Office de la Propriété Intellectuelle du Canada
Un organisme d'Industrie Canada

Canadian Intellectual Property Office
An agency of Industry Canada

CA 2768009 A1 2011/01/20

(21) 2 768 009

(12) DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION

(13) A1

(86) Date de dépôt PCT/PCT Filing Date: 2010/07/15
(87) Date publication PCT/PCT Publication Date: 2011/01/20
(85) Entrée phase nationale/National Entry: 2012/01/12
(86) N° demande PCT/PCT Application No.: US 2010/042128
(87) N° publication PCT/PCT Publication No.: 2011/008948
(30) Priorité/Priority: 2009/07/15 (US61/225,893)

(51) Cl.Int./Int.Cl. *A61F 11/00* (2006.01),
A61B 17/34 (2006.01)

(71) Demandeur/Applicant:
ACCLARENT, INC., US

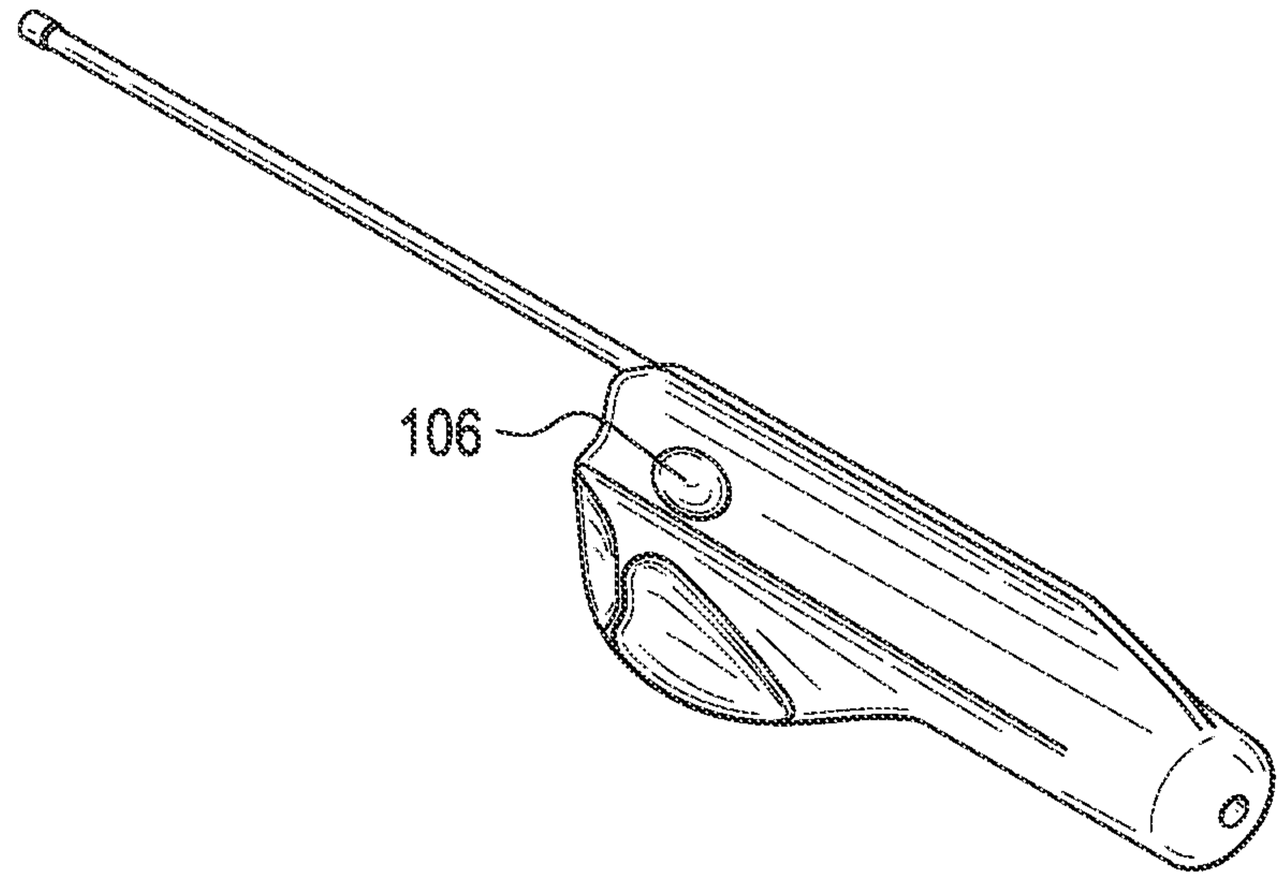
(72) Inventeurs/Inventors:
LIU, GREG, US;
GIROTRA, ROHIT, US;
MORRISS, JOHN H., US;
VRANY, JULIE D., US;
HA, HUNG V., US;
KNODEL, BRYON, US;
WALKER, JEFFREY A., US;
...

(74) Agent: NORTON ROSE CANADA

(54) Titre : SYSTEME DE MISE EN PLACE D'UN TUBE D'EQUILIBRAGE DE PRESSION DE LA MEMBRANE DU TYMPAN

(54) Title: TYMPANIC MEMBRANE PRESSURE EQUALIZATION TUBE DELIVERY SYSTEM

FIG. 1E



(57) Abrégé/Abstract:
Systems and methods are provided for automatically forming an incision in a tympanic membrane of an ear and placing a tympanic membrane pressure equalization tube into the incision. The systems include a housing with a shaft extending therefrom. A mechanism is disposed within the housing. A distal end of the shaft is placed against a tympanic membrane, and the mechanism is triggered to causes the tympanic membrane to be automatically incised and dilated and a tympanic membrane pressure equalization tube to be placed in the dilated incision.

CA 2768009 A1 2011/01/20

(21) 2 768 009

(13) A1

(72) Inventeurs(suite)/Inventors(continued): GROSS, THOMAS DANIEL, US; CLOPP, MATHEW D., US; ANDREAS, BERNARD H., US

(74) Agent(suite/continued): S.E.N.C.R.L.,S.R.L./LLP

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 January 2011 (20.01.2011)

PCT

(10) International Publication Number
WO 2011/008948 A1

(51) International Patent Classification:
A61F 11/00 (2006.01) *A61B 17/34* (2006.01)

(21) International Application Number:
PCT/US2010/042128

(22) International Filing Date:
15 July 2010 (15.07.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/225,893 15 July 2009 (15.07.2009) US

(71) Applicant *(for all designated States except US)*: **ACCLARENT, INC.** [US/US]; 1525-B O'Brien Drive, Menlo Park, CA 94025 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **LIU, Greg** [US/US]; 1244 Parkington Avenue, Sunnyvale, CA 94087 (US). **GIROTRA, Rohit** [IN/US]; 886-A De Haro Street, San Francisco, CA 94107 (US). **MORRISS, John, H.** [US/US]; 725 A Wisconsin Street, San Francisco, CA 94107 (US). **VRANY, Julie, D.** [US/US]; 317 Blue Oak Lane, Los Altos, CA 94022 (US). **HA, Hung, V.** [US/US]; 2974 Delancey Court, San Jose, CA 95135 (US). **KNODEL, Bryon** [US/US]; 6050 W. Saskan Ranch Circle, Flagstaff, AZ 86001 (US). **WALKER, Jeffrey, A.** [US/US]; 2687 Elston Streeet, Livermore, CA 94550 (US). **GROSS, Thomas, Daniel** [US/US]; 200 Kimble Avenue, Los Gatos, CA 95030 (US). **CLOPP, Mathew, D.** [US/US]; 3435 Notre Dame Drive, Santa Clara, CA 95021 (US). **ANDREAS, Bernard, H.** [US/US]; 633 California Way, Redwood City, CA 94062 (US).

(74) Agents: **JOHNSON, Philip, S.** et al.; JOHNSON & JOHNSON, One Johnson & Johnson Plaza, New Brunswick, NJ 08933 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

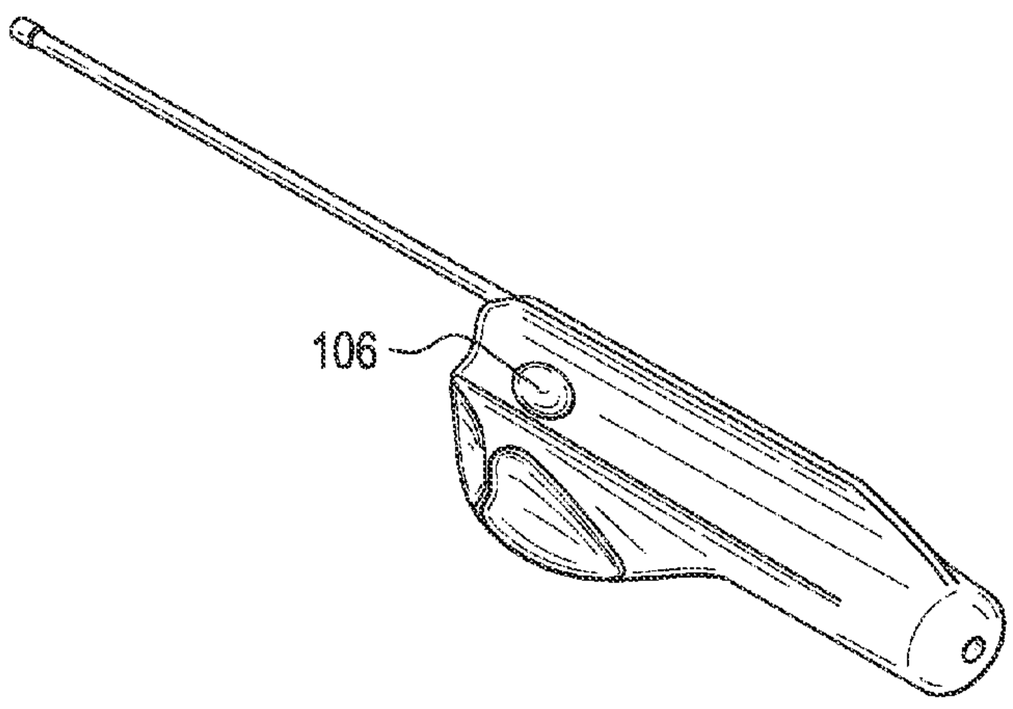
— *as to the identity of the inventor (Rule 4.17(i))*

Published:

— *with international search report (Art. 21(3))*

(54) **Title**: TYMPANIC MEMBRANE PRESSURE EQUALIZATION TUBE DELIVERY SYSTEM

FIG. 1E



(57) **Abstract**: Systems and methods are provided for automatically forming an incision in a tympanic membrane of an ear and placing a tympanic membrane pressure equalization tube into the incision. The systems include a housing with a shaft extending therefrom. A mechanism is disposed within the housing. A distal end of the shaft is placed against a tympanic membrane, and the mechanism is triggered to causes the tympanic membrane to be automatically incised and dilated and a tympanic membrane pressure equalization tube to be placed in the dilated incision.

WO 2011/008948 A1

TYMPANIC MEMBRANE PRESSURE EQUALIZATION TUBE DELIVERY SYSTEM

BACKGROUND OF THE INVENTION

This application claims benefit of provisional application Ser. No. 61/225893, filed July 15, 2009, the disclosure of which is expressly incorporated by reference herein.

The present invention is generally related to medical devices and apparatus. In particular, the invention provides systems and methods for delivering a pressure equalization tube to a tympanic membrane of an ear.

Otitis media is among the most common diagnoses made by pediatricians. A majority of children may have at least one episode of otitis media ("earache") prior to their third birthday. Otitis media is often caused by an inability of the eustachian tube to drain fluid from the middle ear. Otitis media is often treated with antibiotics.

A significant number of children exhibit recurrent episodes of otitis media and/or otitis media with effusion. Treatment of these more severe cases often involves the placement of a tympanostomy tube through the tympanic membrane to provide adequate drainage of the middle ear and reduce the likelihood of future infections. Tympanostomy tubes provide fluid communication between the middle and outer ear (e.g., pressure equalization) and typically fall out spontaneously within about a year of placement. Tympanostomy tube placement is among the most frequent surgical procedures performed in the pediatric population. It has been estimated that more than a million tympanostomy tubes may be placed each year, with typical patients being between about 18 months and 7 years of age at the time of the procedure.

Tympanostomy tube placement is typically performed in an out-patient surgery setting under general anesthesia. The physician typically first examines the external auditory canal and tympanic membrane under microscopic visualization through a hand-held conical shaped speculum. The physician then makes an incision in the tympanic membrane (a "myringotomy"), typically using a standard, small profile scalpel which the physician advances through the conical speculum. In many cases, the physician will then place the tympanostomy tube through the tympanic membrane, typically using a basic tool for holding and advancing the tube into the myringotomy. The physician may then pass a suction device through the tube, into the middle ear, to aspirate fluid/effusion from the middle ear.

A wide variety of tympanostomy tubes is commercially available, and a still wider variety of other tubes has been proposed. Systems have also been proposed to both perform the myringotomy and deploy the tympanostomy tube with a single treatment assembly. In recent years, more complex and expensive systems have been proposed for diagnosis or treatment of the tissues of the ear, including systems using laser energy for forming a myringotomy, video systems for imaging of the ear canal, and the like. These various proposed alternatives for tympanostomy tubes and tube placement systems have met with varying degrees of acceptance. Some proposed alternatives have been overly complex, overly expensive and/or ineffective. Thus, have primarily used standard tubes and tube placement procedures and devices.

A standard tympanostomy tube placement procedure is both effective and quite safe. Nonetheless, further improvements would be desirable. For example, the standard tube placement procedure described above requires multiple tools (speculum, scalpel, tube placement device) and usually requires the patient to be under general anesthesia. Tympanostomy tube placement error can occur due to using multiple operator-performed steps and devices, and/or patient movement. The likelihood of error is increased when operating on young children under local anesthesia, as they often find it difficult to remain in a stationary position for an extended period of time.

One disadvantage of currently available tube placement methods is that the tympanostomy tubes may fall out of the tympanic membrane sooner than would be ideal. This may be due to the fact that the myringotomy must be made large enough to allow the distal flange on a standard tympanostomy tube to pass through it, and thus the typical myringotomy may be larger than ideal for holding the tube in place.

Another disadvantage of currently available tube placement methods is that the myringotomy needed to insert the tympanostomy tube is relatively large and may cause increased scaring during the healing process.

In light of the above, it would be desirable to provide improved devices, systems, and methods for delivering a pressure equalization tube to a tympanic membrane. It would generally be beneficial if these improvements facilitated tympanostomy tube placement without requiring multiple devices and operator-performed steps. At least some of these advantages may be provided by the embodiments described herein.

BRIEF SUMMARY OF THE INVENTION

The present invention provides systems and methods for automatically puncturing and delivering a tympanic membrane equalization tube (i.e., tympanostomy tube) into a tympanic membrane.

In one aspect, a system is provided for delivering a pressure equalization tube. The system includes a housing including a handle. An elongate shaft assembly is coupled with the housing. The shaft assembly includes an outer shaft having a blunt (atraumatic) distal tip portion. The distal tip portion of the elongate shaft has an inner diameter that may be equal to or larger than the inner diameter of the remainder of the outer shaft. A cutter is linearly moveable within the elongate shaft. A pusher is slidably disposed over the cutter within the elongate shaft. A pressure equalization tube is slidably disposed about the cutter at a distal end of the pusher. A shield is slidably disposed over the pusher and the pressure equalization tube. A dilator is slidably disposed over the shield. In one alternate embodiment, the cutter and the dilator may be combined as one feature as hereinafter described.

The system also includes a cam assembly. The cam assembly includes a cam shaft rotationally coupled within the housing. The cam shaft includes a first cam profile, second cam profile, a third cam profile, and a fourth cam profile. A first cam follower is moveably coupled to the first cam profile. The first cam follower is attached to the cutter. A second cam follower is moveably coupled to the second cam profile. The second cam follower is attached to the pusher. A third cam follower is moveably coupled to the third cam profile. The third cam follower is attached to the shield. A fourth cam follower is moveably coupled to the fourth cam profile. The fourth cam follower is attached to the dilator.

In one embodiment, a spring may be biased between the housing and the cam shaft. The spring has a wound position, which places torsion on the cam shaft, and a released position.

A release button may be moveably coupled to the cam shaft. The release button has a first position, which maintains the spring in the wound position, and a second position, which allows the spring to move into the released position. When the release button is moved into the released position, the spring is released to move the cam shaft and cause the cam followers to linearly move respective portions of the shaft assembly to form an incision

in a tympanic membrane using the cutting member, dilate the incision using the dilator, and advance the pressure equalization tube out of the shield and into the incision using the pusher.

In another aspect, a method is provided for forming an incision and placing a pressure equalization tube in a tympanic membrane of an ear. The method includes contacting a blunt (atraumatic) distal end of a shaft of a tube delivery device with a tympanic membrane. A cutter is advanced out of the shaft distal end to form an incision in the tympanic membrane. A dilator is disposed over at least a portion of the cutter. A shield disposed over the cutter and within the dilator is advanced out of the shaft distal end and into the incision to dilate the dilator. The shield is disposed over a pressure equalization tube. The cutter is retracted into the shaft. The shield is retracted into the shaft, thereby releasing a distal flange of the pressure equalization tube such that it assumes an expanded configuration. The pressure equalization tube is pushed out of the shield using a pusher disposed within the shield, thereby releasing a proximal flange of the pressure equalization tube such that it assumes an expanded configuration. After being pushed out of the shield, a middle portion of the pressure equalization tube is disposed within the incision in the tympanic membrane and the distal and proximal flanges are disposed on opposite sides of the incision.

Advantageously, such systems and methods facilitate automatic delivery of a tympanic membrane equalization tube with minimal steps to be performed by an operator, such as advancing the system into an ear canal and triggering a release button.

For a further understanding of the nature and advantages of the invention, reference should be made to the following description taken in conjunction with the accompanying figures. However, each of the figures is provided for the purpose of illustration and description only and is not intended to limit the scope of the embodiments of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1A through 1G are views of delivery systems for delivering a tympanic membrane equalization tube into a tympanic membrane, according to two embodiments of the invention.

