



- (51) **International Patent Classification:**
A61M 25/01 (2006.01) *A61M 25/082* (2006.01)
A61M 25/08 (2006.01) *A61M 25/09* (2006.01)
- (21) **International Application Number:**
PCT/US2018/021150
- (22) **International Filing Date:**
06 March 2018 (06.03.2018)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
62/467,815 06 March 2017 (06.03.2017) US
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- (81) **Designated States** (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) **Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,

(54) **Title:** PERCUTANEOUS DEVICE EXCHANGE

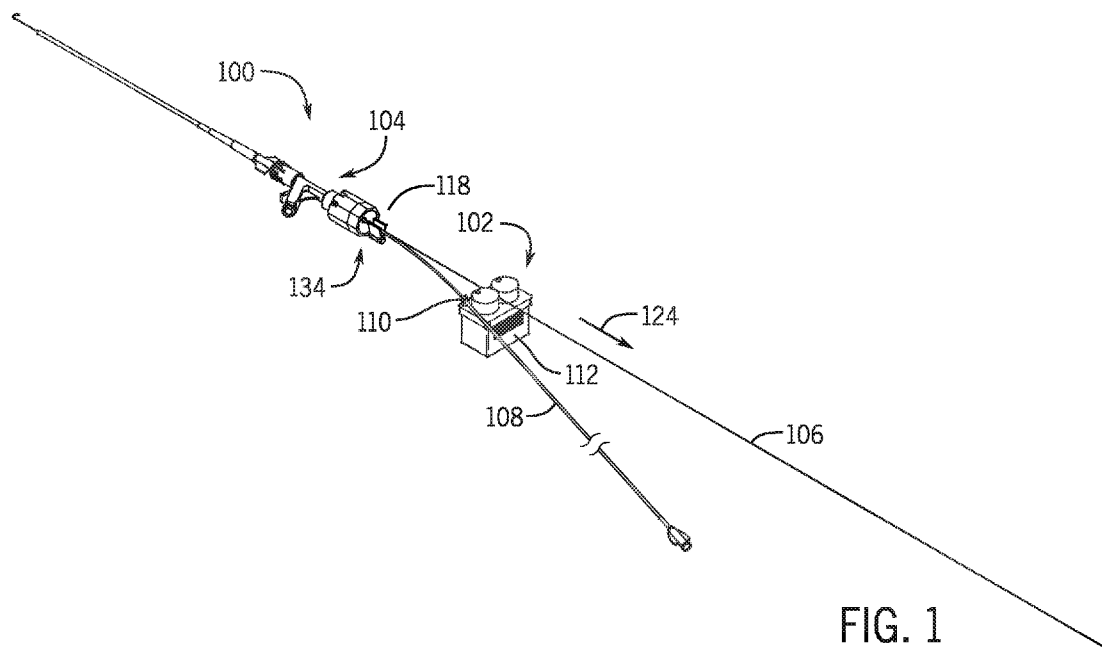


FIG. 1

(57) **Abstract:** An apparatus includes a hemostasis valve; a base having a clamp releasably coupling a catheter to the base; a base drive member moving the base relative to the hemostasis valve along a first path; and a mechanism maintaining the position of an elongated medical device relative to the hemostasis valve while the catheter is being moved along the first path.



TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

- *with international search report (Art. 21(3))*
- *with amended claims (Art. 19(1))*

PERCUTANEOUS DEVICE EXCHANGE

CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

This application claims the benefit of US Provisional Application No. 62/467815 filed on March 6, 2017 and entitled Percutaneous Device Exchange and incorporated herein by reference in its entirety.

BACKGROUND

[0001] The present invention relates generally to the field of robotic percutaneous device systems and more particularly, to a system for exchanging percutaneous devices.

[0002] Vascular disease, and in particular cardiovascular disease, may be treated in a variety of ways. Surgery, such as cardiac bypass surgery, is one method for treating cardiovascular disease. However, under certain circumstances, vascular disease may be treated with a catheter based intervention procedure, such as angioplasty. Catheter based intervention procedures are generally considered less invasive than surgery.

[0003] During one type of intervention procedure, a guide catheter is inserted into a patient's femoral artery through an introducer and positioned proximate the coronary ostium of a patient's heart. A guidewire is inserted into the guide catheter typically through a hemostasis valve and maneuvered through the patient's arterial system until the guidewire reaches the site of the lesion. A percutaneous device is then moved along the guidewire until the device such as a balloon and stent is positioned proximate the lesion to open a blockage to allow for an increased flow of blood proximate the lesion. In addition to cardiovascular disease, other diseases may be treated with catheterization procedures.

[0004] Percutaneous devices are often exchanged during a procedure. For example, during a procedure a balloon catheter may be guided to a lesion along a guidewire pre dilatation. The balloon catheter is then removed, and a stent catheter is guided to the lesion along the guidewire post dilatation.

