a Luer clearing stem connector **6** (FIGS. 2-2A) along with a motor magnetic coupler **13** which itself includes an internal magnet **12** in the coupler bore. To releasably secure the clearing stem **26** to the control box **1**, the clearing stem magnet **33** is passed through the Luer clearing stem connector **6**, through a diaphragm **9** and into the motor magnetic coupler **13** where the clearing stem magnet **33** and magnet **12** come into contact to form the magnetic coupling. The Luer clearing stem fitting **32** and Luer clearing stem connector **6** are then engaged to form

the Luer lock configuration. Advantages to this magnetic connector include: the omission of threads (which can suffer from stripping), the avoidance of any special tools to facilitate connection, reduced occurrence of bio-contamination, and the avoidance of having to disassemble any portion of the control box **1** in order to switch clearing stems **26**. The design of the mechanical components and the strength of the two magnets **33/12** are critical to avoid detaching the clearing stem **26** when the motor **14** is reciprocating. By way of example only, the magnets **12/33** may comprise rare earth magnets (e.g., neodymium) for holding the clearing stem wire **28** to the motor shaft **15**. The appropriately-sized magnets may provide from 0.5 to 3.0 lbs. of holding force. The sheath **30** is held fast to the control box **1** by the Luer lock connector/receptacle combination. It should be understood that clamping of the sheath **30** needs to have a certain force to secure the sheath **30**, but not crush the sheath **30**. The stiffness of the sheath **30** must be adequate to preserve the inner diameter cross section during operation. This is necessary to ensure the wire **28** is not pinched by the operator and its motion impeded. The wire **28** must also be flexible enough to navigate a small radius of curvature, such as 2.54 cm radius, while maintaining operation, as can be seen in FIG. 4. In particular, FIG. 4 depicts a clog **40** blocking the tube inner lumen **41** of an artificial tube **39** and wherein the clearing stem **26** navigates a tight radius of curvature, R, and clears the clog **40** which is located past the radius of curvature R. The magnets **33/12** may be cylindrical in shape and the magnet **12** within the motor magnetic coupler **13** is recessed within the motor magnetic coupler **13** that fits over the motor shaft **15**. The magnet recess **12A** keeps the magnet from sliding along its surface plane and becoming detached while it is reciprocating. A sensor (magnetic or contact, not shown) may also be implemented to illuminate an indicator **75A** (e.g., an LED, see FIGS. 2A and 17A) on the control box **1** to confirm that the magnetic connection is securely made. This feature also alerts the user if the connection becomes broken during use.

In an alternate embodiment, the magnet **33** (or **12**) may only be located on one of the mating pieces, and a disc or cylinder of magnetic material, be located on the other.

It should be understood that this magnetic Luer lock coupling is by way of example only. It is within the broadest scope of the invention to include other types of releasably securable connector mechanisms, such as, but not limited to, threaded couplings.

As mentioned previously, the control box **1** includes a diaphragm **9** which seals the control box **1** from contamination from the outside. As can be seen most clearly in FIGS. 2-2A, the diaphragm **9** permits magnetic attachment of the clearing stem **26** so that the magnets **33/12** can make contact while at the same time sealing the box **1** such that no debris, biological or other, enters the control box **1**. FIG. 16A is an enlarged partial view showing the sealing diaphragm **9** that does not interfere with motor shaft **15** motion. The diaphragm **9** prevents, among other things, the ingress of liquids into the control box **1**. The diaphragm **9** may also be located externally or on the boundary of the control box **1** so that it can be cleaned more easily.

As also mentioned previously, the preferred control box **1** is that shown in FIG. 2B wherein a preferred novel clearing stem-control box interface is used. In particular, FIGS. 16B-16C depict the drive side of the control box **1** which includes a sheath attachment bracket **83**, an alternate diaphragm **9A**, a diaphragm sealing ring **84** (see also FIG. 2B), the motor (e.g., voice coil motor, VCM) shaft **15** along with an alternate motor magnetic coupler **13A** (e.g., a magnetic coupler for a VCM). As can be seen from FIG. 16B, the alternate dia-

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phragm 9A contains no holes or apertures through which the clearing stem 26 passes. The diaphragm sealing ring 84 secures the compliant alternate diaphragm 9A in place. To facilitate coupling the clearing stem 26 to this control box, as can be seen most clearly in FIG. 16C, the proximal end of the clearing stem 26 comprises an alternate clearing stem fitting 32A and an alternate clearing stem magnet 33A positioned within an alternate clearing stem magnetic fitting 33B. In order to couple the clearing stem 26 to the control box motor 14, the alternate clearing stem magnet fitting 33B is brought into close proximity with the alternate diaphragm 9A such that the two magnets 12 and 33A are magnetically coupled and abutting through the alternate diaphragm 9A. Thus, there is no breach of the seal of the control box 1 because the alternate diaphragm 9A remains closed. Simultaneously, the alternate clearing stem fitting 32A is secured in the sheath attachment bracket 83. As a result, reciprocation of the motor shaft 15 can occur without passing through any aperture or opening in the alternate diaphragm 9A. FIGS. 1 and 1A depict a drive-end view of the clearing stem 26 coupled to the control box 1.

As can be appreciated from FIG. 3A, the wire stop 27 limits the amount of travel of the wire 28 to the right (i.e., towards the motor 14) during operation. In an alternate embodiment, as shown in FIGS. 3C and 3D, the wire stop 27 has been removed and instead an alternate wire stop 27A is used closer to the proximal end of the clearing stem 26. This alternate wire stop 27A comprises a stretchable/pliant (e.g., silicon) tube whose ends are bonded to the alternate clearing stem fitting 32A on one side and to the alternate clearing stem magnet fitting 33B on its other side. This alternate wire stop 27A supports the wire 28 that passes through it. During operation, the alternate wire stop 27A compresses and expands accordingly without interfering with wire 28 oscillation/travel. This alternate wire stop 27A is preferred because it is located externally of the artificial tube 39 and thereby avoids having a stop at the working end of the wire 28 that could interfere with operation. Thus, the alternate wire stop 27A serves to keep the wire 28 from sliding out of the sheath 30.

As shown in FIG. 3A, the wire tip 29 of the wire is rounded to allow the wire 28 to break up a clog 40 (FIG. 4), and to resist penetrating an organ (e.g., stomach or other tissue/organ, etc.) should the wire tip 29 ever make its way close to an organ. The wire protrusion 28A may also be given added flexibility by design compared to that of the rest of the wire 28, to further reduce the risk of the clearing stem wire tip 29 having enough force to penetrate an organ (e.g., the stomach) and/or to increase displacement at the wire tip 29 and facilitate clearing of the clog 40. As mentioned previously, the length of the wire protrusion 28A beyond the end of the sheath 28 and the roundness of the wire tip 29 strongly impact the ease of insertion into an artificial tube. Ideally, the wire tip 29 radius is 0.5 to 2.0 times the overall wire 28 diameter. The stiffness of the sheath 30 comprises a balance between being stiff enough to prevent the operator from clamping down on the wire 28 and stopping wire 28 motion versus being flexible enough to enter an artificial (e.g., feeding) tube 39 and to navigate curves in the tube inner lumen 41 of the artificial tube 39.

Another safety feature of the present invention TC1 is that the force generated at the end of the wire tip 29 is less than 5% of the force generated at the motor 14 and therefore, this force reduction provides a safety feature of avoiding puncturing an organ accidentally but yet providing sufficient force to break up the clog 40 and helping to clear the walls of the tube.

As mentioned previously, a stem stiffener 31 (FIGS. 3-3A) is provided at the proximal end of the clearing stem 26 which

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prevents the operator from over-bending the clearing stem 26 and thereby stopping the reciprocation. The stem stiffener 31 may be constructed of the same material (of a larger diameter than the wire 28 or sheath 30), may be integrated into the sheath 30 via custom extrusion, or may be constructed of a different material, such as any polymer or metal.

To prevent the "over-insertion" of the clearing stem 26, a tube depth-control collar 22 (FIGS. 3-3A and 9A-9C) is provided. The tube depth-control collar 22 comprises a tube depth-control collar body 24 which includes an internal spring 25. A tube depth-control collar push button 23 is provided to lock or unlock the tube depth-control collar 22. In particular, as shown most clearly in FIG. 9A, the depth control collar push button 23 has a central passageway of push button 23A and the tube depth-control collar body 24 has a central passageway of collar body 24A. A spring 25 acts to misalign these two passageways 23A/24A. Thus, to re-position the tube depth-control collar 22 along the length of the sheath 30 (not shown), the depth control collar push button 23 is depressed which momentarily relieves any clamping force on the sheath 30 and the tube depth-control collar 22 can then be moved. When the operator wishes to lock the tube depth-control collar 22 in position, he/she releases the tube depth-control collar push button 23 which results in the sheath 30 being clamped between an upper portion of collar body 24B of the tube depth-control collar body 24 and a lower portion 23B of the tube depth-control collar push button 23. The force applied by the depth-control collar to the sheath 30 needs to be compressive enough to hold the tube depth-control collar body 24 in place against the sheath 30, but not to clamp the sheath 30 onto wire 28. Sheath length markings 30A (FIG. 3B) and integer markings 30B (FIG. 3B) are provided to facilitate positioning the tube depth-control collar 22 along the length of the sheath 30 depending on the length of the artificial tube 39 being cleared. The markings 30A/integers 30B are in ascending or descending order from the distal end 30C of the sheath 30 to the proximal end 30D. Along with the stiffness of the sheath 30, the spring constant of the spring 25 comprises a balance between the force necessary to maintain the tube depth-control collar body 24 in place on the sheath 30 while avoiding the tube depth-control collar body 24 from clamping down on the wire 28 and stopping wire 28 motion.

It should be understood that it is within the broadest scope of the present invention to include fixed tube depth-control collars 22A, such as that shown in FIGS. 3C, 3D and 9D. In particular, a plurality of clearing stems 26 may be provided, each having a fixed tube depth-control collar 22A fixed at a predetermined length (e.g., 35 inches, 44 inches, etc.) along the sheath 30. FIG. 9D shows the fixed tube depth-control collar 22A abutting the proximal end of the feeding tube FT thereby preventing the sheath 30 from entering any further within the feeding tube FT. Using this embodiment, the operator selects one clearing stem 26, from a plurality of clearing stems 26, having a particular fixed tube depth-control collar 22A and clearing stem 26 length that is appropriate for the particular feeding tube FT that contains a clog that is to be cleared.

To facilitate clearing, a brush may be included on the wire tip 29 or on the distal end of the sheath 30. For example, FIG. 6 depicts a wire tip brush 35 on the end of the wire 28 whereas FIGS. 7 and 8 depict respective brushes with sheath tip brush 36 and forward swept sheath tip brush 37 on the end of the sheath 30. Therefore, as the wire protrusion 28A reciprocates, the wire tip brush 35 cleans the tube walls or when the sheath 30 is inserted into the artificial tube 39, the insertion motion causes the brush 36 or 37 to clean the tube walls, as well as facilitate the movement of the dislodged blockage and/or its



pieces. In particular, the small brush (e.g., polyester, foam, or twisted in wire) on the distal end of sheath (36 or 37) or wire (35) provides more thorough clearing of tube walls. With particular regard to brush 36 or 37, mounted on the distal end of the sheath 30, the brush 36 or 37 is non-moving in this embodiment, which helps to clear excess particles from tube walls after the wire protrusion 28A has cleared the clog 40 and as the sheath 30 is retracted and moved out of the artificial tube 39. The advantage of the brush 36 or 37 on the sheath 30 is that the brush 36 or 37 does not impede the wire 28 motion at all. It should be noted that the forward swept sheath tip brush 37 on the distal end of the sheath 30 shown in FIG. 8 includes bristles that are swept in the distal direction. This makes clearing effective as the forward swept sheath tip brush 37 is inserted into the tube, but also allows for a smoother retraction because the sweep-direction of the bristles reduces the resistance of the forward swept sheath tip brush 37 when the operator is removing the clearing stem 26 from the artificial tube 39. This reduced resistance minimizes the chance of dislodging the artificial tube 39 from the patient when the clearing stem 26 is removed.

Other configurations of the clearing stem 26 include a range of wire tip 29 designs. For example, a sphere (e.g., metal or plastic) anywhere along the length of the wire protrusion 28A may be included, such as the ball tip 34E in FIG. 5D. If the sphere is included at the wire tip 29, this helps prevent the inadvertent insertion into an organ (e.g., stomach) wall, and also prevents the inadvertent retraction of the wire protrusion 28A into the sheath 30 during use, setup or clearing illustrated in FIG. 5D. Another alternative end may comprise a plastic end wherein a plastic tip is fused or ultrasonically welded to the wire tip 29 and which may comprise the shape of a point, helix, or radius, etc., illustrated in FIG. 5a. In addition, these alternative tips may further comprise ridges or a pattern designed to sweep broken debris away from the clog 40 site. FIG. 5A depicts the distal end of the wire 28 with a plastic wire tip 34. An alternative tip design may include a spring guide wire design possibly exemplified by Lake Region Medical Paragon Pre-coat guidewires. Another alternative tip could be flexible such as a Tecoflex® tip which causes the tip to slide across contacted tissue rather than puncturing tissue, thus providing an additional safety feature.

FIG. 5B depicts another alternative end which may comprise a small spring mechanism which provides increased displacement and protection against an over-insertion puncture. In particular, a plastic or metal alternate tubing tip 34A is positioned over the distal end of the wire 28. The rear end of the alternate tubing tip 34A is secured to one end of a tip compression spring TCS that is slid onto the wire 28. A fixed member 34B is secured to the wire 28 and to the other end of the tip compression spring TCS. Thus, the alternate tubing tip 34A acts as a further protection against accidental contact with soft tissue, since the alternate tubing tip 34A can only be retracted when it encounters a solid object, e.g., a clog, and whereby the wire tip 29 is then exposed to the solid object. Once the clog is cleared, the alternate tubing tip 34A springs back in position ahead of the wire tip 29 to shield it from contact with bodily tissue or organs. Moreover, the wire tip 29 may also comprise a small gripping mechanism wherein the wire tip 29 contains a small cable-actuated gripping mechanism to dislodge clogs 40 or retrieve samples of clog material. In particular, FIG. 5C depicts gripping/chopping mechanism 34C that are hinged or pivoted at pivot point 34D. By actuating a control member (not shown, e.g., a cable, rod, electro-mechanical motor, piezoelectric motor etc.), the gripping/chopping mechanism 34C can be closed around a clog

specimen or used to tear away the clog material to dislodge clogs or retrieve a sample of the clog material.

