



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

(10) **Patent No.:** **US 10,307,340 B2**
(45) **Date of Patent:** **Jun. 4, 2019**

(54) **DEVICES FOR CLEARING BLOCKAGES IN ARTIFICIAL AND NATURAL LUMENS**

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(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 396 days.

(21) Appl. No.: **15/223,787**

(22) Filed: **Jul. 29, 2016**

(65) **Prior Publication Data**

US 2016/0331645 A1 Nov. 17, 2016

Related U.S. Application Data

(63) Continuation-in-part of application No. 15/142,736, filed on Apr. 29, 2016, now abandoned, which is a (Continued)

(51) **Int. Cl.**
A61M 25/00 (2006.01)
A61J 15/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC **A61J 15/0026** (2013.01); **A61B 17/22012** (2013.01); **A61B 17/3207** (2013.01);
(Continued)

(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

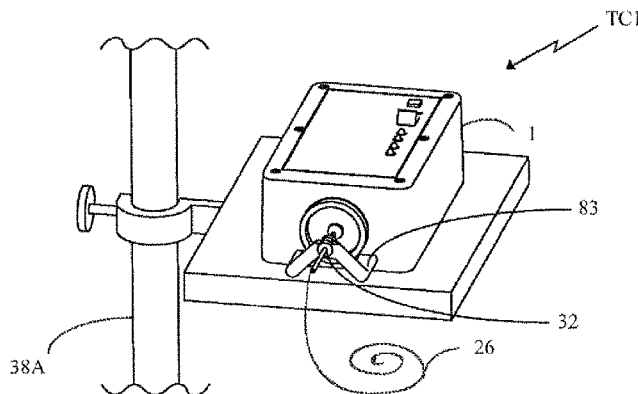
Assistant Examiner — Ilya Y Treyger

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(57) **ABSTRACT**

An occlusion clearing device for a patient has a housing with a motor(s) that generates repetitive motion, which is reciprocating, rotational or both. A clearing stem including a sheath that has a lumen, wherein aspiration is conducted through the sheath lumen. A wire is located in the sheath lumen and receives repetitive motion from the controller. The sheath terminates in a sheath end having at least one sheath opening. The wire terminates in a wire tip, which may

(Continued)



be flat, helical, or tubular. The wire tip is positioned within the sheath end, in proximity to the sheath opening(s), and movement of the wire tip and/or sheath end relative to each other creates shearing forces that break up an adjacent occlusion.

23 Claims, 88 Drawing Sheets

Related U.S. Application Data

continuation of application No. 13/863,108, filed on Apr. 15, 2013, now Pat. No. 9,352,122, which is a continuation-in-part of application No. 13/683,852, filed on Nov. 21, 2012, now Pat. No. 9,308,348, 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 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. 62/198,256, filed on Jul. 29, 2015, provisional application No. 62/266,283, filed on Dec. 11, 2015, provisional application No. 60/989,484, filed on Nov. 21, 2007, provisional application No. 61/099,737, filed on Sep. 24, 2008, provisional application No. 61/563,405, filed on Nov. 23, 2011.

(51) **Int. Cl.**

- A61B 17/22* (2006.01)
- A61B 17/3207* (2006.01)
- A61B 90/70* (2016.01)
- A61M 1/00* (2006.01)
- A61M 3/02* (2006.01)
- A61M 5/00* (2006.01)
- A61M 31/00* (2006.01)
- A61M 25/16* (2006.01)
- A61M 27/00* (2006.01)
- A61M 39/02* (2006.01)
- A61B 17/00* (2006.01)
- A61B 17/32* (2006.01)
- A61B 90/00* (2016.01)
- A61M 39/00* (2006.01)

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

- CPC *A61B 17/320758* (2013.01); *A61B 17/320783* (2013.01); *A61B 90/70* (2016.02); *A61M 1/0084* (2013.01); *A61M 3/0279* (2013.01); *A61M 25/00* (2013.01); *A61M 25/0082* (2013.01); *A61B 17/22* (2013.01); *A61B 2017/00477* (2013.01); *A61B 2017/00685* (2013.01); *A61B 2017/00876* (2013.01); *A61B 2017/22014* (2013.01); *A61B 2017/22079* (2013.01); *A61B 2017/320012* (2013.01); *A61B 2017/320028* (2013.01); *A61B 2017/320733* (2013.01); *A61B 2017/320775* (2013.01); *A61B 2090/034* (2016.02); *A61B 2090/701* (2016.02); *A61B 2217/005* (2013.01); *A61B 2217/007* (2013.01); *A61J 15/0003* (2013.01); *A61M 39/00* (2013.01); *A61M 2025/0019* (2013.01)

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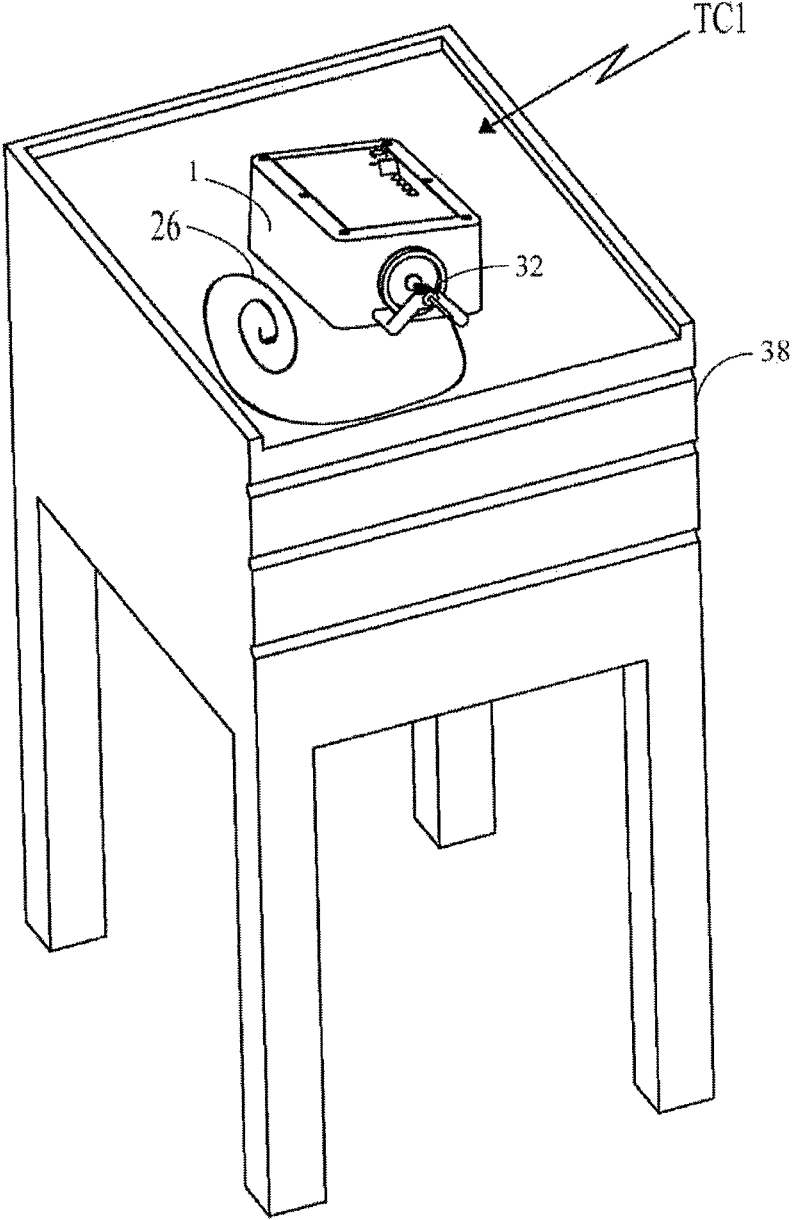


