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(54) **A CATHETER HANDLE**

KATHETERGRIFF

MANCHE DE CATHÉTER

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Description

Technical Field

[0001] This disclosure relates, generally, to a catheter and, more particularly, to a catheter shape adjustment mechanism and to a catheter including such shape adjustment mechanism.

Background Art

[0002] Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

[0003] Catheters are commonly used in medical practice to examine and treat the heart. They may be inserted into the cardiovascular system of the patient through small punctures in the skin. They may then extend through a vein into the heart where they sense the electrical activity of the heart. Some catheters may be able to treat the heart by ablating certain areas of the heart in case of certain types of aberrant electrical activity. Catheters typically include a tubular structure such as a plastic tube with one or more electrodes attached to the tip of the tube, a deflection mechanism for guiding the tubular structure, and a control handle.

[0004] During their use in medical procedures catheters are exposed to biological fluids in the human body. Because catheters come in contact with these bodily fluids they are commonly designed to be single use devices to avoid the transfer of viruses or bacteria from one patient to another. Disposing of the catheters after each procedure leads to significant expenses to the patient and the healthcare system as well as creates a substantial amount of medical waste. Catheters, particularly the handles and sheaths of catheters, are typically an expensive piece of equipment. Catheter handles, in particular, often include proprietary electronics and other expensive components for increased functionality. These valuable components are lost when the device is disposed after a single use. Because catheters and catheter handles are expensive and their use produces a large amount of waste certain institutions resterilize and reprocess catheters for re-use. Reprocessing single use devices reduces the cost of a procedure and minimises medical waste generated.

[0005] Catheters and catheter handles in particular are typically fabricated as substantially integral devices where most components are joined together using permanent connections and seals. These types of catheter handles are difficult or impossible to resterilize reliably, and small particles of biological matter may be trapped within the catheter even after the sterilization process. In addition, because most components are permanently joined together these components are lost when the catheter disposed of after use, even if they were still fully functional.

[0006] US 5 987 344 A describes a catheter assembly with a multifunction wire. JP 4 224 122 B describes a catheter including, among other features, a handle body, a connector and a sheath tube.

[0007] WO 2009114908 describes a catheter assembly including, among other features, a separable handle body.

Summary

[0008] It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.

[0009] An embodiment of the invention provides a catheter handle according to claim 1.

[0010] The catheter handle includes a catheter sheath carrier received in the passage of the handle body, the strain relief being mounted on a distal end of the catheter sheath carrier. The catheter sheath carrier may be slidably received in the passage of the handle body to be slidably displaceable relative to the handle body between a first, retracted position relative to the handle body and a second, extended position relative to the handle body. The catheter sheath carrier may further comprise a sleeve defining a bore, and a support member, for supporting a proximal part of a catheter sheath, being received in the bore of the sleeve. The sleeve may comprise a plurality of parts which are able to be at least partially separated from each other to enable access to be gained to an interior of the sleeve.

[0011] The catheter sheath carrier and the catheter handle preferably include complementary guide formations for guiding displacement of the catheter sheath carrier relative to the handle body. The complementary guide formations may include a locking arrangement for locking the carrier at least in its first position relative to the handle body.

[0012] The steering control mechanism may be axially displaceable relative to the handle body for effecting steering of a stylet of the catheter, in use. The catheter handle may further include an adjustment device for adjusting the friction of displacement of the steering control mechanism relative to the handle body. In addition, the steering control mechanism may include a seat for a component of a multi- component stylet.

[0013] In an embodiment, the catheter handle may further include a size adjuster for adjusting the size of a preformed shape at a distal end of a stylet attached to the handle body, in use. The size adjuster may comprise a stylet carrier slidably displaceably arranged in the handle body and a collar mounted on an exterior of the handle body to be rotatable about a longitudinal axis of the handle body. The collar and the stylet carrier may have complementary motion conversion formations for converting rotary motion of the collar into a predefined motion of the stylet carrier. The stylet carrier may include a mounting formation for mounting a first component of the stylet. In addition, the handle body may define a seat for receiving

a second component of the stylet, in use.

[0014] Another aspect of the disclosure provides a method of producing a catheter handle as described above.

[0015] According to another embodiment there is provided a catheter including a catheter handle according to any one of claim 1 to 12. The catheter further includes a multi-component stylet having a proximal end mounted in the passage of the handle body, the stylet having a distal part preformed into a predetermined shape, and a catheter sheath projecting distally through the strain relief, the catheter sheath defining a lumen
in which the stylet is received so that the shape of the preformed distal part of the stylet is imparted to a distal part of the catheter sheath.

Brief Description of Drawings

[0016] Preferred embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Figure 1 shows a three dimensional view of a catheter with a shape adjustment mechanism in an inoperative position;

Figure 2 shows a three dimensional view of the catheter with the shape adjustment mechanism in an operative position;

Figure 3 shows a three dimensional, exploded view of the shape adjustment mechanism of the catheter;

Figure 4 shows a bottom view of a part of a steering control mechanism of the catheter handle carrying a component of the shape adjustment mechanism;

Figure 5 shows a three dimensional, exploded view of the steering control mechanism and shape adjustment mechanism of the catheter;

Figure 6 shows a sectional side view of a handle of the catheter with the shape adjustment mechanism in its inoperative position;

Figure 7 shows a sectional side view of a handle of the catheter with the shape adjustment mechanism in its operative position;

Figure 8 shows a three dimensional, exploded view of a handle of the catheter;

Figure 9 shows a plan view of a proximal part of a stylet of the catheter;

Figure 10 shows a plan view of a part of a shape adjustment mechanism of the catheter;

Figure 11 shows a three dimensional view of a part of the handle showing the interrelationship between the proximal part of the stylet and the shape adjustment mechanism;

Figure 12 shows a three dimensional view of a distal part of the stylet;

Figure 13 shows a three dimensional view of a distal part of an outer tube of the stylet; and

Figure 14 shows a three dimensional, exploded view of another embodiment of the handle of the catheter.

Detailed Description of Exemplary Embodiments

[0017] In the drawings, reference numeral 10 generally designates an embodiment of a catheter. The catheter 10 comprises a catheter handle 12 from which a catheter sheath or electrode sheath 14 projects. The catheter sheath 14 carries a plurality of electrodes 16 at a distal part 18 of the catheter sheath 14. The electrodes 16 are used for diagnostic and/or therapeutic purposes.

[0018] The catheter further includes a stylet 20 (Figure 9 and Figures 11-13). A proximal part 22 of the stylet 20 is received within the catheter handle 12 as will be described in greater detail below. The catheter sheath 14 has a lumen (not shown) in which the stylet 20 is received. As shown more clearly in Figure 12 of the drawings, a distal part 24 of the stylet 20 is pre-formed into a shape, more particularly a loop shape 26. However, it will be appreciated that the distal part 24 of the stylet could be preformed into any other desired shape such as, for example, a helix, a tapering helix, a pig tail shape, or any other desired shape.

[0019] The stylet 20 fits within the lumen of the catheter sheath 14 and the loop shape 26 of the distal part 24 of the stylet 20 is imparted to the distal part 18 of the catheter sheath 14 as shown in Figure 1 of the drawings. For ease of explanation, the disclosure will be described with reference to the shape at the distal part 24 of the stylet 20 being the loop shape. However, it will be appreciated that what follows could be applicable to any other stylet 20 having a shaped distal part 24.

[0020] In an embodiment, the catheter 10 includes a shape release mechanism 28. The shape release mechanism 28 comprises the catheter handle 12 and an elongate catheter sheath carrier in the form of a sleeve 30 which is slidably received in the handle 12 to protrude distally from the handle 12.

[0021] The handle 12 comprises a handle body 32. The handle body 32 is made up of a plurality of shell parts 34, shown most clearly in Figure 8 of the drawings. In the illustrated embodiment, the handle body 32 comprises two shell parts 34 which are substantially mirror images of each other. The handle body 32 has a proximal end 36 and a distal end 38. A passage 40 (Figure 8) extends between the proximal end 36 and the distal end

38 of the handle body 32.

[0022] In the embodiment illustrated in Figure 8 of the drawings, the two shell parts 34 are secured together by clips 42, carried on one of the shell parts 34, which are received in complementary receiving formations 44 in the other shell parts 34.

[0023] In the embodiment shown in Figure 14 of the drawings, only one side of each shell part 34 has the clips 42 or receiving formations 44, as the case may be. The other side of the shell parts 34 of the handle body 32 are hinged together with wings 46 of the hinges being shown in Figure 14 of the drawings.

[0024] Regardless of the manner in which the shell parts 34 connect together, it is a simple process to open the handle body 32 by disengaging the shell parts 34 to enable access to be gained to an interior of the handle body 32. Further, it will be appreciated that, instead of clips the parts 34 could be held together in other ways, for example, by being screwed together, by means of one or more spring clips received about the handle body 32, or the like.

[0025] With reference to Figure 3 of the drawings, the sleeve 30 of the shape release mechanism 28 comprises two parts 48. In the illustrated embodiment, the two parts 48 clip together via clips 50 and locating formations 52. As described above with reference to the shell parts 34 of the handle body 32, it will be appreciated that these parts 48 could also be hinged together and clipped or screwed together to form the sleeve 30.