An alternative design to the wire 28 is the provision of a flexible portion of wire 28 located between the end of the sheath 30 and the wire tip 29. Thus, the wire protrusion 28A may comprise a material that is more flexible than the remaining part of the wire 28 that couples to the motor shaft 15.

Control Box Motor for TC1

As mentioned previously, the motor 14 drives the wire 28, creating linear displacement. The back and forth displacement of the wire 28 allows it to break up and clear clogs 40 in artificial tubes (e.g., enteral feeding tubes and especially NG feeding tubes), while simultaneously cleaning debris from the tube walls. The wire tip 29 of the wire 28 has a linear displacement, preferably, in the range of 0.25 to 25 mm, more preferably 2-10 mm from the distal end of the sheath 30. The frequency of operation of the motor shaft 15 preferably varies from 10 to 100 Hz but more preferably in the 15-40 Hz range. The motor 14 has a range of displacement preferably from 1-40 mm and more preferably in the range of 10-30 mm. The motor blocking force (i.e., the maximum force output) has a preferable range of 2-25N and more preferably 6-14N.

The reciprocating motion of the clearing stem 26 of the present invention TC1 can be achieved using a variety of motor technologies, such as, but not limited to, voice coil motors (VCMs) as illustrated for the motor 14 (FIGS. 2-2B, 10-10A and 15), DC motors 49 (FIG. 11, 11A-11C), piezoelectric transducers, including amplified piezoelectric actuator motors 59 (APA, such as those disclosed in U.S. Pat. No. 6,465,936 (Knowles, et. al), whose entire disclosure is incorporated by reference herein) (FIGS. 12-12A), piezoelectric actuators, active polymer compound actuators, solenoid motors 55 (FIGS. 13-13A), pneumatic motors 42 (FIGS. 14-14A), magnetostrictive transducers, electrostrictive transducers, etc.

As shown in FIGS. 2-2A, 10-10A, and 15 the motor 14 may comprise a voice coil motor (VCM) having a VCM body 16 mounted within end bearings 18, a displaceable motor shaft 15, dampers or spring 19, and magnets 20 mounted to the motor shaft 15, with pole pieces 21A, 21B and 21C (FIGS. 2A, 10A and 15) located at the ends and within the center of the magnets 20. Coil windings 17 are wound around the VCM body 16 and thus do not interfere with VCM motor shaft 15 displacement. Motor mounts 7 and motor mount dampers 8 secure the motor 14 within the control box 1 while avoiding direct coupling against the bottom surface of the control box 1. A motor printed circuit board (PCB) 11 distributes the current commands from the electronics 10 to the coil windings 17 through wires 53. When an electric current is applied through the coil windings 17, a magnetic field, due to Ampere's Law, is produced inside the coil windings. The non-uniform magnetic field at the ends exerts a force on the permanent magnets 20. Alternating the current alternates the direction of the magnetic field gradients and results in a reciprocating motion of the motor shaft 15 with respect to the VCM body 16. The magnitude of the force is determined by the magnetic flux density, which is proportional to the number of turns per length of the coil, current magnitude, cross-sectional area of the coil, as well as the strength of the permanent magnets 20. The springs 19 absorb the energy associated with abrupt changes in the direction of the inertial force of the magnets 20 and VCM body 16 when actuated, resulting in a lowering of vibration and increasing the tube clearer TC1 usability and efficiency.

By way of example only, the spring constant of the springs 19 can range from 0.5-5 lb/in, and more preferably 1.5-2.5 lb/in.

A soft stop SS may be installed at the free end of the VCM motor shaft 15 because the shaft tends to drift off center during use.

A further variation of the use of a plurality of magnets is to arrange the plurality of magnets into two “driving members” disposed between the pole pieces 21A-21C, mentioned previously. Pole pieces 21A-21C are typically ferromagnetic and are preferably stainless steel. As shown most clearly in FIG. 15, the south poles of the first magnetic driving member 20N and the south poles of the second magnetic driving member 20S are fixedly secured to the opposing faces of the pole piece 21B in order to provide a zone of maximum magnetic flux density which extends radially outwardly from the central portion of the pole piece 21B, similar to the configuration disclosed in U.S. Pat. No. 4,363,980 (Peterson) whose entire disclosure is incorporated by reference herein. Alternatively, each magnetic driving member 20N and 20S may be replaced with a single elongated permanent magnet, rather than using a plurality of magnet elements as shown in FIG. 15. In either case, the driving members 20N and 20S have opposite pole directions.

It is within the broadest scope of the present invention that the relative positions of the coil windings 17 and the magnets 20 are reversed (not shown), i.e., the coil windings 17 are wound directly around the motor shaft 15 and the magnets 20 are positioned around the VCM body 16 and thus do not interfere with the motor shaft’s 15 reciprocation.

Alternatively, a dual coil motor or actuator (also not shown) is also within the broadest scope of the present invention. In particular, instead of using magnets 20, two coil windings are used wherein one coil is wound directly around the motor shaft 15 and a second or outer coil is wound around the first or inner coil but without interfering with shaft displacement. Each coil is supplied with respective alternating current sources which generate respective electromagnetic fields that also generate a reciprocating motion of the motor shaft 15. The inner coil may conduct direct current DC while the outer coil conducts alternating current AC. Alternatively, the inner coil may conduct alternating current AC while the outer coil conducts direct current DC, or both the inner coil and the outer coil may conduct alternating current AC.

Moreover, to reduce vibration caused by the oscillating motion of the motor shaft 15, a secondary VCM or counter balance mechanism 14A of similar size (also referred to as a “countermass” or “counterbalance”) may be included and driven at an opposite phase (e.g., 180° phase lag) for cancelling vibration caused by the motor 14. See FIG. 2B. Thus, when the tube clearer TC1 is operated such that the first VCM is activated to cause the motor shaft 15 to move, a first momentum vector is produced. The second VCM is operated such that it creates a second momentum vector equal in magnitude but opposite in direction to the first momentum vector, such that the net sum of the first and second momentum vectors is minimized and preferably equal to zero. In particular, to maximize vibration reduction, the moving parts (shaft, magnets, pole pieces, attachments, etc.) of the counter balance mechanism 14A should have a moving mass and velocity (frequency and displacement) equal to that of the moving parts of the actuating motor 14. This is based on the principle of Conservation of Momentum. The sine waves that actuate both VCMs must have a 180 degree phase lag between them. This causes their forces to be opposite and (ideally) equal, cancelling each other out. As such, operation of the tube clearer TC1 does not cause “chatter” and therefore there is no irritation to the operator or patient.

#### DC Motor 49

The motor may also comprise DC or DC brushless motor 49 for creating reciprocating displacement via a scotch yoke SY or similar mechanism. FIG. 11 depicts the control box 1 using a DC motor 49 and scotch yoke SY as the actuating mechanism. No signal generating electronics are needed for this application since the DC motor 49 is simply turned on to cause a rotating crank CR to drive the scotch yoke slider 50 and the scotch yoke shaft 52 in reciprocating motion. The adapter 51 transmits the scotch yoke SY motion to the scotch yoke shaft 52. FIGS. 11A-11C show three still frames as an example of scotch yoke SY motion. FIG. 11A and FIG. 11B show Scotch yoke forward displacement direction 50A and FIG. 11C shows Scotch yoke rearward displacement direction 50B are moving in a reciprocating motion.

#### APA Motor 59

An amplified piezoelectric actuator (APA) 60 creates reciprocating displacement in the lower range, preferably (0.1 to 2.0 mm), anchored to the control box 1. One or more APA motors 59 can be used in series, as this increases displacement. FIGS. 12-12A depict the control box 1 with an APA as the actuating mechanism. In particular, the APA actuator 60 is mounted to the control box via an actuator mount 61 which is indirectly coupled to the control box 1 bottom via motor mount damper 8. An actuator shaft 62 conveys the reciprocating motion, from APA actuator 60 expansion and contraction, to the clearing stem (not shown) via the magnetic coupling discussed earlier for the other embodiments.

#### Langevin Transducer 77

A Langevin transducer 77 can be used for the motor 14. As shown in FIG. 12B, the Langevin transducer comprises a plurality of piezoelectric elements 78 are arranged to cause a horn 81 to vibrate to form the reciprocating motion. The horn 81 is secured to an actuator mount 61 using a pre-stress bolt 79. The Langevin transducer 77 includes a tail mass 80 for bolt-clamping the Langevin transducer 77 to the actuator mount 61. The forward end of the horn 81 is tapered such that a distal end of the horn passes through the control box alternate diaphragm 9A. A clearing stem attachment 82 is provided to receive/mate with the clearing stem 26 as discussed previously. A power source (not shown) that provides the proper activation energy is coupled through the power plug 5 and via electronic control wires 53.

It should be noted that activation of the Langevin transducer 77 creates reciprocating motion with the introduction of several overtones (viz., first-fourth overtones), shown in FIG. 12C. As part of the design of the present invention, the lateral displacement caused by these overtones is kept to a minimum. In particular, the piezoelectric elements 78 (e.g., a plurality of piezoelectric ceramic discs) are held in compression between the tail mass 80 and horn 81; and the pre-stress bolt 79 passing from a proximal end of the tail mass 80 and threading into the horn 81. Vibratory motion is caused by the activation of the piezoelectric elements 78 upon being exposed to an alternating electric field such as from an AC electrical current applied to electrical contacts (not shown) formed on opposing sides of each of the piezoelectric elements 78. The vibratory motion is translated as a standing harmonic wave spanning longitudinally across the horn 81 and to the clearing stem (not shown). Therefore, when operated at ultrasonic frequencies, the Langevin transducer 77 translates the ultrasonic energy as a reciprocating vibration to the clearing stem 26, and produces a standing wave within the flexible member. The horn 81 and tail mass 80 are made of a

metal such as titanium, stainless steel or, preferably, aluminum. The pre-stress bolt 79 is generally of stainless steel, but not limited thereto.

#### Solenoid Motor 55

The solenoid motor 55 shown in FIGS. 13-13A mounted in the control box 1 operates in a very similar manner as does the motor 14, discussed previously. A return spring 58 is required with the solenoid 56 since it has one-way actuation. In particular, the electronics 10 are configured to pulse the solenoid 56 such that during the pulse, the solenoid shaft 57 is driven to the left in FIGS. 13-13A and when the pulse is terminated, the return spring 58 restores the solenoid shaft 57 to the right. This action is repeated at the frequencies discussed previously.

#### Pneumatic Motor 42

FIGS. 14-14A depict a pneumatic motor 42 for creating the reciprocating motion. In particular, the pneumatic motor shaft 44 is driven by the pneumatic motor 42 which receives pneumatic pulses from a pneumatic pulse generator (not shown) via an air supply inlet 54 on the control box 1 and through internal tubing 47. The pneumatic motor 42 is positioned within a pneumatic motor housing 43 which includes a pneumatic motor diaphragm 46 for distributing the pneumatic pulse evenly to the pneumatic motor shaft 44, thereby maintaining its alignment, while at the same time providing a tightly-sealed motor configuration. The pneumatic pulse causes the pneumatic motor shaft 44 to be driven to the left while compressing a return spring 58. Once the pneumatic pulse is terminated, the return spring 58 restores the pneumatic motor shaft 44 to the right. This action is repeated at the frequencies discussed previously.

#### Electronics

FIG. 17A provides a block diagram of the electronic system 63 contained within the electronics 10. A microprocessor (e.g., MSP430F2618TPMR) controls the power electronics 73 to the motor 14. Although not shown, a power supply (e.g., an Autodyne UL medically-approved power supply AMP6301-08) converts the 120 VAC from the wall outlet to 24 VDC. A microprocessor power unit MPU 69 (e.g., a voltage regulator circuit, such as the LM317/LM337) reduces the incoming (e.g., +24 VDC) power 67 to a lower power (e.g., +3.3 VDC indicated by 70) for use by the microprocessor 71. The microprocessor 71 controls the motor 14 via power electronics 73, as well as all of the associated indicators, such as LED indicators 3, 4, 75 and 75A. The power electronics 73 convert the microprocessor 71 commands into a power signal to motor 76 (24 Vp-p AC) using internal inverters to activate the motor 14. An enable switch 72 is provided to permit the clearing stem to be continuously reciprocated for a predetermined period of time (e.g., 4-20 minutes), which avoids running the device TC1 for too long but provides sufficient time to effect clearing the clog. A control box power switch 2 is coupled to the microprocessor power unit (MPU) 69 via a fuse 66. A power indicator (e.g., LED) 3 is provided on the control box 1. When the control box 1 is externally powered, e.g., from 120 VDC, 60 Hz wall power, a power-cord (not shown) is supplied with the control box 1, and which includes an AC/DC converter. It should be understood that this does not limit the operation of the present invention to wall power in any manner and that the control box 1 can be operated off any type of power source, including battery power.

The electronic system 63 may also include a displacement sensor DS (e.g., an LVDT (e.g., Macro Sensors CD 375-500) or force sensor/load cell (e.g., Futek LPM 200); or eddy current sensor (e.g., Micro-Epsilon eddy NCDT 3010), etc.) for accomplishing closed loop motor control as well as detecting changes in the clearing process. For example, the

sensor DS forms a closed loop with microprocessor 71 for maintaining the motor shaft 15 in a centered position, which maintains the motor 14 where the force is the greatest and provides optimum control. Alternatively, the sensor DS may comprise a displacement/force feedback sensor or even an optical displacement sensor (e.g., Variohm Eurosensor). The DS sensor output may also be used for self-centering of the wire 28 during operation. As part of the closed loop control, it may be advantageous to also change any DC offset to alter the force profile at the wire tip 29 and to provide more power to one side.