Figs. 1H and 1I are exploded views of the delivery systems of Figs. 1A through 1D and Figs. 1E though 1G respectively.

Figs. 1J/1K and 1N/1O are a partial side views of internal portions of the delivery systems of Figs. 1A though 1D and Figs. 1E through 1G, respectively.

Figs. 1L and 1M are views of internal portions of the cam/switch interface of the delivery system depicted in Figs. 1E through 1G.

Fig. 1P is a cross-sectional view of the distal tip of the delivery systems of Figs. 1A through 1G.

Fig. 2A is a displacement and operational diagram, according to one embodiment of the invention.

Fig. 2-B is a displacement and operational diagram, according to one embodiment of the invention.

Fig. 3 is perspective view of a delivery system for delivering a tympanic membrane equalization tube into a tympanic membrane, according to one embodiment of the invention.

Figs. 4A through 4D are perspective and side views of an integrated cutting member and dilator, according to two embodiments of the invention.

Fig. 4E is a cross-sectional view of a distal tip of a delivery system in use, according to one embodiment of the invention.

Fig. 4 F depicts a schematic of a negative pressure actuation system, according to one embodiment of the invention.

Figs. 5A and 5B are perspective and side views, respectively, of a tympanic membrane equalization tube, according to one embodiment of the invention.

Fig. 5 C is a perspective view of a tympanic membrane equalization tube, according to one embodiment of the invention.

Figs. 5D through G are perspective views of tympanic membrane equalization tubes, according to multiple embodiments of the invention.

DETAILED DESCRIPTION OF THE INVENTION

The embodiments of the invention are intended to provide systems for automatically puncturing and delivering a tympanic membrane equalization tube into a tympanic

membrane. According to embodiments of the invention, tympanic membrane equalization tube delivery systems generally include a housing with a dedicated handgrip, or a graspable housing. A shaft extends out of the housing to access the tympanic membrane, and a tympanic membrane equalization tube is loaded within the tip of the shaft. An internal spring loaded cam-based mechanism is located within the housing and coupled to a button. The mechanism can be triggered to initiate a fast and automatic process which punctures the tympanic membrane, and delivers the tympanic membrane equalization tube. The tympanic membrane equalization tube is a grommet like device which is folded and/or compressed within the tube, and recovers its shape when delivered into the tympanic membrane.

In use, an operator grasps the housing by the handgrip and brings the tip of the shaft into contact with the tympanic membrane. The operator then triggers the cam-based mechanism by pressing the button. The system then automatically punctures and inserts the tympanic membrane equalization tube into the tympanic membrane. Thus, a simple and effective delivery system is provided, which requires minimal operator steps for use.

Embodiments of the invention are compatible for use with a suite of medical devices for visualizing, guiding other medical devices, delivering a tympanic membrane equalization tube, puncturing the tympanic membrane, and anesthetizing the tympanic membrane. Examples of such medical devices are shown in co-assigned U.S. Patent Application 11/749,733, the entirety of which is incorporated by reference. Accordingly, aspects of U.S. Patent Application 11/749,733 may be integrated, combined, and used in conjunction with the embodiments disclosed herein.

Exemplary configurations of the Delivery System:

Two exemplary systems are described below and shown in separate figures (Figs. 1A through 1G). Where possible, the same numbering scheme is used to identify each system's components. Clarification is added when the components of the systems vary in function.

The system represented by Figs. 1E through 1G have several advantages over the system represented by Figs. 1A through 1D. The housing design provides a more stable and ergonomic grip enhancing device stability during usage. The spring 114 is moved to the proximal end of the delivery system 100, which aids in the more balanced and stable delivery of the tympanic membrane equalization tube.

Figs. 1A through 1G shows a delivery system 100 for delivering a tympanic membrane equalization tube into a tympanic membrane, according to one embodiment of the invention. The delivery system 100 includes a housing 102 with a handle, or a provision for a handhold such as depicted in the overall design depicted in Figs. 1E through1G. A shaft assembly 104 is attached to the housing 102. The shaft assembly 104 is constructed from one or more elongate tubes, and is configured to have an outer diameter which is small enough (e.g., 2mm) to navigate a distal portion of the shaft assembly into a tortuous path of an ear canal without requiring significant deformation of the ear canal or shaft assembly 104. In many embodiments, the shaft assembly has a preformed curvature to facilitate access to the tympanic membrane. In some embodiments the shaft assembly may be made of a malleable material(s), adjustable by the user to aid in navigating the ear canal. A tympanic membrane equalization tube (not shown) is preferably housed within the distal portion of the shaft assembly 104. A release button 106 protrudes through housing 102. The release button 106 is configured to release an internal mechanism which causes the shaft assembly 104 to automatically puncture a tympanic membrane and also insert the tympanic membrane equalization tube into the punctured tympanic membrane. In use, the delivery system 100 is used to bring the distal portion of the shaft assembly into contact, or near contact, with a tympanic membrane of an ear of a patient. The release button 106 is then manipulated to release an internal mechanism which causes the shaft assembly to automatically and swiftly puncture the tympanic membrane, and also swiftly deliver the tympanic membrane equalization tube into the punctured tympanic membrane.

Figure 1H/1I shows a partially exploded view of the delivery system 100. The housing 102 is made up of a first housing portion 108 and a second housing portion 110, which mate together in a clamshell manner. A camshaft 112 is rotatably housed between the first housing portion 108 and a second housing portion 110. The camshaft 112 is also coupled to a spring 114, which may be biased (i.e., wound) between the housing 102 and camshaft 112. The shaft assembly 104 is movably attached to four cam followers, 120a, 120b, 120c, and 120d, each of which are slidably housed within the housing 102 along an axis A-A of the shaft assembly 104. The cam followers 120a-d are configured as slidable blocks. The release button 106 is slidably moveable within a button housing 116, which is mounted or otherwise incorporated within the housing 102. A link 118 is moveably connected between a portion of the camshaft 112 and the release button 106. The release button 106 can move or release the link 118 to disengage from the camshaft 112, and allow

the spring 114 to at least partially unwind and rotate the camshaft 112, which in turn moves the cam followers 120a-d, which in turn moves portions of the shaft assembly 104 to automatically puncture the tympanic membrane, and also deliver the tympanic membrane equalization tube into the punctured tympanic membrane. Many embodiments can use other triggering mechanisms, for example, one or more fusable links may be activated by the button 106. A fusable link can be activated to erode and disengage from the camshaft 112. In some embodiments a counter balance spring 147 can be utilized to offset the loads transmitted from the spring 114 through the camshaft 112 and link 118 to the release button 106. This allows the release button 106 to move or release the link 118 with minimal force. Other embodiments may also include a lock tab 148 that holds the release button in place during handling and helps avoid unintended actuation of the device.

Figure 1J/1K shows a portion of the delivery system 100 with the second housing portion 110 removed. The first cam follower 120a is connected to a proximal portion of a cutting member 121a. The cutting member 121a is an elongate wire or tube with a provision for puncturing (e.g. a sharpened tip) a tympanic membrane at its distal end. The second cam follower 120b is directly adjacent to the first cam follower 120a. The second cam follower 120b is connected to a proximal portion of a pusher 121b. The pusher 121b is an elongate tube within which the cutting member 121a slidably resides. The third cam follower 120c is connected to a proximal portion of a shield 121c. The shield 121c is an elongate tube within which the pusher 121b slidably resides. The fourth cam follower 120d is connected to a proximal portion of dilator 121d. The dilator 121d is an elongate tube with a distal tip capable of expanding from a narrow position to an expanded position. The shield 121c slidably resides within the dilator 121d. An outer shaft 121e is attached to the first housing portion 108. The outer shaft 121e is an elongate tube with a distal opening, and can be constructed from a stiff material, such as stainless steel.

The four cam followers 120a-d include pins 122a-d and are housed in cam follower chamber 130. Each pin 122a-d is slidable within a track 123a-d. The tracks 123a-d are profiled grooves in the circumference of the camshaft 112. As each pin 122a-d is attached to a corresponding cam follower 120a-d, movement of a pin 122a-d moves the corresponding cam follower 120a-d and a respective portion of the shaft assembly 104. For example, when the camshaft 112 is rotated, pin 122a follows track 123a, and is moved parallel to axis A-A to translate rotational movement of the camshaft 112 into linear motion of the cutting member

121a along axis A-A. Similarly, track 123b corresponds with pusher 121b; track 123c corresponds with shield 121c; and track 123d corresponds with dilator 121d.

A trigger mechanism chamber 124 houses the button housing 116. The trigger mechanism chamber 124 includes an opening for the button 106 to pass through. The first housing portion 108 is shown holding the camshaft 112 within a camshaft chamber 126, which includes rotational mounting points for the camshaft 112. A portion of the camshaft 112 extends into a spring chamber 128, where the spring 114 mounts to the camshaft 112. The spring 114 can be wound so as to be biased between the camshaft 112 and a portion of the spring chamber 128. The cam followers 120a-d are linearly arranged within a follower chamber 128.

Figures 1L and 1M show further detail of an improved trigger mechanism that provides more consistent actuation motion and force.

Figure 1L shows a camshaft tooth 150 extending from an end of the camshaft 112. A link tooth 151 extending from the link 118 inhibits rotational motion of the camshaft 112 when the link 118 is held in place by the release button 106.

Figure 1M shows a perspective view of the interface 152 between the release button 106 and the link 118. Lateral movement of the release button 106 disengages the interface 152 between the release button 106 and link 118 allowing the link 118 to pivot about the link pin 132 (shown in Figure 1L) allowing the spring 114 to at least partially unwind and rotate the camshaft 112. As described above, the counter balance spring 147 can be utilized to offset the loads transmitted from the spring 114 through the camshaft 112 and link 118 to the release button 106. This allows the release button 106 to move or release the link 118 with minimal force.

Figure 1N/1O shows a portion of the delivery system 100 with the first housing portion 108/110 removed. The interior of the second housing portion 110 is substantially similar to the first housing portion 108 and includes internal members to form the trigger mechanism chamber 124, camshaft chamber 126, spring chamber 128 (not shown), and follower chamber 130, when mated to the first housing portion 108. The link 118 is joined to second housing portion 110/108 by a link pin 132. The link 118 pivots between the release button 106 and a portion of the camshaft 112 about the link pin 132. The spring 114 (not shown) can be wound so as to be biased between the camshaft 112 and a portion of the spring chamber 128 and kept in the biased position by the link 118. The button 106 can be pressed

to decouple the link 118 from the camshaft 112, which in turn causes the wound spring 114 to unwind and rotate the camshaft 112. The camshaft 112 will rotate until it encounters a physical stop in the first or second housing portion 108, 110. The button 106 can be coupled to a safety mechanism (not shown), such as a slidable pin, button cover or lock tab which must be switched from an on position to an off position, or removed, in order to allow the button 106 to be pushed.

In many embodiments, the delivery system 100 includes provisions for noise dampening to reduce shock to the patient. After the spring 114 is released, the camshaft 112 will rotate until it encounters a stop in the first or second housing portion 108, 110, which can result in an unwanted noise which can shock the patient. The camshaft 112 and spring 114 can include lubrication and noise dampening members, such as a rubber stop 149 (such as shown in Fig. 1I and Fig. 1K, for example). The first or second housing portion can also use a non-concentric surface, instead of a sudden stop, which gradually brakes the camshaft 112. Sound baffling in the housing 102 can also be used to muffle and/or direct sound away from the ear. Sound tuning at a selected frequency and amplitude can also be employed directly prior to using the delivery system 100 to reduce shock to the patient. Introducing a noise using sound tuning causes muscles connected to the stapes to contract and reduce noise transmission to the inner ear. Sound tuning can also include generating a noise that is gradually introduced to the patient to acclimate the patient to the noise created by the delivery system 100, thus, reducing shock.

Fig. 1P shows a cross-sectional view of the distal end of the shaft assembly 104. The cutting member 121a is a diamond shaped cutting head 134 connected to an elongate wire 136. Preferably, the diamond shaped cutting head 134 is configured with multiple facets leading to a single sharp point, which can easily puncture a tympanic membrane using minimal axial force. The cutting member 121a is not limited to use of the diamond shaped cutting head 134. In many embodiments, the cutting member 121a employs a knife edged tip or a coring/non-coring needle. The cutting member 121A may also employ a wedge or planar shape with beveled edge, which may allow access to more sites of the tympanic membrane. Generally, the cutting member 121a can utilize any properly sized cutting head 134. In some embodiments, the shape of cutting head 134 may facilitate performing a myringotomy (i.e., incising a TM) without forming flaps in the TM.

The dilator 121d has a folding tip 138 which is capable of expanding from a narrow position to an expanded position. The folding tip 138 has a cone like shape when in the

narrow position, as shown. The folding tip 138 abuts the back of the diamond shaped cutting head 134 when in the narrow position. The folding tip 138 can be formed by making a plurality of triangular cuts at the distal end of a tube to form folding members, and folding the folding members into a cone. The folding tip 138 generally only requires two folding members, while in this embodiment four folding members are used.

The shield 121c is a tube which is placed within the dilator 121d and proximally to the folding tip 138. When the shield 121c is moved in a distal direction, it can force open the folding tip 138. A straightened tympanic membrane equalization tube 140 is placed within the shield 121c. The tympanic membrane equalization tube 140 is restrained within the shield 121c, and proximal and distal flanges of the tube 140, which are forced into a straightened configuration within the shield 121c, apply a constant expansive force to the interior diameter of the shield 121c to stay in place. The tympanic membrane equalization tube 140 can have an interior diameter greater than the outer diameter of the diamond shaped cutting head 134 to allow removal of the tympanic membrane equalization tube 140. The tympanic membrane equalization tube 140 can also have an interior diameter equal to or smaller than the outer diameter of the diamond shaped cutting head 134, as the tympanic membrane equalization tube 140 may comprise an elastic material which allows for slight deformation/stretching of the tympanic membrane equalization tube 140 during movement of the diamond shaped cutting head 134. The pusher 121b is a tube which is placed proximally to the folded tympanic membrane equalization tube 140. The pusher 121b can be moved distally to push the folded tympanic membrane equalization tube 140 out of the shield 121c.

The outer shaft 121e surrounds the dilator 121d and is stationary with respect the movement of the other portions of the shaft assembly 104. The outer shaft 121e provides axial stiffness to the shaft assembly 104, and can be formed from a metal such as stainless steel. A tip 142 is attached to the distal end of the outer shaft 121e. The tip can be composed of a clear material to allow visualization of the tube 140 as well as anatomical structures abutting the delivery system 100 in order to facilitate accurate placement of the tube 140. Alternatively, the tip 142 may be formed from the same piece of material as the outer shaft 121e. The tip 142 includes an inner diameter which is greater than the inner diameter of the outer shaft. This larger inner diameter of the tip 142 allows a proximal flange of the tympanic membrane equalization tube 140 to open into its expanded/unconstrained configuration within the tip 142 when advanced by the pusher 121b. This expansion of the

proximal flange within the tip 142 may help prevent advancement of the entire equalization tube 140 through a myringotomy into the middle ear.

In some embodiments, a pressure/contact/distance sensor may be coupled to the tip 142. The sensor provides a signal when the tip 142 contacts or is near the tympanic membrane. The signal may trigger a visual indicator (e.g., an LED) on the housing 102 to indicate that the tip 142 is in a proper position for inserting the tympanic membrane equalization tube 140 into the tympanic membrane. The sensor can be a piezoelectric, optical, capacitive based sensor, or any other suitable sensor. The signal may also trigger other operations, such triggering movement of the camshaft 112, or a sound tuning operation as described herein.

In some embodiments, the distal portion of the shaft assembly 104 may be configured to better access the tympanic membrane. The tympanic membrane has a conical shape and is angled with respect to the axis of the ear canal. Accordingly, the distal end of the shaft assembly 104 may contact the tympanic membrane at non-optimal angle (e.g. non-perpendicular). In this case, the operator may mistakenly stop short of applying sufficient pressure to the tympanic membrane to ensure complete delivery of the pressure equalization (PE) tube. In other cases, the operator may overcompensate and place too much pressure on the tympanic membrane, thus, driving the tip of the shaft assembly 104 through the tympanic membrane. To overcome these situations, the distal portion of the shaft assembly 104 can incorporate an angle such that the distal tip of the shaft assembly 104 can have better access to the tympanic membrane. In use, the operator can either rotate all or a portion of the system 100 to place the distal tip of the shaft assembly 104 in an optimal position with respect to the tympanic membrane. In some embodiments, the shaft assembly 104 is malleable so that the operator can bend the shaft assembly 104 to a desired position.

In some embodiments, the outer shaft 121e of the shaft assembly 104 includes a flexible zone, such that when the distal tip of the shaft assembly 104 presses against the tympanic membrane, the distal tip of the shaft assembly 104 automatically adjusts to an optimal position. For example, a portion of the outer shaft 121e can utilize a spring section, accordion section, or stent-like scaffold which elastically or plastically compresses when the distal tip of the shaft assembly 104 presses against the tympanic membrane. Compression of the tip can give the operator visual feedback as to the amount of pressure being applied to the tympanic membrane. In some embodiments, the outer shaft 121e has a laser cut portion removed such that a helical section exists between a mid-portion of the outer shaft 121e and a

distal end of the outer shaft 121e. The helical section can be configured to flex only when sufficient pressure has been applied, thus, the operator would need to apply enough pressure to completely compress at least one side of the helical section to ensure a proper tympanic membrane equalization tube 140 delivery. In some embodiments, all or discrete portions of the shaft assembly 104 can include similar flexible zones and/or be constructed from flexible materials, for example, the cutting member 121a may be constructed from a super-elastic material (e.g., nickel-titanium alloy).

Methods of operating of the exemplary Delivery System:

Fig. 2A shows a displacement diagram 200 of the camshaft 112 and corresponding simplistic views of the distal tip of the shaft assembly 104 placed within an ear canal, with the tip 142 against a tympanic membrane TM. The displacement diagram 200 shows patterns of respective tracks 123a-d along axis X and Y. Axis Y represents the linear displacement of the tracks 123a-d along the circumference of the camshaft 112. Axis X represents the linear displacement of the tracks perpendicular axis Y.

