

PRESSURE SENSING GUIDEWIRE SYSTEMS INCLUDING AN OPTICAL CONNECTOR CABLE

CROSS-REFERENCE TO RELATED APPLICATIONS

5 This application claims priority under 35 U.S.C. §119(e) to U.S. Provisional Application No. 62/298,759, filed February 23, 2016, the entire disclosure of which is herein incorporated by reference.

TECHNICAL FIELD

10 The present disclosure pertains to medical devices, and methods for manufacturing medical devices. More particularly, the present disclosure pertains to blood pressure sensing guidewires.

BACKGROUND

15 A wide variety of intracorporeal medical devices have been developed for medical use, for example, intravascular use. Some of these devices include guidewires, catheters, and the like. These devices are manufactured by any one of a variety of different manufacturing methods and may be used according to any one of a variety of methods. Of the known medical devices and methods, each has certain advantages and
20 disadvantages. There is an ongoing need to provide alternative medical devices as well as alternative methods for manufacturing and using medical devices.

BRIEF SUMMARY

 This disclosure provides design, material, manufacturing method, and use
25 alternatives for medical devices. An optical connector cable assembly is disclosed. The optical connector cable assembly comprises:

- an optical connector cable comprising a first optical fiber extending therefrom;
 wherein the optical connector cable includes a distal connector configured to connect to a guidewire, the distal connector comprising an inner housing and a
30 guidewire locking mechanism;
- an actuator, wherein actuation of the actuator moves the inner housing from a first position to a second position;

wherein when the inner housing is in the first position the guidewire locking mechanism is configured to secure the guidewire and the guidewire is rotatable with respect to the optical connector cable; and

wherein when the inner housing is in the second position the guidewire locking mechanism is in an open state for receiving or removing the guidewire.

Alternatively or additionally to any of the embodiments above, the guidewire locking mechanism includes a collet closer.

Alternatively or additionally to any of the embodiments above, the guidewire locking mechanism further comprises a collet spring and a collet.

Alternatively or additionally to any of the embodiments above, the guidewire locking mechanism includes a spring loaded cam assembly.

Alternatively or additionally to any of the embodiments above, the actuator comprises a sliding mechanism, a push button, dual push buttons, a ratchet, a lever and gear assembly, or a combination thereof.

Alternatively or additionally to any of the embodiments above, further comprising an axial spring adjacent the inner housing, when the inner housing is in the second position, the axial spring collapses allowing the guidewire locking mechanism to open.

Alternatively or additionally to any of the embodiments above, the inner housing further comprises a spline gear, when the inner housing is in the second position, the spline gear prevents the inner housing from rotating relative to the optical connector cable.

Alternatively or additionally to any of the embodiments above, further comprising a collet and a collet cap, when the inner housing is in the second position, the collet cap can be rotated relative to the optical connector cable.

Alternatively or additionally to any of the embodiments above, the guidewire locking mechanism includes an offset pinch clamp.

A medical device system for measuring blood pressure is disclosed. The system comprises:

an optical connector cable including a first optical fiber and a distal connector comprising an inner housing and a guidewire locking mechanism, the distal connector capable of being coupled to a pressure sensing guidewire;

the pressure sensing guidewire including a pressure sensor and a second optical fiber extending proximally from the pressure sensor, the second optical fiber being

capable of optically communicating with the first optical fiber, wherein the optical connector cable is designed to be coupled to the pressure sensing guidewire; and

an actuator, wherein actuation of the actuator moves the inner housing from a first position to a second position, wherein when the inner housing is in the first position the guidewire locking mechanism is in a closed state for retaining the pressure sensing guidewire and the pressure sensing guidewire is rotatable with respect to the optical connector cable, and wherein when the inner housing is in the second position the inner housing is moved in a distal direction from the optical connector cable and the guidewire locking mechanism is in an open state for receiving or removing the pressure sensing guidewire.

Alternatively or additionally to any of the embodiments above, the guidewire locking mechanism includes a collet closer.

Alternatively or additionally to any of the embodiments above, the guidewire locking mechanism further comprises a collet spring and a collet, when the inner housing is in the second position, the collet spring is compressed allowing the collet to open, and when the inner housing is in the first position, the collet spring closes the collet closer.

Alternatively or additionally to any of the embodiments above, the guidewire locking mechanism includes a spring loaded cam assembly.

Alternatively or additionally to any of the embodiments above, the actuator comprises a sliding mechanism, a push button, dual push buttons, a ratchet, a lever and gear assembly, or a combination thereof.

Alternatively or additionally to any of the embodiments above, further comprising an axial spring adjacent the inner housing, when the inner housing is in the second position, the axial spring collapses allowing the guidewire locking mechanism to open.

Alternatively or additionally to any of the embodiments above, the inner housing further comprises a spline gear, when the inner housing is in the second position, the spline gear prevents the inner housing from rotating relative to the optical connector cable.

Alternatively or additionally to any of the embodiments above, further comprising a collet and a collet cap, when the inner housing is in the second position, the collet cap may be rotated relative to the optical connector cable.

Alternatively or additionally to any of the embodiments above, the guidewire locking mechanism includes an offset pinch clamp.

An optical connector cable is disclosed. The optical connector cable comprises:
a distal connector comprising an inner housing and a guidewire locking
5 mechanism, the distal connector capable of being coupled to a guidewire; and
an actuator, wherein actuation of the actuator moves the inner housing of the
distal connector from a first position to a second position, wherein when the inner
housing is in the first position the guidewire locking mechanism is in a closed state for
retaining the guidewire and the guidewire is rotatable with respect to the optical
10 connector cable, and wherein when the inner housing is in the second position the inner
housing is moved in a distal direction from the optical connector cable and the
guidewire locking mechanism is in an open state for receiving or removing the
guidewire.

Alternatively or additionally to any of the embodiments above, the distal
15 connector further comprises an axial spring adjacent the inner housing, when the inner
housing is in the second position, the axial spring collapses allowing the guidewire
locking mechanism to open.

The above summary of some embodiments is not intended to describe each
disclosed embodiment or every implementation of the present disclosure. The Figures,
20 and Detailed Description, which follow, more particularly exemplify these
embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

The disclosure may be more completely understood in consideration of the
25 following detailed description in connection with the accompanying drawings, in
which:

Figure 1 is a partial cross-sectional side view of a portion of an example medical
device;

Figure 2 is a partial cross-sectional view of an example medical device disposed
30 at a first position adjacent to an intravascular occlusion;

Figure 3 is a partial cross-sectional view of an example medical device disposed
at a second position adjacent to an intravascular occlusion;

Figure 4 is a perspective view of an example medical device system 11;

Figure 5 is an exploded view of an example of a medical device system 11;

Figures 6-10 are cross-sectional views of an example medical device system;

Figure 11 is a partial cross-sectional side view of an example medical device system;

Figures 12-14B are partial cross-sectional side views of an example medical device system;

Figures 15-17 are partial cross-sectional side views of an example medical device system;

Figures 18 and 19 are partial cross-sectional side views of an example medical device system;

Figures 20 and 21 are partial cross-sectional side views of an example medical device system;

Figures 22 and 23 are partial cross-sectional side views of an example medical device system; and

Figures 24-26 are partial cross-sectional side views of an example medical device system.

While the disclosure is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

DETAILED DESCRIPTION

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

All numeric values are herein assumed to be modified by the term “about,” whether or not explicitly indicated. The term “about” generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the terms “about” may include numbers that are rounded to the nearest significant figure.

The recitation of numerical ranges by endpoints includes all numbers within that range (e.g. 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the content clearly dictates otherwise.

As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise.

It is noted that references in the specification to “an embodiment”, “some embodiments”, “other embodiments”, etc., indicate that the embodiment described may include one or more particular features, structures, and/or characteristics. However, such recitations do not necessarily mean that all embodiments include the particular features, structures, and/or characteristics. Additionally, when particular features, structures, and/or characteristics are described in connection with one embodiment, it should be understood that such features, structures, and/or characteristics may also be used connection with other embodiments whether or not explicitly described unless clearly stated to the contrary.

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the disclosure.

During some medical interventions, it may be desirable to measure and/or monitor the blood pressure within a blood vessel. For example, some medical devices may include pressure sensors that allow a clinician to monitor blood pressure. Such devices may be useful in determining fractional flow reserve (FFR), which may be understood as the ratio of the pressure after or distal of a stenosis (e.g., P_d) relative to the pressure before the stenosis and/or the aortic pressure (e.g., P_a). In other words, FFR may be understood as P_d/P_a .

Figure 1 illustrates a portion of an example medical device 10. In this example, medical device 10 is a blood pressure sensing guidewire 10. However, this is not intended to be limiting as other medical devices are contemplated including, for example, catheters, shafts, leads, wires, or the like. Guidewire 10 may include a tubular member or shaft 12. Shaft 12 may include a proximal portion 14 and a distal portion 16. The materials for proximal portion 14 and distal portion 16 may vary and may include those materials disclosed herein. For example, proximal portion 14, distal portion 16, or both may include a nickel-cobalt-chromium-molybdenum alloy (e.g., MP35-N), a nickel-titanium alloy, stainless steel, or other materials such as those materials disclosed herein. These are just examples. Other materials may also be utilized.

In some embodiments, proximal portion 14 and distal portion 16 are formed from the same monolith of material. In other words, proximal portion 14 and distal portion 16 are portions of the same tube defining shaft 12. In other embodiments, proximal portion 14 and distal portion 16 are separate tubular members that are joined together. For example, a section of the outer surface of portions 14/16 may be removed and a sleeve 17 may be disposed over the removed sections to join portions 14/16. Alternatively, sleeve 17 may be simply disposed over portions 14/16. Other bonds may also be used including welds, thermal bonds, adhesive bonds, or the like. If utilized, sleeve 17 used to join proximal portion 14 with distal portion 16 may include a material that desirably bonds with both proximal portion 14 and distal portion 16. For example, sleeve 17 may include a nickel-chromium-molybdenum alloy (e.g., INCONEL).

A plurality of slots 18 may be formed in shaft 12. In at least some embodiments, slots 18 are formed in distal portion 16. In at least some embodiments, proximal portion 14 lacks slots 18. However, proximal portion 14 may include slots 18. Slots 18 may be desirable for a number of reasons. For example, slots 18 may provide a desirable level of flexibility to shaft 12 (e.g., along distal portion 16) while also allowing suitable transmission of torque. Slots 18 may be arranged/distributed along distal portion 16 in a suitable manner including any of those arrangements disclosed herein. For example, slots 18 may be arranged as opposing pairs of slots 18 that are distributed along the length of distal portion 16. In some embodiments, adjacent pairs of slots 18 may have a substantially constant spacing relative to one another. Alternatively, the spacing between adjacent pairs may vary. For example, more distal regions of distal portion 16 may have a decreased spacing (and/or increased slot density), which may provide increased flexibility. In other embodiments, more distal regions of distal portion 16 may have an increased spacing (and/or decreased slot density). These are just examples. Other arrangements are contemplated.

A pressure sensor 20 may be disposed within shaft 12 (e.g., within a lumen 22 of shaft 12). While pressure sensor 20 is shown schematically in Figure 1, it can be appreciated that the structural form and/or type of pressure sensor 20 may vary. For example, pressure sensor 20 may include a semiconductor (e.g., silicon wafer) pressure sensor, piezoelectric pressure sensor, a fiber optic or optical pressure sensor, a Fabry-Perot type pressure sensor, an ultrasound transducer and/or ultrasound pressure sensor, a magnetic pressure sensor, a solid-state pressure sensor, or the like, or any other suitable pressure sensor.

As indicated above, pressure sensor 20 may include an optical pressure sensor. In at least some of these embodiments, an optical fiber 24 may be attached to pressure sensor 20 and may extend proximally therefrom. An attachment member 26 may attach optical fiber 24 to shaft 12. Attachment member 26 may be circumferentially disposed about and attached to optical fiber 24 and may be secured to the inner surface of shaft 12 (e.g., distal portion 16). In at least some embodiments, attachment member 26 is proximally spaced from pressure sensor 20. Other arrangements are contemplated. In some instance, a centering ring (not shown) may be disposed around optical fiber 24 at a position that is spaced proximally from optical pressure sensor 20.

In at least some embodiments, distal portion 16 may include a region with a thinned wall and/or an increased inner diameter that defines a housing region 52. In general, housing region 52 is the region of distal portion 16 that ultimately “houses” the pressure sensor (e.g., pressure sensor 20). By virtue of having a portion of the inner wall of shaft 12 being removed at housing region 52, additional space may be created or otherwise defined that can accommodate sensor 20.

In at least some embodiments, it may be desirable for pressure sensor 20 to have reduced exposure along its side surfaces to fluid pressure (e.g., from the blood). Accordingly, it may be desirable to position pressure sensor 20 along a landing region 50 defined along housing region 52. Landing region 50 may be substantially free of slots 18 so that the side surfaces of pressure sensor 20 have a reduced likelihood of being deformed due to fluid pressures at these locations. Distal of landing are 50, housing region 52 may include slots 18 that provide fluid access to pressure sensor 20.

Moreover, slots 18 may define a fluid pathway that allows blood (and/or a body fluid) to flow from a position along the exterior or outer surface of guidewire 10 (and/or shaft 12), through slots 18, and into the lumen 22 of shaft 12, where the blood can come into contact with pressure sensor 20. Because of this, no additional side openings/holes (e.g., other than slots 18) may be necessary in shaft 12 for pressure measurement. This may also allow the length of distal portion 16 to be shorter than typical sensor mounts or hypotubes that would need to have a length sufficient for a suitable opening/hole (e.g., a suitable “large” opening/hole) to be formed therein that provides fluid access to sensor 20.

A tip member 30 may be coupled to distal portion 16. Tip member 30 may include a shaping member 32 and a spring or coil member 34. A distal tip 36 may be attached to shaping member 32 and/or spring 34. In at least some embodiments, distal

tip 36 may take the form of a solder ball tip. Tip member 30 may be joined to distal portion 16 of shaft 12 with a bonding member 46 such as a weld.

Shaft 12 may include a hydrophilic coating 19. In some embodiments, hydrophilic coating 19 may extend along substantially the full length of shaft 12. In other embodiments, one or more discrete sections of shaft 12 may include hydrophilic coating 19.

In use, a clinician may use guidewire 10 to measure and/or calculate FFR (e.g., the pressure after an intravascular occlusion relative to the pressure before the occlusion and/or the aortic pressure). Measuring and/or calculating FFR may include measuring the aortic pressure in a patient. This may include advancing guidewire 10 through a blood vessel or body lumen 54 to a position that is proximal or upstream of an occlusion 56 as shown in Figure 2. For example, guidewire 10 may be advanced through a guide catheter 58 to a position where at least a portion of sensor 20 is disposed distal of the distal end of guide catheter 58 and measuring the pressure within body lumen 54. This pressure may be characterized as an initial pressure. In some embodiments, the aortic pressure may also be measured by another device (e.g., a pressure sensing guidewire, catheter, or the like). The initial pressure may be equalized with the aortic pressure. For example, the initial pressure measured by guidewire 10 may be set to be the same as the measured aortic pressure. Guidewire 10 may be further advanced to a position distal or downstream of occlusion 56 as shown in Figure 3 and the pressure within body lumen 54 may be measured. This pressure may be characterized as the downstream or distal pressure. The distal pressure and the aortic pressure may be used to calculate FFR.