FIG. 1

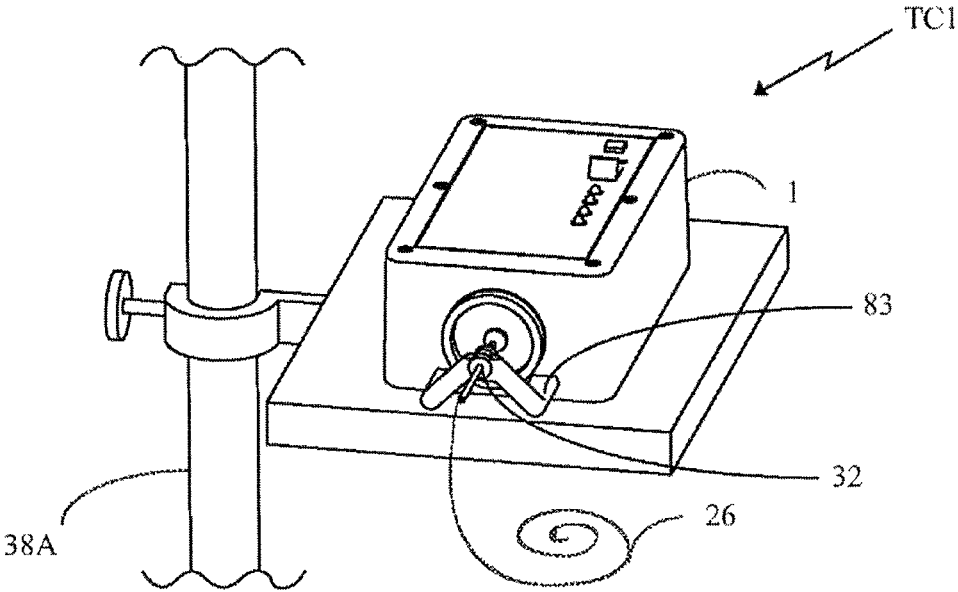


FIG. 1A

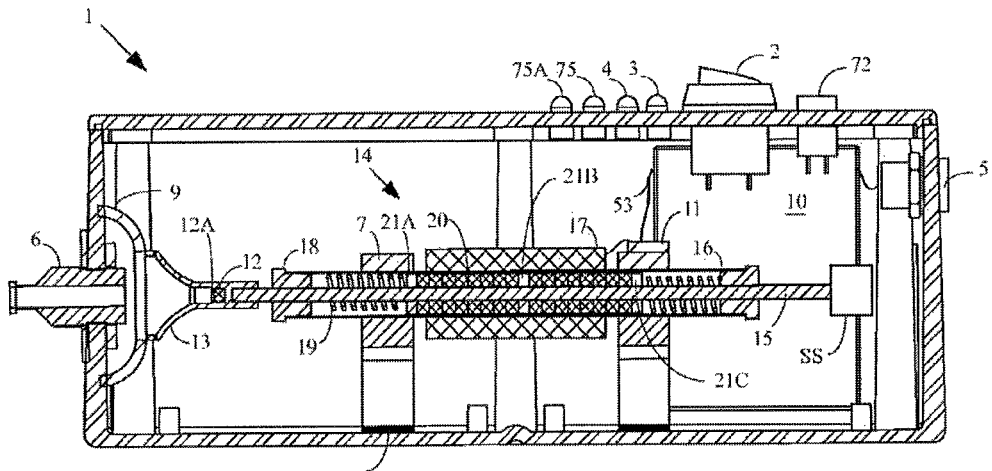


FIG. 2A

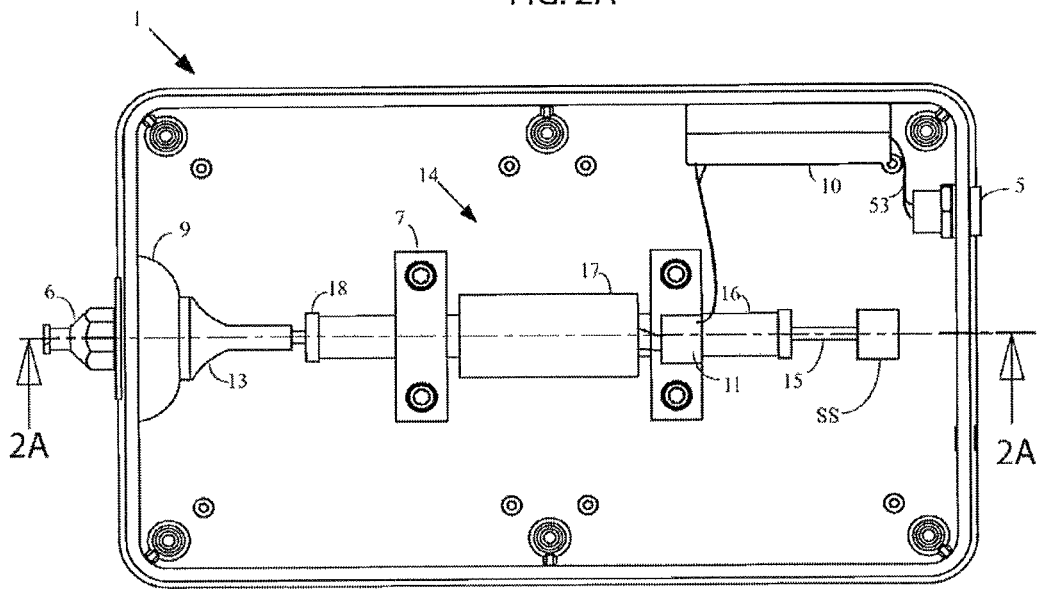


FIG. 2

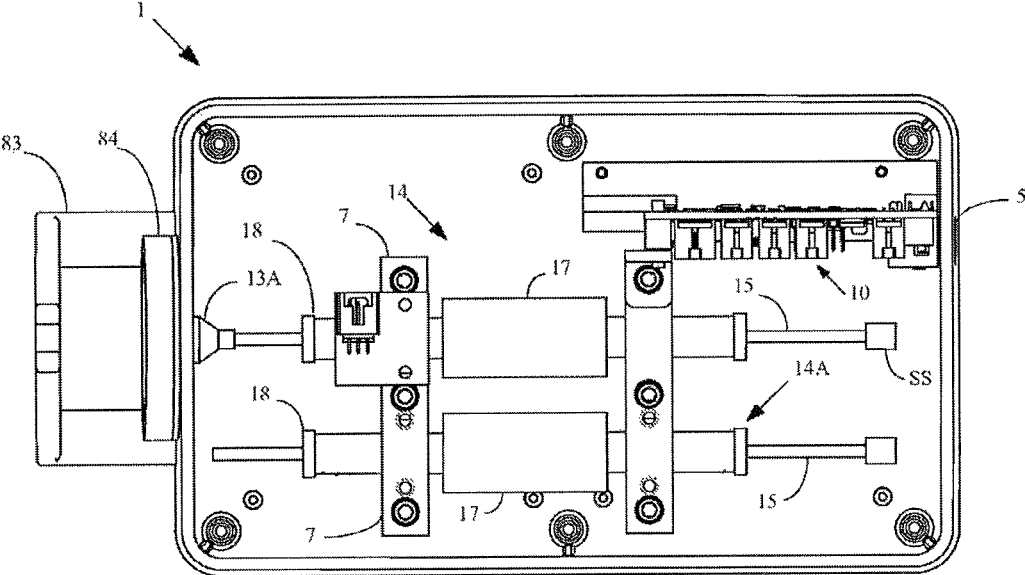


FIG. 2B

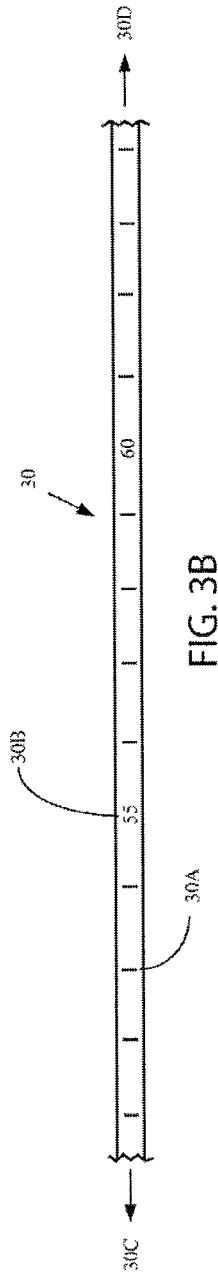


FIG. 3B

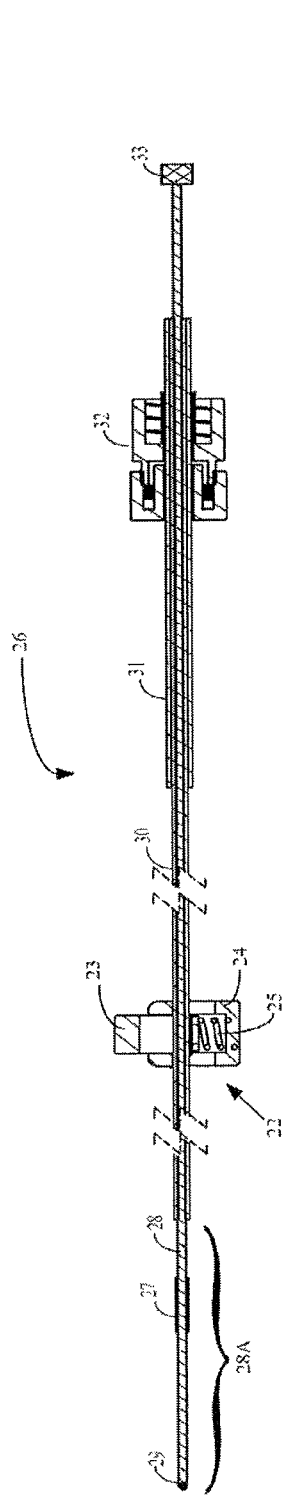


FIG. 3A

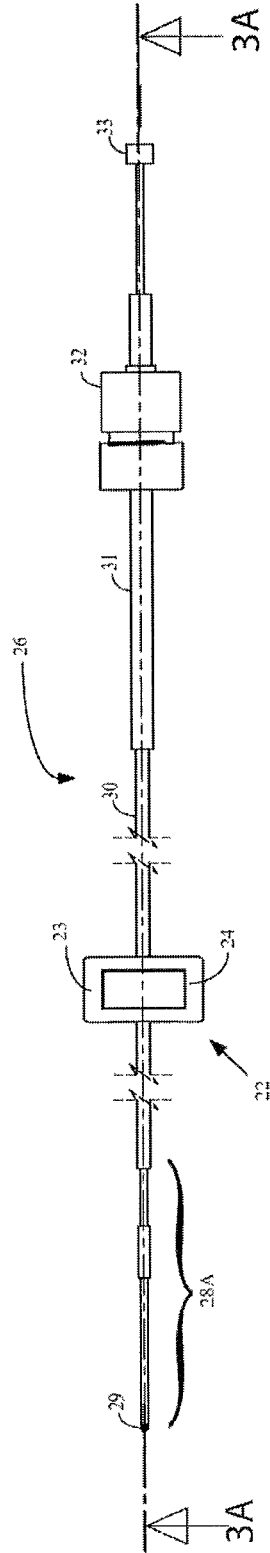


FIG. 3

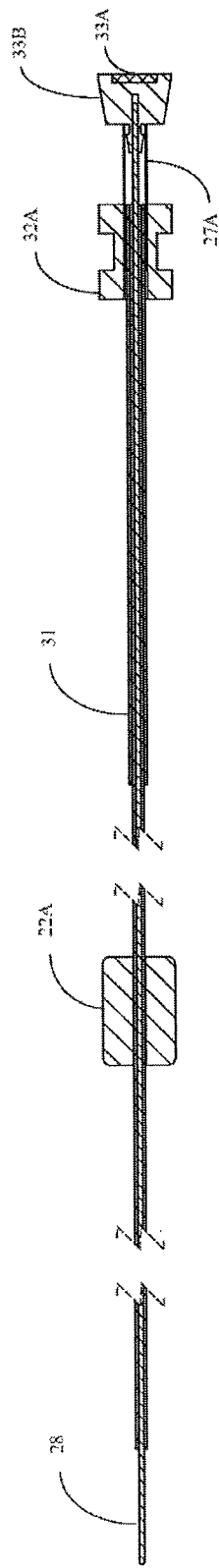


FIG. 3D

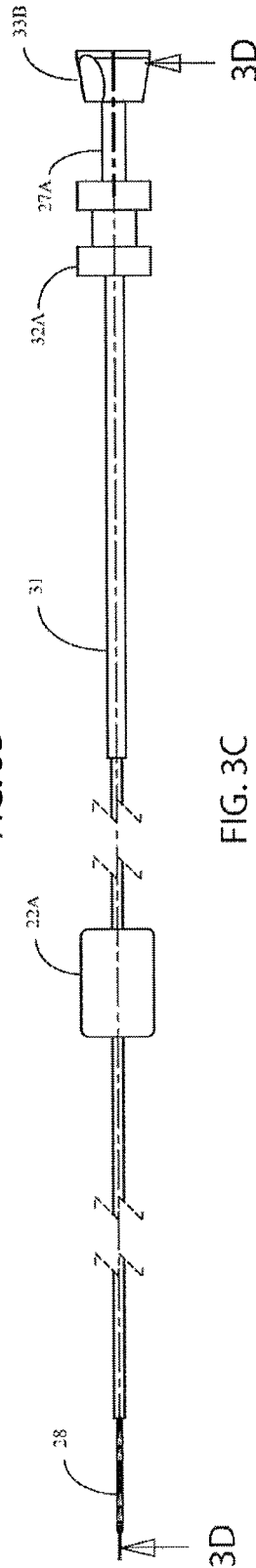


FIG. 3C

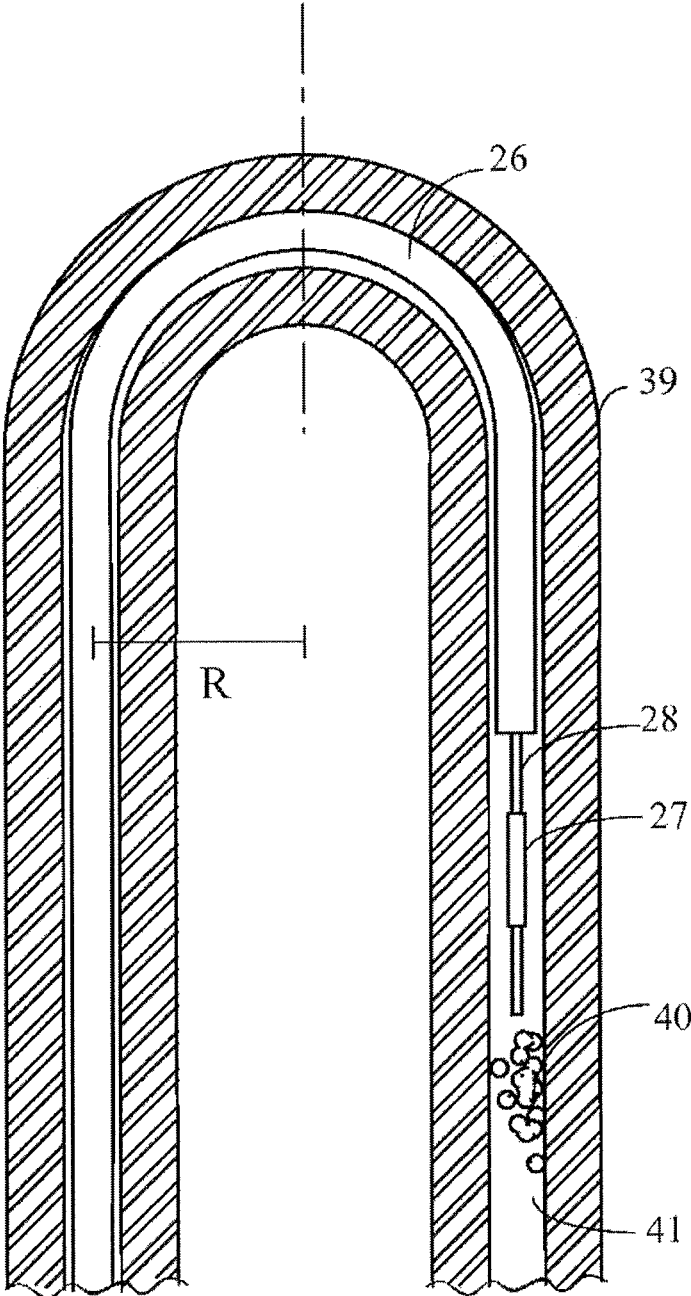


FIG. 4

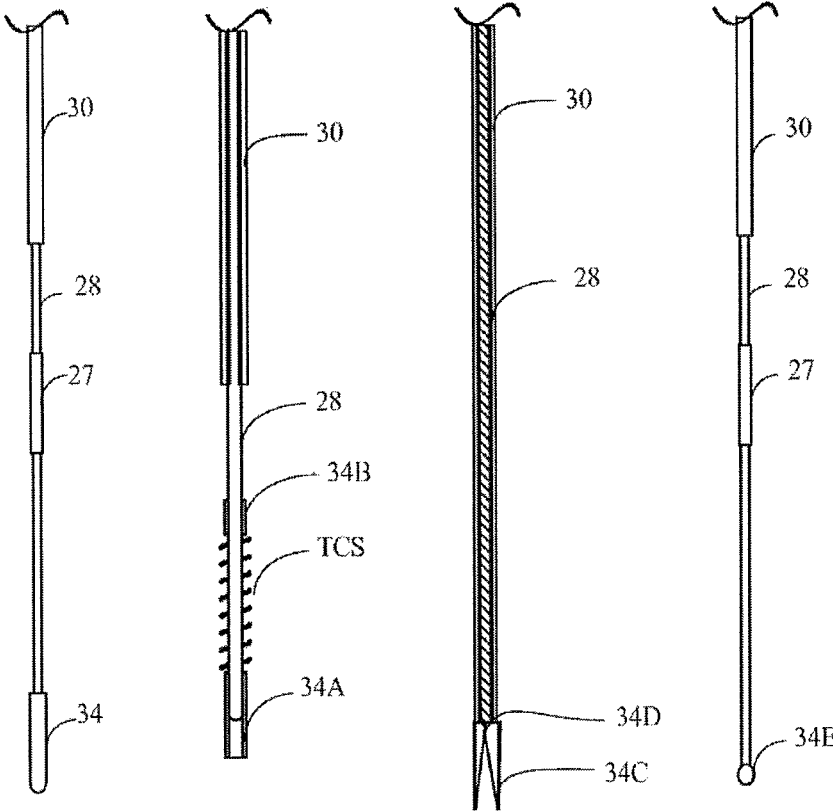


FIG. 5A

FIG. 5B

FIG. 5C

FIG. 5D

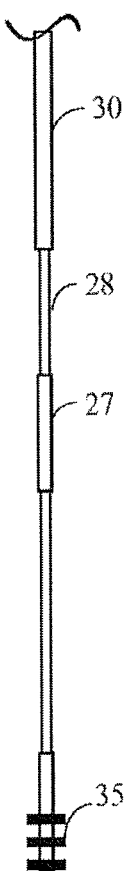


FIG. 6

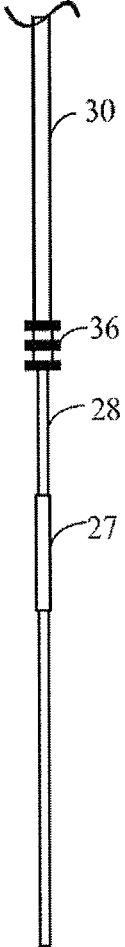


FIG. 7

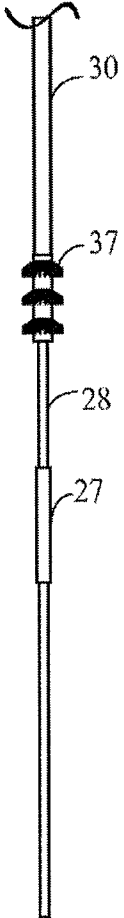


FIG. 8

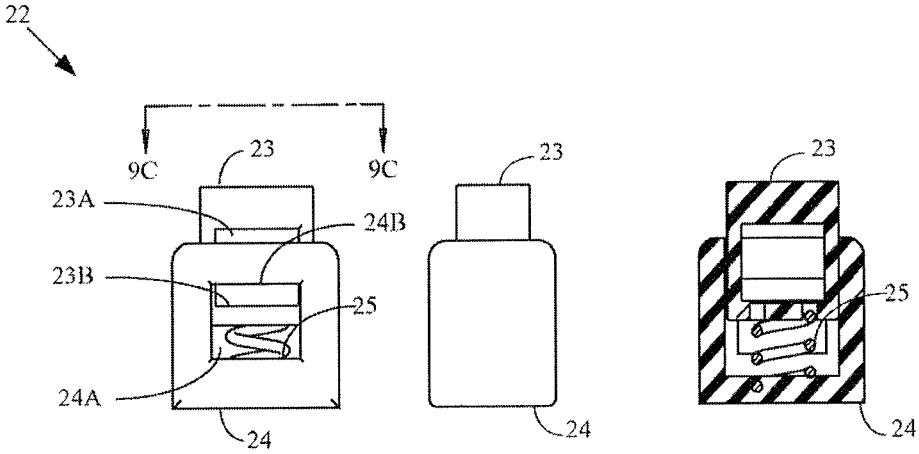


FIG. 9A

FIG. 9B

FIG. 9C

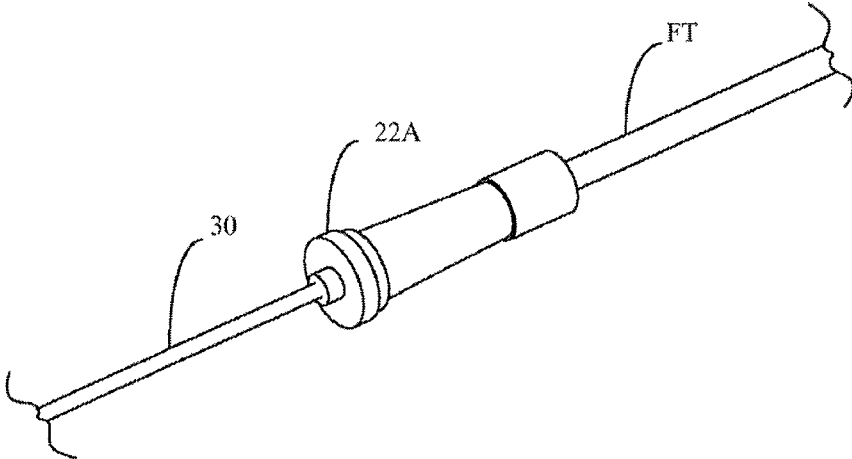


FIG. 9D

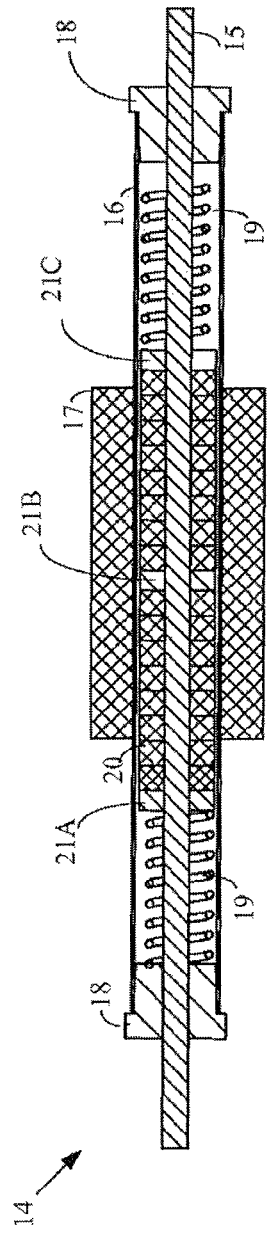


FIG. 10A

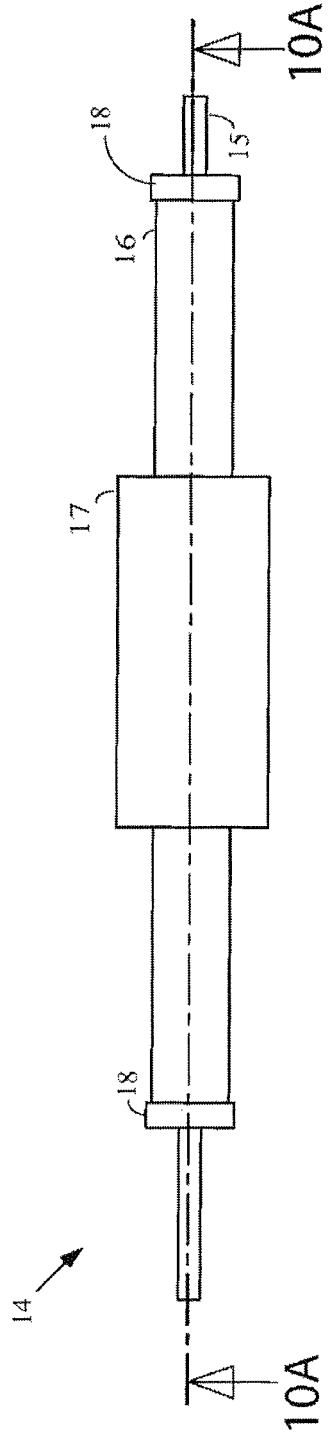


FIG. 10

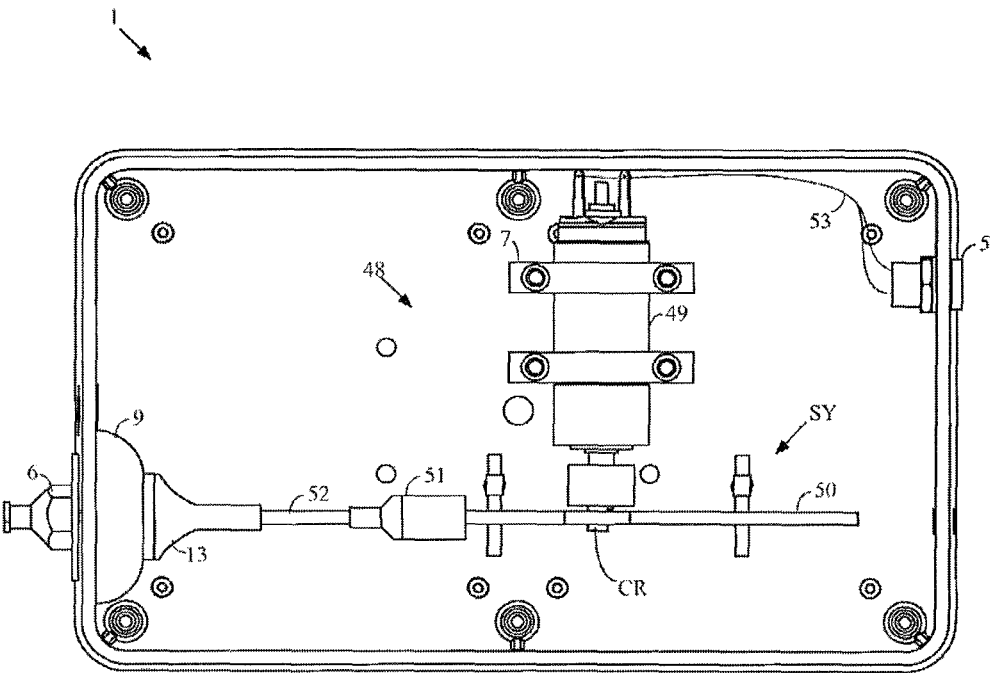


FIG. 11

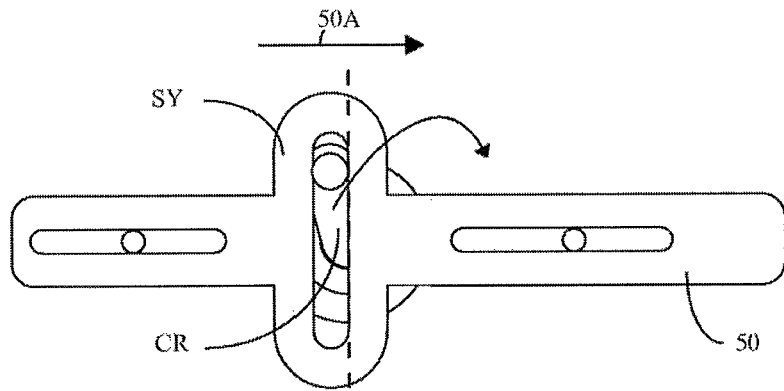


FIG. 11A

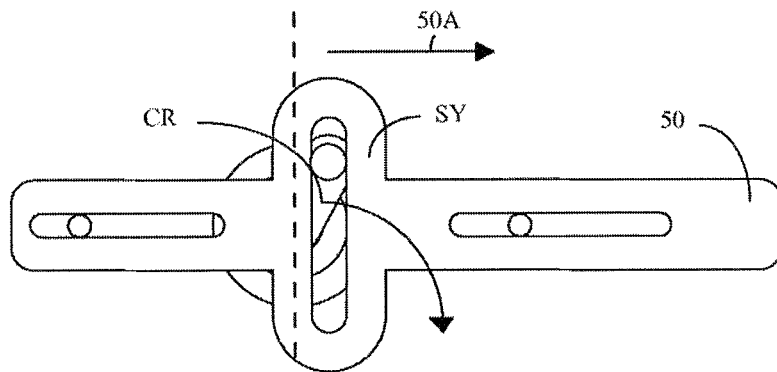


FIG. 11B

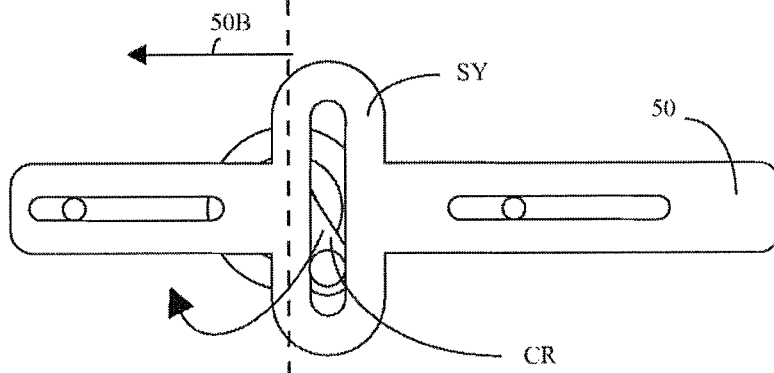


FIG. 11C

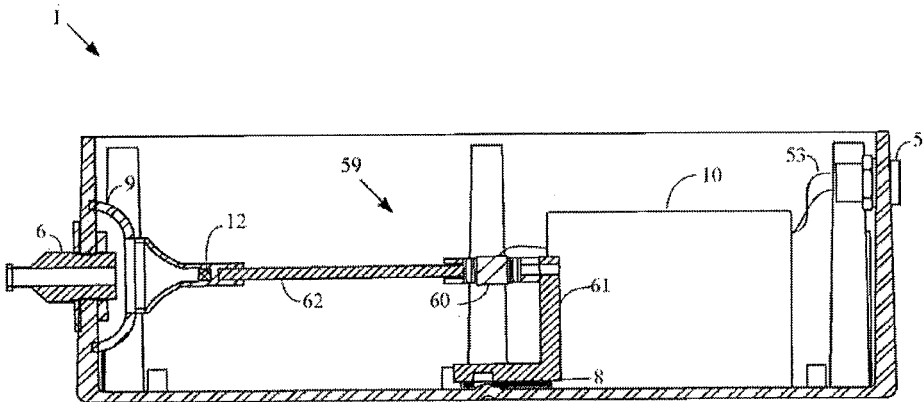


FIG. 12A