[0026] The sleeve 30 surrounds a support member 54. The support member 54 has a longitudinally extending channel 56 formed in it. A proximal part 58 of the catheter sheath 14 is supported in the channel 56 of the support member 54. If desired, the proximal part 58 can be bonded in the channel 56 by means of a suitable adhesive.

[0027] The shape release mechanism 28 also includes a strain relief 60. The strain relief 60 is secured to a distal end 62 (Figures 1 and 2) of the sleeve 30. The strain relief 60 is of a resiliently flexible material and has a proximal collar 64 which engages a shoulder 66 on the parts 48 of the sleeve 30 to hold the strain relief captive when the parts 48 of the sleeve 30 are secured together. The strain relief 60, being of a resiliently flexible material also inhibits ingress of foreign matter, such as bodily fluid into the interior of the sleeve 30 and, therefore the interior of the catheter handle 12.

[0028] The shape release mechanism 28 includes complementary guide formations for guiding sliding displacement of the sleeve 30 relative to the handle body 32. The complementary guide formations comprise a pin 68 arranged at a proximal end of one of the parts 48 of the sleeve 30. A guide plate 70 (Figure 4) is secured to a part of the catheter handle 12, more particularly, a steering mechanism 72 of the catheter handle 12. The steering control mechanism 72 will be described in greater detail below.

[0029] The guide plate 70 defines a guide slot 74 which extends axially in the guide plate 70. The guide slot 74 is cranked and a locking arrangement in the form of a detent 76 is defined at a proximal end of the guide slot 74. Thus, when the sleeve 30 is in its retracted position as shown in Figure 1 of the drawings, the pin 68 is received in the detent 76 at an extremity 78 of the detent 76. To release the sleeve 30 to enable it to slide axially to the position as shown in Figure 2 of the drawings, the sleeve 30 needs to be rotated so that the pin 68 moves away from the extremity 78 into alignment with the remainder of the guide slot 74. The sleeve 30 is then free to be extended to the position as shown in Figure 2 of the drawings.

[0030] The purpose of the shape release mechanism 28 is to release the loop shape 26 when is snags on tissue in the patient's body, in use. This can lead to complications and difficulty. As shown, the loop shape 26 is a tightly wound formation. However, by extending the catheter sheath 14 relative to the stylet 20 from the position shown in Figure 1 of the drawings to the position shown in Figure 2 of the drawings, by extending the sleeve 30 relative to the handle 12, the distal part 24 of the stylet 20 is withdrawn from the distal part 18 of the catheter sheath 14 and adopts a position proximal the distal part 18 of the catheter sheath 14 as shown at 80 in Figure 2 of the drawings. When the distal part 24 of the stylet 20 is withdrawn proximally relative to the distal part 18 of the catheter sheath 14, the tension in the distal part 24 of the stylet is reduced causing the distal part to adopt a more drawn out, less tightly wound shape and facilitates disentanglement or release of the shaped part of the catheter sheath 14 from tissue in which it may have become entangled.

[0031] As described above, the catheter handle 12 includes a steering control mechanism 72. This steering control mechanism 72 is used for steering the distal part of the catheter sheath 18 through the patient's vasculature and, also, for effecting deflection of the loop formation 26 at the distal part of the catheter sheath 14.

[0032] Before describing the steering control mechanism 72 in greater detail, the stylet 20 will also be described to understand the operation of the stylet 20 of the catheter 10. Figure 9 shows a proximal part of the stylet 20, Figure 11 shows the proximal part of the stylet mounted in one of the shell parts 34 of the handle body 32 of the catheter handle 12, Figure 12 shows a distal part of the stylet 20 and Figure 13 shows a distal part of a component of the stylet 20 in the form of an outer tubular member 82.

[0033] The outer tubular member 82 has a distal part 84 which is shown in greater detail in Figure 13 of the drawings. The distal part 84 of the outer tubular member 82 is pre-formed into the loop-shape 26 and has a distal end 86. The distal part 84 is cranked as shown at 88 so that the loop shape 26 lies in plane transverse to a longitudinal axis of the outer tubular member 82. An elongate, cutaway, bend-enhancing portion 90 is formed in the distal part 84 of the tubular member 82 proximally of the cranked region 88. The portion 90 is a scalloped por-

tion and has varying amounts cut away increasing from the proximal end to the distal end of the cutaway portion 90 to facilitate deflection of the distal end of the loop shape 26 of the stylet 20 as will be described in greater detail below.

[0034] The stylet 20 includes an inner, tubular actuator 92. The actuator 92 has a distal end secured at 94 to the distal part 84 of the outer tubular member 82 of the stylet 20. It is to be noted that the connection point 94 is proximally arranged relative to the cranked portion 88 but distally arranged relative to the cutaway portion 90. The tubular actuator 92 has a slotted bend-enhancing region 96 which lies coincident with the cutaway portion 90 of the outer tubular member 82 of the stylet 20. Relative movement between the outer tubular member 82 and the inner tubular actuator 92 causes deflection of the loop shape 26 in the direction of arrows 98 (Figure 13).

[0035] A size adjusting actuator in the form of a pull wire 100 is received through lumens of the outer tubular member 82 and the tubular actuator 92 and a distal end of the pull wire 100 is fast with the distal end 86 of the outer tubular member 82. It is to be noted that there is a second longitudinally extending cutaway portion 102 formed between the distal end 86 of the outer tubular member 82 and the cranked region 88 of the outer tubular member 82. This cutaway portion 102 facilitates adjustment of the size of the loop shape 26 by relative movement between the pull wire 100 and the outer tubular member 82.

[0036] As shown in Figure 9 of the drawings, a proximal end of the pull wire 100 is mounted to a stylet carrier in the form of a slide 104. A proximal end of the outer tubular member 82 carries a mounting sleeve 106 and, similarly, a proximal end of the tubular actuator 92 carries a mounting sleeve 108.

[0037] The steering control mechanism 72 comprises an elongate, hollow cylindrical member 110. As in the case of other components of the catheter handle 12, the cylindrical member 110 comprises two parts 112 which, in the illustrated embodiment, are clipped together via complementary clips 114 and receiving formations 116. As in the case of the shell parts 34 of the handle body 32 the parts 112 of the cylindrical member 110 could also be hinged together and clipped or screwed closed.

[0038] A raised protuberance in the form of a radially outwardly extending knob 118 is defined at a distal end of the steering control mechanism 72 to be engaged by the thumb of a clinician for facilitating steering of the distal end of the catheter sheath 14, in use.

[0039] Referring to Figure 11 of the drawings, the mounting sleeve 106 of the outer tubular member 82 of the stylet 20 is shown mounted in a seat 120 in one of the parts 112 of the steering control mechanism 72. The other part 112 could contain a corresponding part of the seat 120. A further seat 122 is defined proximally of the seat 120 in the passage 40 of the handle body 32 and the mounting sleeve 108 of the tubular actuator 92 is made fast with the seat 122. It will be appreciated that as the steering control mechanism 72 is moved in the direction of arrows 124 relative to the handle body 12, relative movement between the outer tubular member 82 of the stylet 20 and the inner tubular actuator 92 occurs resulting in deflection of the distal end of the stylet 20 as shown by the arrows 98 in Figure 13 of the drawings.

[0040] As illustrated in Figure 11 of the drawings, the proximal part of the pull wire 100 is guided around a semi spherical guidepost 126 fixedly arranged in the passage 40 of the handle body 32 and the proximal end of the pull wire 100 is mounted fast with the slide 104.

[0041] In an embodiment, the catheter 10 includes a shape, or size, adjustment mechanism 128. The size adjustment mechanism 128 includes a size adjuster in the form of a collar 130 arranged on the exterior of the handle body 32 of the catheter handle 12.

[0042] The stylet carrier 104 forms part of the size adjustment mechanism 128 and is axially slidably arranged within the passage 40 of the handle body 32 of the catheter handle 12. The collar 130 is, as with other parts of the catheter handle 12, made up of two parts 132 which clip together via complementary clips 134 and receiving formations 136 (Figure 8). In another embodiment, as illustrated in Figure 14 of the drawings, the parts 132 of the collar 130 are hinged together with a wing 138 of the hinge being shown in Figure 14 of the drawings. The other side of each par 132 clips together via the clips 134 and receiving formations 136.

[0043] As shown more clearly in Figure 8 of the drawings, the shell parts 34 of the handle body 32 of the catheter handle have a waisted region to define a recess 140 (Figure 8). The collar 130 is received in the recess 140 and is constrained against axial motion but is free to rotate about a longitudinal axis of the handle body 32.

[0044] The recessed region 140 of each shell part 34 further has a cutaway portion 142 defined therein so that when the shell parts 34 are mated together a longitudinally extending slot is defined in the handle body 32.

[0045] The size adjusting mechanism 128 of the catheter 10 includes complementary guide formations in the form of a camming groove 144 (shown most clearly in Figure 10 of the drawings) on an internal surface of each part 132 of the collar 130. A complementary guide follower in the form of a pin 146 is arranged at that end of the slide 104 opposite the end to which the pull wire 100 is connected. The pin 146 protrudes through the slot in the handle body formed by the cutaway portions 142 of the shell parts 34 and is received in the camming groove 144 of the collar 130. Rotation of the collar 130 therefore translates into axial displacement of the slide 146. This axial displacement of the slide 146 results in relative movement between the pull wire 100 and the outer tubular member 82 of the stylet 80 resulting in an increase or decrease in the size of the loop shape 26 at the distal part 24 of the stylet 20.

