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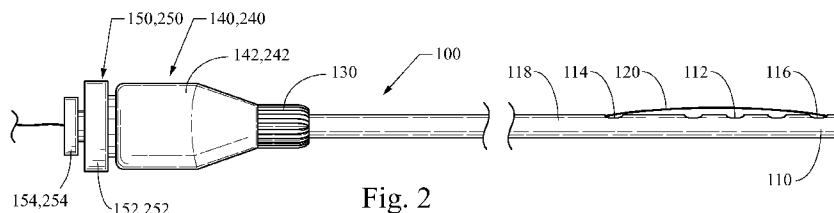


Fig. 2

(57) Abstract: A tension member locking mechanism may include a lock body (140, 240) that is movable between an open position and a closed position. The tension member locking mechanism may include a resilient member (170) having first and second ends and a lumen (174) disposed therein. The lumen (174) may extend in a substantially straight line through the resilient member (170) in a longitudinal direction between the first and second ends. An elongate tension member (120) may extend in a substantially straight line through the lumen (174) from at least the first end to the second end of the resilient member (170). When the lock body is (140, 240) moved from the open position to the closed position, the lock body (140, 240) twistingly engages the resilient member (170) and causes a portion of the resilient member (170) that defines at least a portion of the lumen (174) to compressively engage the elongate tension member (120) such that the elongate tension member (120) cannot freely move through the lumen.

CATHETER TENSION MEMBER LOCKING MECHANISM

BACKGROUND

[0001] The present invention relates generally to catheters and particularly to a lockable connector for drawing and maintaining the distal end of a catheter into a desired configuration.

[0002] Physicians currently use stabilizing elements to immobilize catheters and tubes within various body lumens, including the gastrointestinal tract and the biliary duct. For example, suprapubic catheterization of the bladder is used to drain the bladder after surgery or when the genitourinary system is plugged by an obstruction. Percutaneously inserted catheters are also used to drain the kidney or biliary system as well as to drain abscesses, or other sites of fluid collection, and other viscera. Still other percutaneously inserted catheters are employed as gastrostomy feeding tubes.

[0003] Typically, these catheters are introduced into the patient by means of a large hypodermic needle or trocar, which pierces the abdominal wall. A wire guide is inserted through the needle and then removed. A catheter tube having a stiffening cannula positioned therein is then passed over the wire guide into the cavity. The cannula and wire guide are then withdrawn, leaving the catheter in the desired cavity.

[0004] With respect to the bladder, an advantage of this technique is that irritation and infection of the urinary tract is minimized. However, one problem with these catheters is that the catheter may be easily pulled out by body movement, or by emptying of, for example, the bladder. Another problem is that side ports at the distal end of the catheter may be inadvertently drawn into the abdominal cavity, creating the potential for severe infections.

[0005] Various catheters have been developed with so-called pigtail loops at their distal ends for ensuring drainage of the cavity and preventing

accidental removal therefrom. Generally, the pigtail loop is formed by pulling on a first end of a flexible tension member, for example, a suture, which extends through an inner lumen of the catheter. The second end of the tension member is secured to or within the catheter. The first end of the tension member extends out of a first aperture at or near the distal end of the catheter, and is looped back into the catheter through a second aperture disposed proximal of the first aperture. The first end of the tension member is then directed through the lumen in the proximal direction toward the proximal end of the catheter. When the first end of the tension member is pulled proximally, it causes the distal end of the catheter to bend and assume the aforementioned "pigtail" shape, which is larger than the aperture opened by the trocar, thereby preventing the catheter from being accidentally withdrawn.

[0006] While the pigtail configuration is commonly used to obtain the locked configuration of the distal end of the catheter, other configurations may also be used. For example, another locking configuration utilizes a catheter with axial cuts that subdivide the catheter tube into several sections. In these catheters, a tension member, such as a suture, attaches to the catheter tube at the distal end of the axial cuts, and when the tension member is tensioned the catheter axially shortens and the cut portions flare out to form an anchoring device. However, regardless of the particular "anchor" structure used to achieve the locked configuration at the distal end of the catheter, the first end of the tension member may be held in place by any one of a number of retention means.

[0007] For example, the first end of the flexible tension member may be secured by axially placing a hollow cap into or over the first end of the catheter tube, thus trapping the flexible tension member in place and allowing the protruding first end to be cut. A problem with this catheter design is that once the protruding first end of the flexible tension member is cut, the hollow cap may slip or be inadvertently removed. As a result, the shortened flexible tension member moves distally, releases the pigtail,

and is either difficult or impossible to retrieve. In another case, the flexible tension member is trapped between two or more hollow tubes, one of which is slidably inserted axially into the other. A short length of the flexible member is generally left hanging from the catheter tube so that if the flexible tension member becomes loose, it may be retightened. Alternatively, an external sleeve is slid over the flexible tension member protruding from the side of the catheter tube. This external sleeve may be located within an external locking device in which a lever arm with a cam may be used to press the sleeve tightly against the tension member to lock it in place. Other retention means utilize levers and cam systems to engage and hold the flexible tension member in place.

[0008] Such devices may enlarge the profile of the drainage catheter and require additional connections, thereby complicating the drainage procedure. Additionally, the increased profile may require more space to house the catheter/retention means in cases where the entire catheter is implanted within the patient, potentially impairing patient comfort. Therefore, it has become apparent to the inventor that an improved tension member locking mechanism is desirable.

SUMMARY

[0009] Tension member locking mechanisms are described which may allow for a simpler and lower profile configuration. The embodiments described below may include any of the following aspects in various combinations and may also include any other aspect described below in the written description or in the attached drawings.

[0010] In one aspect, a tension member locking mechanism may include a lock body that is movable between an open position and a closed position. The tension member locking mechanism may also include a resilient member having first and second ends and a lumen disposed therein. The lumen may extend in a substantially straight line through the resilient member in a longitudinal direction between the first and second

ends. An elongate tension member may extend in a substantially straight line through the lumen from at least the first end to the second end of the resilient member. When the lock body is moved from the open position to the closed position, the lock body twistingly engages the resilient member and causes a portion of the resilient member that defines at least a portion of the lumen to compressively engage the elongate tension member such that the elongate tension member cannot freely move through the lumen.

[0011] The foregoing paragraphs have been provided by way of general introduction, and are not intended to limit the scope of the following claims. The presently preferred embodiments, together with further advantages, will be best understood by reference to the following detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The invention may be more fully understood by reading the following description in conjunction with the drawings, in which:

Figure 1 is a side elevation view of a drainage catheter having a distal end in a locked configuration;

Figure 1a is a close-up exploded view of the connection between a lock body and a catheter tube of the drainage catheter of Figure 1;

Figure 2 is a side elevation view of the drainage catheter of Figure 1 in an insertable configuration;

Figure 3 is an exploded side cross-sectional view of an embodiment of a lock body of the drainage catheter of Figure 1;

Figure 4 is an assembled cross-sectional view of the lock body of Figure 3 in an unlocked position;

Figure 5 is a cross-sectional view of the lock body of Figure 3 in a locked position;

Figure 6a is a top cross-sectional view of the lock body along the line A of Figure 4;

Figure 6b is a top cross-sectional view of the lock body along the line B of Figure 4;

Figure 6c is a top cross-sectional view of the lock body along the line C of Figure 5;

Figure 7 is a close-up cross-sectional view of the locking mechanism of the lock body of Figures 4 and 5;

Figure 8 is an elevation side view of a resilient member of the lock body in a twisted, locked configuration;

Figures 9-14 illustrate various embodiments of the resilient member in an unlocked configuration;

Figure 15 is an exploded side cross-sectional view of another embodiment of a lock body of the drainage catheter of Figure 1;

Figure 15a is an orthogonal view of a receiver portion the lock body of Figure 15a;

Figure 16 is an assembled cross-sectional view of the lock body of Figure 14a in an unlocked position;

Figure 17 is a cross-sectional view of the lock body of Figure 15 in a locked position;

Figure 18a is a top cross-sectional view of the lock body along the line A of Figure 16;

Figure 18b is a top cross-sectional view of the lock body along the line B of Figure 16;

Figure 18c is a top cross-sectional view of the lock body along the line C of Figure 17; and

Figure 19 is a close-up orthogonal cross-sectional view of an inner surface of a receiver portion of the lock body of Figures 4 and 5.

DETAILED DESCRIPTION

[0013] Referring now to the figures, Figures 1-2 illustrate a drainage catheter according to an embodiment of the present invention. The drainage catheter 100 may be used for any number of medical procedures

in which a bodily fluid is drained out of a cavity or lumen, for example and without limitation, biliary drainage, nephrostomy, suprapubic bladder drainage, and abscess drainage. Additionally, while the following description is directed to pigtail drainage catheters, it should be understood that any drainage catheter that utilizes an elongate tension member to achieve a locked configuration at the distal end of the drainage catheter is contemplated, for example and without limitation, axially contracting and radially expanding anchoring tips.

[0014] The drainage catheter 100 includes an elongate tension member 120, a lock body 140, 240, and a catheter tube 118. The catheter tube 118 has distal and proximal ends and four apertures 112 disposed in a distal portion 110 thereof, including a distal-most aperture 116 and a proximal-most aperture 114. Note that the number of apertures is not limited to four, and more or fewer than four apertures may be present. Additionally, the placement of the apertures is not limited to the arrangement shown in Figures 1 and 2, and the apertures may be placed anywhere and in any arrangement in the distal portion 110 of the catheter tube 118. In one embodiment, the distal end of the catheter tube 118 may have a tapered shape to aid in insertion and help prevent any bunching of the catheter tube 118 as it is advanced along the wire guide to the treatment site.

[0015] As shown in Figure 1a, the proximal end of the catheter tube 118 has a flared, conical structure that is configured to mate and seal against a conical, tapered surface 146, 246 of the lock body 140, 240. The catheter tube 118 is attached to the lock body 140, 240 by threading a cap 130 onto a threaded portion 146, 246 disposed at a distal end of the lock body 140, 240, thereby compressively fixing the flared portion of the catheter tube between the cap 130 and the threaded portion 146, 246. However, it should be understood that the connection of the catheter tube 118 and the lock body 140, 240 is not limited thereto, and may be connected using a ferrule, adhesive, frictional fit, interference fit, clamps, or other manners known to those skilled in the art.

[0016] The lock body 140, 240 may have a low profile external shape that includes a receiver portion 142, 242, and an actuator portion 150, 250. The actuator portion 150, 250 may include, inter alia, a rotation knob 152, 252, and a luer lock 154, 254 at a distal end thereof. Depending on the application, the lock body 140 may be implanted within the body of a patient for procedures in which it is desirable to transfer a bodily fluid one body cavity or lumen to another, for example and without limitation, biliary drainage. Alternatively, the lock body 140 may remain outside the patient's body for applications in which it is desirable to drain a bodily fluid to an external capturing device, for example and without limitation, suprapubic bladder drainage.

[0017] The drainage catheter 100 also includes an elongate tension member 120 having a first end and a second end. The first end is disposed within a lumen of the catheter tube 118 and may be fixedly attached to the catheter tube 118. However, in some embodiments, the first end may be fixedly attached or anchored to the lock body 140, 240. As shown in Figures 1 and 2, the elongate tension member extends down the length of the catheter tube 118 and is threaded out of the distal-most aperture 116 and back into the lumen through the proximal-most aperture 114, thereby creating a loop of the elongate tension member 120 that is disposed outside of the catheter tube 118. A proximal portion of the elongate tension member 120 extends from the portion of the elongate tension member 120 threaded into the lumen of the catheter tube 118 through the proximal-most aperture 114 and the lock body 140, 240. The second end may be disposed proximal of the luer connector 154, 254 of the lock body 140, 240 to allow a physician to grasp and pull the elongate tension member 120 to cause the distal end 110 of the catheter tube 118 to assume a locked configuration.