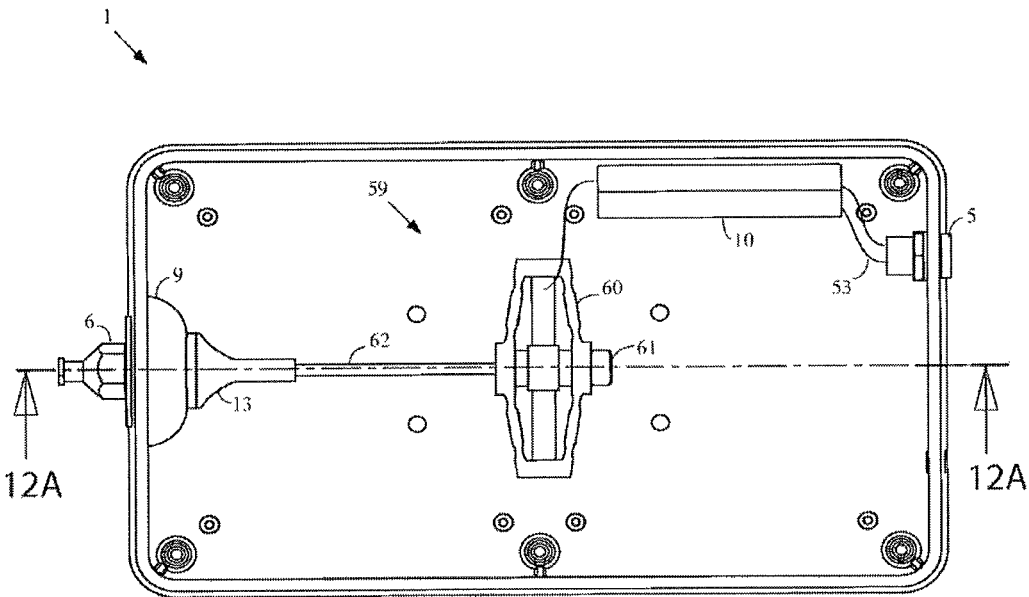


FIG. 12

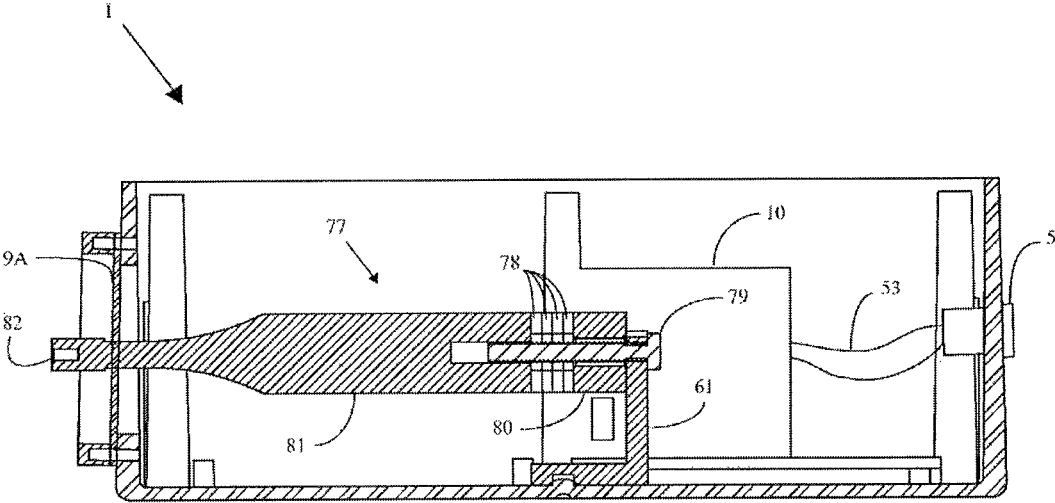


FIG. 12B

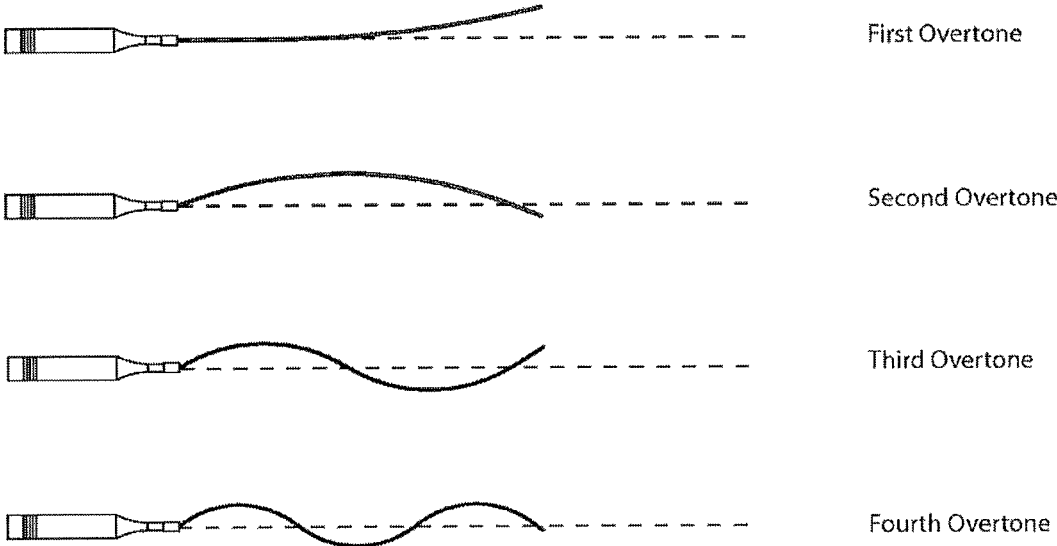


FIG. 12C

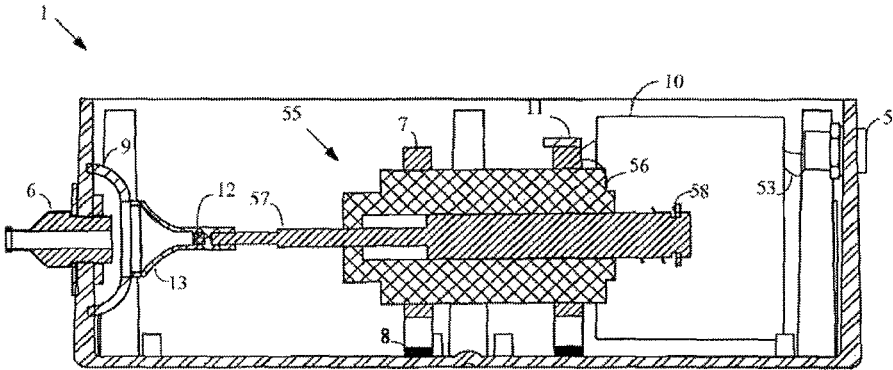


FIG. 13A

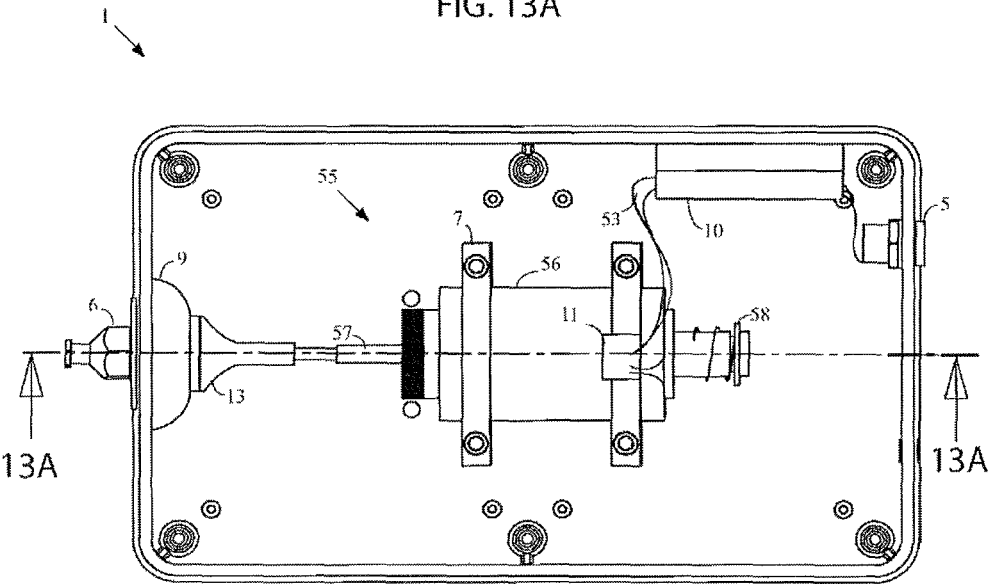


FIG. 13

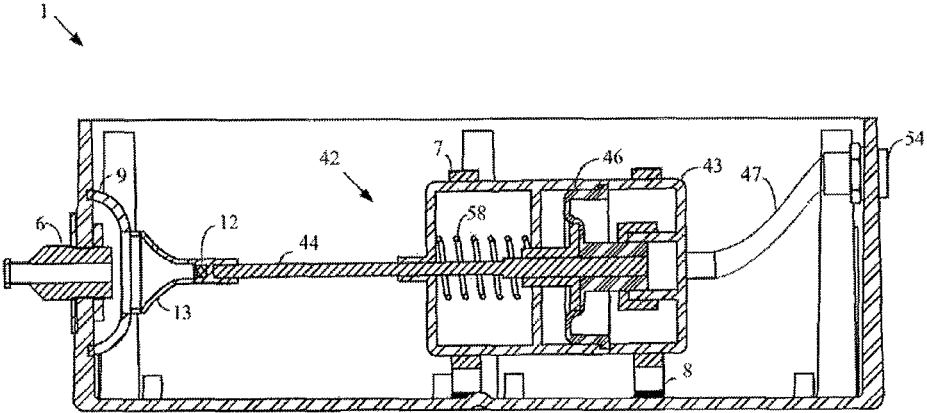


FIG. 14A

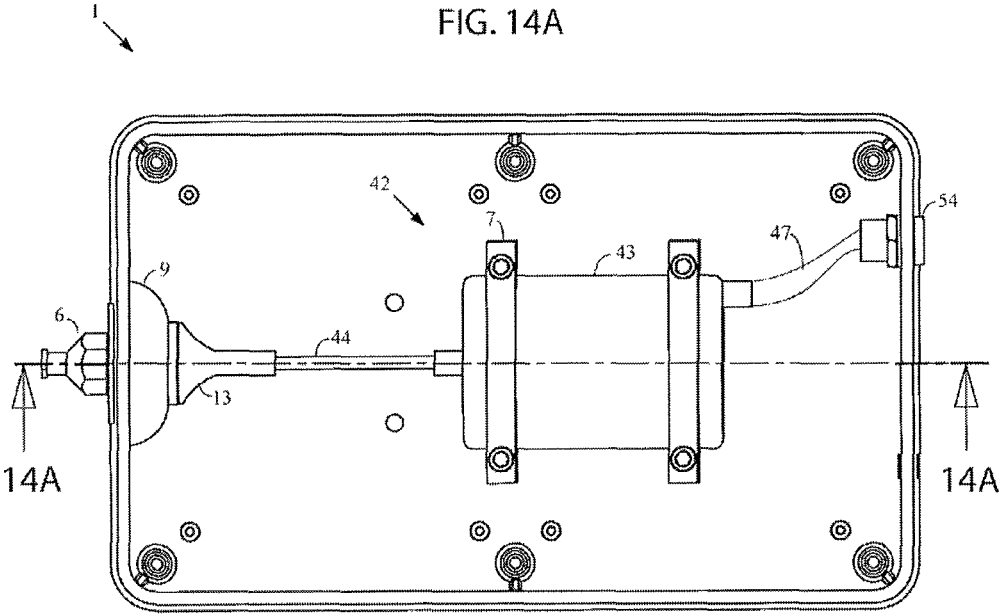


FIG. 14

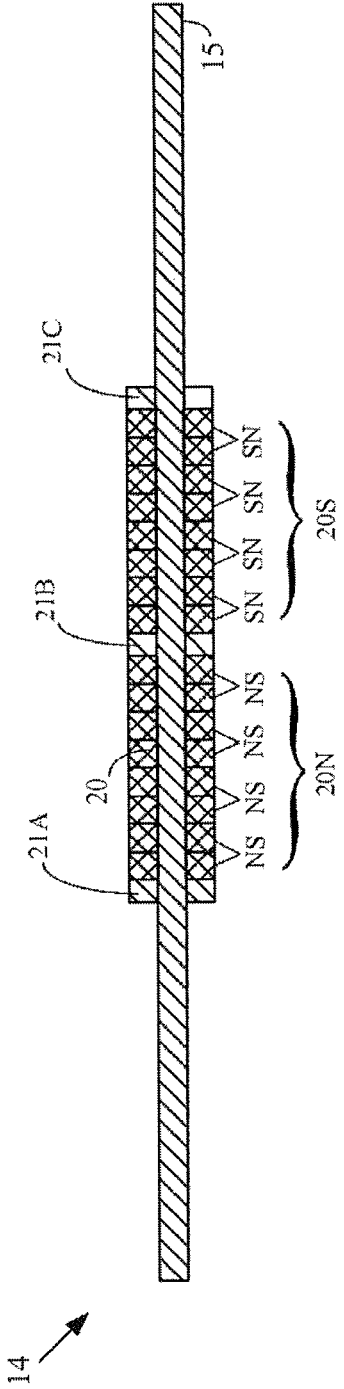


FIG. 15

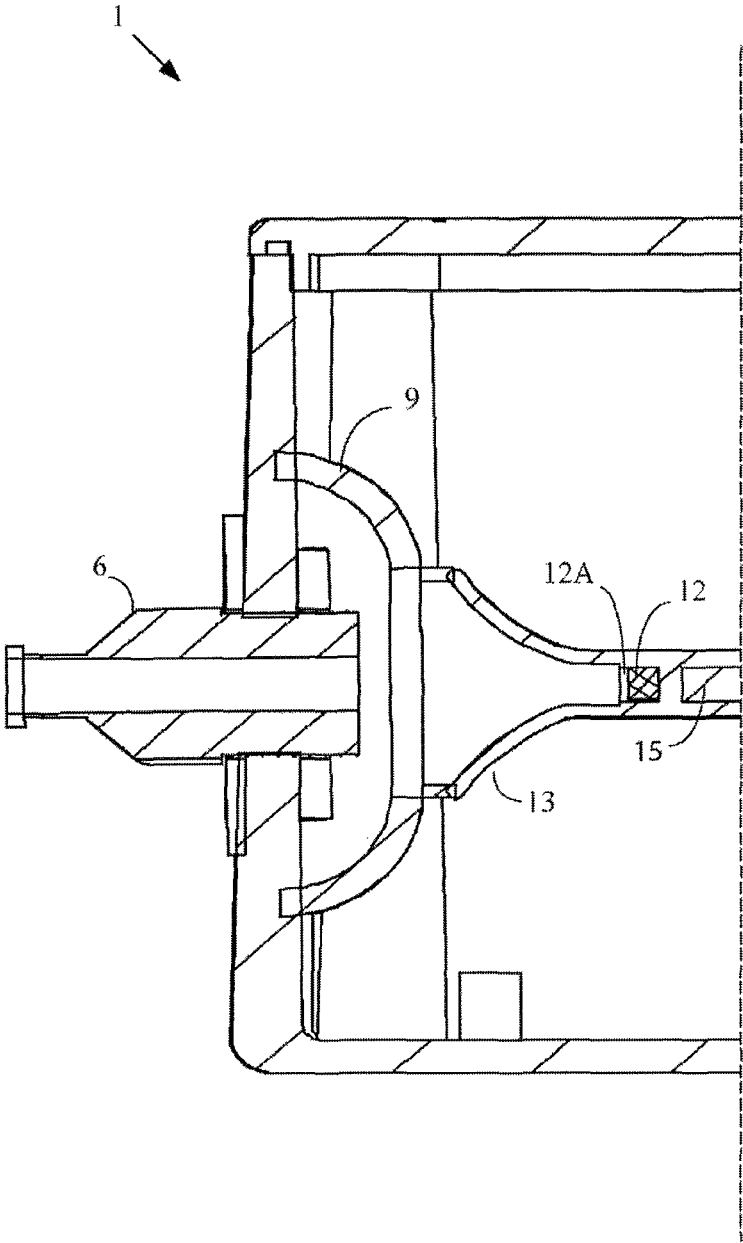


FIG. 16A

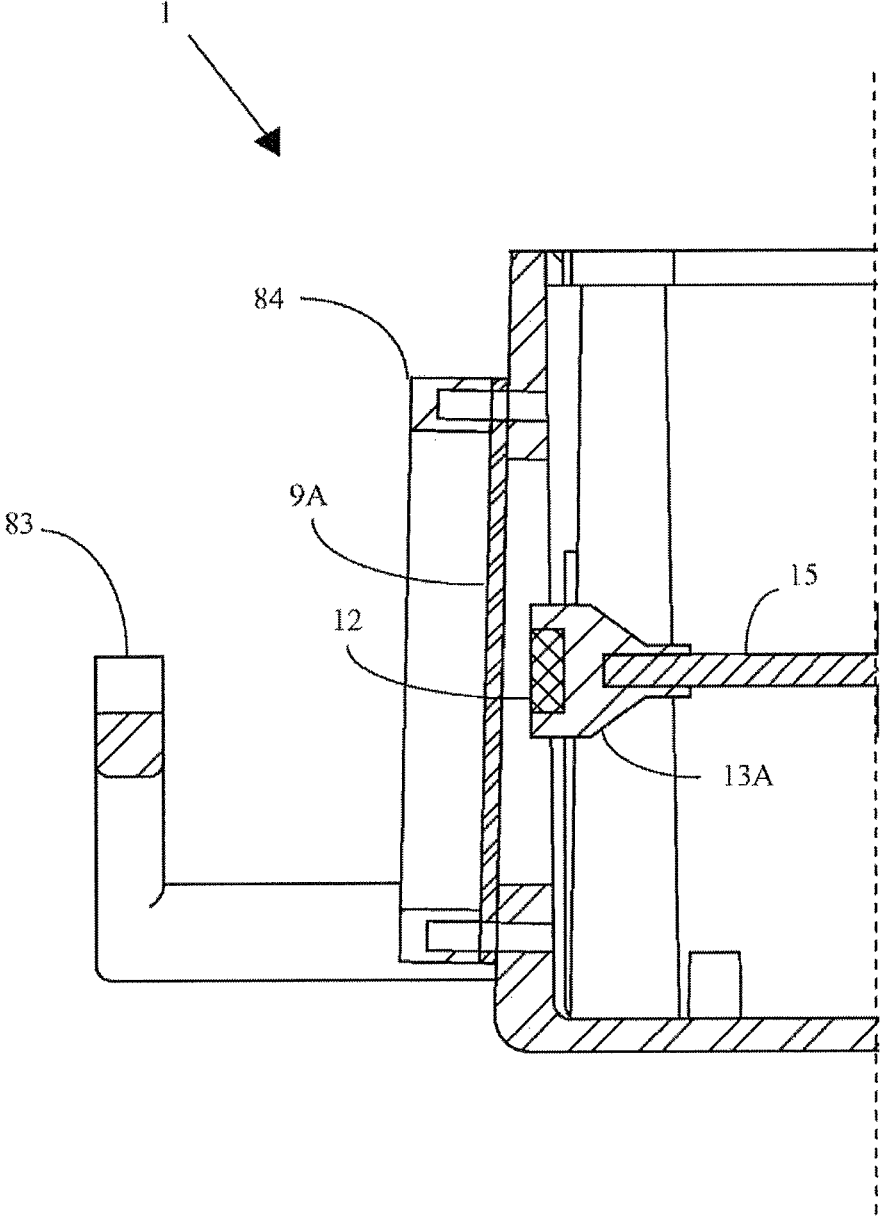


FIG. 16B

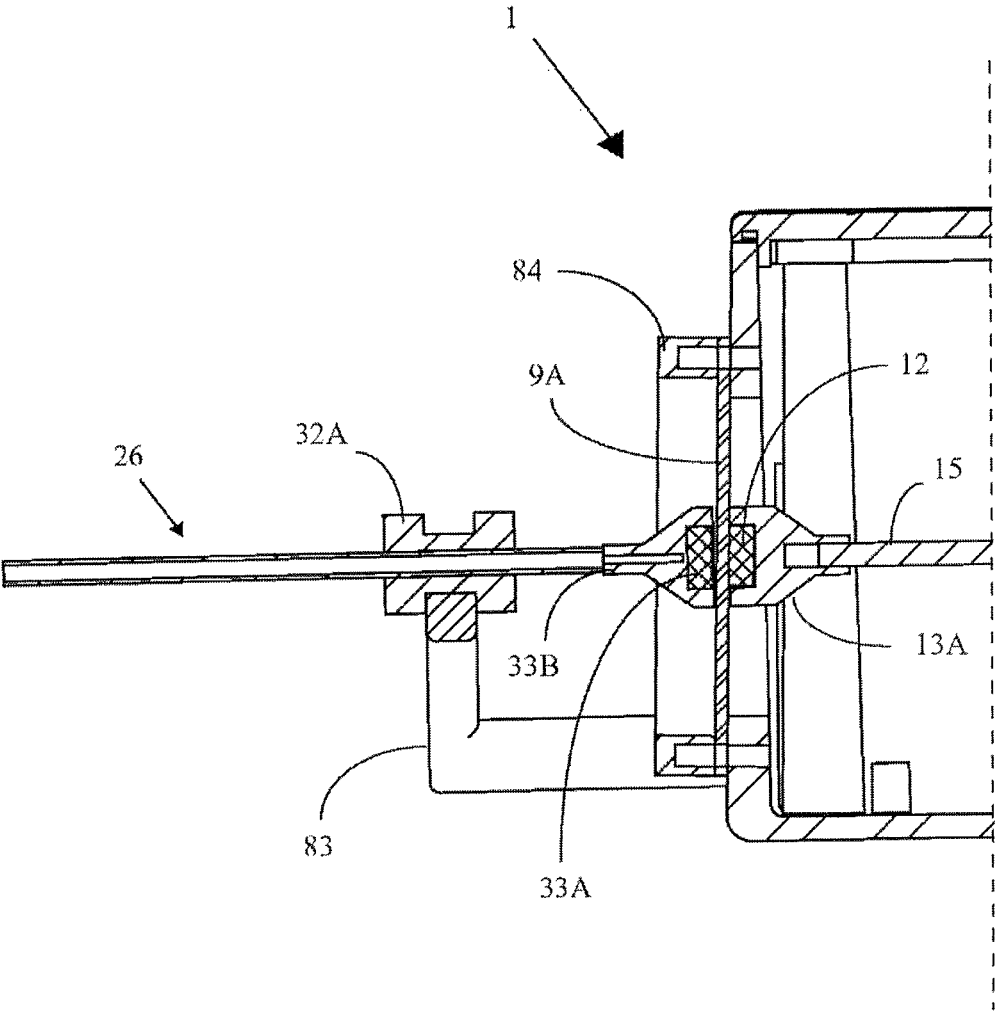


FIG. 16C

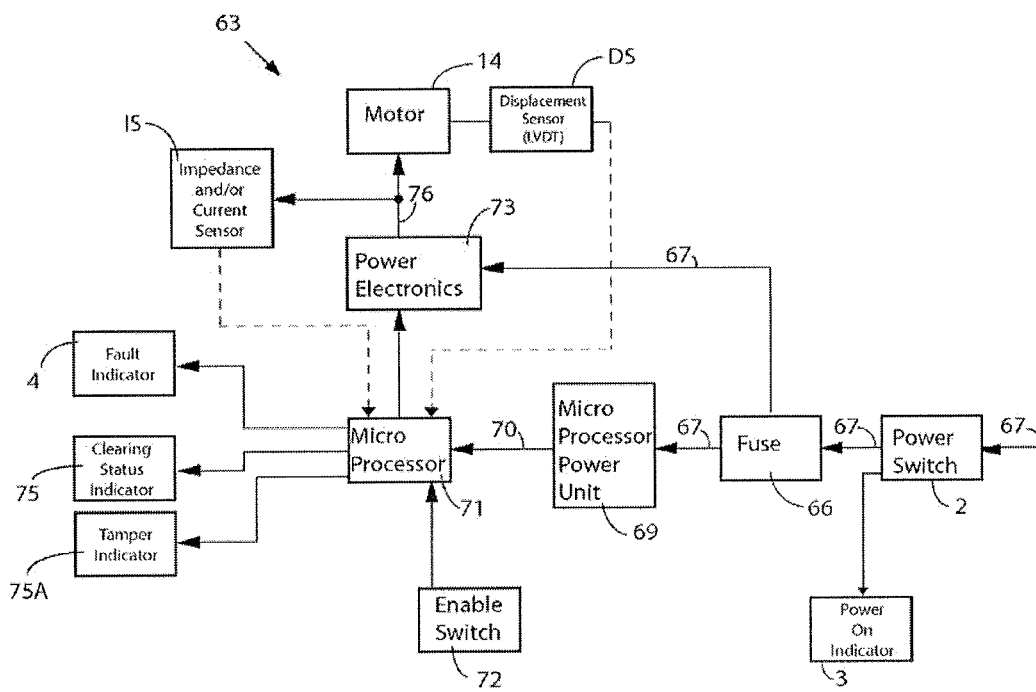


FIG. 17A

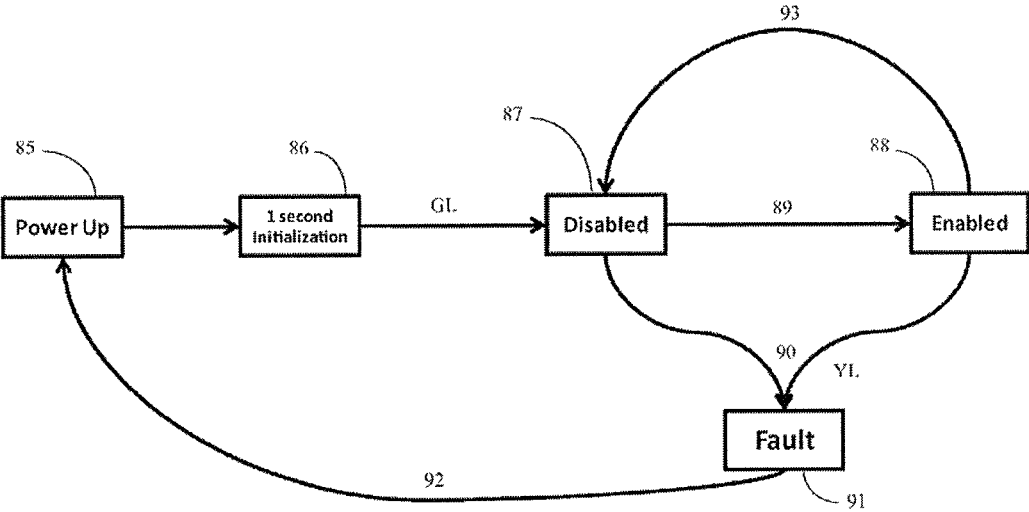


FIG. 17B

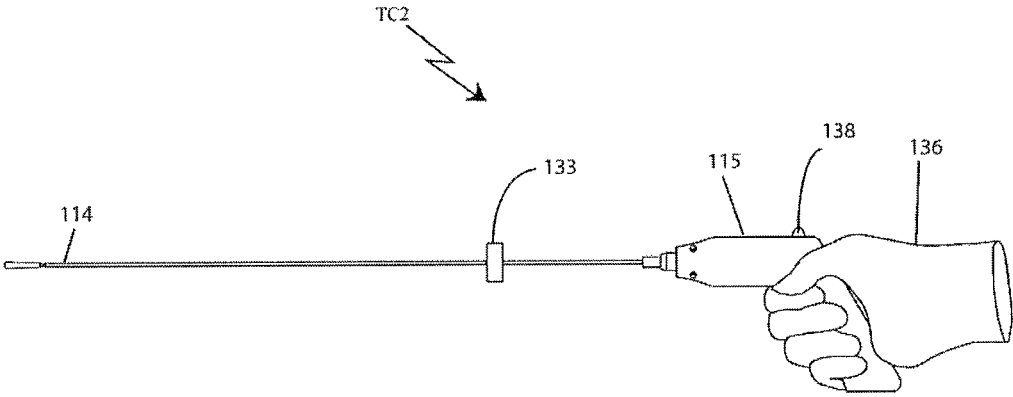


FIG. 18A

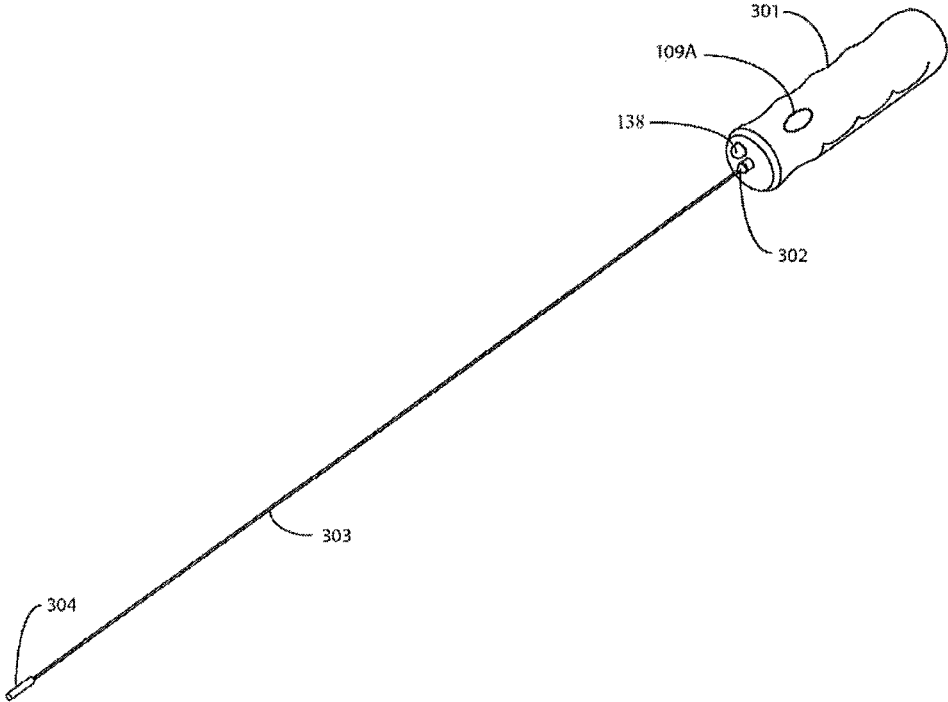


FIG. 18B

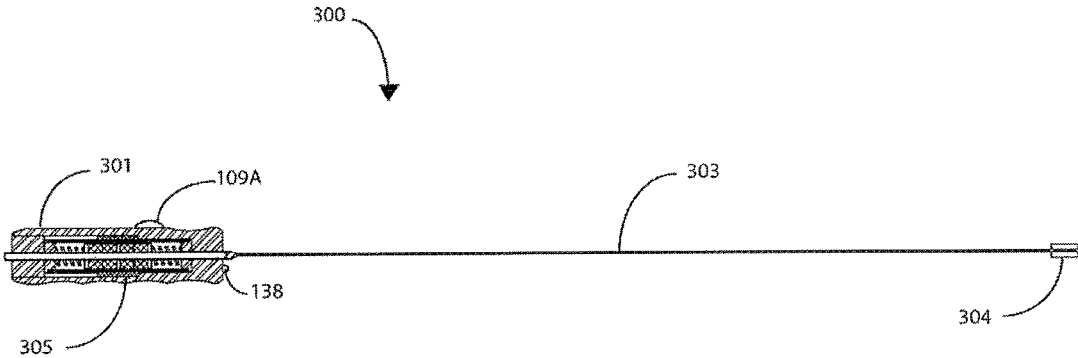


FIG. 18C

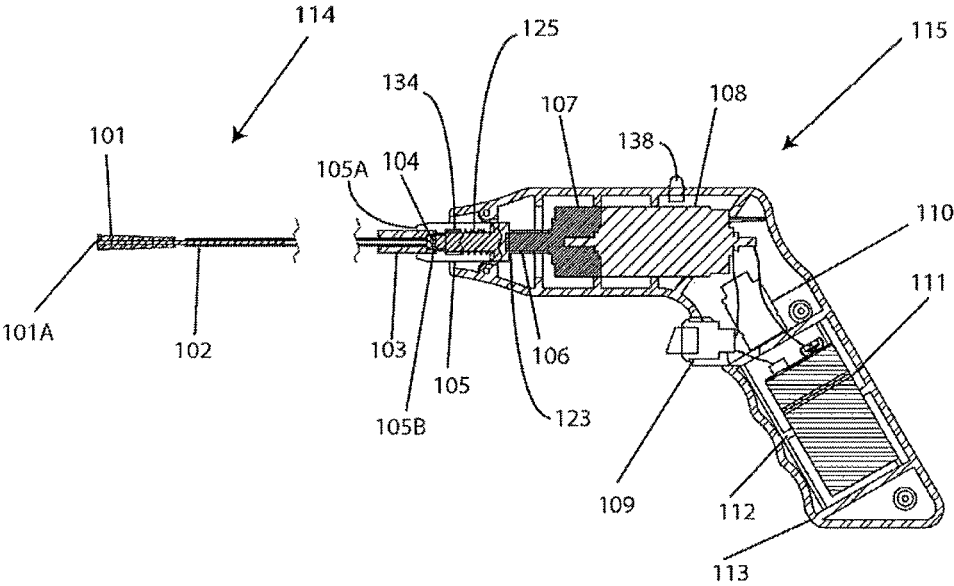


FIG. 19

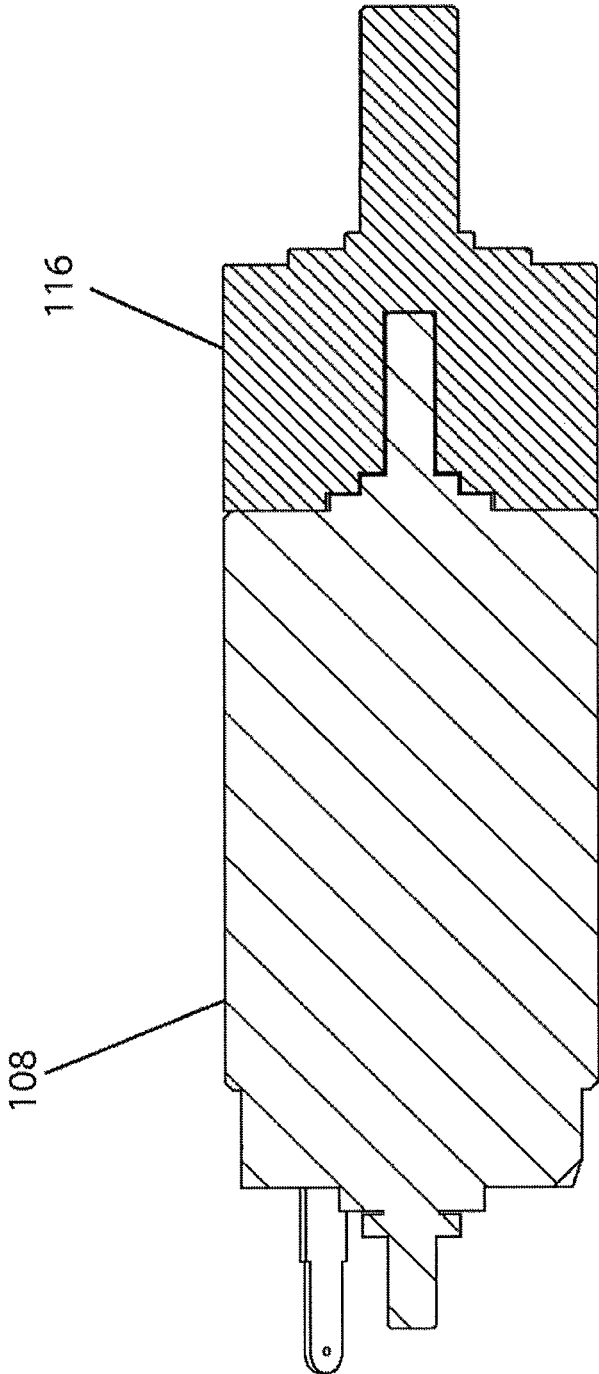


FIG. 20

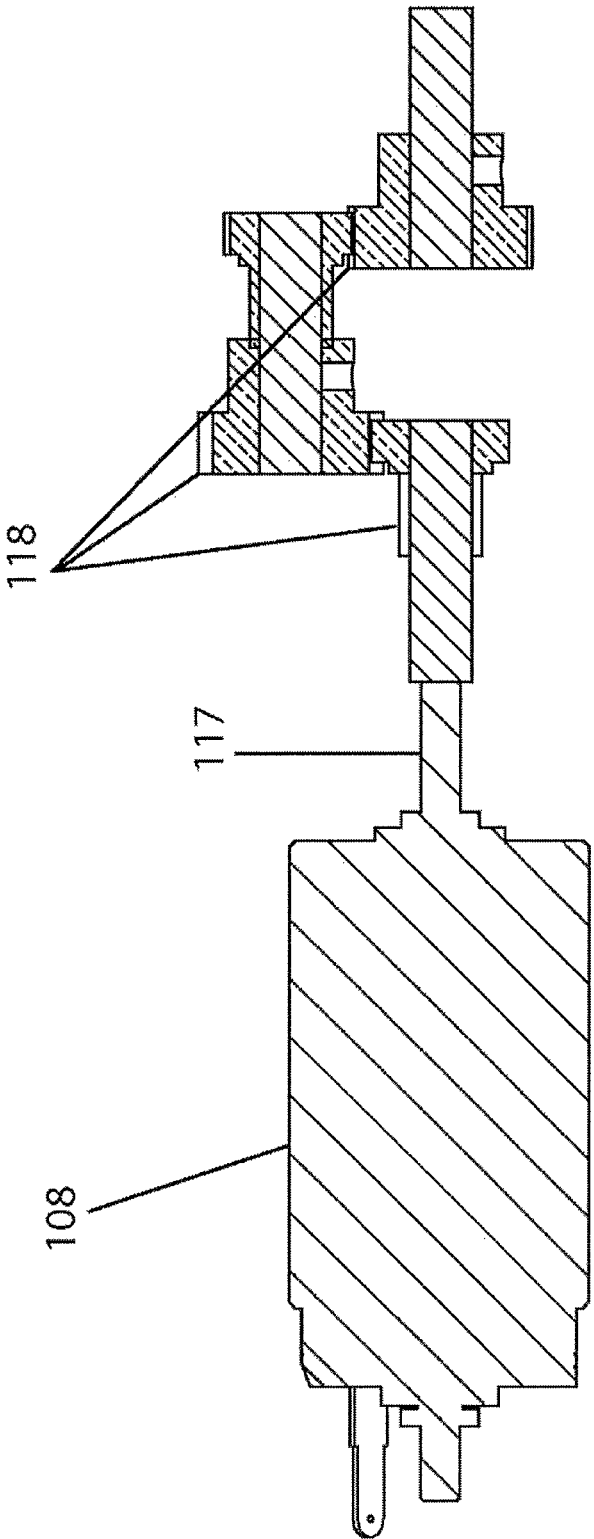


FIG. 21

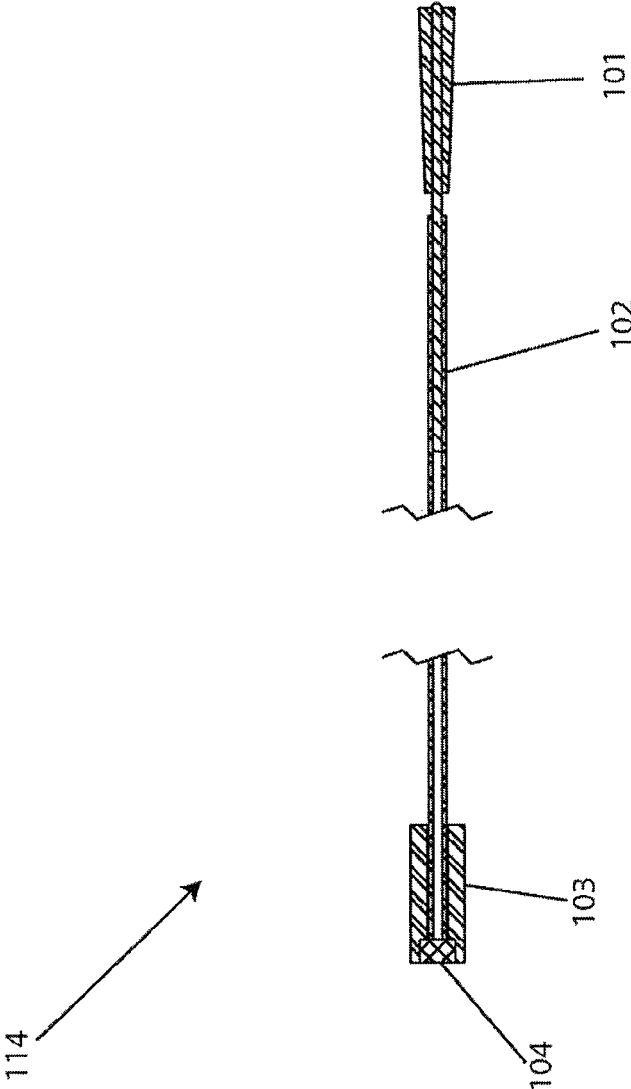


FIG. 22

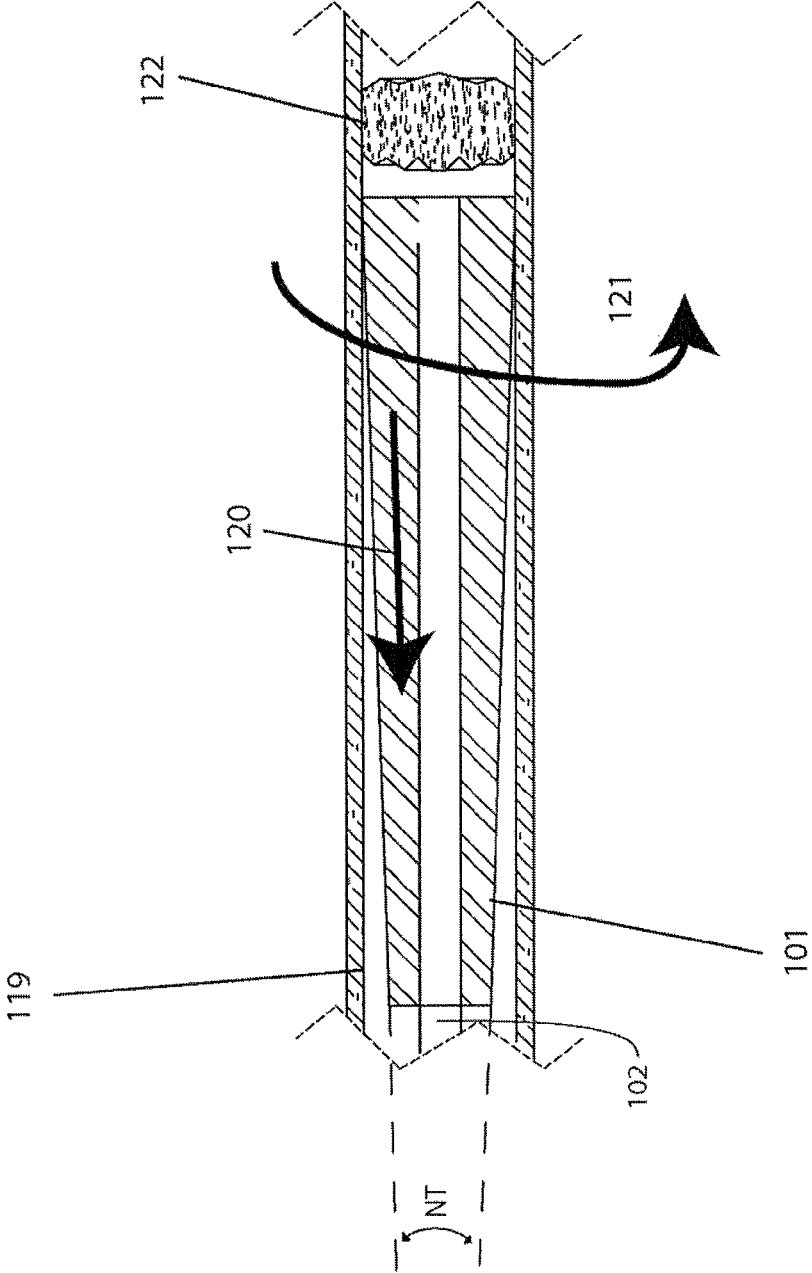


FIG. 23

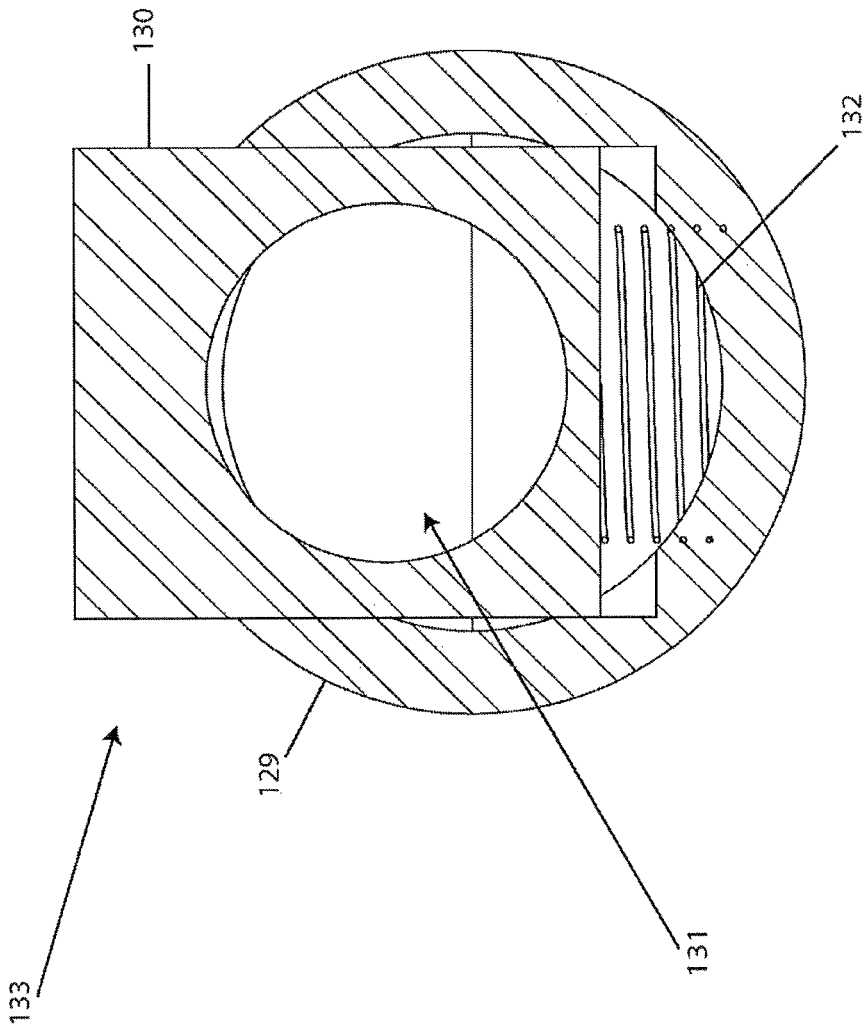


FIG. 24

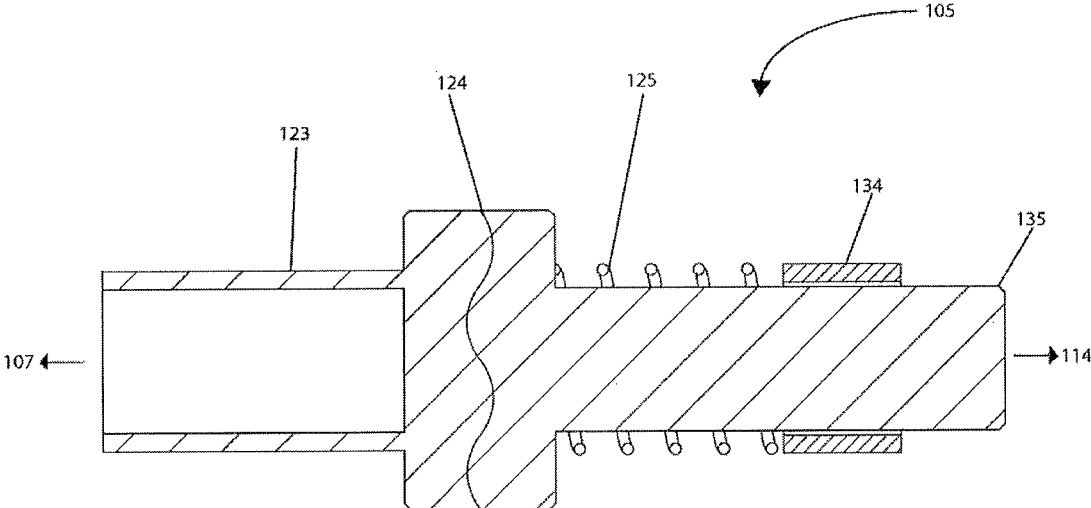


FIG. 25

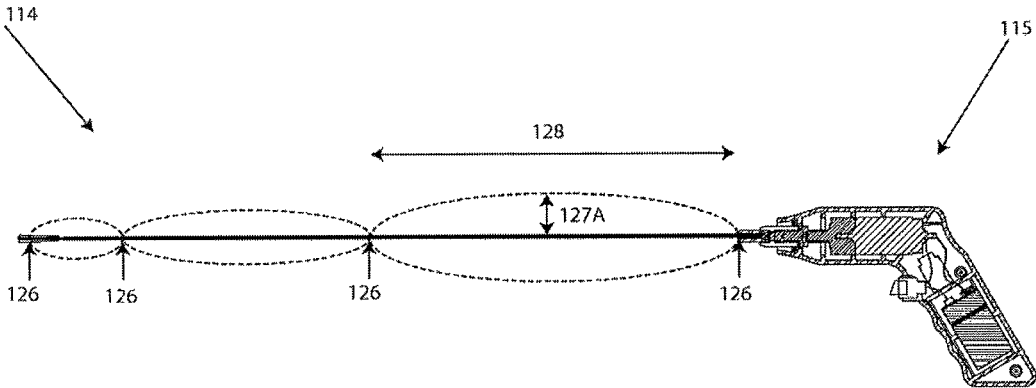