[0046] Thus, by rotation of the collar 130, in use, a clinician can control the size of the loop shape 26. This is a simple, one handed operation. It will be appreciated

that the size adjustment mechanism 128 could, in addition or instead, operate as a second steering or deflection mechanism.

[0047] It is possible to adjust the effort required to displace the steering control mechanism 72 relative to the handle body 32. For this purpose, a frictional element 150 is provided. The frictional element 150 includes a screw 152 and washer assembly 154, the screw 152 being received in a threaded socket 156 in the shell part 34 of the handle body 32, as shown in Figure 8 of the drawings. The screw protrudes through a slot 158 defined in a proximal extension limb 160 of one of the parts 112 of the cylindrical member 110 of the steering control mechanism 72.

[0048] The catheter 10 includes a connector 162 arranged at the proximal end 36 of the handle body 32 of the catheter handle 12. The connector 162 has terminals 164 to which conductors (not shown) of the electrode 16 of the catheter sheath 14 are connected. The connector 162 sits within the handle body 32 and can be removed and replaced if necessary by separating the shell parts 34. The connector 162 connects to a patient cable of a diagnostic/therapeutic system, with which the catheter 10 is used.

[0049] It is a particular advantage of the described embodiments that a compact catheter handle is provided which lends itself to one handled use by a clinician. The handle 12 fits easily within the hand of the clinician and all the operating controls such as the steering control mechanism 72 and the size adjustment mechanism 128 fall readily to hand. The steering control mechanism 72 and the size adjustment mechanism 128 are able to be manipulated one-handed by the clinician which clinicians prefer to do. This enables them more easily to concentrate on positioning and operating the catheter 10.

[0050] In addition, catheters are becoming increasingly expensive. Due to their use in potentially biologically hazardous environments, most catheters are used once and then disposed of. Often times, this is unnecessary and the catheters can be re-processed. With the provision of a modular type of handle 10, as described above, it is an easy process to access the interior of the handle 10 to facilitate replacement or refurbishing of the various components and, more particularly, the catheter sheath 14 and the stylet 20, or the connector element 162. The handle 12 is a molding of a plastics material and is generally low cost. Thus, should the handle 12 be contaminated with bodily fluids and cannot be adequately cleaned, it is a relatively inexpensive process to dispose of the handle 12 and to replace it with a new one. Even so, because the handle 12 is made up of modular parts, if necessary, only those parts need to be replaced.

[0051] Reference throughout this specification to "one embodiment", "some embodiments" or "an embodiment" means that a particular feature, structure or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Thus, appearances of the phrases "in one embodiment", "in some embodiments" or "in an embodiment" in various places throughout this specification are not necessarily all referring to the same embodiment, but may. Furthermore, the particular features, structures or characteristics may be combined in any suitable manner, as would be apparent to one of ordinary skill in the art from this disclosure, in one or more embodiments.

[0052] As used herein, unless otherwise specified the use of the ordinal adjectives "first", "second", "third", etc., to describe a common object, merely indicate that different instances of like objects are being referred to, and are not intended to imply that the objects so described must be in a given sequence, either temporally, spatially, in ranking, or in any other manner.

[0053] In the claims below and the description herein, any one of the terms comprising, comprised of or which comprises is an open term that means including at least the elements/features that follow, but not excluding others. Thus, the term comprising, when used in the claims, should not be interpreted as being limitative to the means or elements or steps listed thereafter. For example, the scope of the expression a device comprising A and B should not be limited to devices consisting only of elements A and B. Any one of the terms including or which includes or that includes as used herein is also an open term that also means including at least the elements/features that follow the term, but not excluding others. Thus, including is synonymous with and means comprising.

[0054] It should be appreciated that in the above description of exemplary embodiments of the invention, various features of the invention are sometimes grouped together in a single embodiment, FIG., or description thereof for the purpose of streamlining the disclosure and aiding in the understanding of one or more of the various inventive aspects. This method of disclosure, however, is not to be interpreted as reflecting an intention that the claimed invention requires more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive aspects lie in less than all features of a single foregoing disclosed embodiment. Thus, the claims following the Detailed Description are hereby expressly incorporated into this Detailed Description, with each claim standing on its own as a separate embodiment of this invention.

[0055] Furthermore, while some embodiments described herein include some but not other features included in other embodiments, combinations of features of different embodiments are meant to be within the scope of the invention, and form different embodiments, as would be understood by those skilled in the art. For example, in the following claims, any of the claimed embodiments can be used in any combination.

[0056] In the description provided herein, numerous specific details are set forth. However, it is understood that embodiments of the invention may be practiced without these specific details. In other instances, well-known methods, structures and techniques have not been shown in detail in order not to obscure an understanding

of this description.

[0057] Similarly, it is to be noticed that the term coupled, when used in the claims, should not be interpreted as being limited to direct connections only. The terms "coupled" and "connected," along with their derivatives, may be used. It should be understood that these terms are not intended as synonyms for each other. Thus, the scope of the expression a device A coupled to a device B should not be limited to devices or systems wherein an output of device A is directly connected to an input of device B. It means that there exists a path between an output of A and an input of B which may be a path including other devices or means. "Coupled" may mean that two or more elements are either in direct physical or electrical contact, or that two or more elements are not in direct contact with each other but yet still co-operate or interact with each other.

[0058] Thus, while there has been described what are believed to be the preferred embodiments of the invention, those skilled in the art will recognize that other and further modifications may be made thereto, and it is intended to claim all such changes and modifications as falling within the scope of the invention. For example, any formulas given above are merely representative of procedures that may be used. Functionality may be added or deleted from the block diagrams and operations may be interchanged among functional blocks. Steps may be added or deleted to methods described within the scope of the present invention.

[0059] It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the disclosure as shown in the specific embodiments without departing from the scope of the claims. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Claims

1. A catheter handle (12) which includes
a handle body (32) having a proximal end (36) and a distal end (38) and a passage (40) extending between the proximal end and the distal end, the handle body comprising a plurality of shell parts (34);a connector (162) mounted at the proximal end of the handle body; and
a strain relief (60) arranged distally of the body, the strain relief and the connector being removably arranged relative to the handle body,
characterized in that
the plurality of shell parts (34) can be at least partially separated from each other to access an interior of the handle body, and
the catheter handle further comprises a steering control mechanism (72) comprising an elongate, hollow cylindrical member (110) in which a catheter sheath carrier is received, and wherein the cylindrical element also comprises a plurality of parts (112) which can be at least partially separated from each otherto facilitate access to an interior of the cylindrical element.

2. The catheter handle of claim 1 which includes the catheter sheath carrier received in the passage of the handle body, the strain relief being mounted on a distal end of the catheter sheath carrier, and, optionally, in which the catheter sheath carrier is slidably received in the passage of the handle body to be slidably displaceable relative to the handle body between a first, retracted position relative to the handle body and a second, extended position relative to the handle body.

3. The catheter handle of claim 2 in which the catheter sheath carrier comprises a sleeve (30) defining a bore, a support member (54), for supporting a proximal part (58) of a catheter sheath (14), being received in the bore of the sleeve, and, optionally, in which the sleeve comprises a plurality of parts (48) which are able to be at least partially separated from each other to enable access to be gained to an interior of the sleeve.

4. The catheter handle of any one of claims 2 or 3 in which the catheter sheath carrier and the catheter handle include complementary guide formations for guiding displacement of the catheter sheath carrier relative to the handle body.

5. The catheter handle of any one of claim 4 in which the complementary guide formations include a locking arrangement for locking the carrier at least in its first position relative to the handle body.

6. The catheter handle of claim 1 in which the steering control mechanism is axially displaceable relative to the handle body for effecting steering of a stylet (20) of the catheter, in use.

7. The catheter handle of claim 7 or claim 8 which includes an adjustment device for adjusting the friction of displacement of the steering control mechanism relative to the handle body.

8. The catheter handle of any one of claims 1 to 7 in which the steering control mechanism includes a seat (120) for a component of a multi-component stylet.

9. The catheter handle of any one of the preceding claims which includes a size adjuster for adjusting the size of a preformed shape at a distal end of a stylet attached to the handle body, in use, and, optionally, in which the size adjuster comprises a stylet carrier (104) slidably displaceably arranged in the

handle body and a collar (130) mounted on an exterior of the handle body to be rotable about a longitudinal axis of the handle body.

10. The catheter handle of claim 9 in which the collar and the stylet carrier have complementary motion conversion formations for converting rotary motion of the collar into a predefined motion of the stylet carrier.

11. The catheter handle of claim 9 or claim 10 in which the stylet carrier includes a mounting formation for mounting a first component of the stylet, and, optionally, in which the handle body defines a seat (122) for receiving a second component of the stylet, in use.

12. A catheter (10) which includes:

the catheter handle of claim any one of claims 1 to 12;
a multi-component stylet (20) having a proximal end mounted in the passage of the handle body, the stylet having a distal part (24) preformed into a predetermined shape (26); and
a catheter sheath (14) projecting distally through the strain relief, the catheter sheath defining a lumen in which the stylet is received so that the shape of the preformed distal part of the stylet is imparted to a distal part (18) of the catheter sheath (14).