[0018] The drainage catheter may be made from plastic or polymeric materials. For instance, in a one embodiment, the catheter tube 118 consists of a urethane material. Additionally, the lock body 140, 240 may

be made of plastic or polymeric materials. However, it should be understood that other suitable materials may be used for both the catheter tube 118 and the lock body 140, 240. In another embodiment, the catheter tube may be made from a urethane material, and the distal portion 110 of the catheter tube 118 may be coated with a hydrophilic material. In yet another embodiment, a radiopaque marker is included on the drainage catheter 100 adjacent to the most proximal opening 114. The radiopaque marker assists a physician in identifying when the drainage catheter has been properly placed at a desired treatment site within the patient using fluoroscopy. The elongate tension member 120 is composed of materials known to be suitable to those skilled in the art, for example and without limitation, wires, plastics, polymers, and natural or synthetic threads.

[0019] Figure 3, illustrates a first embodiment 140 of the lock body 140, 240. The lock body 140 includes a receiver portion 142, and an actuator portion 150 that is inserted into, and rotatably coupled to the receiver portion 142. The receiver portion 142 includes a threaded portion 144 that abuts a conical surface 146 to sealingly interface with the flared proximal end of the catheter tube 118, as described above in connection with Figure 1a. A central lumen 145 is disposed about a central axis of the receiver portion 142, and extends in an axial direction from the distal end of the receiver portion 142 to a distal end of a head receiving cavity 141. A pair of torsion member interface slots 143 are disposed at the junction between the head interface cavity 141 and the central lumen 145, and may be disposed at circumferentially opposite positions on the receiving portion 124.

[0020] A transition portion 148 abuts a proximal end of the head receiving cavity 141 and extends distally to a conically shaped tapered guide surface 147. The transition portion 148 may house two lock chambers 180 on opposite sides of the transition portion 148. That is, the two lock chambers 180 may be circumferentially offset by 180 degrees. Each lock chamber includes a first surface 186 having a gradual or shallow

angle with respect to the inner surface of the transition surface 148, and a second surface 182 having a sharp or steep angle with respect to the inner surface of the transition surface 148. Both the first and second surfaces 186, 182 may be flat, planar surfaces, and the first surface 186 may be longer than the second surface 182. In some embodiments, the first surface 186 may transition into the second surface 182 in a smooth, arced manner. In other embodiments, the flat planes of the first and second surfaces 186, 182 may join at a substantially straight edge.

[0021] The actuator portion 150 includes a tapered head 158 having two elongated U-shaped relief slots 160 disposed on opposite sides of the tapered head 158. However, it should be understood that the tapered head 158 may contain more or less than two relief slots to allow the tapered head 158 to compress to a smaller diameter for assembly. Two locking members 156 are integrally formed with the actuator portion 150 and extend radially outward in a cantilevered manner. Each locking member 156 has a blunt distal end having an angled head that is designed to engage, and in some embodiments mate with, the second surface 182 of the lock chamber 180. The locking members 156 may be disposed on circumferentially opposite sides of the actuator portion 150, and circumferentially offset by 90 degrees from the relief slots 160 to maximize the strength of the tapered head 158. However, it should be understood that the actuator portion 150 may contain more than two locking members 156, and the locking members may be spaced apart from the relief slots 160 at more or less than 90 degrees.

[0022] A central lumen 153 extends from a proximal end of the torsion member interface slots 162 to the proximal end of the luer lock connector 154. The luer lock connector 154 is disposed at the proximal end of the actuator portion 150, and provides an interface for other devices, such as syringes, that a physician may choose to use. However, it should be understood that such an interface is not required and may be eliminated in some embodiments.

[0023] A rotation knob 152 is disposed distal of the luer lock connector 154, and extends radially outward from the outer surface of the actuator portion 150 beyond other portions thereof to provide a handle for rotating the actuator portion between locked and unlocked positions. The rotation knob 152 may be integrally formed with the actuator portion 150 and may have a tacky or high friction coating or surface treatment to promote secure grip and facilitate rotation.

[0024] The lock body 140 also includes a resilient member 170 shown as a tube having two torsion members 172 disposed on circumferentially opposite sides thereof. A tension member lumen 174 extends in a substantially straight line through a wall of the resilient member 170 from one end to the other. A central lumen is defined by the wall and is disposed in the axial center of the resilient member 170. The two torsion members 172 may be integrally formed with the resilient member 170, such that any rotation of the torsion members 172 will cause the wall to rotate therewith. The resilient member 170 may be made from any resilient material having sufficient elasticity to allow the tube to deform in a twisting manner and return to its original shape. Further, the resilient member may be made from a material having a relatively tacky or high friction surface to aid in locking the elongate tension member 120 in place when the lock body 140 is in the locked configuration. For example, the resilient member 170 may be made of silicone. In some embodiments, the resilient member 170 may be made from a material that plastically deforms to collapse against and trap the elongate tension member 120 in place when twisted.

[0025] As shown in Figure 4, when the lock body 140 is assembled, the elongate tension member 120 is fed through the distal end and down the central lumen of the receiving portion 142. The elongate tension member is then threaded through the tension member lumen 174 of the resilient member 170, and through the central lumen 153 of the actuator portion 150. The torsion members 172 of the resilient member 170 are initially

inserted into the torsion member interface slots 162, 143 of either the actuator portion 150 or the receiving portion 142. The actuator portion 150 is then inserted into receiving portion 142. As the actuator portion 150 is advanced toward the receiving portion 142, the tapered head 158 contacts the tapered guide surface 147, which causes the two portions of the tapered head separated by the relief slots 160 to flex radially inward, thereby allowing the tapered head to compress and pass through the transition portion 148. Once the tapered head 158 reaches the head receiving cavity 141, it springs back out to its original diameter, which is larger than the diameter of the transition portion 148. Because the uncompressed tapered head 158 has a larger diameter than the transition portion 148, the lip 184 of the head receiving cavity 141 acts as a reaction surface for the proximal end of the tapered portion 158, thereby rotatably locking the actuator portion 150 into the receiving portion 142. Additionally, when the tapered head is advanced, the distal ends of the locking members 156 also contact the tapered guide surface 147, which forces the lock members 156 to flex radially inward such that they fit within the diameter of the transition portion 148. Note that the lock body may be initially assembled in an unlocked position where the locking members 156 are in contact with the inner surface of the transition portion 148, but are not disposed within the lock chambers 180.

[0026] Figures 6a, and b, illustrate cross-sections taken along the lines A and B of Figure 4, respectively, of the lock body 140 assembled in the unlocked configuration. As shown in Figure 6a, when the lock body 140 is assembled in the unlocked configuration, the distal end of the torsion members 172 of the resilient member 174 are held in place by the torsion member interface slots 143.

[0027] In operation, once the lock body 140 has been assembled, the drainage catheter 100 may be introduced into a patient. Typically, the drainage catheter 100 is introduced into the patient by means of a large hypodermic needle or trocar, which pierces the abdominal wall. A wire

guide is inserted through the needle, and the needle is then removed. A stiffening cannula or other stiffening member is inserted into the drainage catheter 100 through the lock body 140, and the drainage catheter is advanced over the wire guide into the desired cavity. Once the catheter has been satisfactorily placed, the cannula (or other stiffening member) and the wire guide are withdrawn, leaving only the drainage catheter 100 in the desired cavity. After the physician has placed the catheter in the desired location, the physician pulls the second end of the elongate tension member 120 in the proximal direction, thereby tensioning the elongate tension member 120 and causing the distal end 110 of the catheter tube 118 to bend proximally as the distal-most aperture 116 is drawn toward the proximal-most aperture 114. As the distal portion 110 of the catheter tube 118 bends, it assumes a locked configuration having a pigtail shape that is significantly larger than the aperture opened by the trocar, thus preventing the drainage catheter 100 from being accidentally withdrawn or removed from the desired cavity.

[0028] After the second end has been retracted an amount sufficient to cause the catheter tube 118 to assume the locked configuration, the elongate tension member 120 is locked in place by rotating the actuator portion 150 relative to the receiving portion 142. As shown in Figure 5, the locked configuration of the lock body 140 may be achieved by rotating the actuator portion 150 in either a clockwise or counterclockwise direction. As the actuator portion 150 is rotated, the torsion member interface slots 162 engage the torsion members 172 of the resilient member 170, thereby causing the distal end of the resilient member 170 to rotate with the actuator member 150. However, because the proximal ends of the torsion members 172 are held stationary by the torsion member interface slots 143 of the receiving portion 142, the rotation of the actuating portion 150 causes the resilient member 170 to twist. As shown in figure 8, when the resilient member 170 is twisted, the wall housing the tension member lumen 174 distorts and causes the tension member lumen 174 to kink at a

kink/compression location 175. This kinking of the tension member lumen 174 forces the wall to collapse at the kink/compression location 175 in a radially inward direction, thereby compressively engaging and trapping/locking the elongate tension member 120 in place.

[0029] Returning to Figure 5, as the actuator member 150 rotates and causes the resilient member 170 to lock the elongate tension member 120 in place, the locking members 156 rotate into the recessed lock chambers 180. As shown in Figures 6c, and 7, once the locking members 156 enter the lock chamber 180, the locking members 156, which were previously compressed against the inner surface of the transition portion 148, are free to spring back to their original configuration, thereby locking the actuator portion 150 in place, thus preventing further rotation. Note that Figure 6c illustrates a cross-section taken along the line C of Figure 5, which is distal of the kinked/compressively engaged section 175 of the tension member lumen 174, and therefore the wall defining the tension member lumen 174 is not shown compressed against the elongate tension member 120. The locking members 156 may spring out against the outer surface of the lock chambers 180 such that an apex of the locking members 156 substantially mates with a transition or joint between the first and second surfaces 186, 182.

[0030] Once the drainage catheter 100 has been inserted into the desired body cavity, bodily fluids from the desired cavity enter the catheter tube 118 through an opening in the distal end of the catheter tube 118 and the apertures 112. The fluid then travels proximally through the catheter tube 118 and the lock body 140 and is expelled from the drainage catheter 100 internally into another body cavity or lumen, or externally into a collection device.

[0031] In one embodiment, the resilient member 170 may be slightly longer than the space between the proximal surface of the torsion member interface slots 162 of the actuator portion 150 and the distal surface of the torsion member interface slot 143 of the receiver portion 140 when the lock

body 140 is assembled. In this way, when the lock body 140 is assembled, the resilient member 170 is slightly compressed between the actuator portion 150 and the receiver portion 142, including the two pairs of torsion member interface slots 143, 162, thereby creating a seal between the receiving portion 142 and the actuator portion 150 and providing a continuous, hermetically sealed passageway for the bodily fluid to be drained through the lock body 140. Note that in this embodiment, the resilient member 170 is not subjected to compressive forces sufficient to interfere with or prevent the lumen 174 from kinking and radially compressively engaging the elongate tension member 120 as described above. Additionally, the resilient member 170 is not subjected to a compressive force sufficient to cause the tension member lumen 174 to buckle or otherwise distort such that the walls forming the lumen 174 engage the elongate tension member 120 when the actuator portion 150 is in the unlocked position.

[0032] In other embodiments, grommets, o-rings, or other sufficient sealing means, may be used to seal the actuator portion 150 to the receiving portion 140 to provide the continuous, sealed passageway for the bodily fluid to be drained through the lock body 140. Alternatively, the lock body 140 may be covered in a hermetically sealed sheath or cover that prevents fluid from leaking between the actuator portion 150 and the receiving portion 140.

[0033] In the event that the drainage catheter 100 needs to be repositioned or removed, the physician simply forces the actuator portion 150 in the distal direction toward the receiving portion 142 and rotates it to the unlocked position. As the actuator portion 150 is moved, the angled heads of the locking members 156 are forced against the second surface 182. The angled second surface 182 then forces the locking members 156 to flex inward, thereby releasing the actuator portion 150 and allowing it to translate through the head receiving cavity 141 and rotate to the unlocked position, thereby removing the twisting force on the resilient member 170

and releasing the elongate tension member 120. Note that because the second surface 182 is relatively short and has a relatively steep angle, the force required to flex and disengage the locking members is sufficiently high enough to avoid accidental unlocking and release.

[0034] Because the tension member is wholly confined within the lock body 140, and because no additional components are required to maintain the locked configuration, the device may achieve a smaller overall profile as compared to the prior art. This smaller profile may be particularly useful for internal drainage applications.