In addition, an impedance sensor/current sensor IS may be included for detecting the change in voltage/current of the motor 14 and communicating with the microprocessor 71 for determining the status of the clearing process, such as initial contact with blockage, passage therethrough, etc. This status can be conveyed through a display or clearing status indicator 75 (e.g., LEDs, 7-segment displays, audible indicators, etc.) or a series of differently-colored LEDs 75 (e.g., from green to yellow to red). Alternatively, where the displacement sensor DS comprises a displacement/force feedback sensor, this sensor's output can be used to detect when the clog 40 is contacted and when it is penetrated.

As mentioned earlier, in order to indicate that the clearing stem magnet 33 and the control box magnet 12 are coupled properly, a magnetic/conductive sensor to determine if a solid clearing stem connection has been made which can then be provided to an indicator 75A. By way of example only, a magnetic sensor could be implemented to determine safe connectivity between magnets in operation, such as a Honeywell Magnetometer, HMR2300. These magnetometers measure both magnetic field intensity and direction using their Anisotropic Magneto-Resistive sensors. The ability to acquire this information can be utilized by the microprocessor 71 to ensure the magnet polarities are correct, and that the magnets field intensity is at a safe level (e.g., they have not been de-magnetized). Similarly, an anti-tamper circuit may also be included in the electronic system 63 which interrupts operation if the control box 1 is attempted to be opened. A corresponding tamper sensor may also be provided that causes the indicator 75A on the control box 1 to indicate if someone has opened, or attempted opening the lid of the control box 1. Furthermore, control box screws can be configured to disable operation of the control box 1, if they are attempted to be removed during activation.

The microprocessor 71 can be programmed to drive the electronic system 63 at the needed voltage and frequency, converting 120V 60 Hz wall power to needed parameters to drive the motor 14 at, for example 15-40 Hz (e.g., 25 Hz). In particular, several fault conditions are programmed into the microprocessor 71 for which it interrupts device TC1 operation:

$$V_{input} < 20 \text{ VDC};$$

$$V_{input} > 25 \text{ VDC};$$

Overtemperature condition pertaining to the amplifier IC;

Short circuit condition pertaining to the amplifier IC;

Should any of these fault conditions occur, the microprocessor 71 activates a fault indicator 4. Also, as discussed earlier, the enable switch 72 permits the operator to initiate the reciprocating motion without the need to hold any trigger. The enable switch 72 permits the control box 1 to maintain the reciprocating motion for a predetermined period of time (e.g., 4-20 minutes) before the reciprocating motion is terminated.

FIG. 17B provides a flow diagram of the microprocessor 71 operation: at step power up 85, the microprocessor 71 is powered up following activation of the power switch 2 by the operator. The microprocessor 71 then conducts a one second

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step initialization 86. Once the initialization 86 is completed the microprocessor 71 activates the power indicator 3 (e.g., typically a green light (GL) or indication). At this point, device TC1 remains in a disabled state until the enable switch 72 is activated by the operator; “enable button pressed” step 89 of the flow diagram represents activation of the enable switch 72 resulting in the enabled state 88 of the device where the clearing stem 26 is being reciprocated as described previously. The microprocessor 71 then maintains operation of this reciprocation for the predetermined period (e.g., 4-20 minutes) shown as time interval 93 in the flow diagram. At the end of the predetermined period, the microprocessor 71 terminates the reciprocating movement of the clearing stem 26 and returns to step disabled 87. In addition, upon activation of the enable switch 72 by the operator, the microprocessor 71 monitors the device TC1 for the faults described above, indicated by the paths-fault detected 90 of the flow diagram. If a fault 91 is detected by the microprocessor 71, the microprocessor 71 terminates clearing stem reciprocation and activates the fault indicator 4 (e.g., typically a yellow light (YL) or indication). The microprocessor 71 then shuts down (step power cycle 92) the device TC1.

Operation of the present invention tube clearer TC1 is as follows: if wall power is being used, the connector end of the power cord (not shown) is inserted into power plug 5 (FIGS. 2-2A) on the control box 1 and the other end of the power cord is coupled to a power supply which is coupled to a standard 120V RMS/60 Hz three-prong outlet. The control box 1 is turned on using the power switch 2 which turns on the power indicator 3 which verifies that the control box 1 is operating properly.

A new clearing stem 26 is removed from its packaging (but not discarded since the contaminated clearing stem 26 will be placed in the packaging and then discarded). If a plurality of clearing stems 26 are provided with tube depth-control collars fixed at different positions, the operator needs to select the clearing stem which has the appropriate fixed collar position; if, the tube depth-control collar is adjustable, the operator needs to position the collar appropriately along the clearing stem.

The following discussion of the operation is based upon the control box shown in FIGS. 2-2A, it being understood that this is by way of example only. The wire end of the wire 28 comprising the clearing stem magnet 33 is gently pulled out from within the sheath 30 and then the clearing stem magnet 33 is inserted into the bore of the Luer clearing stem connector 6 until the operator feels the pull of the clearing stem magnet 33 to the other magnet 12 and/or hears the magnets connect. The sheath 30 is then pushed until the Luer clearing stem fitting 32 is flush with the Luer clearing stem connector 6 on the control box 1. The Luer clearing stem fitting 32 is then twisted onto the Luer clearing stem connector 6. Next, the distal end wire tip 29 of the clearing member 26 is inserted a few inches into the artificial tube. The enable switch 72 is pressed to activate the reciprocating motion. While holding the artificial tube 39 in one hand, the clearing stem 26 is held in the other hand while the clearing stem 26 is advanced into the artificial tube. When the clog is initially encountered, the clearing status indicator 75 changes to alert to the initial contact, and the operator begins to apply a slight force to the clearing stem 26. Facilitating clog clearance can be achieved by the operator moving the clearing stem 26 back and forth slightly to clear the clog. These steps are repeated until the clog has cleared, in which case, the clearing status indicator 75 showing that the clog has been cleared activates. If the clog is cleared before the predetermined period (e.g., 4-20 minutes) is reached, the operator can depress the enable switch 72

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again to stop the reciprocating movement and then depress the power switch 2 to shut off power to the device TC1. The clearing stem 26 can then be removed from the artificial tube (e.g., feeding tube FT) and then the working end of the clearing stem 26 can be inserted into the packaging. The artificial tube should be flushed with water to verify that the clog has been cleared; if not, the working end of the clearing stem 26 should be removed from the packaging and the clearing procedure repeated. If the clog is verified as being cleared, the clearing stem 26 is disengaged from the control box 1 in accordance with the version of the control box 1 being used. For example, if the preferred control box 1 (e.g., FIG. 16C) is being used, the alternate clearing stem fitting 32A is disengaged from the sheath attachment bracket 83 and the alternate clearing stem magnet 33A is pulled away from the alternate diaphragm 9A; alternatively, where the Luer fitting version of the control box 1 (e.g., FIG. 16A) is used, the operator twists the Luer clearing stem fitting 32 and removes the clearing stem magnet 33 end of the clearing stem 26 from the control box 1. In either situation, the clearing stem 26 is placed back in the packaging and this is discarded in a suitable biohazard container.

FIG. 29 provides a partial isometric end view of a working end 401 of the wire 28 of the clearing stem 26 which utilizes a sheath with channels 30E that includes ports 402 which can be used for irrigation and/or aspiration. These ports 402 form the end of conduits in the sheath with channels 30E whose other ends are coupled to an aspiration source (not shown, e.g., a vacuum source, etc.) and/or an irrigation source (also not shown, e.g., a saline solution source, or other liquid source). During clog break-up, broken pieces of the clog can be aspirated out of the artificial tube using the sheath with channels 30E and where irrigating the clog vicinity is required, the sheath with channels 30E can be used to deliver such liquids. When aspirating and irrigating simultaneously, aspiration flow should equal irrigation flow rate. The appropriate flow rates are preferably 1-15 mL/min.

Another alternate clearing stem configuration is replacing the wire 28 with a hollow lumen or wire 403 to allow aspiration or irrigation down the hollow lumen or wire 403 to achieve the same purposes discussed with regard to FIG. 29. This alternative configuration is shown in FIG. 29B. Thus, the sheath ports 402 and the hollow lumen or wire 403 may cooperate in different configurations to achieve irrigation/aspiration alternatively or simultaneously. By way of example, the sheath ports 402 can be irrigating while the hollow lumen or wire 403 is suctioning, or vice versa. Alternatively, all of the ports 402 and the hollow lumen or wire 403 can be operating as irrigators or aspiration.

Another alternate clearing stem configuration is to use the indwelling artificial tube 39 effectively as the sheath, as illustrated in FIG. 29C. In this case, a wire 28 or hollow lumen or wire 403 is inserted directly into an artificial tube 39 without the sheath 30. The motor 14 drives the wire 28 or hollow lumen or wire 403 with motion as described previously, to disrupt the clog 40. Although not shown, the tube depth-control collar 22 may also be secured at the desired length to prevent over-insertion of the wire 28 or hollow lumen or wire 403, with the collar 22 impacting the end of open proximal end of the artificial tube 39 during operation. Alternatively, the wire 28 or hollow lumen or wire 403 may include the fixed tube depth-control collar 22A to also limit over-insertion. Using this configuration, the hollow lumen or wire 403 can achieve irrigation or suction alternatively. An advantage of this configuration is that elimination of the sheath can allow

access to narrower lumens. The phrase “completely exposed” when used with the device TC1 means a device TC1 that does not use a sheath.

Another alternate clearing stem configuration is a very narrow hollow lumen or wire 403 compared to the sheath 30 such that the areal differential between the hollow lumen or wire 403 and sheath 30 allows for aspiration/irrigation as illustrated in FIG. 29D.

Another alternate clearing stem configuration is the sheath 30 has two ports. One is quite small and is possibly used for a very narrow hollow lumen or wire 403 and the port 402 is used for aspiration/irrigation as illustrated in FIG. 29E. Rotating Tube Clearer TC2

As with TC1, tube clearer TC2 is a mechanical tube clearer but instead of generating reciprocating motion, tube clearer TC2 generates rotating motion to achieve artificial tube clearing, preferably for PEG feeding tubes. FIG. 18A depicts the tube clearer TC2 which comprises a reusable handset 115 (which remains outside the artificial tube and the patient) having a motor 108 (e.g., a DC motor) that drives (rotates) a disposable or limited-reuse clearing member 114. The handset 115 is held by the operator’s hand 136 during the clearing procedure.

It should be noted that, alternatively, clearing member 114 may also be hollow for irrigation or aspiration, or other features.

The tube clearer TC2 (FIG. 19) comprises a clearing member 114 that includes a magnetic connector 103 at one end which attaches to a torque limiter 105 of the handset 115. Attached at the distal end of the clearing member 114 is a narrow flexible rod, preferably a polymer piece of tubing with a clearing brush 101 located on its distal end. The clearing member 114 can be solid or hollow. In the solid embodiment, the distal end of the clearing member 114 is attached to the clearing brush 101 and the proximal end of the clearing member 114 is attached to a magnetic connector 103. In the hollow embodiment, the wire holding the clearing brush 101 may extend the central length of the clearing member 114 to the magnetic connector 103. The clearing member 114 is flexible in order to conform to various radius of curvatures R. It is rotated by the motor 108 within the handset 115. The rotary motion of the clearing brush 101 clears the clog, occlusion, or debris from the tube (not shown).

#### Clearing Member and Connectors

The clearing member 114 comprises a polymer tube with a clearing brush 101 inset at its distal end. The preferred polymer materials are nylon and polyurethane, although other materials may be used, such as polytetrafluoroethylene (PTFE), Polyvinyl chloride (PVC), polyethylene, polypropylene, and fluoropolymer. The length of the clearing member 114 is equal to the length of the feeding tube+/-one inch, depending on application. FIG. 22 shows the layout of the clearing member 114. At the proximal end of the clearing member 114 is a polymer magnetic connector 103 which includes a clearing member magnet adapter 104 in its inner bore and which sits flush to the proximal end of the clearing member 114. To attach the clearing member 114 to the handset, as shown in FIG. 19, the magnetic connector 103 is inserted into a receiving bore 105A within the torque limiter 105 of the handset 115. Disposed within the bore end is a magnetic element 105B and wherein when the magnetic connector 103 is inserted into the receiving bore 105A, the clearing member magnet adapter 104 and magnetic element 105B contact. To facilitate a tight connection, the magnetic connector 103 comprises a hexagonal-shape, or other non-round shape, that fits into a correspondingly-shaped receiving bore

105A. DC motor 108 output is conveyed to the clearing member stem 102 through a gear train 107 and gear train output shaft 106.

The clearing brush 101 at the distal end has several unique features. It could be a twisted-in-wire type clearing brush 101 with a negative taper NT, as shown in FIG. 23. By way of example only, the clearing brush 101 may comprise a twisted-in wire type; alternatively, the brush 101 may comprise a helical-wound wire or other type brush design. “Negative taper” implies that the clearing brush 101 bristles are wider in diameter at the distal end than at the proximal end of the clearing brush 101. There are several reasons for this configuration in the clearing member’s 114 design. Most conventional brushes have a taper smaller at the distal end and larger at the proximal end. However, for this application it would require over-insertion to clear the full bore of the end of the artificial tube (e.g., feeding tube) 119. The negative taper NT also allows the helix-type wound clearing brush 101 to be extended rearward, as shown by the path of freed clog particles arrow 120 in FIG. 23. When rotating (indicated by the rotation of brush arrow 121), this clearing brush 101 design forces wicking of the loosened clog debris away from the clog 122 also in the direction of the path of freed clog particles arrow 120. This is important for fast, effective clearing. If the clog 122 was not removed from the clog site, it could be compacted further, making the clog 122 even more difficult to remove. The negative taper NT also allows for contact with the tube walls (in order to clean them), but only in a limited area. Having contact only in a limited area reduces the amount of drag on the artificial tube 119 and the torque transmitted to it and thus this minimizes any chance of dislodging the artificial tube 119 from within the patient when the clearing member 114 is removed from the artificial tube 119. The shape of the (distal) tip of the clearing brush 101 is also important for this application. Unlike many standard twisted-in-wire brushes, which are cut at the ends after twisting, the TC2 clearing brush 101 could possibly be wound with a rounded tip—the wire bends 180 degrees. This bend prevents any sharp end from coming into contact with the stomach, intestine, or other organs/tissues if over-inserted past the end of the artificial tube 119. Thus, the clearing brush 101 transfers minimal torque due to its unique geometry, but its helical design is also able to remove loosened debris from the clog 122.