As previously noted, the pins 122a-d follow movement of the tracks 123a-d. The pins 122a-d are attached to corresponding cam followers 120a-d. Thus, movement of the pins 122a-d results in movement of the corresponding cam followers 120a-d and respective movement of portions of the shaft assembly 104 along axis A-A, which is parallel to Axis X. Each track 123a-d is shown with a numeric displacement value at the various positions. The numeric displacement values are the distances in millimeters between the distal end of the tip 142 and the distal most position of the related shaft assembly 104 portions 121a-d. The views of the distal tip of the shaft assembly 104 show incremental positioning with respect to the displacement diagram, however, the movement of the shaft assembly 104 and camshaft 112 is one continuous movement. In various embodiments, the camshaft 112 may take between about 5 milliseconds and about 500 milliseconds to rotate from the initial position to a final position, after the button 106 has been pressed. In other words, it may take from about 5 to about 500 milliseconds from the time the button 106 is pressed until a pressure equalization tube 140 is deployed in a TM using the device 100. In some embodiments, this time period may be between about 30 milliseconds and about 250 milliseconds, with average times of between about 100 milliseconds and about 130 milliseconds. In other embodiments, the time period may be outside the ranges listed above.

1. Initial camshaft position:

At the initial position of the camshaft 112, the shaft assembly 104 is positioned as shown in Fig. 1P. At this position, the button 106 has not been pressed to release the wound spring 114. The shaft assembly 104 has been advanced into the ear canal such that the tip 142 abuts a portion of the tympanic membrane TM. At the initial camshaft position, the cutting member 121a is 0.25 mm behind (i.e., proximal) the extreme distal end of the tip 142; the pusher 121b is 7.04 mm behind the tip 142; the shield 121c is 4.09 mm behind the tip 142; and the dilator 121d is 1.68 mm behind the tip.

2. First camshaft position:

At a first camshaft position, the button 106 has been pressed to release the wound spring 114 which rotates the camshaft 112 from the initial camshaft position to the first camshaft position. Accordingly, as described herein, movement of the camshaft causes the cam followers 120a-d to move respective portions of the shaft assembly 104. At the first camshaft position the cutting member 121a punctures the tympanic membrane TM and the dilator 121d follows to dilate the puncture site to a larger diameter. The pusher 121b and shield 121c also advance, but remain behind the tip 142. At the first camshaft position the cutting member 121a is 2.79 mm ahead (i.e., distal) of the extreme distal end of the tip 142; the pusher 121b is 1.66 mm behind the tip 142; the shield 121c is 1.04 mm behind the tip 142; and the dilator 121d is 1.37 mm ahead of the tip 142.

3. Second camshaft position:

The camshaft 112 rotates from the first camshaft position to a second camshaft position. At the second camshaft position, the shield 121c advances past the tip 142 to open the folding tip 138 of the dilator 121b and further dilate the puncture site, and the cutting member 121a retracts behind the dilator 121b. The pusher 121b also advances, but remains behind the tip 142. At the second camshaft position the cutting member 121a is 0.58 mm ahead of the extreme distal end of the tip 142; the pusher 121b is 1.55 mm behind the tip 142; the shield 121c is 0.66 mm ahead of the tip 142; and the dilator 121d remains 1.37 mm ahead of the tip 142.

4. Third camshaft position:

The camshaft 112 rotates from the second camshaft position to a third camshaft position. At the third camshaft position, the cutting member 121a and dilator 121d retract

behind the tip 142. The shield 121c also retracts, while the pusher 121b advances to partially push the tympanic membrane equalization tube 140 out of the shield 121c. A medial flange 144 (or "distal flange") of the tympanic membrane equalization tube 140 is pushed out of the shield 121c to expand medial (or "distal") to the tympanic membrane. At the third camshaft position the cutting member 121a is 1.78 mm behind the extreme distal end of the tip 142; the pusher 121b is 1.45 mm behind the tip 142; the shield 121c is 1.02 mm behind the tip 142; and the dilator 121d is 1.23 mm behind the tip 142.

5. Final camshaft position:

The camshaft 112 rotates from the third camshaft position to a final camshaft position. At the final camshaft position, the cutting member 121a, shield 121c, and dilator 121d remain stationary with respect to the third camshaft position. The pusher 121b advances to a final position, but remains behind the tip 142, to push a lateral flange 146 (or "proximal flange") of the tympanic membrane equalization tube 140 outside of the shield 121c to expand within the tip 142 of the device 100 and lateral (or "proximal") to the tympanic membrane. At the final camshaft position the cutting member 121a is 1.78mm behind the extreme distal end of the tip 142; the pusher 121b is 0.84 mm behind the tip 142; the shield 121c is 1.02 mm behind the tip 142; and the dilator 121d is 1.23 mm behind the tip 142.

An alternative embodiment for the camshaft design is depicted in Fig. 2B. Reference to the above description of the various camshaft positions are applicable to this embodiment with the exception of slightly modified advancement points along the tracks of the cam as noted in the figure. The most noticeable variation is that shield 123c retracts further back into the shaft in the final camshaft position relative to the camshaft depiction of Fig. 2A.

When the pressure equalization tube 140 has been successfully placed, with the medial flange 144 and lateral flange 146 flanking the TM, the shaft assembly 104 may then be withdrawn from the ear canal, leaving the tube 140 behind. The above steps may then be repeated, if desired, in the patient's other ear using a second device 100 or by reloading the first device 100 with another equalization tube 140. In some embodiments, device 100 may be reloadable, while in alternative embodiments device 100 may be a one-use device only. Thus, according to the method described above, by simply positioning the delivery system 100 within the ear canal, with the tip 142 against the tympanic membrane TM, and pressing

button 106, the delivery system 100 both punctures the tympanic membrane TM and also delivers the tympanic membrane equalization tube 140 in one effective movement.

Alternative Structure of the Delivery System:

Referring now to Fig. 3, in one alternative embodiment, a tympanic membrane pressure equalization tube delivery system 300 may include a pencil grip 302 handle and a trigger 304 for activating the delivery system 300. The delivery system 300 may be configured similarly to the delivery system 100, and may include a substantially similar internal tympanic membrane equalization tube delivery mechanism and shaft assembly. However, the delivery system 300 features the pencil grip 302 which may be ergonomically similar to grips of standard myringotomy spears. The trigger 304 may be placed in any convenient ergonomic location, such as on the top of the system 300, as shown. In other alternative embodiments, other handle and/or trigger configurations may be used including the configuration depicted in Figs. 1E through 1G.

With reference now to Figs. 4A-4D, in two alternative embodiments, a TM tube delivery device may include a cutting dilator 400 at its distal end, rather than including a separate cutter and dilator. In other words, the cutting dilator 400 integrates the cutting member 121a and dilator 121d. The cutting dilator 400 is capable of puncturing a tympanic membrane and also expanding to dilate a puncture site. The cutting dilator 400 includes a plurality of fingers 402 arranged as a cone. In the examples shown, four fingers 402 are used. More fingers 402 generally allow easier expansion. At least one of the fingers 402 includes a sharpened tip (Figs. 4A and 4B) or cutting blade (Figs. 4C and 4D) for puncturing the tympanic membrane. The cutting dilator 400 may be made from any suitable material that can be expanded from a closed to a dilated configuration. For example, in one embodiment, the dilator 400 may be formed from a super-elastic nickel-titanium alloy. In another embodiment, the cutting dilator 400 may be formed from a malleable material, such that when the cutting dilator 400 dilates it retains approximately the dilated configuration.

Fig. 4E shows, in one alternative embodiment, an alternate construction, and method for use, for the distal end of the shaft assembly 404. The shaft assembly 404 is constructed similarly to the shaft assembly 104 shown in Fig. 1E. However, outer shaft 406 includes an outer wall 408 and an inner wall 410, with a space 412 therebetween. The space 412 can be fluidly connected to a negative air pressure source, which is connected to the housing 102. The housing 102 can include an additional trigger device for enabling negative

pressure to be applied to the space 412. Negative pressure may also be enabled and/or disabled by an automatic process, for example by port/valve triggered by the rotation of the camshaft 112. The outer shaft 406 can be a constructed, for example, from two individual tubes, from a double walled extrusion with a connecting member therebetween, or from a single walled extrusion including a plurality of lumens. The outer shaft 406 remains small enough in diameter, compared to the outer shaft 121e, to enable visualization and access through typical ear canal, and also reach any quadrant of TM. The outer shaft 406 can provide a suction force to the tympanic membrane TM in order to elevate a portion of the tympanic membrane TM away from a normal position.

Elevating the tympanic membrane can result in reduction of noise admittance during penetration of the cutting member 136. Elevating the tympanic membrane can also provide local stabilization of a target site to enhance the reliability of use of the system 100, thus preventing accidental deviation or slipping of the cutting member 136 during penetration. Elevation of tissue, can also be especially useful for patients with retraction pockets. Long term retraction of the eardrum, caused by negative pressure in the middle ear, will cause erosion of the ear canal and formation of a deep pocket. Eventually the pocket may trap skin, forming a skin cyst or cholesteatoma. Further progression of retraction pockets can cause destruction of the tympanic membrane. Tissue elevation enhances safety by providing additional space away from anatomical structures distal to the tympanic membrane for penetration and placement of the tympanic membrane pressure equalization tube 140. Accordingly, tissue elevation also allows a larger patient population to be treated, as a significant portion of patients who require placement of tympanostomy tubes have some degree of retraction.

In use, with reference to Figs. 2A/2B and 4E, negative pressure may be applied to the space 412 of the outer shaft 406, before pressing button 106. The distal end of the outer shaft 406 may brought into contact, or near contact, with the tympanic membrane TM before, or after applying negative pressure. The negative pressure causes the tympanic membrane TM to temporarily attach to the distal end of the outer shaft 406. The tympanic membrane TM may then be elevated by pulling or placing the distal end of the outer shaft 406 in a proximal position (i.e., towards the outer ear) from the current position of the tympanic membrane TM. Tissue elevation is illustrated by movement of the dotted lines to solid lines, which represent the tympanic membrane TM in pre- and post-elevation positions, respectively. Thus, after elevation, additional space is provided away from anatomical structures distal to the tympanic

membrane TM, for penetration and placement of the tympanic membrane pressure equalization tube 140. After the tympanic membrane TM has been elevated to a desired position, the button 106 may be pressed to initiate automatic placement of the tympanic membrane pressure equalization tube 140 in the tympanic membrane TM, while negative pressure is continually applied to the tympanic membrane TM. After the tympanic membrane pressure equalization tube 140 is placed, application of negative pressure to the space 412 of the outer shaft 406 can be stopped, thus releasing the tympanic membrane TM from the outer shaft 406. Alternatively, application of negative pressure to the space 412 of the outer shaft 406 can be stopped at other points of the method shown in Figs. 2A/2B, for example after the medial flange 144 of the tympanic membrane equalization tube 140 is pushed out of the shield 121c to expand medial to the tympanic membrane.

An addition to the above alternate embodiment would include using the applied negative pressure as a means to actuate the device. Fig. 4 F depicts a schematic of a potential negative pressure actuation system. A piston or bellows 400 within the delivery system 100 connected to the link 118 could move upon exposure to negative pressure and trigger the camshaft 112 rotation. The negative pressure on the piston or bellows could be generated when the tip 142 of the device attains apposition against the tympanic membrane thus ensuring the device position relative to the tympanic membrane.

The system includes a vacuum chamber 402 that has a contiguous, sealed lumen providing communication between the device tip 142 (that comes into contact with the tympanic membrane) and the proximal end of the delivery system 100. The chamber includes a vacuum actuated trigger mechanism such as vacuum cylinder 404 and piston 400 and a vacuum port 406 that can be attached to a vacuum source such as through a vacuum line normally available in an operating room or other clinical setting.

Advantages of the above embodiment include more accurate and consistent PE tube deployment into the tympanic membrane, minimal button actuation force providing greater device stability, and ensuring delivery system actuation when the device tip is fully opposed to the tympanic membrane.

Other mechanisms or structure may be employed in lieu of, or in conjunction with, application of negative pressure to the tympanic membrane, for elevation thereof. For example, an adhesive or sticky substance may be used, or a mechanical application using micro-barbs.

Tympanic Membrane Pressure Equalization Tube:

Figs. 5A and 5B show a tympanic membrane pressure equalization tube 500, according to one embodiment of the invention. In this embodiment, the tube 500 is configured as a grommet made of silicone or some other pliable elastomeric material and is intended to be placed within a tympanic membrane to vent to the middle ear. Although a number of suitable pressure equalization tubes 500 may be used in conjunction with a delivery system as described above, in one embodiment the tube 500 may have an axial length of between about 2.0 mm and about 2.5 mm and ideally about 2.3 mm. The tube 500 may have an inner diameter of about 1.1 mm.

A central lumen 502 of the tube 500 is flanked by an integral medial flange 504 and lateral flange 506. The medial flange 504 and lateral flange 506 prevent the tube 500 from falling out of an opening created in the tympanic membrane. In some embodiments, the lateral flange 504 can be smaller in diameter than the medial flange 506, as shown, as the lateral flange 504 can be expanded within the tip 142 of the delivery system 100, while the medial flange is intended to expand distally past the tympanic membrane. In alternative embodiments, the lateral flange 504 and medial flange 506 are of equal diameters. The exterior surface of the tympanic membrane equalization tube 500 includes optional flexible zones 508 which facilitate straightening of the medial flange 504 and lateral flange 506 for loading into a delivery system, as shown in Fig. 1P. The medial flange 504 and lateral flange 506 may also include optional notches or cutouts 504a, 506a which may further facilitate straightening of the flanges 504, 506. Fig. 5C, depicts one such further embodiment containing 3 notches or cutouts 504a and 506a on each of the flanges 504, 506. Alternative embodiments may of course contain any combination of these optional notches or cutouts 504a and 506a on the flanges, including having more notches on one flange compared with the other flange and also including optional flexible zones 508.

Figs. 5D-5G show tympanic membrane pressure equalization tubes, according to other alternative embodiments of the invention. In some instances, the flanges of the tube, when constrained within a delivery system in a straightened position for a long period of time as shown in Fig. 1P, may not spring back (i.e., expand into) their unconstrained, natural position quickly enough for effective delivery into the TM. Therefore, in some embodiments, internal scaffolding may be included within the wall of the tube 510, 514, 518, 520 to help it reassume its natural shape. Such scaffolding may be constructed, for example, from a super-elastic or shape-memory material, such as a nickel-titanium alloy, other metals, or polymers

or other suitable materials. Also any of these embodiments may include the optional flexible zones 508 described above.

Fig. 5D shows a tympanic membrane pressure equalization tube 510 including an internal wire 512. The wire 512 provides a fast shape recovery for the tube 510. Fig. 5E shows a tube 514 including an internal double loop 516. The double loop 516 provides fast shape recovery for the tube 514, especially for the flanges. Fig. 5F shows a tube 518 including a plurality of wires 520. Using a plurality of wires 520 ensures uniform shape recovery of the tube 518. Fig. 5G shows a tube 520 including internal stent scaffolding 522, which promotes uniform shape recovery of the tube 520.

In many embodiments, the tympanic membrane equalization tubes disclosed herein can include features which help recover a misplaced tympanic membrane equalization tube. A misplaced tympanic membrane equalization tube located distally to the tympanic membrane can be especially difficult to remove. Such features can include tethers attached to any portion of the tympanic membrane equalization tubes. The tethers can be grasped proximally to the tympanic membrane and used to pull the misplaced tympanic membrane equalization tube out of the ear.

The present invention may be embodied in other specific forms without departing from the essential characteristics thereof. These other embodiments are intended to be included within the scope of the present invention, which is set forth in the following claims.

WHAT IS CLAIMED IS:

1. A system for forming an incision in a tympanic membrane and delivering a pressure equalization tube into the incision, the system comprising:

a housing including a handle;

an elongate shaft assembly coupled with the housing, the shaft assembly comprising:

an outer shaft having a blunt distal tip portion

a cutter linearly moveable within the outer shaft;

a pusher slidably disposed over the cutter within the outer shaft;

a pressure equalization tube slidably disposed about the cutter at a distal end of the pusher;

a shield slidably disposed over the pusher and the pressure equalization tube; and

a dilator slidably disposed over the shield;

a cam assembly comprising:

a cam shaft rotationally coupled within the housing, the cam shaft including a first cam profile, a second cam profile, a third cam profile, and a fourth cam profile;

a first cam follower moveably coupled to the first cam profile, the first cam follower attached to the cutter;

a second cam follower moveably coupled to the second cam profile, the second cam follower attached to the pusher;

a third cam follower moveably coupled to the third cam profile, the third cam follower attached to the shield;

a fourth cam follower moveably coupled to the fourth cam profile, the fourth cam follower attached to the dilator;

a spring biased between the housing and the cam shaft, the spring having a wound position which places a torsional load on the cam shaft, and a released position; and

a release member moveably coupled to the cam shaft, the release member having a first position which maintains the spring in the wound position and a second position which allows the spring to move into the released position;

wherein when the release member is moved into the released position, the spring is released to move the cam shaft and cause the cam followers to linearly move

respective portions of the shaft assembly to form an incision in a tympanic membrane using the cutting member, dilate the incision using the dilator, and advance the pressure equalization tube out of the shield and into the incision using the pusher.

2. The system of claim 1, wherein the housing comprises a first housing portion and a second housing portion, and wherein each housing portion is a molded clamshell.

3. The system of claim 2, wherein the housing portions form a camshaft chamber, a cam follower chamber, a spring chamber, and a trigger mechanism chamber.

4. The system of claim 1, wherein the outer shaft is constructed from rigid tubing.

5. The system of claim 1, wherein the outer shaft comprises an outer wall, an inner wall, and a space therebetween in which negative pressure may be applied.

6. The system of claim 5, wherein the negative pressure may be used to actuate the release member.

7. The system of claim 1, wherein the cutting member comprises an elongate wire with a diamond headed tip.

8. The system of claim 1, wherein the shield comprises an elongate tube.

9. The system of claim 1, wherein the pressure equalization tube comprises a grommet with a lumen, a medial flange, and a lateral flange.