FIG. 26

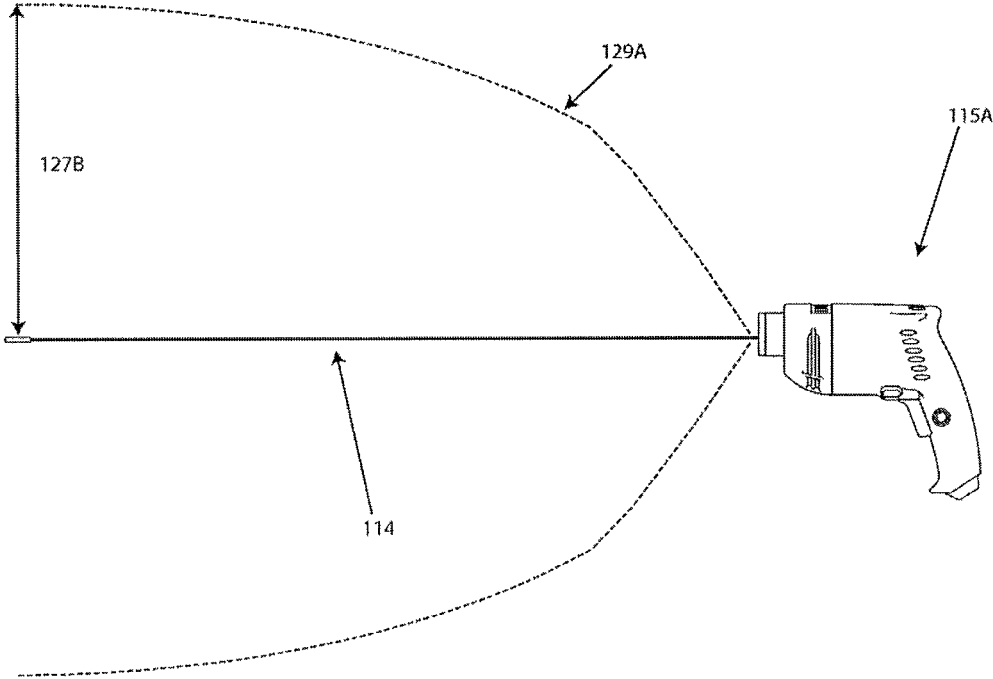


FIG. 27

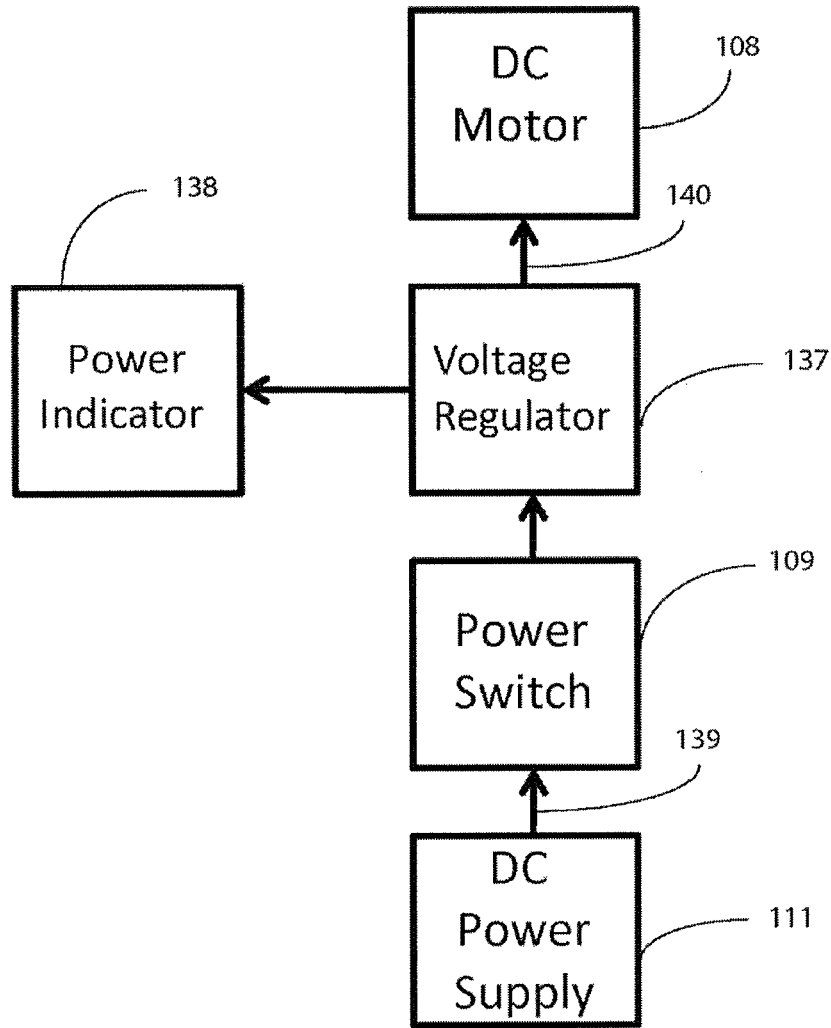


FIG. 28

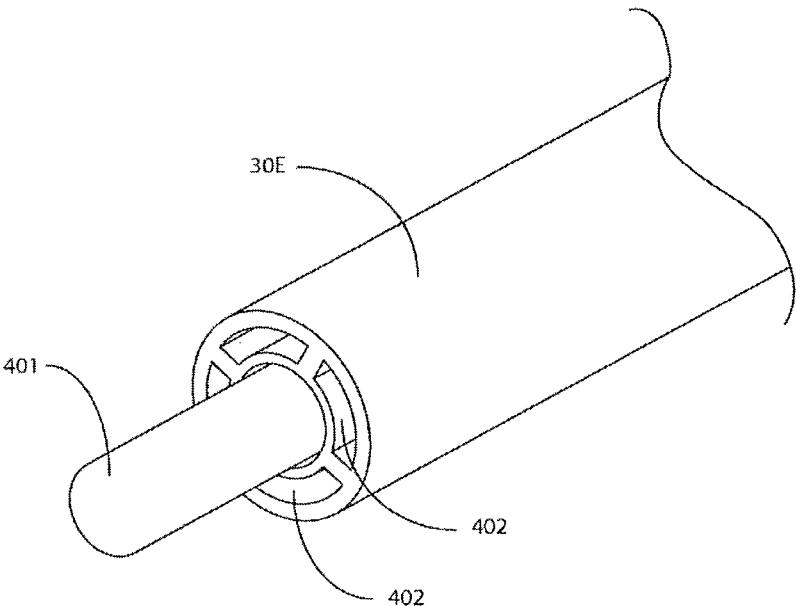


FIG. 29

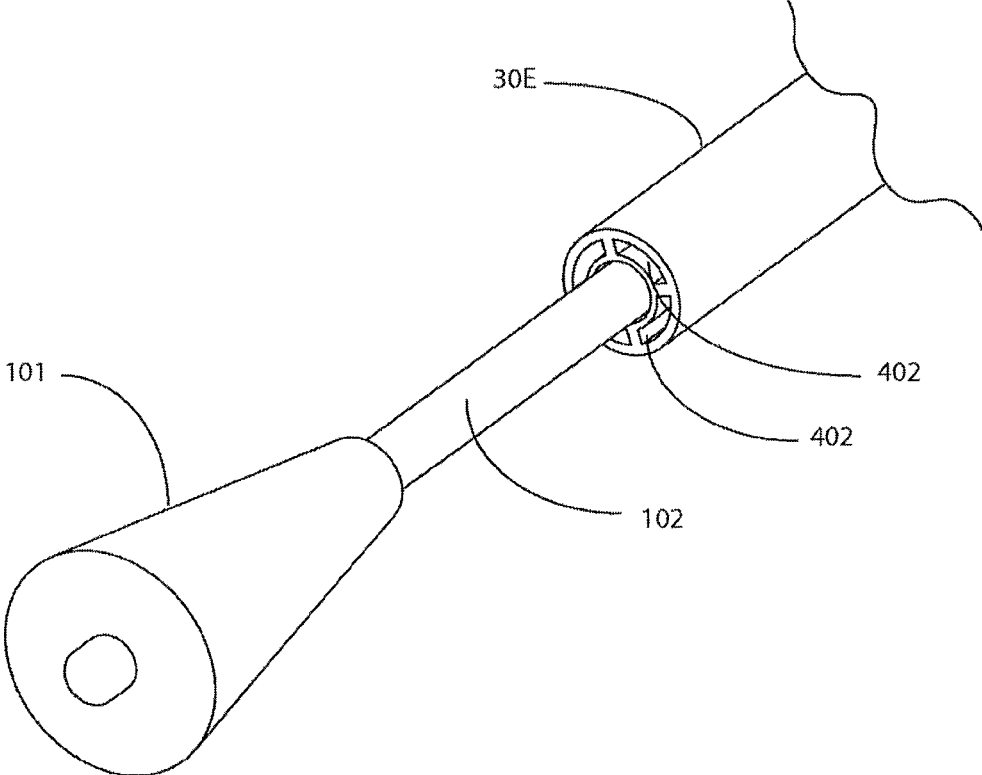


FIG. 29A

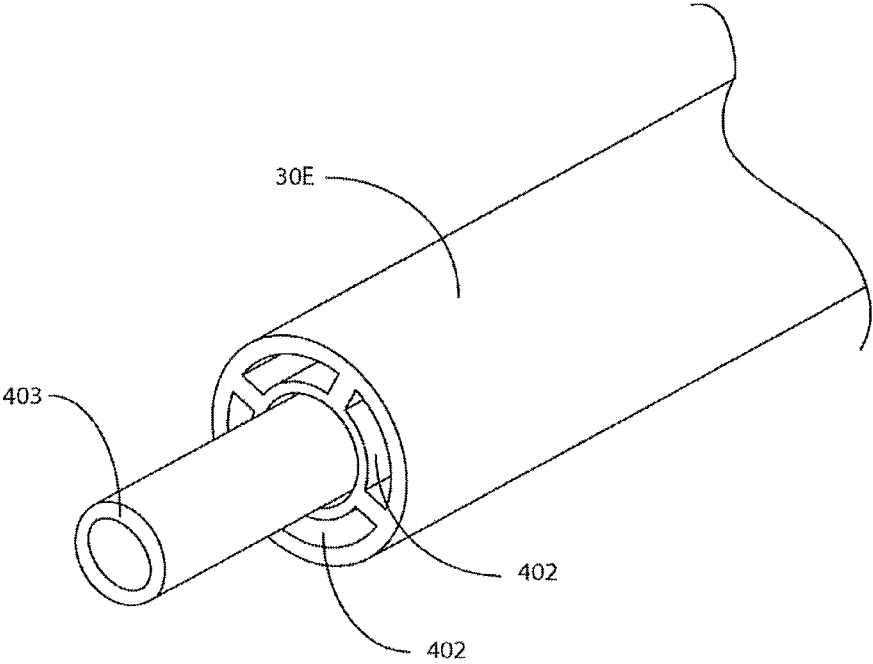


FIG. 29B

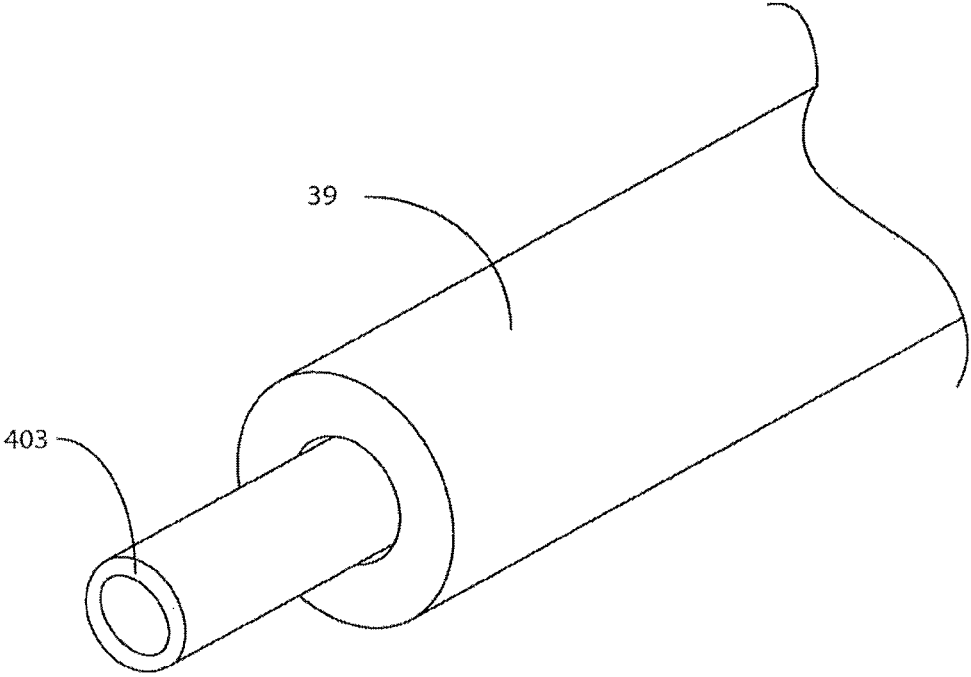


FIG. 29C

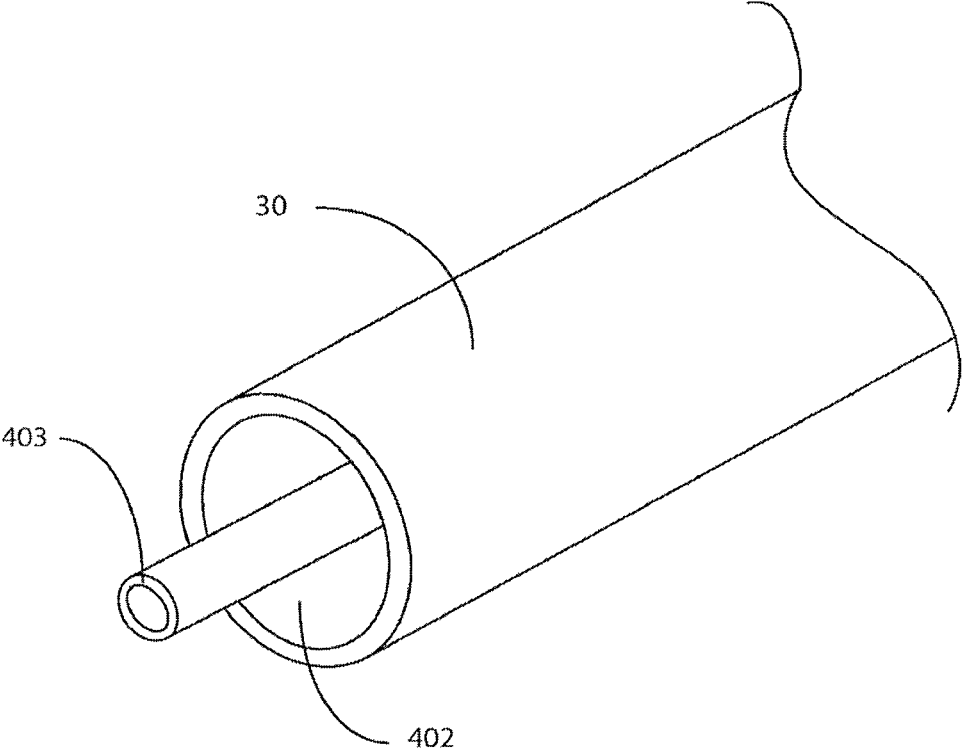


FIG. 29D

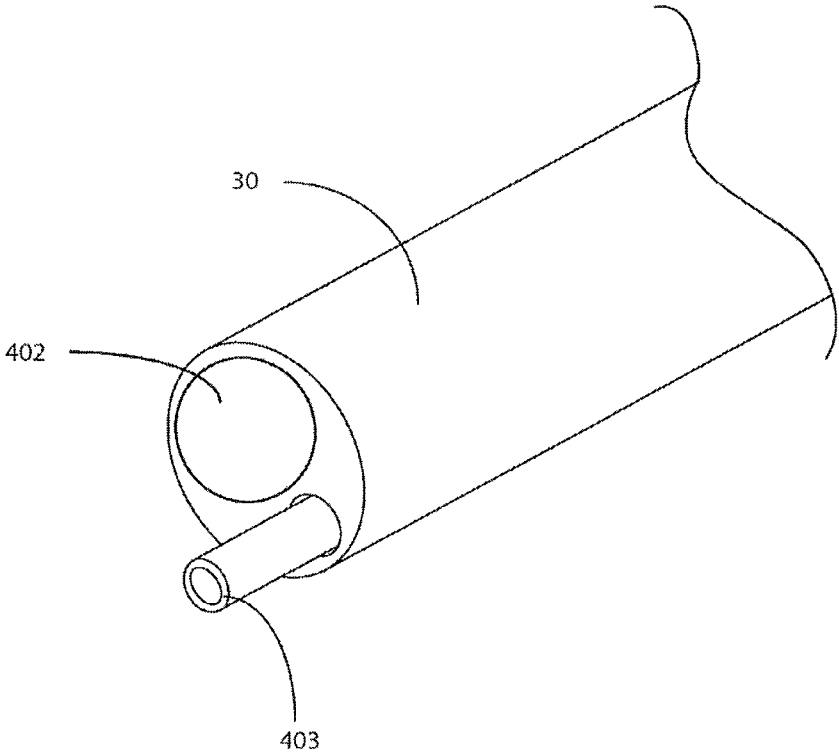


FIG. 29E

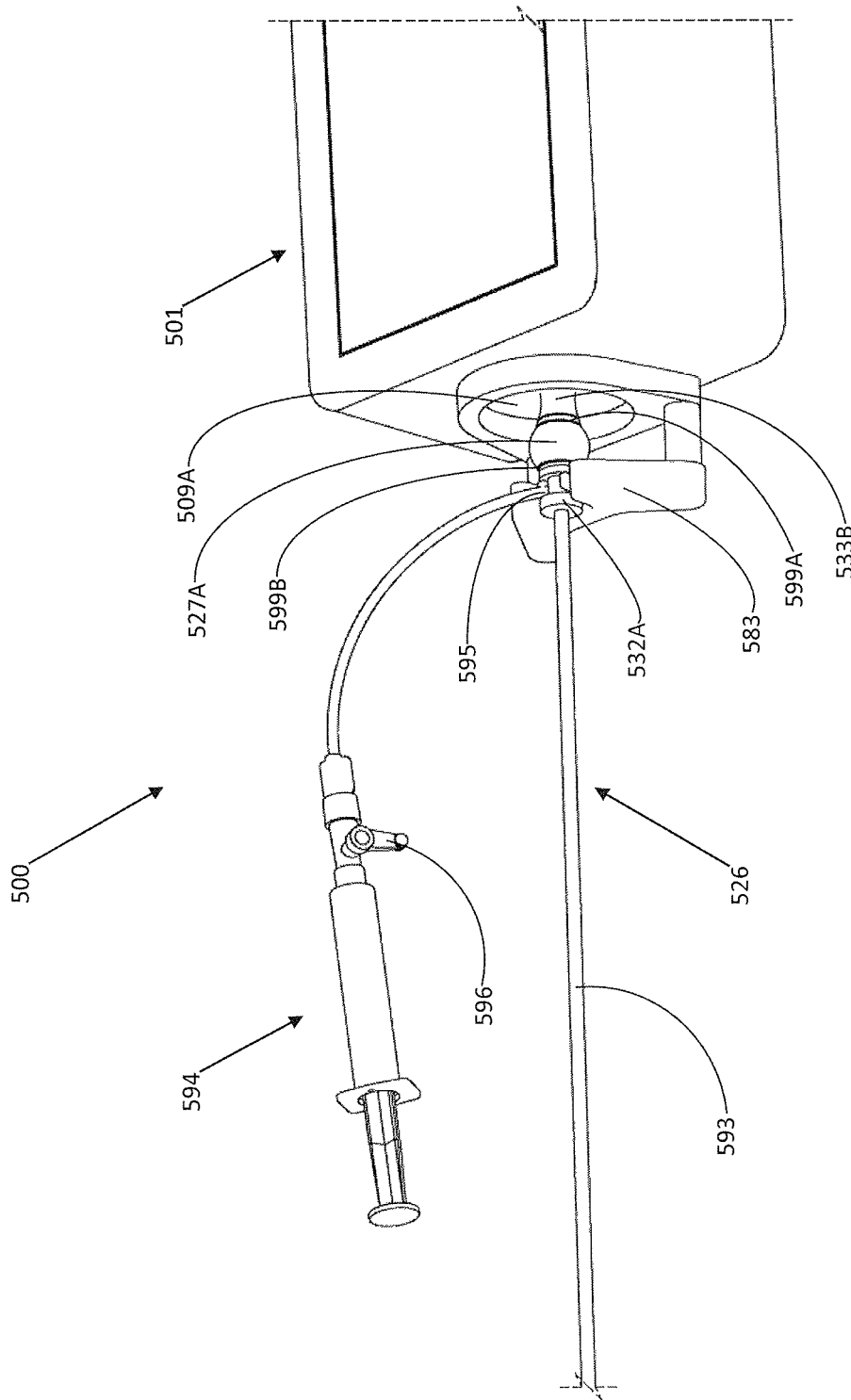


FIG. 30

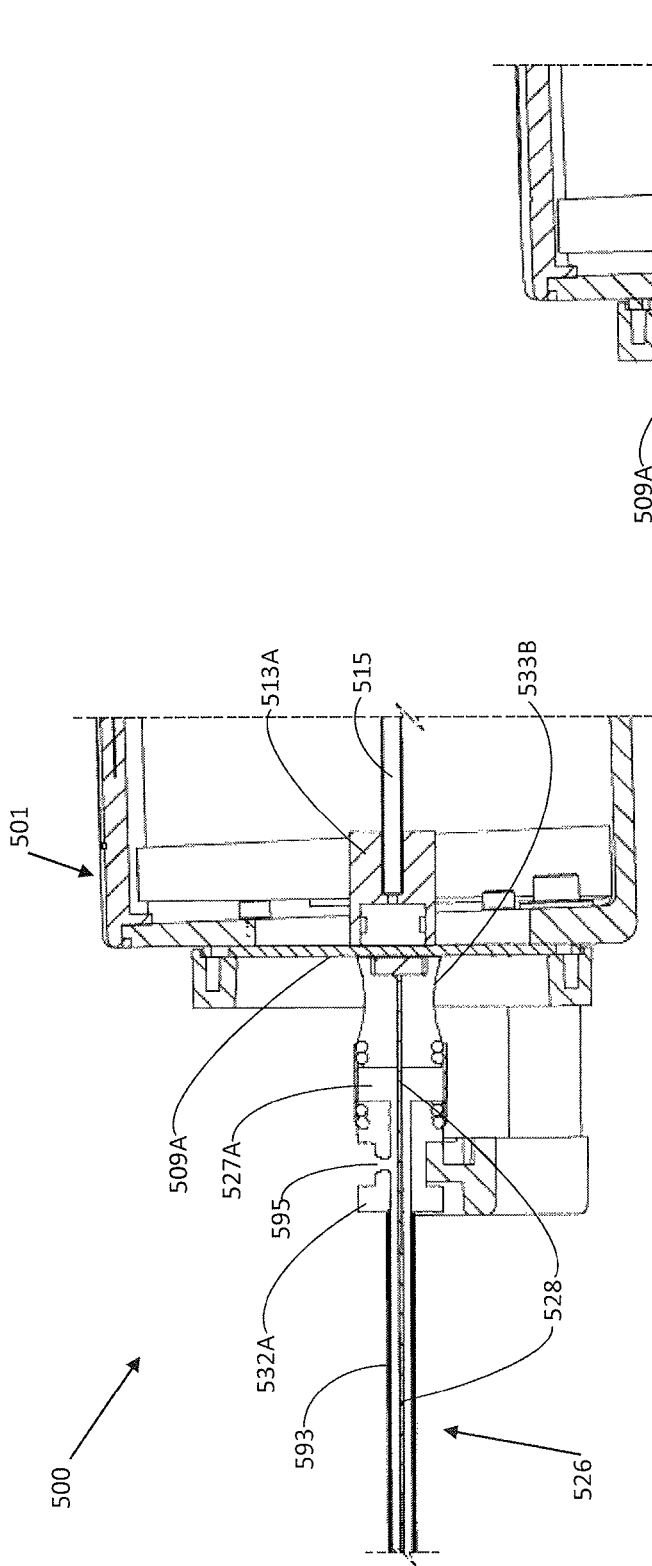


FIG. 31A

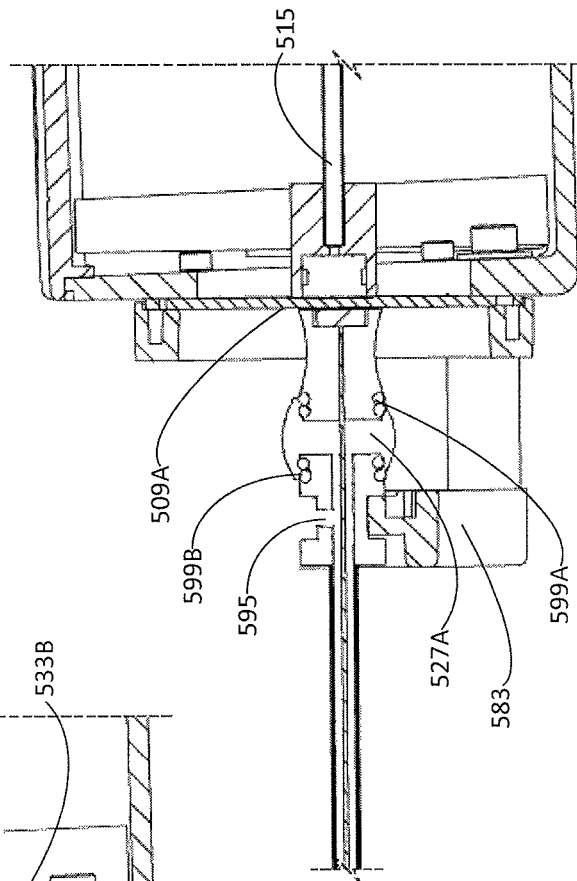


FIG. 31B

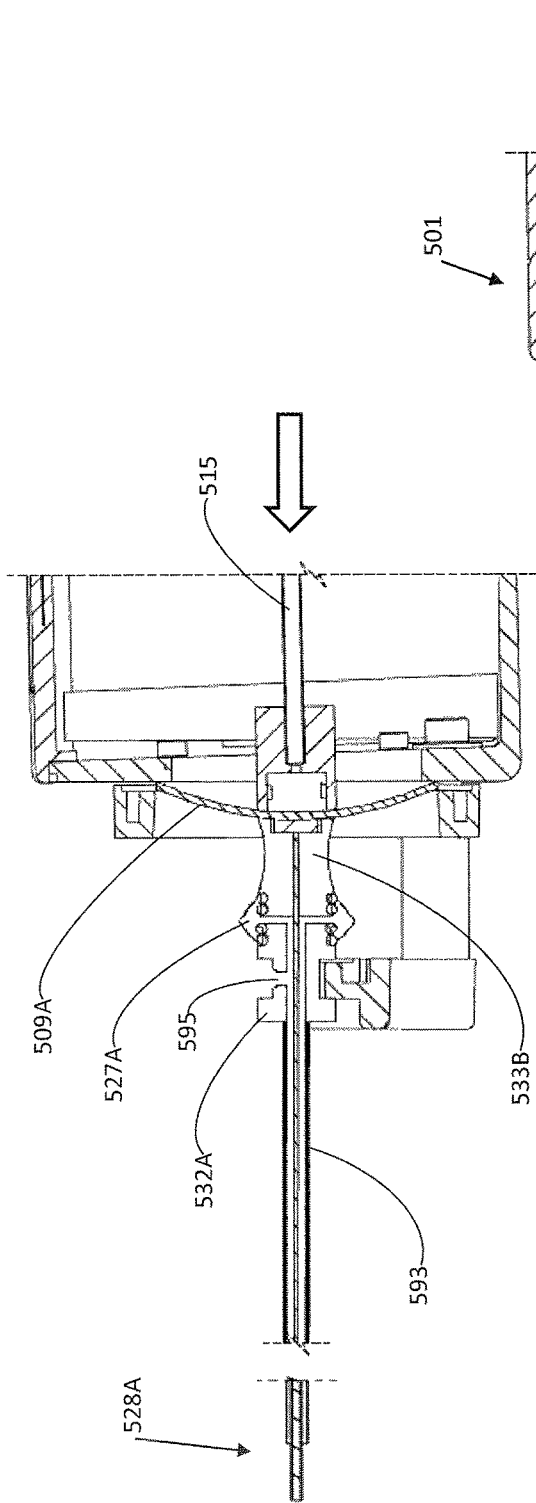


FIG. 31C

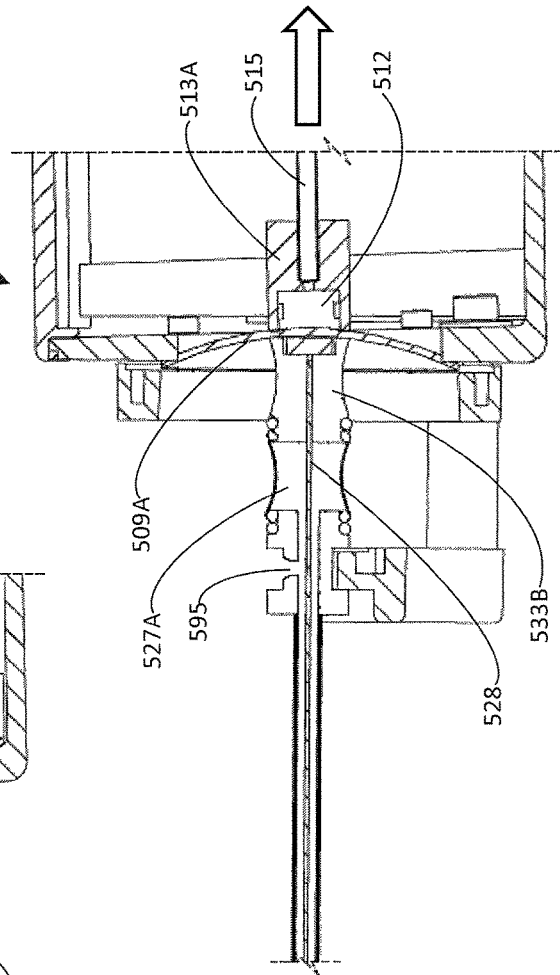


FIG. 31D

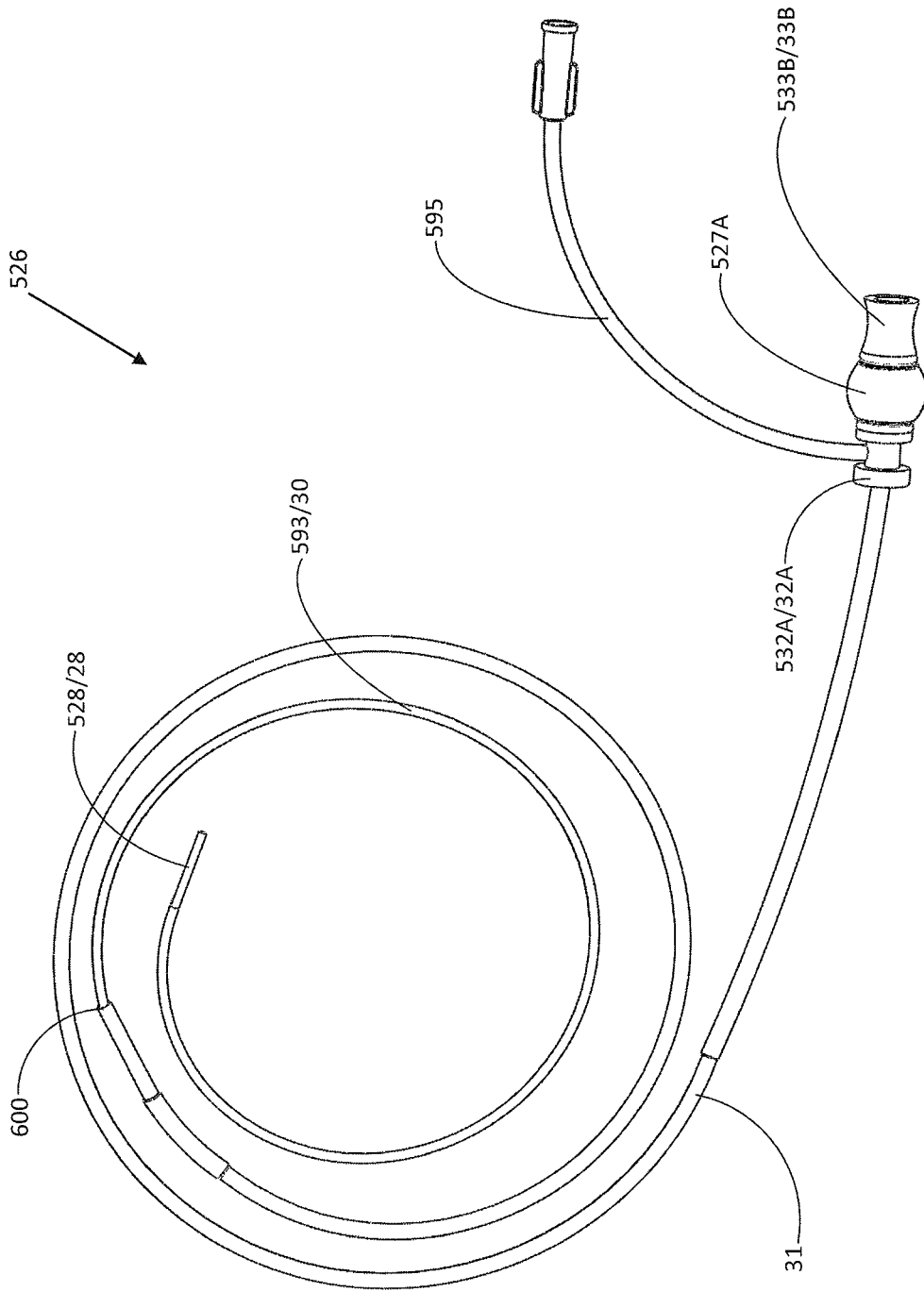
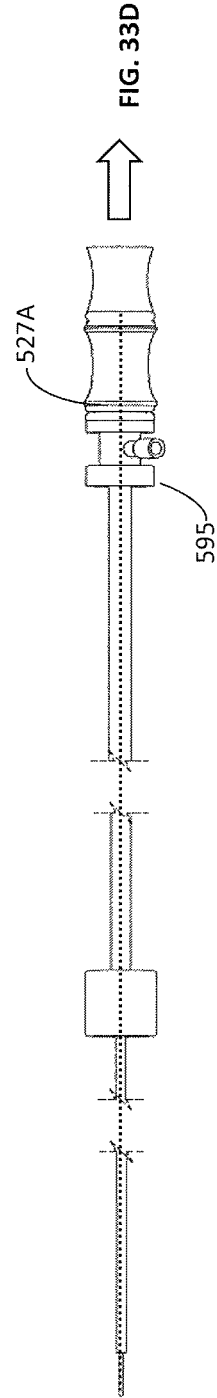
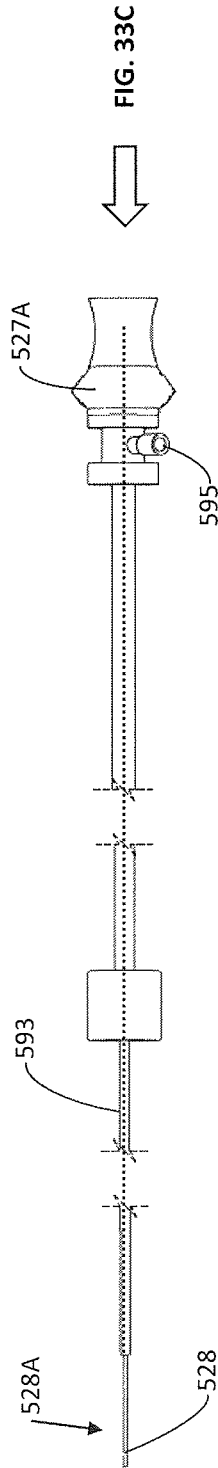
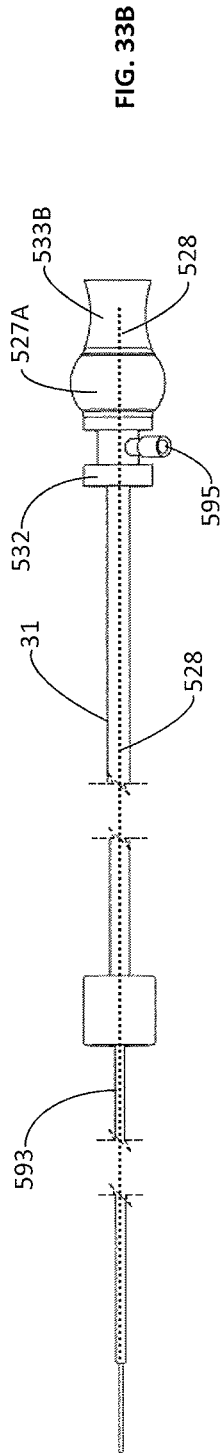
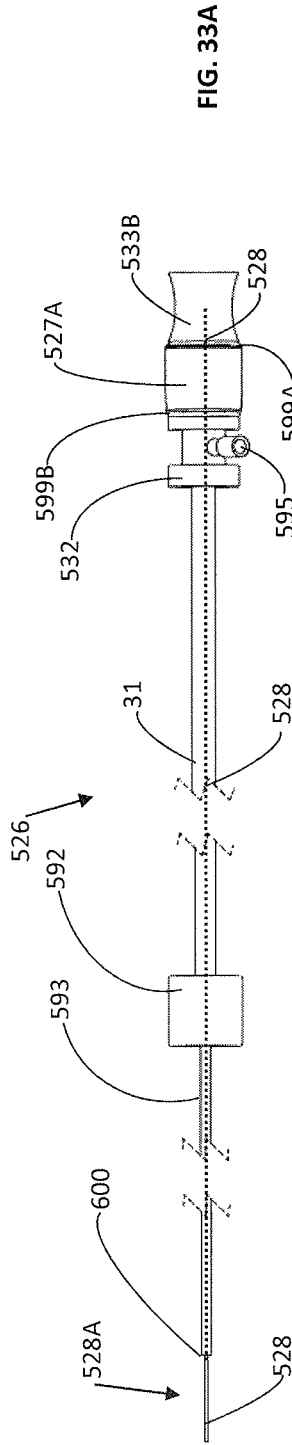


FIG. 32



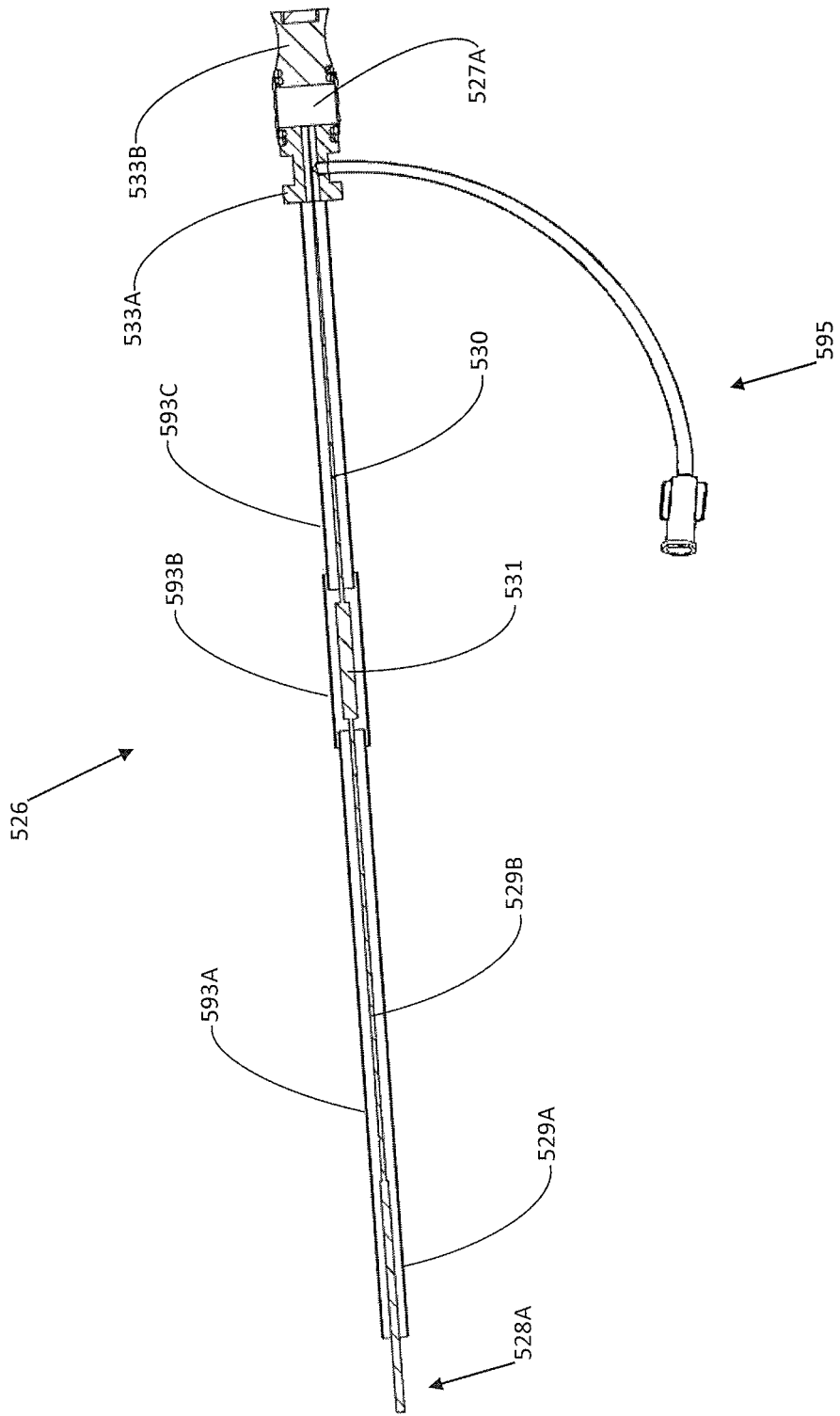


FIG. 34

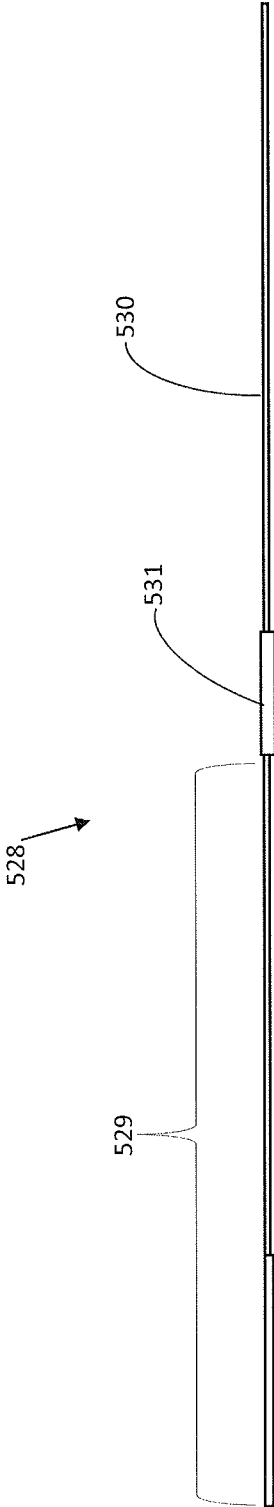


FIG. 35A

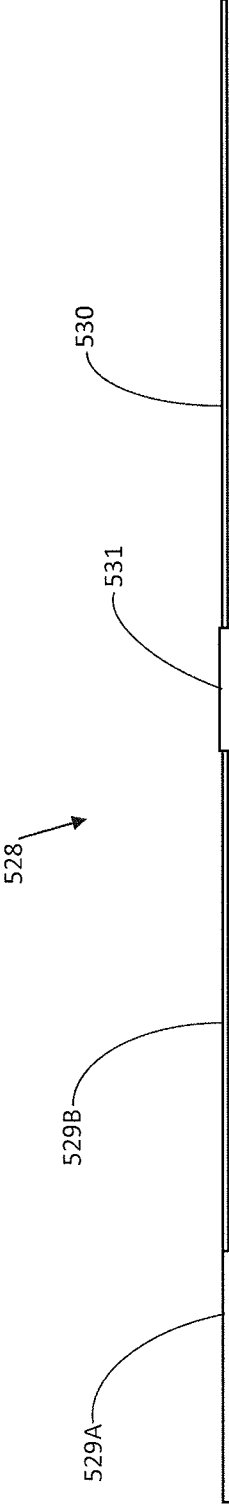


FIG. 35B

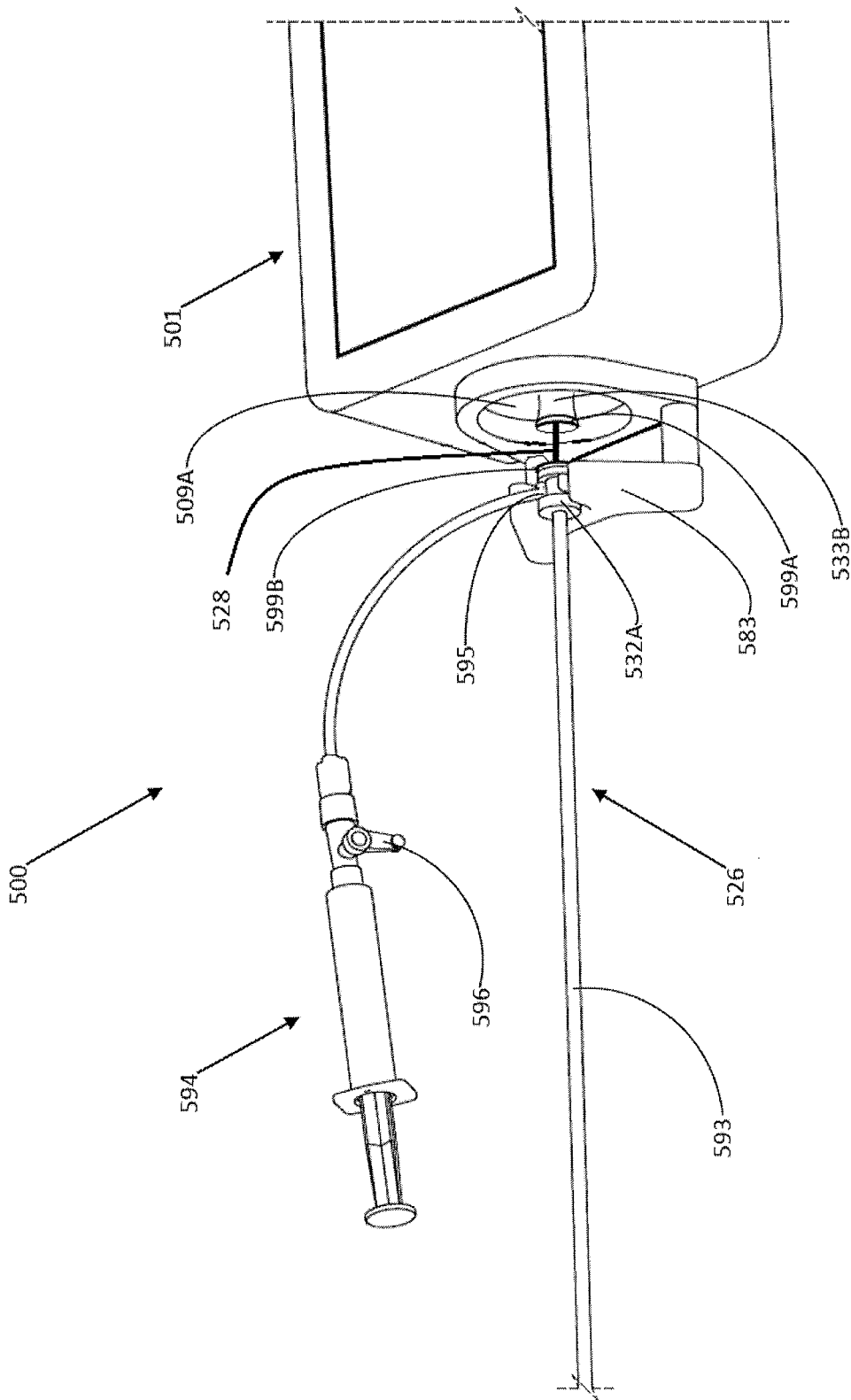
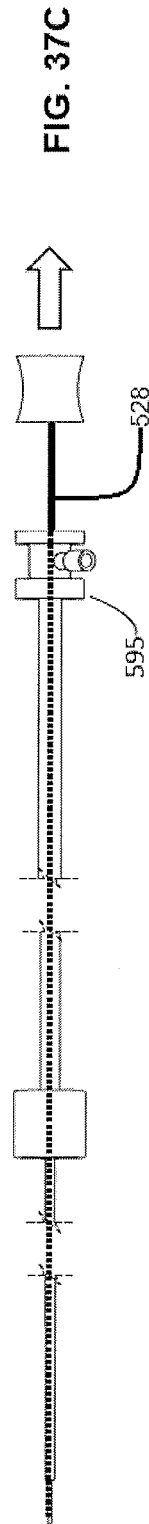
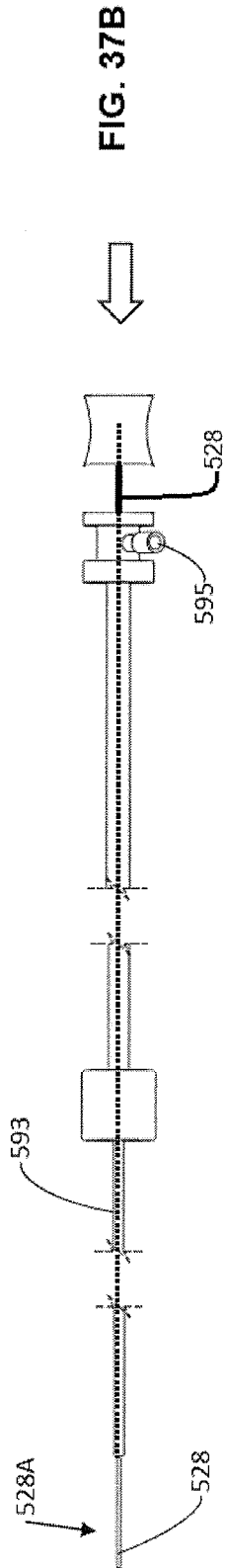
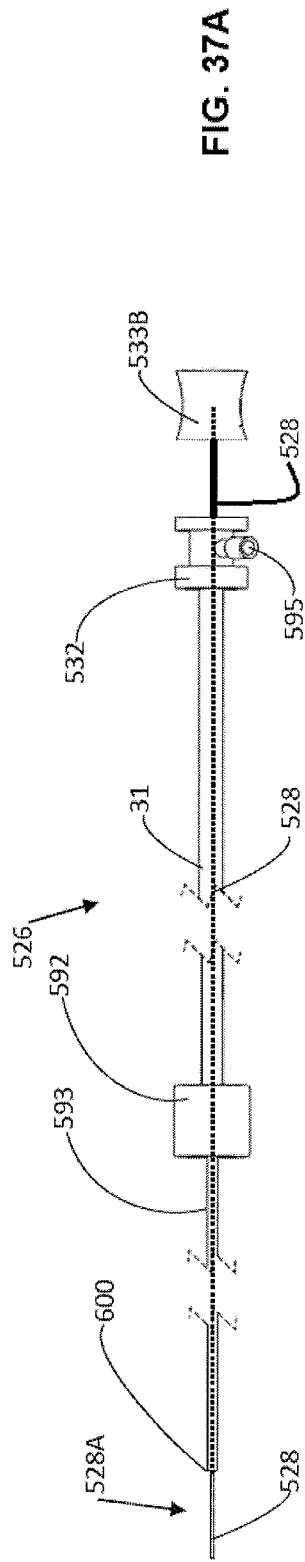