Patentansprüche

1. Kathetergriff (12), der aufweist:

einen Griffkörper (32) mit einem proximalen Ende (36) und einem distalen Ende (38) und einem Durchlass (40), der sich zwischen dem proximalen Ende und dem distalen Ende erstreckt, wobei der Griffkörper eine Vielzahl von Schalenteilen (34) umfasst; einen Verbinder (162), der an dem proximalen Ende des Griffkörpers angebracht ist; und
eine Zugentlastung (60), die distal von dem Körper angeordnet ist, wobei die Zugentlastung und der Verbinder relativ zu dem Griffkörper abnehmbar angeordnet sind,
dadurch gekennzeichnet, dass
die Vielzahl von Schalenteilen (34) für einen Zugang zu einem Inneren des Griffkörpers mindestens teilweise voneinander trennbar ist und
der Kathetergriff ferner einen Lenkungs-Steuermechanismus (72) umfasst, der ein längliches, hohlzylindrisches Glied (110) umfasst, in dem ein Katheterhüllenträger aufgenommen ist, und wobei das zylindrische Element auch eine Vielzahl von Teilen (112) umfasst, die mindestens teilweise voneinander trennbar sind, um den Zugang zu einem Inneren des zylindrischen Elements zu ermöglichen.

2. Kathetergriff nach Anspruch 1, der den in dem Durchlass des Griffkörpers aufgenommenen Katheterhüllenträger aufweist, wobei die Zugentlastung an einem distalen Ende des Katheterhüllenträgers angebracht ist, und wobei optional der Katheterhüllenträger gleitbeweglich in dem Durchlass des Griffkörpers aufgenommen ist, um relativ zu dem Griffkörper zwischen einer ersten, eingezogenen Position relativ zu dem Griffkörper und einer zweiten, ausgefahrenen Position relativ zu dem Griffkörper gleitbeweglich verschiebbar zu sein.

3. Kathetergriff nach Anspruch 2, bei dem der Katheterhüllenträger eine Hülse (30) umfasst, die eine Bohrung bestimmt, wobei ein Stützglied (54) zum Stützen eines proximalen Teils (58) einer Katheterhülle (14) in der Bohrung der Hülse aufgenommen ist, und wobei optional die Hülse eine Vielzahl von Teilen (48) umfasst, die mindestens teilweise voneinander trennbar sind, um das Erlangen von Zugang zu einem Inneren der Hülse zu ermöglichen.

4. Kathetergriff nach einem der Ansprüche 2 oder 3, wobei der Katheterhüllenträger und der Kathetergriff komplementäre Führungsausbildungen zum Führen der Verschiebung des Katheterhüllenträgers relativ zu dem Griffkörper aufweisen.

5. Kathetergriff nach Anspruch 4, bei dem die komplementären Führungsausbildungen eine Sperranordnung zum Sperren des Trägers mindestens in seiner ersten Position relativ zu dem Griffkörper aufweisen.

6. Kathetergriff nach Anspruch 1, bei dem der Lenkungs-Steuermechanismus axial relativ zu dem Griffkörper verschiebbar ist, um in Verwendung das Lenken eines Mandrins (20) des Katheters zu bewirken.

7. Kathetergriff nach Anspruch 7 oder Anspruch 8, der eine Einstellvorrichtung zum Einstellen der Reibung bei der Verschiebung des Lenkungs-Steuermechanismus relativ zu dem Griffkörper aufweist.

8. Kathetergriff nach einem der Ansprüche 1 bis 7, bei dem der Lenkungs-Steuermechanismus eine Aufnahme (120) für eine Komponente eines Mehrkomponenten-Mandrins aufweist.

9. Kathetergriff nach einem der vorstehenden Ansprüche, der eine Größeneinstelleinrichtung zum Einstellen der Größe einer vorgebildeten Form an einem distalen Ende eines Mandrins, der an dem Griffkör-

per befestigt ist, in Verwendung aufweist, und bei dem optional die Größeneinstelleinrichtung einen Mandrinträger (104), der gleitbeweglich verschiebbar in dem Griffkörper angeordnet ist, und ein Halsstück (130) umfasst, das so an der Außenseite des Griffkörpers angebracht ist, dass dasselbe um eine Längsachse des Griffkörpers drehbar ist.

10. Kathetergriff nach Anspruch 9, bei dem das Halsstück und der Mandrinträger komplementäre Bewegungsumsetzungs-Ausbildungen zum Umsetzen einer Drehbewegung des Halsstücks in eine vorbestimmte Bewegung des Mandrinträgers haben.

11. Kathetergriff nach Anspruch 9 oder Anspruch 10, bei dem der Mandrinträger eine Anbringungsausbildung zum Anbringen einer ersten Komponente des Mandrins aufweist und bei dem optional der Griffkörper eine Aufnahme (122) zum Aufnehmen einer zweiten Komponente des Mandrins in Verwendung bestimmt.

12. Katheter (10), der aufweist:

den Kathetergriff nach einem der Ansprüche 1 bis 12;
einen Mehrkomponenten-Mandrin (20) mit einem proximalen Ende, das in dem Durchlass des Griffkörpers angebracht ist, wobei der Mandrin einen distalen Teil (24) hat, der zu einer vorbestimmten Form (26) vorgebildet ist; und
eine Katheterhülle (14), die distal durch die Zugentlastung vorsteht, wobei die Katheterhülle ein Lumen bestimmt, in dem der Mandrin so aufgenommen ist, dass die Form des vorgebildeten distalen Teils des Mandrins auf einen distalen Teil (18) der Katheterhülle (14) übertragen wird.

Revendications

1. Poignée de cathéter (12) qui comporte
un corps de poignée (32) possédant un embout proximal (36), un embout distal (38) et un passage (40) s'étendant entre l'embout proximal et l'embout distal, le corps de poignée comprenant plusieurs parties d'enveloppes (34) ; un connecteur (162) monté sur l'embout proximal du corps de poignée ; et
une décharge de traction (60) agencée distalement par rapport au corps, la décharge de traction et le connecteur étant agencés de manière amovible par rapport au corps de poignée,
caractérisée en ce que
les plusieurs parties d'enveloppes (34) peuvent être séparées au moins partiellement les unes des autres afin d'accéder à un intérieur du corps de poignée, et la poignée de cathéter comprend par ailleurs un mécanisme de réglage de commande (72) comprenant un élément cylindrique creux allongé (110) dans lequel un support de manchon de cathéter est réceptionné, et dans lequel l'élément cylindrique comprend également plusieurs parties (112) qui peuvent être séparées au moins partiellement les unes des autres afin de faciliter l'accès à un intérieur de l'élément cylindrique.

2. Poignée de cathéter selon la revendication 1, qui comporte le support de manchon de cathéter réceptionné dans le passage du corps de poignée, la décharge de traction étant montée sur un embout distal du support de manchon de cathéter, et, en option, dans laquelle le support de manchon de cathéter est réceptionné de manière coulissante dans le passage du corps de poignée afin d'être mobile de manière coulissante par rapport au corps de poignée entre une première position escamotée par rapport au corps de poignée et une seconde position étendue par rapport au corps de poignée.

3. Poignée de cathéter selon la revendication 2 dans laquelle le support de manchon de cathéter comporte une gaine (30) définissant un perçage, un élément de support (54), en vue du support d'une partie proximale (58) d'un manchon de cathéter (14) étant reçu dans le perçage de la gaine, et, en option, dans laquelle la gaine comprend plusieurs parties (48) qui sont aptes à être séparées au moins partiellement les unes des autres afin de permettre l'accès en vue d'être reçues à un intérieur de la gaine.

4. Poignée de cathéter selon une quelconque des revendications 2 ou 3, dans laquelle le support de manchon de cathéter et la poignée de cathéter comportent des formations de guidage complémentaires afin de guider le déplacement du support de manchon de cathéter par rapport au corps de poignée.

5. Poignée de cathéter selon la revendication 4, dans laquelle les formations de guidage complémentaires comportent un agencement de blocage afin de bloquer le support au moins dans sa première position par rapport au corps de poignée.

6. Poignée de cathéter selon la revendication 1, dans laquelle le mécanisme de réglage de commande est mobile axialement par rapport au corps de poignée afin de déclencher la commande d'un stylet (20) du cathéter, en cours d'utilisation.

7. Poignée de cathéter selon la revendication 7 ou la revendication 8 qui comporte un dispositif d'ajustement en vue d'ajuster la friction de déplacement du mécanisme de réglage de commande par rapport au corps de poignée.

8. Poignée de cathéter selon une quelconque des re-

vendications 1 à 7, dans laquelle le mécanisme de réglage de commande comporte un siège (120) destiné à un composant d'un stylet multi-composants.

9. Poignée de cathéter selon une quelconque des revendications précédentes, qui comporte un ajusteur de taille en vue d'ajuster la taille d'une forme préfaçonnée sur un embout distal d'un stylet fixé au corps de poignée en cours d'utilisation et, en option, dans laquelle l'ajusteur de taille comporte un support de stylet (104) agencé de manière coulissante mobile dans le corps de poignée et un collier (130) monté sur un extérieur du corps de poignée afin d'être rotatif autour d'un axe longitudinal du corps de poignée.

10. Poignée de cathéter selon la revendication 9, dans laquelle le collier et le support de stylet possèdent des formations de conversion de mouvement complémentaires en vue de convertir le mouvement rotatif du collier en un mouvement prédéfini du support de stylet.