In another embodiment, the brush tip 101A (FIG. 19) radius of the clearing brush 101 can be modified, e.g., rounded to allow the clearing brush 101 to break up a clog, but to not penetrate an organ (e.g., stomach or other tissue/organ, etc.) should the brush tip 101A ever make its way close to an organ. The clearing brush 101 may also be retracted from the distal end of the clearing member to decrease the chance of the clearing brush 101 catching in stomach or other tissue. In another embodiment, the brush tip 101A can be modified by the addition of a flexible tip such as a Tecoflex® tip. In another embodiment, brush tip 101A can be modified by the addition of ball tip 34E as illustrated in FIG. 5D. Handset 115

Preferably, the handset 115 is shaped like a pistol, with contours to fit the user’s fingers comfortably while he/she is using it, as shown by the operator’s hand 136 (FIG. 18A). An index finger trigger 109 controls operation. The trigger 109 is a momentary power switch that only provides power when being pressed. The handset 115 is composed of three parts, one battery cover and two halves which are fastened together by screws or built-in snap fit connectors to form a handset housing 113. It also contains an isolated battery compartment 112 to facilitate battery 111 changes without exposing any

components to contaminants that could cause device failure or reduce reliability. A control circuit **110** (FIG. **19**) conveys power to the DC motor **108**.

In this embodiment the handset contains an isolated compartment in which a common battery size is used. For example, the handset **115** can be designed to accommodate any battery size such as 9V, AA, AAA, or a specialty size and a plurality of batteries where required. Alternatively, the handset **115** may comprise a rechargeable battery such that there is no need to remove any batteries. A charger (not shown) may accompany the handset **115** such that the rechargeable battery can be inductively charged and this configuration has advantages over the battery operated setup, including: no panels are removable on the handset **115** which eliminates the possibility of contamination; and also reduces cost and disposal of batteries. The inductive charger may comprise a base unit, rechargeable battery, and circuitry. The base unit may comprise an enclosure with a slot or depression or cradle into which the handset **115** is positioned. The base unit plugs into a standard 120V outlet. A coil in the base unit transmits a magnetic field to a coil in the handset **115**, and a charging circuit would transform the signal to the correct voltage and route it to the rechargeable battery located in the handset **115**.

#### Motor

The motor **108** of the tube clearer TC2 is preferably a DC motor or a brushless DC motor and gear combination. The gear mechanism may be a precision gear head, such as one utilizing a planetary gear train **116** or a compound gear train **118** utilizing two or more standalone gears. Motor and gear output speed ranges from 600 RPM to 1800 RPM, more preferably 740 to 1140 RPM. The torque limiter **105** is also preferred in this embodiment. The maximum output torque can preferably range from 20 mNm to 40 mNm with a more preferable torque of 24 to 34 mNm. A voltage of less than or equal to 9 volts DC is preferred to drive the motor **108**, such that standard commercially-available batteries can be used. FIG. **20** shows a DC motor **108** with a planetary gear train **116** whereas FIG. **21** shows a DC motor **108** with a compound gear train **118** configuration that is coupled to the motor output shaft **117**. Thus, torque, speed and geometry of the clearing stem define the optimal operation of the device TC2. Alternatively, the motor **118** itself may have a torque output of preferably 20 mNm to 40 mNm, with a more preferable torque of 24 to 34 mNm, in which case the torque limiter **105** would not be necessary.

In another embodiment, a DC or brushless DC motor **108** and gear combination is used in combination with a torque limiter **105**. The torque limiter **105** is attached in-line with the motor output shaft **117** and allows slippage once the maximum output torque is reached. In another embodiment, a DC or brushless DC motor **108** and gear combination is used in combination with a hammering device, similar to that found in hammer drills (U.S. Pat. No. 5,653,294 (Thurler, et al.) and whose entire disclosure is incorporated by reference herein). This device creates an oscillatory motion along with the rotary motion to clear the clog. In another embodiment, the DC or brushless DC motor in all examples above is replaced with a piezoelectric motor with similar specifications.

#### Tube Depth-Control Collar

As with TC1, tube clearer TC2 comprises a tube depth-control collar **133**, as shown in FIG. **24**. This depth-control collar permits one-handed operation using no special tools. The tube depth-control collar **133** mounts along the rod portion of the clearing member **114**. The tube depth-control collar **133** is formed to be well-balanced and lightweight so as to not cause unwanted harmonics in the clearing member **114**

during rotation. The tube depth-control collar **133** comprises a lightweight, circular tube depth-control collar housing **129** which includes a displaceable tube depth-control collar push button **130** that acts against a preloaded spring **132** bias and which locks against the clearing member **114** which passes through the opening for clearing member **131**. FIG. **18A** depicts the tube depth-control collar **133** on the clearing member **114**.

#### Motor Torque Limiting

In a preferred embodiment of the handset **115**, the torque applied to the clearing member **114** is limited by controlling the voltage and current applied to the DC motor and ultimately to the gears. These voltage and current limits are established by testing and determining the minimum angle of twist that are unacceptable when the clearing brush **101** is in a locked condition within tubes under test. An alternative method involves the use of a DC motor with a torque limiter **105** as depicted in FIGS. **19** and **25**. The torque limiter **105** is a two-piece patterned disc, preloaded by a preload spring **125**. The spring force controls torque at which disc slippage occurs. In particular, the torque limiter **105** comprises an input coupler **123**, a torque limiter output shaft **135**, a preload collar **134** and a torque limiter profile **124**. The input coupler **123** couples to the gear train **107** and the torque limiter output shaft **135** couples the clearing member **114**. As can be appreciated, when a certain applied torque is exceeded, the torque limiter **105** is designed to slip at the interface or torque limiter profile **124** to disengage and thereby prevent the clearing member **114** from exceeding the torque limit.

#### Clearing Member Control

The tube clearer TC2 must control harmonics so that the clearing member **114** does not become uncontrollable and cause injury/damage. During device activation, the tube clearer TC2 rotates the clearing member **114** with a displacement diameter that is preferably from 0 mm to 40 mm and a more preferred diameter of 25.4 mm or less. FIG. **26** shows multi-nodal harmonics (i.e., node points **126**) occurring in the clearing member **114** while spinning and also depicts the maximum desired displacement **127A**. This is preferred as its shape limits the displacement by geometry. The distance between the first two nodal points **126** is indicated by distance between nodal points **128**, and as can be seen in FIG. **26**, this distance decreases for subsequent nodal points **126**. The maximum desired displacement **127A** of the clearing stem is preferred to be kept to 25.4 mm or less. In contrast, FIG. **27** depicts a commercially-available rotary tool **115A** (e.g., a hand-held drill) rotating the clearing member **114**, showing the undesirable profile of rotating stem **129A** (and its undesirable corresponding maximum radial displacement **127B**) of the clearing stem motion because there is only one nodal point at the proximal end of the clearing member **114**. This type of deformation is not preferred because it is more likely to be unstable.

FIG. **28** depicts a block diagram of the electronics of the device TC2. In particular, a DC motor **108** provides the rotational motion to the clearing stem **114**. The motor **108** receives its input voltage **140** from a voltage regulator **137** which in turn receives power **139** from a power source or battery **111** (e.g., 9V battery, a rechargeable battery, etc.) when the trigger **109** is activated by the operator. A power indicator **138** (see FIG. **18A** also), driven by the voltage regulator, is also provided.

FIG. **29A** provides a partial isometric end view of the device TC2 showing the clearing brush **101** coupled to the clearing member stem **102** which utilizes a sheath with channels **30E** that includes ports **402** which can be used for irrigation and/or aspiration. These ports **402** form the end of

conduits in the sheath with channels **30E** whose other ends are coupled to an aspiration source (not shown, e.g., a vacuum source, etc.) and/or an irrigation source (also not shown, e.g., a saline solution source, or other liquid source). During clog break-up, broken pieces of the clog can be aspirated out of the artificial tube using the sheath with channels **30E** and where irrigating the clog vicinity is required, the sheath with channels **30E** can be used to deliver such liquids. When aspirating and irrigating simultaneously, aspiration flow should equal irrigation flow rate. The appropriate flow rates are preferably between 1-15 mL/min. The clearing brush **101** can also be placed back along the clearing member stem **102** away from the distal end of the clearing member **114** to decrease the potential for the clearing brush **101** grabbing or interacting with the stomach or other organ or tissue. Alternatively, the various configurations shown in FIGS. **29** and **29B-29E** can also be used with the device **TC2**. The phrase “completely exposed” when used with the device **TC2** means a device **TC2** that does not use a sheath.

FIGS. **18B-18C** depict an alternative voice coil motor tube clear device **TC2**. Instead of using a “pistol-style” housing, the device **TC2** of FIGS. **18B-18C** comprise an elongated hand grip **301**. In addition, unlike the rotational motion of the **TC2** device shown in FIG. **18A**, the alternative voice coil motor tube clear device **300** generates reciprocating motion (as discussed previously with regard to the **TC1** devices). In particular, within the hand grip **301** is positioned a voice coil motor **305** that, when energized, causes the clearing stem **303** to reciprocate. The tip of the clearing stem **303** includes a clearing brush **304**. As shown most clearly in FIG. **18B**, a clearing stem adapter **302** is provided on an end of the hand grip **301** for securing the clearing stem **303** to the voice coil motor **305** in the hand grip **301**. A power indicator **138** is also provided to indicate when power is being provided to the clearing stem **303** for reciprocating motion. A power switch/trigger **109A** is provided so that the user can manually control the activation of the device, similar to the pistol-style embodiment.

It should be noted that, alternatively, clearing stem **303** may also be hollow for irrigation or aspiration, or other features and may have similar configurations as shown in FIGS. **29-29E**.

It should be further understood that the preferred embodiments of the present invention are for the in-situ clearing of artificial lumens in a living being, but that these embodiments can be used for clearing lumens located outside of the living being, as well as for clearing other types of lumens not associated with living beings.

#### ADDITIONAL EMBODIMENTS

As discussed above, embodiments include devices, as well as methods for using and operating the devices, for effectively removing, moving or breaking up a clog from the internal portions of an artificial tube or catheter, among other types of lumens, including natural lumens such as veins, pulmonary channels, digestive pathways and the like. For example, the first type of tube clearing device discussed above, **TC1**, includes several embodiments that not only generate reciprocating motion of a clearing member for removing, moving or otherwise breaking up a clog in the artificial and natural tubes and lumens, but can also deliver a flowable medium, such as a fluid, including a liquid or a gas. For simplicity, such an embodiment shall be referred to as **TC1'**. For example, additional features can be provided for delivering and/or removing fluid to/from an occlusion site in a feeding tube such as to/from or around blockages caused by medication or nutri-

tional formulas, to/from or around a vascular occlusion such as a blood clot, or even to/from or around occlusions in feeding and endotracheal tubes such as those occlusions caused by mucous or other natural fluids. Accordingly, additional embodiments of the Tube Clearing Device **TC1**, referred to herein as **TC1'**, and corresponding features thereof, are shown in FIGS. **30-37C** and described below. It is noted that features of the clearing device as described and labeled above for **TC1** may similarly be included in embodiments of **TC1'** so as to comprise a clearing and irrigation device **500** as described below.

As illustrated in FIG. **30**, clearing and irrigation device **500** can include a controller (i.e., control box) **501** with an actuator (not visible), and a stem **526** that includes at least one fluid source, a reciprocating member **528**, and a conduit **593**. In an embodiment, the at least one fluid source can be selected from the group consisting of a deformable reservoir **527A** and port, as well as a conduit **593**. Accordingly, stem **526** can include at least one deformable reservoir and/or at least one port. That is, stem **526** can include one deformable reservoir and one port. Stem **526** can include one or more than one deformable reservoir but no port at all. Stem **526** can include one or more than one port but no deformable reservoir at all. The port, which can be at least one port, such as port **595** can be configured with or without valve **596**. Stem **526** can also include fixed adaptor **532A** coupled to reciprocating member **528**, and displaceable adaptor **533B**.

In some embodiments, controller **501** can include the features described above for activation unit/control box **1**, including at least one motor, such as motor **14**, for producing a reciprocating motion. The reciprocating motion can be achieved using a variety of motor technologies, such as, but not limited to, voice coil motors as described above, DC motors, piezoelectric transducers, including amplified piezoelectric transducers, piezoelectric actuators, active polymer compound actuators, solenoid motors, pneumatic motors, magnetostrictive transducers, electro restrictive transducers, and the like. Thus, controller **501** can include at least one actuator such as a voice coil motor (not visible) for generating repetitive reciprocating motion, separator **509A** and fixed support arm **583**.

In an embodiment, the clearing and irrigation device **500** can include at least one motor, for example at least one actuator for providing reciprocating motion, and a stem **526** (as shown in FIGS. **31A** and **31D**) that is coupled to the at least one actuator for receiving the reciprocating motion. The at least one actuator can be a voice coil motor, such as that shown in FIGS. **2-2A**, **10-10A** and **15**, and previously described. The voice coil motor can include motor shaft **515**, as depicted in FIGS. **31A-D**, which can be coupled directly or indirectly to stem **526** via an adaptor **533B**.