10. The system of claim 9, wherein the medial and lateral flanges are compressed within the shield.

11. The system of claim 10, wherein the pressure equalization tube includes internal wire scaffolding.

12. The system of claim 10, wherein the pressure equalization tube is constructed from an elastomeric material and includes flexible portions between the lumen and flanges.

13. The system of claim 10, wherein the flanges include notches that facilitate compression of the tube within the shield.

14. The system of claim 1, wherein the pusher comprises an elongate tube.

15. The system of claim 1, wherein the dilator comprises an elongate tube with a distal tip, the distal tip being capable of expanding from narrow position to an open position.

16. The system of claim 15, wherein the distal tip comprises a plurality of members which are spring biased in the narrow position and can be forcibly opened into the open position.

17. The system of claim 1, wherein the cam shaft comprises an elongate cylinder, with first and second ends rotationally attached to the housing, a mid-section therebetween, and a spring holder extending from the second end.

18. The system of claim 15, wherein the cam profiles each comprise a patterned groove in the mid-section.

19. The system of claim 1, wherein the cam followers each comprise a block which is slidably housed in the housing, each block including a drive pin for following a respective cam profile.

20. The system of claim 19, wherein the blocks are arranged linearly with respect to the elongate shaft.

21. The system of claim 1, wherein a link couples the release member to the camshaft, and wherein the release member pushes the link to release the camshaft when moved into the second position.

22. The system of claim 1, wherein a link couples the release member to the camshaft, and wherein the release member, when moved laterally, releases the link to release the camshaft when moved into the second position.

23. The system of claim 1, wherein the release member is selected from the group comprising a button, a trigger or a switch.

24. A method for forming an incision and placing a pressure equalization tube in a tympanic membrane of an ear, the method comprising:

contacting a blunt distal end of a shaft of a tube delivery device with a tympanic membrane;

advancing a cutter out of the shaft distal end to form an incision in the tympanic membrane, wherein a dilator is disposed over at least a portion of the cutter;

advancing a shield disposed over the cutter and within the dilator out of the shaft distal end and into the incision to dilate the dilator, wherein the shield is disposed over a pressure equalization tube;

retracting the cutter into the shaft;

retracting the shield into the shaft, thereby releasing a distal flange of the pressure equalization tube such that it assumes an expanded configuration; and

pushing the pressure equalization tube out of the shield using a pusher disposed within the shield, thereby releasing a proximal flange of the pressure equalization tube such that it assumes an expanded configuration;

wherein, after being pushed out of the shield, a middle portion of the pressure equalization tube is disposed within the incision in the tympanic membrane and the distal and proximal flanges are disposed on opposite sides of the incision.

25. The method of claim 26, wherein the steps of retracting the shield and pushing the equalization tube occur simultaneously.

26. The method of claim 24, wherein the advancing, retracting and pushing steps are initiated by pressing a button on the tube delivery device.

27. The method of claim 26, further comprising moving a safety member on the tube delivery device from an off position to an on position before pushing the button.

28. The method of claim 26, further comprising removing a safety lock member from the delivery device before pushing the button.

29. The method of claim 24, wherein advancing the cutter comprises rotating a camshaft of the tube delivery device to a first cam position which causes a first cam follower to extend the cutter out of the outer shaft and also causes the fourth cam follower to extend the dilator out of the outer shaft.

30. The method of claim 29, wherein advancing the shield and retracting the cutter comprises rotating the camshaft to a second cam position which causes a second cam follower to move the shield out of the shaft to expand a distal portion of the dilator and also causes the first cam follower to move the cutting member back into the shaft.

31. The method of claim 30, wherein retracting the shield comprises rotating the camshaft to a third cam position which causes the second cam follower to move the shield back into the outer shaft and also causes a fourth cam follower to move the dilator back into the outer shaft, and also causes a third cam follower to move and push the pressure equalization tube partly out of the outer shaft.

32. The method of claim 31, wherein pushing the pressure equalization tube comprises rotating the cam shaft to a final position which causes the third cam follower to further move the pusher and further push the pressure equalization tube partly out of the outer shaft.

33. The method of claim 32, wherein the cam shaft is rotated from the first position to the final position in a single continuous motion.

34. The method of claim 32, wherein the steps of pushing the pressure equalization tube and retracting the shield occur simultaneously.

35. The method of claim 32, wherein contacting the blunt distal end comprises applying negative pressure to the tympanic membrane with the blunt distal end of the shaft to elevate the TM and enhance contact of the distal end of the shaft with the tympanic membrane.