FIG. 36



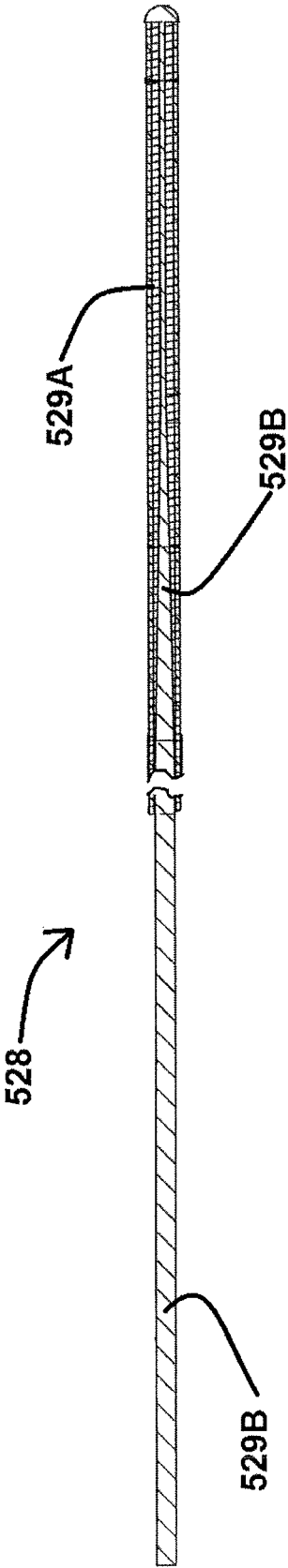


FIG. 38

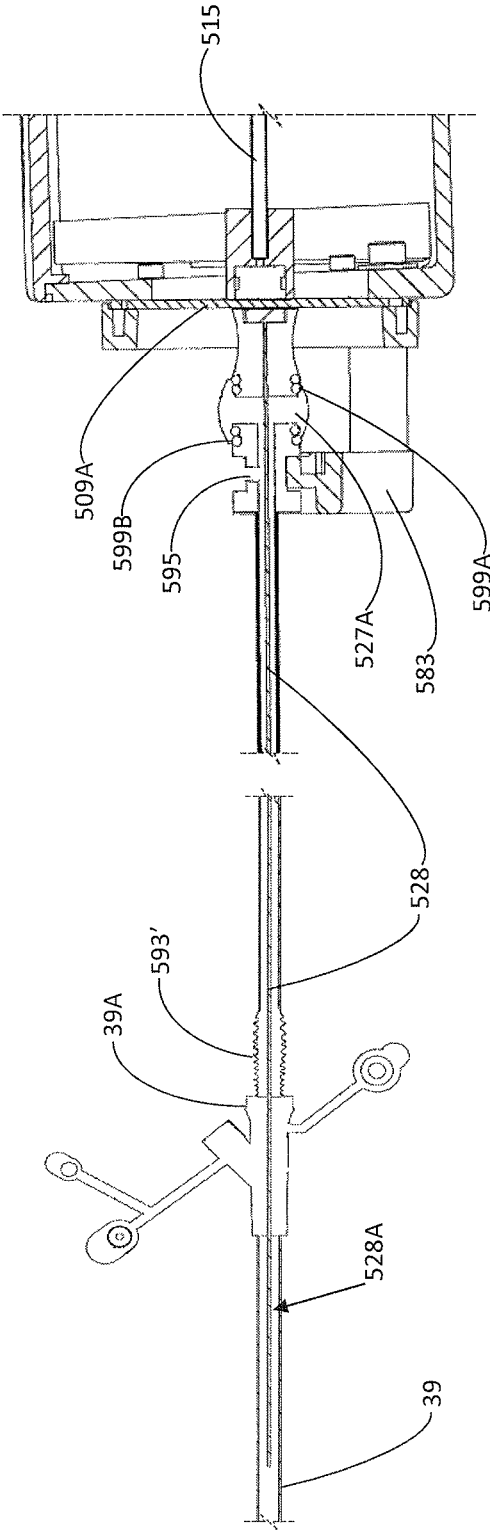


FIG. 39

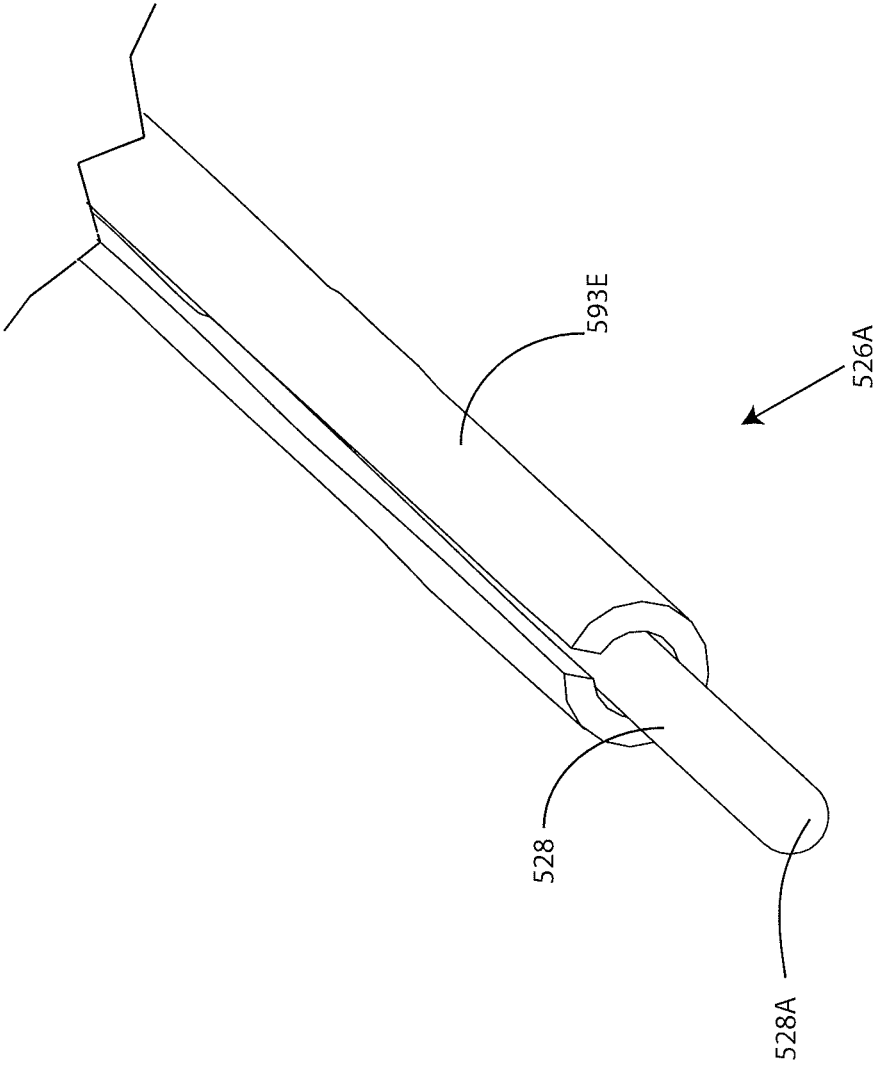


FIG. 40

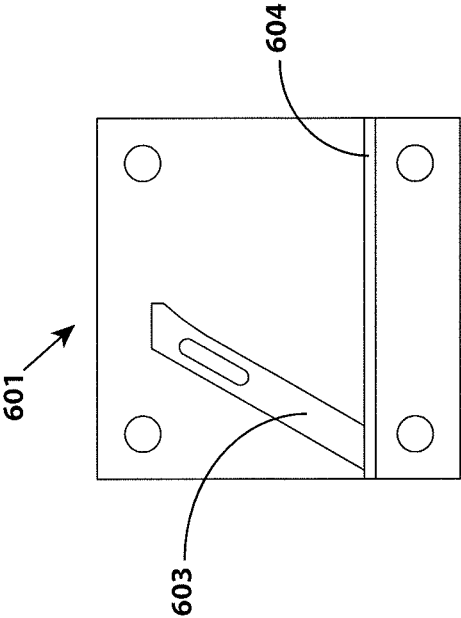


FIG. 41A

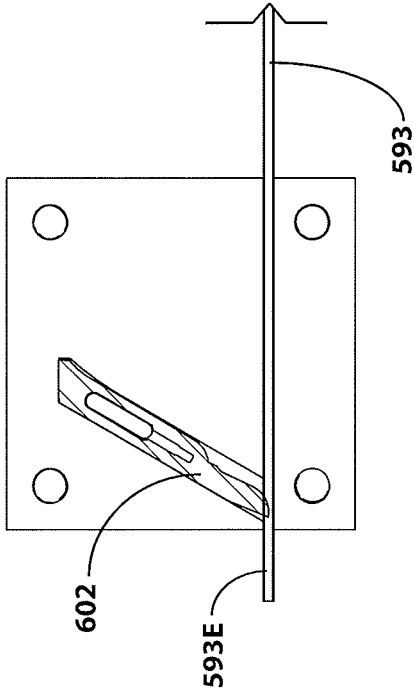


FIG. 41B

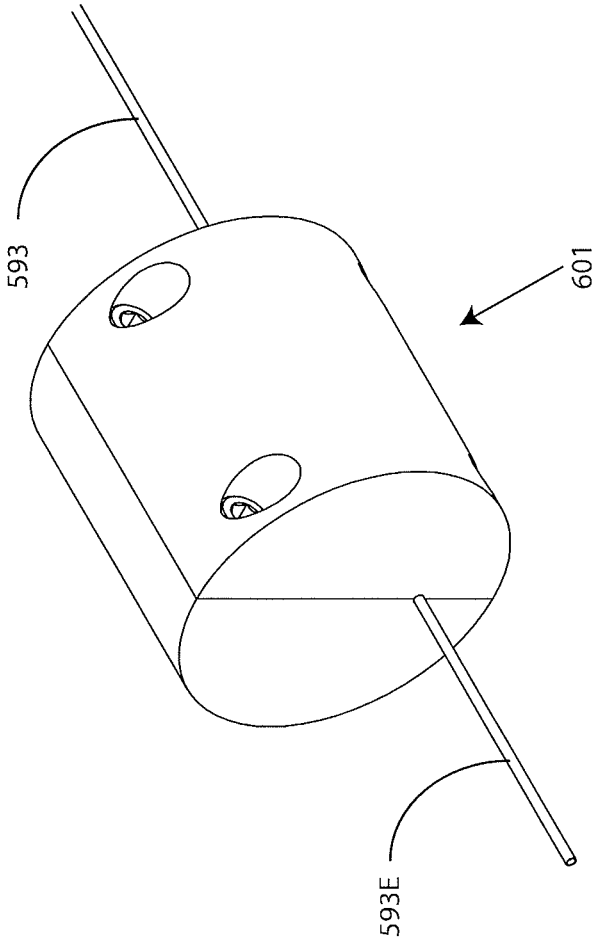


FIG. 41C

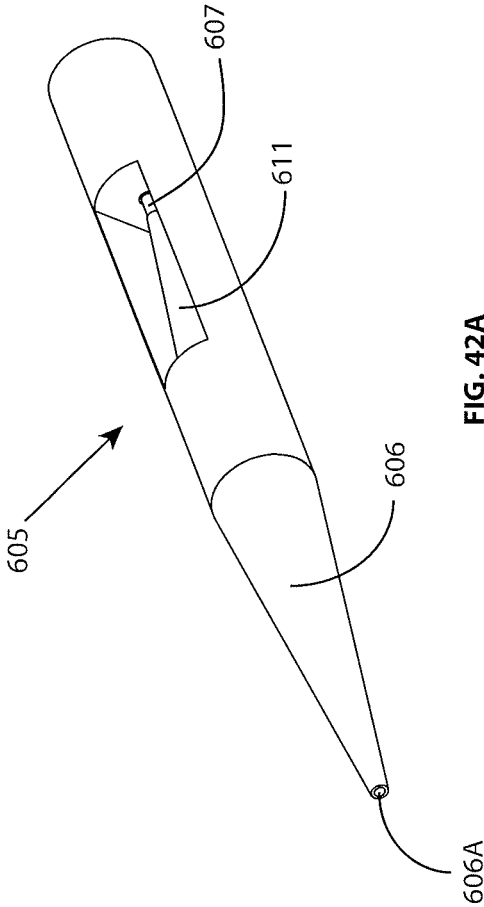


FIG. 42A

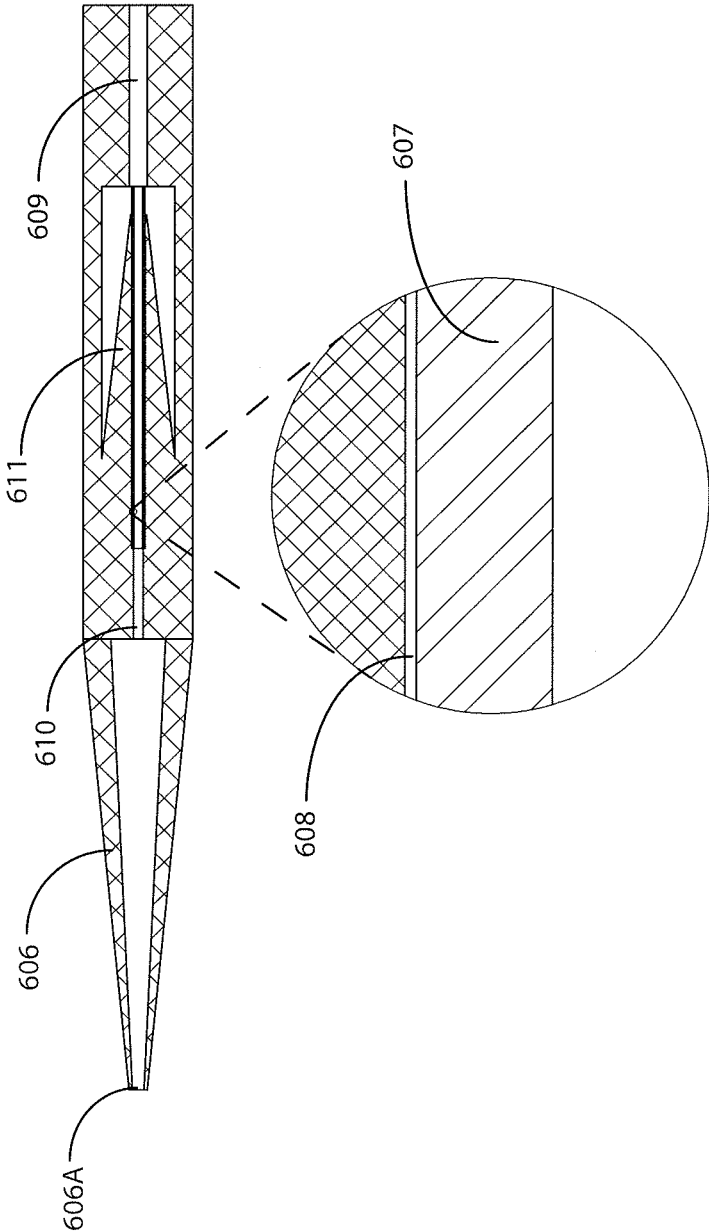


FIG. 42B

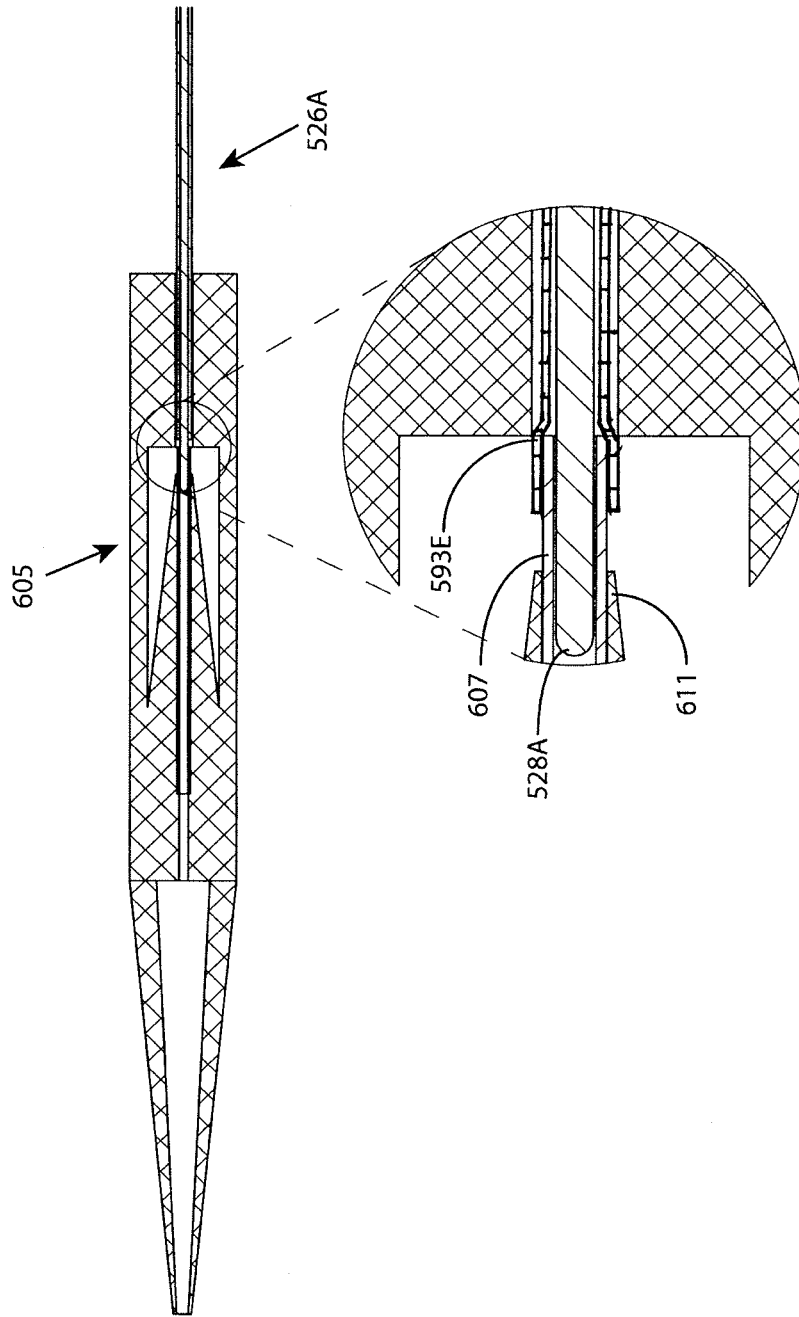


FIG. 43A

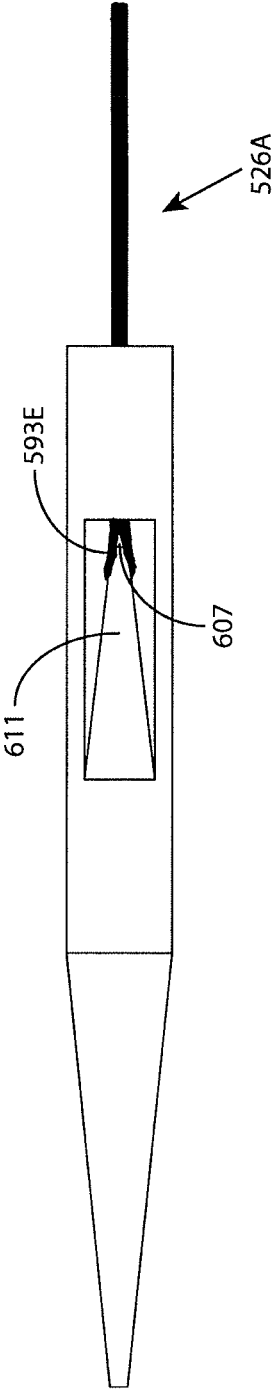


FIG. 43B

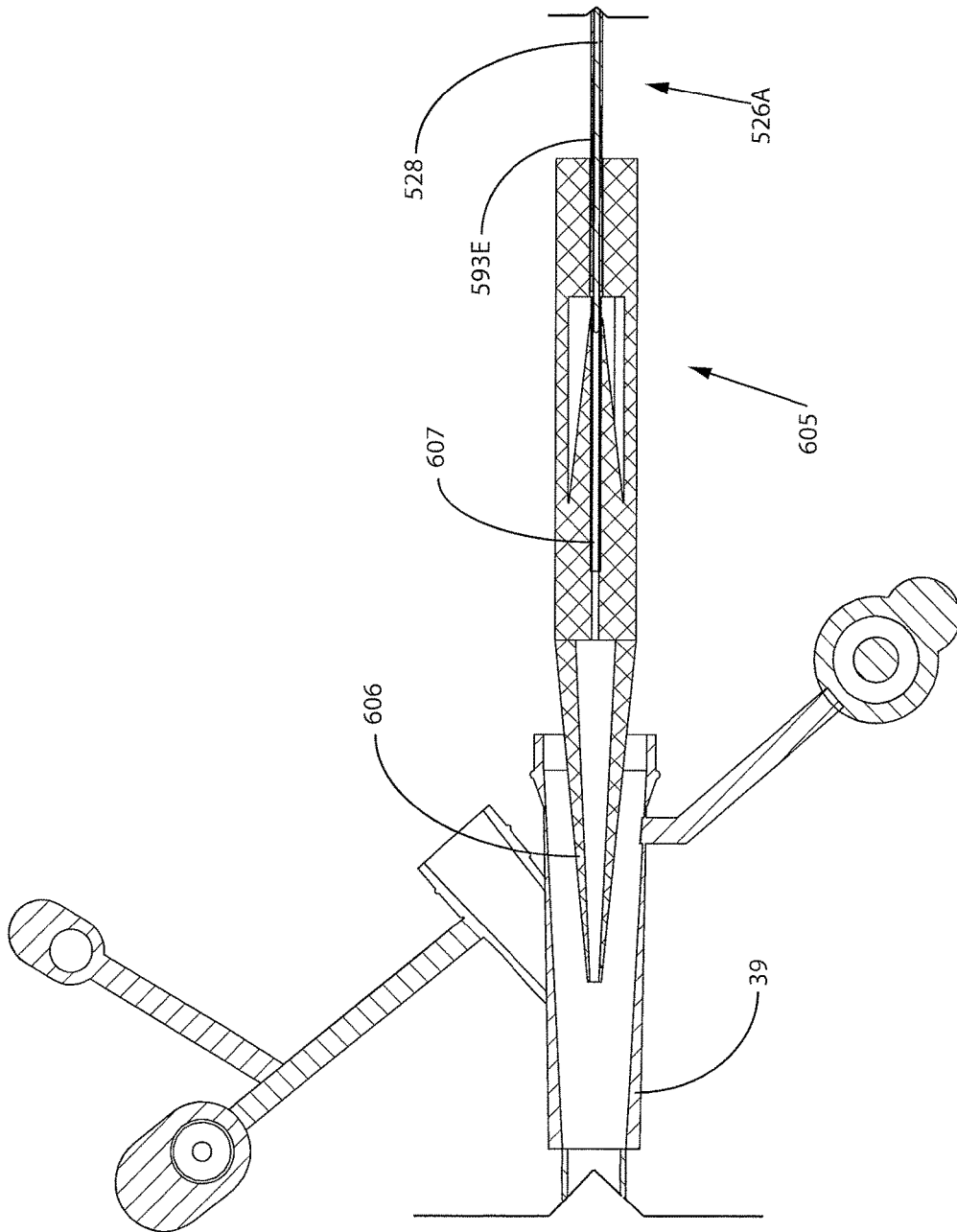


FIG. 44

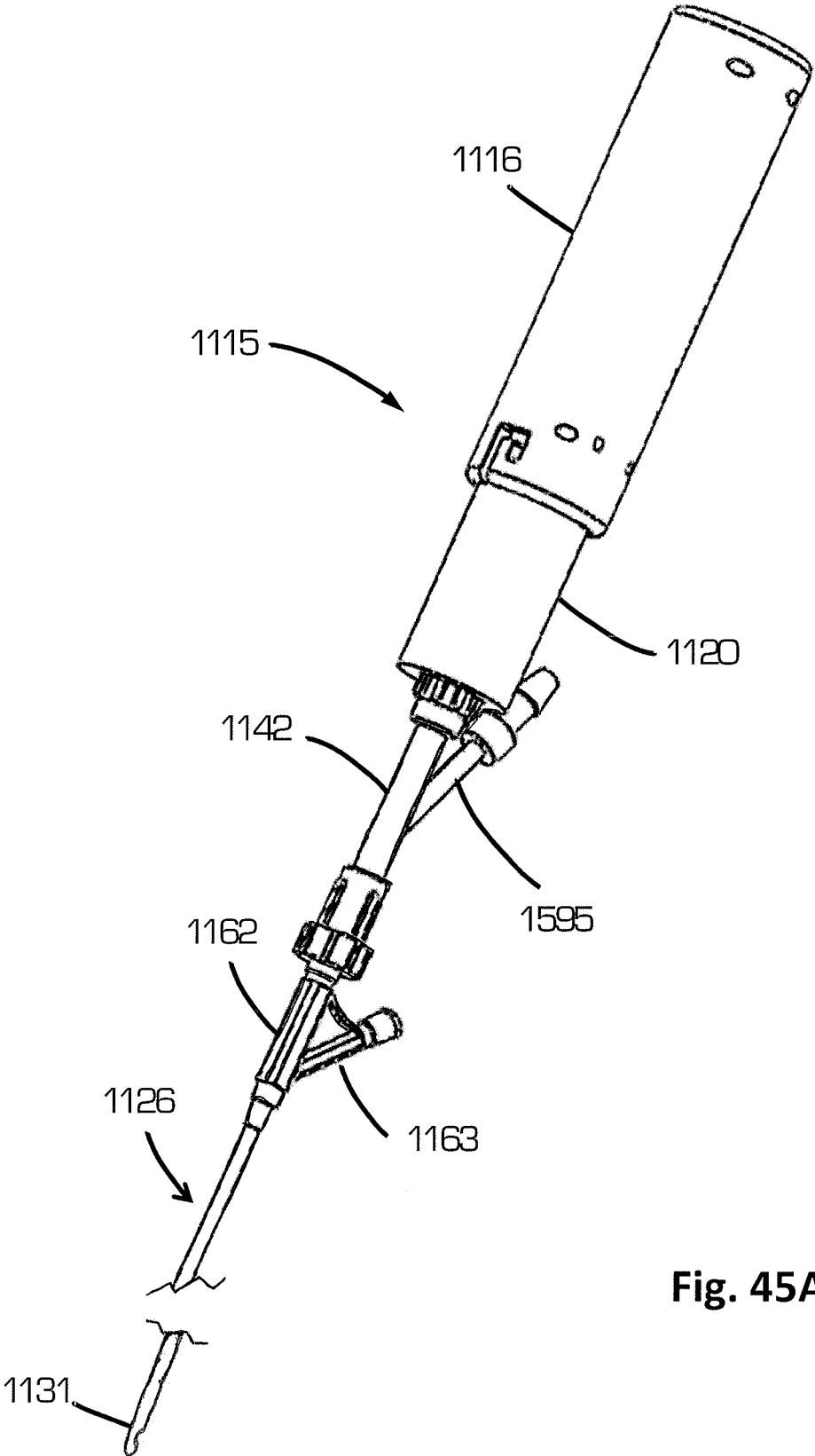


Fig. 45A

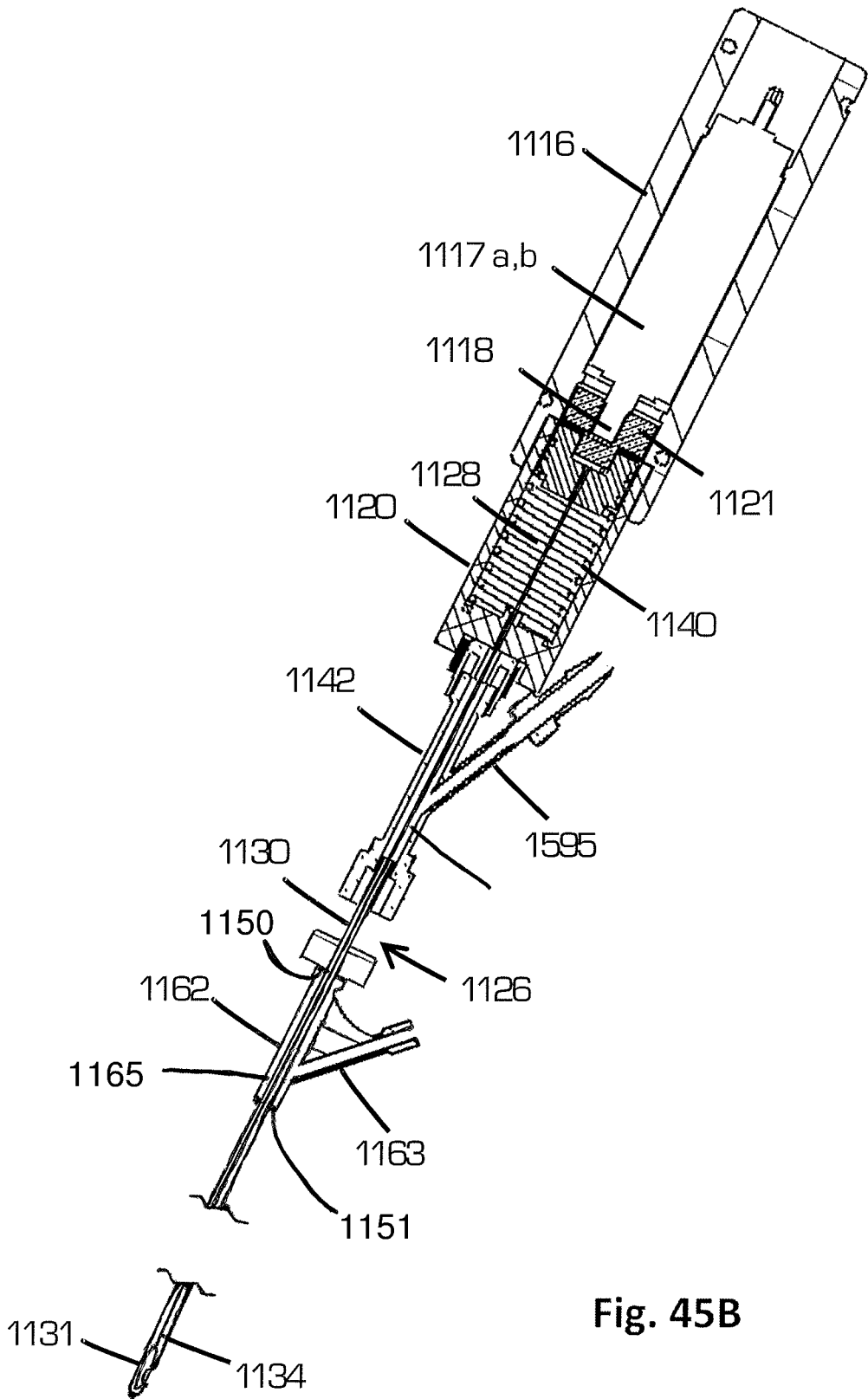


Fig. 45B

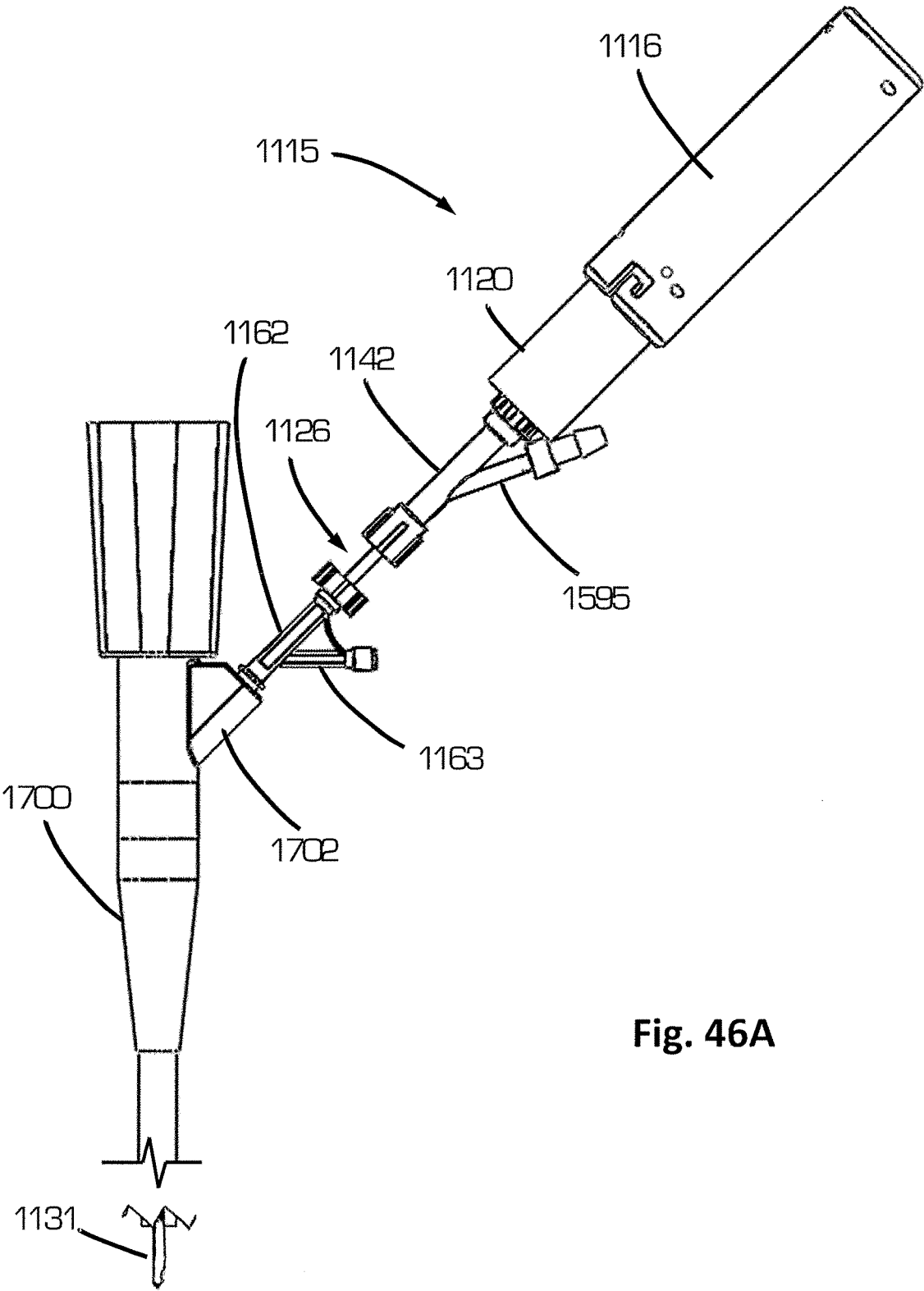


Fig. 46A

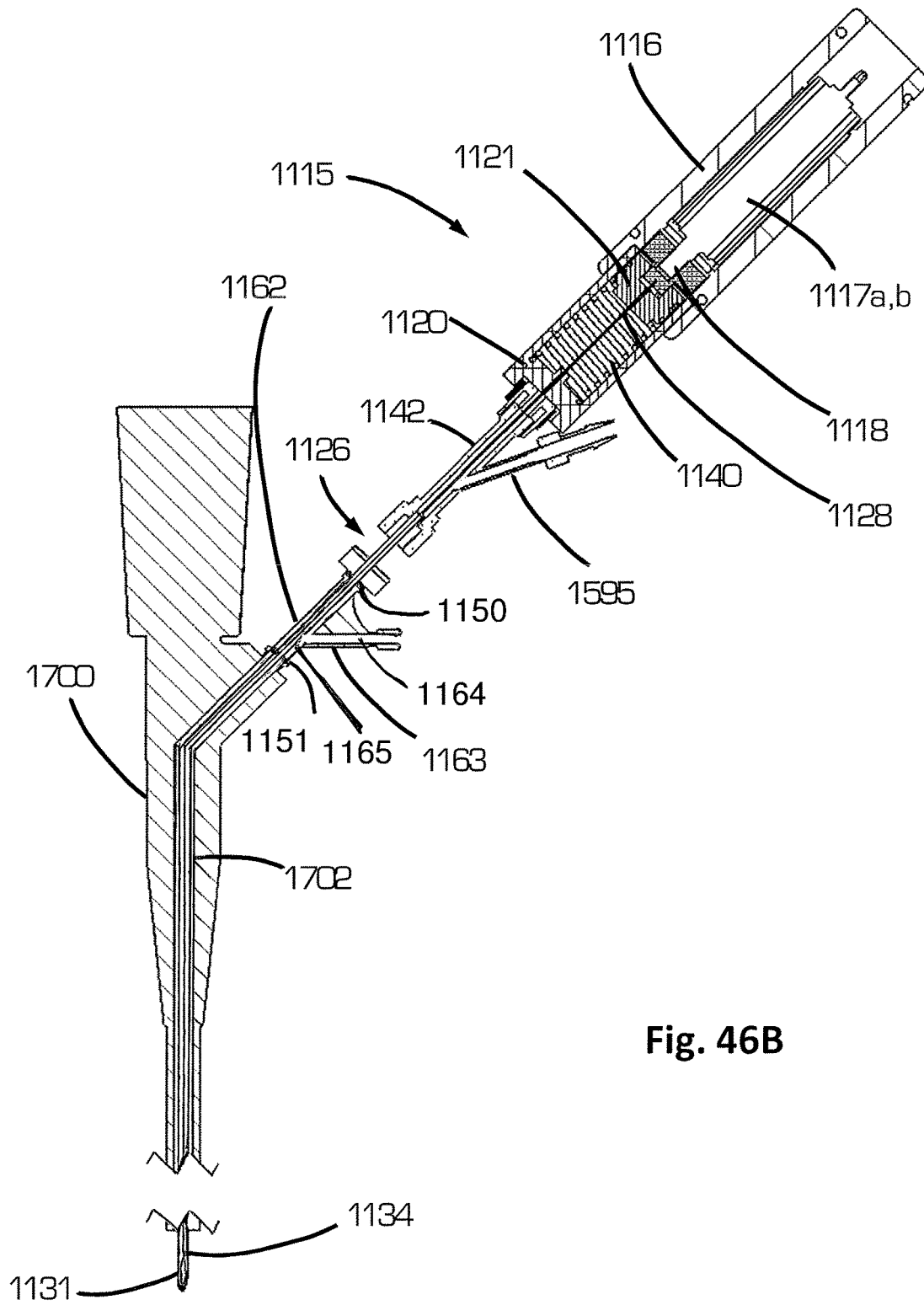


Fig. 46B

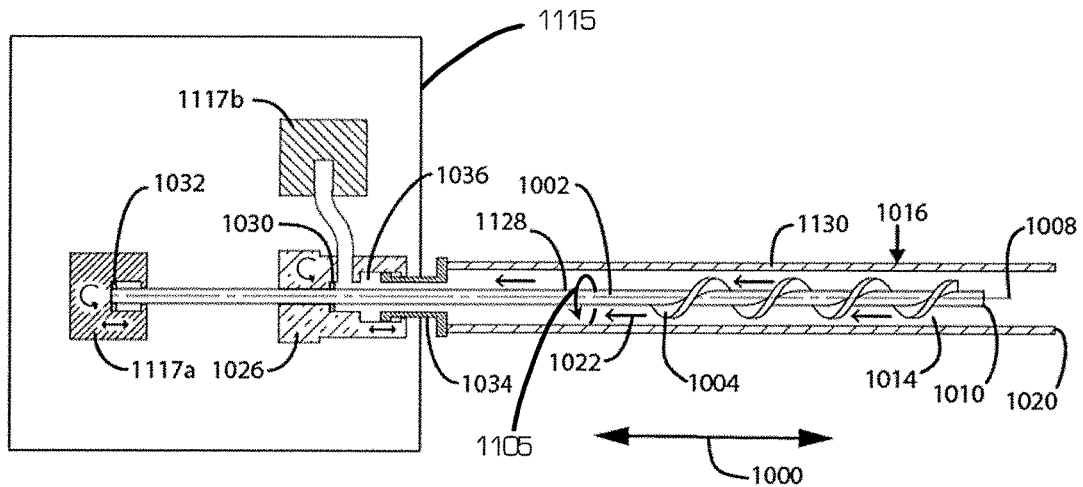


Fig. 47

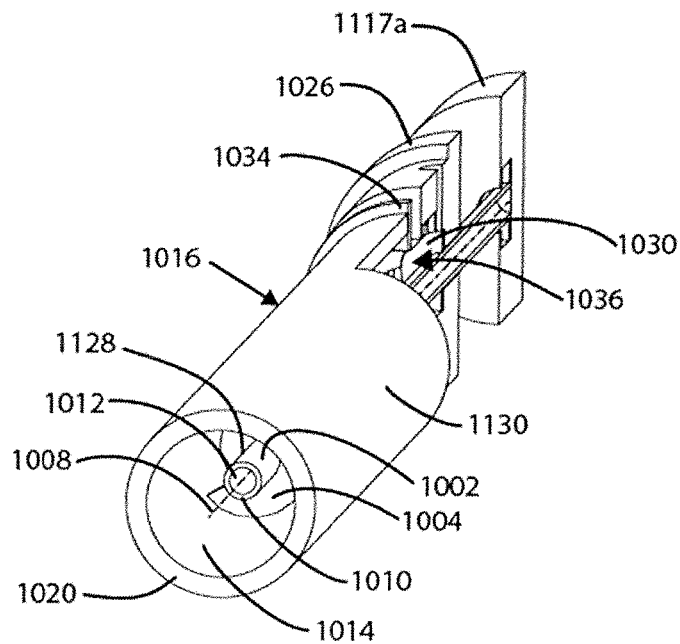


Fig. 48

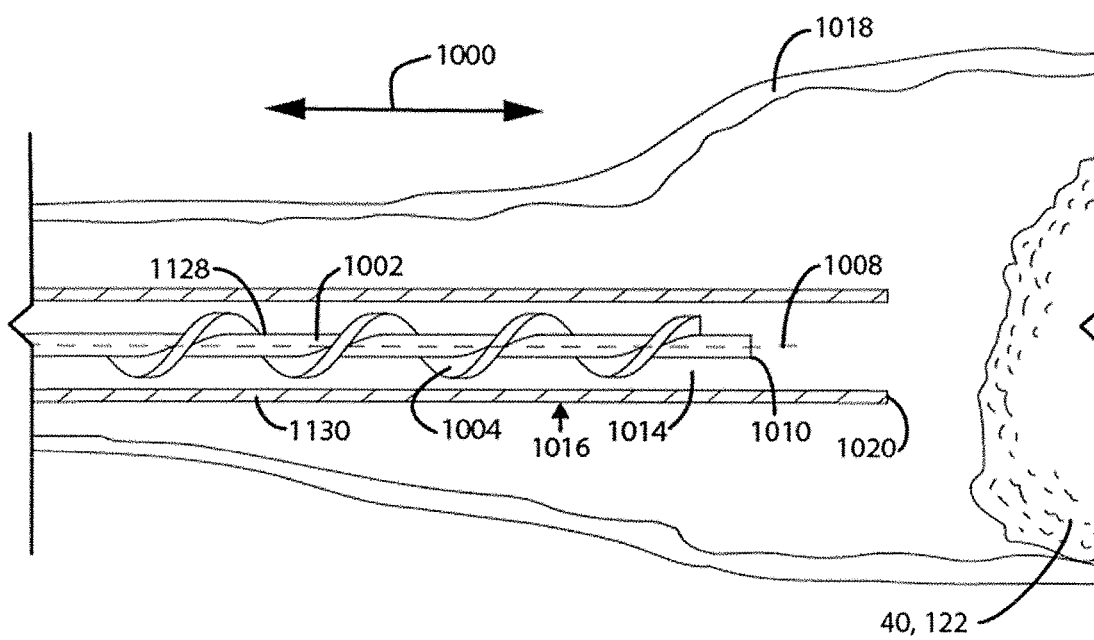


Fig. 49A

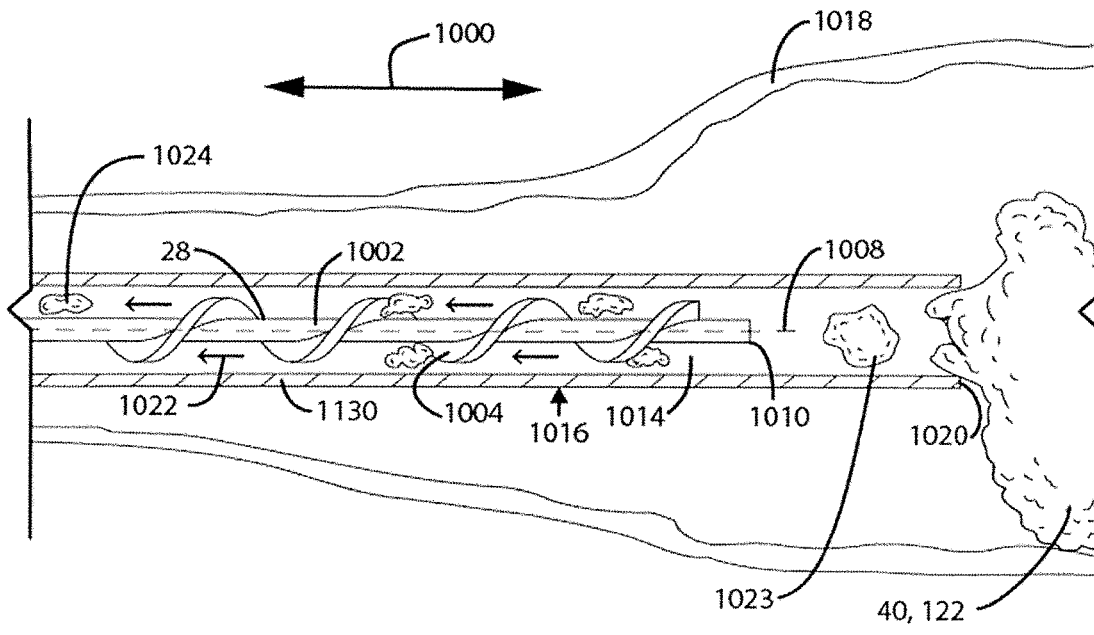
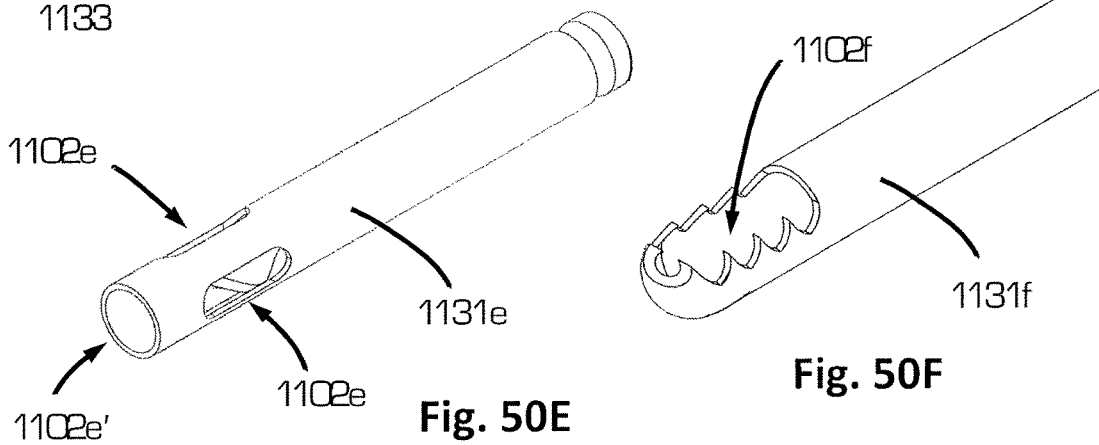
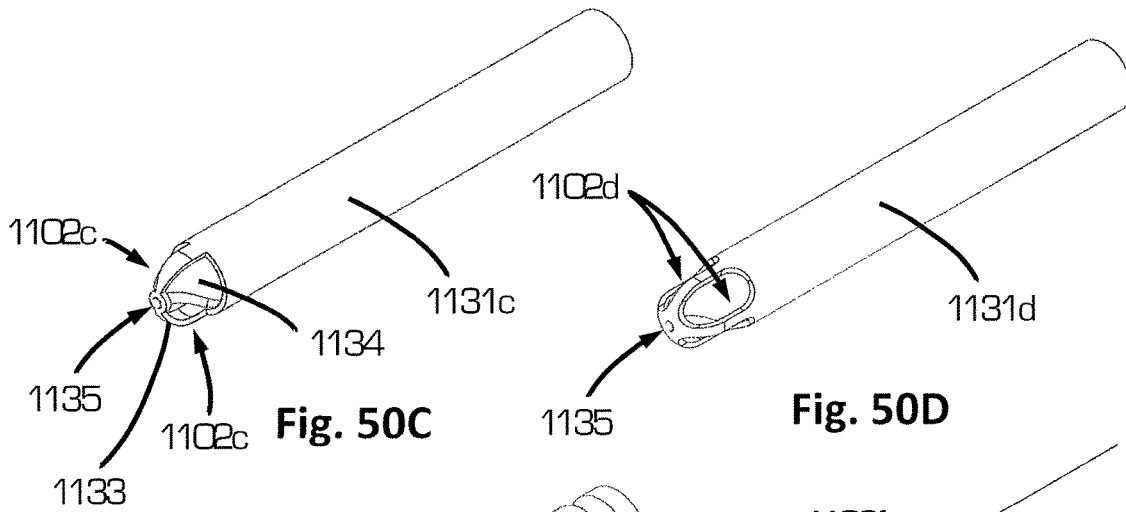
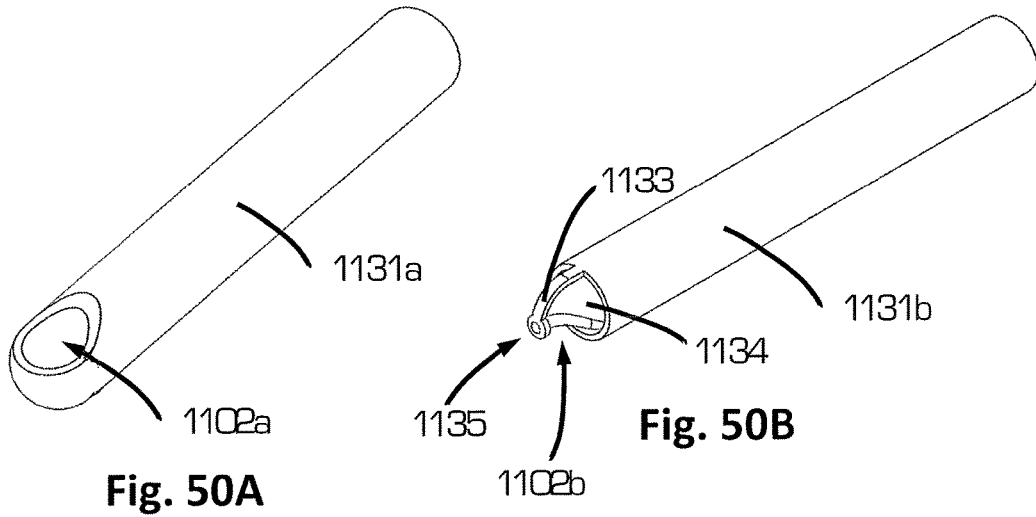
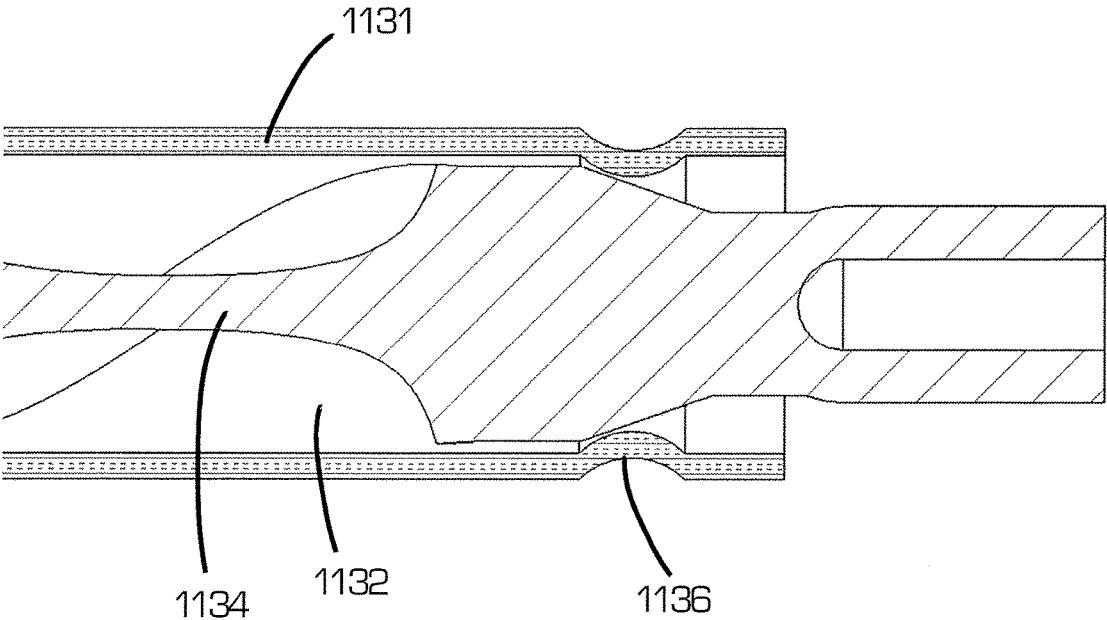
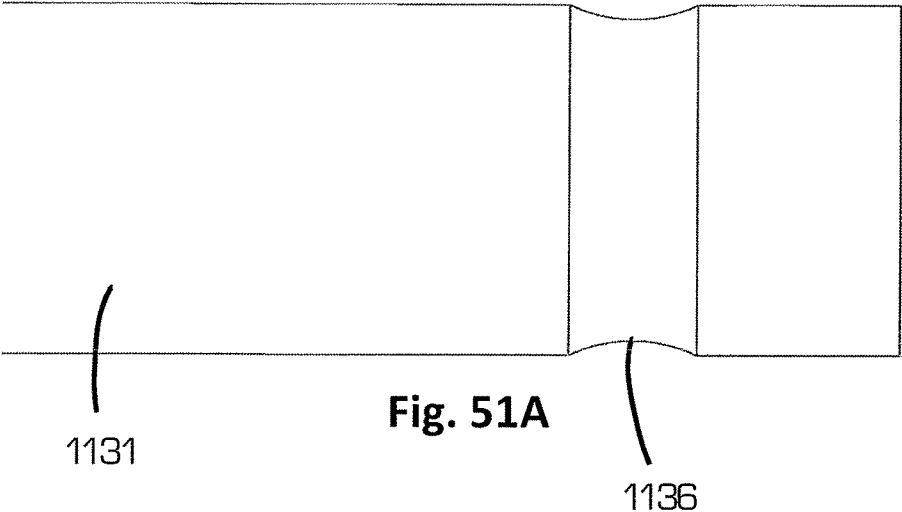