The stem **526** can include at least one fluid source which can include a deformable reservoir **527A** fluidically coupled to a port, such as port **595**, for example, a port integrated with stem **526** and including a flange-fitting (as that shown in FIGS. **33A-D**) or the polyurethane tube (as that shown in FIGS. **30**, **32** and **34**). The port **595** can be formed as a channel extending from an outside surface, through a sidewall, and to an inner surface of fixed adaptor **532A** and can be in fluidic communication with an internal volume of the deformable reservoir **527A**. In other words, the port **595** provides a pathway through which an external source of flowable medium can be fluidically connected to the deformable reservoir for transferring flowable medium between the external source **594** and the deformable reservoir **527A**. The stem **526** can further include a conduit **593** in fluidic communication with the deformable reservoir **527A** of the fluid source.

Referring now to FIGS. 30-31, the clearing and irrigating device 500 can include a reciprocating member 528, such as an elongate wire portion of the stem 526. Reciprocating member 528 can extend substantially the length of the stem 526. A portion of the reciprocating member 528 can extend through deformable reservoir 527A at a proximal end of the stem 526. That is, reciprocating member 528 can at least be partially disposed within the conduit member. For example, reciprocating member 528 can be slidably disposed in the internal volume of the deformable reservoir, as depicted by the dashed line in FIGS. 31A-31D. In other words, reciprocating member 528 can be configured to extend through and be slidably disposed in the conduit 593.

In an embodiment, the at least one fluid source can include at least one port. The at least one port can include a first port. The first port, such as port 595, can be in fluid communication with an internal volume of the stem to provide/remove, for example, a flowable medium, such as an irrigant/aspirant, to/from areas adjacent to the distal end of the stem. The internal volume can be defined by an internal volume of the deformable reservoir 527A and a volume defined by the space between the outer diameter of the reciprocating member 528 and the inner diameter of the conduit 593, the volume extending longitudinally from a proximal end of the stem to a distal end of the stem. Such a volume defined by that space can be illustrated by port 402 of sheath 30 in FIG. 29D.

In an embodiment, the at least one port includes a first port and a second port. The first port, such as port 595, can be in fluid communication with a first volume to provide/remove, for example, a flowable medium, such as an irrigant/aspirant to/from areas adjacent to the distal end of the stem. Such a first volume defined by that space can be illustrated by port 402 of sheath 30 in FIG. 29D and can be in communication with an internal volume of the deformable reservoir 527A. The second port (not shown) to which an external fluid/aspiration source can be connected at a location along the length of the clearing stem but preferably at a distal portion thereof, can be in fluid communication with a second volume distinct from the first volume, to provide/remove, for example, at least the flowable medium as irrigant/aspirant to/away from areas adjacent to the distal end of the stem. The second volume can be defined by at least one channel formed longitudinally within the sidewalls of the conduit 593, for example the at least one channel depicted as port 402 of sheath 30E in FIG. 29B and/or sheath 30 in FIG. 29E.

In an embodiment, the at least one port includes a first port, a second port, and a third port. The first port, such as port 595, can be in fluid communication with a first volume to provide, for example, a flowable medium, such as an irrigant to areas adjacent to the distal end of the stem. Such a first volume defined by that space can be illustrated by port 402 of sheath 30 in FIG. 29D and can be in communication with an internal volume of the deformable reservoir 527A. The second port (not shown) to which an external fluid/aspiration source can be connected at a location along the length of the clearing stem but preferably at a distal portion thereof, can be in fluid communication with a second volume distinct from the first volume, to provide/remove, for example, at least the flowable medium as irrigant/aspirant to/away from areas adjacent to the distal end of the stem. The second volume can be defined by at least one channel formed longitudinally within the sidewalls of the conduit 593, for example the at least one channel depicted as port 402 of sheath 30E in FIG. 29B and/or sheath 30 in FIG. 29E. The third port (not shown) to which an external/aspiration source can be connected at a location along the length of the clearing stem but preferably at a distal portion thereof, can be in fluid communication with a third

volume distinct from the first volume and the second volume, such as the volume defined by an internal hollow space along the length of the reciprocating member, for example, that of hollow lumen or wire 403 in FIG. 29E.

In an embodiment, a single actuator can provide reciprocating motion to both the deformable reservoir 527A and reciprocating member 528 as illustrated in FIGS. 31A-D. Thus, in one example, an actuator can provide linear reciprocating compression motion to the deformable reservoir 527A and linear reciprocating motion to the reciprocating member 528. However, other configurations with more than one actuator are possible.

For example, an occlusion clearing device can include a first actuator configured to provide motion to the deformable reservoir 527A, and a second actuator configured to provide motion, independent of the first actuator, to the reciprocating member 528. For instance, the first actuator can be configured to provide linear reciprocating motion to the deformable reservoir (causing it to be compressed and expanded), and the second actuator can be configured to provide reciprocating linear and/or reciprocating rotational motion, and/or non-reciprocating axial rotational motion to the reciprocating member 528. Alternatively, the second actuator can be configured to provide both reciprocating linear and/or axial rotational motion to the reciprocating member 528. The motion of the deformable reservoir 527A provided by the first actuator and the motion of the reciprocating member 528 provided by the second actuator can be the same or different with respect to at least one of amplitude, frequency and/or direction.

Stem

Referring now to FIGS. 31-32, stem 526 can include at least one fluid source, a conduit 593, and a reciprocating member 528. The at least one fluid source can be selected from the group consisting of: (i) a deformable reservoir 527A and (ii) port 595. Conduit 593 can be in fluid communication with port 595 and/or deformable reservoir 527A. Port 595 can be configured as a channel through displaceable adaptor 533B and/or a channel through fixed adaptor 532A. Reciprocating member 528 can be coupled to displaceable adaptor 533B and can be slidably disposed through or adjacent to fixed adaptor 532A. The proximal end of the stem 526 can be releasably coupled to the at least one actuator. For example, the proximal end of the stem 526 can include displaceable adaptor 533B to which ends of deformable reservoir 527A and reciprocating member 528 can be coupled.

Stem 526 can be magnetically coupled to the actuator via displaceable adaptor 533B, which itself can include a magnet for magnetically coupling with shaft magnetic adaptor 513A of the actuator shaft 515. In this way, the reciprocating member 528 and deformable reservoir 527A can be configured to accept the repetitive motion of the motor via the linear, reciprocating motion of the shaft 515.

An indirect coupling is formed when components of the stem and those of the actuator are physically separated from one another but still capable of being in mechanical communication. That is, the displaceable adaptor 533B can be magnetically coupled to shaft 515 in a similar fashion as described above for clearing stem 26 when it is magnetically coupled to shaft 15 as depicted in FIGS. 3 and 3A. In other words, displaceable adaptor 533B can be coupled to the actuator via shaft magnetic adaptor 513A, which is attached to shaft 515, while being physically separated from adaptor 513A by separator 509A. Separator 509A can be a flexible wall portion of the control box such as a polymer membrane. Thus, separator 509A can be formed between the at least one actuator and the stem 526, and separator 509A can be of whatever thickness



allows stem **526** and shaft **515** to remain magnetically coupled to one another, thus providing for indirect coupling of the stem to the actuator.

In other embodiments, the proximal end of stem **526** can be directly coupled non-magnetically to shaft **515**. Such a direct coupling can be made releasable if it is formed by corresponding male-female thread/screw fittings attached to the proximal end of stem **526** and distal end of the actuator stem **515**. This allows the stem to be suitably connected for device operation and easily separated from the actuator when the stem needs to be removed for disposal or sterilization.

In an embodiment, stem **526** is reusable. For example, stem **526** can be reused for several occlusion clearing procedures within a single patient. In another example, the stem **526** can be reused for more than one occlusion clearing procedure on different patients if it is cleaned and sterilized according to medical norms. In another embodiment, the stem **526** is single-use, for example, with respect to the use of the device in a single occlusion clearing procedure.

Stem **526** can also include a narrow tube-depth control collar **592** for preventing over-insertion of the stem when in use for clearing occlusions. The narrow tube depth control collar **592** can include a first portion having a first diameter and a second portion having a second diameter larger than the first diameter. When used for clearing occlusions in a feeding tube or other artificial lumen, the first diameter can be less than, equal to or larger than the artificial lumen's inner diameter, and the second diameter can be larger than the artificial lumen's outer diameter. The narrow tube-depth-control collar **592** can be a polymer.

The reciprocating member **528** can extend from a displaceable end **599A** of the deformable reservoir **527A**, through a fixed end **599B** of the deformable reservoir, and through the length of the conduit, protruding through a distal end **600** of the conduit member **593** at **528A** at all times. In an embodiment, rather than protruding through a distal end **600** of the conduit member **593** at all times, the reciprocating member can be caused to protrude through the distal end **600** on a positive stroke (e.g., actuation from right to left such as the direction depicted in FIG. **31C**) of the actuator, and can recede either partially or completely back into the conduit **593** on a negative stroke (e.g., actuation from left to right such as the direction depicted in FIG. **31D**).

In an embodiment, a stem can be provided with a fluid source that does not include a deformable reservoir as shown in FIGS. **36-37C**. In this embodiment, stem **526** can include reciprocating member **528**, displaceable adaptor **533B**, fixed adaptor **532A**, conduit **593**, and port **595**. The proximal end of the stem **526** can be releasably coupled to the at least one actuator as described above. For example, the proximal end of the stem **526** can include displaceable adaptor **533B** to which an end of reciprocating member **528** is coupled, and which can include a magnet for magnetically coupling with shaft magnetic adaptor **513A** of the actuator shaft **515** (such as those within controller **501** in FIG. **31A-D**). In this way, the reciprocating member **528** (shown as dashed lines within stem **526** in FIGS. **37A-C**, and shown protruding from a distal end thereof as **528A**) can be configured to accept the repetitive motion of the motor via the linear, reciprocating motion of the shaft **515**. It is noted that in this embodiment, fluid source can receive a flowable medium provided by an external source such as external source **594** including a reservoir or an external pump. Thus, flowable medium provided by an external source can flow through a port **595** and through conduit **593** in fluid communication with the port.

In some embodiments, stem **526** with a fluid source that does not include the deformable reservoir can be provided

“pre-filled” with a flowable medium included in the conduit **593** and provided thereto through port **595**. That is, conduit **593** can be provided pre-filled prior to attachment of the stem to an external source when it is coupled to controller **501**. Thus, a prefilled conduit **593** stores the flowable medium until the flowable medium is caused to exit the conduit, for example, when the reciprocating member **528** is caused to reciprocate by the actuator.

In some embodiments, stem **526** without a fluid source (i.e., without a deformable reservoir or a port) can be provided “pre-filled” with a flowable medium included in the conduit **593**. That is, conduit **593** can be provided pre-filled prior to attachment of the stem to an external source when it is coupled to controller **501**. Thus, a prefilled conduit **593** stores the flowable medium until the flowable medium is caused to exit the conduit, for example, when the reciprocating member **528** is caused to reciprocate by the actuator.

In an embodiment shown in FIG. **39**, a stem can include components that allow for the clearing of occlusions of natural or artificial lumens having smaller inner volumes and/or diameters. For example, a stem having conduit **593** that includes a deformable proximal end, such as deformable distal end **593'**, stem **526** can be used to clear occlusions from tubes such as those of sizes 8 Fr and below (i.e., inner diameters equal to or smaller than those of tubes rated size 8 Fr). The deformable distal end **593'** of conduit **593** can be the same rigidity or a different rigidity, such as being less rigid, compared to the remaining portions of conduit **593**. The deformable distal end **593'** of conduit **593** can be the same material or a different material from the remaining portions of conduit **593**. Deformable distal end **593'** of conduit **593** can have the same sidewall thickness or a different sidewall thickness than the remaining portions of conduit **593**. Conduit **593** can be of a length that it extends from a proximal end adjacent to or coupled to fixed adaptor **532A**, up to or beyond a distal end of reciprocating member **528**. Conduit **593** can be of a length that it is the same length or shorter than a length of the reciprocating member that extends from a proximal portion of the reciprocating member adjacent to the fixed adaptor **532A**.

During use, such as during a clearing procedure, a user can position the stem in such a manner that some or all of conduit **593** remains outside the tube that is being cleared, such as outside a proximal end **39A** of artificial tube **39**, while a distal portion **528A** of reciprocating member **528** is inserted/fed into the tube. As shown in FIG. **39**, as the reciprocating member **528** is inserted into the artificial tube, the sidewalls at deformable distal end **593'** of conduit **593** can be configured to collapse. As the deformable distal end **593'** remains outside of the tube and collapses as the remaining portions of the stem are advanced toward it, and the distal end **528A** continues to be fed into the tube, the collapsed portion can be configured to attain a shape of collapsing bellows/accordion, or any other shape that allows for the reciprocating member to be fed into the tube.

It is to be understood that upon activating an actuator of a controller **501** to which the stem is coupled, such as described above and shown in FIG. **39**, the reciprocating member **528** can be caused to reciprocate. As it is slidably disposed in conduit **593**, and generally supported by an inner surface of the conduit, at least the reciprocating member's distal end **528A** that protrudes from a distal end of the conduit is caused to displace, thereby allowing it to come into contact with occlusion material and clear the occlusion from the tube. Thus, the deformable distal end **593'** of the conduit, for example in a natural state or a collapsed state, should be configured so as to not prohibit the reciprocating member

from performing the function of clearing an occlusion. The distal portion **528** of the reciprocating member is therefore supported by the inner surface of the tube.

Additionally, the conduit **593** is configured to allow irrigant, provided from the stem's fluid source, to reach an inner volume of the tube (or for aspirant to be removed from the tube). That is, during use, the conduit **593** can be in fluid communication with the tube **39**. Accordingly, an interface between a proximal end of the tube **39A** and collapsible distal end **593'** of the conduit can be configured to form a leak-proof seal. Fluid can also or instead be provided from an external source that is fluidically coupled to the tube **39** via a tube port (not shown). It is noted that the stem that includes a conduit **593** with a deformable distal end **593'** may or may not also include deformable reservoir **527A** and/or port **595**.