36. The method of claim 35 wherein the applied negative pressure actuates rotation of the camshaft.

FIG. 1A

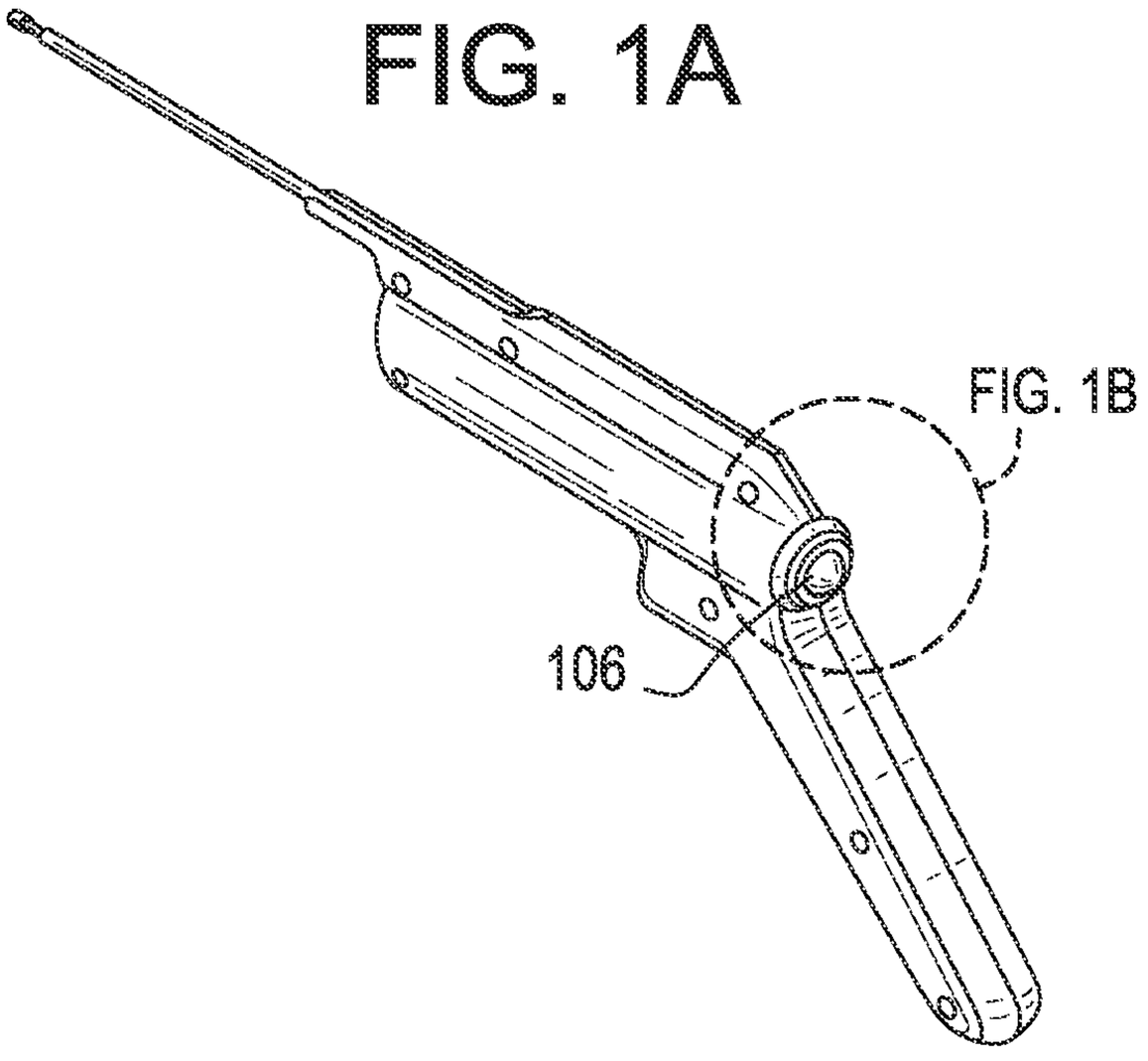


FIG. 1B

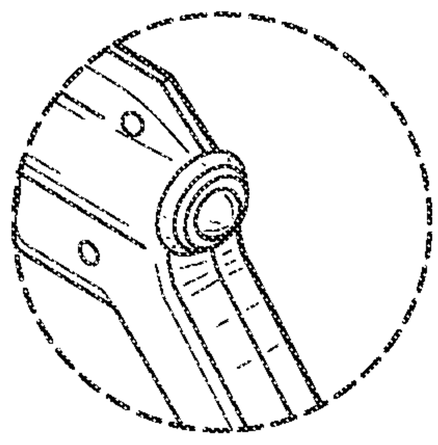


FIG. 1C

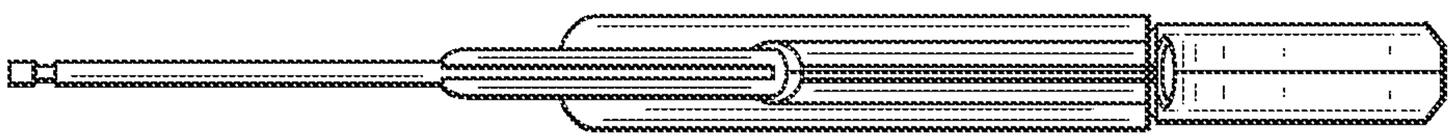


FIG. 1D

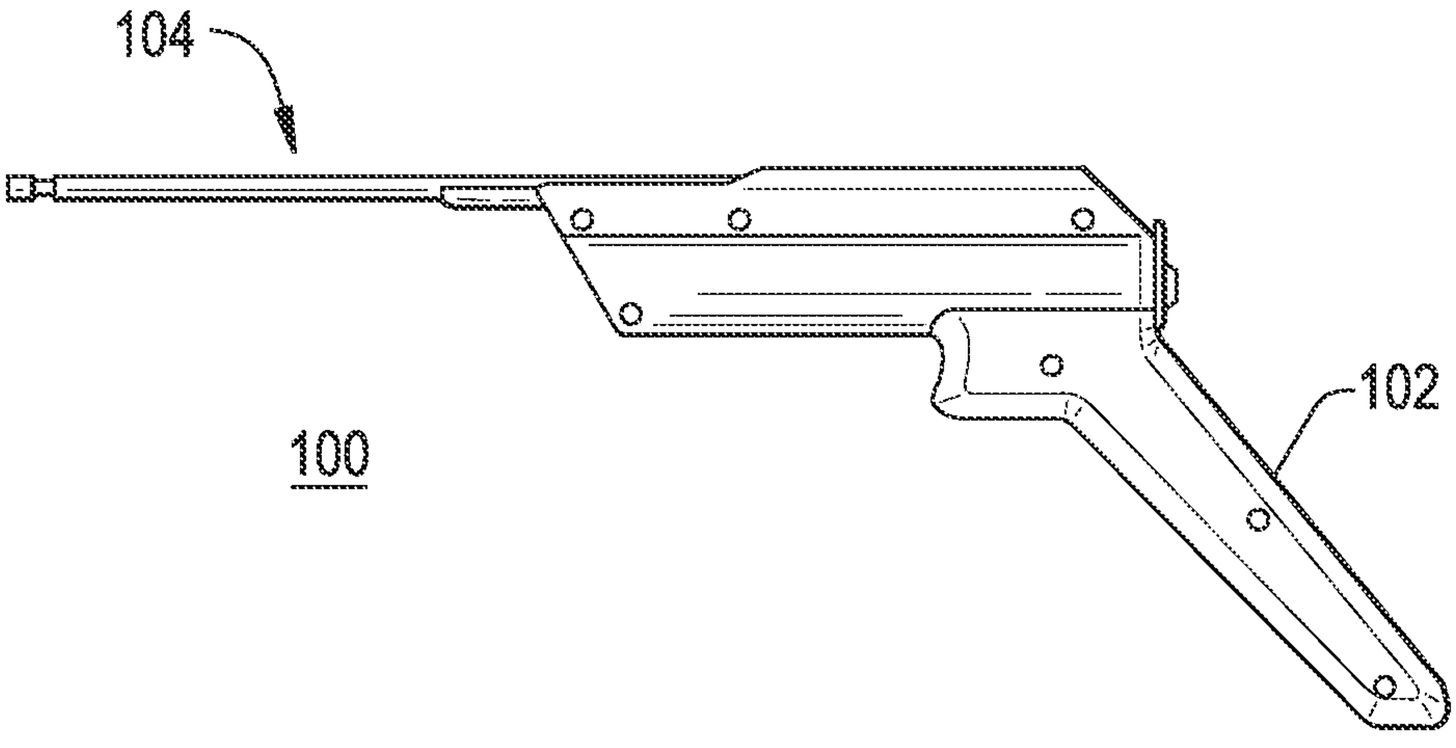


FIG. 1E

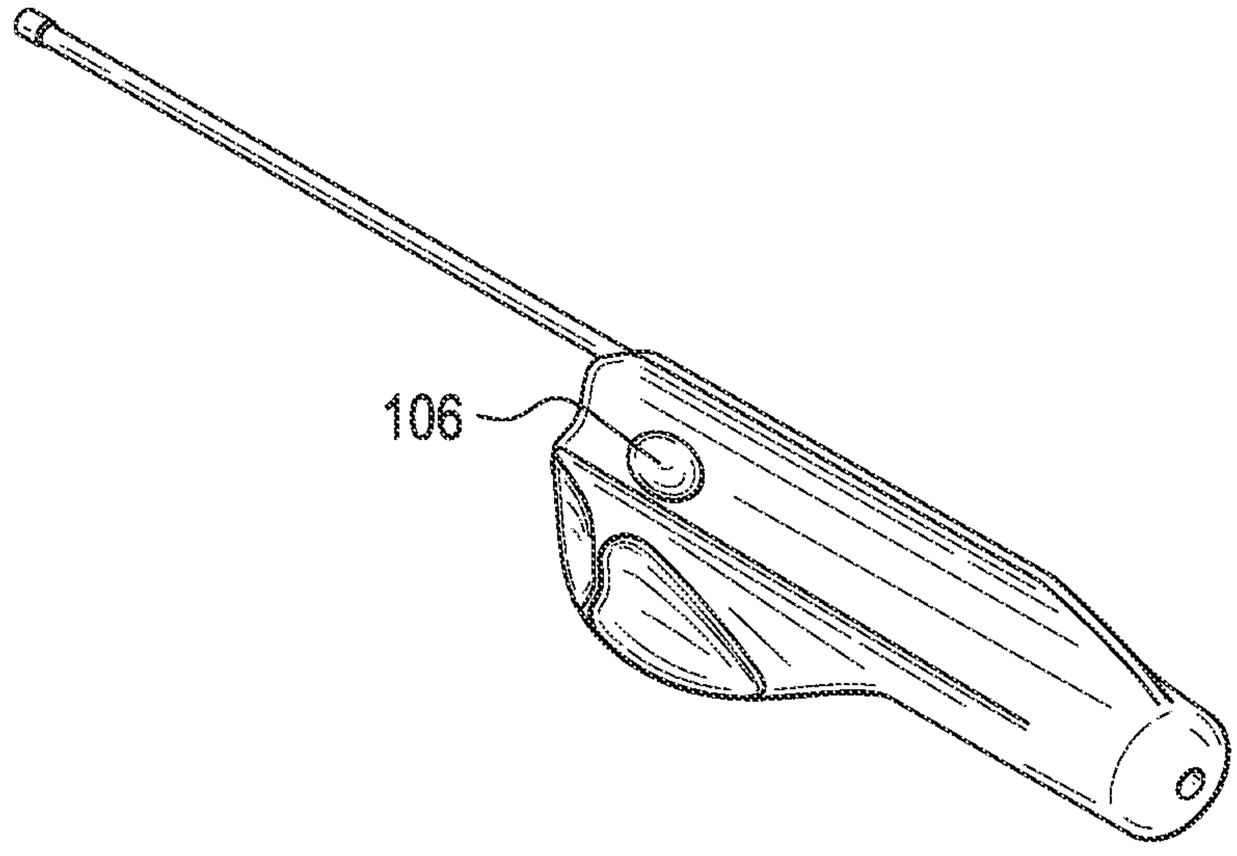


FIG. 1F

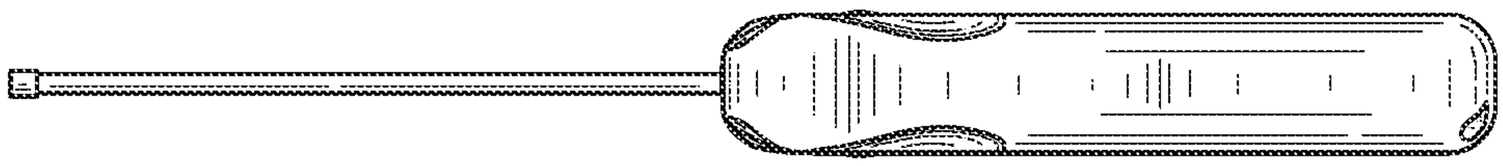


FIG. 1G

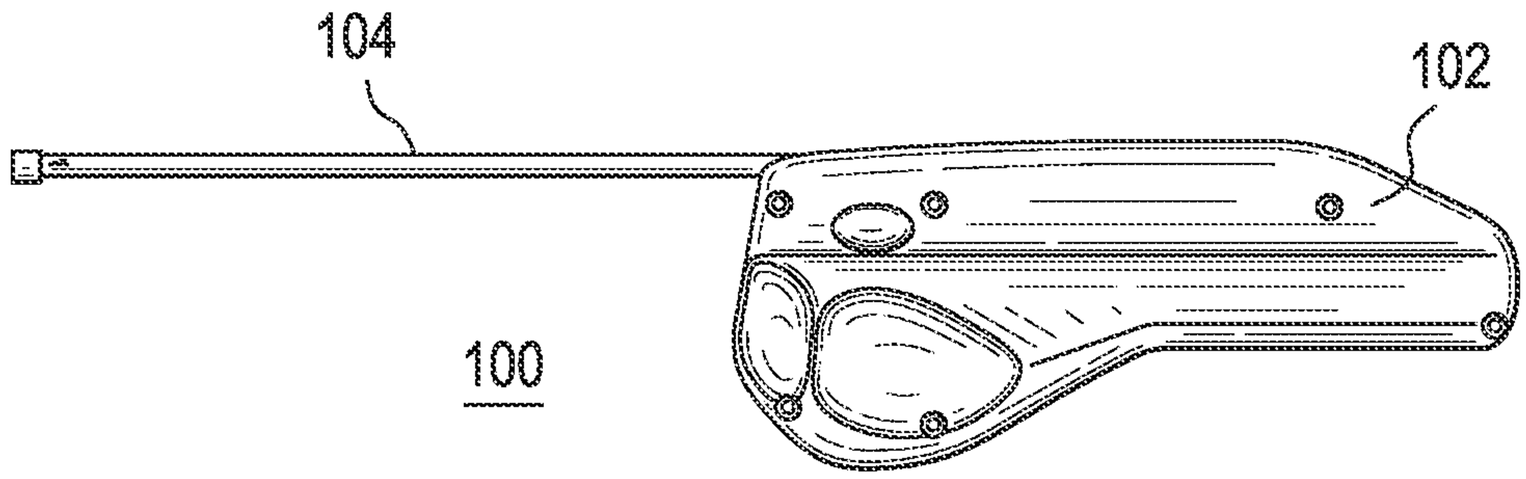
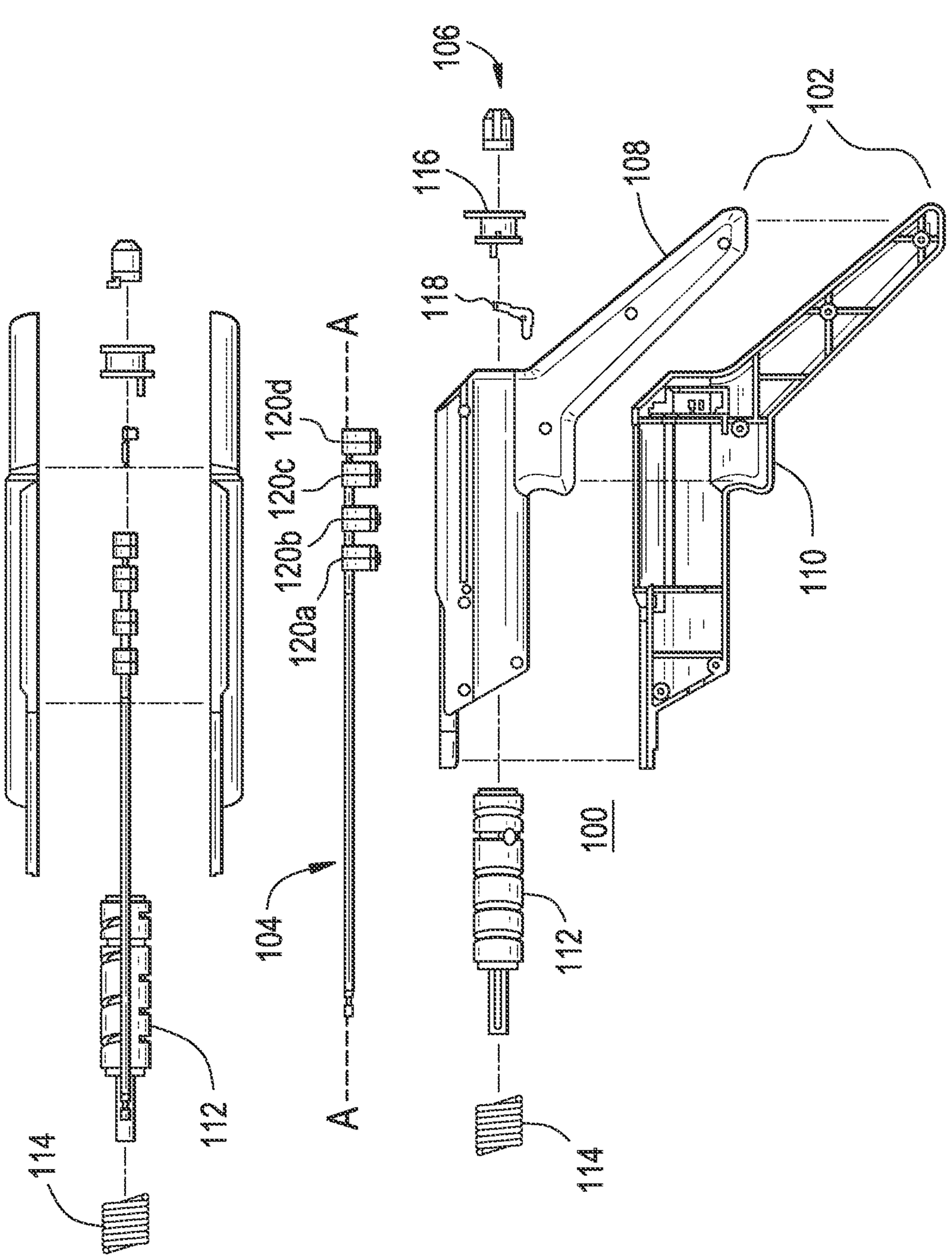


FIG. 1H


106
116
118
108
102
110
100
112
114
104
120a
120b
120c
120d
A
A
112
114

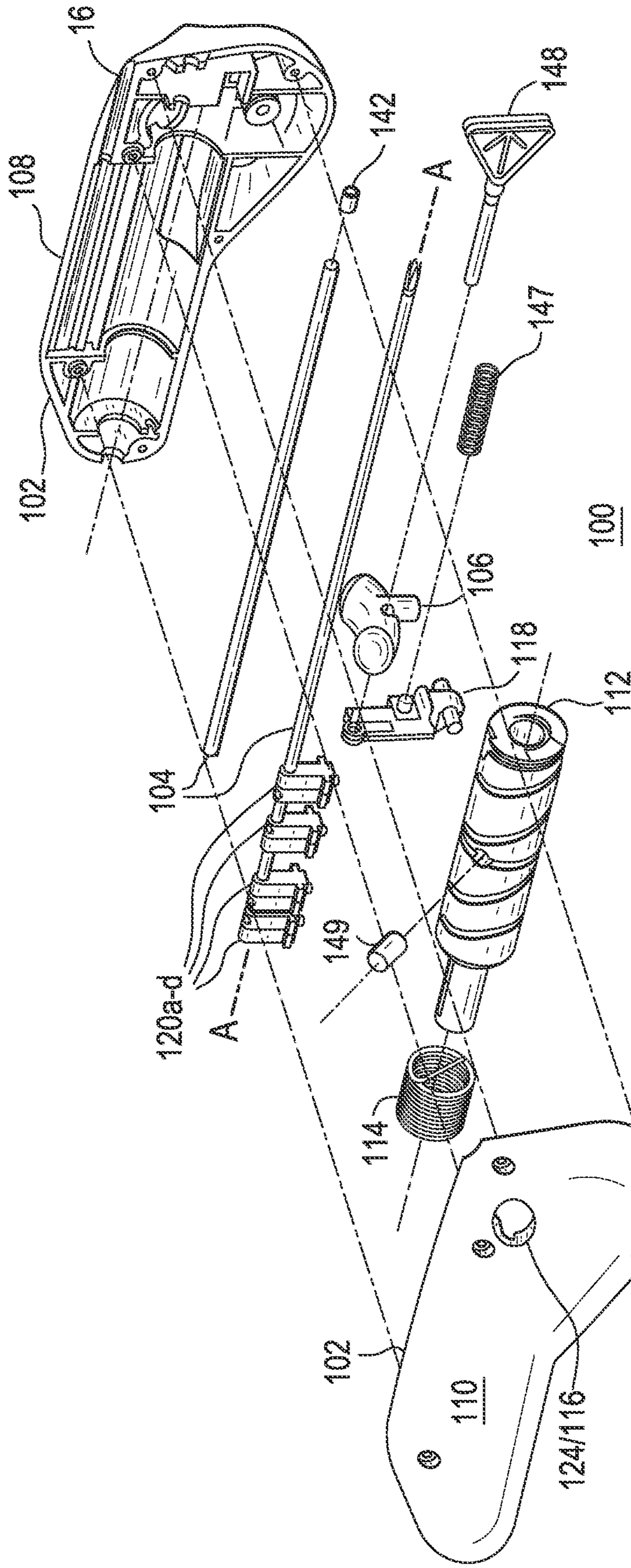
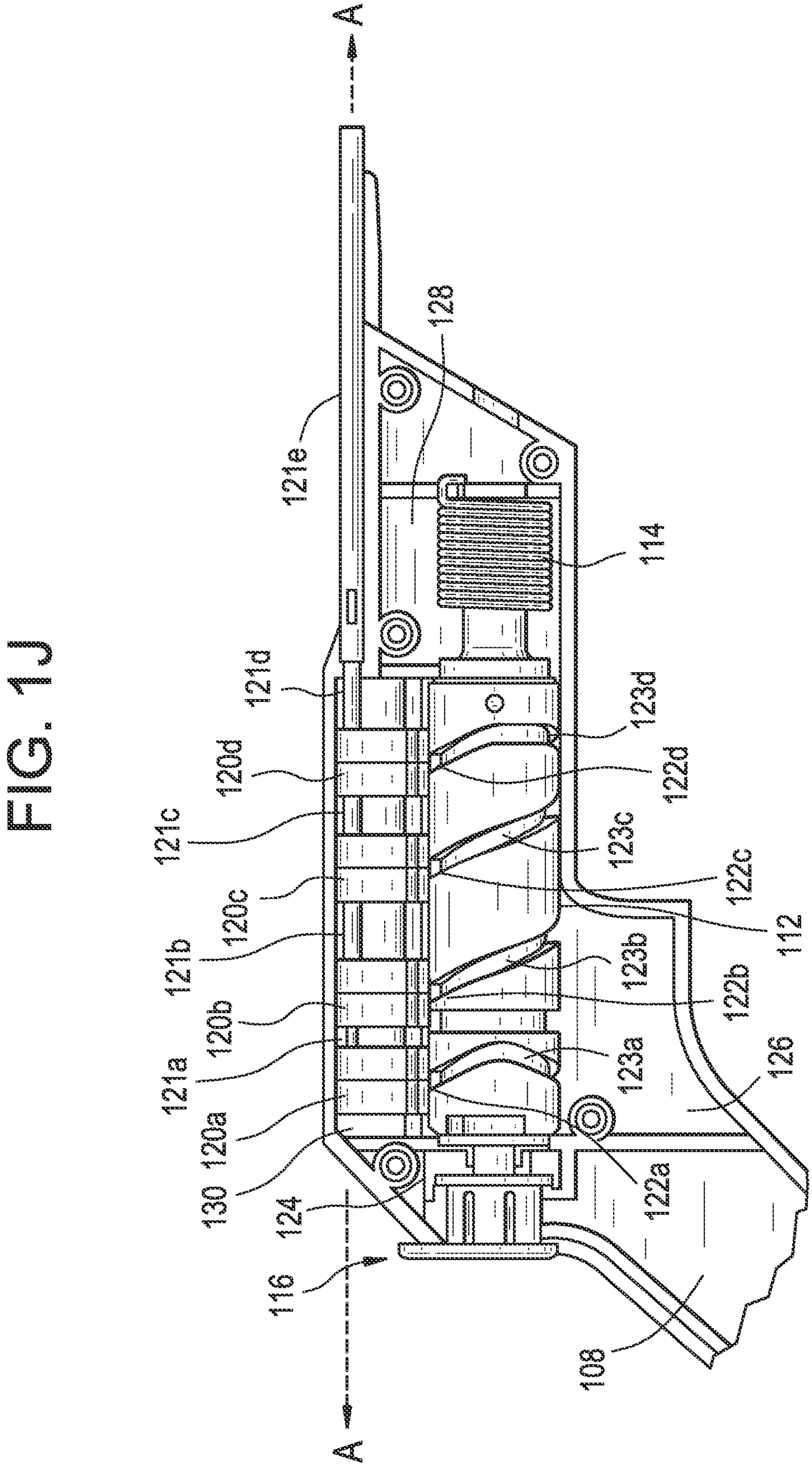

16
142
148
108
A
147
102
106
100
118
112
104
149
120a-d
A
114
102
110
124/116

FIG. 1I

FIG. 1J


A
121e
128
114
121d
120d
123d
122d
121c
120c
123c
122c
112
121b
120b
123b
122b
126
121a
123a
120a
130
124
122a
116
108
A

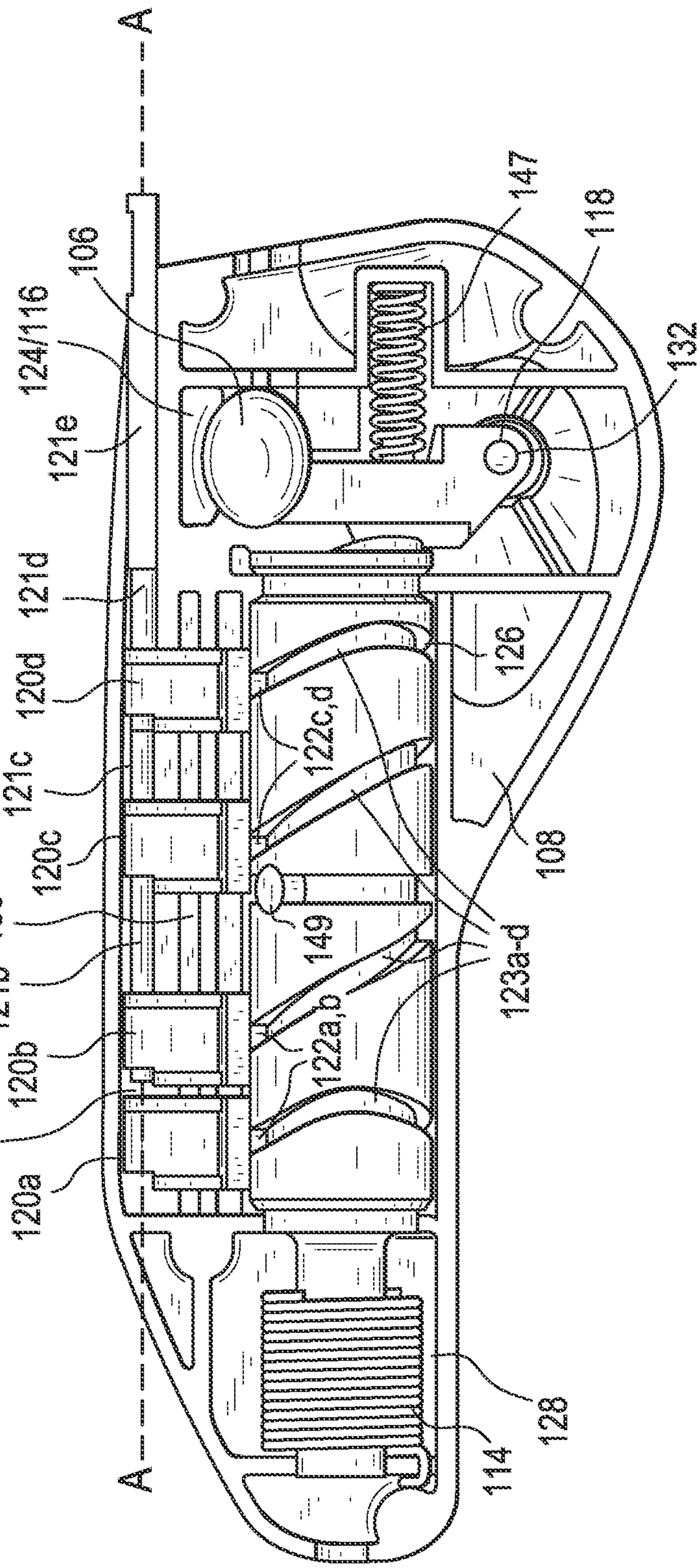

A
A
106
124/116
121e
121d
120d
121c
120c
130
121b
120b
121a
120a
126
122c,d
108
149
122a,b
123a-d
118
132
114
128