SUMMARY

[0005] In one embodiment an apparatus includes a hemostasis valve; a base having a clamp releasably coupling a catheter to the base; a base drive member moving the base relative to the hemostasis valve along a first path; and a mechanism maintaining the position of an elongated medical device relative to the hemostasis valve while the catheter is being moved along the first path.

[0006] In a further embodiment a portion of the elongated medical device is removably positioned within a lumen of the catheter.

[0007] In a further embodiment the first path is a direction that is substantially parallel to both a longitudinal axis of the elongated medical device and a longitudinal axis of the catheter.

[0008] In a further embodiment a distal portion of the elongated medical device is maintained in a substantially fixed location relative to an anatomical feature within a patient as the base moves in the first direction, and wherein the distance between the distal portion of the elongated medical device and the base changes as the base moves along the first path.

[0009] In a further embodiment at least a portion of the first path is linear.

[0010] In a further embodiment at least a portion of the first path is not-linear.

[0011] In a further embodiment the base moves along the elongated medical device as the base moves in the first direction.

[0012] In a further embodiment the mechanism includes a discrete movement drive mechanism that moves the elongated medical device relative to the base in a series of discrete distances.

[0013] In a further embodiment the base drive member moves the base with one or more degrees of freedom.

[0014] In a further embodiment the base drive member is being moved by a robotic arm having one or more degrees of freedom.

[0015] In a further embodiment the robotic arm moves the base relative to an access site of a patient.

[0016] In a further embodiment the robotic arm moves the base relative to a position on a patient bed.

[0017] In a further embodiment the catheter is a rapid exchange device having a monorail portion having a lumen therein for a fixed length, the elongated medical device being movably received in the lumen of the monorail portion.

[0018] In a further embodiment a distal clamp is removably clamping a portion of the elongated medical device once a distal end of the monorail portion of the catheter is between the distal clamp and the base.

[0019] In a further embodiment the distal clamp is positioned between the hemostasis valve and the base.

[0020] In a further embodiment the elongated medical device is free to move relative to the mechanism when the distal clamp clamps the elongated medical device thereto.

[0021] In a further embodiment the elongated medical device is removed from the monorail by an elongated medical device removal drive that moves the elongated medical device through the monorail in a second direction such that the proximal end of the elongated medical device is pulled through the monorail toward the hemostasis valve.

[0022] In a further embodiment the mechanism includes a pair of wheels operatively moving the elongated medical device relative to the base.

[0023] In a further embodiment the mechanism includes a first clamp member and a second clamp member moving in direction away from the hemostasis valve.

[0024] In a further embodiment the first clamp member moves from a first position where the first clamp is intermediate the second clamp and the hemostasis valve and to a second position where the second clamp is intermediate the first clamp and the hemostasis valve.

[0025] In a further embodiment the elongated medical device is a guidewire.

[0026] In a further embodiment the catheter is an over the wire device having a lumen extending from a proximal end to a distal end of the catheter, the elongated medical device being movably received in the lumen.

[0027] In a further embodiment a portion of the elongated medical device is maintained in a substantially fixed location relative to the hemostasis valve as the base moves in the first direction, and wherein the distance between the portion of the elongated medical device and the base changes as the base moves along the first path.

[0028] In a further embodiment the catheter is positioned within a hemostasis valve directly without being in a lumen of another catheter device in the hemostasis valve.

[0029] In a further embodiment a second hemostasis valve is positioned such that a first hemostasis valve is intermediate the base and the second hemostasis valve.

[0030] In one embodiment an apparatus for loading an elongated medical device through a lumen of a catheter includes a catheter support positioning a distal end of a catheter having a catheter lumen; and a drive moving the elongated medical device relative to the catheter inserting a proximal end of the elongated medical device into a distal opening of the catheter lumen.

[0031] In a further embodiment the drive moves the proximal end of the elongated medical device to exit through a proximal end of the catheter lumen.

[0032] In a further embodiment, the catheter support and drive are moveably positioned between an in-use position and a non-use position.

[0033] In a further embodiment a base having a first base portion supporting a first portion of the drive and a first portion of the catheter support, and a second base portion supporting a second portion of the drive and a second portion of the catheter support.

[0034] In a further embodiment the first base portion and second base portion move along a linear path toward and away from the in-use position.

[0035] In a further embodiment the first base portion and second base move a long a non-linear path toward and away from the in-use position.

[0036] In a further embodiment the catheter support includes a plurality of regions selectively contacting portions of the catheter.

[0037] In a further embodiment the plurality of regions are movably controlled by a controller in one or more degrees of freedom.

[0038] In a further embodiment an imaging system detecting the location of the distal tip of the elongated medical device and the proximal opening of the catheter lumen.