#### Conduit and Reciprocating Member

As described above, reciprocating member **528** can be slidably disposed within conduit **593**. In an embodiment, the reciprocating member **528** can be a wire having an outer diameter that allows it to reciprocate within the conduit. Accordingly, the conduit **593** can be a hollow flexible tube and the reciprocating member can be an elongate, flexible wire with an outer diameter equal to or less than an inner diameter of the conduit.

A volume defined by the space between the outer diameter of the reciprocating member and an inner diameter of the conduit **593** can provide a coaxial route through which flowable medium can flow through a proximal end and through a distal end **600** of the conduit **593**. For example, flowable medium stored in a volume of the deformable reservoir **527A** can be caused to flow out of the volume during an actuation cycle, via the reciprocating motion of the actuator, such as that depicted in FIGS. **31A-D**. While not limited to any particular theory, it is believed that the flowable medium can be caused, during compression of the deformable reservoir, such as depicted in FIG. **31C**, to flow from an internal volume of the deformable reservoir, through an open end of the deformable reservoir, such as at fixed end **599B**, and through a fixed adaptor and through the conduit, then finally exiting through a distal end **600** of the conduit.

Conduit **593** can be a single tube as shown or can be more than one tube formed in series to provide a continuous channel for flowing flowable medium as shown in FIG. **34**. The conduit can be hollow through its length including open distal and proximal ends. Likewise, reciprocating member **528** can be a single elongate member, such as a single wire, or can be formed of more than one wire connected in series to form a single continuous member as shown in FIGS. **34** and **35A-B**. Reciprocating member **528** can be longer than the conduit **593**, allowing it to extend through the conduits distal and proximal ends. For example, a distal tip **528A** of reciprocating member **528** can be configured to protrude past a distal opening of conduit **593** at all times, or during certain times when the device is operated.

As shown in FIG. **34**, conduit **593** can include a first portion **593A** and a second portion **593C**, each having an end bonded to conduit interdisposed tubing member **593B**. The first **593A** and second **593C** portions of conduit **593** can each be about 20-30 cm lengths of coiled sheath of nylon 12 tubing, such as cut from 55.12" length of Coiled Sheath available from AdancedCath Technologies, Inc. (San Jose, Calif.), having an inner diameter of 0.039"±0.001", an outer diameter of 0.0565"±0.0015" with a braid of 0.002"/304 SS/60PPI/16 count, and inner liner and outer jacket made of VESTAMID® L2101 extruded, unfilled polyamid **12** (available from Evonik Industries of Marl, Germany). The first portion **593A** and second portion **593C** of conduit **593** can be separated by an

interdisposed tubing member **593B** made of Nylon 11 having an outer diameter of 0.1.25", an inner diameter of 0.073" and a length of about 4 cm. In another embodiment, the conduit **593** comprises a single length of teflon tubing AWG **18-24**.

Reciprocating member **528** can be formed of a distal portion **529** including guide-wire formed of a core section **529B** and a coiled section **529A**, and a proximal portion **530** including a stranded wire. Interdisposed connecting member **531**, as shown in FIG. **35A-B**, can be formed between the proximal portion **530** and distal portion **529** of reciprocating member **528**. The proximal **530** and distal **529** portions of reciprocating member **528** can each have an end bonded to the interdisposed connecting member **531**. Alternatively, rather than being formed of the distal portion **529**, interdisposed connecting member **531**, and the proximal portion **530**, reciprocating member **528** can be formed of a single section, such as a length of the guide-wire described above. However, for costs savings, less of the guide-wire can be used if the reciprocating member **528** is formed in three sections instead of a single section.

As shown in FIG. **35B**, the core section **529B** and coiled section **529A** of the guide-wire can be adapted from the guide wire used in a Cope Gastrointestinal Suture Anchor Set (Part No. GIAS-100 available from Cook Medical Inc. of Bloomington, Ind.). The coiled portion **529A** can have an outer diameter of 0.035" and a length of 25 cm. The core portion **529B** can have an outer diameter of 0.018", a length of 50 cm, and can extend through (not visible) the coiled portion as further described below. The proximal stranded wire portion **530** can be 1×7 Stranded Wire (Part No. 3461T4 available from McMaster-Carr of Santa Fe Springs, Calif.), having an outer diameter of 0.02" and length of 65 cm. The interdisposed connecting member **531** can be a PEEK tubing adaptor having an outer diameter of 0.625", an inner diameter of 0.03" and a length of about 2-4 cm. An end of proximal stranded wire portion and an end of distal portion guide-wire can be inserted into opposing ends of the interdisposed tubing member adaptor, and bonded inside the adaptor using TRA-Bond epoxy, cured at 150° C. for 10 minutes.

In an embodiment, the reciprocating member **528** can include a core section **529B** and a coiled section **529A** of 304 stainless steel, such as that shown in FIG. **38**. At a distal portion of the core section, the core section **529B** tapers from one diameter to another diameter, the other diameter defining a distal end of the core section. For example, the core wire can have an outer diameter of 0.035±0.003 inches and taper down to an outer diameter of 0.0060±0.0005 inches. The core section **529A** can be subject to a gradual taper grind in order to provide these diameters. At one portion, for example at a distal end of the core section, the coiled section can be brazed onto the core section. At another portion, the coiled section can be welded onto the core section. The coiled wire **529A** can be a flattened wire having cross-sectional dimensions such as 0.005 in×0.010 in. The weld can form a ball-shape which provides a rounded distal end to the reciprocating member. Due to the coiled section extending over the tapered section of the core, the distal portion of the reciprocating member has added flexibility as compared to sections where the core is not tapered.

#### Deformable Reservoir

As shown in FIGS. **30-34**, and more particularly with reference to FIG. **31**, the deformable reservoir **527A** is coupled between a first end of the reciprocating member **528**, such as its proximal end, and a stationary/fixed fitting/adaptor **532A**. Thus, the motion provided by the at least one actuator, as described above, provides displacive motion to at least an end, for example displaceable end **599A**, of the deformable

reservoir 527A. The proximal end of the reciprocating member 528 and an end, such as displaceable end 599A of the deformable reservoir, can be fixed to a common fitting, such as a moveable/displaceable fitting/adaptor 533B. Fixed end 599B of the deformable reservoir 527A is configured to remain fixed relative to displaceable end 599A. In one embodiment, fixed end 599B is coupled to fixed adaptor 532A which is supported by fixed support arm 583 extending from control box/controller 501 as shown in FIGS. 31A-31D.

The deformable reservoir can store a volume of up to 10 mL of flowable medium. Accordingly, the deformable reservoir can be made of a polymer that expands upon providing it with the volume of flowable medium from an external source. In one embodiment the deformable reservoir is made of nitrile tubing having wall thickness of 0.004".

The deformable reservoir can be made of nitrile tube. The tube can be formed by removing a portion of a nitrile finger cot (part no. 5516T2, available from McMaster-Carr of Santa Fe Springs, Calif.). The ends 599B and 599A of the deformable reservoir can be connected to fixed adaptor 532A and displaceable adaptor 532B, respectively, and held in place. The ends can be connected in a manner to prevent leakage of flowable medium at their respective attachment points. O-rings may be utilized to hold the ends of the deformable reservoir over outer surface portions of adaptors 532A and 532B. Alternatively, adaptors 532A and 532B may each be formed of snap-caps (a first cap that snaps into place with a second cap) or another kind of compression fitting, wherein each of the ends of the deformable reservoir are held in place between the first and second caps of the snap caps. Other methods, such bonding, including solvent or epoxy bonding, may be used to attach the deformable reservoir to the adaptors of the stem. In other embodiments, one end of the deformable reservoir, such as end 599A, can be attached to only one adaptor, such as displaceable adaptor 532B, and the other end, such as end 599B can be attached to an outer surface of the stem, for example, an outer surface of conduit 593. In such an embodiment, when the stem is attached to the control box and caused to be reciprocated by the actuator, a user can hold the stem or outer surface of the conduit in place as a substitute for the fixed adaptor 532A.

In some embodiments, an end of the deformable reservoir can be connected to displaceable adaptor 532B. The displaceable adaptor, as discussed above, can include a magnet which couples to a corresponding magnet of opposite polarity of the shaft of the actuator. When magnetically coupled, the displaceable adaptor 532B does not need to physically contact the actuator but may be separated by the separator/diaphragm 509A. In other embodiments, the shaft of the actuator may include an attachment member (not shown) which protrudes through separator/diaphragm 509A and mates with a corresponding attachment member of the stem (also not shown). The attachment members may include a clip that includes features that allow the stem to be physically coupled, via the displaceable adaptor's clip, to the actuator and accept the actuators reciprocating motion and eliminates the expense of the magnets. In an embodiment, the displaceable diaphragm and actuator shaft may include a combination of magnets and attachment members, such as the clips described above, to hold the stem in place with the actuator.

In an embodiment, a proximal portion of reciprocating member 528 can be fixed in displaceable adaptor 533B. To hold reciprocating member 528 in place, a proximal end thereof can be passed through on one end of the displaceable adaptor, and then bent in a manner so that it cannot be tugged from a distal end out of displaceable adaptor 533B.

In an embodiment, the fixed adaptor 532A is seated in fixed support arm 583. Fixed support arm 583 can be made of metal or plastic and can include a portion to which a corresponding section of fixed adaptor 532A is snapped into place. Fixed adaptor 532A can be attached to control box 501 as shown in FIG. 30.

#### External Reservoir

In an embodiment, an external reservoir 594 can be in fluidic communication with the stem's fluid source such as the deformable reservoir 527A via, for example, the port 595 such as illustrated in FIG. 30. The external reservoir can provide a flowable medium to the deformable reservoir 527A. The external reservoir 594 can be a pump, such as a centrifugal pump, diaphragm pump, pneumatic pump or a syringe pressurized with a plunger as shown in FIG. 30. Upon filling the deformable reservoir with a flowable medium, valve 596 disposed between the external reservoir 594 and deformable reservoir 527A can be closed to break fluidic communication between fluid source and external reservoir (e.g., the deformable reservoir 527A and external reservoir 594). In other embodiments, either no valve is present or the valve discussed above can remain open so that the deformable reservoir 527A and external reservoir 594 remain in fluidic communication during operation of the device, so that the external reservoir can continuously provide flowable medium to the conduit. In another embodiment, the external reservoir provides flowable medium to the conduit without the presence of the deformable reservoir.

An end of the deformable reservoir can be fluidically coupled to conduit 593, for example at fixed end 599B in FIG. 30, which can be an open end of the deformable reservoir through which the flowable medium, provided by the external source or by the deformable reservoir (for example in a pre-filled deformable reservoir), can flow. The device can be configured to prevent flow of the flowable medium from the deformable reservoir to a distal end of the stem when not in operation. On the other hand, the device can be configured to provide flow of the flowable medium from the deformable reservoir through the distal end of the stem when the actuator is in operation. For example, when the actuator is operated in the range of approximately 10-60 Hz, or preferably when the actuator is operated in the range of 15-40 Hz. The flow of the flowable medium can be provided at a volume of about 0.4 to about 0.5 ml/min to the occlusion site, preferably from the deformable reservoir and through a distal end of the stem. For example, conduit 593 can be provided with a valve along its length that, when it is "off" or closed, it prevents fluid from reaching the distal end of the conduit. In one example, tube-depth control collar 22 described above and shown in FIGS. 3A and 9A-9C that includes tube depth control push button 23 can be modified such that the spring 25 provides enough compression force against the stem, for example, a conduit on which the control collar is placed, so as to prevent fluid flow from the fluid source from reaching a distal end of the stem.

#### Methods of Use

Embodiments include non-limiting methods for operating device 500 to clear occlusions and/or deliver fluid. For example, at least one actuator, such as the actuator that includes actuator shaft 515 in FIGS. 31A-D, can be energized to provide reciprocating motion to the deformable reservoir 527A. The deformable reservoir, being coupled to the actuator, for example, via displaceable adaptor 533B which is magnetically coupled to shaft magnetic adaptor 513A, accepts the reciprocating motion. The reciprocating motion causes the deformable reservoir 527A to contract (as shown in FIG. 31C) and expand (as shown in FIG. 31D).

Due to the compression and expansion of the reservoir, a flowable medium stored in deformable reservoir **527A** (as indicated by the expanded deformable reservoir **527A** shown in FIG. **31B**) can be caused to flow through an open end of the reservoir. For example, the flowable medium can flow out of the reservoir via an opening at fixed end **599B**, through an opening at fixed adaptor **532A**, through conduit **593** and exit through a distal open end of the conduit.

Meanwhile, the reciprocating member **528** can also be coupled to displaceable adaptor **533B** and can, therefore, also be caused to reciprocate. In other words, because reciprocating member **528** extends through an inner volume of the deformable reservoir **527A** and is slidably disposed in the conduit **593** as described above, it reciprocates within the conduit and within the deformable reservoir **527A**.

While not limited to any particular theory it is believed that the flowable medium is caused to flow toward the distal end of the conduit by the reciprocating contraction/expansion motion of the deformable reservoir and/or the reciprocating back and forth motion of the reciprocating member.

Stem **526** can be provided "pre-filled" with flowable medium. That is, the deformable reservoir **527A** and/or conduit **593** can be pre-filled to store the flowable medium until the flowable medium is caused to exit the reservoir and/or conduit, for example, when the deformable reservoir **527A** and/or reciprocating member **528** are/is caused to reciprocate by the actuator. Alternatively, an external source of flowable medium, such as a syringe, can be fluidically connected, via port **595**, to an internal volume of the deformable reservoir **527A** and/or conduit **593**.