It can be appreciated that an FFR system that utilizes an optical pressure sensor in a pressure sensing guidewire may be connected to a number of processing/conditioning units, displays, and the like. When making these connections, the various cables/connections may be designed so that the optical signals can be transmitted between adjacent optical fibers in an efficient manner.

A wide variety of optical connectors exist that are designed to allow for efficient communication between adjacent optical fibers. Such connectors are typically utilized in industries such as telecommunication. The use of optical fibers in medical devices may provide a variety of challenges. For example, when optical fibers are utilized in medical devices, it may be desirable for the connectors to allow for the connection of various devices and/or components while allowing for movement (e.g., rotation) of the

components relative to one another during use. At least some of the medical devices, medical device systems, and connectors disclosed herein may include features that improve the connection of components of a fiber optic system such as the connection of a guidewire with an optical fiber to an optical connector cable.

5 For the purposes of this disclosure, reference will be made to “medical device systems”. The medical device systems may be understood to be one or more medical devices that may be used together. In at least some embodiments, the medical device systems disclosed herein may be systems for measuring FFR. These systems may include a pressure sensing guidewire, an optical connector cable coupled to the
10 guidewire, a signal conditioning unit and/or processing unit coupled to the optical connector cable, and a display unit or output. The systems may also include additional intermediate cables and/or devices, guide catheters, other pressure measuring devices and/or components, and the like. References made to a system are not meant to imply that all of these components are present.

15 Figure 4 is a perspective view of an example optical connector cable 61. Optical connector cable 61 is designed to be coupled to a guidewire (e.g., guidewire 10) in a manner that permits rotation of the guidewire relative to optical connector cable 61. Optical connector cable 61 includes a distal connector 66 for securing the guidewire to optical connector cable 61. Distal connector 66 may include a housing 100 and an
20 actuator 102. Actuator 102, which may take the form of a slidable button, may be used to actuate a guidewire locking mechanism as described in more detail herein. Some example guidewire locking mechanisms contemplated are disclosed herein. A cable body 62 may extend from distal connector 66. At the proximal end of cable body 62, optical connector cable 61 may include a proximal connector (not shown) for
25 connecting optical connector cable 61 to other components such as signal conditioning and/or processing devices.

Figure 5 is an exploded view of optical connector cable 61. Optical connector cable 61 may include structural features that allow connector cable 61 to communicate with other components and may optionally include a flanged body that is secured (e.g.,
30 via an adhesive bond or other suitable bond) to a ferrule 86. Connector cable 61 may be utilized to optically connect an optical fiber (e.g., optical fiber 24 within guidewire 10) with an optical fiber 64, which extends to one or more components of a medical device system (and/or other systems) including, for example, a signal conditioning unit.

Movement and/or contact between adjacent optical fibers such as fibers 24/64 could lead to damage of the polished ends of the fibers 24/64. This could impact the communication between fibers 24/64. In order to improve the communication between fibers 24/64, a coupler 70 may be disposed within distal connector 66. Coupler 70 may be disposed between the ends of fibers 24/64. In at least some embodiments, coupler 70 may be a deformable disc or cylinder. For example, coupler 70 may take the form of a polymer disc. This may include a disc or cylinder formed from a compliant material such as an optically clear (e.g., aliphatic) polyurethane. Other forms are also contemplated for coupler 70. For example, coupler 70 may be a gel (e.g., a relatively thick gel), a coating on one or both of fibers 26/64, a membrane, or the like. Coupler 70 may be formed from one or more polymers or from other suitable materials including those disclosed herein. In at least some embodiments, coupler 70 may function as a “cushioning member” or a structural feature that provides some level of deformability at the interface between fibers 24/64 when bringing together fibers 24/64 (and/or bringing together guidewire 10 and optical connector cable 61).

It can be appreciated that optical fibers 24/64 may include an inner core and an outer cladding. In some instances, optical fibers 24/64 may have cores with the same diameter (e.g., about 62.5 μm). In other instances, optical fibers 24/64 may have cores with differing diameters. For example, optical fiber 24 may have a core diameter of about 62.5 μm and optical fiber 64 may have a core diameter of about 105 μm . These are just examples. Other diameters are contemplated. In addition, the outer diameter of optical fibers 24/64 may be the same or different. For example, the outer diameter of optical fibers 24/64 may be about 125 μm . These are just examples. Other diameters are contemplated.

As indicated above, distal connector 66 may include a guidewire locking mechanism that is designed to be secured to a guidewire 10 while permitting relative rotation of guidewire 10 relative to optical connector cable 61. For example, distal connector 66 may include a guidewire locking structure for releasably locking guidewire 10 to distal connector 66. In the example embodiment shown in Figure 5, the guidewire locking structure includes a locking collet 72. Other guidewire locking structures are contemplated including those disclosed herein. A collet retainer 94, an axial spring 92 and a pair of bearings 96 may also be disposed within housing 100.

In some instances, the locking collet 72 may be actuated with an actuator 102. In the embodiment shown in Figure 5, for example, a sliding mechanism which can be

actuated by pushing actuator 102, forward. Housed within the optical connector cable 61 is included a collet closer 88, bearings 96 and a collet spring 90. Distal connector 66 further includes a housing 100, a wire ferrule 82, a polymer disc 70, a ferrule 86, a split sleeve 84, a flanged body 76, a body 68 and a cable body 62. In some instances, an O-ring (not shown) may be disposed between the housing 100 and the body 68. The O-ring may provide additional cushioning (e.g., cushioning for a guidewire inserted into the distal connector 66 when the guidewire is urged against the coupler 70).

The optical connector cable 61, distal connector 66 and a guidewire locking mechanism 72 is couplable to a guidewire 10. In use, an actuator 102 can be employed to actuate the inner housing 74 from a first position to a second position wherein the guidewire locking mechanism 72 is open when the inner housing 74 is in the second position allowing insertion of the guidewire 10 therein, and the guidewire locking mechanism 72 is closed when the inner housing 74 and moves to the first position, which closes the guidewire locking mechanism 72 for retaining the guidewire 10. When the inner housing 74 is in the first position, the guidewire is secured to the distal connector 66 and the guidewire is rotatable relative to the distal connector 66.

Figures 6-10 are partial cross-sectional views of medical device 11 and the actuation of the guidewire locking mechanism. For example, Figure 6 is a partial cross sectional view of medical device 11 before a guidewire has been inserted into distal connector 66. In this figure, the actuator 102 has not been actuated and is disposed at a first or proximal position along distal connector 66, the axial spring 92 adjacent to the distal connector housing 103 pushes (and/or otherwise exerts a force upon) the actuator 102 proximally or to the right adjacent the housing 100 and the collet 72 is closed by the collet spring 90 between the collet retainer 94 and the collet closer 88. The collet spring 90 pushes against the collet retainer 94 holding the collet retainer 94 over a portion of the collet 72 thus closing the collet 72 to lock guidewire 10 in place. Bearings such as bearings 96a/96b/96c help to keep the various structures of distal connector 66 oriented in a desired manner. When arranged as shown in Figure 6, the distal end of the collet retainer 94 may extend to a position that is substantially flush with or proximal of the distal end of the distal connector housing 103. In some instance, the collect retainer 94 may be slightly shortened (e.g., shortened relative to what is shown in Figures 6-10) so that the distal end of the collect retainer 94 may extend to a position that is substantially axially aligned with a distal end or edge of the bearing 96b.

Figure 7 is a partial cross-sectional view illustrating the actuator 102 being advanced to the point where the collet retainer 94 comes into contact with the distal bearing 96b of the actuator 102, which stops the forward motion of the collet retainer 94 and the collet 72. In some instances, the distal end of the collet retainer 94 may extend distally beyond the distal end of the distal connector housing 103 as shown in Figure 7. Alternatively, the distal end of the collet retainer 94 may extend to a position that is substantially flush with the distal end of the distal connector housing 103 or to a position that is proximal of the distal end of the distal connector housing 103. In some of these instances, the collect retainer 94 may be slightly shortened (e.g., relative to what is shown in Figures 6-10) in order to be arranged in such a manner. As actuator 102 is further advanced, as shown in Figure 8, the collet closer 88 moves distally, compressing the collet spring 90. The distal movement of the collet closer 88 allows the collet 72 to open for insertion of a guidewire 10. Once the guidewire 10 is in place, actuator 102, collet retainer 94 and collet closer 88 move proximally to close the collet 72. The guidewire 10 is gripped by the collet 72 and is stopped adjacent the polymer disc 70. The axial spring 92 pushes on the assembly so that the proximal end of the guidewire 10 is pushed into the ferrule 82 to provide the axial force necessary for achieving a good optical connection.

With collet 72 open, guidewire 10 may be inserted into distal connector 66 as shown in Figure 9. Guidewire 10 is pushed in all the way into distal connector 66 until it is stopped at a position adjacent the polymer disc 70 which is disposed between the wire ferrule 82 and the ferrule 86, allowing for close contact between optical fibers (not shown) to facilitate optical communication. Figure 10 is a partial cross-sectional view wherein the actuator 102 has been released, the collet 72 is closed to grip the guidewire 10. Releasing the actuator 102 allows the locking mechanism 88 to close and grip the guidewire 10 securing the guidewire 10 to the cable body 62. The actuator 102 and collet closer 88 move proximally which closes the collet 72 with the force generated by the collet spring 90. Once the guidewire 10 is gripped by the collet 72, the internal assembly can no longer move proximally and the axial spring 92 generates a force on the guidewire 10/optical connector cable 61 junction to ensure a good optical connection. When so positioned/connected with distal connector 66, guidewire 10 can be rotated relative to optical connector cable 61. For example, the collet retainer 94, collet spring 90, collet 72, and collet closer 88 are all free to rotate allowing guidewire

10 to rotate similarly to facilitate navigation through the vasculature without having to disconnect the guidewire 10 from optical connector cable 61.

Figure 11 is a partial side view of another example medical device system 211 having an actuator in the form of one or more buttons 202 on either side of housing 200 of the distal connector 266 which is connected to cable body 262. In some instances, a
5 single button 202 is used. In other instances, two or more buttons 202 may be utilized. Buttons 202 may be simultaneously pressed for actuation of the guidewire locking mechanism (not shown). When the one or more buttons 202 are not pressed, the inner housing 274 is disengaged from the teeth/grooves of the spline gear 298 so that the
10 guidewire 10 can be rotated. Pressing the buttons 202 engages the inner housing 274 with the teeth/grooves of the spline gear 298 so that the collet cap 278 can be rotated to actuate collet 272 and lock the guidewire 10. Once a guidewire 10, is inserted in the distal end of distal connector 266, the buttons 202 can be released allowing rotation of
15 collet cap 278. The dual buttons 202 prevent accidental actuation of the inner assembly including the guidewire locking mechanisms (now shown). The example medical device is explained in more detail below with respect to Figures 12-14.

Figure 12 is a partial cross-sectional view of an example medical device system 211. Medical device system 211 includes a distal connector 266 and an optical connector cable 261. Distal connector 266 includes a guidewire locking mechanism
20 that may include a collet 272, a collet retainer 294, and a rotatable collet cap 278. Housing 200 of optical connector cable 261 includes a distal axial spring 292, a guidewire ferrule 282, an optical cable ferrule 286, a split sleeve 284, a polymer disc disposed between ferrule 282 and ferrule 286, collet spring 290, bearing assembly 296, actuator 202 in the form of dual buttons and three living hinges 299. Other
25 configurations and/or button shapes are contemplated.

Housing 200 of distal connector further includes an inner housing 297 having a spline gear 298. Spline gear 298 prevents inner housing 274 of optical connector cable 261 from rotating when the actuator buttons 202 are fully depressed as shown in Figure 12. When the actuator buttons 202 are depressed as shown in Figure 13, the inner
30 housing 297 is moved distally moving the collet 272, the inner housing 274, the collet cap 278, the collet retainer 294, and the bearing assembly 295 distally. The spline gear 298 in the inner housing 297 engages grooves in inner housing 274 which prevents rotation of the system 211 such that the collet cap 278 can be tightened by rotation to grip the guidewire 10 as shown in Figure 14. Once the guidewire 10 is in place and the

collet cap 278 tightened, the buttons 202 can be released, disengaging the spline gear 298 from the grooves in the inner housing 274, allowing the assembly to rotate. With the buttons 202 released, the guidewire 10 is gripped in the collet 272 and optical fiber 24 is in contact with the polymer disc 270 and the ferrule 282. The distal spring 292 provides axial force on the guidewire 10 against the polymer disc 270 and the ferrule 282 to ensure a good connection. Figure 14B is a partial cross-sectional view of a medical device system 211 wherein actuator buttons 202 have been fully released and the inner housing 274 along with guidewire 10 are free to rotate for maneuverability of the guidewire 10 through a patient's body lumen without disconnecting guidewire 10.

Figure 15 is a partial cross-sectional view of an example medical device 311 before a guidewire has been inserted therein. In this figure, the actuator 302, in this embodiment, a button 302, has not been actuated, the collet spring 390 forces the inner housing 374 in a proximal direction and the collet 372 is in a closed state and the collet 372, guidewire 10 and collet retainer 374 are free to rotate.

Figure 16 is a partial cross-sectional view illustrating the partial depression of the actuator button 302 which pushes the inner housing 374 in a distal direction and the axial spring 392 collapses first. As the actuator button 302 is fully depressed as shown in Figure 17, the collet spring 390 collapses allowing the collet 372 to open for insertion or removal of guidewire 10.

Figure 18 is a partial cross-sectional view illustrating of an example medical device system 411 having a distal connector 466 and an optical connector cable 460. Housing 400 of distal connector further includes an inner housing 474 having a spline gear 498.

Spline gear 498 prevents inner housing 474 of distal connector 466 from rotating when the actuator 402, in this embodiment, a sliding mechanism, is pushed in a distal direction over a stop or detent 405 as shown in Figure 19. Actuator 402 in its forward position, moves the inner housing 474 with spline gears 498 in a distal direction allowing rotation of the collet cap 478 for removal of the guidewire. The spline gear 498 of the inner housing 474 is in a locked position with matching grooves of inner housing 474 which prevents rotation of the inner housing 474.

Figure 20 is a partial cross-sectional view illustrating of an example medical device system 511 having a guidewire locking mechanism, a distal connector 566, and an optical connector cable 560. Housing 500 of distal connector further includes an inner housing 574 including a collet 572 and a collet retainer 594. In the resting state,

an inner housing 597 coupled to an actuator prevents spline gear 598 from contacting inner housing 574 of distal connector 566 allowing for rotation of a guidewire relative to distal connector 566.

When actuator 502, in this case a lever, is pushed forward as shown in Figure 21, the distal connector 566 is separated from the housing 597 and the housing 574 with matching groves contacts the spline gears 598 and the collet cap 578 can be rotated to open the collet 572 and release guidewire 10.

Figure 22 is a partial cross-sectional view illustrating of an example medical device system 611 having a guidewire locking mechanism, a distal connector 666, and an optical connector cable 661. Distal connector 666 includes an actuator 602 for actuation of inner housing 674, a housing 600 having a locking pin 698 and a guidewire locking mechanism, in this embodiment, in the form of an offset pinch clamp 672. The offset pinch clamp 672 is in a closed state when the actuator 602, the inner housing 674, and the locking pin 698 are in the distal position. When actuator 602 is moved proximally as shown in Figure 23, the inner housing is actuated, the locking pin engages and is seated within the grooves of gear 690 allowing rotation of the cap 678 and opening of the offset pinch clamp 272 for removal or insertion of a guidewire 10.