Fig. 49B





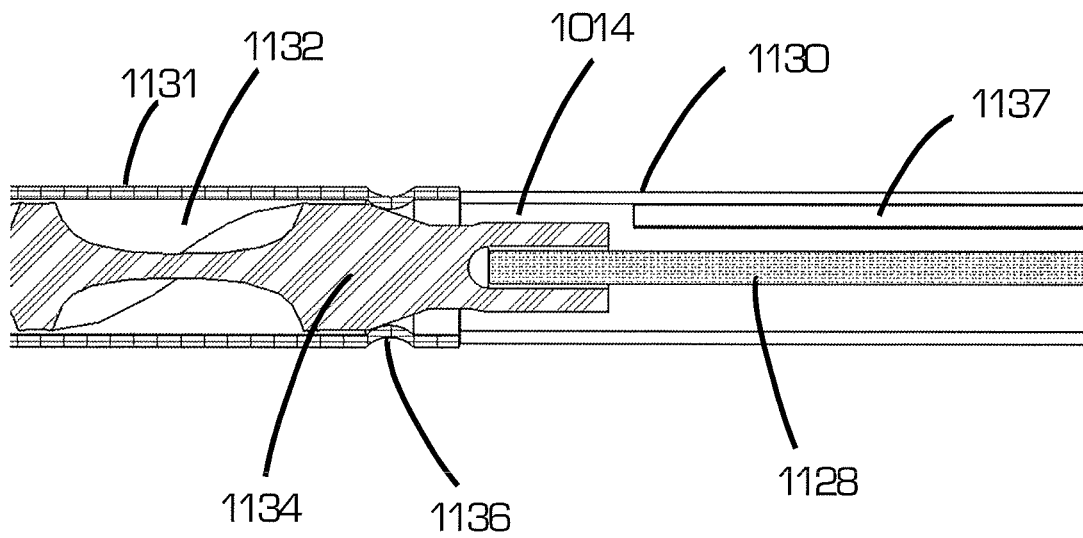


Fig. 52A

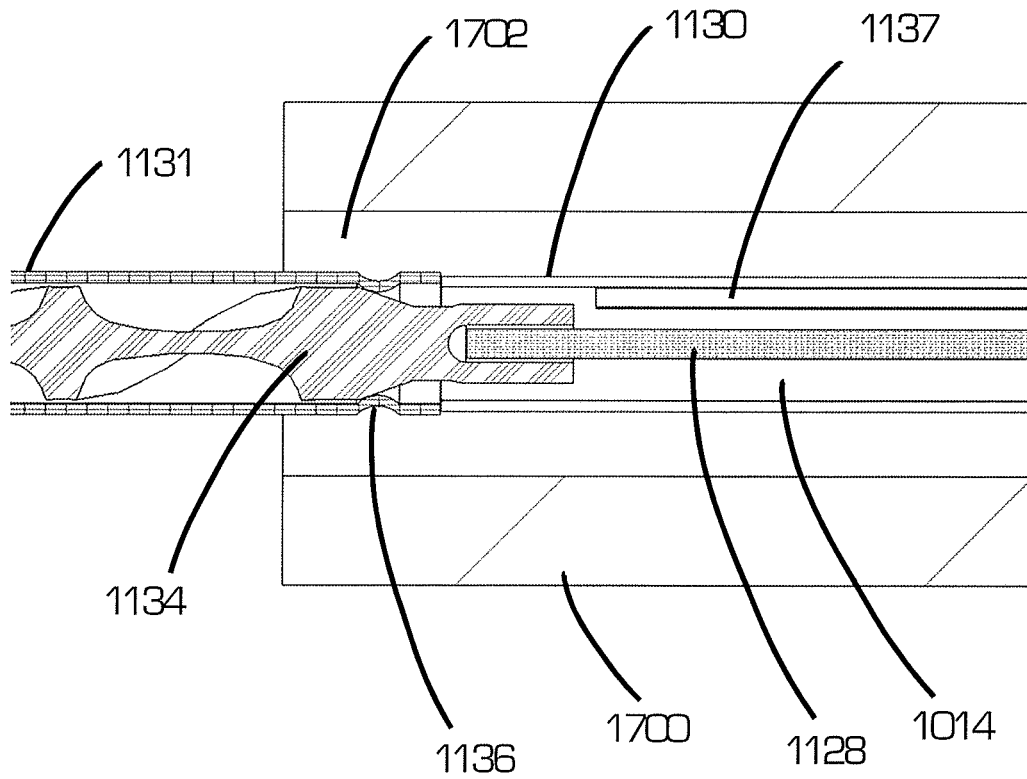


Fig. 52B

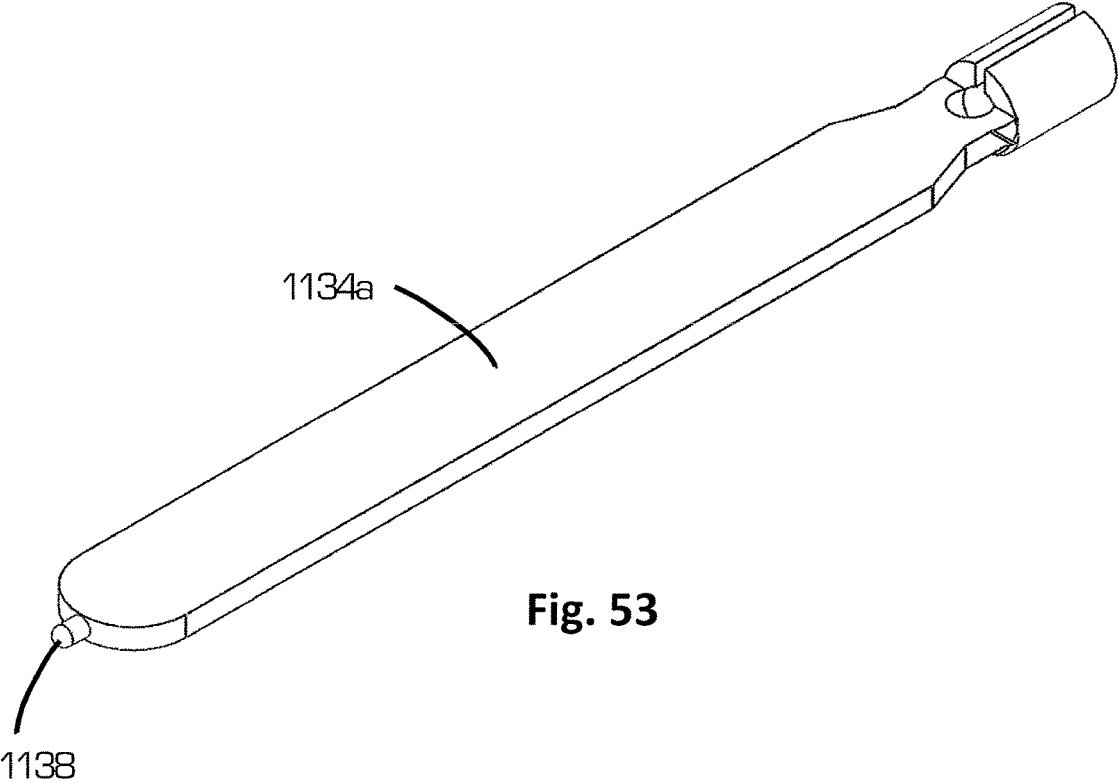


Fig. 53

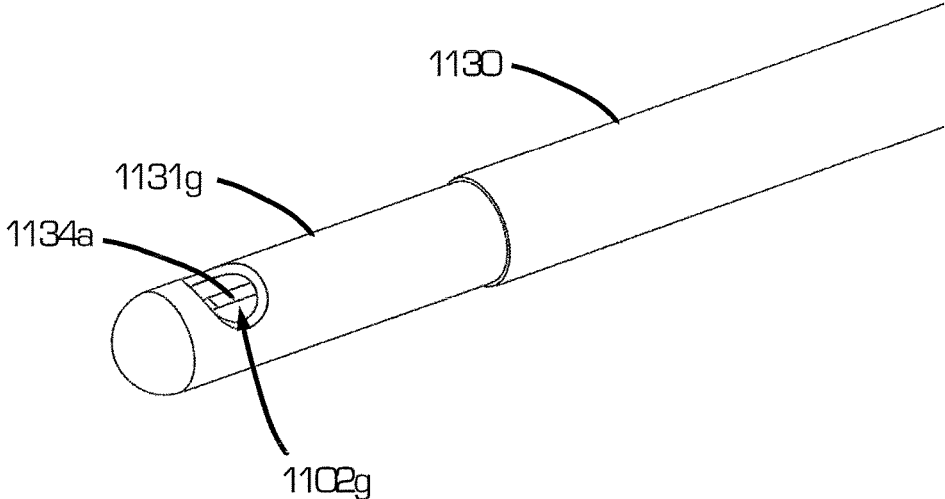


Fig. 54A

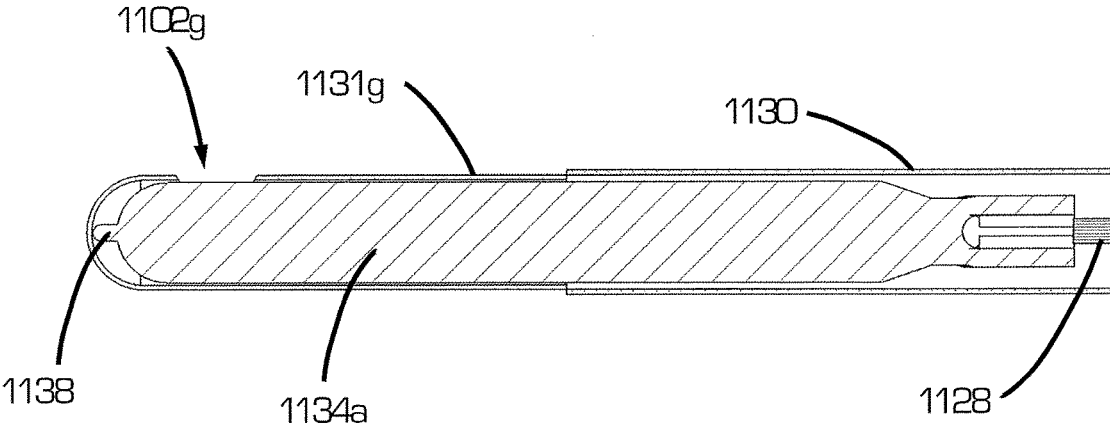


Fig. 54B

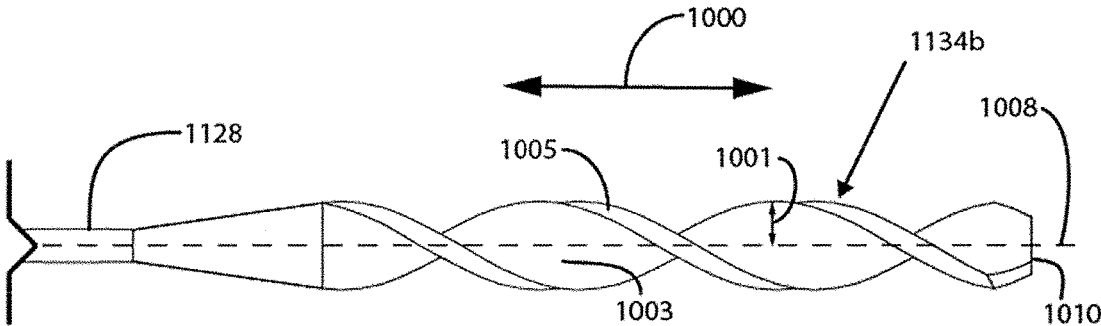


Fig. 55A

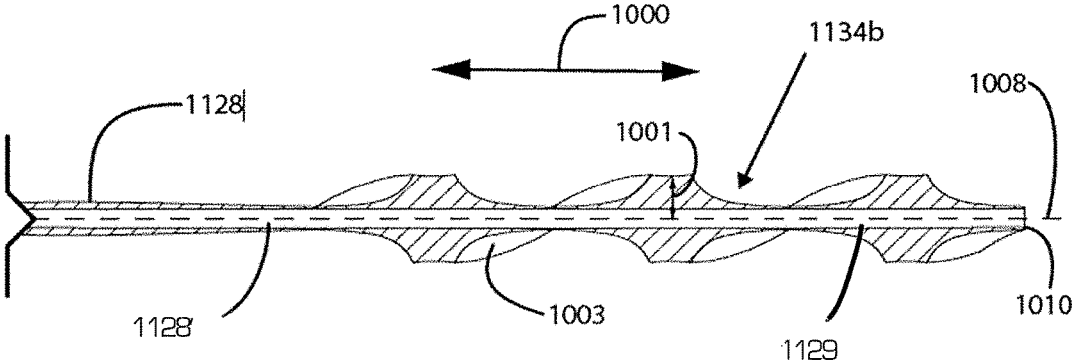


Fig. 55B

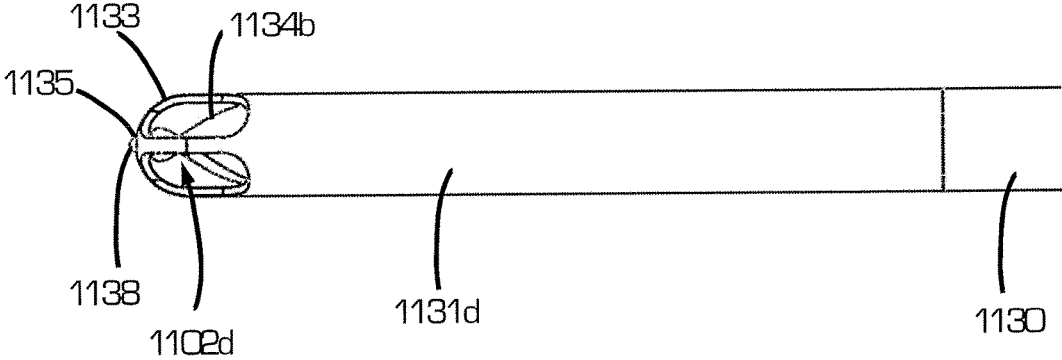


Fig. 56A

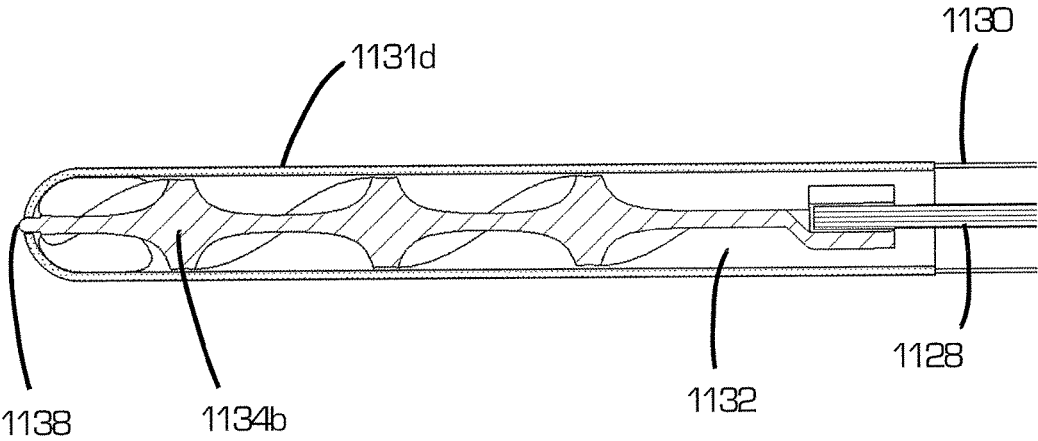


Fig. 56B

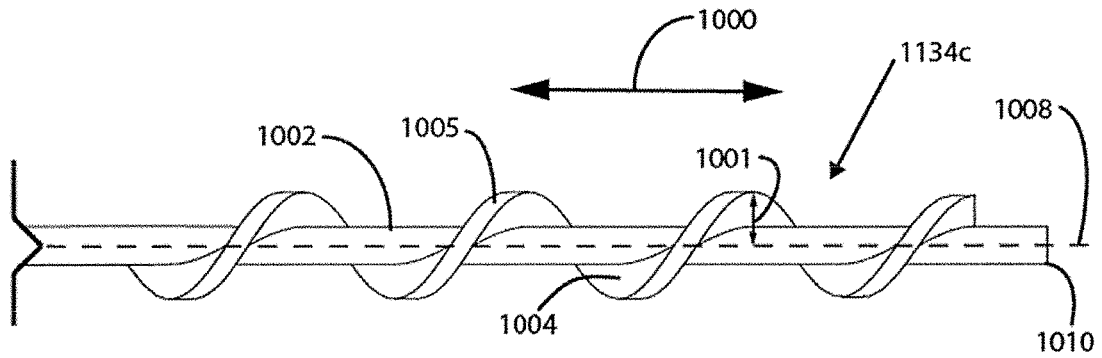


Fig. 57A

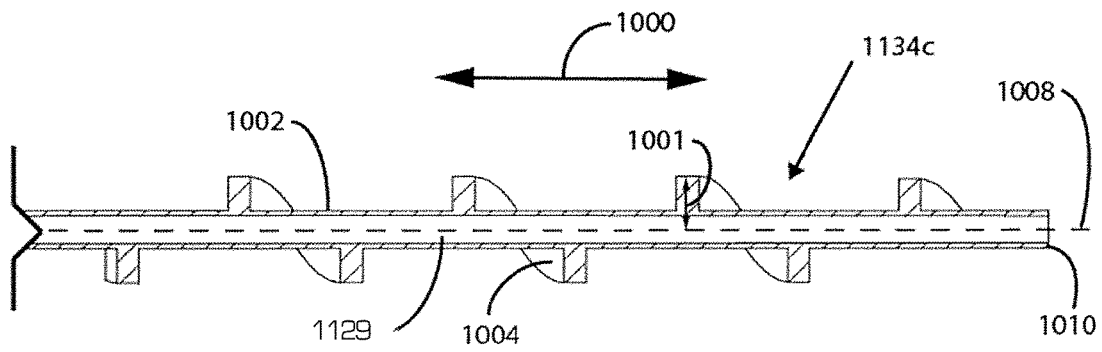


Fig. 57B

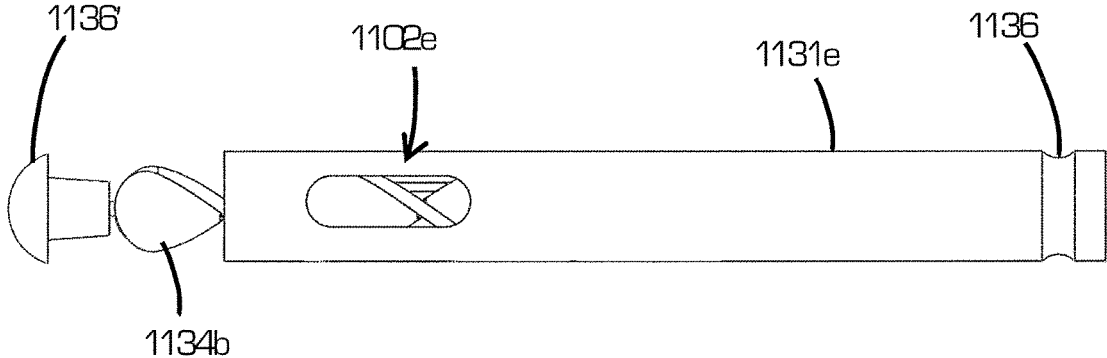


Fig. 58A

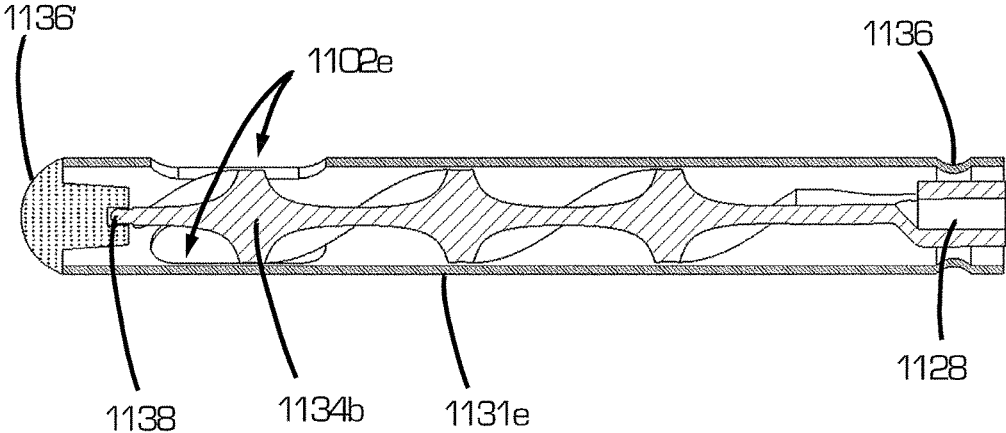
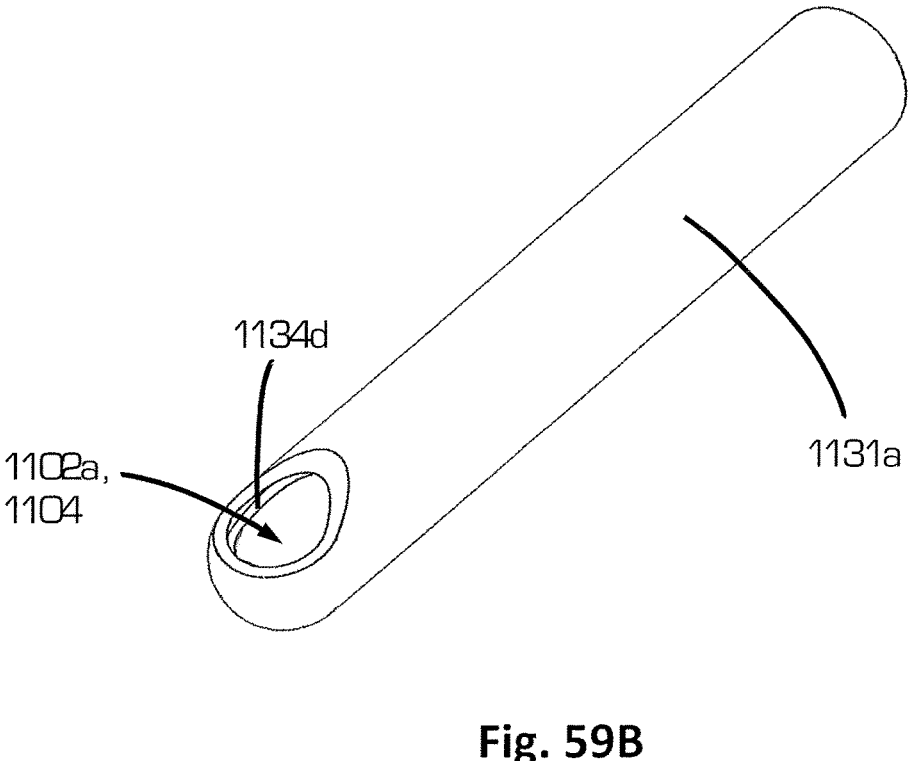
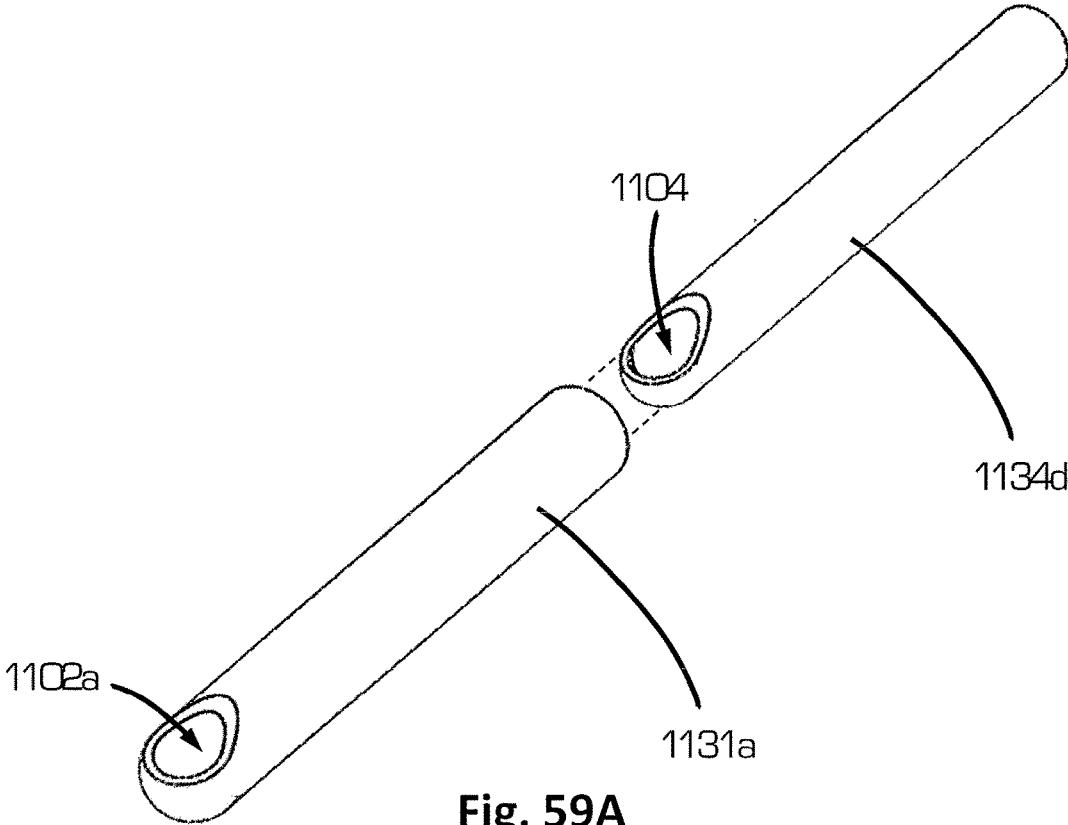


Fig. 58B



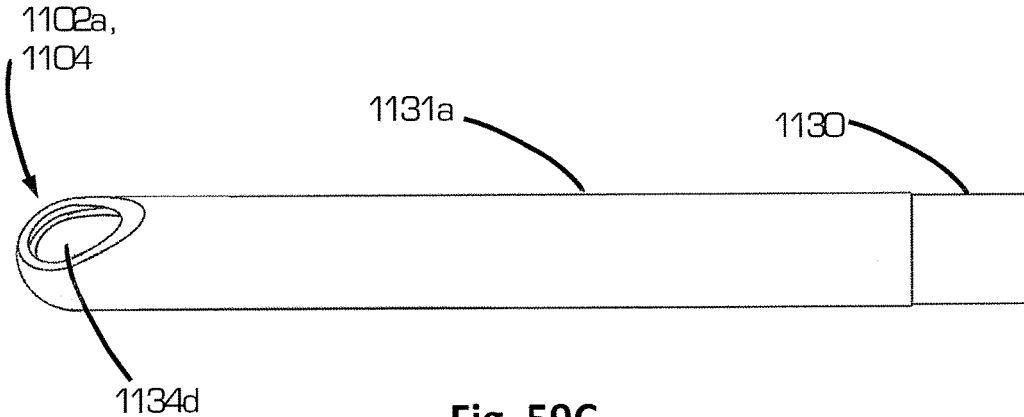


Fig. 59C

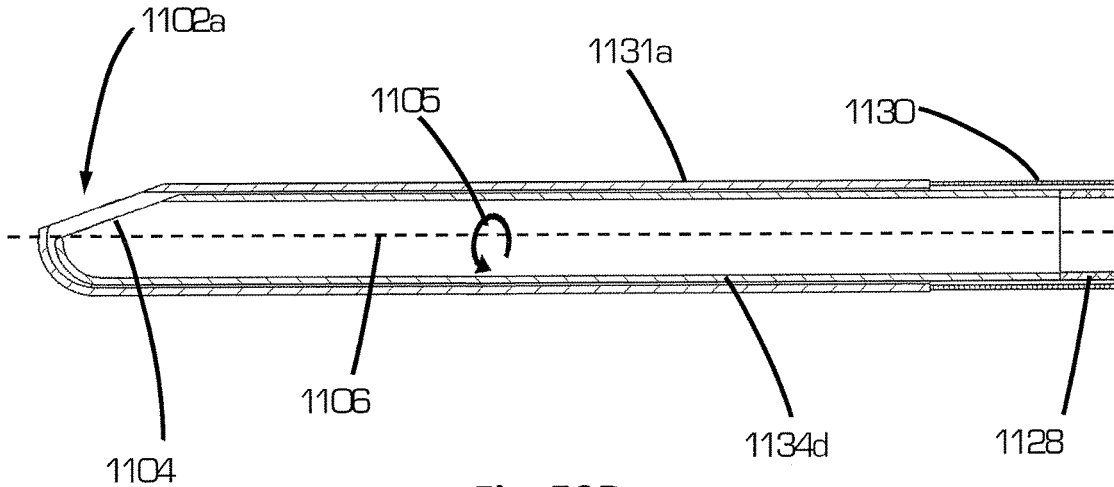
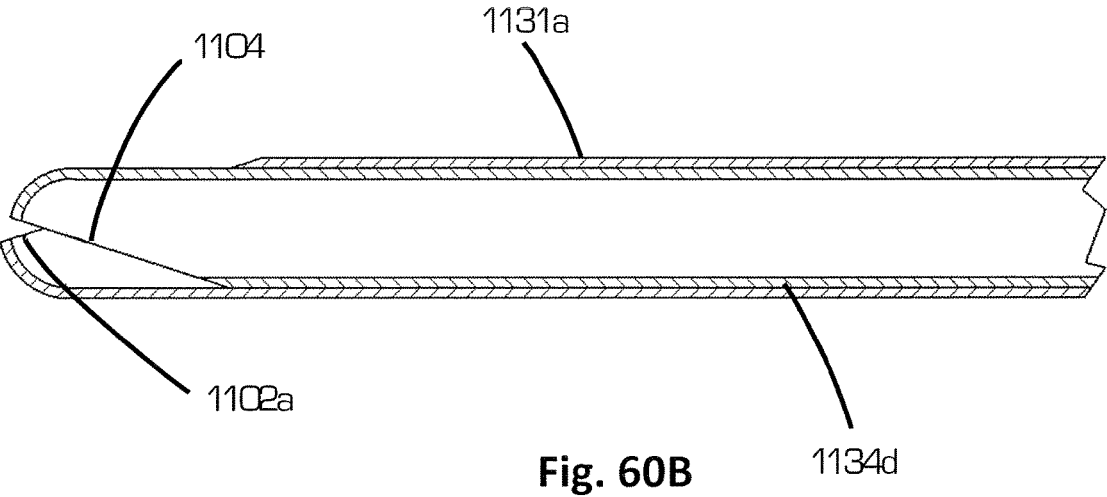
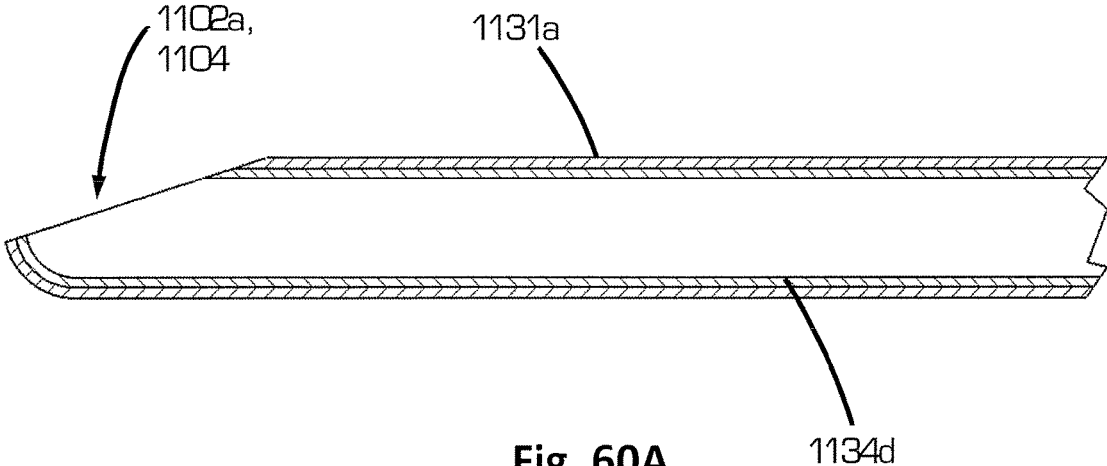