FIG. 1K

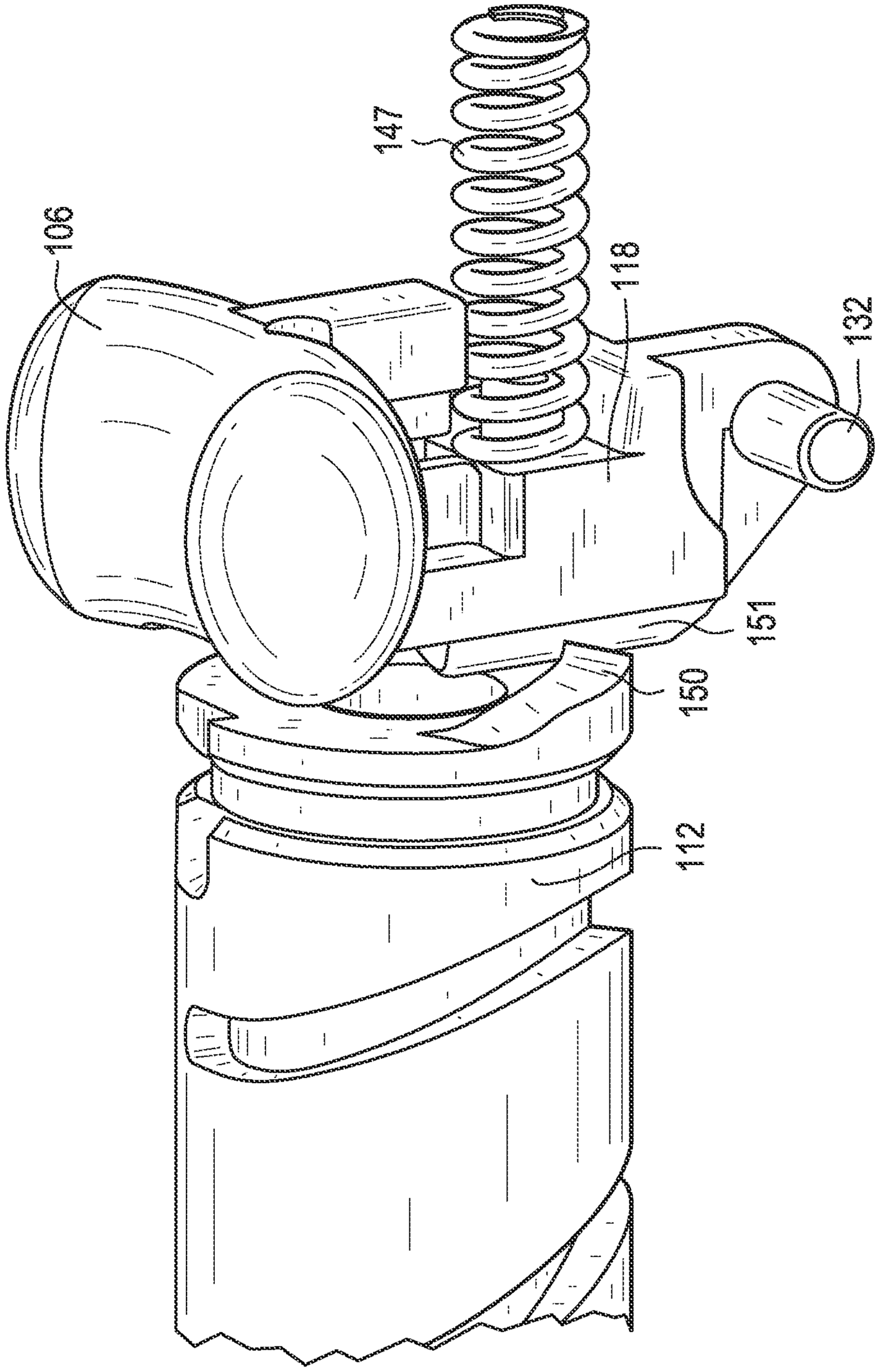


FIG. 1L

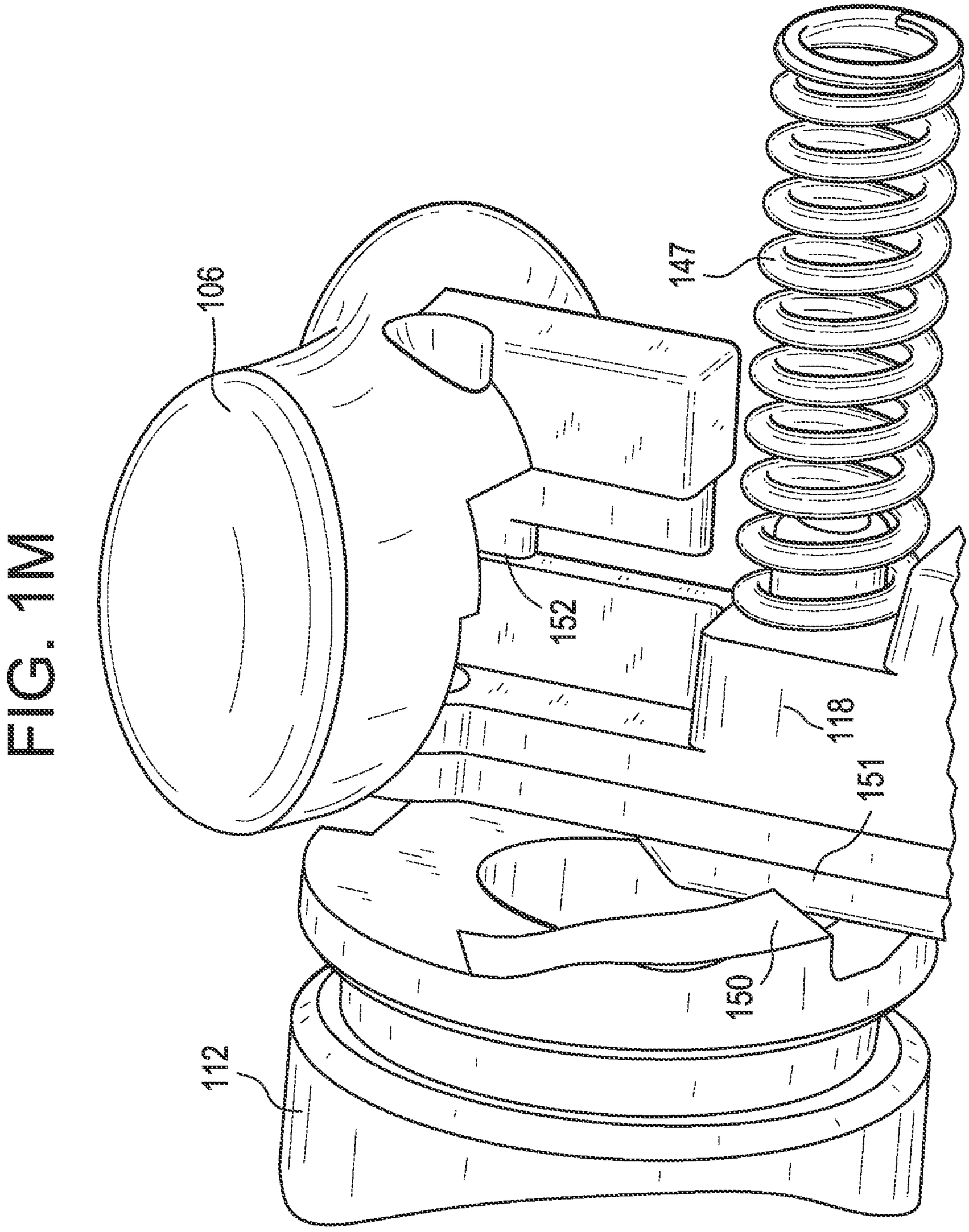


FIG. 1M

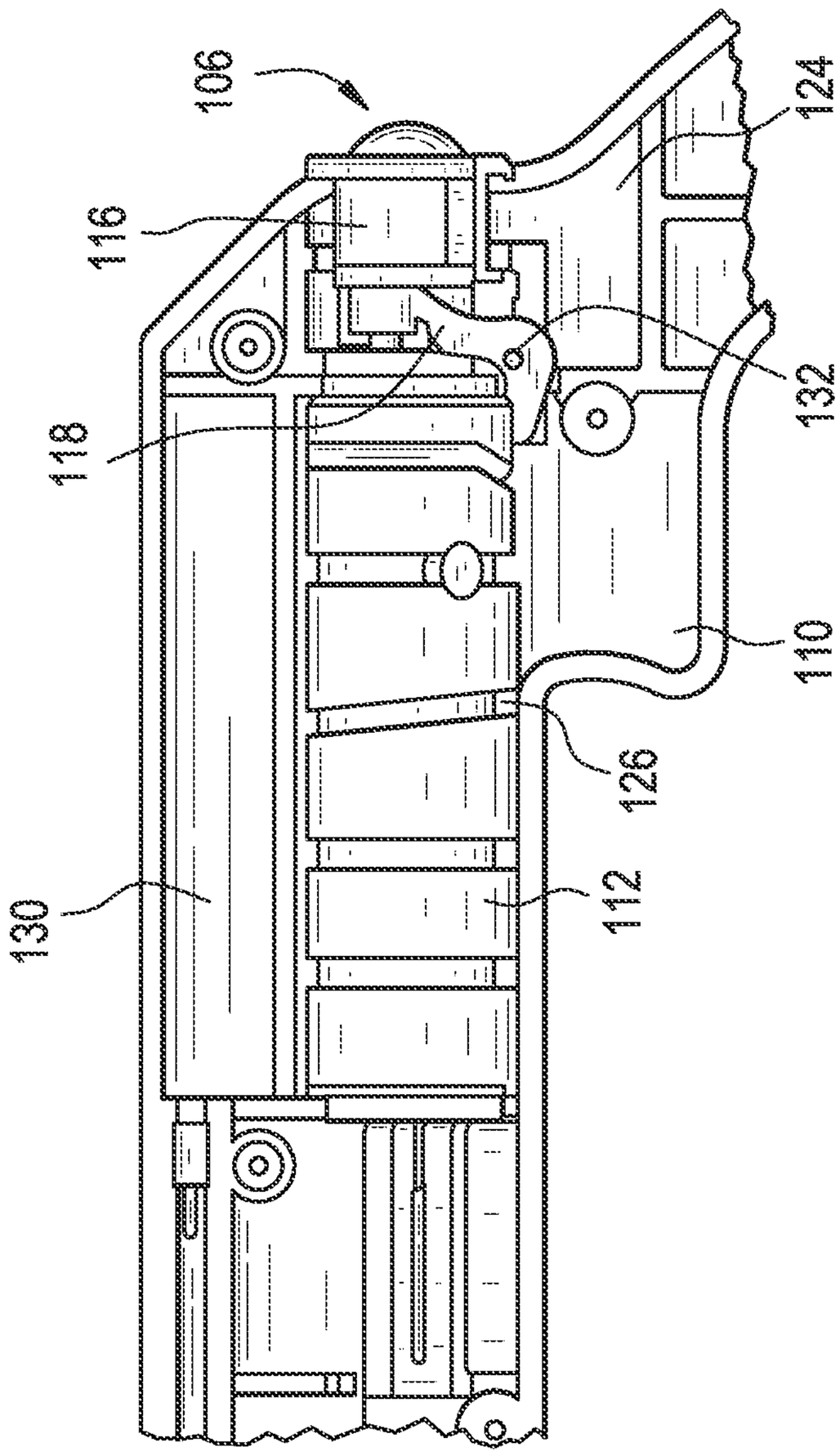


FIG. 1N

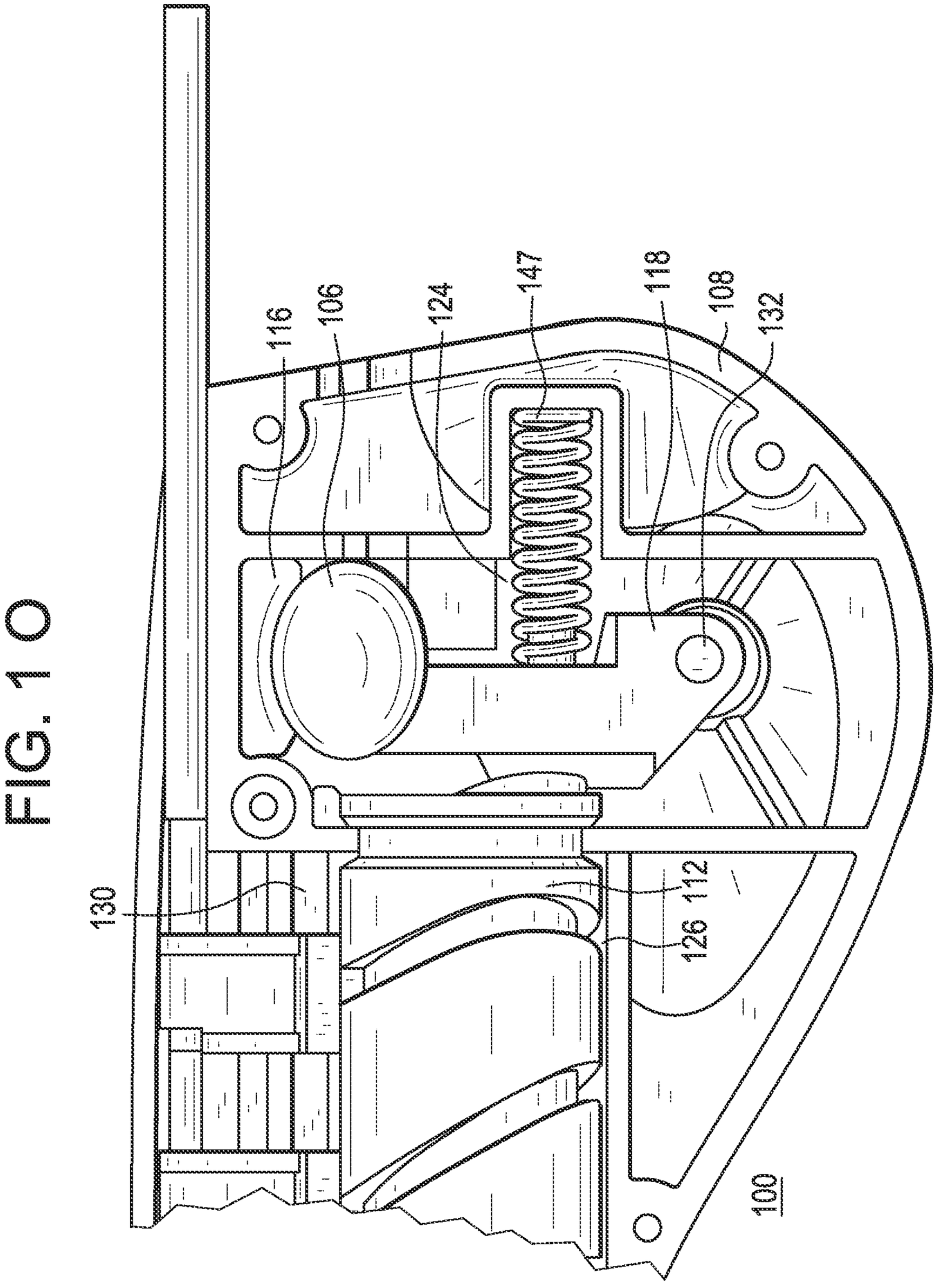


FIG. 10

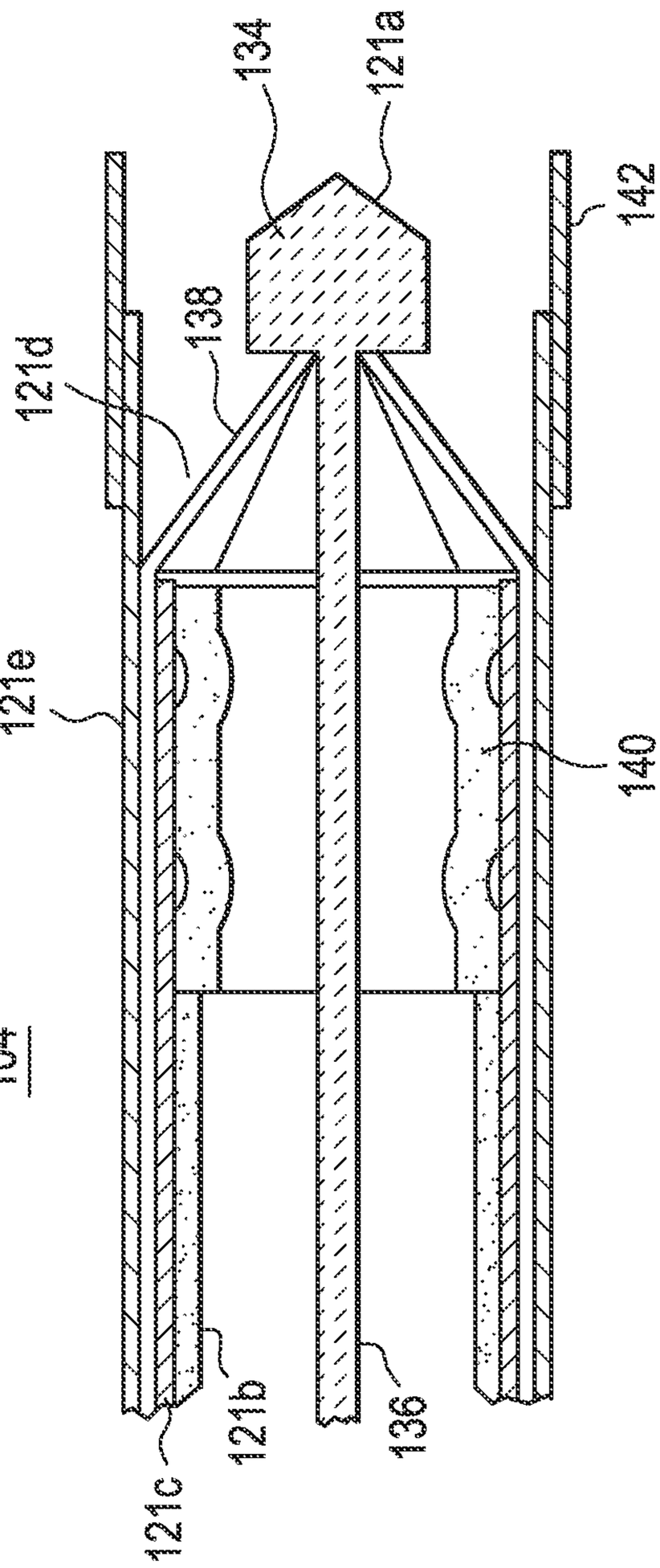


FIG. 1P

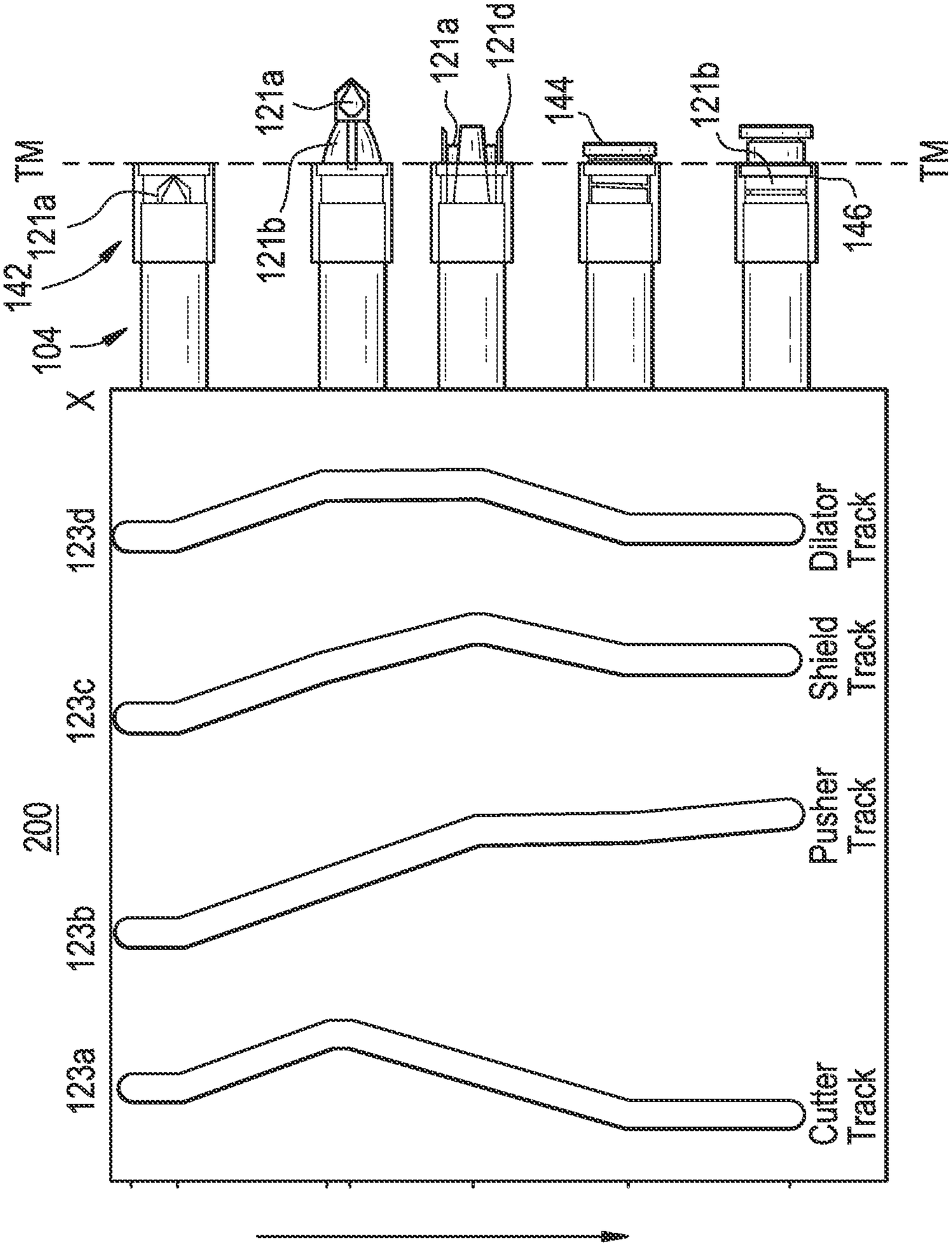

Cam Rotation Y
200
123a
123b
123c
123d