[0035] Figures 9-14 illustrate various alternative embodiments of the resilient member 170 for frictionally locking the elongate tension member 120 in place through the same kinking, radially compressive engagement caused by twisting the resilient member 170, as described above in connection with figures 5 and 8. Note that while various embodiments of the resilient members are shown in Figures 9-14, it should be understood that corresponding and complementary modifications to the actuator portion 150 and the receiver portion 142, including inter alia the torsion member interface slots 162, 143, are also contemplated. Moreover, additional designs and shapes of the resilient member 170 beyond those depicted in Figures 9-14 are contemplated.

[0036] Figure 9 depicts an alternative embodiment of the resilient member 170 having attachment rings 980 fixedly attached at each end of a cylindrical resilient member 982. Each torsion ring includes at least two torsion members 972 and an aperture in fluid communication with a tension member lumen 974. Figure 10 illustrates an embodiment 1000 having an elongated cuboid shape. In this embodiment, each of the corner surfaces 1072 acts as a torsion member. Figure 11 shows a resilient member 1100 having an elongated oval columnar shape. In this embodiment the portions of the ellipse extending most radially outward act as torsion members 1172. Figure 12 illustrates an embodiment 1200 having one end with a quadrilateral shape with the corners forming the

torsion members 1272, and another end having a circular shape with a single structure 1278 protruding radially outward from the outer surface of the circle. A circular lumen 1276 is disposed around the axial center of the resilient member and extends the length thereof. Figure 13 illustrates an embodiment 1300 that is similar to the resilient member 170 described above in connection with Figures 4-8, but includes four integrally formed torsion members 1372 extending substantially the entire length of the resilient member. Finally, Figure 14 depicts an embodiment 1400 having four grooves constituting inverted torsion members 1472, which engage with radially inwardly protruding members attached to the receiver portion 142 to achieve the same torque/twisting configuration described above in connection with Figures 5-8.

[0037] Figure 15, illustrates a second embodiment 240 of the lock body 140, 240. As shown in Figure 15, the lock body 240 includes a receiver portion 242, and an actuator portion 250 that is inserted into, and rotatably coupled to the receiver portion 242. Like the lock body 140 of the first embodiment, the receiver portion 242 includes a threaded portion 244 that abuts a conical surface 246 to sealingly interface with the flared proximal end of the catheter tube 118. A central lumen 245 is disposed about a central axis of the receiver portion 242, and extends in an axial direction from the distal end of the receiver portion 242 to a distal end of a head receiving cavity 241. A pair of torsion member interface slots 243 are disposed at the junction between the head interface cavity 241 and the central lumen 245. The receiver portion 242 also includes a spring retention slot 230 disposed in a proximal face of the head receiving cavity 241. The spring retention slot 230 may extend in a continuous ring around the central axis of the receiving portion 242, and may be disposed radially outward of the torsion member interface slots 243.

[0038] A transition portion 286 abuts a proximal end of the head receiving cavity 241 and extends distally to a conically shaped tapered guide surface 247. Two guide channels 220, each having an axially

extending portion, a circumferentially extending portion, and a locking notch 222, are disposed in the wall of the transition portion 286. The guide channels 220 may be disposed on circumferentially opposite sides of the transition portion 248, as shown in Figures 17b and c.

[0039] Returning to Figures 15a and b, the actuator portion 250 includes a tapered head 258 having two elongated U-shaped relief slots 260 disposed on opposite sides of the tapered head 258. However, it should be understood that the tapered head 258 may contain more or less than two relief slots to allow the tapered head 258 to compress to a smaller diameter for assembly. Two locking members 256 may be integrally formed with the actuator portion 250 and extend radially outward from an outer surface of the actuator portion 250 just below a proximal surface of the tapered head 258. The locking members 256 may be disposed on circumferentially opposite sides of the actuator portion 250, and circumferentially offset 90 degrees from the relief slots 260 to maximize the strength of the tapered head 258. However, it should be understood that the actuator portion 250 may contain more than two locking members 256, and the locking members may be spaced apart from the relief slots 260 at more or less than 90 degrees.

[0040] A central lumen 253 extends from a proximal end of the torsion member interface slots 262 to the proximal end of the luer lock connector 254. As with the first embodiment, the luer lock connector 254 is disposed at the proximal end of the actuator portion 250, and provides an interface for other devices, such as syringes, etc.

[0041] A rotation knob 252 is disposed distal of the luer lock connector 254, and extends radially outward from the outer surface of the actuator portion 250 beyond other portions thereof to provide a handle for rotating the actuator portion between the locked and unlocked positions. The rotation knob 252 may be integrally formed with the actuator portion 250 and may have a tacky or high friction coating or surface treatment to promote a secure grip and facilitate rotation. The lock body 240 also

includes the same resilient member 170 employed by the first embodiment.

[0042] As shown in Figure 16, when the lock body 240 is assembled, the elongate tension member 120 is fed through the distal end and down the central lumen of the receiving portion 242, and through the spring 210, the tension member lumen 174 of the resilient member 170, and the central lumen 253 of the actuator portion 250. The torsion members 172 of the resilient member 170 are then inserted into the torsion member interface slots 243 of the receiving portion 242 to ensure proper engagement therewith. Next, the actuator portion 250 is inserted into the receiving portion 242. As the actuator portion 250 is advanced distally toward the receiving portion 242, the tapered head 258 contacts the tapered guide surface 247, which causes the two portions of the tapered head, which are separated by the relief slots 260, to flex radially inward, thereby allowing the tapered head to compress and pass through the transition portion 286.

[0043] As with the first embodiment, once the tapered head 258 reaches the head receiving cavity 241, it springs back out to its original diameter, which is larger than the diameter of the transition portion 286. Because the uncompressed tapered head 258 has a larger diameter than the transition portion 248, the lip 284 of the head receiving cavity 241 acts as a reaction surface for the proximal end of the tapered portion 258, thereby rotatably locking the actuator portion 250 into the receiving portion 242. The spring 210 contacts the tapered portion 258 and compresses in the axial direction as the actuator portion 250 is advanced distally. Because the spring is restrained against the receiving portion 242 in the spring retention slot 230, the spring exerts a biasing force against the actuator portion 250 in the proximal direction. At the same time, the locking members 256 are guided along the guide channels 220 until they reach the end of the axially extending portion of the guide channels 220.

[0044] Figures 18a and b illustrate cross-sections taken along the lines A and B of Figure 16, respectively, of the lock body 240 assembled in the unlocked configuration. As shown in Figure 18a, when the lock body 140 is assembled in the unlocked configuration, a distal end of the torsion members 172 of the resilient member 174 are held in place by the torsion member interface slots 243.

[0045] In operation, the drainage catheter 100 employing the lock body 240 of the second embodiment is placed within a patient and locked in the same manner described above in connection with the first embodiment. As with the first embodiment, the elongate tension member 120 is locked in place by rotating the actuator portion 250 relative to the receiving portion 242. The locked configuration of the lock body 240 may be achieved by rotating the actuator portion 250 clockwise such that the locking members travel along the circumferentially extending portion of the guide channels 220, as shown in Figures 16-19. Figure 19 illustrates the shape of the guide channel 220 and includes arrows indicating the path the locking members 256 travel as they are moved from the unlocked to the locked positions.

[0046] As with the first embodiment, when the actuator portion 250 is rotated, the torsion member interface slot 262 engages the torsion members 172 of the resilient member 170, thereby causing the distal end of the resilient member 170 to rotate with the actuator member 250, which forces the resilient member 170 to twist and frictionally lock the elongate tension member 120 in place, as described above in connection with Figure 8.

[0047] While the actuator member 250 is being rotated, the spring 210 continuously exerts force against the distal end of the tapered head 258. However, while the locking members 256 are disposed within the circumferentially extending portion of the guide channels 220, the actuator member 250 is prevented from translating in the proximal direction.

[0048] Once the locking members 256 are rotated to the point that they are substantially aligned with the locking notches 222, the spring 210 forces the actuator portion 250 to move in the proximal direction until the locking members 256 contact the proximal end of the locking notches 222, thereby locking the actuator portion 250 in place and preventing further rotation. Note that like Figure 6c, Figure 18c illustrates a cross-section taken along the line C of Figure 17, which is proximal of the kinked/compressively engaged section 175 of the tension member lumen 174, and therefore the wall defining the tension member lumen 174 is not shown compressed against the elongate tension member 120.

[0049] Bodily fluids pass through the drainage catheter 100 incorporating the second embodiment of the lock body 240 in the same way described above in connection with the first embodiment. The lock body 240 may be sealed using any of the methods described above in connection with the first embodiment.

[0050] The lock body 240 may be returned to the unlocked configuration and disengage the elongate tension member 120 by simply pushing the actuator portion 250 in the distal direction to compress the spring 210. As the spring is compressed, the locking members 256 are moved out of the locking notches 222 and into the circumferentially extending portion of the guide channel 220. Once disposed in the circumferentially extending portion, the actuator portion 250 can then be rotated counterclockwise to remove the twisting force applied to the resilient member 270 and release the elongate tension member 120. The spring 210 has a high enough spring constant/spring force to exert sufficient force to prevent accidental unlocking and release.

[0051] While the above description of the embodiments has referred to a resilient member 170 having at least one attached or integral torsion member 172, it should be understood that the resilient member is not limited thereto, and may not include a torsion member 172. In such embodiments, the resilient member may be fixedly attached or otherwise

held in place relative to both the receiver portion 140, 240 and the actuator portion 150, 250 by adhesives or the like.

[0052] While presently preferred embodiments of the invention have been described, it should be understood that the invention is not so limited, and modifications may be made without departing from the invention. The scope of the invention is defined by the appended claims, and all devices that come within the meaning of the claims, either literally or by equivalence, are intended to be embraced therein. Furthermore, the features described above are not necessarily the only features of the invention, and it is not necessarily expected that all of the described features will be achieved with every embodiment of the invention.

CLAIMS:

1. A tension member locking mechanism for a medical device, comprising:

a lock body movable between an open position and a closed position; and

a resilient member having first and second ends and a lumen disposed therein, said lumen extending in a substantially straight line through said resilient member in a longitudinal direction between said first and second ends; and

an elongate tension member extending in a substantially straight line through said lumen from at least said first end to said second end,

wherein when said lock body is moved from said open position to said closed position, said lock body twistingly engages said resilient member and causes a portion of said resilient member defining at least a portion of said lumen to compressively engage said elongate tension member such that said elongate tension member cannot freely move through said lumen.

2. The tension member locking mechanism of claim 1, wherein said lock body comprises a receiver portion and an actuator portion, and said lock body is moved from said open position to said closed position by rotating said actuator portion relative to said receiver portion.

3. The tension member locking mechanism of claims 1 or 2, wherein said resilient member is a longitudinally extending tube and said lumen is disposed in a wall of said tube.

4. The tension member locking mechanism of any of claims 1-3, further comprising a torsion member attached to said resilient member, wherein when said lock body is moved from said open position to said closed position, said receiver portion and said actuator portion twistingly engage said torsion member thereby twisting said resilient member and causing a portion of said resilient member including said lumen to compressively engage said elongate tension member such that said elongate tension member cannot freely move through said lumen.

5. The tension member locking mechanism of claim 4, wherein said torsion member is integrally formed with said resilient member such that said resilient member and said torsion member form a single monolithic structure.

6. The tension member locking mechanism of any of claims 1-5, wherein at least one end of said resilient member is fixedly attached to said lock body.

7. The tension member locking mechanism of claims 5 or 6, wherein said integrally formed torsion member comprises at least one structure protruding radially outward from an outer surface of said resilient member and said lock body comprises at least one recessed portion that substantially mates with said at least one structure.

8. The tension member locking mechanism of claim 5, wherein said integrally formed torsion member comprises at least one recessed portion extending inward from an outer surface of said resilient member, and said lock body comprises at least one interface member that substantially mates with said at least one recessed portion, said at least one interface member protruding inward from an inner surface of said lock body

9. The tension member locking mechanism of claims 4 or 5, wherein said torsion member is affixed to at least one of said first or second ends of said resilient member.

10. The tension member locking mechanism of claims 4 or 5, wherein said compression of said lumen is in a radial direction of said lumen.