11. Poignée de cathéter selon la revendication 9 ou la revendication 10 dans laquelle le support de stylet comporte une formation de montage en vue du montage d'un premier composant du stylet, et, en option, dans laquelle le corps de poignée définit un siège (122) en vue de réceptionner un second composant du stylet, en cours d'utilisation.

12. Cathéter (10) qui comporte :

la poignée de cathéter selon une quelconque des revendications 1 à 12 ;
un stylet multi-composants (20) possédant un embout proximal monté dans le passage du corps de poignée, le stylet possédant une partie distale (24) préformée en une partie prédéterminée (26) ; et
un manchon de cathéter (14) se projetant distalement à travers la décharge de traction, le manchon de cathéter définissant un lumen dans lequel le stylet est réceptionné de manière telle que la forme de la partie distale préfaçonnée du stylet est donnée à une partie distale (18) du manchon de cathéter (14).

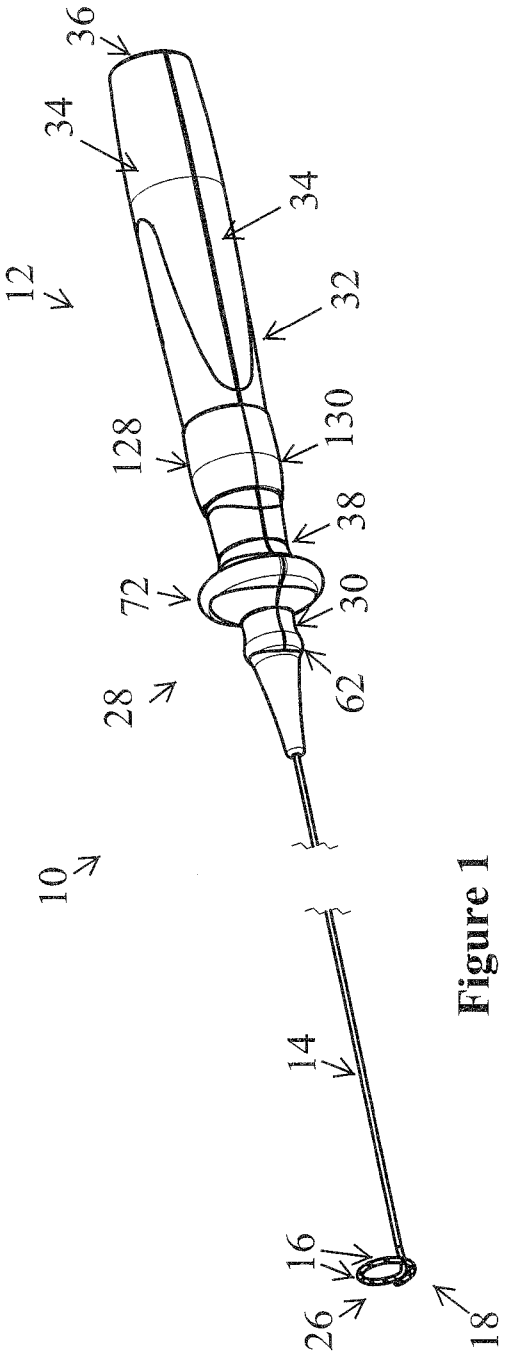


Figure 1

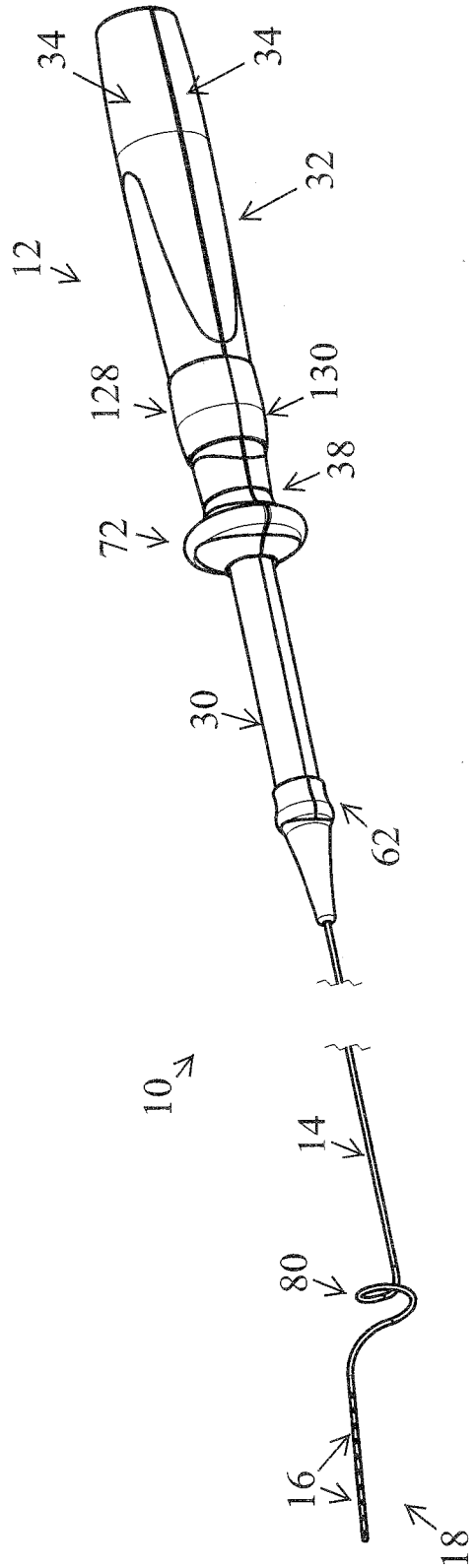
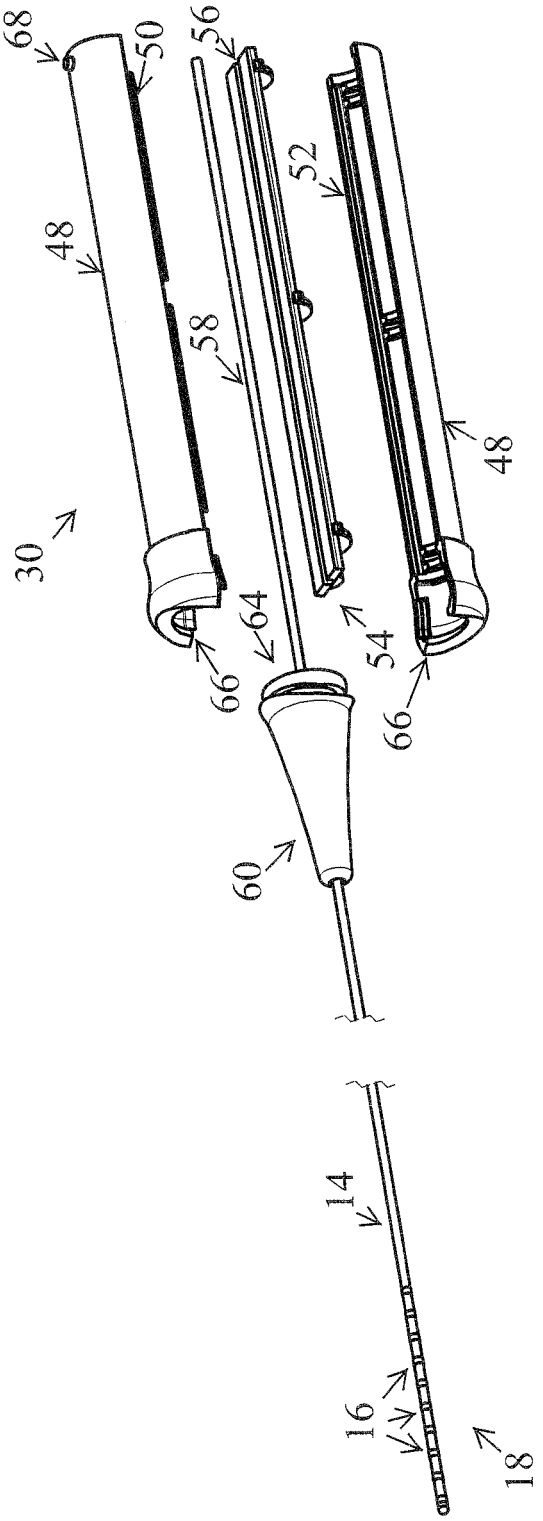


Figure 2



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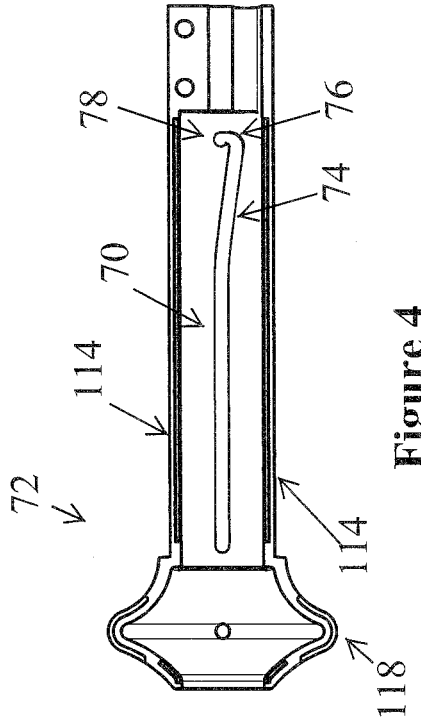