Cutter Track
Pusher Track
Shield Track
Dilator Track
X
104
142
121a
TM
121b
121a
121d
144
121b
146
TM

FIG. 2A

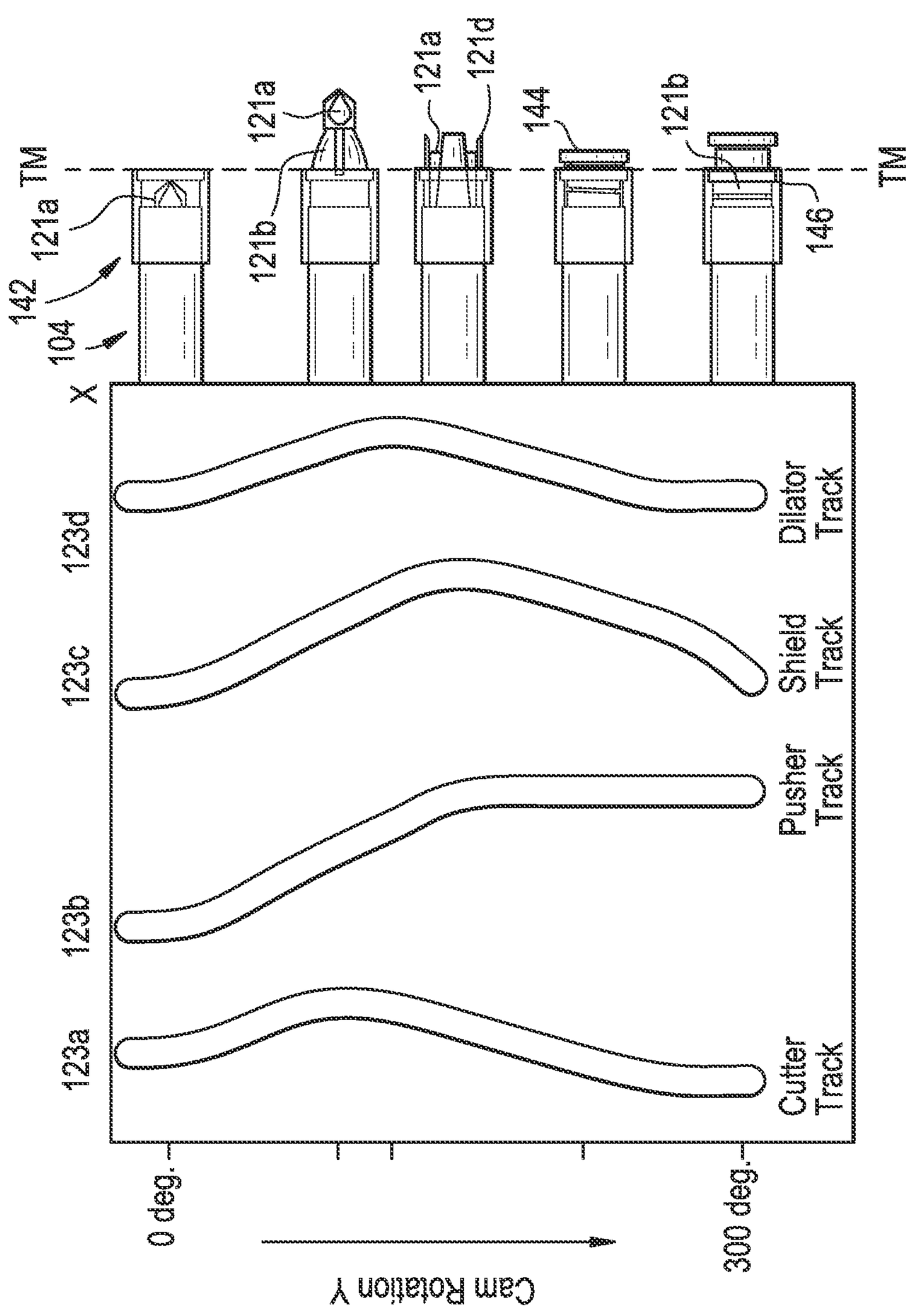
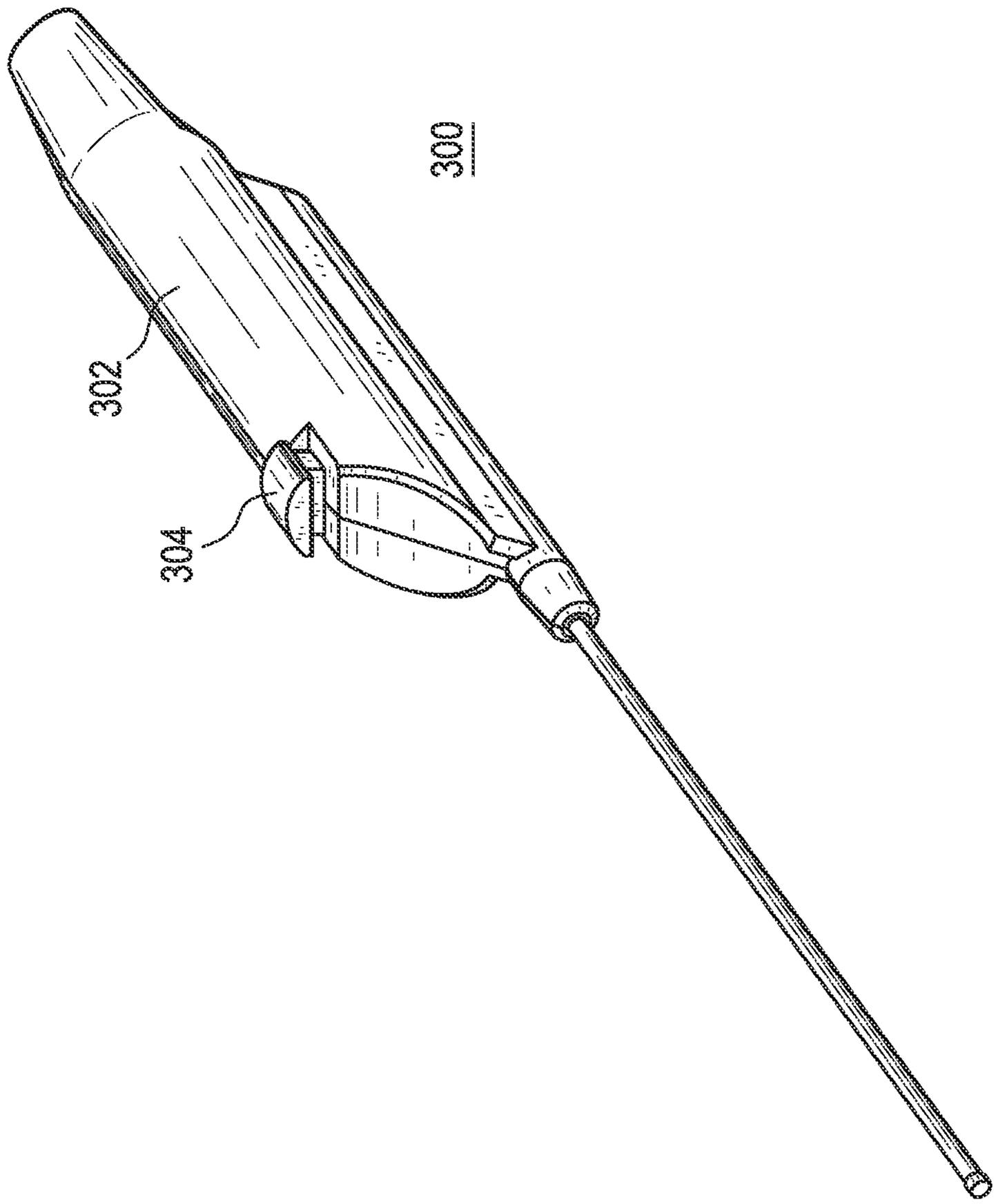

142
121a
TM
104
X
121a
121b
121b
144
121b
146
TM
123a
123b
123c
123d
Cutter Track
Pusher Track
Shield Track
Dilator Track
0 deg.
300 deg.
Cam Rotation Y