11. The tension member locking mechanism of claim 5, wherein said integrally formed torsion member extends along substantially an entire length of said resilient member.

12. The tension member locking mechanism of claim 8, wherein the integrally formed torsion member is a groove in an outer surface of said resilient member.

13. The tension member locking mechanism of claim 5, wherein both ends of said resilient member are quadrilateral in shape and said resilient member extends in a substantially straight line manner between both ends such that said resilient member has a columnar cuboid structure, and wherein said at least one integrally formed torsion member is a corner of said cuboid structure.

14. The tension member locking mechanism of claim 2, further comprising a spring disposed between said actuator portion and said receiver portion, said spring exerting a biasing force between said actuator portion and said receiver portion.

15. The tension member locking mechanism of any of claims 1-14, wherein said lock body is capable of repeatedly releasably securing said elongate tension member within said lumen by twisting and untwisting said resilient member.

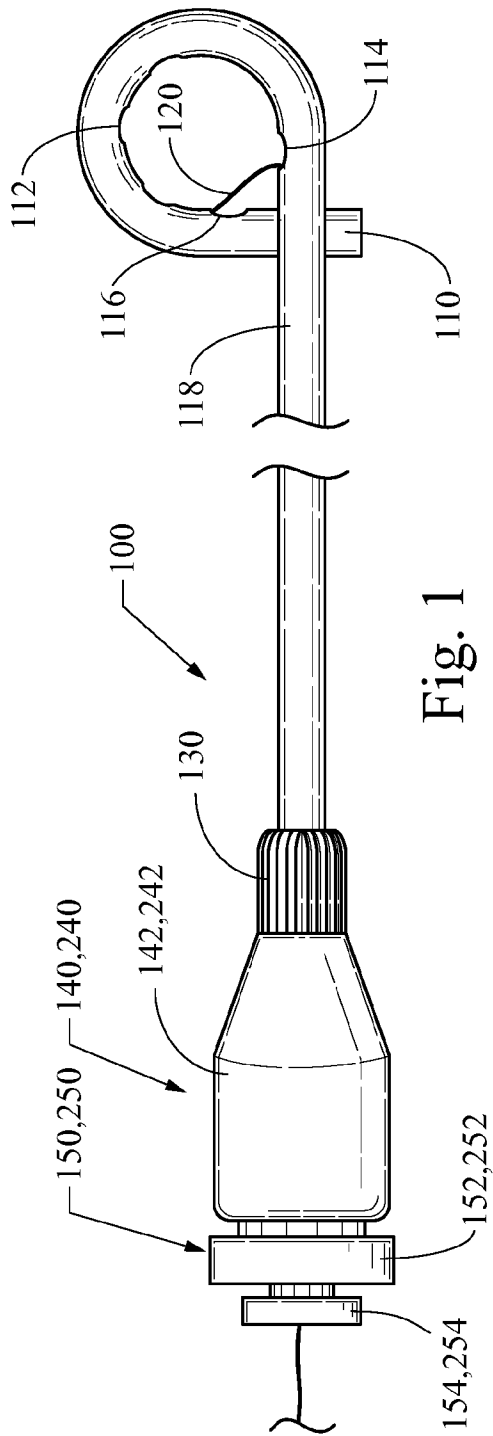


Fig. 1

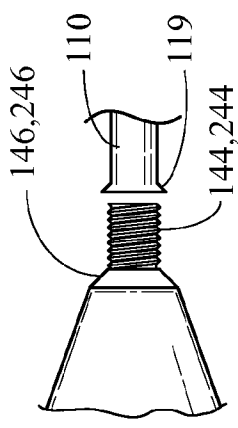


Fig. 1a

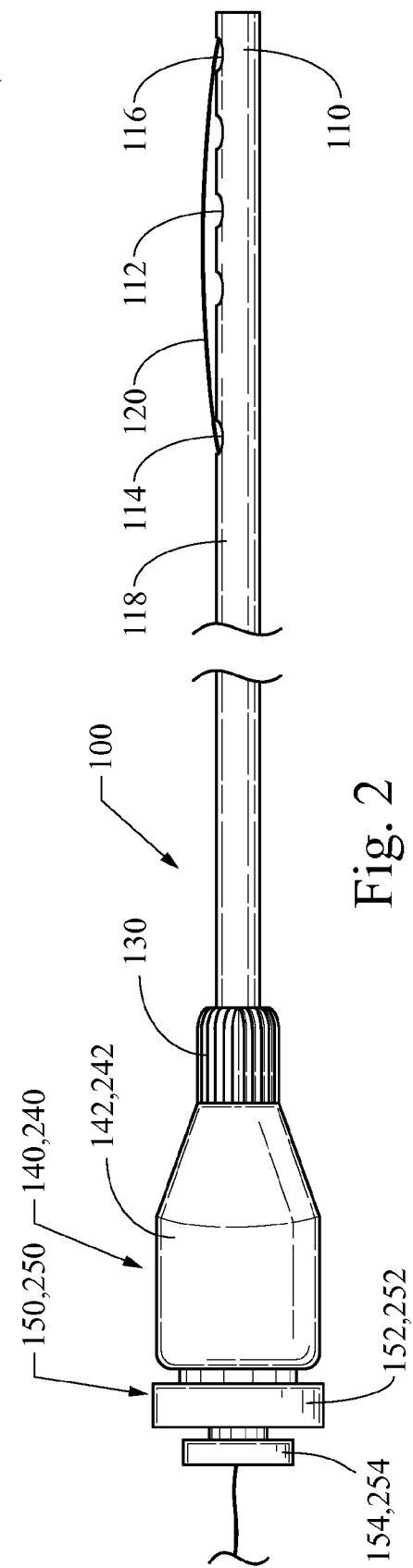


Fig. 2

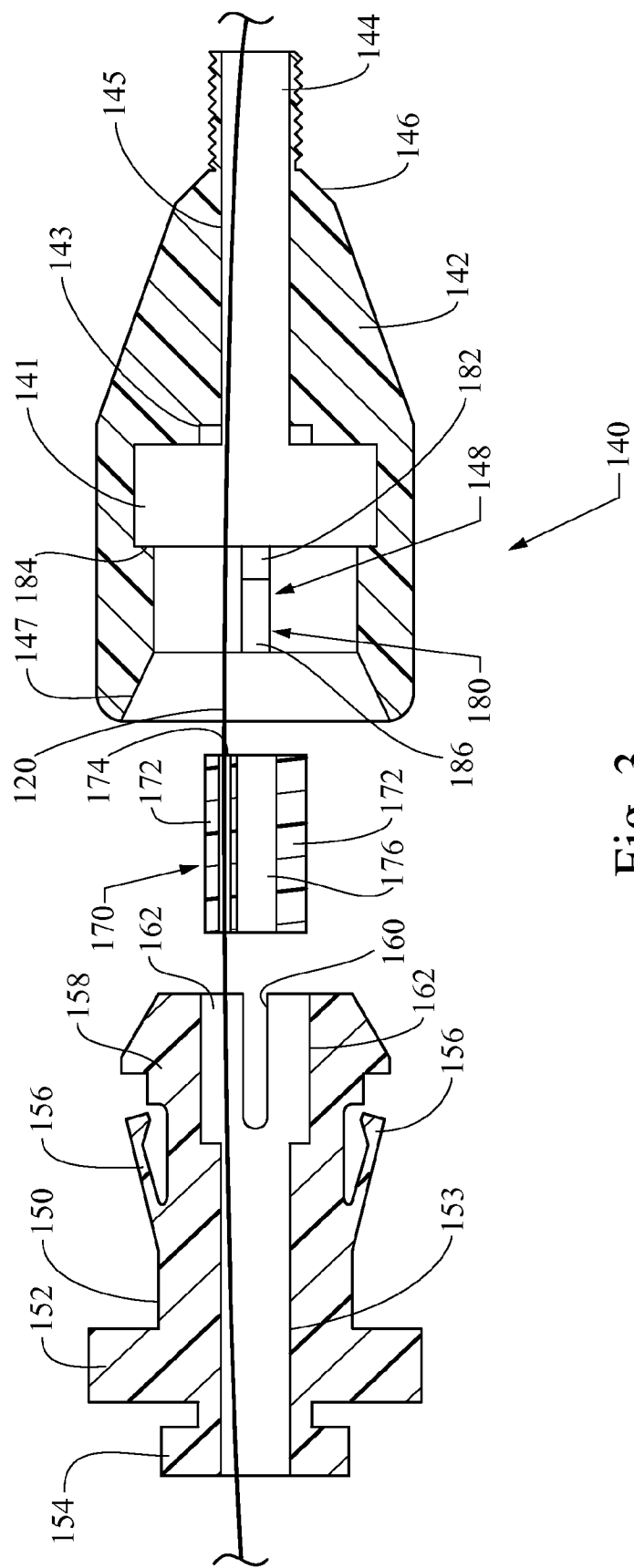
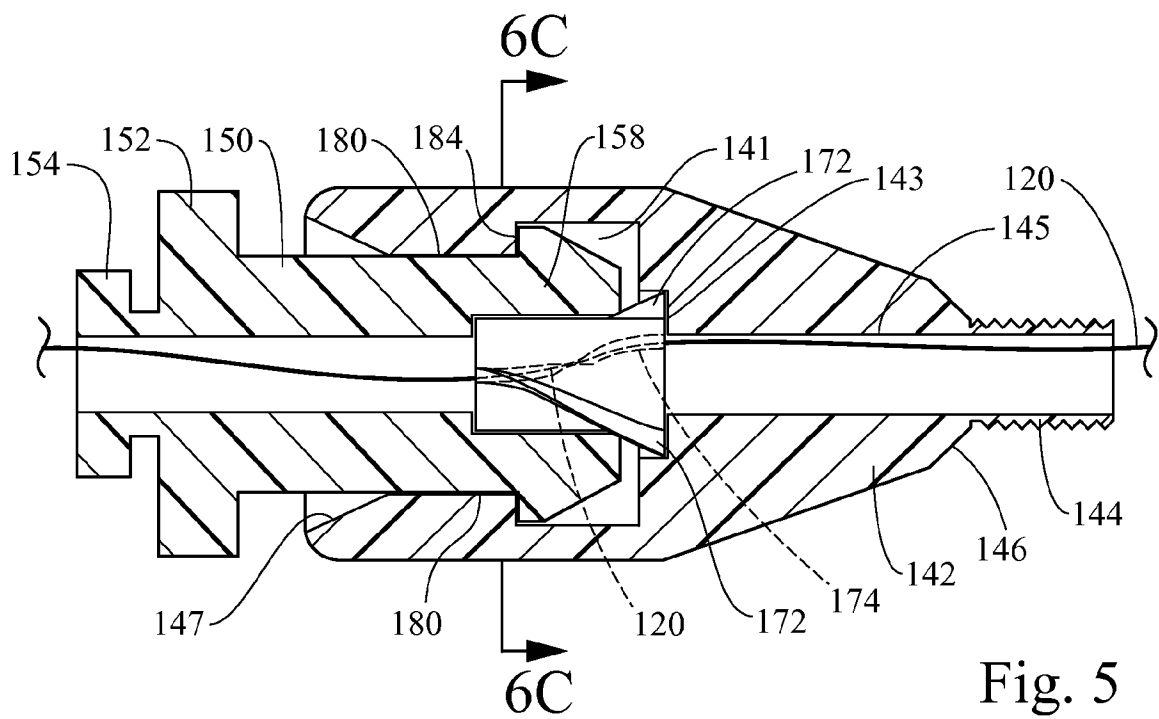
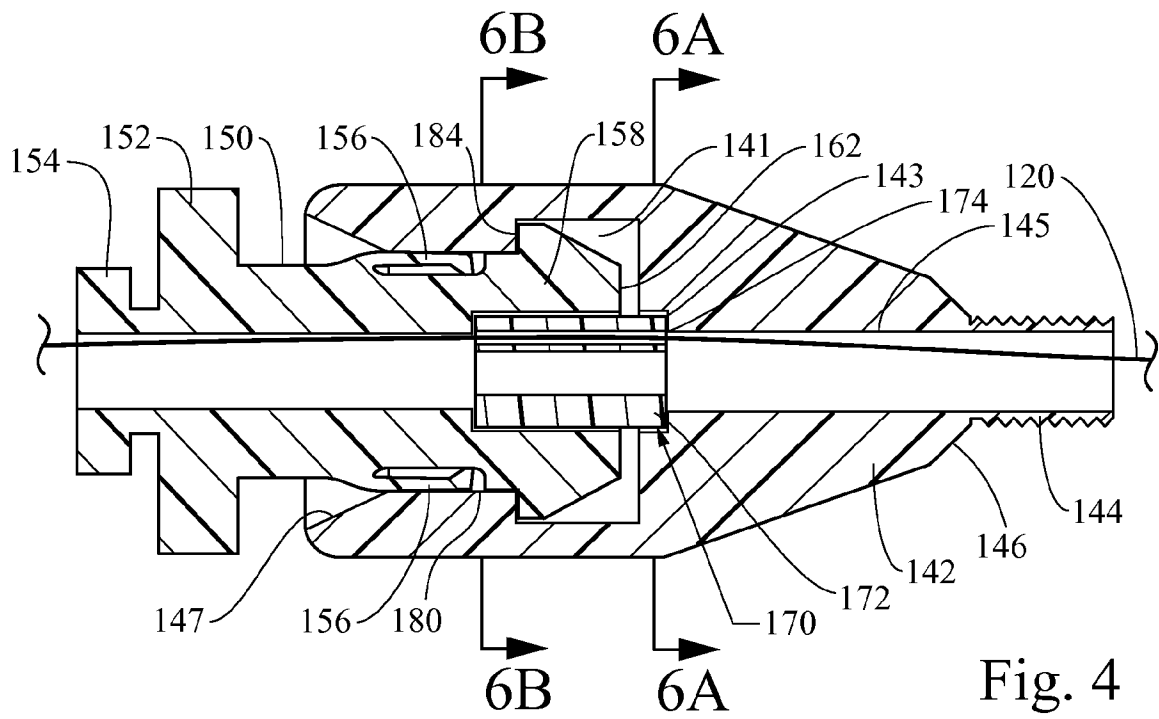