Fig. 59D



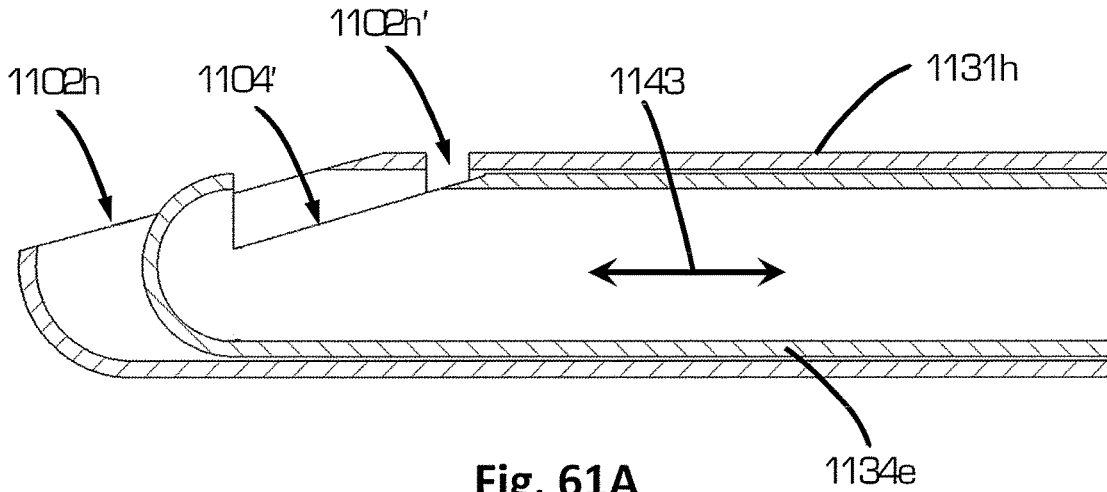


Fig. 61A

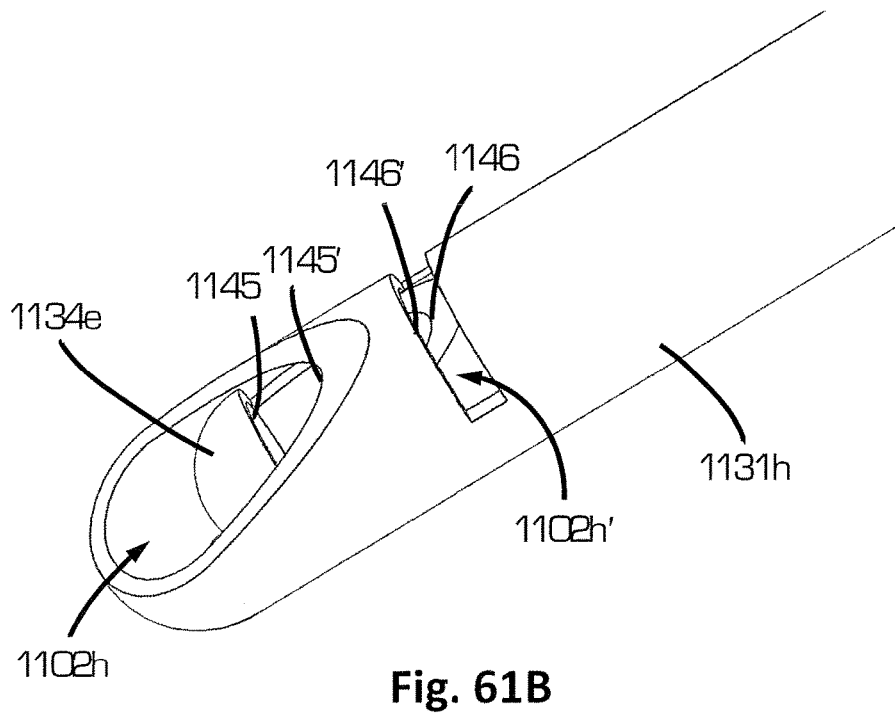


Fig. 61B

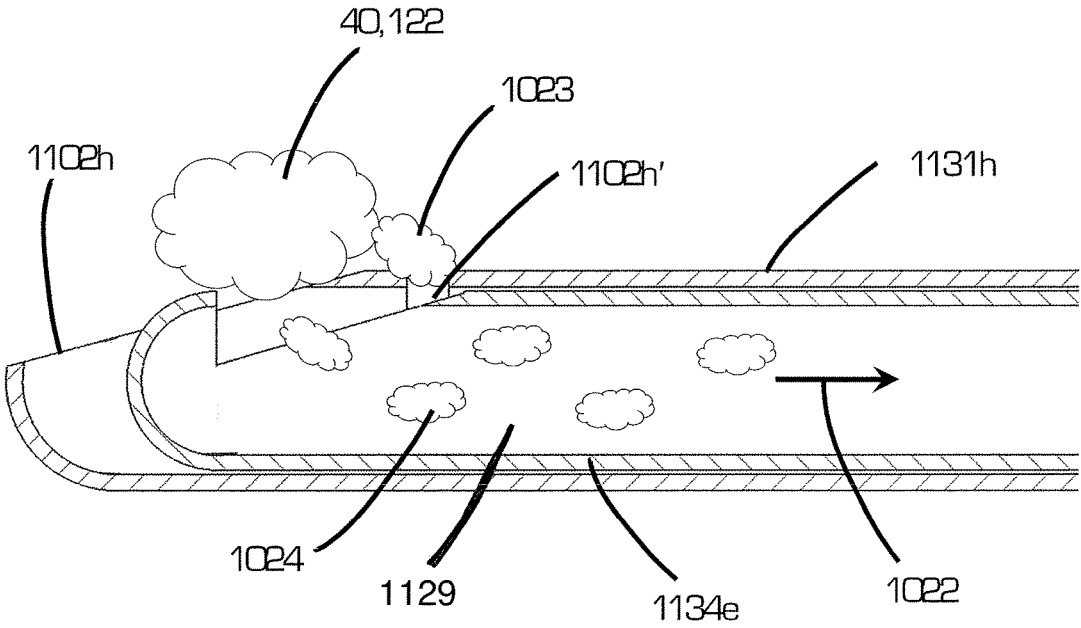


Fig. 62

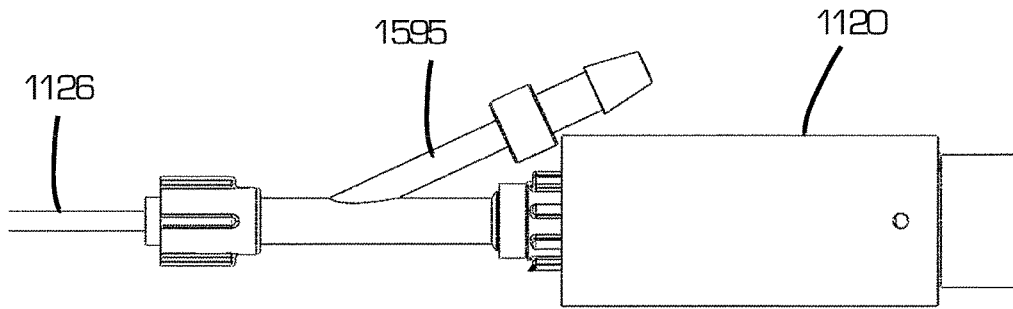


Fig. 63A

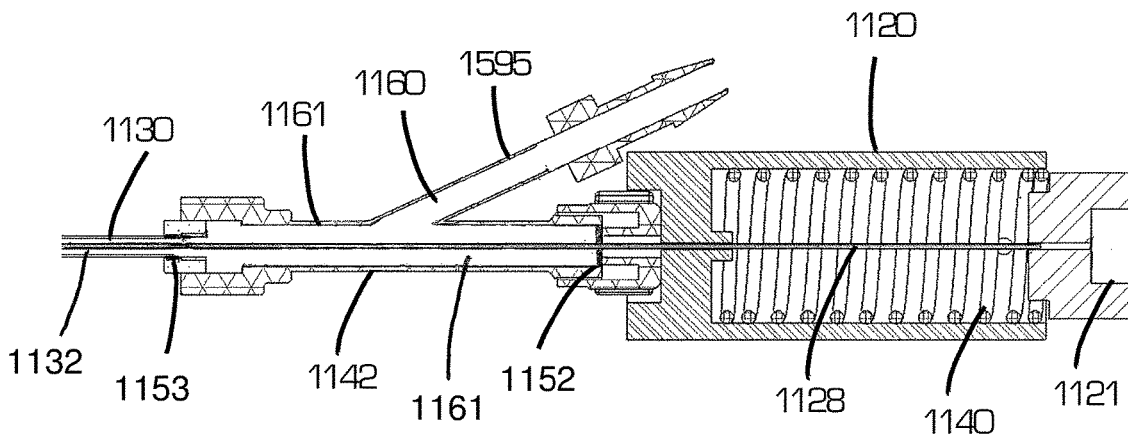


Fig. 63B

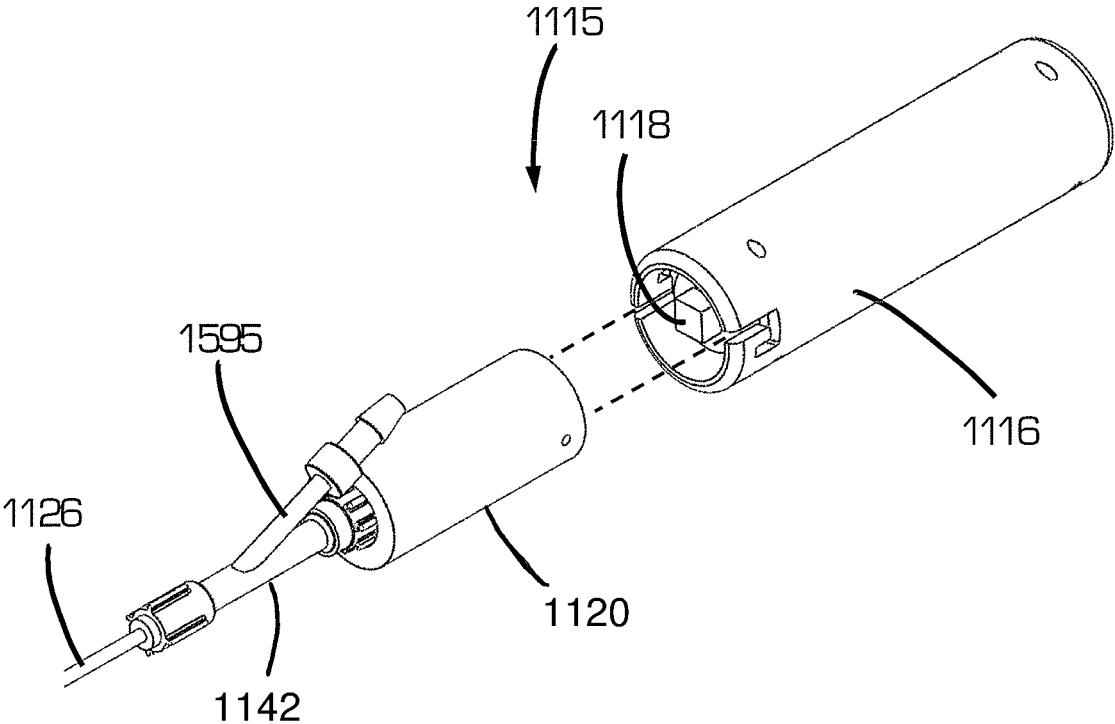


Fig. 64

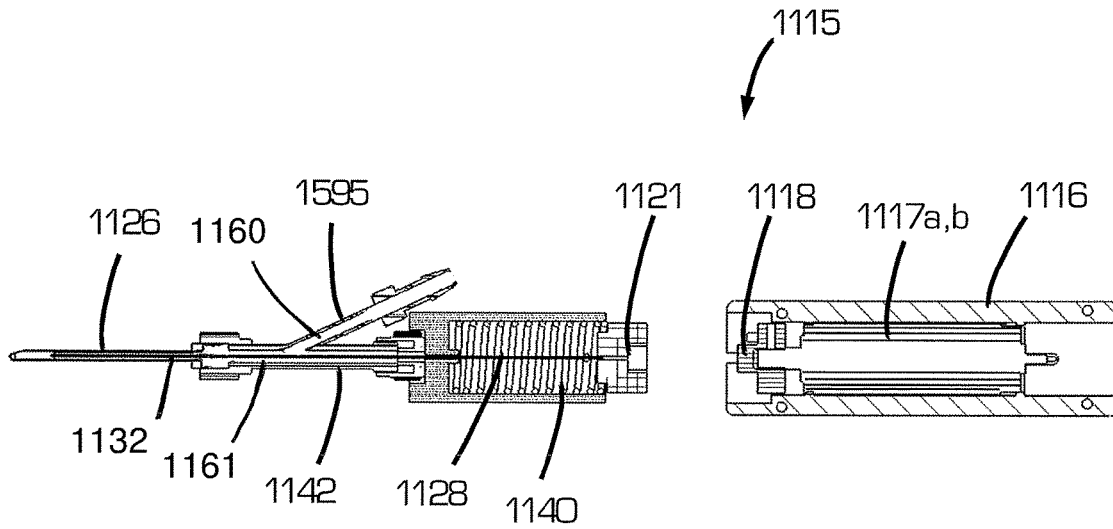


Fig. 65A

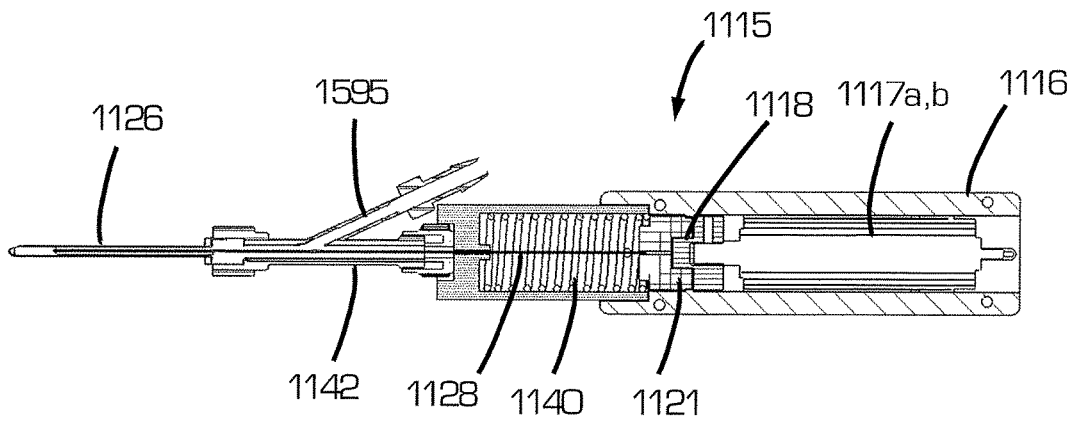


Fig. 65B

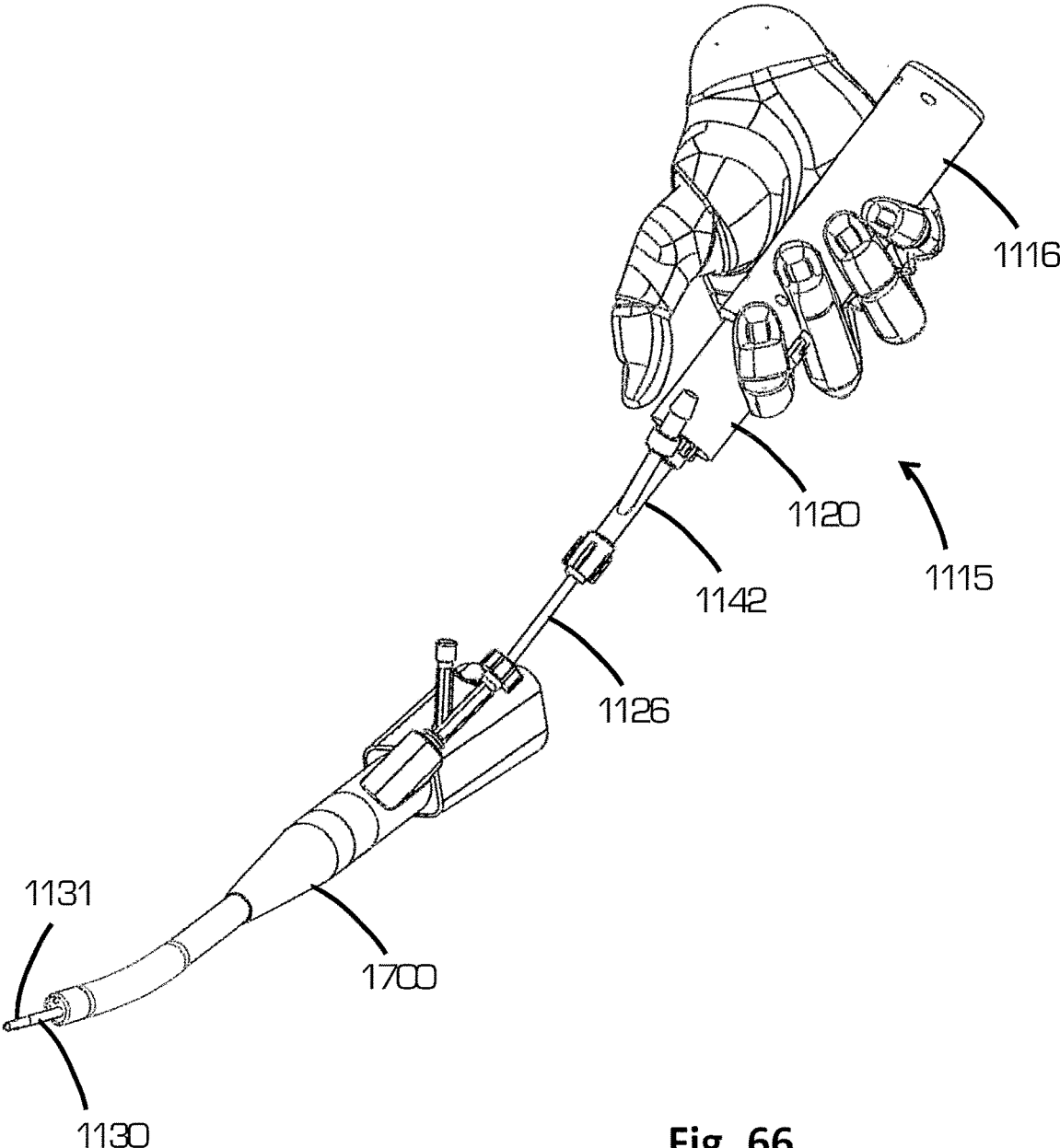


Fig. 66

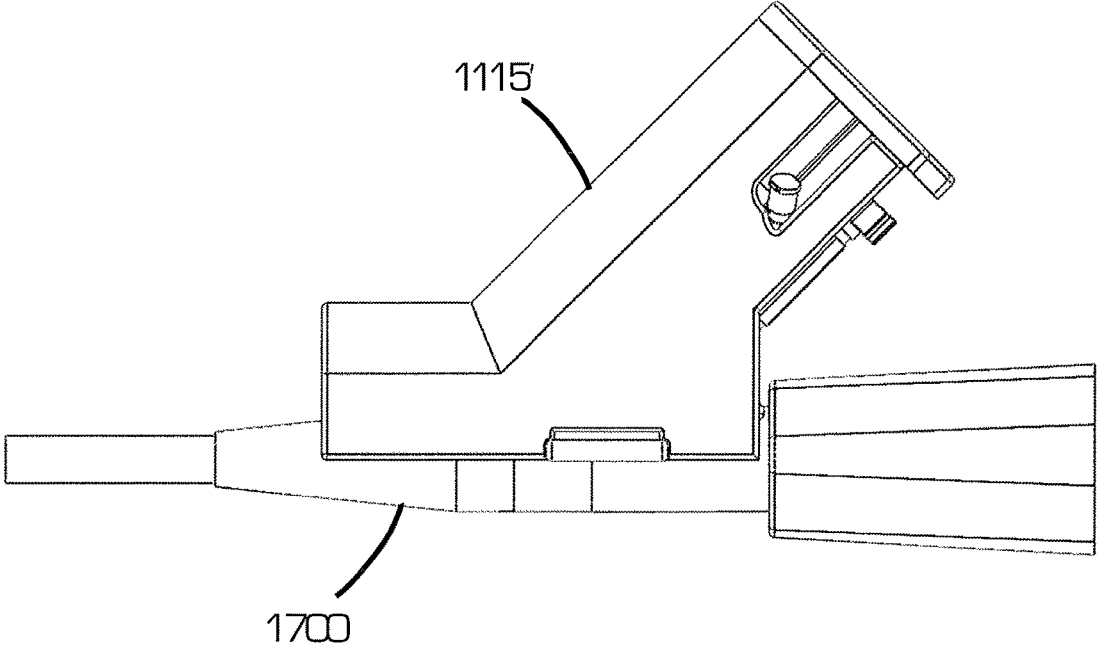


Fig. 67

DEVICES FOR CLEARING BLOCKAGES IN ARTIFICIAL AND NATURAL LUMENS

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims the benefit of U.S. Patent Application Ser. No. 62/198,256 filed on Jul. 29, 2015 entitled OCCLUSION CLEARING DEVICE FOR REMOVING MATERIAL FROM ARTIFICIAL LUMENS AND FROM WITHIN THE BODY OF A PATIENT and also claims the benefit of U.S. Patent Application Ser. No. 62/266,283 filed on Dec. 11, 2015 entitled OCCLUSION CLEARING DEVICE FOR REMOVING MATERIAL FROM NATURAL LUMENS WITHIN THE BODY OF A PATIENT, and is also a Continuation-In-Part of pending U.S. patent application Ser. No. 15/142,736 filed on Apr. 29, 2016 entitled DEVICES FOR CLEARING BLOCKAGES IN ARTIFICIAL LUMENS, which is a Continuation of U.S. patent application Ser. No. 13/863,108 filed on Apr. 15, 2013 and entitled DEVICES FOR CLEARING BLOCKAGES IN SMALL BORE IN-SITU ARTIFICIAL LUMENS, which issued as U.S. Pat. No. 9,352,122 on May 31, 2015, which 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, which issued as U.S. Pat. No. 9,308,348 on Apr. 12, 2016, which is a Continuation-in-Part 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 issued as U.S. Pat. No. 8,690,861 on Apr. 8, 2014, 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 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 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 INFEEDING TUBES, and all of whose entire disclosures are incorporated by reference herein. U.S. patent application Ser. No. 13/683,852 also claims the benefit of U.S. Provisional Patent Application 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, the contents of which are also incorporated by reference herein in its entirety.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

This invention was made with government support under grant number HD065365 and DK107381 awarded by the National Institutes of Health, 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

5 The present invention generally pertains to cleaning or clearing devices and methods of using such devices for the in-situ clearing of clots and other occlusions from artificial and natural lumens within a living being, including the in-situ clearing of feeding tubes, gastrointestinal tract, blood vessels and the like.

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.

10 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 140 k PEG clogs annually.

65 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, gastrojejunostomy-(G), jejunostomy-(J) or gastrojejunostomy-(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. In addition, bleeding within the gastrointestinal system can lead to coagulated blood masses that may clog a gastrically placed tube, or may interfere with a clinician's ability to properly view the area for medical diagnostic and monitoring purposes. Therefore, clearing coagulated blood and blood clots may also be important to the functioning of gastrically placed in-dwelling tubes.

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/her 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 downside 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

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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. What is also needed is a way to more efficiently clear clogged material which may be very viscous or difficult to remove, such as coagulated blood or blood clots.

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, as well as natural lumens within the body such as in the gastrointestinal tract or blood vessels. The device comprises: a controller that remains outside of the living being, and wherein the controller comprises an actuator or motor (e.g., voice coil motor; DC motor; piezoelectric actuator such as amplified piezoelectric actuators and Langevin transducers; solenoid motor; pneumatic motor, etc.) for generating repetitive motion (e.g., reciprocating, rotating, etc.); a clearing member or stem having a sheath and a wire disposed within the sheath. The clearing stem has a first end or proximal end that is releasably coupled to the controller, actuator or motor and having a second working end or distal end that is insertable into an opening in the artificial or natural tube; wherein the second working end has a portion, such as a sheath end and/or wire tip that comes into repetitive contact with a blockage or occlusion in the artificial or natural 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 or natural 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

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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.

In some embodiments, the distal ends of the sheath and wire may include a sheath end and wire tip, respectively, attached thereto, either one of which or both can reciprocate and/or rotate. The sheath end and wire tip are of a rigid material and as they move with respect to one another, they create shearing forces that break up the occlusion or blockage when positioned adjacent or proximal to the occlusion. At least one of the sheath end and wire tip includes at least one opening where the occlusion can enter the clearing stem for being broken up with shearing forces, and removed from the site by aspiration. The occlusion clearing device may therefore include an alignment member having a first port for irrigation and/or aspiration through either the sheath or wire, if hollow. In at least one embodiment, the occlusion clearing device may further have an adaptor that is exterior to and movably positionable along the length of the clearing stem. The adaptor may include a second port for irrigation, aspiration, and/or insufflation that occurs exterior to the sheath. The occlusion clearing device may be used directly with an artificial or natural lumen to clear the occlusion, or in some embodiments may be used with an access device, such as an endoscope or trocar, to access the interior of the artificial or natural lumen within the body to gain access to the occlusion for breakage and removal.

BRIEF DESCRIPTION OF SEVERAL VIEWS OF THE DRAWINGS

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

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 micro-processor 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.

FIG. 45A is a side isometric view of one embodiment of the clearing device of the present invention that can be inserted directly into any lumen or medical access device.

FIG. 45B is a cross-section of FIG. 45A.

FIG. 46A is a side isometric view of another embodiment of the clearing device inserted into an access device, here an endoscope.

FIG. 46B is a cross-section of FIG. 46A.

FIG. 47 is a partial cross-sectional view of the occlusion clearing device in which a pair of controllers or motors provide repetitive motion to the wire and sheath.

FIG. 48 is an isometric view of the occlusion clearing device of FIG. 47.

FIG. 49A is a cross-sectional view of a sheath and a wire in which the sheath is in its most proximal position when repetitive motion is applied thereto.

FIG. 49B is a cross-sectional view of the sheath and wire of FIG. 49A in which the sheath is in its most distal position when repetitive motion is applied thereto and the sheath engages an occlusion in a portion of a patient's body.

FIG. 50A shows one embodiment of a sheath end having a slanted distal opening that does not intersect the central axis of the sheath end.

FIG. 50B shows another embodiment of a sheath end, having a caged design with a single distal opening.

FIG. 50C shows another embodiment of a sheath end, having a caged design with two distal openings.

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FIG. 50D shows another embodiment of a sheath end, having a caged design with four distal openings.

FIG. 50E shows another embodiment of a sheath end, having an open distal end and multiple distal openings.

FIG. 50F shows another embodiment of a sheath end, having a distal opening with a toothed design.

FIG. 51A shows a side of one embodiment of a sheath end that connects to a sheath, where the sheath end includes a restricting member.

FIG. 51B shows a cross-sectional view of the sheath end of FIG. 51A, with a wire disposed there through.

FIG. 52A is a cross-sectional view of another embodiment of the clearing device illustrating an inner sheath conduit within the sheath for irrigation purposes.

FIG. 52B is a cross-sectional view of another embodiment of the clearing device disposed within an access device, showing both irrigation through the access device channel and an inner sheath conduit for irrigation within the clearing device.

FIG. 53 shows one embodiment of a wire tip in the shape of a flat blade.

FIG. 54A shows an isometric view of one embodiment showing a wire tip having a flat blade within a sheath end.

FIG. 54B shows a cross-sectional view of the embodiment of FIG. 54A.

FIG. 55A is a side view of another embodiment of a wire tip having a helical blade configuration.

FIG. 55B is one cross-sectional embodiment of the wire tip of FIG. 55A.

FIG. 56A shows a side view of a sheath end of FIG. 50D with a wire tip of FIG. 55A.

FIG. 56B is a cross-sectional view of the embodiment of FIG. 56A.

FIG. 57A is a side view of another embodiment of a wire tip having a helical ribbon configuration.

FIG. 57B is one cross-sectional embodiment of the wire tip of FIG. 57A.

FIG. 58A is a side view of the sheath end of FIG. 50E with the wire tip of FIG. 46A and a restricting member on the wire tip.

FIG. 58B is a cross-sectional view of FIG. 58A with the restricting member engaging the sheath end.

FIG. 59A shows an exploded view of another embodiment of a wire tip having a tube configuration, used in conjunction with a sheath end of FIG. 50A.

FIG. 59B shows the sheath end and wire tip of FIG. 59A combined.

FIG. 59C shows an isometric view of FIG. 59B.

FIG. 59D shows a cross-sectional view of FIG. 59C.

FIG. 60A shows a side view of the sheath end and wire tip of FIG. 59B.

FIG. 60B shows a side view of the sheath end and wire tip of FIG. 60A rotated 180° with respect to one another.

FIG. 61A illustrates another embodiment of the wire tip having a tube configuration and further having shearing structures, used in conjunction with a sheath end, demonstrating reciprocating motion.

FIG. 61B is an isometric view of FIG. 61A.

FIG. 62 is a cross-sectional view of the sheath end and wire tip of FIG. 62A engaging a clog or occlusion for clearing.

FIG. 63A shows a side view of the proximal end of the alignment member and clearing stem of one embodiment where a wire is disposed within a sheath.

FIG. 63B is a cross-sectional view of FIG. 63A.

FIG. 64 shows an exploded view of one embodiment of the housing.

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FIG. 65A shows a cross-sectional view of the proximal end of the clearing stem, alignment member, receiver housing and drive housing of FIG. 64 showing the disposable receiver housing and reusable drive housing.

FIG. 65B shows the device of FIG. 65A where the receiver housing and drive housing are connected.

FIG. 66 shows an embodiment of the occlusion clearing device used in connection with an access device, and demonstrating how the housing is held by a hand.

FIG. 67 shows another embodiment of the housing of the occlusion clearing device.

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 various types of tube clearing devices used to clear artificial or natural lumens within the body of a patient. Initially, 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 componentry 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 pro-

vide 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 diaphragm 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 28 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 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, electromechanical 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 2-25 N and more preferably 6-14 N.

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 (24Vp-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., VariohmEurosensor). 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 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

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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** 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

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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 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 nutritional 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 side-wall, 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/aspitant, 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/aspitant 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/aspitant 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 config-

ured 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 538 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 interdispersed 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 interdispersed 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. Interdispersed 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 interdispersed connecting member 531. Alternatively, rather than being formed of the distal portion 529, interdispersed 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 interdispersed 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 interdispersed 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 dis-

placeable 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 overfilled 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 TC1' 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.

Further Embodiments

Occlusions or clogs may occur within both artificial lumens disposed within the body, such as feeding tubes discussed above, but may also occur in natural lumens as well. “Occlusion” as used herein will refer to any material that may need to be removed from an artificial or natural lumen or cavity. Occlusions can include, but are not limited to, masses or material such as tumors, bowel obstructions, clotted or coagulated blood, or food. Occlusion does not necessarily imply a complete blockage, but also includes materials that need to be removed from the artificial or natural lumen or cavity for various reasons, such as for better visualization of a target area, or to remove a potentially harmful substance. For instance, coagulated blood attached to the side of the stomach wall may make it difficult to visualize sources of bleeding.

Therefore, the occlusion clearing device can be used to clear clogs or occlusions within not only feeding tubes, but also within natural lumens of a patient, such as the esophagus, intestines or stomach of the gastrointestinal system, and blood vessels such as veins and arteries within the body. Repetitive motion, such as reciprocating and/or rotating motion as described above, can be employed along with aspiration and/or irrigation to facilitate the disruption and clearing of the clog. Particular tips may also be used to increase the speed and efficiency with which the occlusion is broken up for removal.

The occlusion clearing device as described herein results in aspiration that is more uniform and finer than using an open suction tube alone. Also, occlusions such as blood clots may be cleared more efficiently and quickly than standard open suction tubes. In at least one embodiment, the occlusion clearing device with sheath ends and wire tips discussed herein have been demonstrated to clear a 60 g blood clot in under 15 minutes with 200 mmHg aspiration suction in 90% of trials conducted. A standard open suction tube of similar diameter operated under identical conditions was only able to clear a 60 g blood clot in under 15 minutes in only 20% of trials conducted. The clearance rate is also 84% higher using the occlusion clearing device with sheath ends and wire tips described herein, removing approximately 6.7 g/min of occlusion material. Increasing the aspiration increases the efficiency. For instance, using aspiration at 250 mmHg produces a three-fold increase in mass removal or clearance rate, to about 20 g/min. These are provided for illustrative purposes. It should be appreciated that higher or lower levels of aspiration suction can be used, including no aspiration, such as in the range of 0-300 mmHg. Occlusions or clogs having less or greater mass are also contemplated, and may include partial or full blockages of the artificial or natural lumen.

With reference to FIGS. **45A-46B**, the occlusion clearing device includes a clearing stem **1126**, which is comprised of a sheath **1130** having a sheath lumen **1014**, and a wire **1128** disposed within the sheath lumen **1014**. The sheath **1130** may be made of materials such as, but are limited to, plastic tubing, wire-reinforced plastic tubing, laser cut hypodermic or plastic tubing, and elastomeric materials, and other such materials as may be sufficiently flexible to maneuver turns within an artificial or natural tube to reach an occlusion. In at least one embodiment, aspiration is provided through the sheath lumen **1014** around the wire **1128**. The distal end of the sheath **1130** includes a sheath end **1131**, discussed in greater detail below. The distal end of the wire **1128** includes a wire tip **1134**, also discussed in detail below. The sheath end **1131** and wire tip **1134** move by repetitive motion, either reciprocating or rotational or both, to break up and dislodge occlusions.

At the proximal end, the clearing stem **1126** connects to an alignment member **1142** that maintains the alignment of the sheath **1130** and wire **1134** during movement. The alignment member **1142** includes a first port **1595** that provides an exit of the device to an irrigation or aspiration source. The first port **1595** includes a first port lumen **1160** and first chamber **1161** in fluid communication. The sheath **1130** is in fluid communication with the first chamber **1161** and first port lumen **1160**, so that materials such as air, fluid and occlusion matter may be aspirated away from the occlusion site through the sheath lumen **1014** and exit through the stem port **1595**. In other embodiments, the wire **1128** may be hollow, having a wire lumen **1128'** defined along an interior length. In some embodiments, the wire **1128** is hollow **1129**. It should therefore be understood that, as used herein, “wire” may refer to both a solid elongate structure as well as a tubular structure with a hollow interior. The wire lumen **1128'** may be in fluid communication with the first chamber **1161** and first port lumen **1160** for irrigation and/or aspiration through the first port **1595**. Accordingly, aspiration can occur through either the sheath lumen **1014** or the wire lumen **1128'**, or both. In some embodiments, the sheath lumen **1014** and/or wire lumen **1128'** may provide irrigant, or one may provide irrigant while the other aspirates.

An adaptor **1162** may also present along the exterior of the clearing stem **1126**, and in at least one embodiment is slidable along the length of the clearing stem **1126** to any desired point. The adaptor **1162** includes a second port **1163** having a second port lumen **1164** extending there through. The adaptor has an interior second chamber **1165** that is in fluid communication with the second port lumen **1164**. The second chamber **1165** of the adaptor **1162** creates a conduit around the exterior of the clearing stem **1126**, specifically the exterior of the sheath **1130**. Irrigation and/or aspiration may occur through the second port **1163**. For instance, in the embodiment of FIGS. **45A-45B**, the second chamber **1165** of the adaptor **1162** is in fluid communication with a lumen where the occlusion is located. Thus, irrigant can be introduced to the occlusion through second port **1163** for primary irrigation and softening of the occlusion to facilitate breaking up and removal of the occlusion. In some embodiments, as in FIGS. **46A-46B**, the second chamber **1165** and second port lumen **1164** are in fluid communication with a channel **1702** of an access device **1700**, such as an endoscope, allowing fluid such as irrigant to be supplied through the access device **1700** to the site of the occlusion.

The alignment member **1142** connects to handset **1115** which is be gripped and maneuvered by a clinician or practitioner during use of the occlusion clearing device. The handset **1115** includes two separate yet selectively attachable components. A drive housing **1118** includes motor(s) **1117** which produce the repetitive motion, which may be reciprocating motion in a longitudinal direction and/or rotating motion about an axis. The motion generated by the motor(s) **1117a, b** is transferred to the clearing stem **1126** through the receiver housing **1120**. The motion drives the sheath **1130** and/or wire **1128**, and therefore the sheath end **1131** and/or wire tip **1134** to create shearing forces to break up the occlusion with greater efficiency than previously seen.

In some embodiments, as in FIGS. **45A** and **45B**, it is possible to use the occlusion clearing device directly with the natural or artificial lumen in which the occlusion is located, such as a feeding tube or exposed vessel. In other embodiments, such as in FIGS. **46A-46B** the occlusion clearing device can be used with an access device, such as an endoscope or other device used to gain access to an artificial or natural lumen disposed within a patient, such as a feeding tube or GI tract. The access device **1700** includes a channel **1702** which extends through at least a portion of the access device **1700** and defines a space through which materials may pass through and be introduced to, or removed from, a space within the body of a patient. In the case of an endoscope, the channel **1702** may be a biopsy channel that is used to access the interior of the GI tract. The access device **1700** further includes an access port **1703** that includes a lumen that is in fluid communication with the channel **1702**. The distal tip of the clearing stem **1126** is introduced into the access port **1703** and thereby gain entry into the channel **1702**, as best seen in FIG. **46B**. The distal end of the clearing stem **1126** extends beyond the end of the access device **1700**, which includes a sheath end **1131** and wire tip **1134** that can be used to engage the clog or occlusion and morcellate the material, as described in greater detail below.

The adaptor **1162** may be used with the access device **1700** to provide irrigation to the occlusion through the channel **1702** and exterior of the sheath **1130** disposed therein. In such embodiments, as in FIG. **46B**, the channel **1702** of the access device **1700** may be in fluid communication with the second chamber **1165** and second port lumen **1164**, which may be connected to an irrigation source as

described previously. The irrigant may be liquid or gas, and therefore the second port **1163** may be used for irrigation and/or insufflations of the target occlusion site as appropriate. For instance, liquid fluid can be introduced through the second **1163** to irrigate the channel **1702** and provide moistening fluid to aid in the removal and evacuation of occlusion material, to provide medication, and to provide replacement materials for the fluids being removed, among other functions. In some embodiments, the fluid may be a gas, such as to insufflate a body cavity to permit better viewing of the target area, provide tension, or for some other function. Further, the adaptor **1162** may include a first seal **1150** where the clearing stem **1126** enters the adaptor **1162**, and a second seal **1151** where the adaptor **1162** and access port **1702** meet. The first and second seals **1150, 1151** may each be circumferentially disposed around the sheath **1130** and joint of the access port **1702** to form a fluid-tight seal, such as a hermetic seal. The first and second seals **1150, 1151** collectively maintain any fluid introduced into the second chamber **1165** therein.

As depicted in FIGS. **47A-47C**, the occlusion clearing device moves by repetitive motion, such as reciprocating motion along a longitudinal direction **1000** and/or a rotating motion about an axis **1008**. The housing **1115**, specifically the drive housing **1116**, may include a plurality of motors **1117**. A single motor **1117** may provide both reciprocating and rotational motion, or there may be one motor **1117a** that provides rotational motion, and another motor **1117b** that provides reciprocating motion. As used herein, "repetitive motion" includes reciprocating motion, rotational motion, or both. For instance, there may be a first motor **1117a** that provides repetitive motion through a moveable member **1032** to the wire **1128**. The moveable member **1032** engages a proximal terminal end of the wire **1128**. The first motor **1117a** may be arranged in any manner as previously discussed herein, or may be configured in any manner capable of generating repetitive motion that is transferred to the wire **1128** through the movable member **1032**. The repetitive motion generated by the first controller may be reciprocal motion in the longitudinal direction **1000**, back and forth rotation about axis **1008** where the direction of rotation alternates, or may be continuous rotation about axis **1008** in one direction, or it may be both reciprocation and rotation. When capable of generating both longitudinal reciprocation and rotational motion, the first motor **1117a** may generate both reciprocal and rotational motion simultaneously, or may be capable of generating rotational motion or reciprocal motion independently as desired. In some embodiments, the repetitive motion transferred to the wire **1128** may be repetitive motion such that the wire **1128** reciprocates in the longitudinal direction **1000**. In another embodiment the repetitive motion transferred to the wire **1128** may be back and forth or continuous rotation such that the wire **1128** rotates about the axis **1008** in alternating directions. In yet another embodiment the repetitive motion can be simultaneous longitudinal reciprocation and back and forth or continuous rotation. The back and forth or continuous rotation of the wire **1128** allows the wire tip **1134** (discussed in greater detail below) to break up the occlusion **1023**, which is then aspirated into the lumen of the sheath **1014**. This allows the broken pieces **1024** of the occlusion **1023** to be more easily transferred to the proximal end of the device for removal.

The wire **1128** includes a shaft **1002** that extends from the first motor **1117a** through the seal **1030**. This is similar to the third seal **1152** discussed later. The shaft **1002** engages the seal **1030** such that a fluid-tight seal is formed circumfer-

entially around the shaft **1002** to prevent fluid from being transferred across the exterior of the shaft **1002** at this point. The seal **1030** may thus be a resilient member or can be sized and configured in a manner that allows for reciprocal movement or rotation of the shaft **1002** but not sufficient space to allow fluid to move between the shaft **1002** and the seal **1030** at the engagement point. The shaft **1002** continues extending in the distal direction toward the distal terminal end **1010** of wire **1128** that is located proximal to the distal terminal end **1020** of the sheath **1130**. Although shown as being solid, the shaft **1002** may have a lumen **1012** or be multi lumen in accordance with other exemplary embodiments. This lumen **1012** may be similar to the wire lumen **1128'** discussed previously. The first motor **1117a** may have a port for the receipt or transmission of aspiration or irrigation that can likewise be transferred through the lumen(s) **1012** of the shaft **1002**. The shaft **1002** may be centered relative to the sheath **1130** such that the axis **1008** of the wire **1128** is located at the central axis of the sheath **1130**.

The occlusion clearing device may also include a second motor **1117b** that is capable of producing repetitive motion that is transferred to the sheath **1130**. The repetitive motion generated by the second motor **1117b** may be reciprocal motion in the longitudinal direction **1000**, back and forth rotation about axis **1008**, or may be continuous rotation about axis **1008**, or may be both, longitudinal reciprocation and back and forth or continuous rotation. When capable of generating both longitudinal reciprocation and rotational motion, the second motor **1117b** may generate both reciprocal and rotational motion simultaneously, or may be capable of generating rotational motion or reciprocal motion independently as desired. The second motor **1117b** may be arranged in manners previously described herein that are capable of generating repetitive motion, or may be any type of controller capable of generating reciprocal and/or rotational motion. The second motor **1117b** may have a moveable member **1034** that reciprocates and/or rotates and is connected to a proximal terminal end of the sheath **1130**. Repetitive motion of the moveable member **1034** is translated to the sheath **1130** to likewise cause the sheath **1130** to reciprocate and/or rotate.

The second motor **1117b** may also have a seal **1030** that along with other portions of the motor **1117b**, such as the moveable member **1034**, defines a sealed cavity **1036** within the second motor **1117b** that is in fluid communication with the sheath lumen **1014**. A vacuum source **1028** may be provided and placed in fluid communication with this cavity **1036** so that aspiration **1022** is capable of being conducted through the sheath lumen **1014** and into the cavity **1036** of the second motor **1117b**. Debris such as broken pieces **1024** may be aspirated through the sheath lumen **1014** and into the cavity **1036** of the second motor **1117b** and out with the vacuum source **1028** for removal.

The occlusion clearing device can be arranged so that the wire **1128** and sheath **1130** are moved independently from one another. In this regard, the wire **1128** may reciprocate and/or rotate while the sheath **1130** remains stationary. Alternatively, the sheath **1130** can reciprocate and/or rotate while the wire **1128** remains stationary. In other arrangements, the wire **1128** may reciprocate and/or rotate while at the same time the sheath **1130** reciprocates and/or rotates. In another arrangement, the wire **1128** may rotate and reciprocate while at the same time the sheath **1130** reciprocates and/or rotates but at a different rate of reciprocation and/or rotation than the wire **1128**. The wire **1128** and sheath **1130** may thus be independently controllable by the motors **1117a**, **1117b** such that their repetitive motions are not linked

to one another but are instead independently controlled. Although not shown, the motors **1117a**, **1117b** could be rigidly connected together while still allowing movable members **1032**, **1034** to move independently of one another. However, the wire **1128** and the sheath **1130** could be linked to one another such that their rotation and/or reciprocation are dependent upon one another. For example, a single motor **1117** may be in communication with both the wire **1128** and the sheath **1130** so that both of these elements rotate and/or reciprocate at the same rate at the same time.

With reference to FIGS. **47A-49B**, rotation of the wire **1128** about the axis **1008** causes both the shaft **1002** and the wire **1128** to rotate about the axis **1008**. In some embodiments, this type of repetitive motion may cause the wire **1128** to function as an auger such that the turns of the wire **1128** engage larger portions **1023** of the occlusion **40**, **122** after they are aspirated into sheath **1130** and break them into smaller broken pieces **1024**. The wire **1128** may reciprocate and/or rotate while the sheath **1130** remains stationary or reciprocates and/or rotates. The reciprocation of the wire **1128** is in the longitudinal direction **1000** such that the wire **1128** moves proximal and distal in the longitudinal direction **1000** in a repetitive manner. Likewise, the reciprocation of the sheath **1130** is in the longitudinal direction **1000** such that the sheath **1130** moves in the proximal direction and in the distal direction in the longitudinal direction **1000** in a repetitive motion.

FIGS. **49A** and **49B** illustrate an exemplary embodiment of the occlusion clearing device being used to clear an occlusion **40**. The occlusion clearing device includes a sheath **1130** and a wire **1128** that has a shaft **1002** as previously discussed. The occlusion clearing device may be inserted into an artificial tube **39** (as shown in FIG. **4**) in order to clear an occlusion **40** in the artificial tube **39** such as food, as previously discussed. However, the occlusion clearing device may also be used directly inside the natural cavity of a patient such that the occlusion clearing device is not located within the artificial tube **39** (as shown in FIG. **4**) but is instead located within a portion of the body of the patient **1018**, such as the gastrointestinal tract. In a third scenario the occlusion clearing device may be introduced into a natural body cavity through an artificial lumen such as a trocar or endoscope, or other access device **1700**. With reference to FIGS. **49A** and **49B**, the occlusion clearing device is located within a portion **1018** of the body of the patient and is not located within the artificial tube **39**. The portion **1018** may be, but is not limited to, body cavities, the vascular system, or the gastrointestinal tract. The occlusion **40** may include but is not limited to tumors, bowel obstructions, clotted/coagulated blood, or food. For sake of example, the portion **1018** in FIGS. **49A** and **49B** may be a cavity of the patient, and the occlusion **40** may be pooled blood or blood clot.

The occlusion clearing device may be inserted inside a portion of the body of the patient **1018**. The sheath **1130** may be advanced so as to be in proximity to the blood clot or occlusion **40** that is to be removed. Repetitive motion may be applied to the sheath **1130** in order to cause the sheath **1130** to reciprocate in the longitudinal direction **1000** so that the sheath **1130** moves proximal and distal in a repetitive manner. FIG. **49A** shows the sheath **1130** in its most proximal position during reciprocation and before engagement with the occlusion **40**. The wire **1128** is arranged with respect to the sheath **1130** so that the distal terminal end **1010** of the wire **1128** is proximal to the distal terminal end **1020** of the sheath **1130**.

FIG. 49B shows the sheath 1130 reciprocated to its most distal position during the repetitive motion, or in the case where the sheath is stationary, FIG. 49B shows the device as positioned by the user to engage the occlusion 40. The distal terminal end 1020 comes into engagement with the occlusion 40 to break up the occlusion 40 so that larger portions 1023 of the occlusion 40 are broken off and pulled into the sheath lumen 1014 through aspiration 1022 applied through the sheath lumen 1014. Repetitive motion of the distal terminal end of the sheath 1020, when applied, may enhance the breaking up of the occlusion 40 to be aspirated through sheath lumen 1014. The sheath lumen 1014 may be single or two or more lumens providing irrigation and aspiration. Irrigation may also aid in breaking off larger portions 1023 from the occlusion 40, as seen in FIGS. 47C, 52A and 52B. The larger portions 1023 may move into engagement with the reciprocating and/or rotating wire 1128, and this engagement may further function to break up the occlusion into smaller portions 1024 or may assist in the portions 1024 in moving to the proximal end of the device. The wire 1128 may remain stationary and may not rotate or reciprocate while the sheath 1130 does in fact reciprocate and/or rotate relative to the wire 1128, or vice-versa. Although described as using aspiration 1022, aspiration 1022 may not be used or needed in other embodiments of the occlusion clearing device. In such embodiments it may only be the wire 1128 that is rotating and thereby creating a vacuuming effect. Irrigation may be conducted through the sheath lumen 1014 so that the irrigation fluid flows in the distal direction over the wire 1128 and out of the terminal distal end 1020 of the sheath 1130. The sheath lumen 1014 may be used for both aspiration 1022 and irrigation 1021 by way of a valve that selectively allows for one or the other to flow through the sheath lumen 1014 (not shown). Sheath lumen 1014 may also be two or more lumens allowing for simultaneous irrigation and aspiration.

In some arrangements, the wire 1128 may reciprocate, may rotate back and forth, or may rotate continuously while the sheath 1130 remains stationary. The wire 1128 may also reciprocate and rotate simultaneously. The repetitive motion of the wire 1128 would break the larger portions of the occlusion 1023 into smaller portions 1024. By breaking the occlusion 40 into smaller portions 1024 it allows the occlusion 40 to be removed from the artificial or natural lumen/cavity and aspirated to the proximal end of the device without clogging the sheath 1130. The stationary sheath 1130 could be realized by stopping the second motor 1117b or by only having one motor 1117 in the device not connected to the sheath 1130. In such an embodiment, the sheath 1130 would not be connected to a second motor 1117b or movable member 1034. The sheath 1130 could, however, still provide aspiration and/or irrigation through sheath lumen(s) 1014. In this embodiment, FIG. 49B shows the sheath 1130 advanced to its most distal position by the user to engage the occlusion 40.

In some embodiments, the wire 1128 may also reciprocate and/or rotate while the sheath 1130 reciprocates and/or rotates. The larger portions 1023 may engage the reciprocating and/or rotating wire 1128 and this repetitive motion may cause the portions 1023 to become further agitated and broken into smaller portions 1024 so that their removal through the sheath lumen 1014 is made easier. The reciprocating and/or rotating wire 1128 may function to break up clogs within the sheath lumen 1014 of the portions 1023 to aid the occlusion clearing device in removing the occlusion 40. The wire 1128 may be arranged so that it remains inside of the sheath 1130 at all times during reciprocation of the

sheath 1130 when the sheath 1130 is engaging and removing the occlusion 40. In this regard, the distal terminal end 1010 of the wire 1128 is proximal to the distal terminal end 1020 of the sheath 1130 when the sheath 1130 is moved into its most proximal position in the longitudinal direction 1000 during the application of the repetitive motion to the sheath 1130. This positioning is shown in FIG. 49A. As previously mentioned, when the sheath 1130 moves to its most distal position in the longitudinal direction 1000 during the application of the repetitive motion, as shown with reference to FIG. 49B, the distal terminal end 1010 is still proximal to the distal terminal end of sheath 1020. It is therefore the case that, at least in some embodiments, the distal terminal end 1010 of wire 1128 is always proximal to the distal terminal end of sheath 1020 during application of the repetitive motion to the sheath 1130 and wire 1128.

In some embodiments, the wire 1128 can be extended from the sheath 1130 so that the distal terminal end 1010 of wire 1128 is located beyond the distal terminal end 1020 of sheath 1130, as in FIG. 58A. The wire 1128 may engage the occlusion 40 to cause the occlusion 40 to break up into the smaller portions 1024. Repetitive motion of the sheath 1130 may also be used by the healthcare provider to engage and remove the occlusion 40 so that the distal terminal end 1020 engages the occlusion 40. In this manner, the healthcare provider may use a combination of the wire 1128 and sheath 1130 in engaging the occlusion 40 and breaking up the occlusion 40 into smaller portions 1024 as needed. Although not shown in FIGS. 49A and 49B, the shaft 1002 of the wire 1128 may in some embodiments be hollow or in other embodiments a multi-lumen so that irrigation and/or aspiration may be conducted through a wire lumen 1128' to further aid in removing the occlusion 40.

It is specifically the distal ends of the sheath 1130 and wire 1128 that engage an occlusion 40 to break it up by mechanical interaction. Accordingly, as seen in FIGS. 45A-46B, the sheath 1130 terminates in a sheath end 1131. In at least one embodiment, the sheath end 1131 is a separate structure that is secured to the distal terminal end of the sheath 1130, such as through welding, adhesion, and other permanent forms of attachment. In other embodiments, the sheath end 1131 may be formed integrally with the sheath 1130. Regardless of the method of attachment, the sheath end 1131 provides structural reinforcement for the distal terminal end of the sheath 1130. The sheath end 1131 may be made of any suitable material providing structural rigidity that is appropriate for use within a body, such as but not limited to, stainless steel, copper, plastics, and hard polymeric materials. In preferred embodiments, the sheath end 1131 is shaped to engage an occlusion 40, 122 and permit aspiration of the occlusion 40, 122 or smaller portions 1023 into a sheath lumen 1014 therein for removal through aspiration, as described above. For instance, in at least one embodiment, the sheath end 1131 includes at least one sheath opening 1102 at or near the distal end. The sheath end 1131 is further structured to limit potential damage to the surrounding portion of the body of the patient 1018 in which the clearing stem 1126 of the occlusion clearing device is positioned. For instance, in at least one embodiment, the sheath end 1131 includes a blunted configuration.