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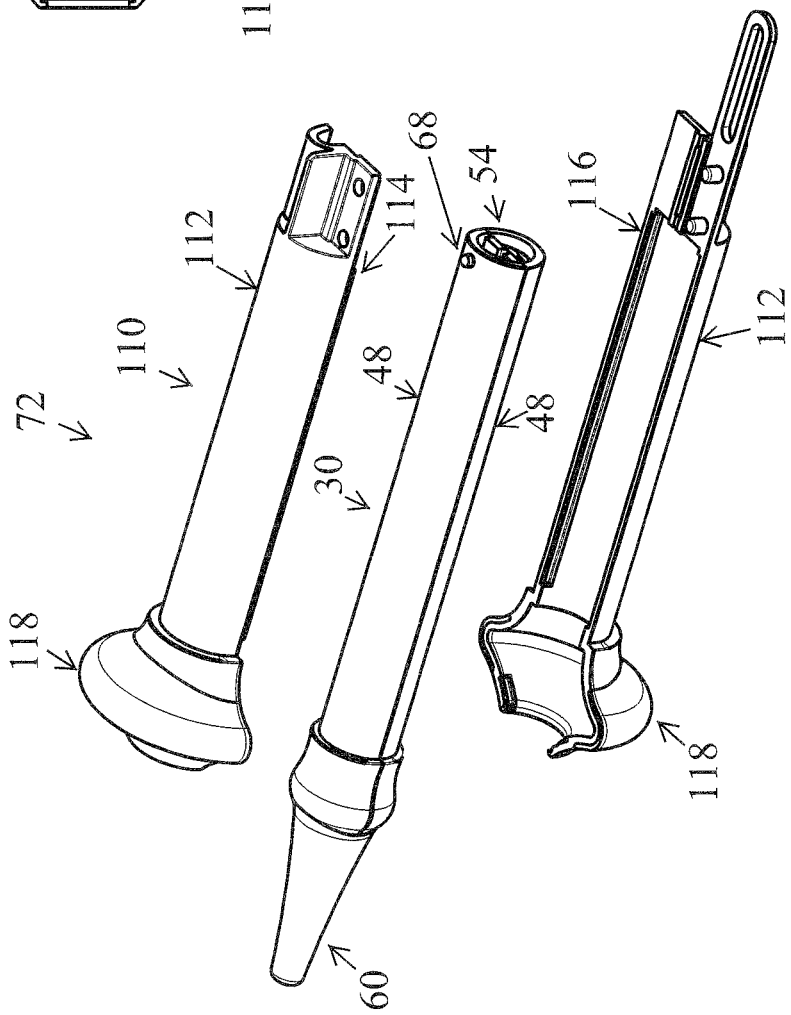

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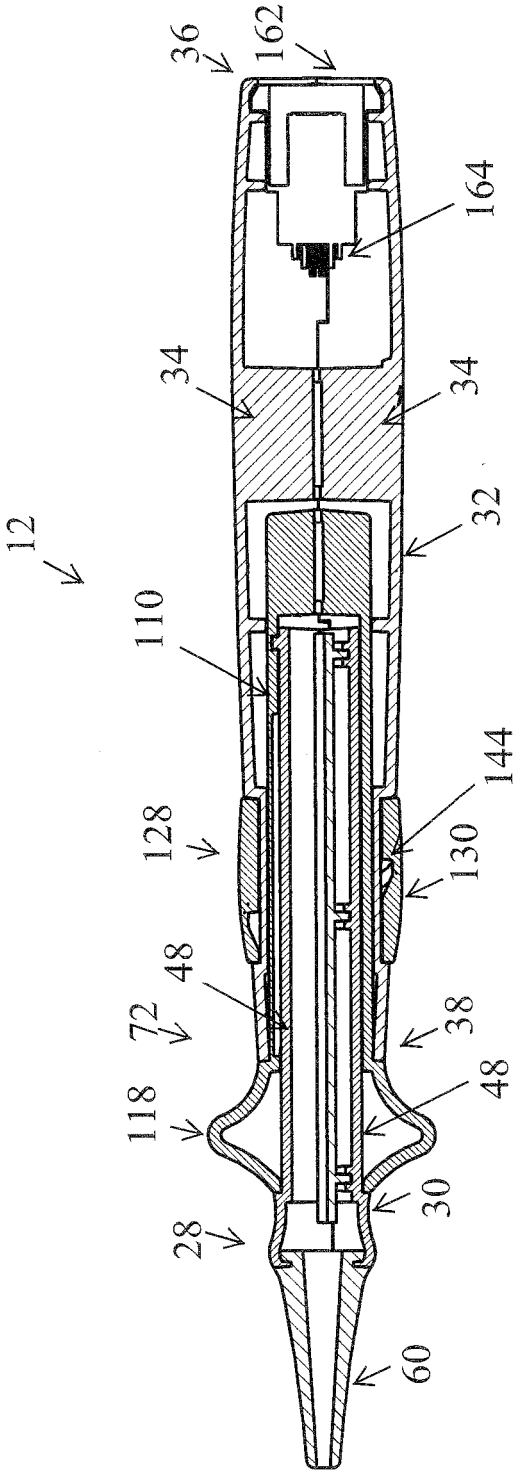

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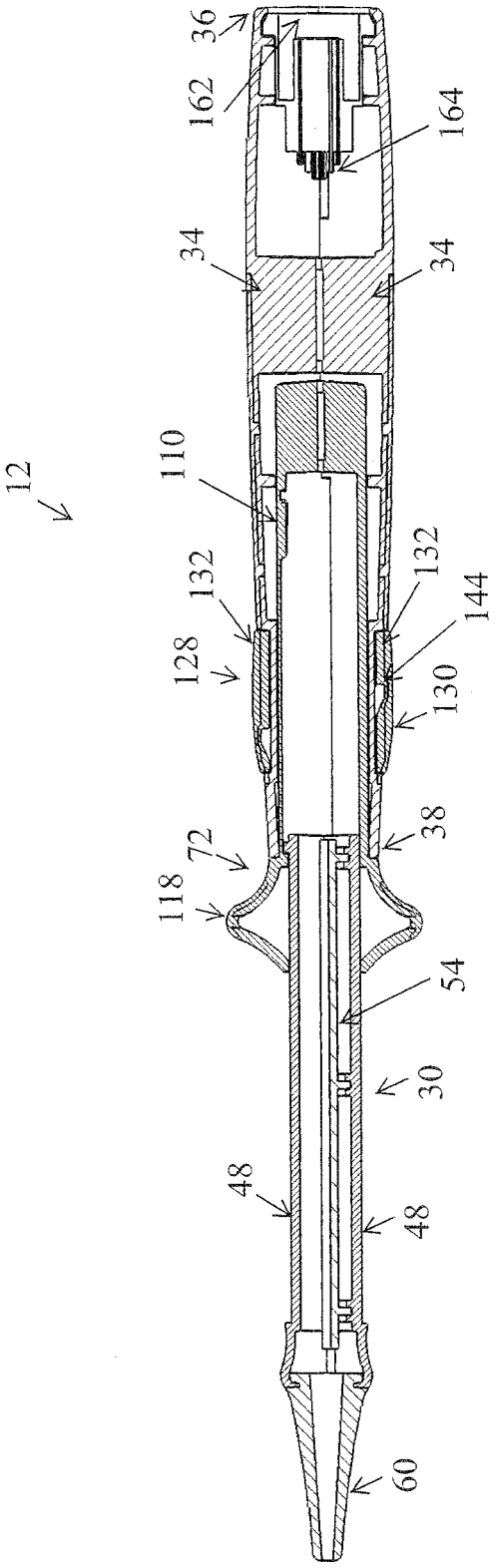