Fig. 3

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Fig. 6a

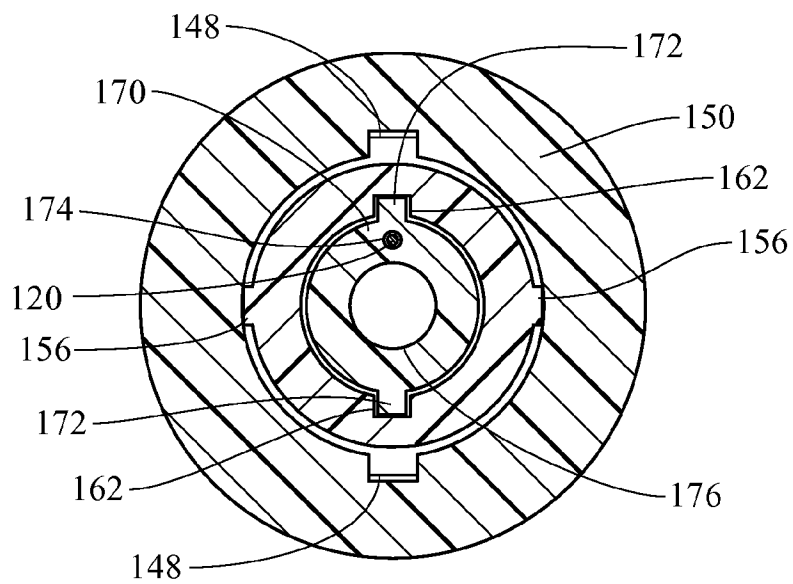
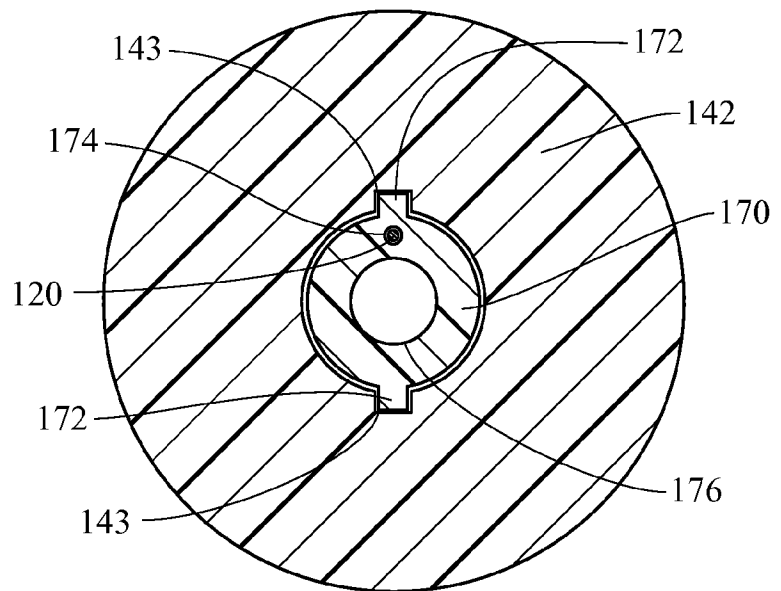
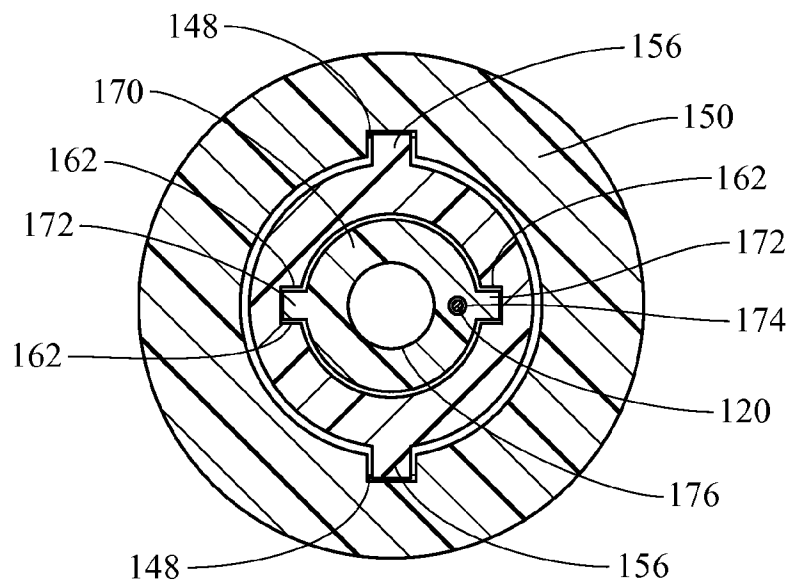


Fig. 6b

Fig. 6c



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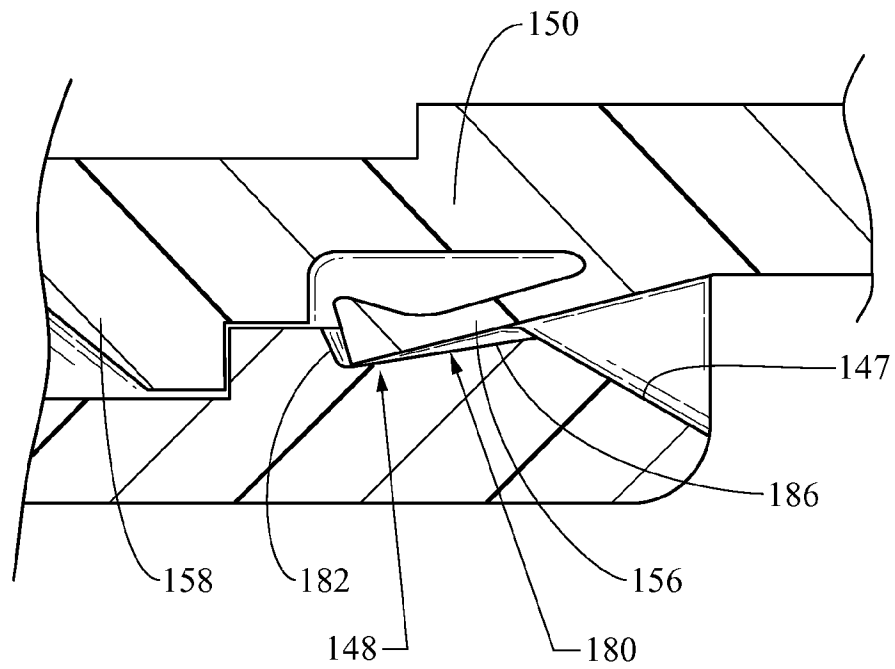