Figure 24 is a partial cross-sectional view illustrating of an example medical device system 711 having a guidewire locking mechanism and a distal connector 766. Distal connector 766 includes a housing 700 with an inner housing 797 having a spring loaded cam assembly including springs 772 and cams 773. The cams 773 of the cam assembly allow rotation of the guidewire 10 while sufficiently locking the guidewire 10 to the distal connector 766. The actuator includes a ratchet 702 and a release button 703. When the ratchet 702 is compressed, the cams 773 are compressed and the guidewire 10 is pressed against the wire ferrule (not shown). When the release button 703 is compressed as shown in Figure 25, the ratchet 702 releases and the cam assembly 772 returns to a resting state which frees the guidewire 10. This allows removal or insertion of the guidewire as shown in Figure 26.

The materials that can be used for the various components of guidewire 10 (and/or other guidewires disclosed herein) and the various tubular members disclosed herein may include those commonly associated with medical devices. For simplicity purposes, the following discussion makes reference to shaft 12 and other components of guidewire 10. However, this is not intended to limit the devices and methods

described herein, as the discussion may be applied to other similar tubular members and/or components of tubular members or devices disclosed herein.

The various components of the devices/systems disclosed herein may include a metal, metal alloy, polymer (some examples of which are disclosed below), a metal-polymer composite, ceramics, combinations thereof, and the like, or other suitable material. Some examples of suitable metals and metal alloys include stainless steel, such as 304V, 304L, and 316LV stainless steel; mild steel; nickel-titanium alloy such as linear-elastic and/or super-elastic nitinol; other nickel alloys such as nickel-chromium-molybdenum alloys (e.g., UNS: N06625 such as INCONEL® 625, UNS: N06022 such as HASTELLOY® C-22®, UNS: N10276 such as HASTELLOY® C276®, other HASTELLOY® alloys, and the like), nickel-copper alloys (e.g., UNS: N04400 such as MONEL® 400, NICKELVAC® 400, NICORROS® 400, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nickel-molybdenum alloys (e.g., UNS: N10665 such as HASTELLOY® ALLOY B2®), other nickel-chromium alloys, other nickel-molybdenum alloys, other nickel-cobalt alloys, other nickel-iron alloys, other nickel-copper alloys, other nickel-tungsten or tungsten alloys, and the like; cobalt-chromium alloys; cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like); platinum enriched stainless steel; titanium; combinations thereof; and the like; or any other suitable material.

Some examples of suitable polymers may include polytetrafluoroethylene (PTFE), ethylene tetrafluoroethylene (ETFE), fluorinated ethylene propylene (FEP), polyoxymethylene (POM, for example, DELRIN® available from DuPont), polyether block ester, polyurethane (for example, Polyurethane 85A), polypropylene (PP), polyvinylchloride (PVC), polyether-ester (for example, ARNITEL® available from DSM Engineering Plastics), ether or ester based copolymers (for example, butylene/poly(alkylene ether) phthalate and/or other polyester elastomers such as HYTREL® available from DuPont), polyamide (for example, DURETHAN® available from Bayer or CRISTAMID® available from Elf Atochem), elastomeric polyamides, block polyamide/ethers, polyether block amide (PEBA, for example available under the trade name PEBAX®), ethylene vinyl acetate copolymers (EVA), silicones, polyethylene (PE), Marlex high-density polyethylene, Marlex low-density polyethylene, linear low density polyethylene (for example REXELL®), polyester, polybutylene terephthalate (PBT), polyethylene terephthalate (PET), polytrimethylene

terephthalate, polyethylene naphthalate (PEN), polyetheretherketone (PEEK), polyimide (PI), polyetherimide (PEI), polyphenylene sulfide (PPS), polyphenylene oxide (PPO), poly paraphenylene terephthalamide (for example, KEVLAR®), polysulfone, nylon, nylon-12 (such as GRILAMID® available from EMS American
5 Grilon), perfluoro(propyl vinyl ether) (PFA), ethylene vinyl alcohol, polyolefin, polystyrene, epoxy, polyvinylidene chloride (PVdC), poly(styrene-*b*-isobutylene-*b*-styrene) (for example, SIBS and/or SIBS A), polycarbonates, ionomers, biocompatible polymers, other suitable materials, or mixtures, combinations, copolymers thereof, polymer/metal composites, and the like. In some embodiments the sheath can be
10 blended with a liquid crystal polymer (LCP). For example, the mixture can contain up to about 6 percent LCP.

U.S. Patent Application Publication No. US 2014/0350414 is herein incorporated by reference. U.S. Patent Application Publication No. US 2014/0058275 is herein incorporated by reference. U.S. Patent Application No. 14/196,740 filed
15 March 4, 2014 is herein incorporated by reference.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the disclosure. This may include, to the extent that it is appropriate, the use of any of the features of one example embodiment being
20 used in other embodiments. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

WHAT IS CLAIMED IS:

1. An optical connector cable assembly, comprising:
an optical connector cable comprising a first optical fiber extending therefrom;
wherein the optical connector cable includes a distal connector configured to connect to a guidewire, the distal connector comprising an inner housing and a guidewire locking mechanism;
an actuator, wherein actuation of the actuator moves the inner housing from a first position to a second position;
wherein when the inner housing is in the first position the guidewire locking mechanism is configured to secure the guidewire and the guidewire is rotatable with respect to the optical connector cable; and
wherein when the inner housing is in the second position the guidewire locking mechanism is in an open state for receiving or removing the guidewire.
2. The optical connector cable assembly of claim 1, wherein the guidewire locking mechanism includes a collet closer.
3. The optical connector cable assembly of claim 2, wherein the guidewire locking mechanism further comprises a collet spring and a collet.
4. The optical connector cable assembly of claim 1, wherein the guidewire locking mechanism includes a spring loaded cam assembly.
5. The optical connector cable assembly of any one of claims 1-4, wherein the actuator comprises a sliding mechanism, a push button, dual push buttons, a ratchet, a lever and gear assembly, or a combination thereof.
6. The optical connector cable assembly of any one of claims 1-5, further comprising an axial spring adjacent the inner housing, when the inner housing is in the second position, the axial spring collapses allowing the guidewire locking mechanism to open.

7. The optical connector cable assembly of any one of claims 1-6, wherein the inner housing further comprises a spline gear, when the inner housing is in the second position, the spline gear prevents the inner housing from rotating relative to the optical connector cable.

8. The optical connector cable of claim 7, further comprising a collet and a collet cap, when the inner housing is in the second position, the collet cap can be rotated relative to the optical connector cable.

9. The optical connector cable assembly of any one of claims 1, wherein the guidewire locking mechanism includes an offset pinch clamp.

10. A medical device system for measuring blood pressure, the system comprising:

an optical connector cable including a first optical fiber and a distal connector comprising an inner housing and a guidewire locking mechanism, the distal connector capable of being coupled to a pressure sensing guidewire;

the pressure sensing guidewire including a pressure sensor and a second optical fiber extending proximally from the pressure sensor, the second optical fiber being capable of optically communicating with the first optical fiber, wherein the optical connector cable is designed to be coupled to the pressure sensing guidewire; and

an actuator, wherein actuation of the actuator moves the inner housing from a first position to a second position, wherein when the inner housing is in the first position the guidewire locking mechanism is in a closed state for retaining the pressure sensing guidewire and the pressure sensing guidewire is rotatable with respect to the optical connector cable, and wherein when the inner housing is in the second position the inner housing is moved in a distal direction from the optical connector cable and the guidewire locking mechanism is in an open state for receiving or removing the pressure sensing guidewire.

11. The system of claim 10, wherein the guidewire locking mechanism includes a collet closer.

12. The system of claim 11, wherein the guidewire locking mechanism further comprises a collet spring and a collet, when the inner housing is in the second position, the collet spring is compressed allowing the collet to open, and when the inner housing is in the first position, the collet spring closes the collet closer.

13. The system of claim 10, wherein the guidewire locking mechanism includes a spring loaded cam assembly.

14. The system of any one of claims 10-13, further comprising an axial spring adjacent the inner housing, when the inner housing is in the second position, the axial spring collapses allowing the guidewire locking mechanism to open.

15. An optical connector cable, comprising:
a distal connector comprising an inner housing and a guidewire locking mechanism, the distal connector capable of being coupled to a guidewire; and
an actuator, wherein actuation of the actuator moves the inner housing of the distal connector from a first position to a second position, wherein when the inner housing is in the first position the guidewire locking mechanism is in a closed state for retaining the guidewire and the guidewire is rotatable with respect to the optical connector cable, and wherein when the inner housing is in the second position the inner housing is moved in a distal direction from the optical connector cable and the guidewire locking mechanism is in an open state for receiving or removing the guidewire.