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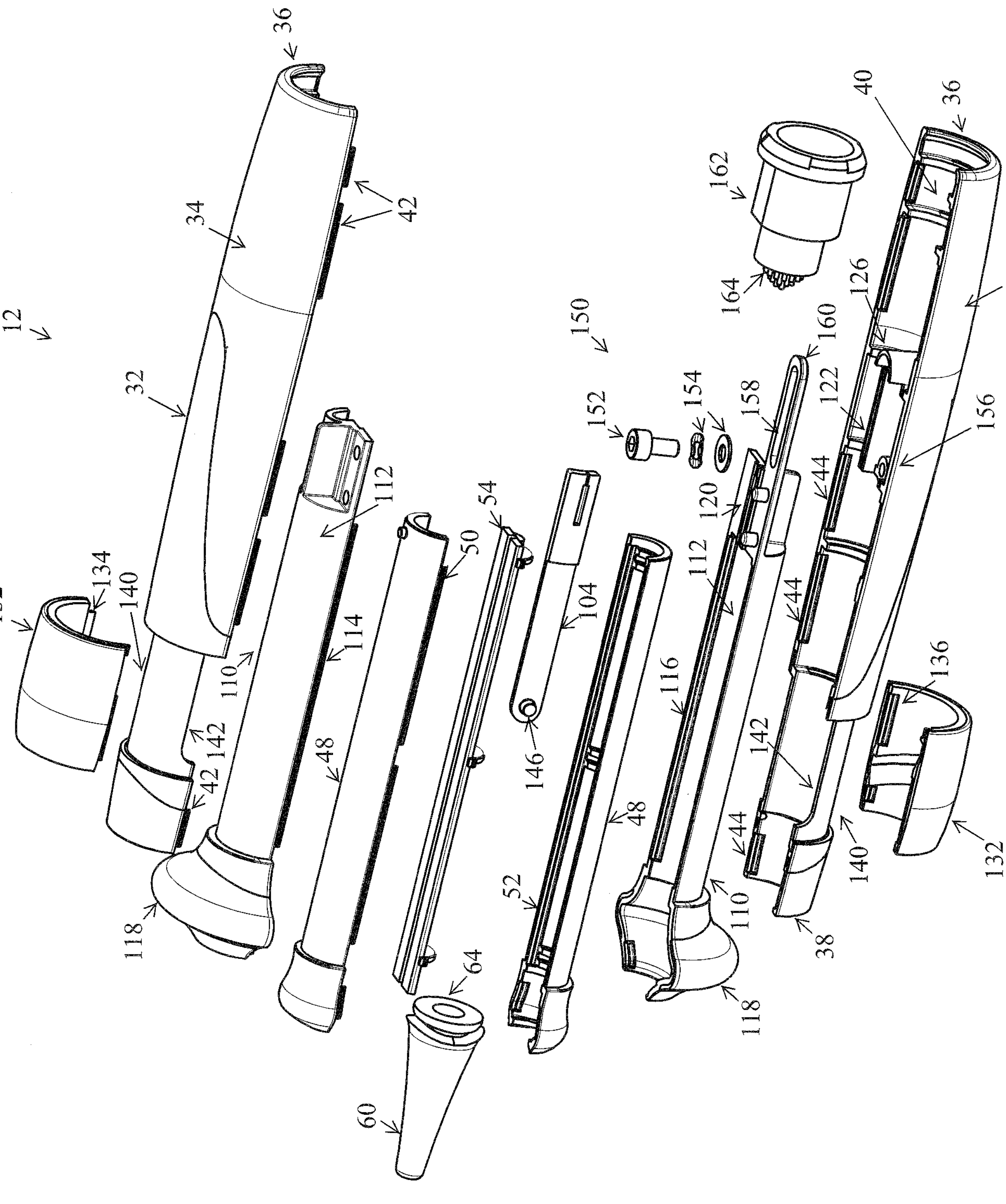
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Figure 8