Fig. 7

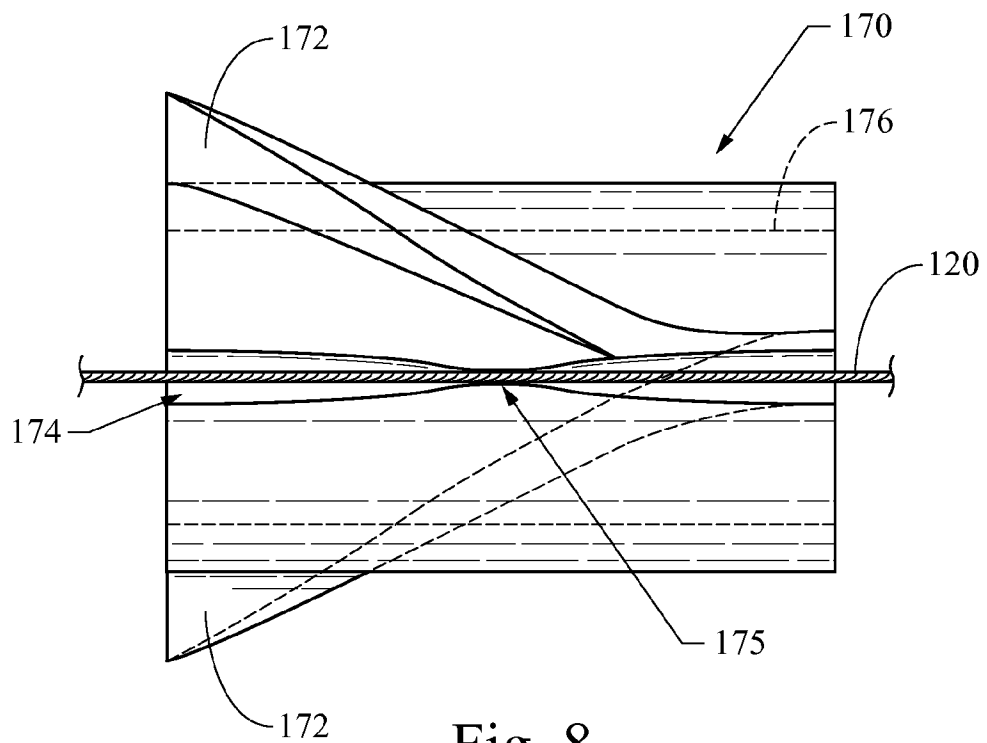
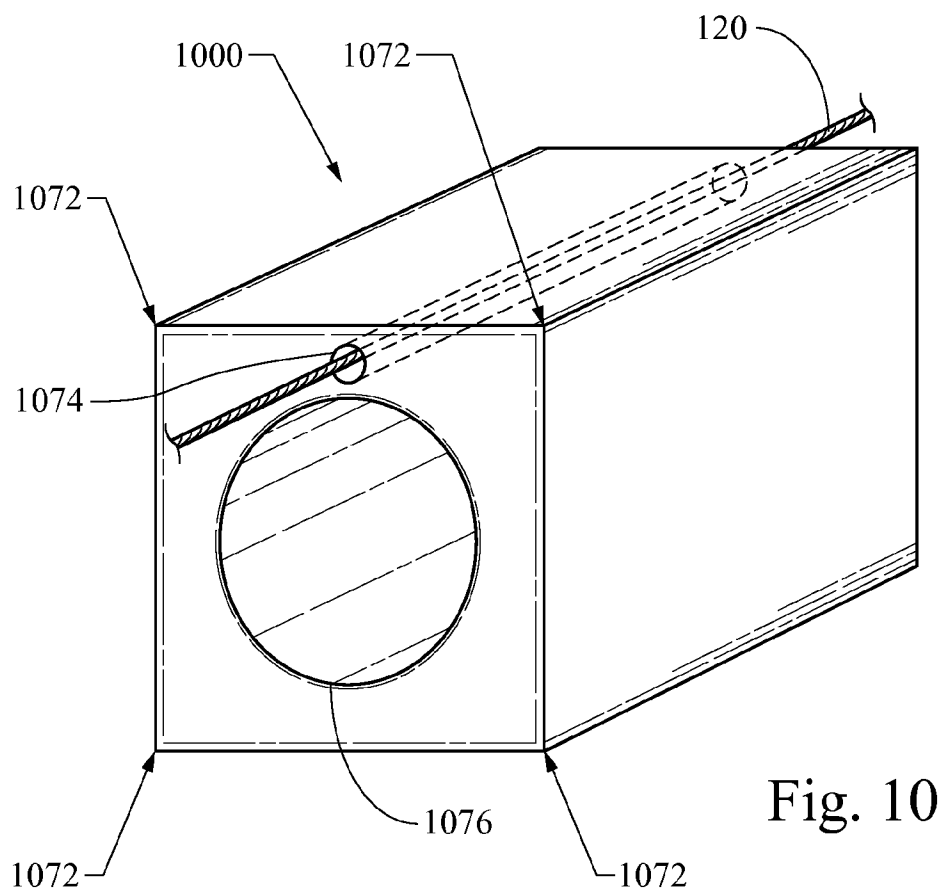
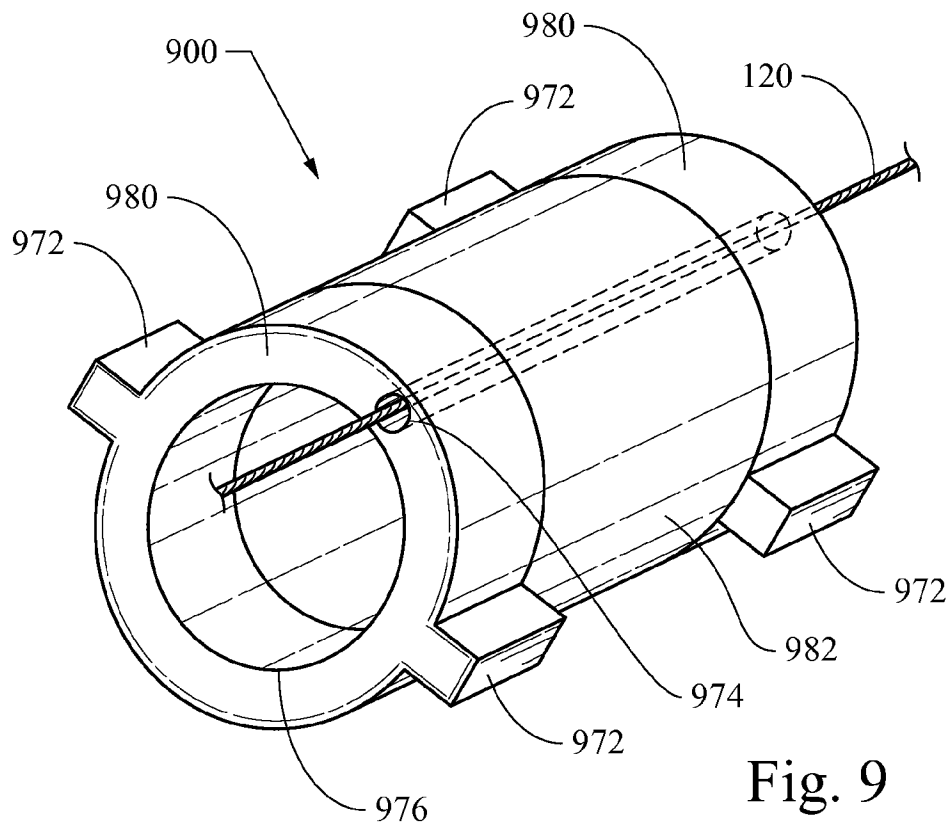
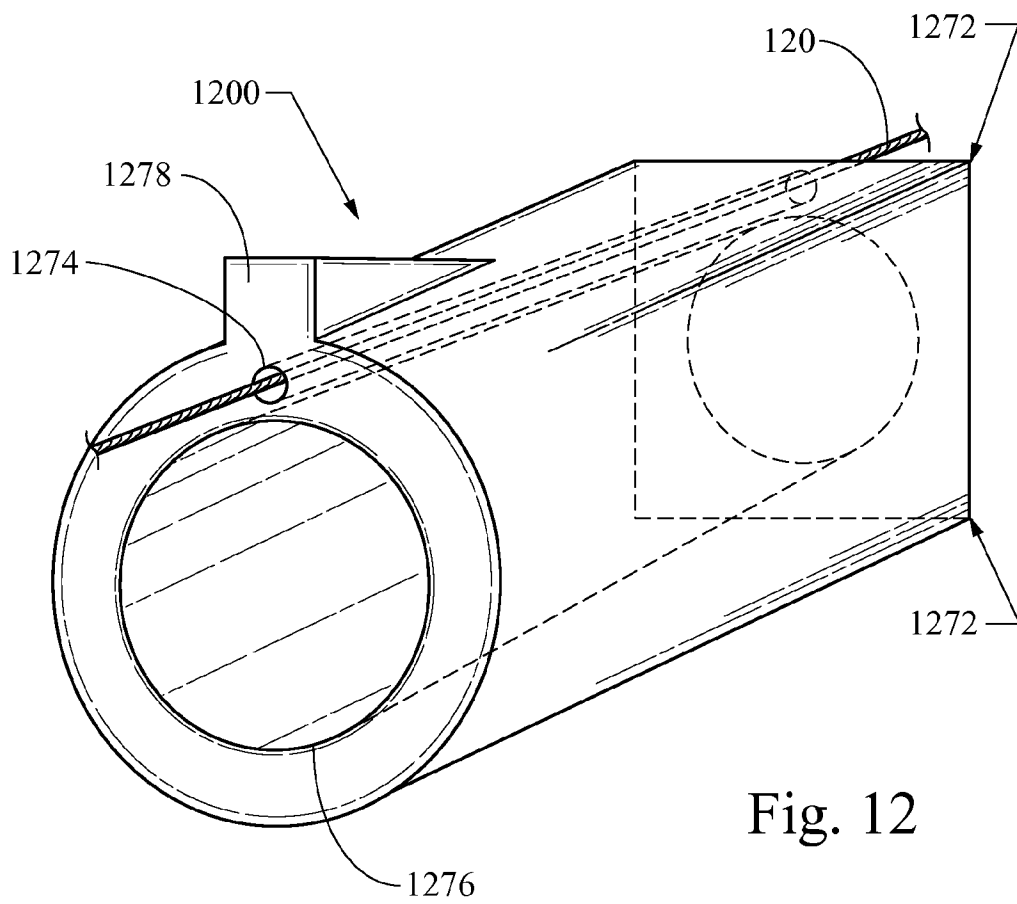
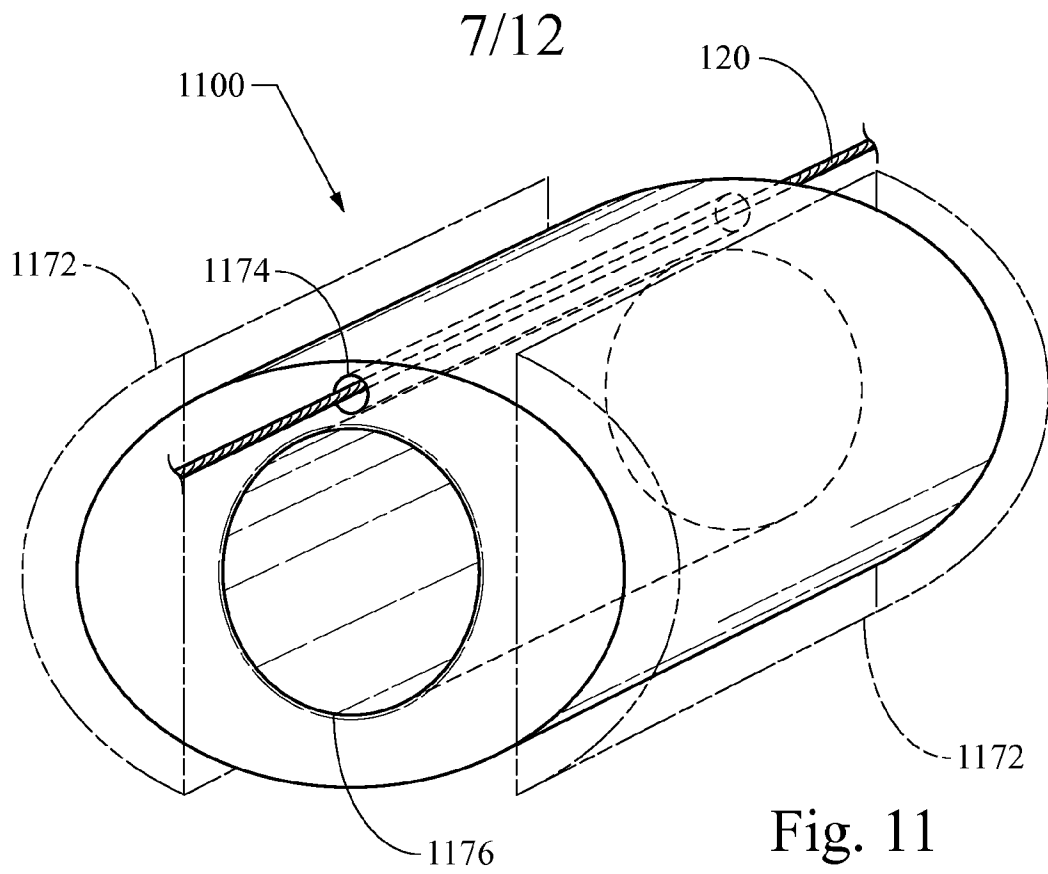


Fig. 8

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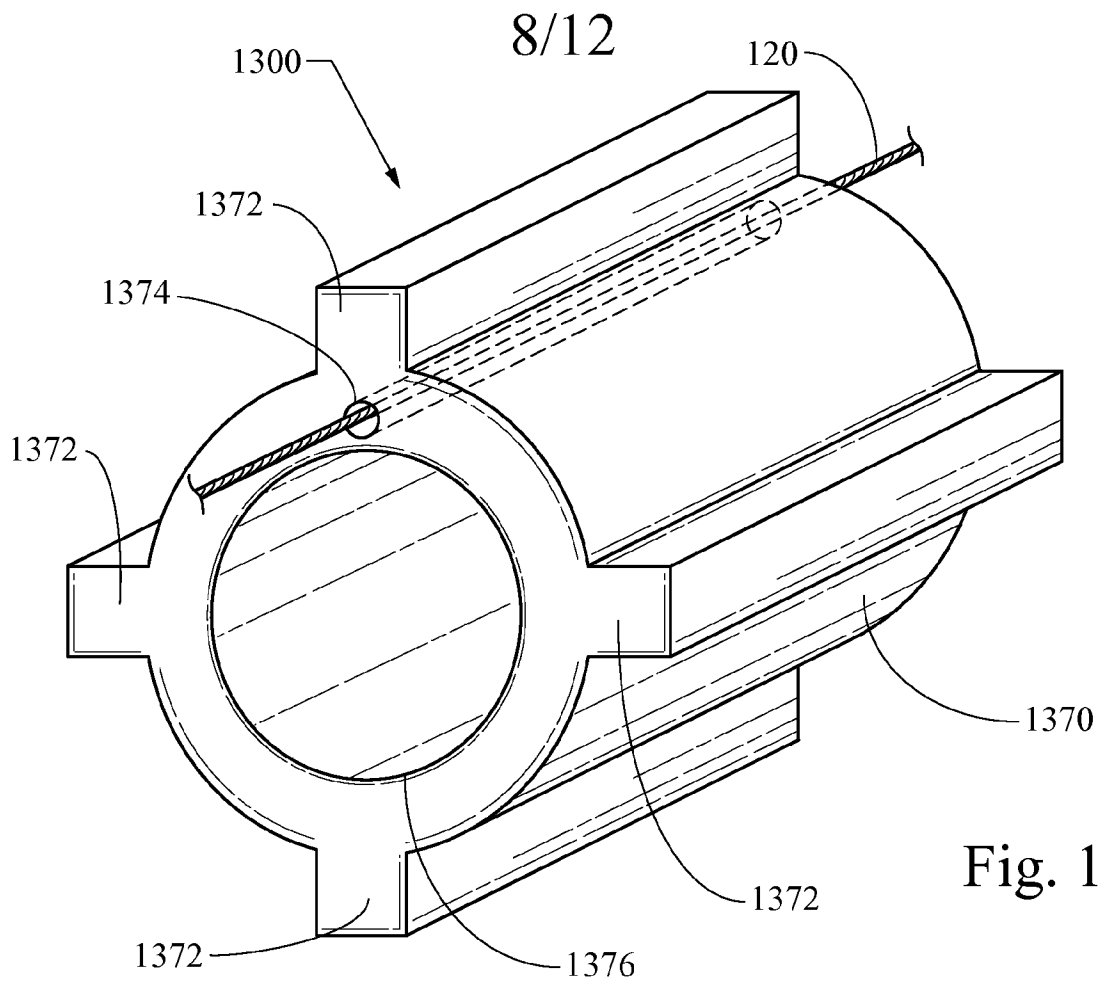