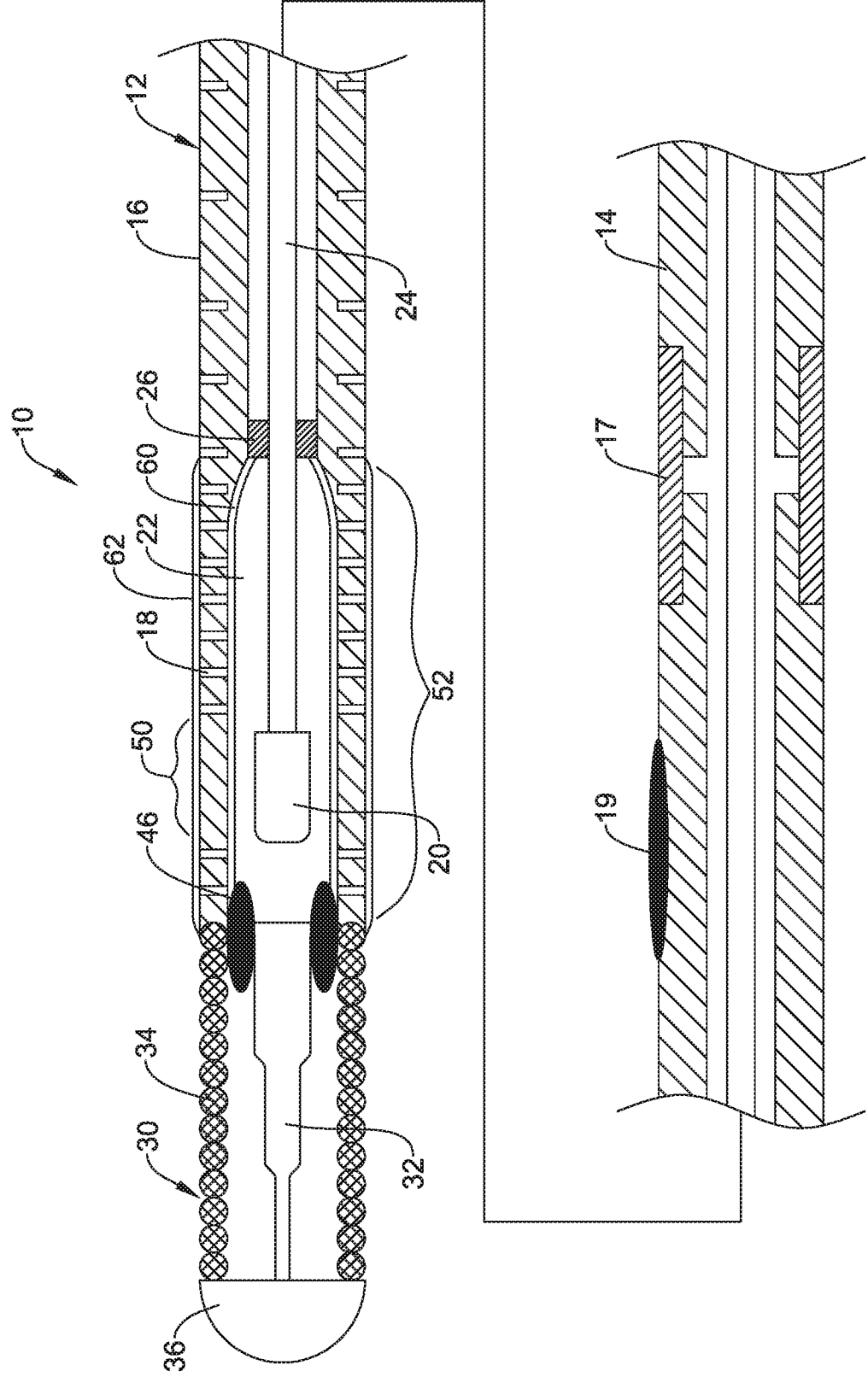


FIG. 1

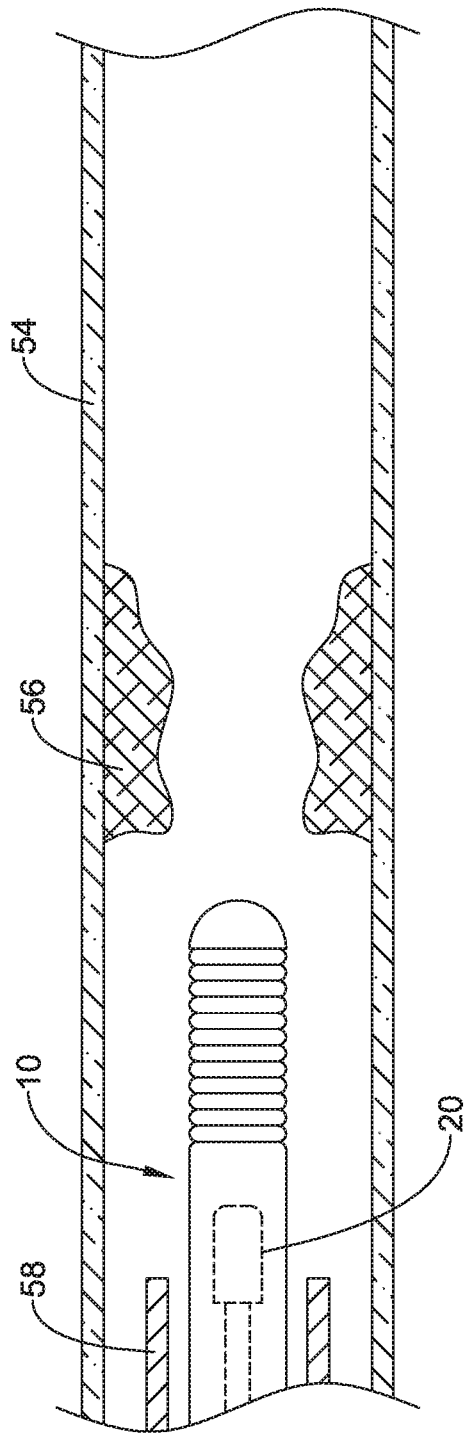


FIG. 2

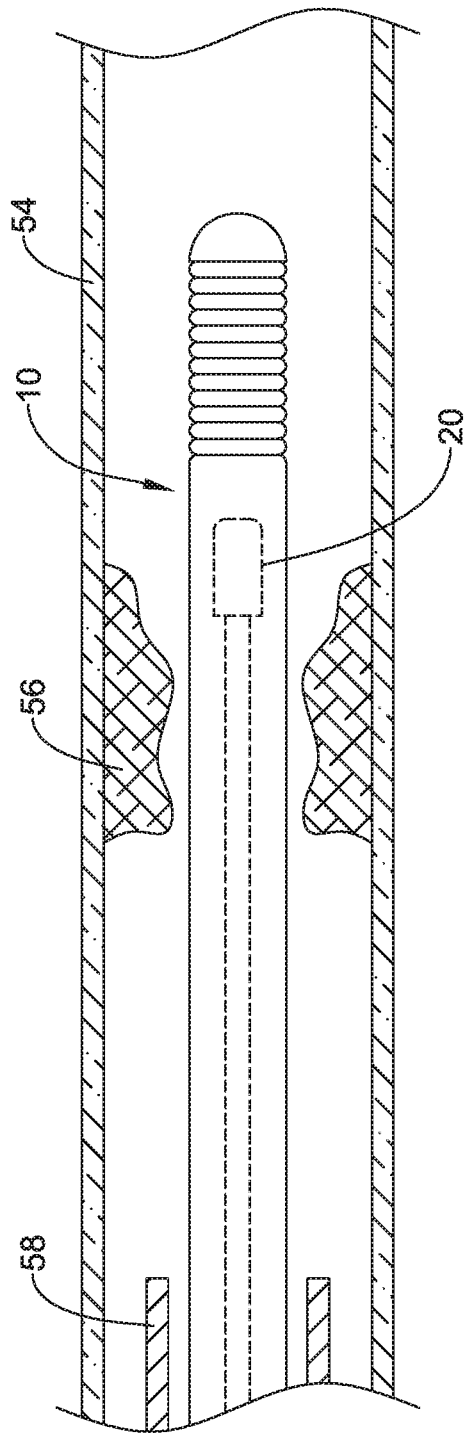


FIG. 3

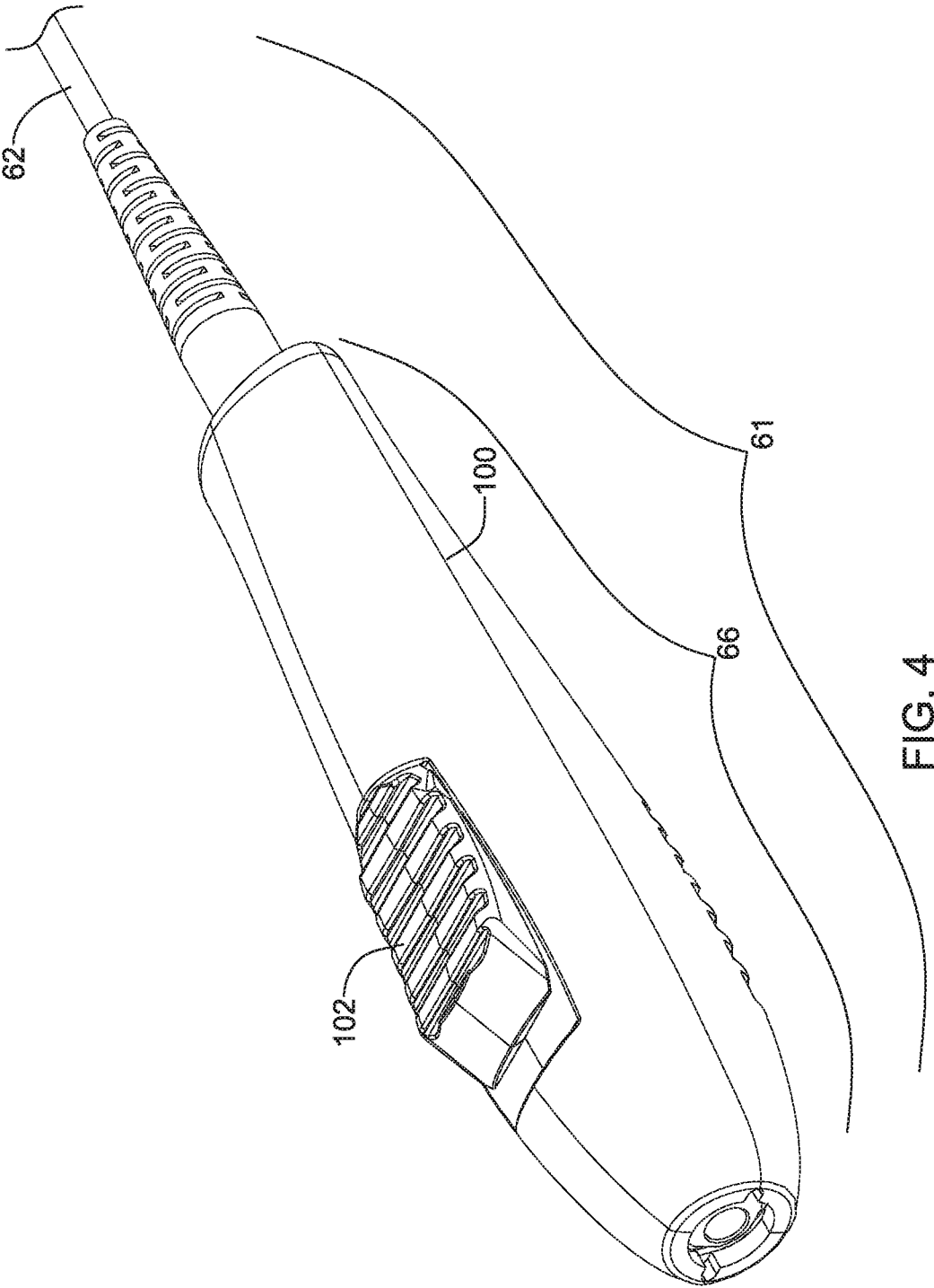
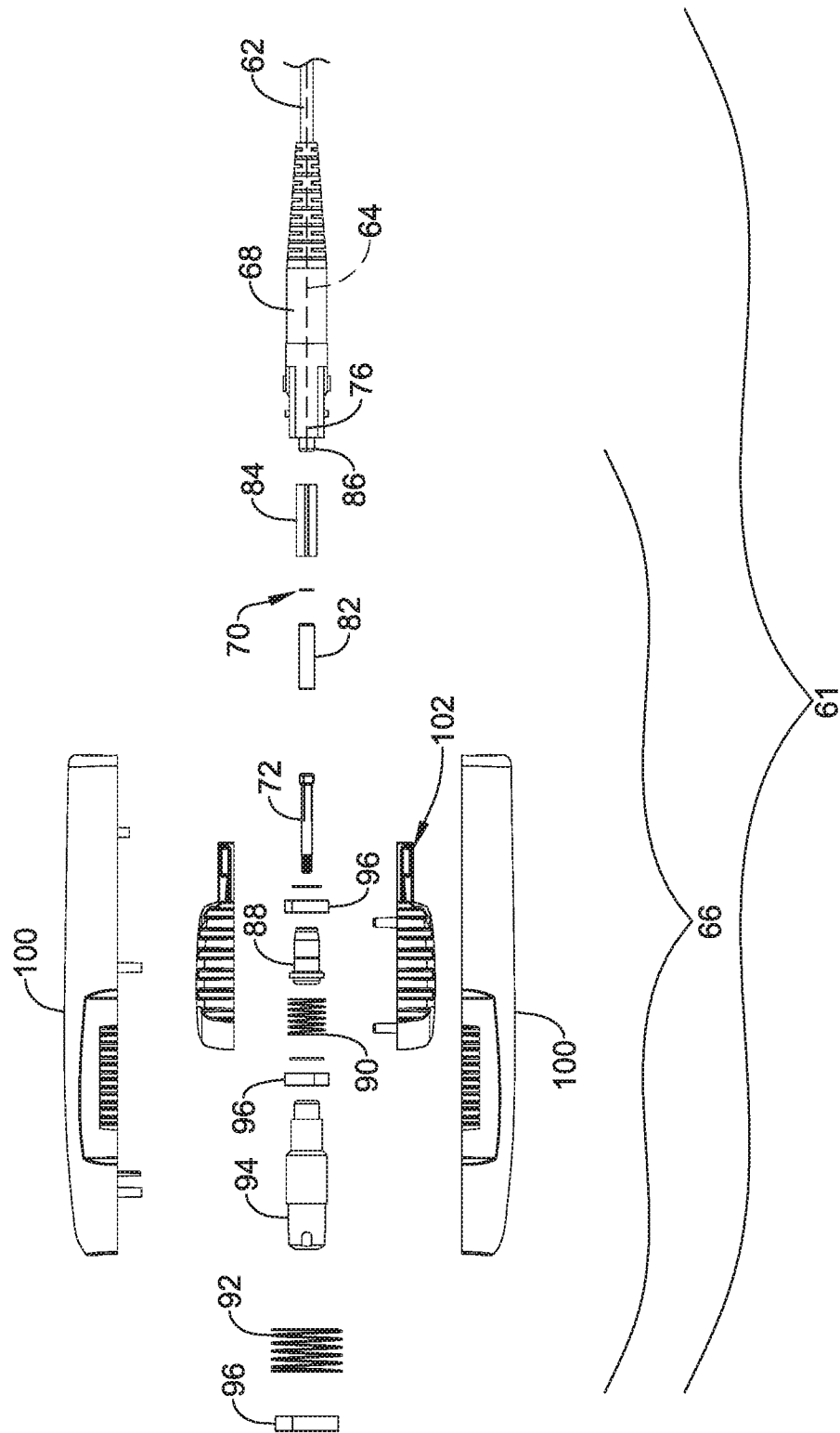