Flowable medium can be provided from the external source **594** to the deformable reservoir **527A**, filling the deformable reservoir **527A** with a predetermined volume or predetermined pressure and causing the deformable reservoir to expand from a natural volume (such as shown in FIG. **31A**) to an extended volume (such as shown in FIG. **31B**). In one example, the external source provides the deformable reservoir with 10 mL of flowable medium. In another example, deformable reservoir is filled with flowable medium so as to be pressurized up to 150, 140, 130, or 120 mmHg or between 100-140 mmHg of pressure prior to operation of the device **500**. However, the deformable reservoir should not be over-filled because overfilling can cause the displaceable end **533B** to expand toward the controller **501**, thereby keeping the actuator stem **515** from reciprocating the reciprocating member **528**. In other words, if the reservoir is overfilled, the actuator stem is limited in reciprocating distally by the volume of the reservoir pushing it proximally.

Prior to insertion of the stem into a lumen such as a feeding tube, an outside surface of the stem can be lubricated with a hydrophobic coating such as PAM® cooking spray (available from ConAgra Foods of Omaha, Nebr.) or a hydrophilic coating such as HYDAK® (available from BioCoat, Inc. of Horsham, Pa.).

As discussed above, the device TCI' can be used for breaking up or eliminating occlusions in artificial lumens such as feeding tubes. In such a method of use, the device's stem is inserted directly through the feeding tube until the reciprocating member is brought into contact with the occlusion. The device can also be used for breaking up occlusions such as blood clots in veins. In such a method of use, the stem can be inserted into a vein via a catheter until the reciprocating member is brought into contact with the blood clot. In both methods of use, the reciprocating motion of the reciprocating member, caused by energizing the actuator, is used to break up the occlusion. It is advantageous, however, to provide a flowable medium, such as a liquid, for example, at least one of

tissue plasminogen activator, water, enzyme (and other compatible fluids selected for successfully causing the occlusion to break apart), directly to at least a surface of the occlusion or adjacent to the occlusion. Thus, the flowable medium provided by the external source and/or the at least one fluid source (e.g., a port and/or a deformable reservoir), and flowed through the conduit, can be brought into contact with the occlusion or adjacent thereto. For example, after exiting from the distal opening of the conduit, the flowable medium may continue to flow distally toward the distal tip of the reciprocating member as it coats the reciprocating member. Such a flow can be characterized as pulses, or drop-by-drop delivery, of fluid at the distal tip of the reciprocating member. In other words, the flowable medium can flow beyond the distal end of the conduit along a distal portion of the reciprocating member, such as distal tip **528A**, that protrudes beyond the distal end of the conduit. However, the flowable medium need not coat the distal tip of the reciprocating member **528** upon exiting the conduit, but may exit from the distal opening of the conduit without coating the distal tip **528A** of the reciprocating member. Additionally, the flow of the flowable medium need not actually exit the conduit member in pulses or drop-by-drop fashion but may be a continuous stream, either in laminar or turbulent flow.

In some embodiments, the reciprocating member can be caused to reciprocate and the conduit is not configured to reciprocate. However, in other embodiments, the conduit can be configured to reciprocate either in the same direction as the reciprocating member or in opposite direction to the reciprocating member's reciprocating motion. To provide the conduit with reciprocating motion, it can be coupled to the same actuator as the reciprocating member and the deformable reservoir, or may be coupled to a different actuator.

Additionally, the conduit and the deformable reservoir can comprise a common section of tubed material. For example, a common section of tubed material can comprise a more flexible portion, such as a proximal portion thereof, relative to a less flexible portion, such as a distal portion thereof. In such an embodiment, the more flexible portion may accept motion from an actuator and work in a similar fashion as described in the above deformable reservoir **528**. In some embodiments, the more and less flexible portions of the common section of tubed material may be made of the same material, or of different materials joined together to form the common section of tubed material. In some embodiments the deformable reservoir can comprise bellows.

In another embodiment, at least one actuator, for example the actuator in controller **501**, is energized to provide reciprocating motion to reciprocating member **528** slidably disposed within conduit **593**. A flowable medium can be provided to the conduit **593**, for example, from a fluid source of stem **526**, and caused to flow through the conduit's distal end. The flowable medium can be caused to flow by providing it with a pressure so that it flows through a volume defined by the space between an outer side of the reciprocating member and an inner side of the conduit.

Appropriate fluids for clearing occlusions in feeding tubes are known in the art and can include enzyme based fluids, water, weak acid, saline, or a combination of each. Appropriate fluids for clearing occlusions in vascular systems, such as blood clots, are known in the art and can include tissue plasminogen activator (tPA) and the like.

FIG. **39** illustrates a stem that can include components that allow for the clearing of occlusions of natural or artificial lumens. For example, during use, such as during a clearing procedure, a user can position the stem in such a manner that some or all of the conduit **593** remains outside of the artificial

tube 39 being cleared, while the distal portion of the reciprocating member/wire 528 is inserted/fed into the tube.

FIG. 40 illustrates the concept of the split stem 526A. The split stem 526A is comprised of a reciprocating member/wire 528 and a split conduit 593E. The splitting of the split conduit 593E allows for the reciprocating member/wire 528 to be peeled out away from the split conduit 593E. The split stem 526A is the basis for the novel solution to inserting only the reciprocating member/wire 528 into a clogged lumen while maintaining its reciprocation for the purposes of clearing it.

Although called a split conduit 593E, it is to be understood that the object with the slit can be a tube in other exemplary embodiments, and may thus be referred to as a split tube. The tube may be a sheath, a conduit, or another member in accordance with yet additional exemplary embodiments. The tube is referred to as a conduit, and hence a split conduit 593E for purposes of explanation and example in the present description. Other elements that incorporate the term "conduit" are also described in this manner for purposes of explanation and example and this term may be removed in other instances when the tube is not a conduit.

FIG. 41A and FIG. 41B illustrate the interior construction of a cutter which may be a conduit cutter 601 which is used to create the split conduit 593E. The conduit splitter 601 is made up of two symmetrical pieces, one of which is shown in FIG. 41A. There are two channels which are machined into the interior surface. The first is the conduit channel 604 which is machined to be slightly larger than the diameter of the conduit 593. The second channel is the scalpel blade channel 603 which is machined to allow a No. 15 scalpel blade 602 to sit recessed in it. FIG. 41B is the same view as FIG. 41A with the addition of the No. 15 scalpel blade 602 and a conduit 593. FIG. 41B illustrates an uncut conduit 593 passing through the conduit channel 604 which guides the conduit 593 passed the No. 15 scalpel blade 602. This process turns the uncut conduit 593 into the split conduit 593E. FIG. 41C is an illustration of the two halves of the conduit cutter 601 fastened together with the conduit 593 being passed through it. The slit in the split conduit 593E may extend some or all of the axial length of the conduit 593E and may extend completely through a wall of the conduit 593E in various exemplary embodiments. The slit may have a length in the axial direction that is longer than its length in the radial direction of the conduit 593E.

FIG. 42A and FIG. 42B illustrate the construction of the splitter which may be a conduit splitter 605 used to take the input of the split stem 526A and give an output of the reciprocating member/wire 528. FIG. 42A is an isometric view of the conduit splitter 605 which is further explained in the section in FIG. 42B. The interior of the conduit splitter 605 is comprised of three concentric channels. The first concentric channel is the stem channel 609, which has a diameter slightly larger than the diameter of the split stem 526A. The stem channel 609 extends to the proximal terminal end of the conduit splitter 605. This allows the passage of the split stem 526A into the interior of the conduit splitter 605. As seen in the magnified view in FIG. 42B, the next concentric channel is the hypodermic tubing channel 608, which is machined to have a slightly larger diameter than the hypodermic tubing 607 which is placed into it. In turn the inner diameter of the hypodermic tubing 607 is slightly larger than the diameter of the reciprocating member/wire 528.

The hypodermic tubing 607 is located distal to the stem channel 609. As used herein, distal refers to the direction closer to the patient and thus away from the health care provider, while proximal references the direction closer to the health care provider and thus moving away from the patient.

The final concentric channel is the wire channel 610 which is slightly larger than the reciprocating member/wire 528. The wire channel 610 is distal to the hypodermic tubing channel 608. The final portion of the conduit splitter 605 is the spike 606 which is used to secure the conduit splitter 605 to the lumen which requires clearing. The reciprocating member/wire 528 would exit the wire channel 610, enter the spike 606, and exit out through the spike exit port 606A. The spike exit portion 606A extends to the distal terminal end of the conduit splitter 605.

FIG. 43A is a section view which illustrates the moment when the split stem 526A approaches the hypodermic tubing 607 and the reciprocating member distal tip 528A first enters the hypodermic tubing 607. The size of the hypodermic tubing 607 allows it to position itself in the space between the reciprocating member/wire 528 and the split conduit 593E. Therefore the reciprocating member/wire 528 continues through the interior lumen of the hypodermic tubing 607 unimpeded. At this moment the hypodermic tubing 607 simultaneously widens the slit in the split conduit 593E and guides it over the outer diameter of the hypodermic tubing 607. The split conduit 593E may never be located within the hypodermic tubing 607 and at all times be on the outside of the hypodermic tubing 607 while the reciprocating member/wire 528 is located within the hypodermic tubing 607.

From this point on the reciprocating member/wire 528 is isolated from the split conduit 593E and is contained by the sequential channels of the conduit splitter 605. Because the hypodermic tubing 607 widens the split conduit 593E and guides it away from the reciprocating member 528, there is no chance for the cut edges of the split conduit 593E to impede the motion of the reciprocating member/wire 528.

FIG. 43B is an illustration of how the continued advancing of the split stem 526A in the distal direction causes the split conduit 593E to reach a conical guide 611 that may be a conical conduit guide 611. In order to better visualize the splitting of the split conduit 593E, it has been shaded. Because the conical conduit guide 611 increases in diameter in the distal direction the Split Conduit 593E is forced to continue to split apart over the outer surface of the conical conduit guide 611. The reciprocating member/wire 528 will at all times be located within the conical conduit guide 611 and will at no time engage the outer conical surface of the conical conduit guide 611.

One or more openings may be present in the conduit splitter 605 that are located along a portion of the length of the conduit splitter 605 at some point between the proximal terminal end and the distal terminal end of the conduit splitter 605. The opening may extend through an outer wall of the conduit splitter 605, and can be seen for example in FIGS. 42A and 43B. The opening is made such that the conical guide 611 is visible. The opening does not extend circumferentially around the entire diameter of the conduit splitter 605 but rather part way around. An identical opening located 180 degrees from the illustrated opening may be present on the other side, or a single opening may only be included. The split conduit 593E after separation from the reciprocating member/wire 528 can move up along the conical guide 611 and then through the opening illustrated in order to be moved outside of the conduit splitter 605. The split conduit 593E after moving through the opening can continue to move in the distal direction as the reciprocating member/wire 528 moves in the distal direction. Alternatively, the split conduit 593E due to its material of construction may curl backwards and in fact move in the proximal direction as the reciprocating member/wire 528 moves in the distal direction. Regardless of its direction of travel, the split conduit 593E remains separated

from the reciprocating member/wire 528 upon movement of the reciprocating member/wire 528 in the distal direction through the conduit splitter 605. The device may be arranged so that the reciprocating member/wire 528 never moves through the one or more openings through which the split conduit 593E moves.

FIG. 44 is an illustration of how the tapered spike 606 is inserted into an artificial tube 39 to secure the conduit splitter 605 in place. Once in position, the split stem 526A can be advanced as far as desired for the reciprocating member/wire 528 to reach and break up the occlusion. The tapered spike 606 can be retained to the artificial tube 39 through a frictional fit engagement between the outside of the tapered spike 606 and the interior of the artificial tube 39. The reciprocating member/wire 528 may exit out of the tapered spike 606 through the terminal distal end of the conduit splitter 605.

The split stem 526A may be advanced through the conduit splitter 605 so that at least 10% of the length of the reciprocating member/wire 528 is located outside of the lumen of the split conduit 593E. The length located outside of the lumen may be the distal most portion of the reciprocating member/wire 528. The split stem 526A may be advanced so that at least 50% of the length of the reciprocating member/wire 528, which is the distal most portion, is located outside of the lumen of the split conduit 593E. In other arrangements, the split stem 526A can be advanced so that from 60%-80%, from 80%-90%, or from 90%-100% of the length of the reciprocating member/wire 528 which is the distal most portion is removed from or otherwise located outside of the lumen of the split conduit 593E.

Another feature of the conduit splitter 605 is that when the split stem 526A is retracted out of the artificial tube 39, and hence moves in the proximal direction, the splitting process is reversed and the internal channels of the conduit splitter 605 act to reseal the split conduit 593E around the reciprocating member/wire 528. This process ensures that the reciprocating member/wire 528 is not exposed to the operator, thus preventing the chance of the provided reciprocation being impeded. This two way process of sealing and resealing also allows the operator to push and pull the split stem 526A to supplement the reciprocation force when breaking up occlusions.

Proximal movement of the reciprocating member/wire 528 causes this element to be simply pulled back through the conduit splitter 605 in the proximal direction. Proximal movement of the split conduit 593E causes this component to be first pulled back into the conduit splitter 605 through the opening in side of the conduit splitter 605 as previously discussed. The split conduit 593E may, but does not have to, engage the outer surface of the conical guide 611. Next, the split conduit 593E may engage the outer surface of the hypodermic tubing 607 and be pulled through an opening between the proximal terminal end of the hypodermic tubing 607 and an inner surface of the body of the conduit splitter 605 that faces in the distal direction. Proximal movement of the split conduit 593E at this point through this opening causes it to be located around the reciprocating member/wire 528 so that the reciprocating member/wire 528 is again located within the lumen of the split conduit 593E.

Although the tube that is slit has been described as a split conduit 593E and other components have been described as incorporating the term "conduit," it is to be understood that the use of this term is for illustration of an exemplary embodiment and that a split tube that could be a conduit, a sheath, or other element may be present in other exemplary embodiments. As such, it is to be understood that the device includes other variations in which a conduit is not present, and although the terminology of the associated components may

no longer include the term "conduit," they may still be present and may still function in the same or similar manner.

Now that exemplary embodiments of the present invention have been shown and described in detail, various modifications and improvements thereon will become readily apparent to those skilled in the art. Accordingly, the spirit and scope of the present invention is to be construed broadly and limited only by the appended claims, and not by the foregoing specification.