Fig. 13

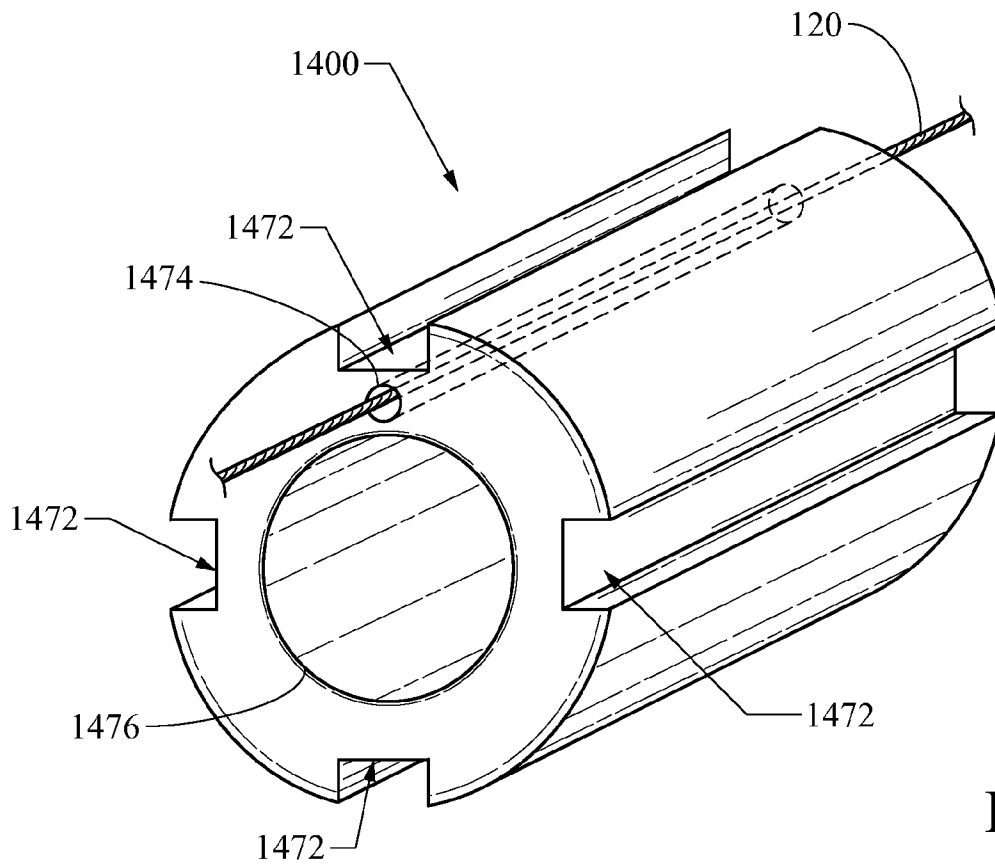


Fig. 14

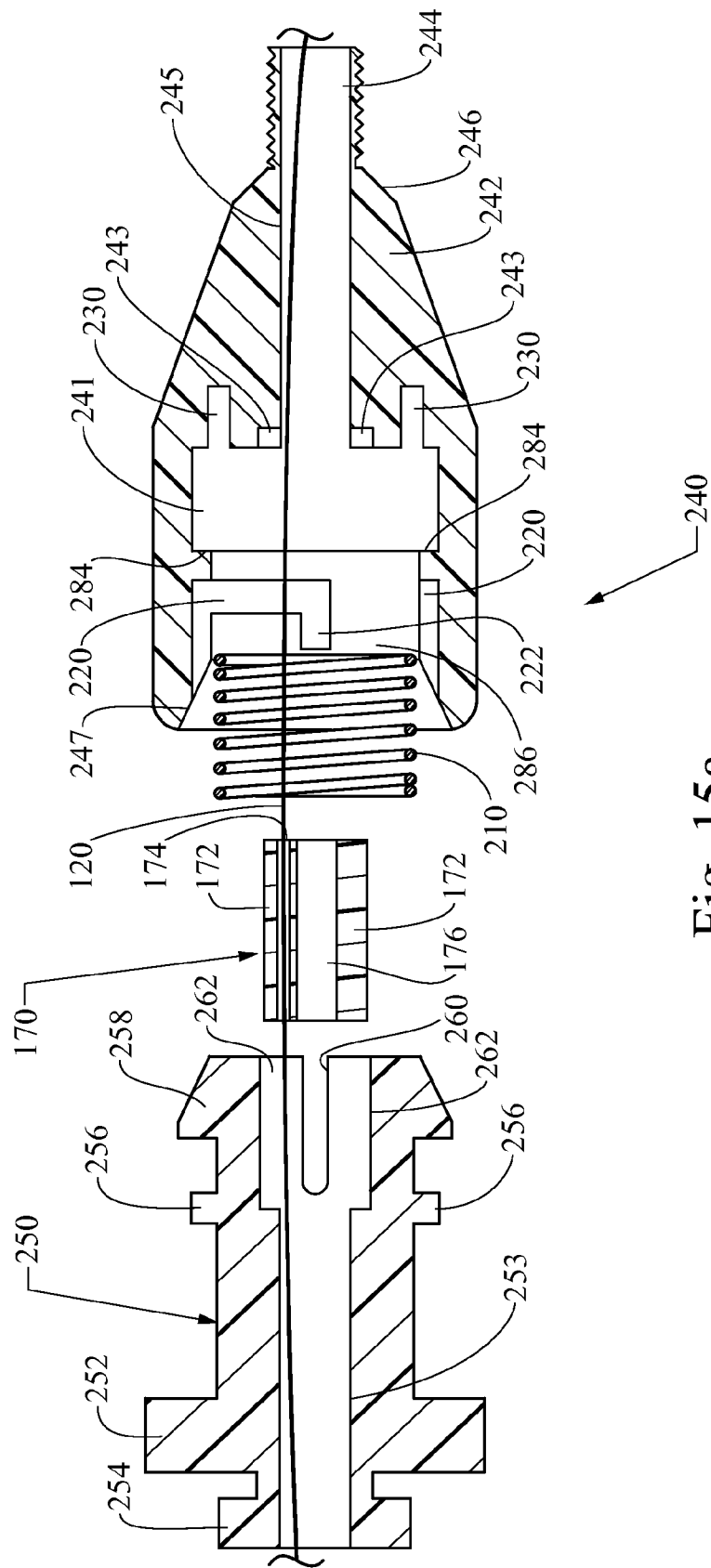


Fig. 15a

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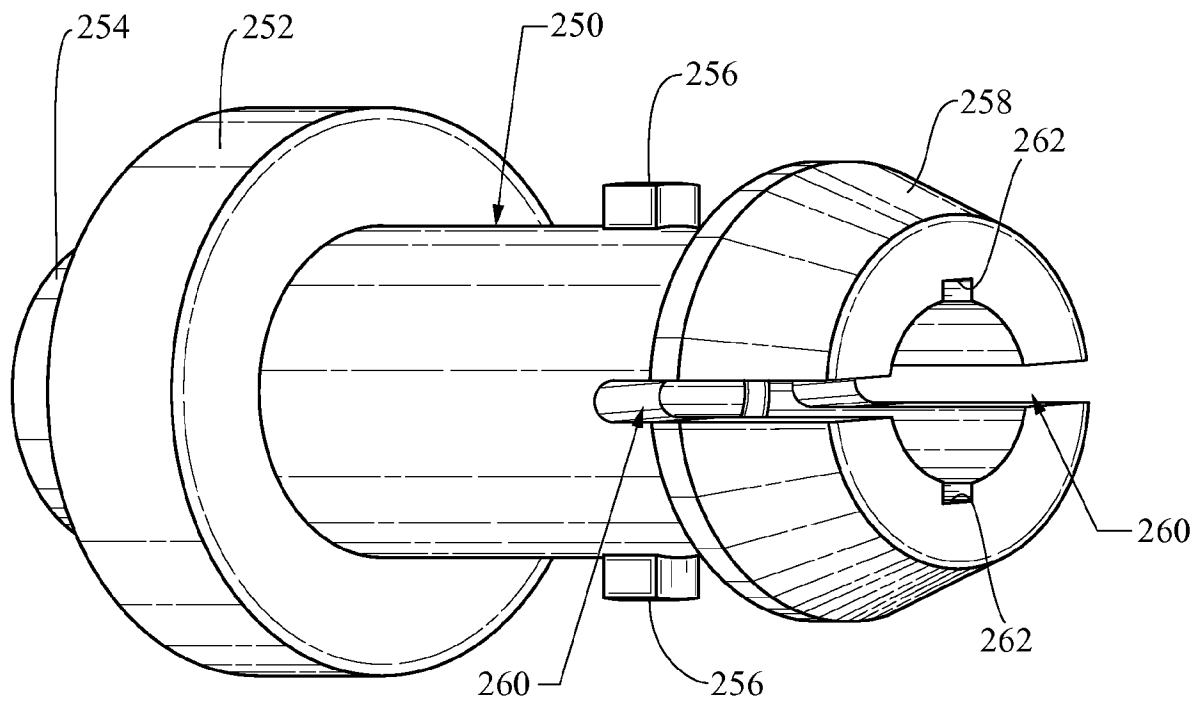