FIG. 4





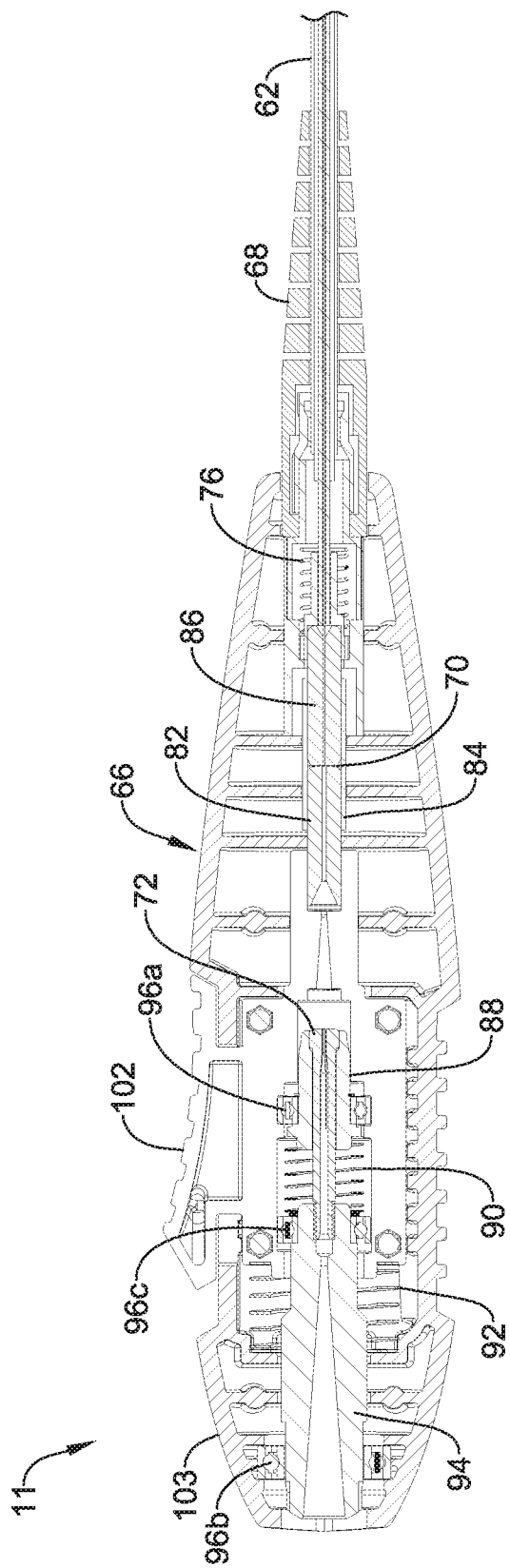


FIG. 6

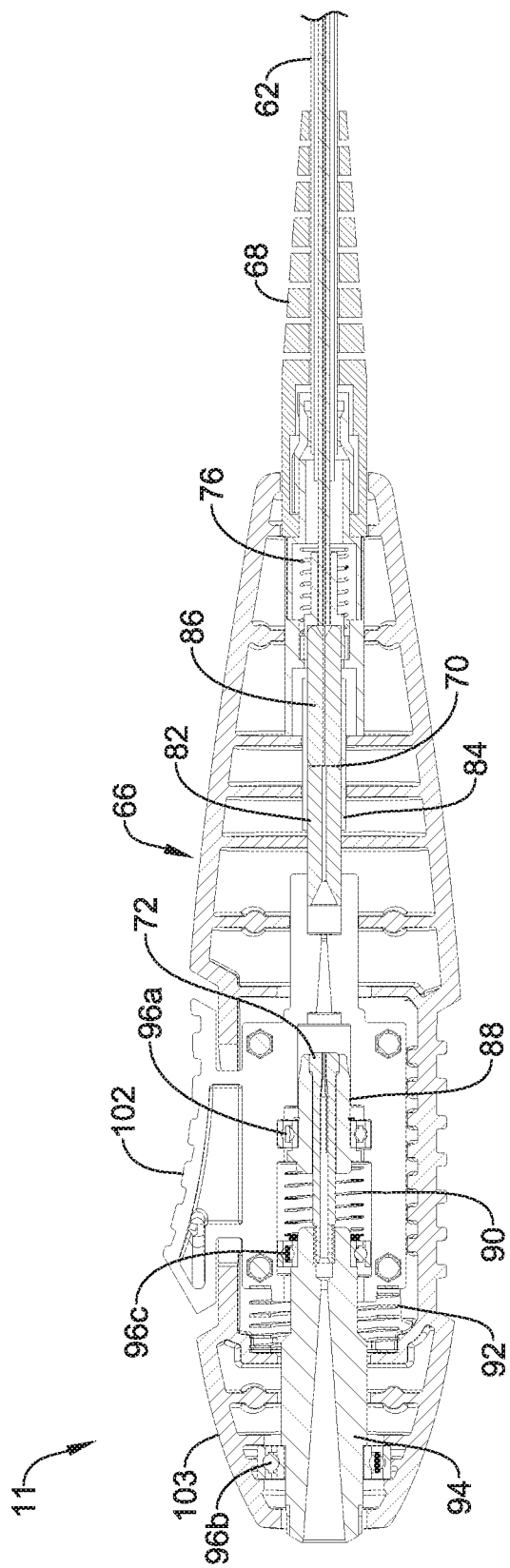


FIG. 7

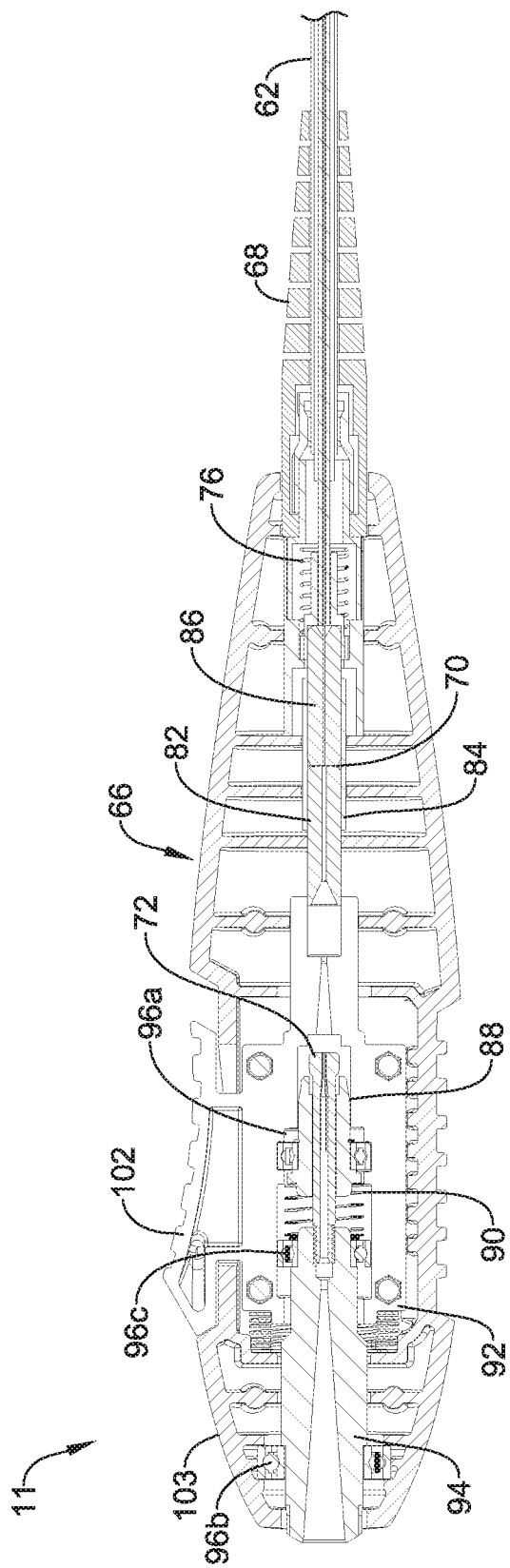


FIG. 8

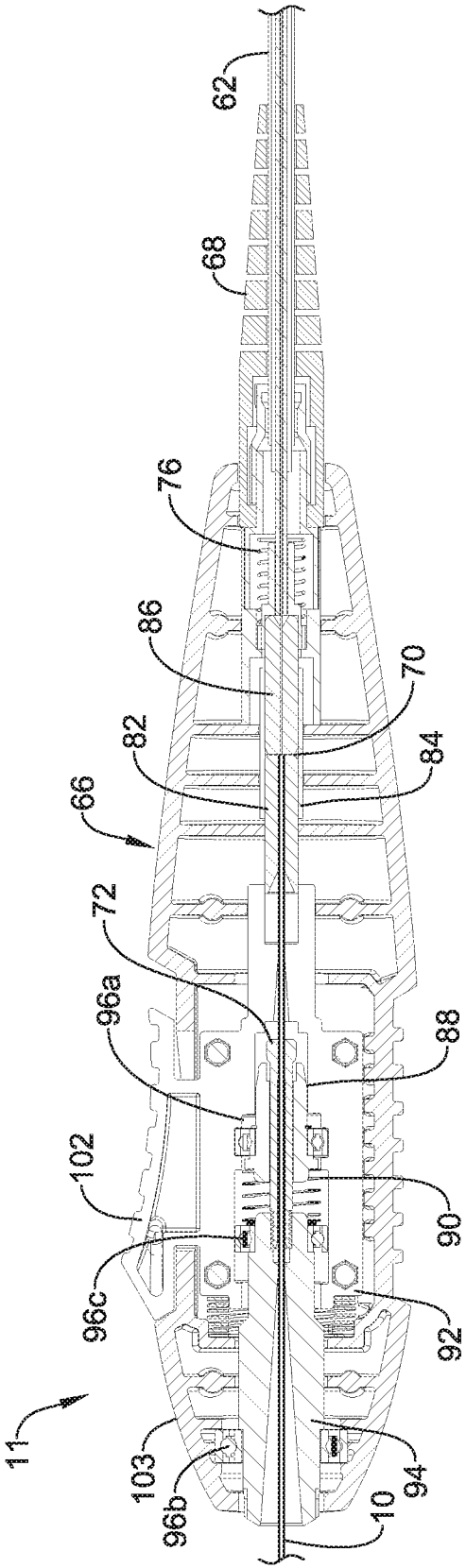


FIG. 9

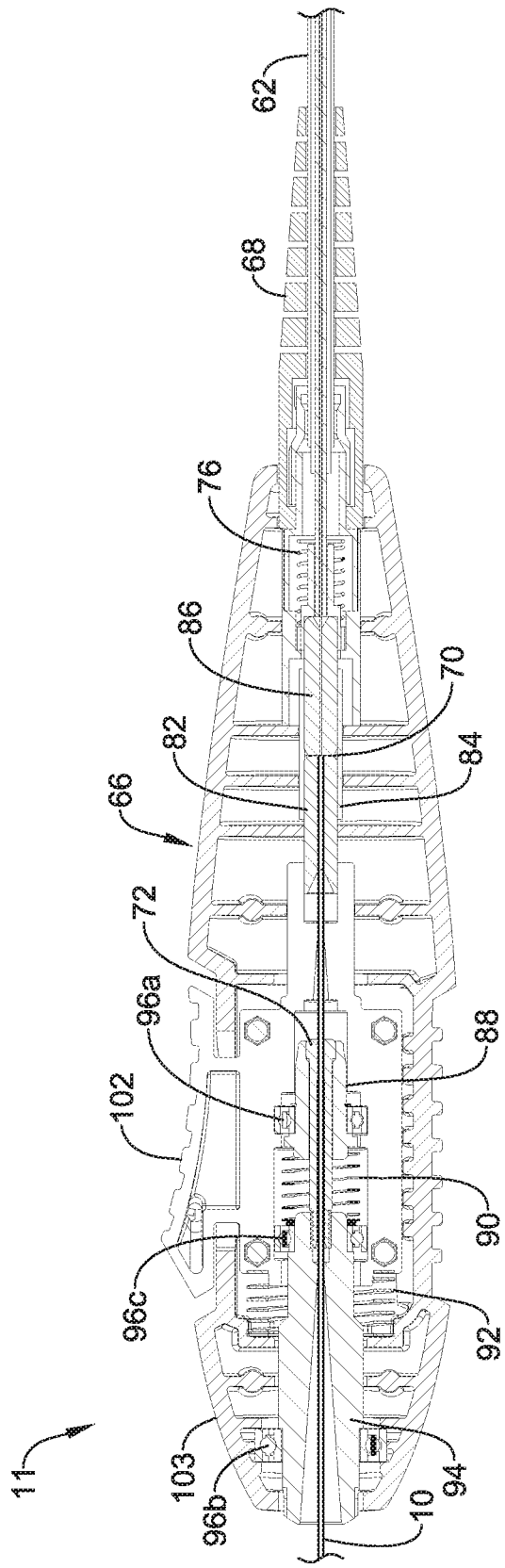


FIG. 10

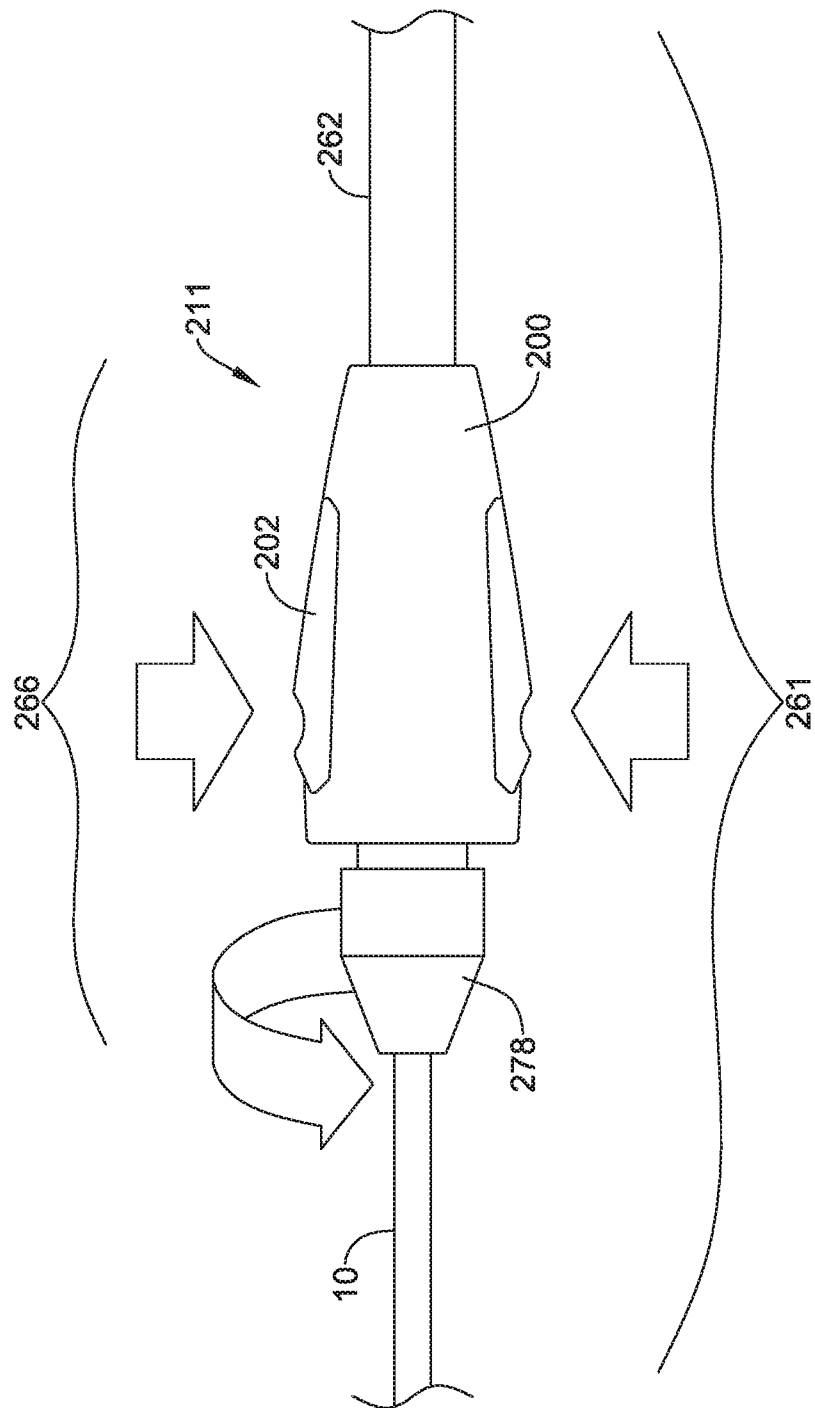


FIG. 11