## APPENDIX

## Reference Characters and Their Associations

APA	Amplified Piezoelectric Actuator	TC1
CR	Crank	TC1
DS	Displacement Sensor	TC1
IS	Impedance Sensor	TC1
NT	Negative Taper Angle	TC2
SY	Scotch Yoke	TC1
SS	Soft Stop	TC1/TC2
TC1	Tube Clearing Device 1	TC1
TC2	Tube Clearing Device 2	TC2
TCS	Tip Compression Spring	TC1
GL	Green Light	TC1
YL	Yellow Light	TC1
FT	Artificial/Feeding Tube	TC1/TC2
R	Radius of Curvature	TC1
1	Control Box	TC1
2	Power Switch	TC1
3	Power Indicator	TC1
4	Fault Indicator	TC1
5	Power Plug	TC1
6	Clearing Stem Connector	TC1
7	Motor Mount	TC1
8	Motor Mount Damper	TC1
9	Diaphragm	TC1
9A	Alternate Diaphragm	TC1
10	Electronics	TC1
11	Motor PCB	TC1
12	Magnet	TC1
12A	Magnet Recess	TC1
13	Motor Magnetic Coupler	TC1
13A	Alternate Motor Magnetic Coupler	TC1
14	Motor	TC1
14A	Counter Balance Mechanism	TC1
15	Motor Shaft	TC1
16	VCM Body	TC1
17	Winding	TC1
18	End Bearing	TC1
19	Spring	TC1
20	Magnets	TC1
20N-20S	Magnetic Driving members	TC1
21A-21C	Pole Pieces	TC1
22	Tube Depth-Control collar	TC1
22A	Fixed Tube Depth-Control collar	TC1
23	Depth Control Collar Push Button	TC1
23A	Central passageway of push button	TC1
23B	Lower portion of press button	TC1
24	Tube Depth-Control Collar Body	TC1
24A	Central passageway of collar body	TC1
24B	Upper portion of collar body	TC1
25	Spring	TC1
26	Clearing Stem	TC1
27	Wire Stop	TC1
27A	Alternate Wire Stop	TC1
28	Wire	TC1
28A	Wire Protrusion	TC1
29	Wire Tip	TC1
30	Sheath	TC1
30A	Sheath length markings	TC1
30B	Integer markings	TC1
30C	Distal End	TC1
30D	Proximal End	TC1
30E	Sheath with Channels	TC1
31	Stem Stiffener	TC1
32	Clearing Stem Fitting	TC1

-continued

Reference Characters and Their Associations		
32A	Alternate Clearing Stem Fitting	TC1
33	Clearing Stem Magnet	TC1
33A	Alternate Clearing Stem Magnet	TC1
33B	Alternate Clearing Stem Magnet Fitting	TC1
34	Plastic Wire Tip	TC1
34A	Alternate Tubing Tip	TC1/TC2
34B	Fixed Member	TC1/TC2
34C	Gripping/Chopping Mechanism	TC1
34D	Pivot Point	TC1
34E	Ball Tip	TC1/TC2
35	Wire Tip Brush	TC1
36	Sheath Tip Brush	TC1
37	Forward Swept Sheath Tip Brush	TC1
38	Nursing Cart	TC1
38A	Pole	TC1
39	Artificial Tube	TC1
40	Clog	TC1
41	Tube Inner Lumen	TC1
42	Pneumatic Motor	TC1
43	Pneumatic Motor Housing	TC1
44	Pneumatic Motor Shaft	TC1
46	Pneumatic Motor Diaphragm	TC1
47	Internal Tubing	TC1
48	Scotch Yoke Motor	TC1
49	DC Motor	TC1
50	Scotch Yoke Slider	TC1
50A	Scotch Yoke Forward Displacement direction	TC1
50B	Scotch Yoke Rearward Displacement direction	TC1
51	Adapter	TC1
52	Scotch Yoke Shaft	TC1
53	Wires	TC1
54	Air Supply Inlet	TC1
55	Solenoid Motor	TC1
56	Solenoid	TC1
57	Solenoid Shaft	TC1
58	Return Spring	TC1
59	APA Motor	TC1
60	Actuator	TC1
61	Actuator Mount	TC1
62	Actuator Shaft	TC1
63	Electronic System	TC1
66	Fuse	TC1
67	Power	TC1
69	Micro Processor Power Unit (MPU)	TC1
70	+3.3 VDC	TC1
71	Microprocessor	TC1
72	Enable Switch	TC1
73	Power Electronics	TC1
75	Clearing Status Indicator	TC1
75A	Indicator	TC1
76	power signal to motor	TC1
77	Langevin Transducer motor	TC1
78	Piezoelectric elements	TC1
79	Pre-stress bolt	TC1
80	Tail Mass	TC1
81	Horn	TC1
82	Clearing Stem Attachment	TC1
83	Sheath Attachment Bracket	TC1
84	Diaphragm Sealing Ring	TC1
85	Power Up	TC1
86	Initialization	TC1
87	Disabled	TC1
88	Enabled	TC1
89	Enable Button Pressed	TC1
90	Fault Detected	TC1
91	Fault	TC1
92	Power Cycle	TC1
93	Time Interval	TC1
101	Clearing Brush	TC2
101A	Brush tip	TC2
102	Clearing Member Stem	TC2
103	Magnetic Connector	TC2
104	Magnetic Adapter	TC2
105	Torque Limiter	TC2

-continued

Reference Characters and Their Associations		
105A	Receiving Bore	TC2
105B	Magnetic Element	TC2
106	Gear Train Output Shaft	TC2
107	Gear Train	TC2
108	Motor	TC2
109	Trigger	TC2
109A	Power Switch/trigger	TC2
110	Control Circuit	TC2
111	Battery	TC2
112	Battery Compartment	TC2
113	Handset Housing	TC2
114	Clearing Member	TC2
115	Handset	TC2
115A	Commercial Available Rotary Tool	TC2
116	Planetary Gear Train	TC2
117	Motor Output Shaft	TC2
118	Compound Gear Train	TC2
119	Artificial Tube	TC2
120	Path of Freed Clog Particles	TC2
121	Rotation of Brush Arrow	TC2
122	Clog	TC2
123	Input Coupler	TC2
124	Torque Limiter Profile	TC2
125	Preload Springs	TC2
126	Nodal Points	TC2
127A	Maximum Desired Displacement	TC2
127B	Undesirable Displacement	TC2
128	Distance between nodal points	TC2
129	Tube depth-control collar housing	TC2
129A	Undesired Profile of Rotating Stem	TC2
130	Tube Depth-Control Collar Push Button	TC2
131	Opening for Clearing Member	TC2
132	Preloaded Spring	TC2
133	Tube depth-control collar	TC2
134	Preload Collar	TC2
135	Torque Limiter Output Shaft	TC2
136	Operator's Hand	TC2
137	Voltage Regulator	TC2
138	Power Indicator	TC2
139	Power	TC2
140	Input Voltage	TC2
300	Voice Coil Motor (VCM) Tube Clear	TC2
301	Hand Grip	TC2
302	Clearing Stem Adapter	TC2
303	Clearing Stem	TC2
304	Clearing Brush	TC2
305	Voice Coil Motor	TC2
401	Working End	TC1/TC2
402	Port	TC1/TC2
403	Hollow Lumen or Wire	TC1/TC2
500	Clearing and Irrigation Device	TC1'
501	Controller (Control Box)	TC1'
509A	Separator	TC1'
512		TC1'
513A	Shaft Magnetic Adaptor	TC1'
515	Shaft	TC1'
526	Stem	TC1'
527A	Deformable Reservoir (Pliant Wire Stop)	TC1'
528	Reciprocating Member/Wire	TC1'
528A	Reciprocating Member Distal Tip	TC1'
529	Reciprocating Member Distal Portion	TC1'
529A	Distal Portion Coiled Section	TC1'
529B	Distal Portion Core Section	TC1'
530	Reciprocating Member Proximal Portion	TC1'
531	Interdisposed Connecting Member	TC1'
532A	Fixed Adaptor	TC1'
533B	Displaceable Adaptor	TC1'
583	Fixed Support Arm	TC1'
592	Narrow Tube Depth Control Collar	TC1'
593	Conduit	TC1'
593A	Conduit First Portion	TC1'
593B	Interdisposed Tubing Member	TC1'
593C	Conduit Second Portion	TC1'
593'	Conduit Deformable Distal End	TC1'

-continued

Reference Characters and Their Associations		
594	External Flowable-Medium Source	TC1'
595	Port	TC1'
596	Valve	TC1'
599A	Displaceable End	TC1'
599B	Fixed End	TC1'
600	Distal End Portion	TC1'
526A	Split Stem	
528	Reciprocating Member/Wire	
528A	Reciprocating Member Distal Tip	
593	Conduit	
593E	Split Conduit	
601	Conduit Cutter	
602	No. 15 Scalpel Blade	
603	Scalpel Blade Channel	
604	Conduit Channel	
605	Conduit Splitter	
606	Spike	
606A	Spike Exit port	
607	Hypodermic Tubing	
608	Hypodermic Tubing Channel	
609	Stem Channel	
610	Wire Channel	
611	Conical Conduit Guide	

While the invention has been described in detail and with reference to specific examples thereof, it will be apparent to one skilled in the art that various changes and modifications can be made therein without departing from the spirit and scope thereof.

What is claimed is:

1. A device for clearing blockages, comprising:  
a tube that comprises a slit, wherein the tube has a lumen;  
a reciprocating member, wherein a portion of the reciprocating member is located within the lumen; and  
a splitter that receives the tube and the reciprocating member, wherein the splitter has a conical surface that decreases in size in a proximal direction of the device, and wherein the tube engages the conical surface.
2. The device as set forth in claim 1, wherein the tube is a sheath.
3. The device as set forth in claim 1, wherein the tube is a conduit.
4. The device as set forth in claim 1, wherein the portion of the reciprocating member that is located within the lumen is a proximal portion of the reciprocating member, wherein a distal portion of the reciprocating member is located outside of the lumen, wherein the distal portion is at least 10% of a length of the reciprocating member.
5. The device as set forth in claim 1, further comprising a cutter, wherein the cutter comprising:  
a body;  
a channel that extends through the body;  
a blade carried by the body; and  
wherein the tube is located in the channel, wherein the blade engages the tube and cuts the tube to create the slit when the tube is moved through the channel.
6. The device as set forth in claim 1, wherein the slit extends in an axial direction of the tube and extends completely through a wall of the tube.
7. The device as set forth in claim 1, wherein the reciprocating member is removed from the lumen of the tube at the splitter upon distal movement of the reciprocating member through the splitter, wherein the conical surface is an outer surface of a conical conduit guide, wherein the reciprocating member extend through the conical conduit guide.

8. A device for clearing blockages, comprising:  
a tube that has a lumen;  
a reciprocating member that has a diameter that is smaller than a diameter of the tube; and  
a splitter that engages the tube as the reciprocating member moves in a distal direction, wherein the splitter has a body that has a tubular section that engages the tube as the reciprocating member moves in the distal direction, wherein the tubular section is located between the reciprocating member and the tube and separates the reciprocating member from the tube.
9. The device as set forth in claim 8, wherein a proximal portion of the reciprocating member is located within the lumen, and wherein a distal portion of the reciprocating member is located outside of the lumen, wherein all of the reciprocating member located distal of the splitter is located outside of the lumen.
10. The device as set forth in claim 8, wherein a portion of the reciprocating member is located in the lumen, wherein movement of the reciprocating member in the distal direction causes an increase in the amount of the reciprocating member that is located outside of the lumen.
11. A device for clearing blockages, comprising:  
a tube that has a lumen;  
a reciprocating member that has a diameter that is smaller than a diameter of the tube; and  
a splitter that engages the tube as the reciprocating member moves in a distal direction;  
wherein the splitter has a body that defines a stem channel, wherein a portion of the reciprocating member is simultaneously located in the lumen and the stem channel;  
wherein the body has a tubular section that engages the tube as the reciprocating member moves in the distal direction to cause the reciprocating member to be removed from the lumen of the tube as the reciprocating member is moved through a tubing channel of the tubular section and the tube is located outside of the tubing channel; and  
wherein the tubular section is located distal to the stem channel.
12. The device as set forth in claim 11, wherein the splitter has a spike that is located distal to the tubular section, wherein the reciprocating member moves through the spike in the distal direction and exits through a spike exit port at a distal terminal end of the splitter, wherein the tube is not located within the spike.
13. A device for clearing blockages, comprising:  
a tube that has a lumen;  
a reciprocating member that has a diameter that is smaller than a diameter of the tube; and  
a splitter that engages the tube as the reciprocating member moves in a distal direction;  
wherein the splitter has a conical guide that decreases in radial size in a proximal direction, wherein the reciprocating member moves through the conical guide and wherein the tube is located outside of the conical guide.
14. A device for clearing blockages, comprising:  
a tube that has a lumen;  
a reciprocating member that has a diameter that is smaller than a diameter of the tube; and  
a splitter that engages the tube as the reciprocating member moves in a distal direction;  
wherein the splitter defines a radial opening that is located between a distal terminal end of the splitter and a proximal terminal end of the splitter, wherein the tube is



moved through the radial opening, and wherein the reciprocating member is not moved through the radial opening.

15. The device as set forth in claim 8, wherein the tube is a conduit, and wherein the tubular section is hypodermic tubing. 5

16. A cutter for creating a slit in a tube, comprising:

a body;

a channel that extends through the body;

a blade carried by the body; and 10

a tube that is located in the channel, wherein the blade engages the tube and cuts the tube to create the slit when the tube is moved through the channel;

wherein the body is made of a first half and a second half, wherein the channel is defined by both the first half and the second half, wherein the channel extends through a portion of the body such that the portion of the body is located 360 degrees around the channel. 15

17. The cutter as set forth in claim 16, wherein the blade is a scalpel blade and is located inside of the body and extends into the channel, wherein the tube is a conduit and wherein the slit extends completely through a wall of the conduit. 20

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