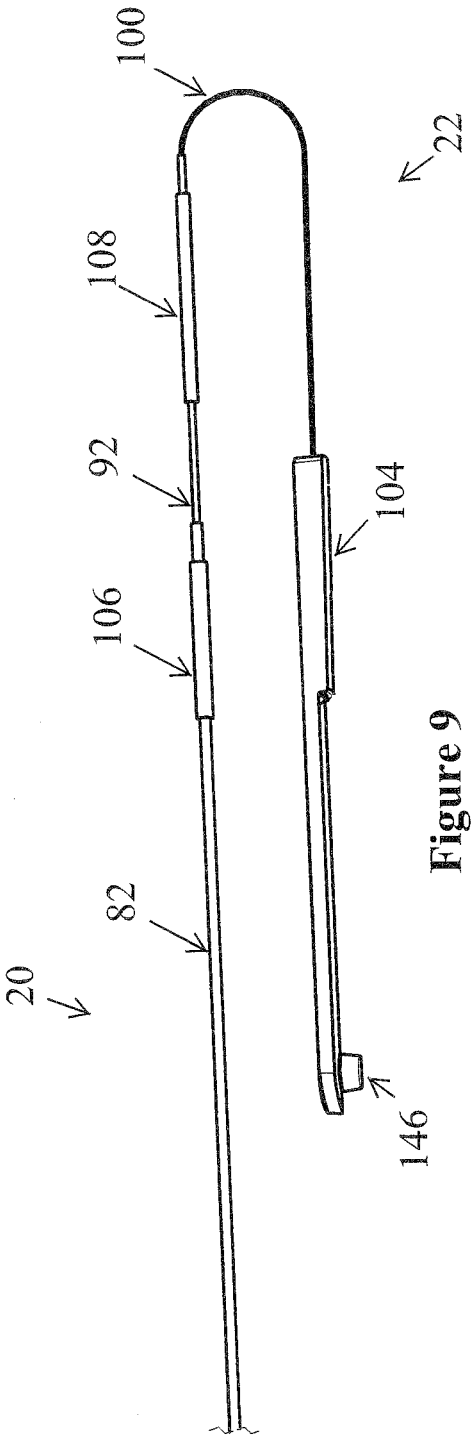

Figure 9

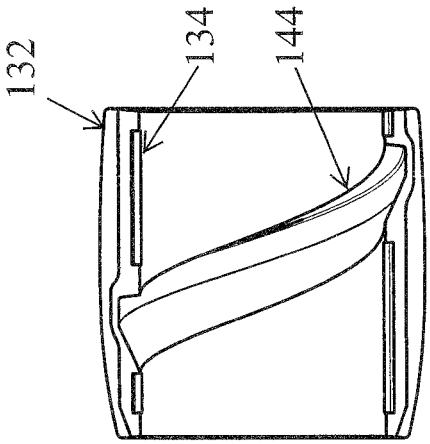

Figure 10

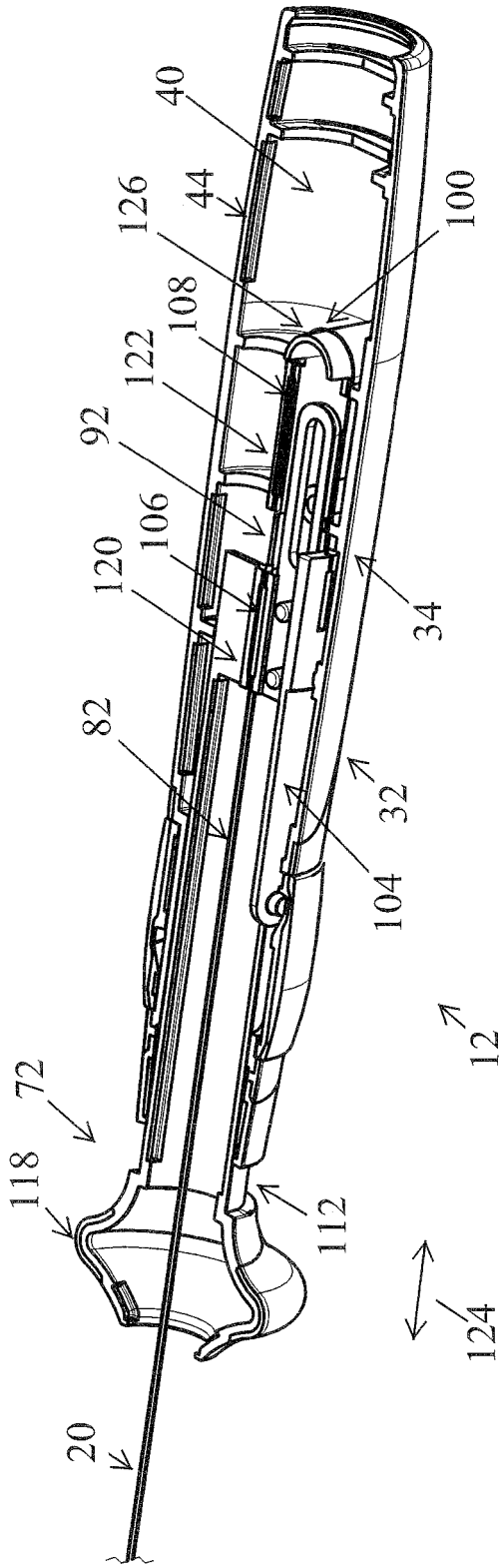

Figure 11

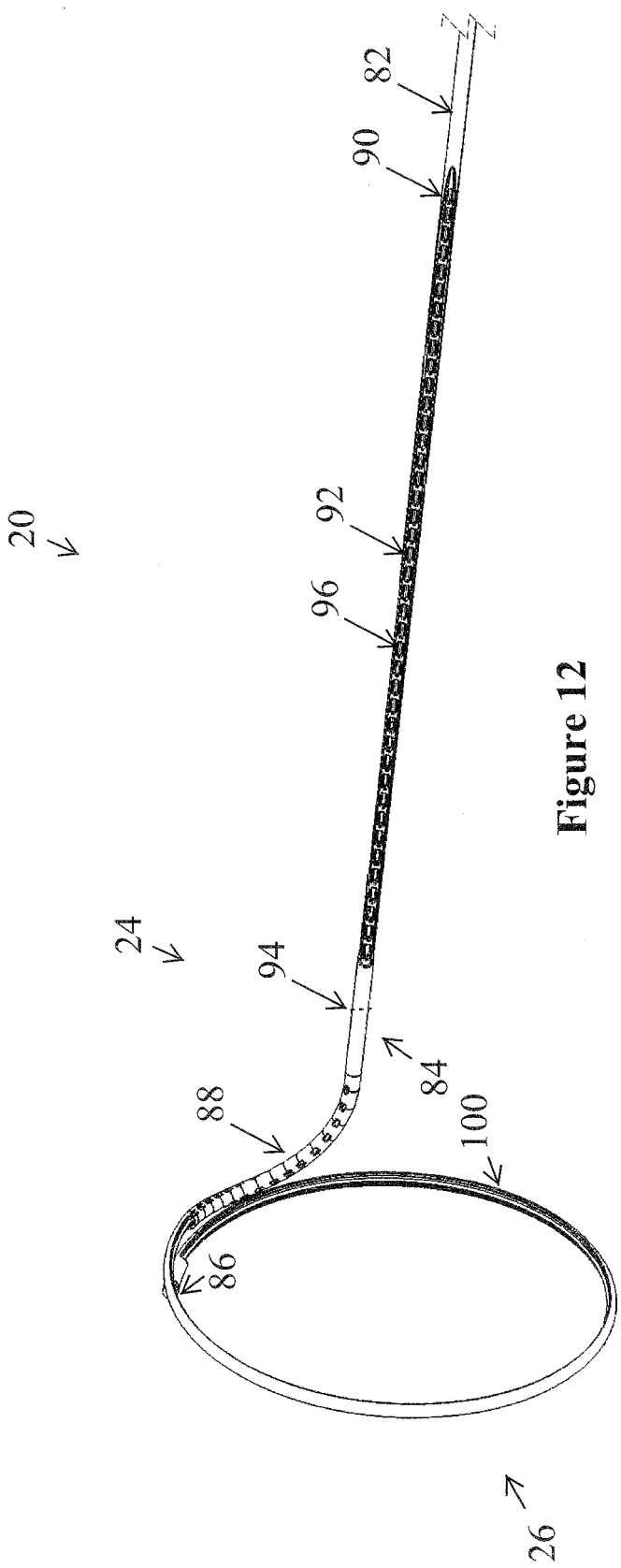

Figure 12

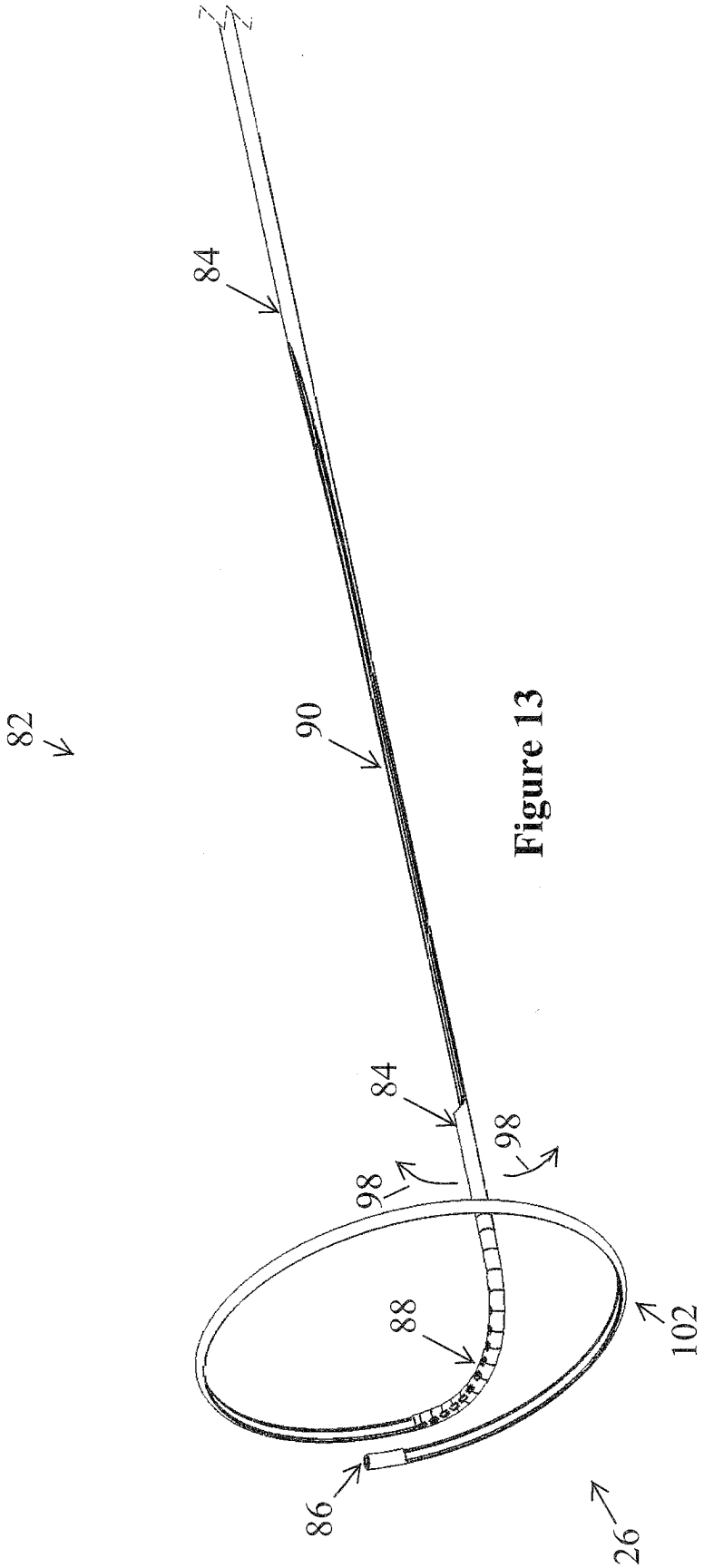

Figure 13

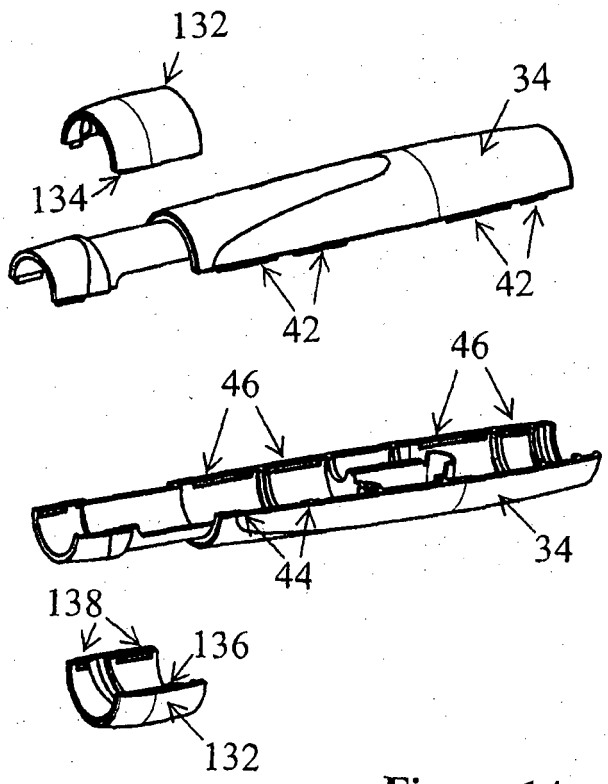

Figure 14

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 5987344 A **[0006]**
- JP 4224122 B **[0006]**
- WO 2009114908 A **[0007]**

专利名称(译)	导管手柄		
公开(公告)号	EP2569040B1	公开(公告)日	2019-02-06
申请号	EP2011779961	申请日	2011-05-10
[标]申请(专利权)人(译)	导管治疗有限公司		
申请(专利权)人(译)	CATHRX LTD		
当前申请(专利权)人(译)	CATHRX LTD		
[标]发明人	OGLE DAVID		
发明人	OGLE, DAVID		
IPC分类号	A61B5/00 A61B5/042 A61B18/14 A61M25/00 A61M25/01 A61B5/04		
CPC分类号	A61M25/0136 A61B5/04 A61B5/0422 A61B5/6856 A61B18/148 A61B2018/1407 A61M25/0147 A61M25/0152 A61M2025/0098 A61M2025/0161 A61M2025/0163		
优先权	61/333576 2010-05-11 US		
其他公开文献	EP2569040A4 EP2569040A1		
外部链接	Espacenet		

摘要(译)

导管手柄包括手柄主体，手柄主体具有近端和远端，以及在近端和远端之间延伸的通道。手柄本体包括多个壳体部分，这些壳体部分可以分开以进入手柄本体的内部。手柄主体还包括安装在手柄主体的近端处的连接器和布置在远端的应变释放件，应变释放件和连接器相对于手柄主体可拆卸地布置。

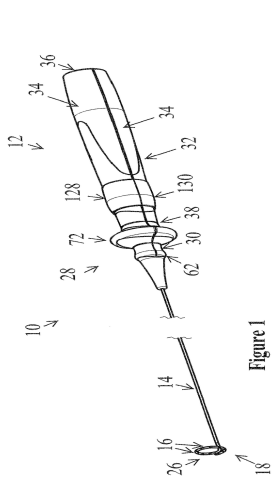

Figure 1

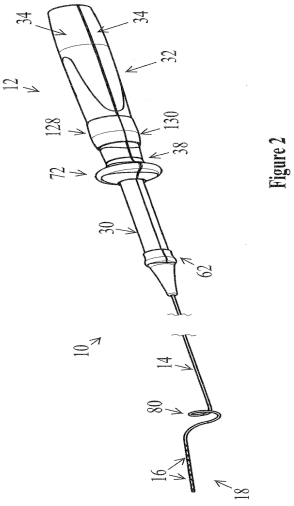

Figure 2