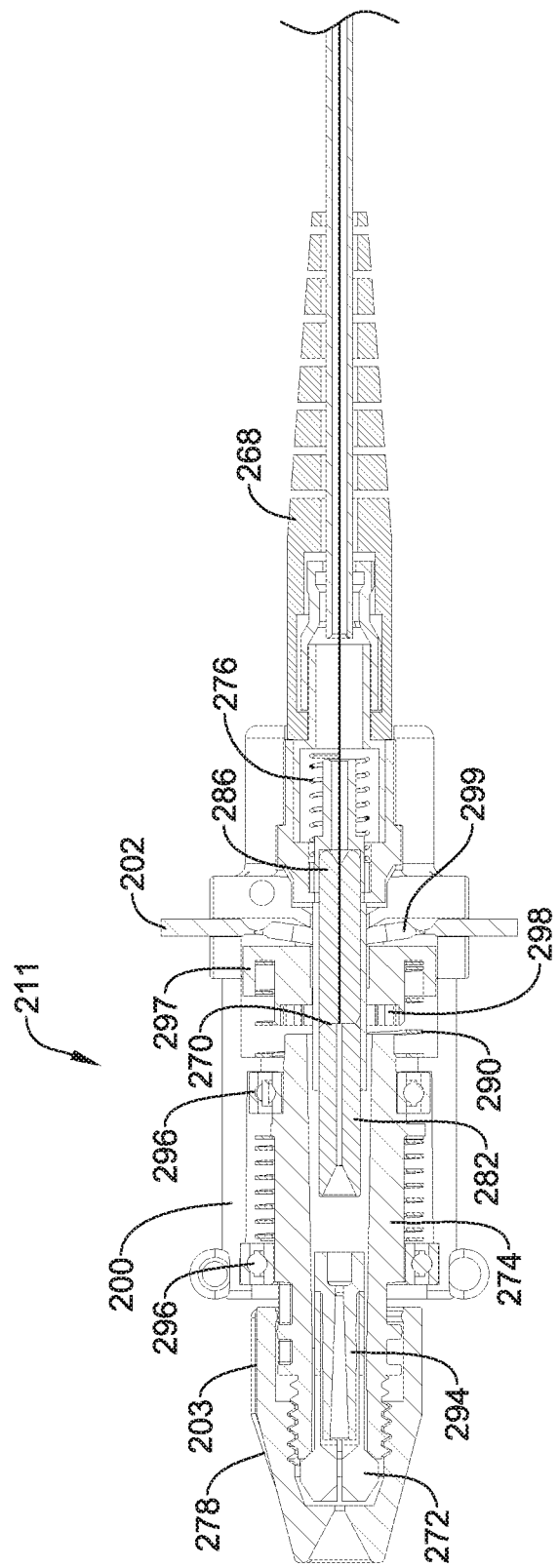


FIG. 12

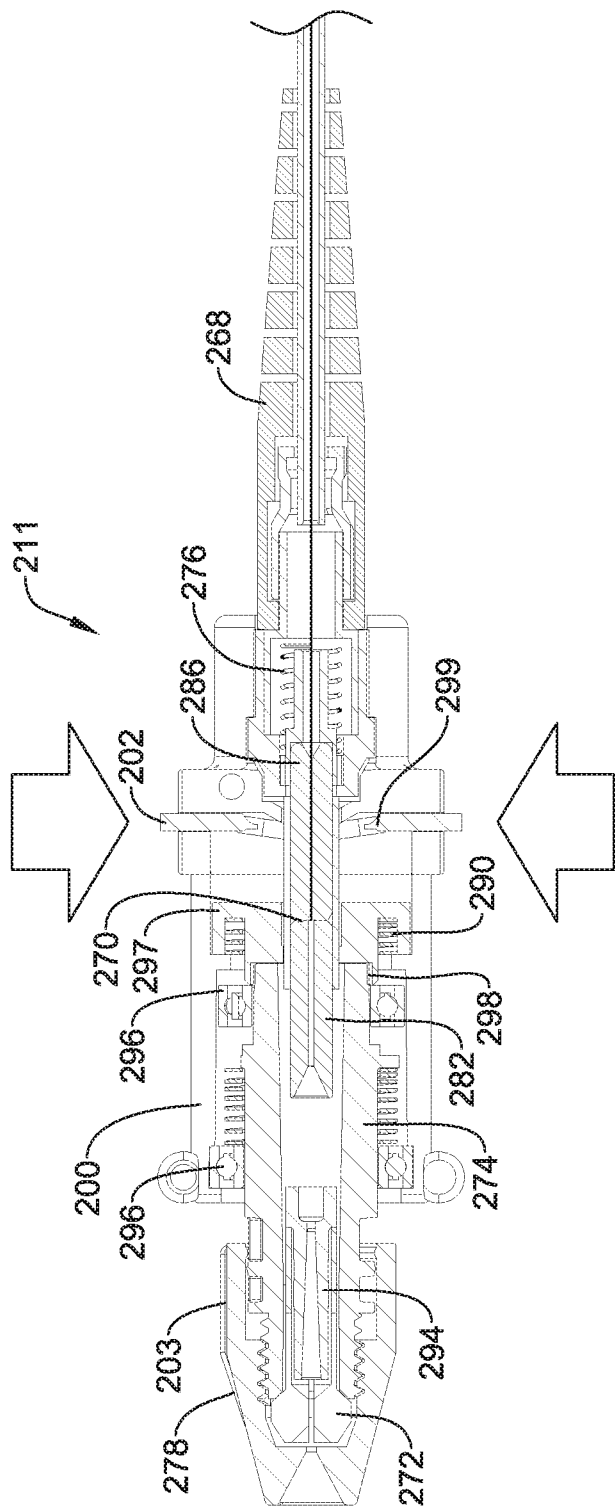


FIG. 13

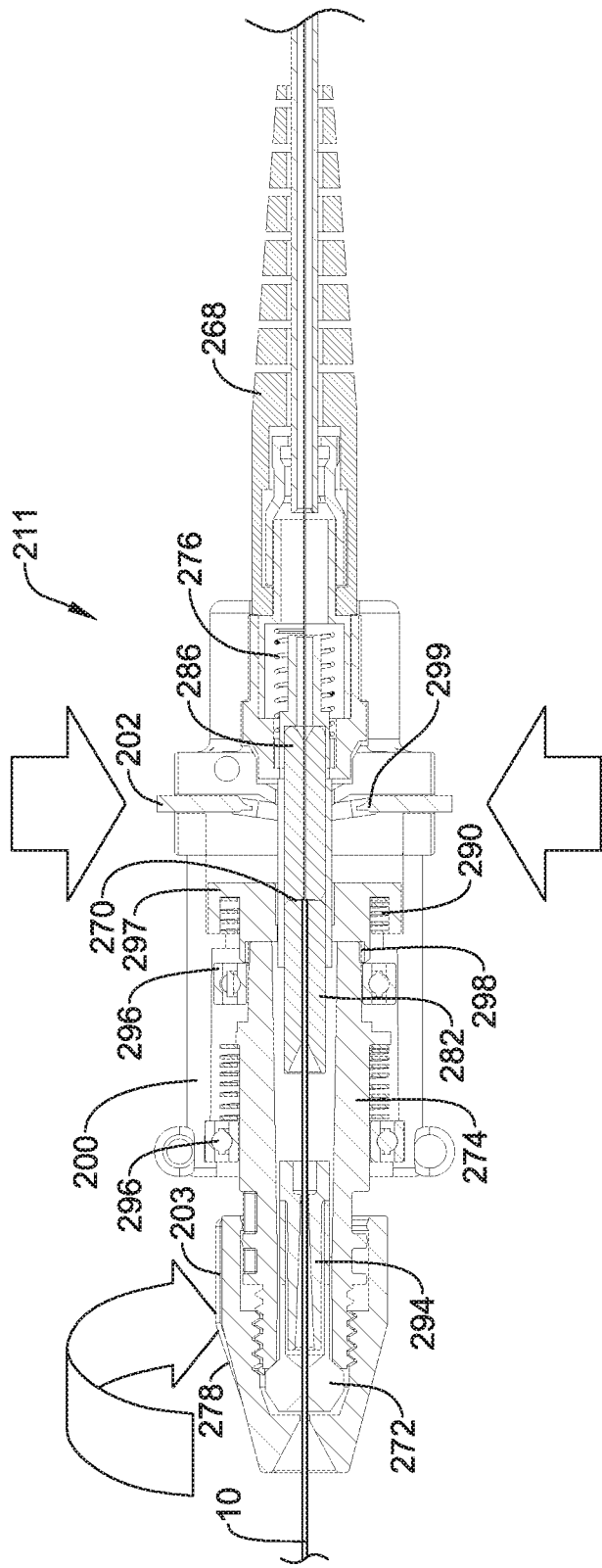


FIG. 14

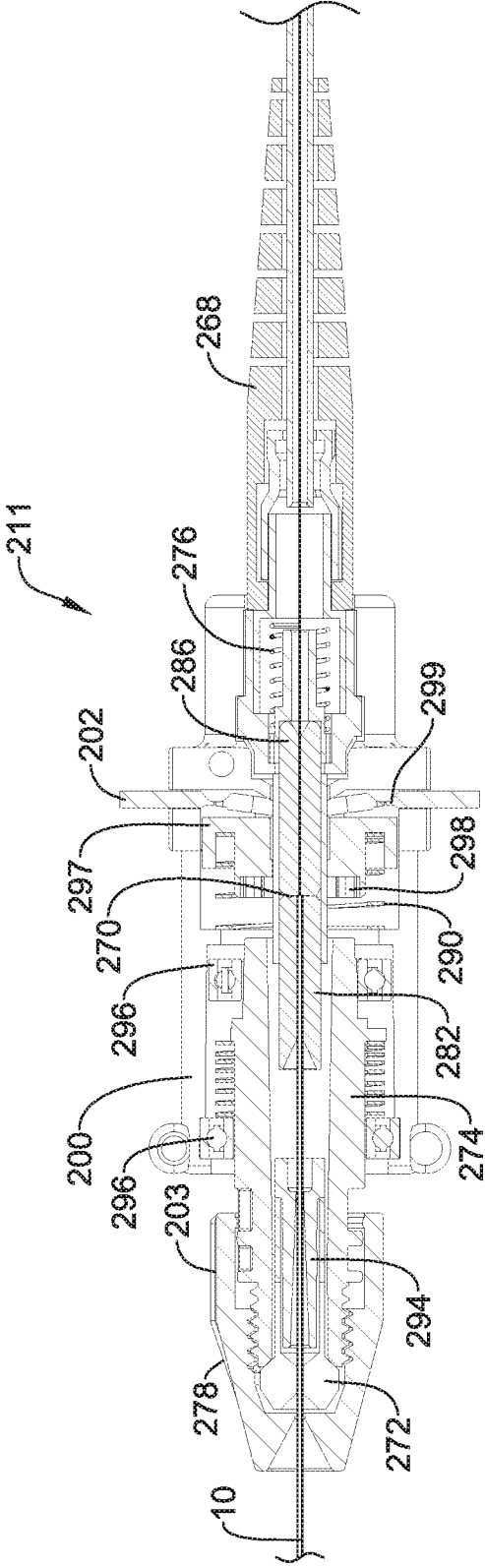


FIG. 14B

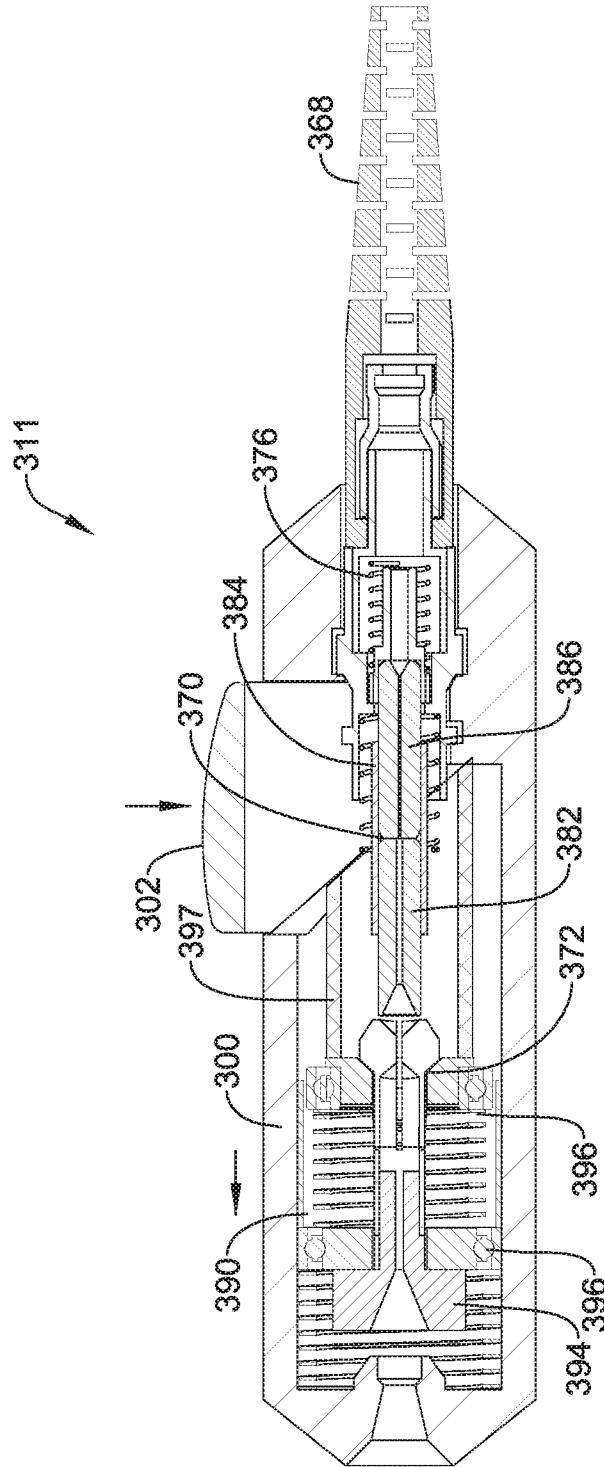


FIG. 15

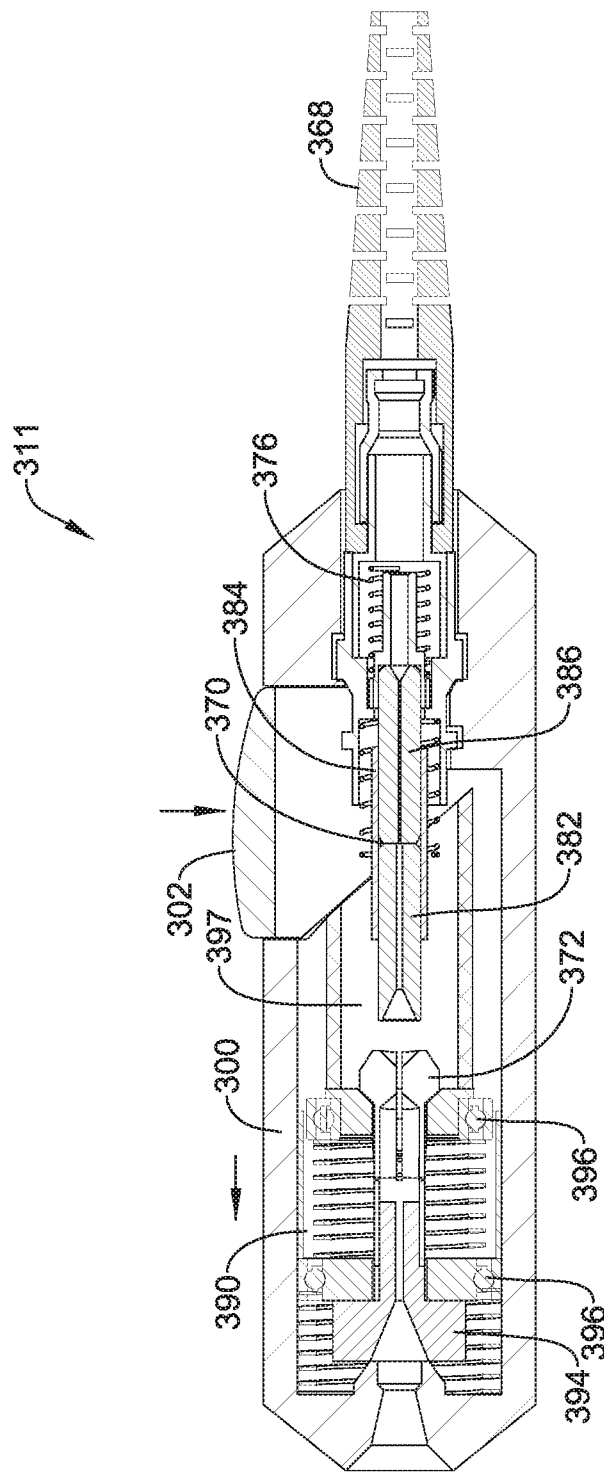
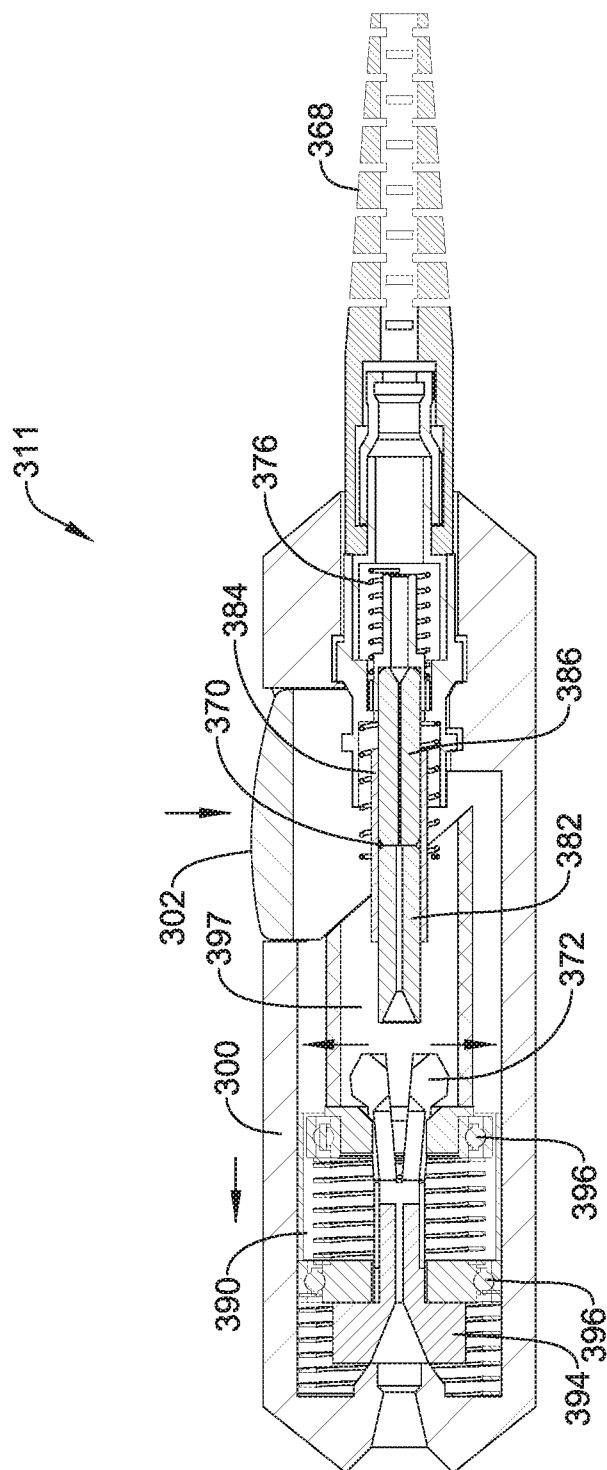