FIG. 2B

FIG. 3



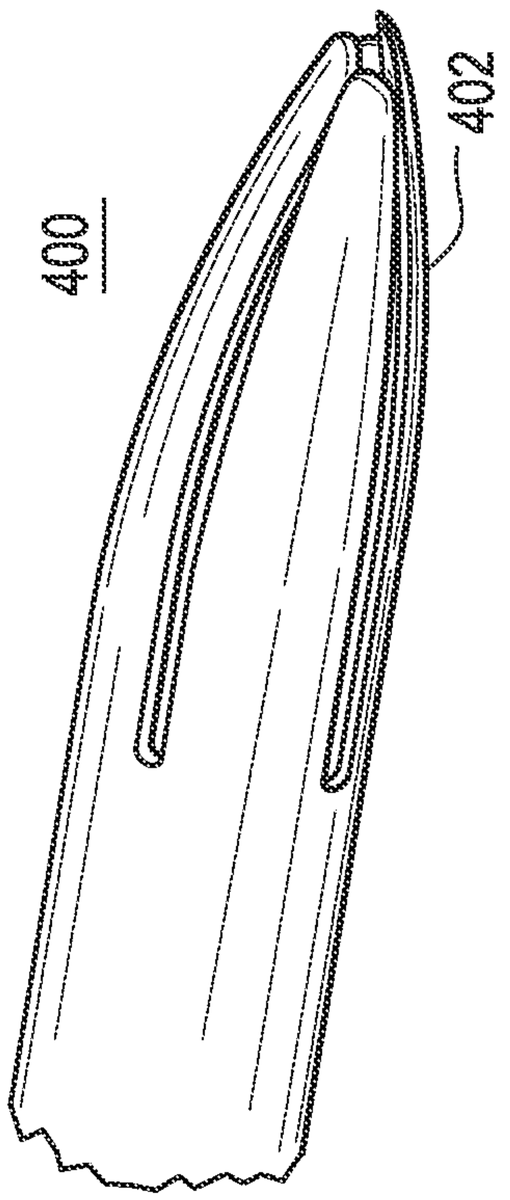


FIG. 4C

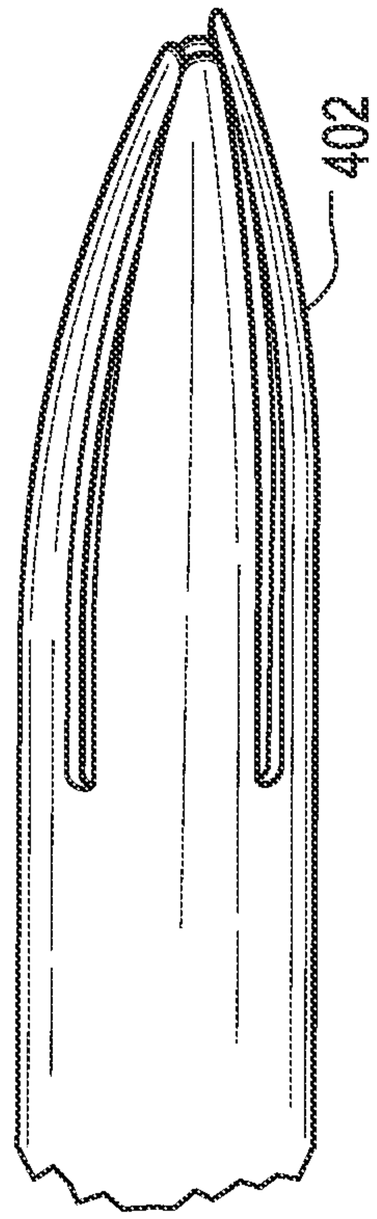


FIG. 4D

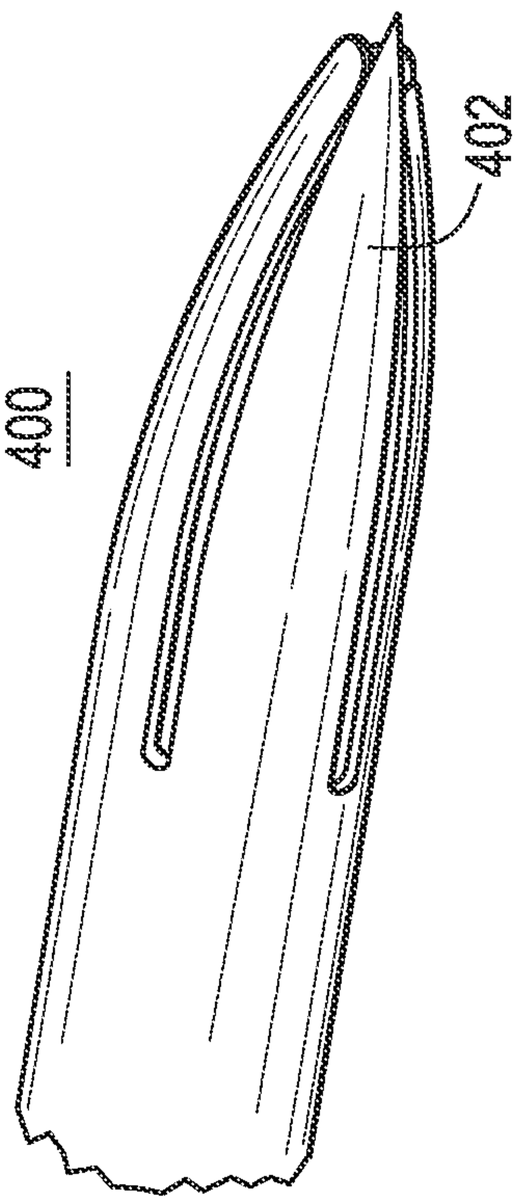


FIG. 4A

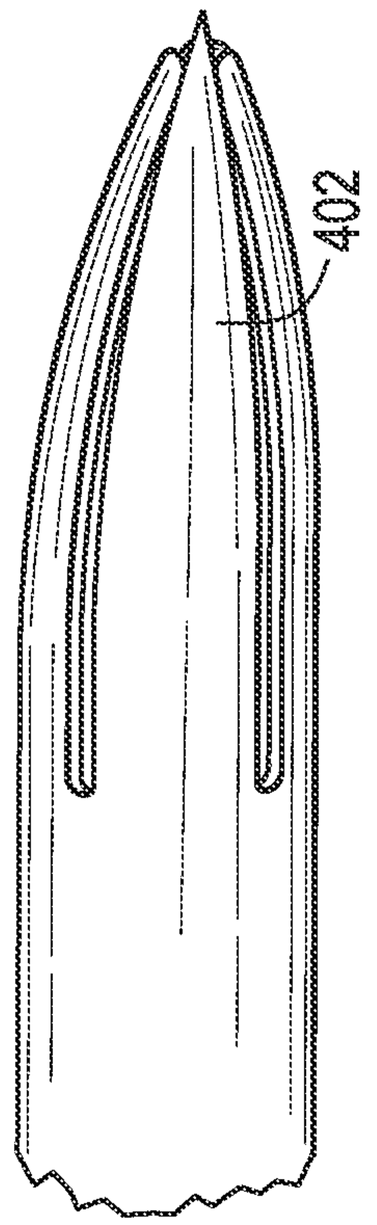


FIG. 4B

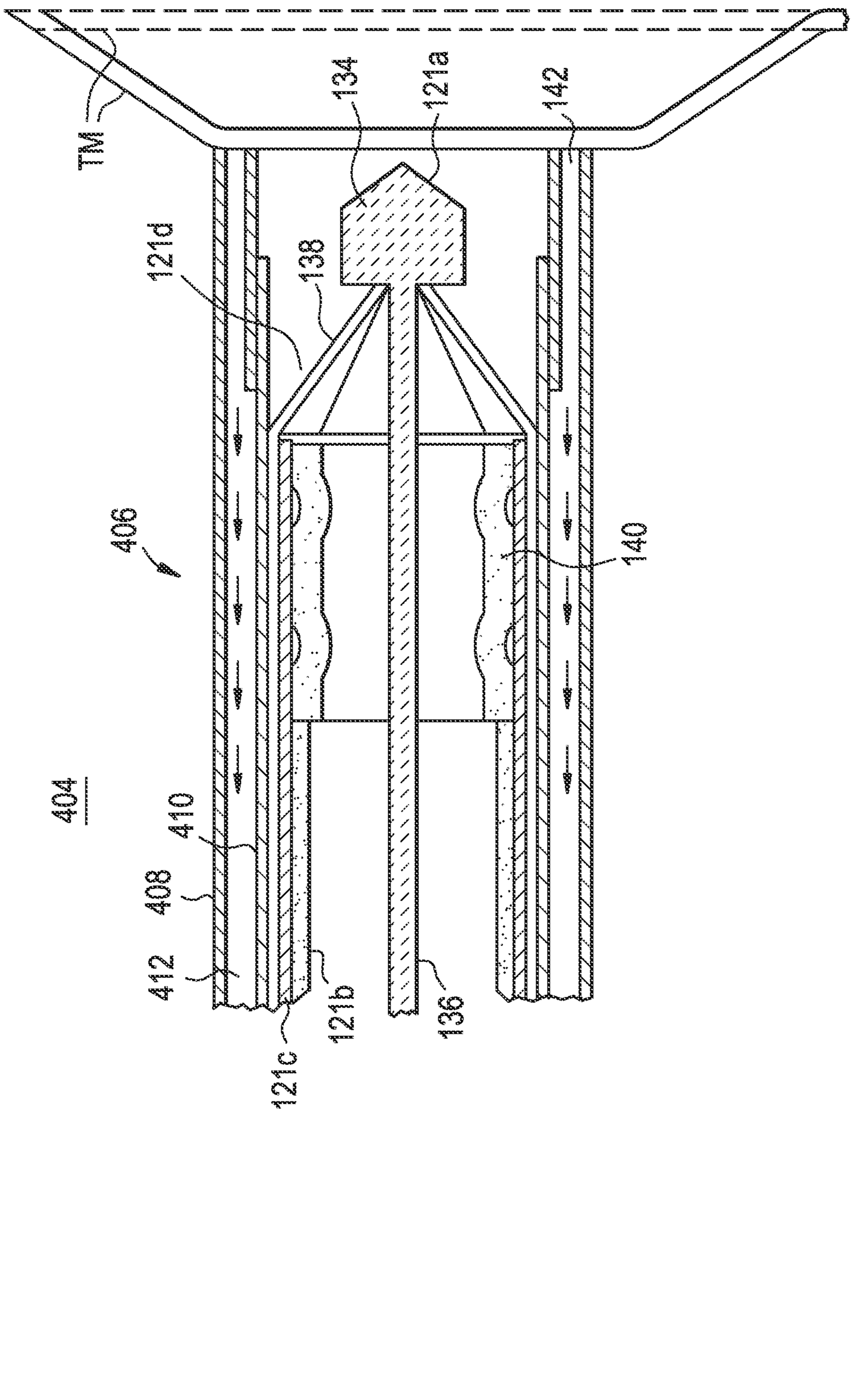


FIG. 4E

FIG. 4F

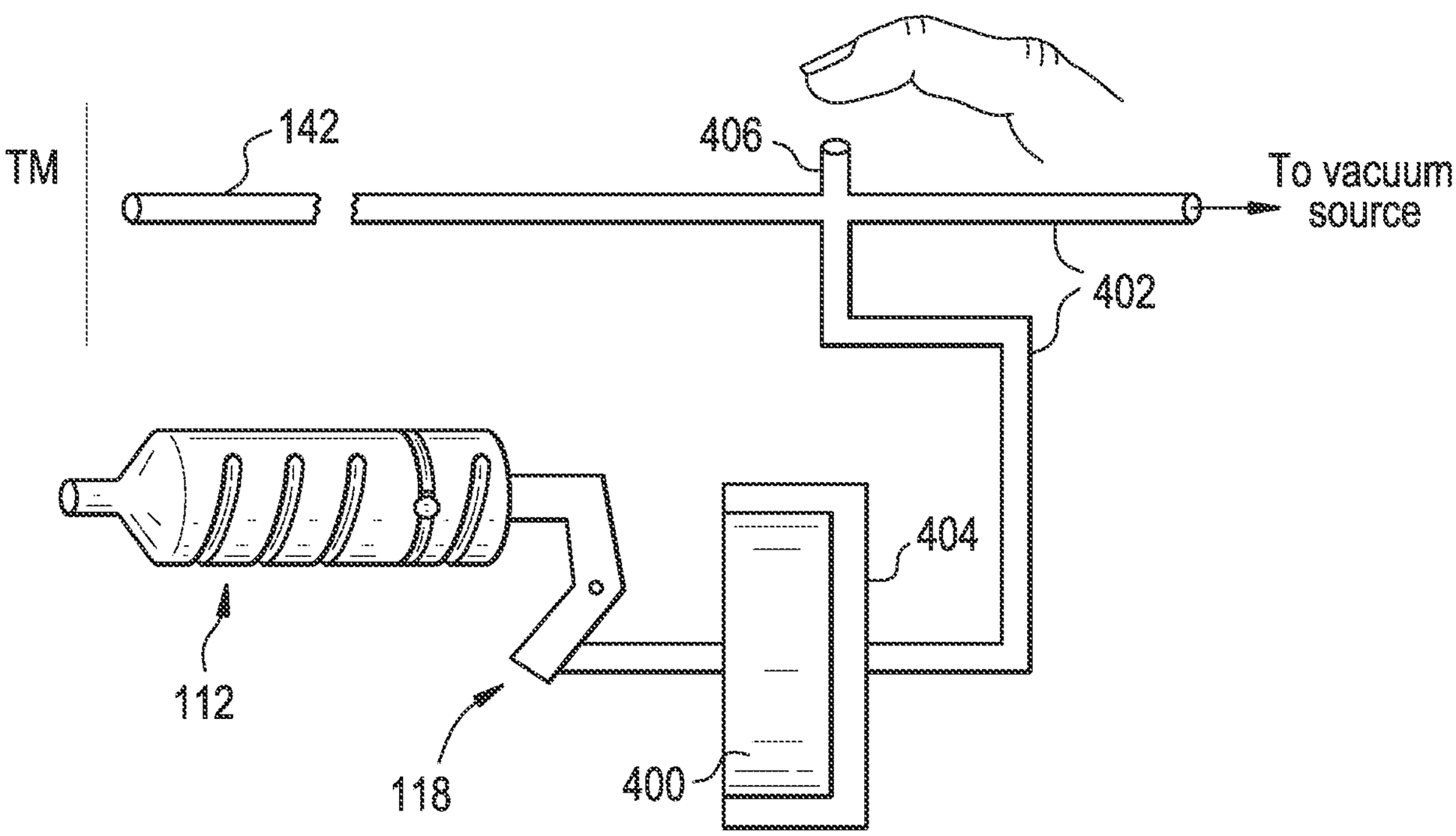


FIG. 5A

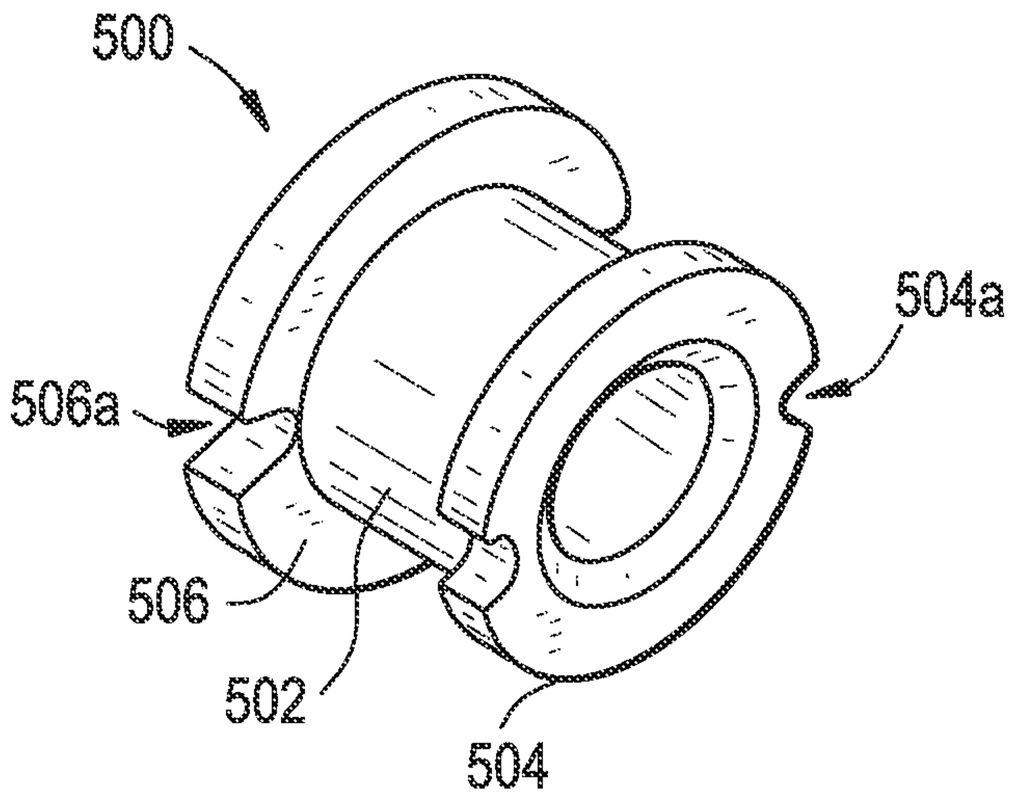


FIG. 5B

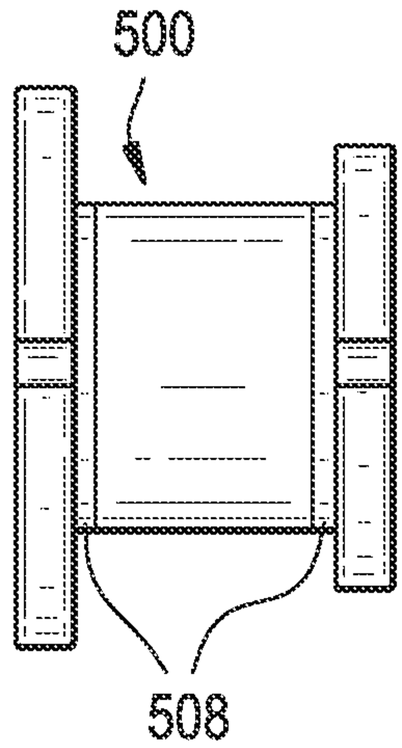


FIG. 5C

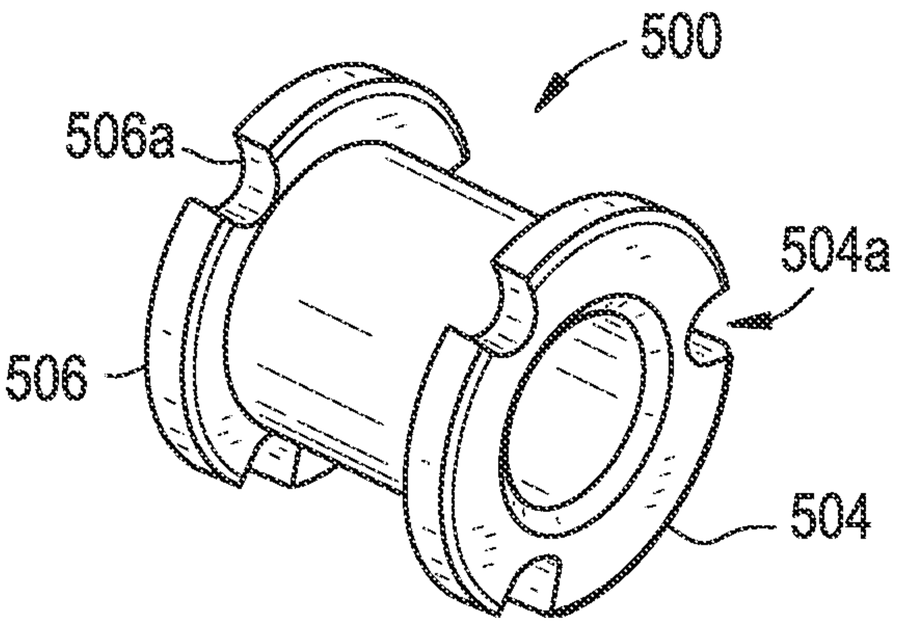


FIG. 5F

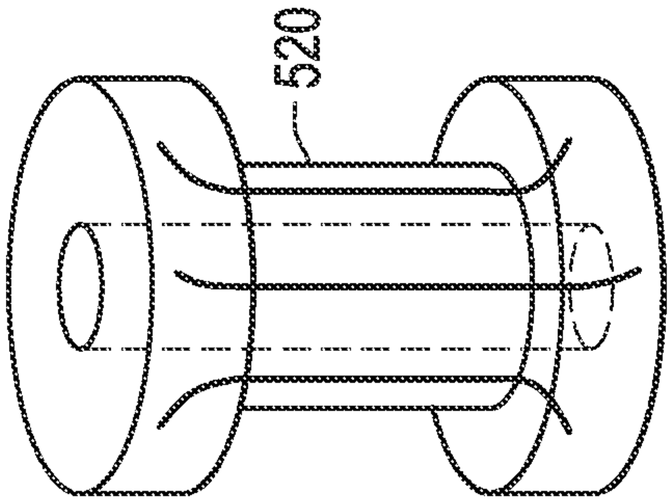


FIG. 5E

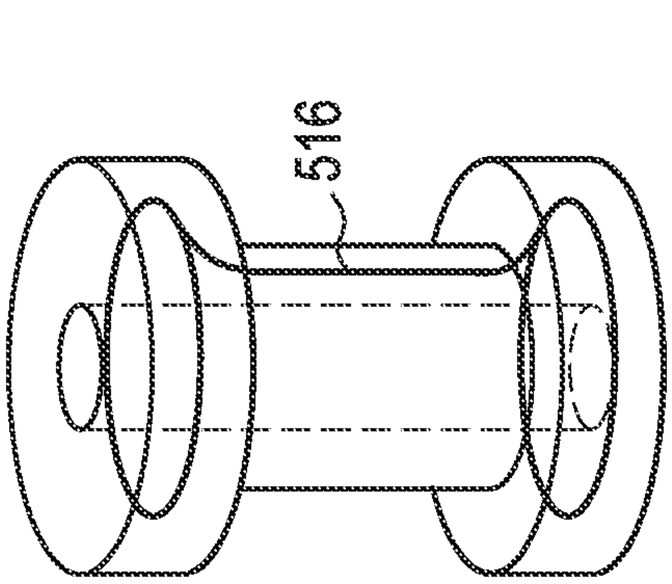


FIG. 5G

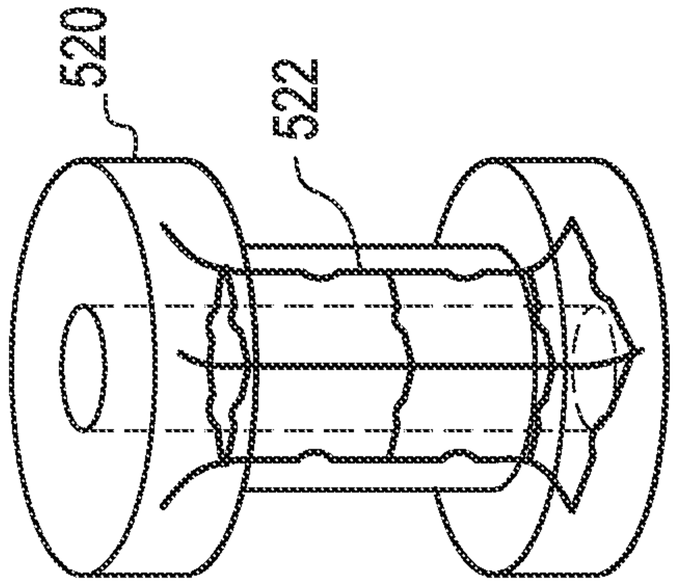


FIG. 5D

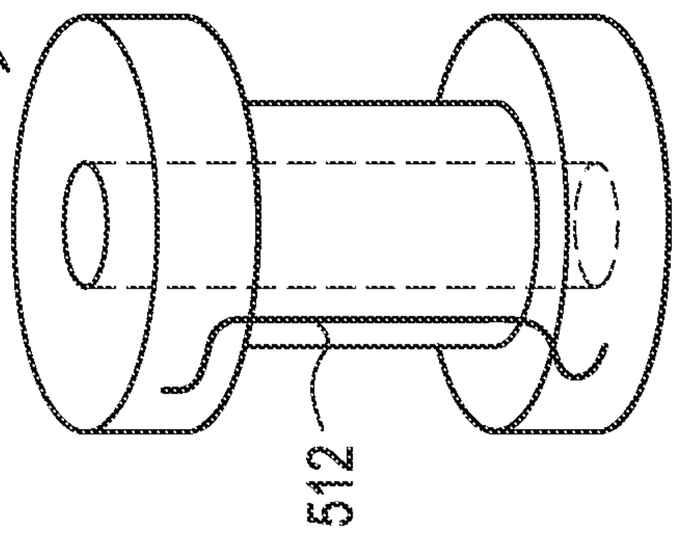


FIG. 1E