Various configurations of sheath ends 1131 are contemplated, such as depicted in FIGS. 50A-50E. It is noted that any of these sheath end 1131 designs may be used with any wire tip 1134, discussed in greater detail below. Regardless of configuration, the sheath end 1131 includes at least one sheath opening 1102 located at or near the distal tip. When a wire tip 1134 is disposed within the sheath end 1131, and

one or both move by repetitive motion (such as reciprocating motion, rotational motion, or both), the movement of the wire tip 1134 past the sheath opening(s) 1102 creates a shearing force that shears or breaks up material from a nearby occlusion 40, 122. As used herein, “shearing” may include tearing, cutting, slicing, ripping, or any other method by which to separate material from itself. Further, each of these sheath end 1131 designs could be used as part of an assembly that functions as a sheath end 1131 or wire tip 1134, including assemblies that are not fixed and permit the free or driven rotation or linear motion (reciprocating motion in the longitudinal direction) of one component relative to another.

FIG. 50A shows one embodiment of a sheath end 1131a having a single sheath opening 1102a. The sheath opening 1102a is slanted, and is offset from the central axis of the sheath end 1131a such that the sheath opening 1102a does not intersect or coincide with the central axis. The sheath end 1131a further provides a blunt tip to minimize damage to any material or portion of the body of a patient 1018 that the sheath end 1131a may contact.

In another embodiment, as in FIG. 50B, the sheath end 1131b includes a caged design. In this embodiment, the sheath end 1131b contains a bearing tip 1135 that receives or otherwise engages a wire tip 1134 to align the wire tip 1134 axially within the sheath end 1131b and hold it in place while still permitting rotational movement of either the sheath end 1131b, wire tip 1134 or both. Thus, alignment is maintained. The bearing tip 1135 also provides a bearing to prevent displacement and add rigidity to the entire assembly or either of the components. The bearing tip 1135 may be coincident with the axis of the sheath end 1131b, or in other embodiments it may be offset from the center axis. The sheath end 1131b also includes a support arm 1133 that supports the bearing tip 1135. The remainder of the terminal distal end of the sheath end 1131b is open, such that the open end, support arm 1133 and bearing tip 1135 collectively define a distal opening 1102b.

FIG. 50C shows another embodiment of a caged configuration sheath end 1131c, which is similar to that of FIG. 50B but includes two support arms 1133 both connecting to the bearing tip 1135, and thus defining two sheath openings 1102c. In other embodiments, three or more support arms 1133 may be present and connecting to the bearing tip 1135, thus defining a plurality of sheath openings 1102. For instance, FIG. 50D shows another embodiment of the sheath end 1131d having four support arms 1133 and a bearing tip 1135 collectively defining four sheath openings 1102d.

FIG. 50E shows still another embodiment of the sheath end 1131e whereas plurality of sheath openings 1102e are disposed along the length of the sheath end 1131e. In this example, three sheath openings 1102e are provided equidistant around the circumference near the distal tip, although any number of sheath openings 1102e is contemplated. The sheath openings 1102e may be of any shape, including round, slotted, angular, and irregular to name but a few. Further, the sheath openings 1102e may or may not be aligned along the length of the sheath end 1131e or spaced out equally around the circumference of the sheath end 1131e. In addition, a sheath opening 1102e' is located at the distal tip of the sheath end 1131e, effectively creating an open distal tip.

FIG. 50F illustrates another embodiment of a sheath end 1131f having a sheath opening 1102f shaped with a toothed design. This embodiment provides for sharpened teeth along the edges of the sheath opening 1102f to provide additional grip on tissue or material of the occlusion 40, 122. The teeth

also provide additional benefits in the cutting, slicing, or shearing as well as the potential for tearing of the occlusion 40, 122. The particular number, size, shape and disposition of the teeth defining the edge of sheath opening 1102f may vary in different embodiments, and may vary the side clearance, tooth spacing, gullet depth, clearance angles, set and rake.

FIGS. 54A and 54B show another embodiment of the sheath end 1131g having a closed distal tip and at least one sheath opening 1102g. The closed distal tip may preferably be blunted, and the sheath opening 1102g may be recessed or spaced in a longitudinal direction along the sheath end 1131g from the blunted distal tip so as to minimize damage to any material or tissue that the distal tip of the sheath end 1131g may contact. In at least one embodiment, the sheath end 1131g has a single sheath opening 1102g, which permits one side of the device to be placed alongside occlusion material or tissue without risk of damage to the surrounding tissue that is not desired to be removed. Accordingly, more targeted clot removal is possible.

In still another embodiment, as in FIGS. 61A and 61B, a sheath end 1131h includes a plurality of sheath openings 1102h, 1102h'. A primary sheath opening 1102h is located at the distal end of the sheath end 1131h and is slanted. A secondary sheath opening 1102h' is located along the sheath end 1131h a distance apart from the distal tip. As in FIG. 62, the primary sheath opening 1102h is larger than the secondary sheath opening 1102h', and allows bulkier portions of the occlusion 40, 122 to enter the sheath end 1131h. The secondary sheath opening 1102h' permits smaller portions 1023 of the occlusion 40, 122 to enter, to increase the speed at which occlusions 40 may be cleared.

In some embodiment, the sheath end 1131 may also include a restricting member 1136. As shown in FIGS. 51A and 51B, the restricting member 1136 is a structural aspect of the sheath end 1131 to restrict the longitudinal or axial movement of a wire tip 1134 disposed within the sheath end 1131 past the location of the restricting member 1136. For example, a restricting member 1136 can be used to prevent retraction of the wire tip 1134 into the rest of the sheath 1130. Accordingly, the restricting member 1136 may ensure optimal alignment of the wire tip 1134 and sheath end 1131 and prevent axial misalignment of the two components. In at least one embodiment, the restricting member 1136 is an indentation of at least some portion of the circumference of the sheath end 1131, which, in turn, creates a small restriction at one or more locations around the internal dimension of the sheath end lumen 1132 as shown in cross-sectional view in FIG. 51B. In this example, the restricting member 1136 is uniform around the entire circumference of the sheath end 1131, although a non-uniform restricting member 1136 such as a single extrusion or series of extrusions could also function to restrict motion. This small restriction of axial motion, in conjunction with the relatively tight fit of the wire tip 1134 inside the sheath end lumen 1132, prevents the retraction of the wire tip 1134 beyond a defined point. It therefore keeps the wire tip 1134 within the sheath end 1131, preventing it from slipping out into the remainder of the sheath 1130, and maintaining the wire tip 1134 in near proximity to the sheath opening 1102 for shearing purposes.

In one embodiment, as illustrated in FIGS. 52A and 52B, the sheath 1130 further includes an inner sheath conduit 1137 that extends inside the sheath 1130 for the purpose of providing fluids—including liquid and gas—to one or more locations along the inside of the sheath 1130, wire tip 1134, or sheath end 1131. In this example, the inner sheath conduit 1137 provides irrigation to a location just proximal to the

junction of the sheath **1130** and sheath end **1131**. In other embodiments, this inner sheath conduit **1137** may be located in the sheath end lumen **1132**; in the wall thickness of the sheath **1130**, wire tip **1134**, or sheath end **1131**; or in a separate lumen. The inner sheath conduit **1137** provides a flow of material to the sheath lumen **1014** which helps prevent the agglomeration of smaller portions of occlusion **1024** and provides a medium through which the smaller portions of occlusion **1024** can be evacuated through the sheath lumen **1014** even if no fluid (liquid or gas) is present at the distal tip. Accordingly, as demonstrated in FIG. **52B**, the inner sheath conduit **1137** may provide irrigation that is secondary to that being primarily applied to the occlusion **40**, **122**, such as through a channel **1702** of an access device **1700** such as an endoscope, or otherwise applied surrounding the exterior of the sheath **1130**. The flow of materials through the inner sheath conduit **1137** may be steady, constant, or discontinuous as needed.

The clearing stem **1126** of the occlusion clearing device also includes a wire tip **1134** at the terminal distal end of the wire **1128**. The wire tip **1134** may be secured to the wire **1128**, such as through welding, adhesive, crimping, clamping, or other methods of permanent affixation. In other embodiments, the wire tip **1134** may be integrally formed with the end of the wire **1128**. The wire **1128** may be a torque wire, such as depicted in FIG. **54B**, that permits rotational movement with less crimping, bunching, twisting and other unintended motion within the sheath **1130**. In some embodiments, the wire **1128** is a solid shaft. In other embodiments, the wire **1128** includes an interior wire lumen **1128'** as discussed above. The wire tip **1134** may therefore be affixed to the end of the wire **1128** by any method that is appropriate for the type of wire **1128** being used.

The wire tip **1134** is made of a rigid material that provides structural stability to the end of the wire **1128**. For instance, the wire tip **1134** may be made of metal, such as stainless steel, or hard plastic, although other rigid materials are also contemplated. In at least one embodiment, the wire tip **1134** is made of the same material as the sheath end **1131**. The wire tip **1134** is sized to fit within the sheath end **1131**, and is shaped and positioned to work with the sheath end **1131**, and specifically with the sheath opening(s) **1102**, to create shearing forces that break up the occlusion **40**, **122** into smaller pieces **1023**. For instance, in at least one embodiment the wire tip **1134** moves by rotational motion about an axis. The sheath end **1131** may also rotate, such as in an opposite direction, or may remain stationary. The movement of the edge of the wire tip **1134** against the sheath opening **1102** creates shear forces that tear or pull at the occlusion **40**, **122**. In other embodiments, the sheath end **1131** may rotate while the wire tip **1134** also rotates, such as in an opposite direction, or remains stationary. In still other embodiments, the wire tip **1134** may move by reciprocating motion in a longitudinal direction, and the sheath end **1131** also moves by reciprocating motion in an opposite direction. Alternatively, the sheath end **1131** may remain stationary while the wire tip **1134** reciprocates. In still other embodiments, the sheath end **1131** reciprocates while the wire tip **1134** remains stationary. It should be appreciated that either or both of sheath end **1131** and wire tip **1134** can move by reciprocation, rotation, or both, or remain stationary while the other moves to create the shear forces used to break up the occlusion **40**, **122**.

Various shapes are contemplated for the wire tip **1134**. For instance, FIG. **53-54B** show one embodiment in which the wire tip **1134a** in the shape of a flat blade or paddle. In FIG. **53**, the wire tip **1134a** may have a proximal end that may be

crimped over the end of the wire **1128** to secure to the wire **1128**. The opposite distal end may include a bearing tip **1138** or other alignment structure that fits into a corresponding bearing point **1135** on a sheath end **1131** to maintain axial alignment of the wire tip **1134a** during rotational movement. In other embodiments, as in FIG. **54B**, no bearing member **1138** is required.

As seen in FIGS. **54A** and **54B**, a wire tip **1134a** having a flat blade configuration is disposed within a sheath end **1131g**. In this embodiment, the edge of the wire tip **1134a** can be either smooth or textured, and creates a shearing force with the sheath opening **1102g** as they pass each other. Wire tip **1134a** may be used with any configuration of sheath end **1131** discussed above.

In other embodiments, the wire tip **1134** is has a helical shape. For instance, in FIGS. **55A** and **56B**, the wire tip **1134b** has a helical blade configuration, such as may be formed by twisting a flat blade. The wire tip **1134b** may be solid throughout, and may be attached to the wire **1128** by crimping or welding. Alternatively, as mentioned previously and seen in the cross-section of FIG. **55B**, the wire tip **1134b** may have a hollow interior **1012** (similar to a wire lumen **1128'**) which can be used for aspiration. In such cases, the wire tip **1134b** is not crimped to the wire **1128**, but may be affixed by adhesion or integrally formed therewith. The wire tip **1134b** may be used with any sheath end **1131**, but for example can be used with a caged design such as shown in FIGS. **56A** and **56B**. At least one of the wire tip **1134b** and sheath end **1131d** may rotate for repetitive motion to break up the occlusion **40**. A wire **1128**, such as a torque wire transmits mechanical motion to the wire tip **1134b**. A torque wire permits a rotational force applied at a proximal end, and transmits that force its distal end, even after the whole structure undergoes many turns, similar to those that can be found when passing a medical device into a lumen or into the body. This is just one example. Other types of wires **1128** are also contemplated. Reciprocating motion of the wire tip **1134b** is also possible. In at least one embodiment, the wire tip **1134b** is rotated within the sheath end **1131d**, and aspiration occurs through the sheath lumen **1132** around the wire tip **1134b**. The wire tip **1134b** may also have a bearing tip **1138** that coordinates with a bearing point **1135** of the sheath end **1131d** to support and align the wire tip **1134b** during rotation.

In other embodiments, as shown in FIGS. **57A** and **57B**, the wire tip **1134c** may have a helical ribbon **1004** configuration. The wire **1128** may have a shaft **1002** that extends in a longitudinal direction **1000**. The shaft **1002** and the helical ribbon **1004** may be integrally formed with one another, or may be formed from separate pieces to create wire tip **1134c**. The shaft **1002** and helical ribbon **1004** may be made of any type of material such as metal, plastic, composites, or any combination thereof. The helical ribbon **1004** of wire tip **1134c** is located on the exterior surface of the shaft **1002** and extends along at least a portion of the longitudinal length of the shaft **1002**. In addition, the various turns of the helical ribbon **1004** or helical blade **1003** may be identical to one another, or in other embodiments may be different from one another, such as, but not limited to, tapering, modulating, or discontinuous amplitude, variation in the pitch, changes in material type, changes in helical edge **1005** geometry. The helical blade **1003** of wire tip **1134b** and helical ribbon **1004** of wire tip **1134c** can have any shape and may be sized with respect to the shaft **1002** such that the amplitude **1001** is greater than the diameter of the shaft **1002**, or is less than or equal to the diameter of the shaft **1002**. Although shown with three to four turns, any number of turns may be

included in the helical portion. For example, from 1-5, 6-10, 10-20, or up to 50 turns may be present in the helical shape about the axis 1008. As stated, the various turns may all have the same cross-sectional shape, or various turns of the helical blade 1003 of wire tip 1134b or helical ribbon 1004 of wire tip 1134c may have different cross-sectional shapes and sizes with respect to other turns of the helical blade 1003 or helical ribbon 1004.

The wire tip 1134c may define a wire tip lumen 1129 there through as in FIG. 57B. The wire tip lumen 1129 extends to the distal terminal end 1010 such that the distal terminal end 1010 of the wire tip 1134c is open, and on the proximal end connects to a wire 1128 also having a lumen, which may ultimately connect to first port 1595 to exit the clearing stem 1126. In other exemplary embodiments the wire tip lumen 1129 may terminate at the end of the shaft 1002 before the helical shape portion of wire tip 1134c. The wire tip lumen 1129 is shown as a single lumen in the view but may also be two or more lumens. Aspiration and/or irrigation may be conducted through the wire tip lumen(s) 1129. The wire tip lumen 1129 may be circular in cross-sectional shape, or may have various cross-sectional shapes such as square, triangular, hexagonal, or ovalar. Again, the material making up the shaft 1002, and other portions of the wire tip 1134c may be plastic, metal, or any other material or combination of materials.

The wire tip 1134 may also include a restricting member 1136'. As seen in FIGS. 58A and 58B, a restricting member 1136' may be located on a distal end of the wire tip 1134 (seen here as wire tip 1134b) to provide one or more of several functions. Primarily, the restricting member 1136' prevents retraction of the wire tip 1134 relative to the sheath end 1131 (seen here as sheath end 1131e), to maintain the wire tip 1134b within the sheath end 1131e. The restricting member 1136' also provides a bearing surface against the tip of the sheath end 1131e, as seen in FIG. 58B, to prevent displacement and add rigidity to the wire tip 1134b. Indeed, the restricting member 1136' may receive or otherwise coordinate with the bearing tip 1138 of the wire tip 1134b to join to the end of the wire tip 1134b. This functional restricting member 1136' may be an integrated component, such as formed integrally with, either the wire tip 1134b or sheath end 1131e. In other embodiments it maybe a separate component affixed to either the wire tip 1134b or sheath end 1131e. Also, it may be used with any configuration of wire tip 1134 or sheath end 1131. In the embodiment of FIGS. 58A and 58B, the restricting member 1136' is attached to the wire tip 1134b and rotates with the wire tip 1134b while preventing retraction into the sheath end 1131e. Depending on the design of the rest of the occlusion clearing device, the restricting member 1136' and the wire tip 1134b could be permitted to extend beyond the sheath end 1131e, as in FIG. 58A, either as part of the morcellating action or as a way of clearing clogs in the inner lumen where the clog is located or varying the morcellating action. In another embodiment, the restricting member 1136' could be attached to, or integral with, the sheath end 1131e. Further, the restricting member 1136' may be attached to a wire tip 1134 or sheath end 1131 during assembly to ease the assembly process.

In still another embodiment, the wire tip 1134 may have a tubular configuration, such as defining an interior hollow or wire tip lumen 1129, as seen in FIGS. 59A-60B. FIG. 59A shows an exploded view of the wire tip 1134d and sheath end 1131a, and FIG. 59B shows the components combined such that the wire tip 1134d is placed inside the sheath end 1131a. When so positioned, the wire opening 1104 lines up with the sheath opening 1102a, and together they provide for

a cutting, shearing, or slicing action when rotational or reciprocating linear motion is applied to one or both the wire tip 1134d and sheath end 1131a.

As seen in the cross-section of FIG. 59D, the wire tip 1134d may be attached to, or is an integral part of the wire 1128. A sheath end 1131a is attached to or is an integral part of the sheath 1130.

In this embodiment, the wire 1128 and wire tip 1134d are hollow. The distal tip of the wire tip 1134d is shaped with wire opening 1104 that is positioned and resides within a similarly shaped part of the sheath end 1131a. As the wire tip 1134d is moved with by otational motion, indicated by arrow 1105, the wire opening 1104 is positioned so that it aligns with the sheath opening 1102a, creating a continuous path between the two openings 1102a, 1104. As shown in FIGS. 60A-60B, as the wire tip 1134d rotates, the wire opening 1104 also rotates, such that, when rotated 180° shown in FIG. 60B the wire opening 1104 is then positioned facing away from the sheath opening 1102a. The action from this rotation and alternating of opening and closing on a clog 40 breaks the clog 40 into smaller portions of occlusions 1024. The clog 40 maybe aspirated into the wire tip 1134d, broken into smaller portions of occlusions 1024 from the slicing action caused by the opening and closing of the sheath opening 1102a due to the rotation of the wire tip 1134d, and pulled proximally through the wire tip lumen 1129 and wire lumen 1128', and removed from the lumen or patient at the first port 1595.

In this example, the wire tip 1134d is rotated while the sheath end 1131a is held stationary, but other embodiments include a stationary wire tip 1134d and a rotating sheath end 1131a, and a design where both wire tip 1134d and sheath end 1131a rotate in either co-rotating or counter-rotating directions. In still other embodiments, the wire tip 1134 and sheath end 1131 move with linear motion, reciprocating in the longitudinal direction, with or without rotational motion.

In the embodiment shown in FIGS. 59A-59D, neither the wire opening 1104 nor the sheath opening 1102a intersects the central axis 1106. When the wire tip 1134d is rotated relative to the sheath end 1131a, the continuous path between then openings 1102a, 1104 is broken momentarily.

In other embodiments, as shown in FIGS. 60A-60B, the wire opening 1104 and the sheath opening 1102a maintain a continuous path when the wire tip 1134d is rotated relative to the sheath end 1131a. For example, if the wire opening 1104 and sheath opening 1102a intersect the central axis 1106 of the sheath end 1131a, this provides an orifice or aperture that is continuously open even as the wire tip 1134d is rotated relative to the sheath end 1131a. This ensures constant suction as well as preventing any cutting, shearing, or slicing action in this central aperture. In still other embodiments, as depicted in FIGS. 61A-62, a wire tip 1134e includes a slanted wire opening 1104' that coordinates with sheath openings 1102h, 1102h' of a sheath end 1131h during reciprocating longitudinal motion to shear occlusion material. Although other designs could be used, the sheath end 1131h in this example includes a primary slanted sheath opening 1102h at the distal end and an additional secondary sheath opening 1102h' proximal to the primary slanted sheath opening 1102h. linear reciprocating motion in the longitudinal direction (indicated by arrow 1143) of the wire tip 1134e relative to the sheath end 1131h permits a cutting, shearing, or slicing action at both the sheath openings 1102h, 1102h'. As depicted in FIG. 61B, the primary wire tip 1134e contains a backward shear point 1145 that permits cutting, shearing, or slicing in conjunction with a corresponding backward shear point 1145' on the sheath end 1131h when

the wire tip **1134e** is moved rearward (proximally) in a longitudinal direction. The secondary sheath opening **1102h'** provides for continued material flow through the wire tip lumen **1129** to help evacuate the dislodged contents. In addition, the wire tip **1134e** also includes a forward hear point **1146** that permits cutting in conjunction with a corresponding forward shear point **1146'** on the sheath end **1131h** on the forward (distal) stroke of longitudinal motion. During the forward (distal) stroke, the blunt tip of the wire tip **1134e**, which matches the shape of the sheath end **1131h**, causes the ejection of any material that has gathered in the area of the primary sheath opening **1102h** during the stroke in the rearward (proximal) direction of the wire tip **1134e**. In another embodiment, a wire tip **1134e** has an open end that performs the cutting, slicing, or shearing on the forward (distal) stroke by providing an additional forward shear point on the end of the wire tip **1134e**. This open end design maybe integrated into the wire tip **1134e** to permit a cutting, slicing, or shearing action in both directions. Although described above as being used with linear motion, other embodiments contemplate using this or similar designs with rotational motion, including with both rotational and linear motion. When used with rotational motion, the secondary sheath opening **1102h'** maybe offset around the circumference of the sheath end **1131h** by any number of degrees of rotation.

FIG. **62** illustrates the device shown in FIGS. **61A** and **61B** being used to clear a clog **40**, **122** or other larger portion of occlusion **1023**. The larger portion of occlusion **1023** or other material is permitted to enter the aligned primary sheath opening **1102h** of the sheath end **1131h** and the wire opening **1104'** of the wire tip **1134e**—which can be aided by suction being applied to the inner wire tip lumen **1129** of the wire tip **1134e**. As the wire tip **1134e** is moved rearward (proximally) relative to the sheath end **1131h**, the occlusion or clog **40**, **122** is broken up, with the smaller portions of occlusion **1024** being evacuated out rearward (proximally) through the inner wire tip lumen **1029**. At some point, including during the entire stroke, the wire opening **1104'** on the wire tip **1134e** passes the secondary sheath opening **1102h'** of the sheath end **1131h**, allowing the larger portion of occlusion **1023** or other material to enter the secondary sheath opening **1102h'**, even if the primary sheath opening **1102h** is closed or blocked. On the return forward (distal) stroke, the larger portion of occlusion **1023** is broken up at the forward shear point **1146**, **1146'** and is evacuated out rearward through the inner lumen, while at the same time, the blunt tip of the wire tip **1134e** ejects any material that has flowed into the vacated area of the primary sheath opening **1102h**.

Turning now to the proximal end of the clearing stem **1126**, FIGS. **63A** and **63B** show the proximal end of one embodiment of the clearing stem **1126** illustrating the proximal end of the sheath **1130** and having a solid wire **1128**, such as a torque wire, disposed within the sheath lumen **1014**. Wire tips **1134a**, **1134b**, and **1134c** may be used at the distal end of such wire **1128**. The sheath lumen **1014** is in fluid communication and continuous with the first chamber **1161** and first port lumen **1160** that exits the device through the first port **1595**. Accordingly, materials aspirated through the sheath lumen **1014** and around the wire **1128** may exit through the first port **1595**. Although not shown, it is contemplated that in other embodiments, the clearing stem **1126** includes a sheath **1130** and a wire **1128** having a wire lumen **1128'**, such as may be used in conjunction with wire tips **1134d**, **1134e** at the distal end. In such embodiments, the wire lumen **1128'** is continuous and in fluid communication

with the first chamber **1161** and first port lumen **1160** that exits the device through the first port **1595**, for aspiration and exit of occlusion particles from the device through the wire **1128**.

FIG. **64** shows one embodiment of the housing **1115** that includes a receiver housing **1120** where the proximal end of the clearing stem **1126** connects to the remainder of the occlusion clearing device through the alignment member **1142**. As shown in FIG. **65A**, the proximal end of the sheath lumen **1014** is continuous with and in fluid communication with the first chamber **1161** and first port lumen **1160** that exits the device through the first port **1595**, so as to provide an exit for the occlusion material being aspirated through the sheath lumen **1014** of the sheath **1130**. The wire **1128** extending through the sheath lumen **1014** exits the sheath **1130** and continues through a third seal **1152** in the stem housing **1120**. The third seal **1152** creates a fluidically tight seal around the wire **1128** so that material being aspirated through the sheath lumen **1014**, first chamber **1161** and first port lumen **1160** cannot go beyond the third seal **1152**. In other embodiments, the wire **1128** terminates at the third seal **1152**. The alignment member **1142** includes a fourth seal **1153** opposite from the third seal **1152**. The fourth seal **1153** forms a fluid tight seal around the sheath **1130**, so that the first chamber **1161** is fluidically sealed. In some embodiments, the stem port **1595** may provide irrigation or aspiration, or both if a switch is used to control irrigation or vacuum sources. In still further embodiments, additional stem ports **1595** may be included, such as when the sheath **1130** includes an inner sheath conduit **1137** for secondary irrigation, as in FIGS. **52A** and **52B**.

Returning to FIGS. **64-65B**, the housing **1115** also includes a drive housing **1116** that includes at least one motor **1117a**, **b** that is used to provide linear and/or rotational motion as described previously to one or more of the sheath **1130** and sheath end **1131**, and wire **1128** and wire tip **1134**. As discussed previously, a motor **1117a**, **b** may provide both reciprocating motion and rotational motion, or as depicted in FIG. **47A**, there may be multiple motors **1117a**, **1117b**, where one provide rotational motion and the other provides reciprocating motion. Motors **117a**, **b** that can produce reciprocating or rotational motion are discussed in detail above, and can be used similarly in these embodiments. In addition, the drive housing **1116** may also contain controls for stopping, starting, or varying the motor(s)' **1117** speed and direction, vacuum suction level, or irrigation flow. The controls may include valves, such as binary on/off switches or variable valves or controls.

The drive housing **1116** is preferably separate from the receiver housing **1120** so that the receiver housing **1120** may be disposable and and the drive housing **1116** and motor(s) **1117** are reusable. However, in some embodiments, the drive housing **1116** and receiver housing **1120** are in a single unified housing **1115** that is either disposable or reusable.

In the embodiment of FIGS. **64-65A**, the receiver housing **1120** is separate from, but selectively attached to the drive housing **1116**. The housing **1115** contains a mechanism for connecting the drive housing **1116** and receiver housing **1120**, and for transmitting the motor(s) **1117a**, **b** motion to the clearing stem **1126**, specifically, the sheath **1130** and wire **1128**. In the embodiment of FIGS. **64-65B**, the drive housing **1116** includes a connector **1118** that extends from the surface of the drive housing **1116** and is shaped to interact with or fit into a correspondingly shaped and dimensioned receiver **1121** on the receiver housing **1120**. For instance, the connector **1118** may be a square shaped extension, and the receiver **1121** may be a square shaped recession, although

other shapes and configurations are also contemplated. For instance, in other embodiments, the connector 1118 and receiver 1121 may be hexagonal, octagonal, triangular, rhomboidal, or may even be shaped as a bayonet catch or include friction plates or textured plates or cones. Because of the shaped connector 1118 and receiver 1121, not only are the two components connected, but also the rotational motion produced by the motor 1117a, b is transferred to the receiver housing 1120 and on to the sheath 1130 and/or wire 1128. Further, the receiver housing 1120 may incorporate a biasing element 1140, such as a spring, that provides several functions. For instance, the biasing element 1140 provides a positive force on the wire 1128 that can be used in conjunction with, for example, the restricting member 1136, 1136' and/or bearing tip 1138 to hold the wire tip 1134 and sheath end 1131 in specific positions relative to one another, while still allowing rotational or linear reciprocating motion. The biasing element 1140 also provides a positive force against the receiver 1121 and/or connector 1118 for to hold the receiver housing 1120 and drive housing 1116 together. Further, depending on the design and depth of the receiver 1121, the biasing element 1140 can allow the receiver 1121 to act as clutch to limit the force provided or transmitted to the distal components of the clearing stem 1126 by the motor(s) 1117a, b. The clutch action can be used to prevent the slicing of specific tissues not associated with the clog 40, 122 or to prevent damage of any of the other device components due to excessive force from clogging, jamming, or contacting hard or tough material. Although not shown, the motor(s) 1117a, b can be powered internally, externally, or even manually.

As is shown in FIG. 65B, the repetitive motion generated by the motor 1117a, 1117b is transferred to the sheath 1130 and/or wire 1128 through the components of the receiver housing 1120. For instance, in one embodiment the motor 1117a provides reciprocating motion, which is conveyed to the wire 1128 through the connection between the connector 1118 and receiver 1121. The opposite end of the receiver 1121 may be connected to a shaft or elongate member that reciprocates with the transferred motion from the motor 1117a. The opposite end of this elongate member or shaft may be connected to the wire 1128 to similarly move the wire 1128, or may be connected to the third seal 1152 or alignment member 1142 to transfer the motion to the sheath 1130. In another embodiment, in which the motor 1117b provides rotating motion, the interlocking shapes of the connector 1118 and receiver 1121 transfer the rotating motion to the elongate shaft or wire 1128 that may be connected to the receiver 1121. The elongate shaft may in turn connect to the third seal 1152 or sheath to permit transfer of rotational motion to the sheath 1130. These are exemplary embodiments, and any method of transferring the repetitive motion, be it reciprocating or rotational, to the wire 1128, sheath 1130 or both, is contemplated.

The handset or housing 1115 of the occlusion clearing device is intended to be gripped or held in the hand of a practitioner or clinician using the device, such as is seen in FIG. 66. In this embodiment, the clinician inserts the distal end of the clearing stem 1126, leading with the sheath end 1131 and wire tip 1134, into the working channel 1702 of an access device 1700, such as an endoscope. The working channel 1702 permits the clearing stem 1126 to pass through and exit out the tip of the access device 1700. The motion of the clearing stem 1126, and correspondingly the sheath end 1131 and wire tip 1134, is controlled by the motor(s) 1117a, 1117b, which generate mechanical motion to be transmitted to the sheath 1130, sheath end 1131, wire 1128, and wire tip

1134 where the mechanical motion helps break up and remove an occlusion or clog 40 from within a lumen or opening within the body. Although depicted here with an endoscope, it should be appreciated that any access device 1700 may be used to access the interior of a patient's body. Also, as discussed previously, such as in the embodiments of FIGS. 45A and 45B an access device 1700 is not needed to access the lumen within the patient's body. For instance, in at least one embodiment, the distal end of the clearing stem 1126, leading with the sheath end 1131 and wire tip 1134, may be inserted directly into the lumen, such as a feeding tube or other natural or artificial lumen that is accessible from outside the patient's body. Regardless of the embodiment, the handset or housing 1115 is gripped by the hand of a user for placement, positioning, and actuation of the motor(s) 1117a, 1117b that create the repetitive motion (reciprocating and/or rotational) as well as the controls for irrigation and/or aspiration flow control.

FIG. 67 shows another embodiment of the handset or housing 1115', which is attached to an access device 1700, such as an endoscope. Here, the housing 1115' may include all the components of the alignment member 1142, receiver housing 1120 and drive housing 1116 discussed above, but can be mounted and affixed directly onto the access device 1700. This embodiment permits a single user to handle both the access device 1700 and the occlusion clearing device by the housing 1115'.

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

APPENDIX-continued

Reference Characters and Their Associations		
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
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

APPENDIX-continued

Reference Characters and Their Associations		
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
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'

Reference Characters and Their Associations		
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'
594	External Flowable-Medium Source Port	TC1'
595	Valve	TC1'
596	Displaceable End	TC1'
599A	Fixed End	TC1'
599B	Distal End Portion	TC1'
600	Split Stem	TC1'
528	Reciprocating Member/Wire	TC1'
528A	Reciprocating Member Distal Tip	TC1'
593	Conduit	TC1'
593E	Split Conduit	TC1'
601	Conduit Cutter	TC1'
602	No. 15 Scalpel Blade	TC1'
603	Scalpel Blade Channel	TC1'
604	Conduit Channel	TC1'
605	Conduit Splitter	TC1'
606	Spike	TC1'
606A	Spike Exit port	TC1'
607	Hypodermic Tubing	TC1'
608	Hypodermic Tubing Channel	TC1'
609	Stem Channel	TC1'
610	Wire Channel	TC1'
611	Conical Conduit Guide	TC1'
1000	Longitudinal Direction	TC1'
1001	Amplitude	TC1'
1002	Shaft	TC1'
1003	Helical Blade	TC1'
1004	Helical Ribbon	TC1'
1005	Helical Edge	TC1'
1008	Axis	TC1'
1010	Distal Terminal End of Wire	TC1'
1012	Lumen	TC1'
1014	Sheath Lumen	TC1'
1016	Exterior Outer Surface	TC1'
1018	Portion of Body of Patient	TC1'
1020	Distal Terminal End of Sheath	TC1'
1021	Irrigation	TC1'
1022	Aspiration	TC1'
1023	Larger Portions of Occlusions	TC1'
1024	Smaller Portions of Occlusions	TC1'
1026	Second Controller	TC1'
1028	Vacuum Source	TC1'
1030	Seal	TC1'
1032	Wire Moveable Member	TC1'
1034	Shaft Moveable Member	TC1'
1102	Sheath End Opening	TC1'
1102a	Sheath End Opening (slanted opening)	TC1'
1102b	Sheath End Opening (caged, 1-port opening)	TC1'
1102c	Sheath End Opening (caged, 2-port opening)	TC1'
1102d	Sheath End Opening (caged, 4-port opening)	TC1'
1102e, 1102e'	Sheath End Opening (open distal end, side openings)	TC1'
1102f	Sheath End Opening (toothed opening)	TC1'

Reference Characters and Their Associations		
1102g	Sheath End Opening (side opening only)	5
1102h, 1102h'	Sheath End (slant opening + secondary)	5
1104, 1104'	Wire Tip Tube Opening	10
1105	Rotation	10
1106	Axis of Rotation	10
1115, 1115'	Housing	10
1116	Drive Housing	10
1117a	Motor (reciprocating)	10
1117b	Motor (rotating)	10
1118	Connector	10
1120	Receiver Housing	10
1121	Receiver	15
1128	Wire	15
1128'	Wire Lumen	15
1126	Clearing Stem	15
1129	Wire Tip Lumen	15
1130	Sheath	15
1131	Sheath End	15
1131a	Sheath End (slanted opening)	15
1131b	Sheath End (caged, 1-port opening)	15
1131c	Sheath End (caged, 2-port opening)	15
1131d	Sheath End (caged, 4-port opening)	15
1131e	Sheath End (open distal end, side openings)	15
1131f	Sheath End (toothed opening)	15
1131g	Sheath End (side opening only)	15
1131h	Sheath End (slant opening + secondary)	15
1132	Sheath End Lumen	15
1133	Support Arm	15
1134	Wire Tip	30
1134a	Wire Tip (flat paddle)	30
1134b	Wire Tip (helical blade)	30
1134c	Wire Tip (helical ribbon)	30
1134d	Wire Tip (tube)	30
1134e	Wire Tip (tube with shearing points)	30
1135	Bearing Point	35
1136	Restricting Member (on sheath - corset)	35
1136'	Restricting Member (on wire - cap)	35
1137	Inner Sheath Conduit	35
1138	Bearing Tip	35
1140	Biasing Element	40
1145	Backward Shear Point (on wire tip)	40
1145'	Backward Shear Point (on sheath end)	40
1146	Forward Shear Point (on wire tip)	40
1146'	Forward Shear Point (on sheath end)	40
1150	First Seal	45
1151	Second Seal	45
1152	Third Seal	45
1153	Fourth Seal	45
1160	First Port Lumen	45
1161	First Chamber	45
1162	Adaptor	45
1163	Second Port	45
1164	Second Port Lumen	45
1165	Second Chamber	45
1595	First Port	50
1700	Access Device	50
1702	Channel	50
1703	Access Port	50

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. An occlusion clearing device, comprising:
 - a sheath having a distal end and a proximal end and a lumen extending from said proximal end to said distal end;

a sheath end attached to said distal end of said sheath, said sheath end having at least one sheath opening and a sheath end lumen extending through said sheath end from said sheath opening to said lumen of said sheath;

a wire having a distal end and a proximal end, said wire positioned in said lumen of said sheath;

a wire tip attached to said distal end of said wire and positioned within said sheath end;

at least one motor generating repetitive motion including at least one of reciprocating motion in a longitudinal direction and rotational motion about an axis;

said proximal end of at least one of said sheath and said wire in mechanical communication with said at least one motor and receiving said repetitive motion;

said sheath end and said wire tip collectively creating shearing force during said repetitive motion to break up an occlusion; and

a housing including a receiver housing including a receiver, and a drive housing including said at least one motor and a connector, wherein said receiver housing and said drive housing are selectively attached in mechanical communication of said repetitive motion from said at least one motor to at least one of said sheath and said wire.

2. The occlusion clearing device of claim 1, wherein said rotational motion comprises at least one of rotating in a consistent direction about said axis and rotating in alternating directions about said axis.

3. The occlusion clearing device of claim 1, wherein each of said sheath and said wire receive repetitive motion from said at least one motor.

4. The occlusion clearing device of claim 3, wherein each of said sheath and said wire receive reciprocating motion in a longitudinal direction.

5. The occlusion clearing device of claim 3, wherein each of said sheath and said wire receive rotational motion about an axis.

6. The occlusion clearing device of claim 1, further comprising a first motor generating repetitive motion including at least one of reciprocating motion in a longitudinal direction and rotational motion about said axis, and a second motor generating repetitive motion including at least one of reciprocating motion in a longitudinal direction and rotational motion about said axis, wherein said wire receives repetitive motion generated by said first motor and said sheath receives repetitive motion generated by said second motor.

7. The occlusion clearing device of claim 6, wherein said repetitive motion generated by both said first and second motors are reciprocating motion in a longitudinal direction.

8. The occlusion clearing device of claim 6, wherein said repetitive motion generated by both said first and second motors are rotational motion about said axis.

9. The occlusion clearing device of claim 1, wherein said wire tip includes at least one of a flat, helical, and tubular configuration.

10. The occlusion clearing device of claim 9, wherein said wire tip includes a tubular configuration and at least one wire opening that is at least partially aligned with said sheath opening during a portion of said repetitive motion.

11. The occlusion clearing device of claim 10, wherein said wire further includes a wire lumen extending from said proximal end to said distal end of said wire and providing at least one of irrigation and aspiration and said wire tip includes a wire tip lumen extending between and in fluid communication with said wire opening and said wire lumen.

12. The occlusion clearing device of claim 1, wherein said at least one sheath opening is located along at least one of a length of said sheath end and a distal terminal end of said sheath end.

13. The occlusion clearing device of claim 1, wherein said sheath end includes a partially closed distal tip.

14. The occlusion clearing device of claim 1, wherein said sheath end lumen provides at least one of irrigation and aspiration.

15. The occlusion clearing device of claim 1, wherein said sheath further includes an inner sheath conduit providing irrigation to said sheath lumen.

16. The occlusion clearing device of claim 1, further comprising a first port having a first port lumen and first chamber in fluid communication with said first port lumen, said first chamber and said first port lumen in fluid communication with at least one of said sheath lumen and said wire lumen for providing at least one of irrigation and aspiration.

17. The occlusion clearing device of claim 1, wherein at least one of said sheath end and said wire tip includes a restricting member limiting the movement of said wire tip within said sheath end beyond a defined point.

18. The occlusion clearing device of claim 1, wherein said receiver and said connector are correspondingly configured for selectively releasable interlocking attachment.

19. The occlusion clearing device of claim 1, wherein said receiving housing further comprises a biasing element positioned in biasing relation to at least one of said receiver and said wire.

20. The occlusion clearing device of claim 1, wherein said receiver housing is disposable and said drive housing is reusable.

21. The occlusion clearing device of claim 1, further comprising an adaptor movably disposable along said sheath, said adaptor having a second chamber and a second port with a second port lumen in fluid communication with second chamber and providing at least one of irrigation and aspiration through said second chamber.

22. A system for occlusion clearing comprising the occlusion clearing device of claim 21, and further comprising an access device having an access port and a channel in fluid communication with said access port, wherein said sheath end and said wire tip of said occlusion clearing device are inserted through said adaptor and into said access device port for entry into said channel, and wherein said channel is in fluid communication with said second chamber and said second port lumen.

23. A system for occlusion clearing comprising the occlusion clearing device of claim 1, and further comprising an access device having an access port and a channel in fluid communication with said access port, wherein said sheath end and said wire tip of said occlusion clearing device are inserted into said access port for entry into said channel.