FIG. 16



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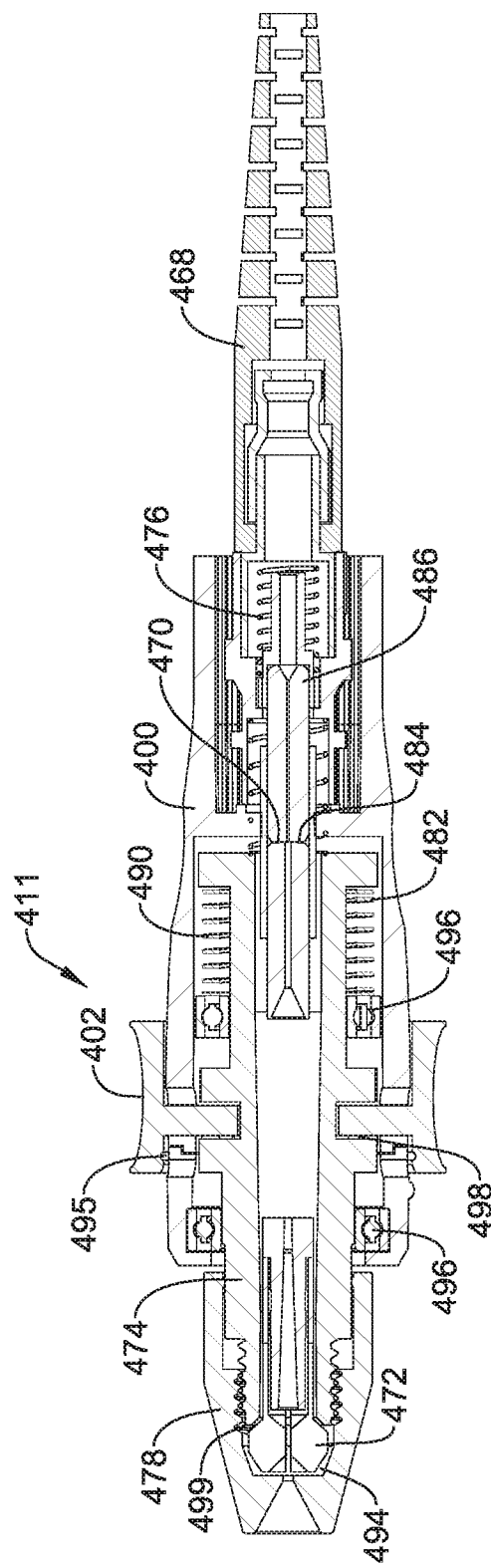