Fig. 15b

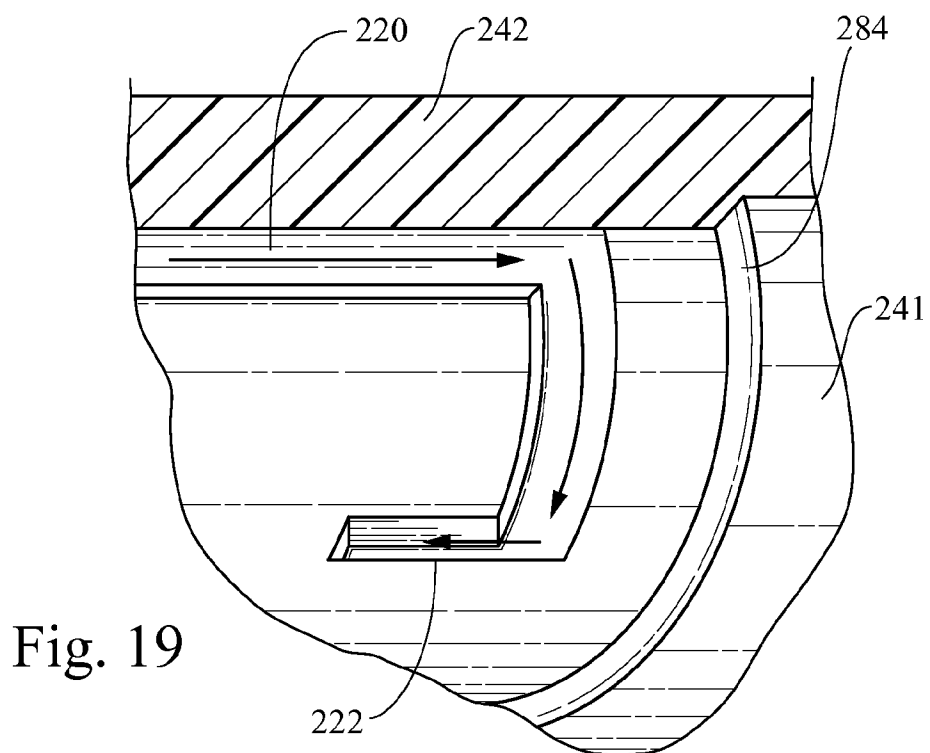
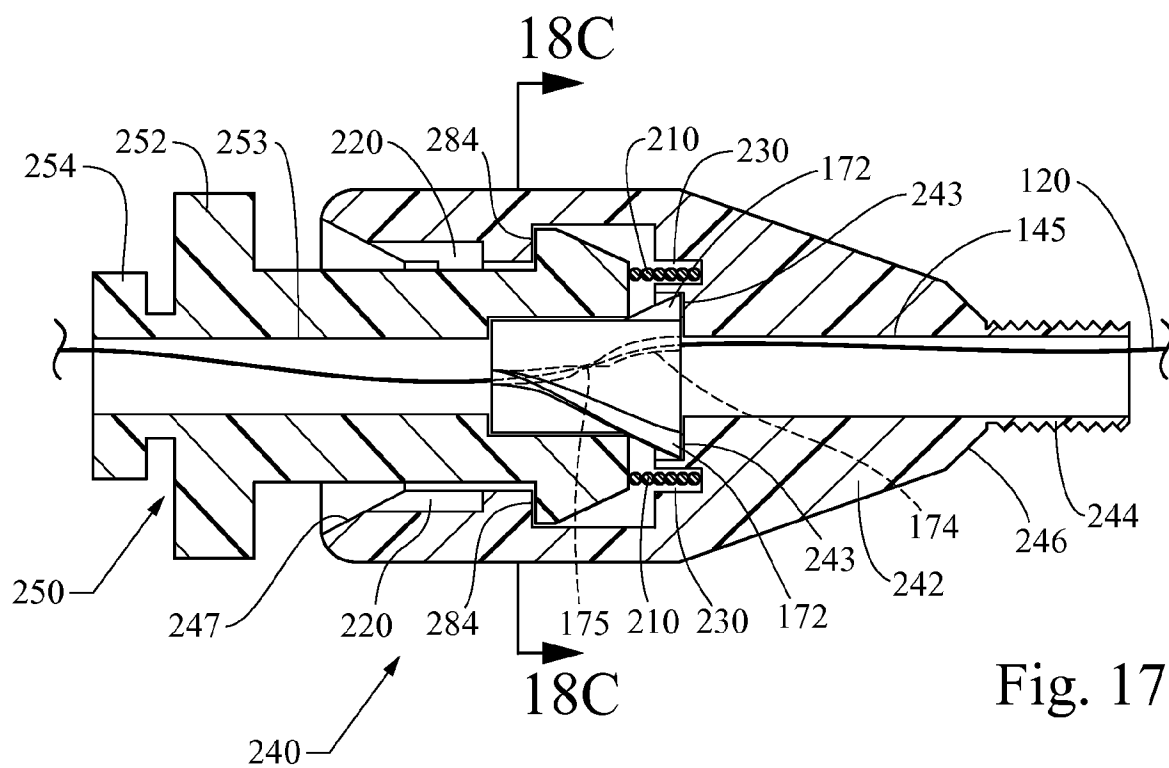
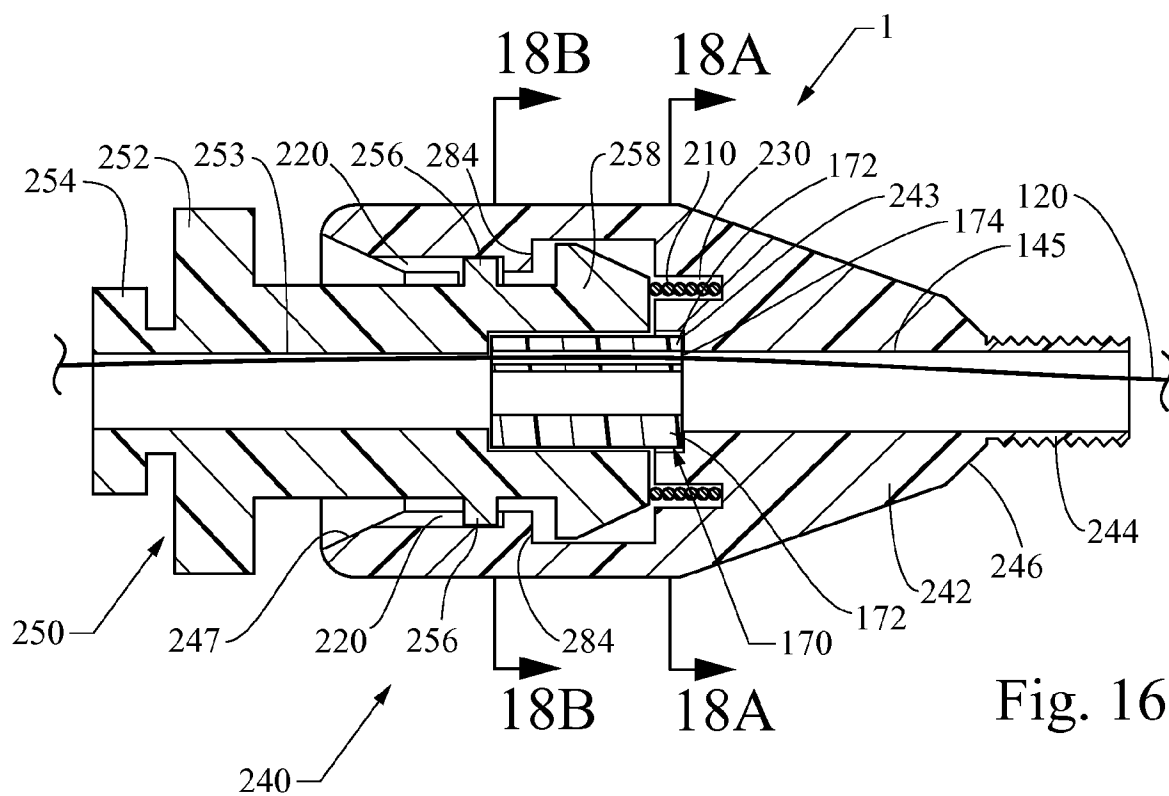


Fig. 19

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Fig. 18a

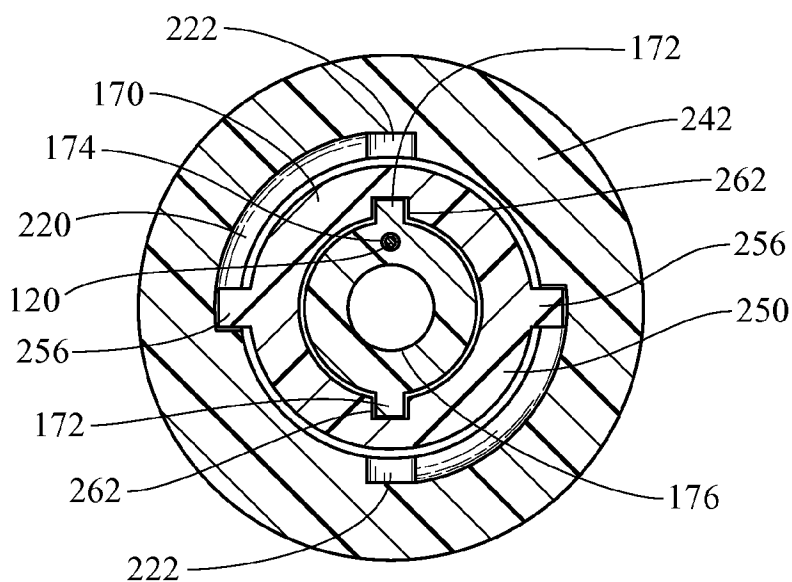
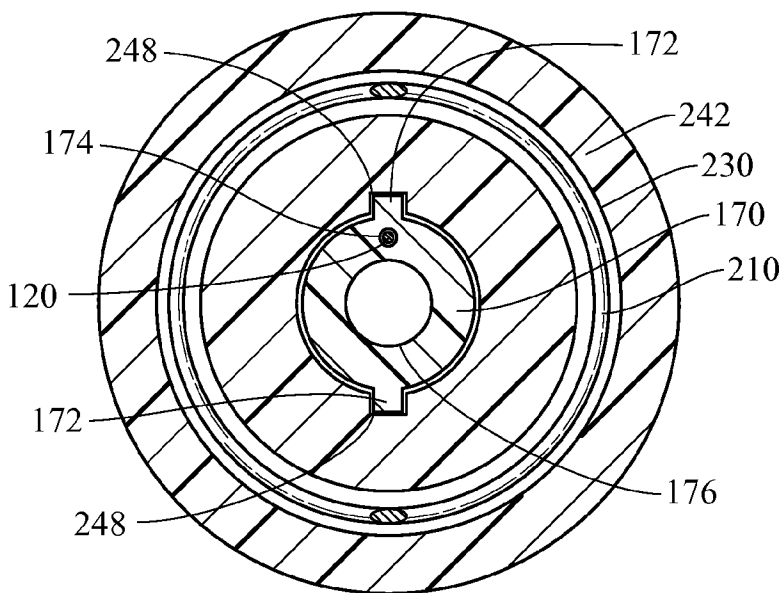
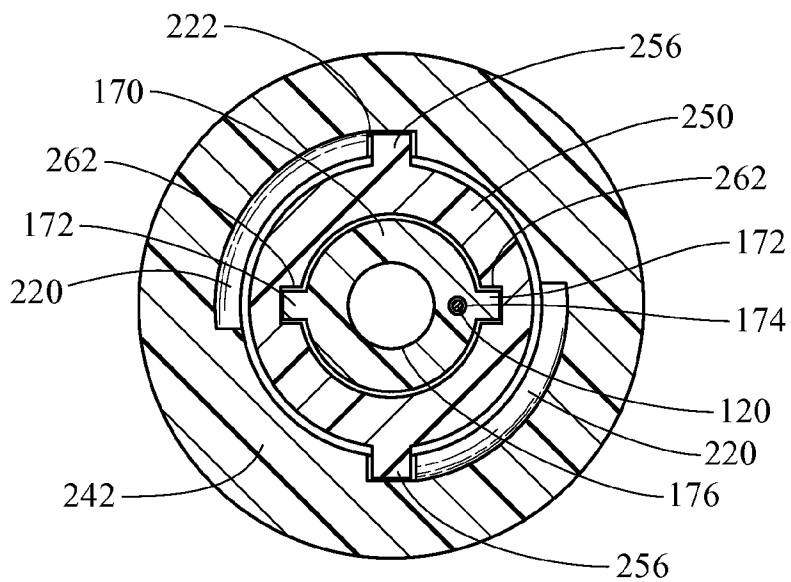


Fig. 18b

Fig. 18c



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/022318

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/01
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2001/049490 A1 (SLANDA JOZEF [US] ET AL) 6 December 2001 (2001-12-06) paragraph [0006] - paragraph [0008] paragraphs [0054], [0057] paragraph [0061] - paragraph [0068] figures 3D,9	1-3, 15
X	EP 0 609 020 A1 (COOK INC [US]) 3 August 1994 (1994-08-03) column 2, line 23 - column 3, line 30 column 5, line 10 - column 6, line 40 figures 1,2,4	1
A	US 6 042 577 A (CHU MICHAEL S H [US] ET AL) 28 March 2000 (2000-03-28) column 3, line 15 - line 45 column 4, line 18 - column 5, line 65 figures 1,2	1-15

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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Date of the actual completion of the international search

11 June 2010

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2010/022318

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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