FIG. 18

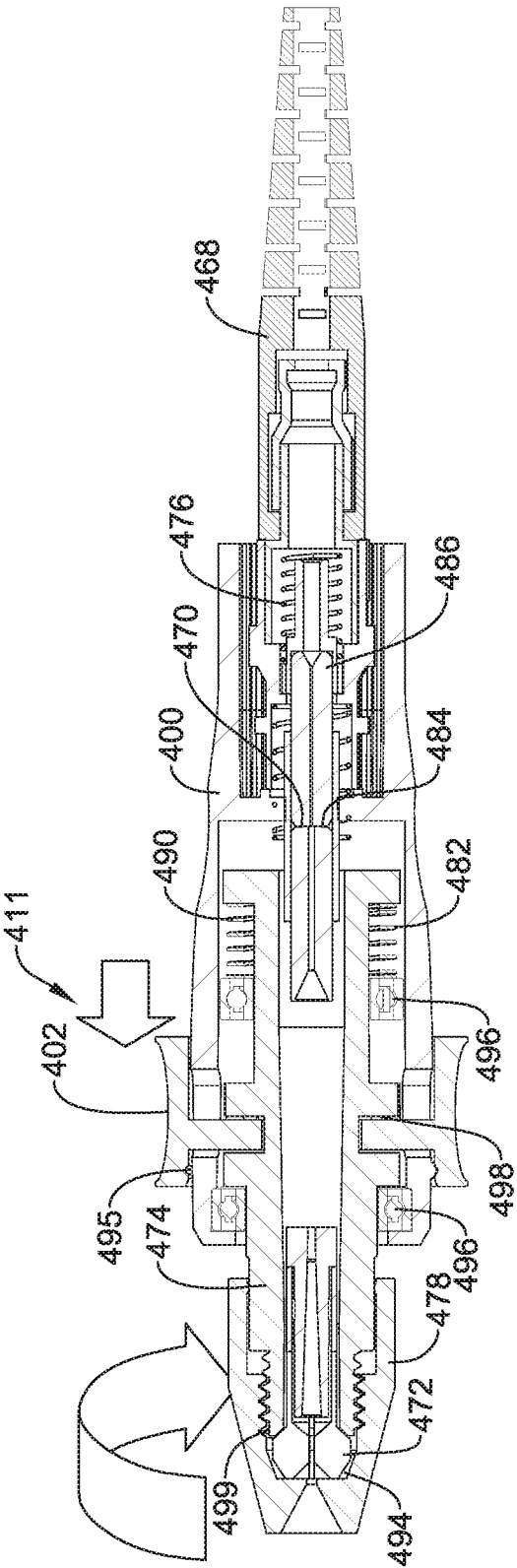


FIG. 19

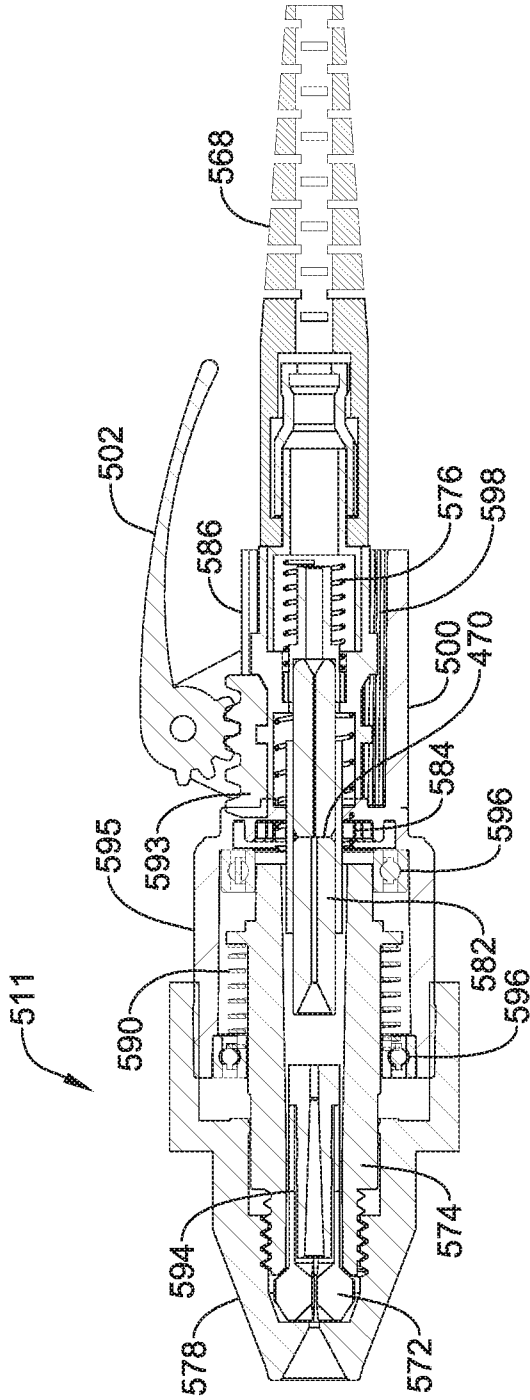


FIG. 20

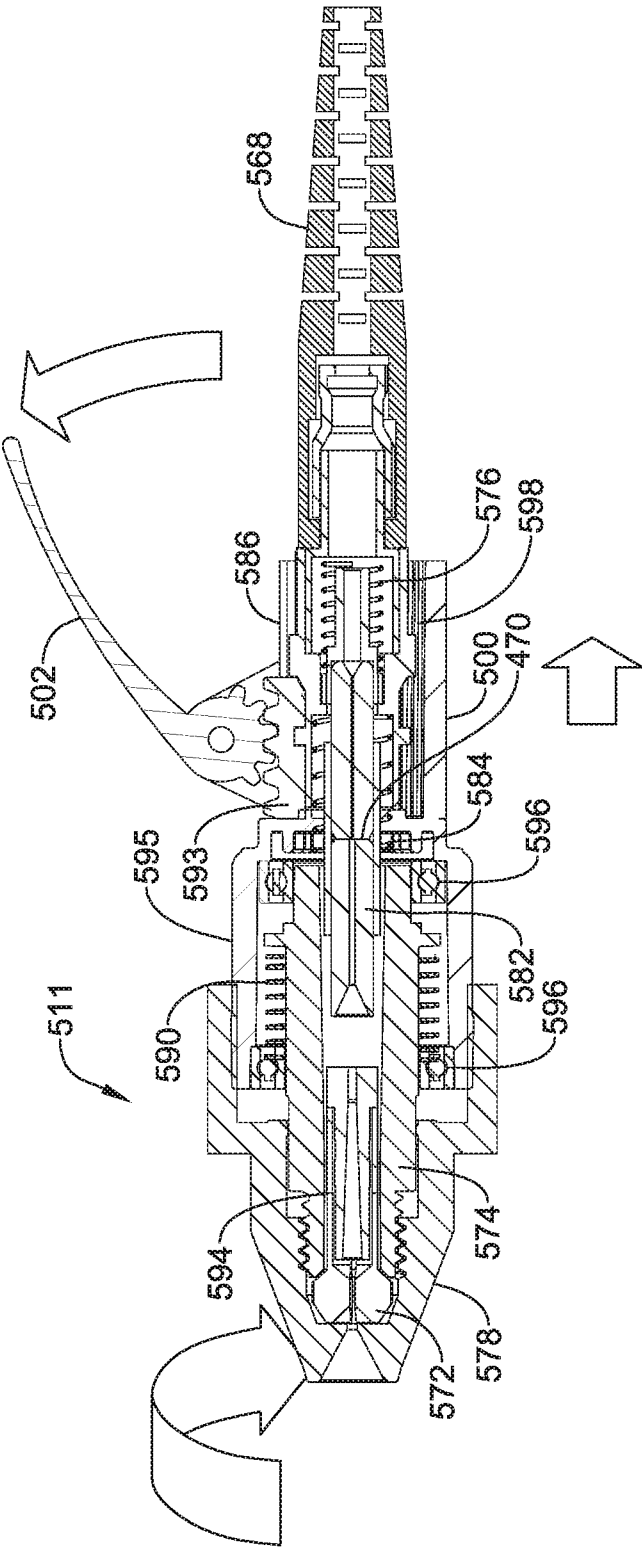


FIG. 21

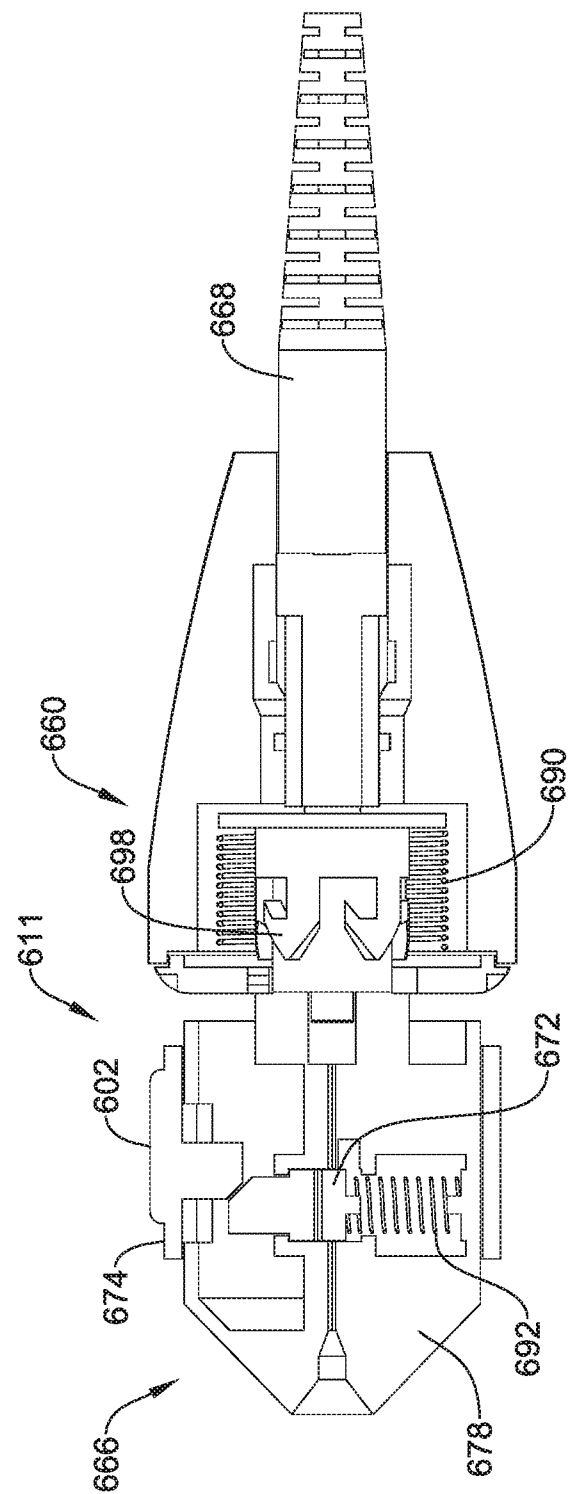


FIG. 22

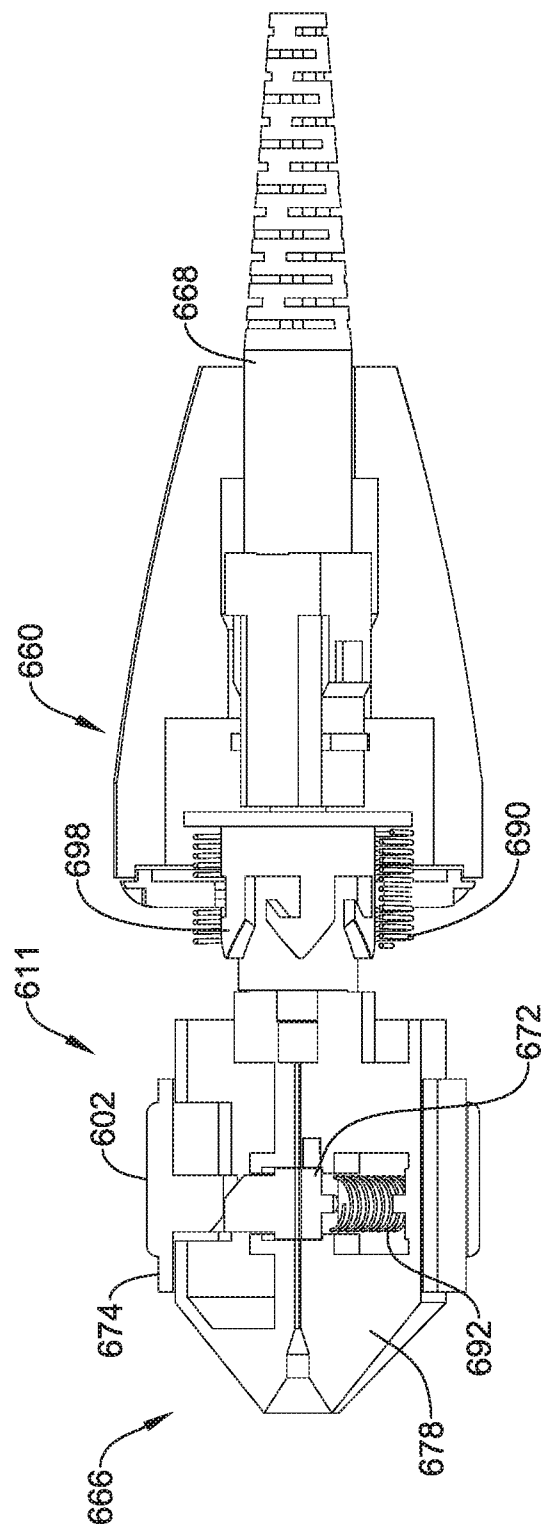
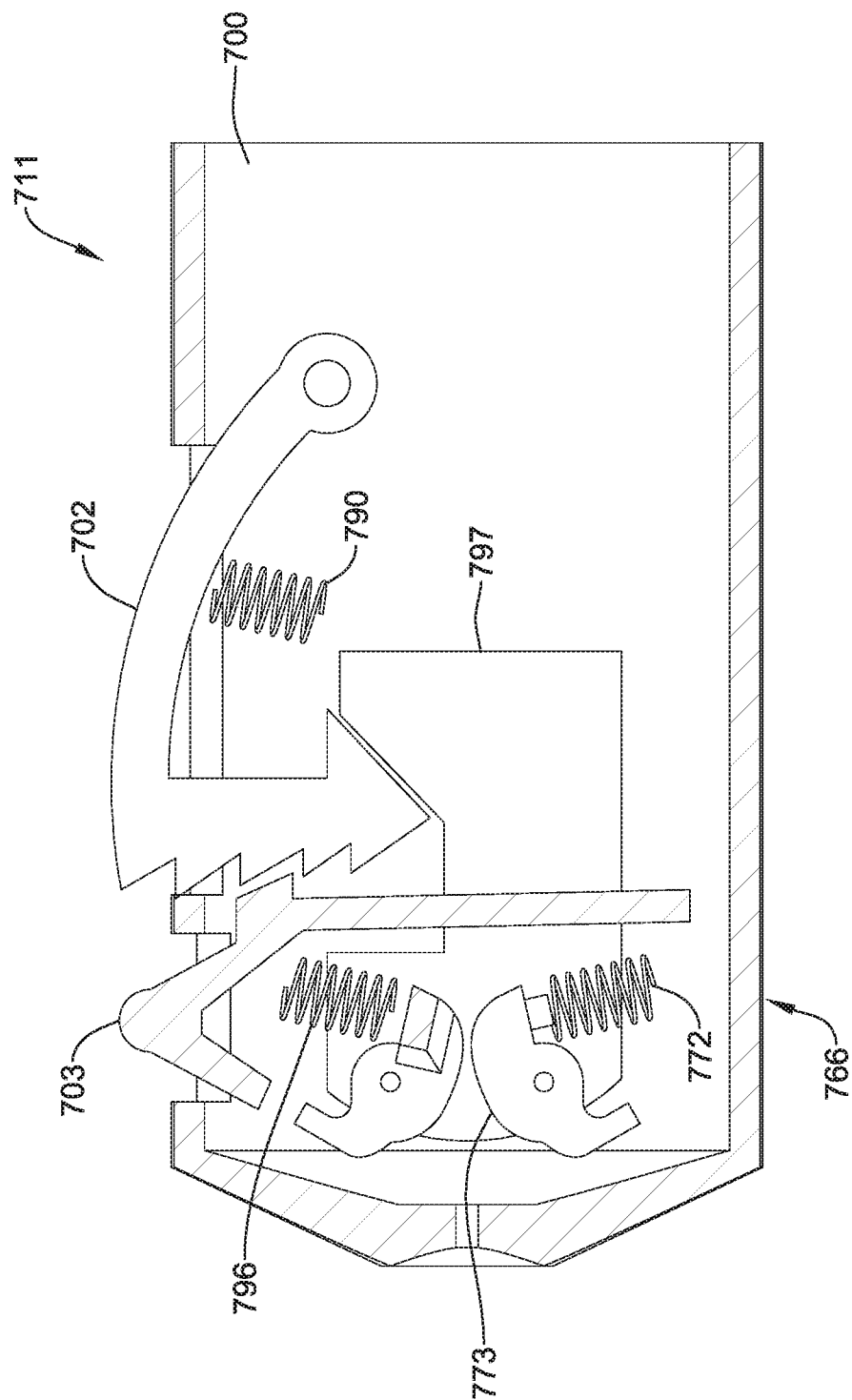


FIG. 23



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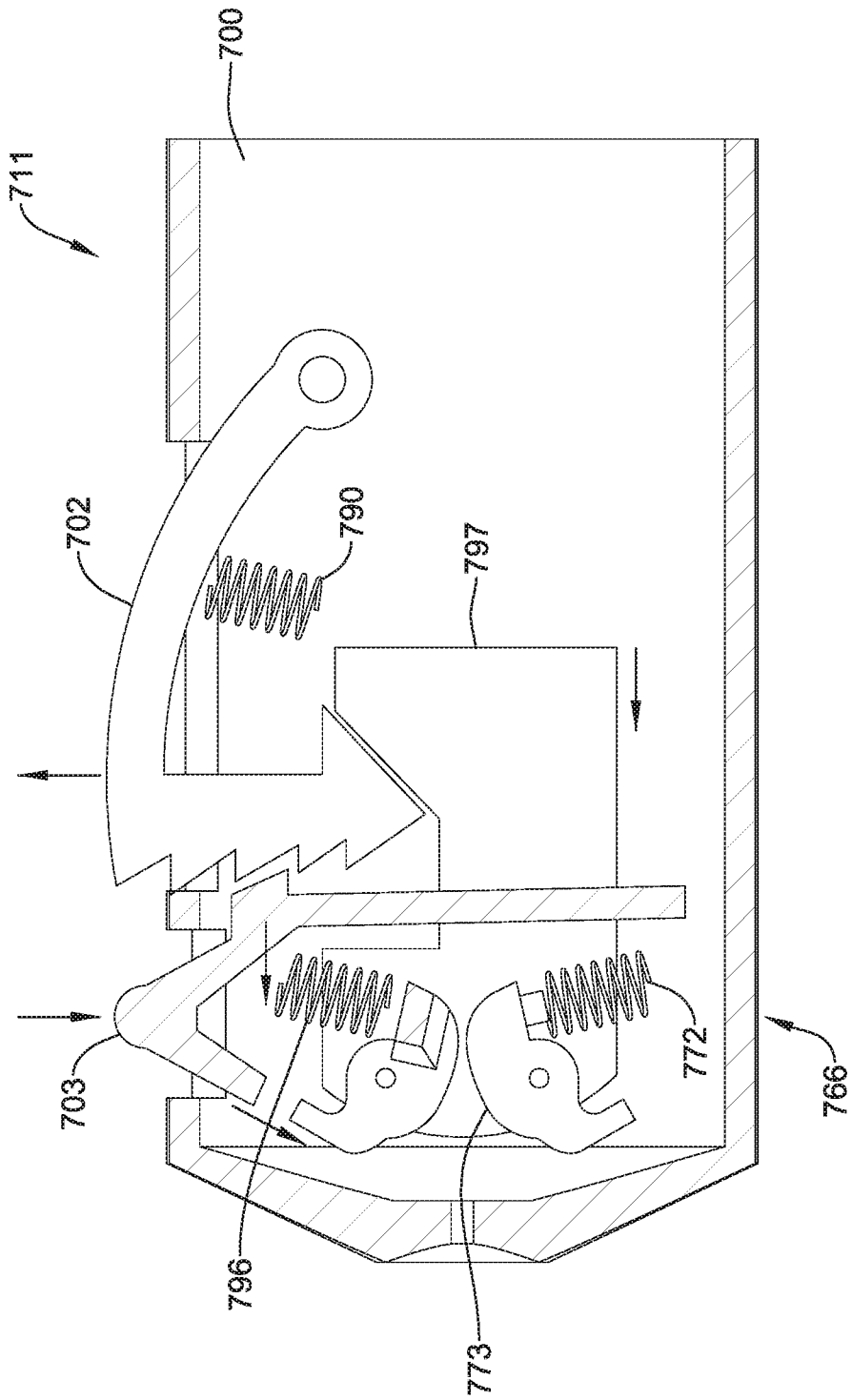


FIG. 25

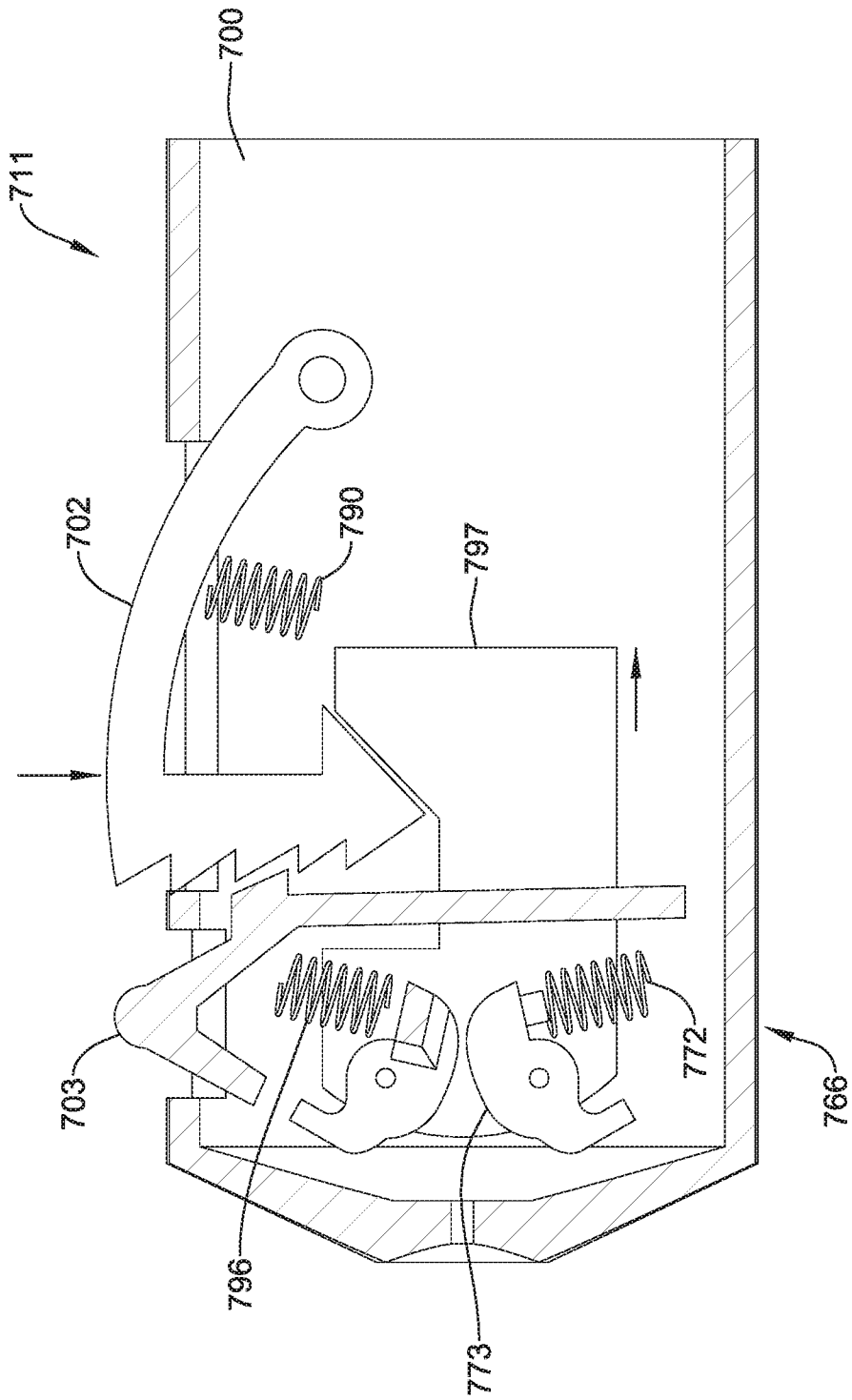


FIG. 26

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2017/018905

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/0215 G02B6/36 G02B6/38 A61B5/00
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)

A61B G02B

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 practicable, 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 2014/350414 A1 (MCGOWAN ROGER W [US] ET AL) 27 November 2014 (2014-11-27) cited in the application paragraphs [0050] - [0066]; figures 5-15 -----	1,5,10, 15
X	US 2015/003789 A1 (WEBLER WILLIAM E [US] ET AL) 1 January 2015 (2015-01-01) -----	1,2,4,5, 7-11,13, 15
Y	paragraphs [0003] - [0004], [0122] - [0137]; figures 13a-13c -----	3,6,12, 14
Y	US 5 949 929 A (HAMM MARK A [US]) 7 September 1999 (1999-09-07) column 6, line 13 - column 7, line 54; figures 9-14c -----	3,6,12, 14
A	US 2003/159518 A1 (SAWATARI TAKEO [US] ET AL) 28 August 2003 (2003-08-28) paragraphs [0144] - [0150]; figures 23-25 -----	3,6,12, 14



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

17 May 2017

Date of mailing of the international search report

29/05/2017

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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Fax: (+31-70) 340-3016

Authorized officer

Kronberger, Raphael

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2017/018905

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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			US 5949929 A 07-09-1999
			WO 9823984 A2 04-06-1998
US 2003159518	A1	28-08-2003	NONE

专利名称(译)	压力传感导丝系统包括光学连接器电缆		
公开(公告)号	EP3419514A1	公开(公告)日	2019-01-02
申请号	EP2017710085	申请日	2017-02-22
[标]申请(专利权)人(译)	波士顿科学西美德公司		
申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED , INC.		
当前申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED , INC.		
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发明人	YOUNG, MISHA THORNTON, PETER, JR. D'ALESSANDRO, ALFONSO HIGHAM, COREY		
IPC分类号	A61B5/0215 G02B6/36 G02B6/38 A61B5/00		
CPC分类号	A61B5/02154 A61B5/6851 A61B2562/228 A61B5/0084 A61B2090/3614 A61B2562/0233 A61B2562/223 A61M25/09 A61M2025/09083 A61M2025/09116 A61M2025/09125		
优先权	62/298759 2016-02-23 US		
外部链接	Espacenet		

摘要(译)

公开了包括光学连接器电缆组件的医疗设备。 光学连接器电缆组件可以包括具有从其延伸的第一光纤的光学连接器电缆。 光学连接器电缆可包括构造造成连接至导丝的远侧连接器。 远端连接器可包括内部壳体和导丝锁定机构。 远端连接器还可包括致动器。 致动器的致动可以将内壳体从第一位置移动到第二位置。 当内壳体处于第一位置时，导丝锁定机构构造造成固定导丝，并且导丝相对于光学连接器电缆可旋转。 当内壳体处于第二位置时，导丝锁定机构处于打开状态以用于接收或移除导丝。