[0039] In a further embodiment a control system using information from the imaging system to provide instructions via a controller to position the drive and the catheter locator to align the proximal tip of the elongated medical device with the opening of the distal end of the catheter lumen.

[0040] In a further embodiment the catheter locator includes a portion configured to avoid contact with a therapeutic element positioned on the catheter.

[0041] In a further embodiment the catheter support and drive are moved between an in-use and non-use position by one of a robotic arm, linear actuator, movable base and a rotational base.

[0042] In a further embodiment the elongated medical device is a guidewire.

[0043] In one embodiment an apparatus includes a hemostasis valve; a base having a clamp releasably coupling a first catheter to the base; a base drive member moving the

base relative to the hemostasis valve along a first path; a mechanism maintaining the position of an elongated medical device relative to the hemostasis valve while the catheter is being moved along the first path; a catheter support positioning a distal end of a second catheter having a catheter lumen; and an elongated percutaneous drive moving the elongated medical device relative to the second catheter inserting a proximal end of the elongated medical device into a distal opening of the catheter lumen.

[0044] In one embodiment an apparatus includes a hemostasis valve; and a loader including a catheter support positioning a distal end of a catheter having a catheter lumen; and an elongated percutaneous drive moving the elongated medical device relative to the catheter inserting a proximal end of the elongated medical device into a distal opening of the catheter lumen. An unloader includes a base having a clamp releasably coupling the catheter to the base and a base drive member moving the base relative to the hemostasis valve along a first path; the unloader includes a mechanism maintaining the position of an elongated medical device relative to the hemostasis valve while the catheter is being moved along the first path.

BRIEF DESCRIPTION OF THE DRAWINGS

[0045] FIG 1 is a schematic view of the exchange system in a first position.

[0046] FIG 2 is a schematic view of the exchange system in a second position

[0047] FIG 3 is a schematic view of the exchange system in a first position with a proximity sensor.

[0048] FIG 4 is a schematic view of the exchange system in the second position with a proximity sensor.

[0049] FIG 5 is a top plan schematic view of the exchange system in the first position.

[0050] FIG 6 is a top plan schematic view of the exchange system in the first position.

[0051] FIG 7 is a schematic view of the exchange system in the first position with a slide.

[0052] FIG 8 is a schematic view of the exchange system in the second position with a slide.

[0053] FIG 9 is a schematic view of the exchange system in the first position with a robotic arm.

[0054] FIG 10 is a schematic view of the exchange system in the second position with a robotic arm.

[0055] FIG 11 is a schematic cross section of a mechanical sensor when the exchange system is in the first position.

[0056] FIG 12A-12G are schematic views of the exchange system with a first pair of clamps in multiple positions.

[0057] FIG 13A-13F are a schematic view of the exchange system with a second pair of clamps in multiple positions.

[0058] FIG 14 is a schematic view of an exchange system for an over the wire catheter in a clamped position.

[0059] FIG 15 is a schematic view of an exchange system for an over the wire catheter in an unclamped position.

[0060] FIG 16 is a partial cross-sectional view of a rapid exchange catheter and guidewire.

[0061] FIG 17 is a schematic view of an over the wire catheter and guidewire.

[0062] FIG 18 is a schematic view of a robotic catheter system with a bedside unit and a remote work station.

[0063] FIG 19 is a schematic view of an exchange system with a loader in a first mode.

[0064] FIG 20 is a schematic view of the exchange system with a loader in another mode.

[0065] FIG 21 is a schematic view of the exchange system with a loader in another mode.

[0066] FIG 22 is a schematic view of the exchange system with a loader in another mode.

[0067] FIG 23 is a schematic view of the exchange system with a loader in another mode.

[0068] FIG 24 is a schematic view of the exchange system with a loader in another mode.

- [0069] FIG 25 is a schematic view of the exchange system with a loader in another mode.
- [0070] FIG 26 is a schematic view of the loader of the exchange system of FIG 19.
- [0071] FIG 27 is a schematic view of locator members.
- [0072] FIG 28 is a schematic view of the loader of the exchange system with a sensor.
- [0073] FIG 29 is a cross sectional view of the locator members and actuating mechanism in a first position.
- [0074] FIG 30 is a cross sectional view of the locator members and actuating mechanism in a second position.
- [0075] FIG 31 is a cross sectional view of the locator members in an open position.
- [0076] FIG 32 is a cross sectional view of the locator members in an engaged position.
- [0077] FIG 33 is a detail view of the edge portions of the locator members in one embodiment.
- [0078] FIG 34 is a detail view of the edge portions of the locator members in a second embodiment.
- [0079] FIG 35 is a schematic view of the loader base in an open position.
- [0080] FIG 36 is a schematic view of the loader in a closed position.
- [0081] FIG 37 is a schematic view of the loader and locator members in a closed position.
- [0082] FIG 38 is a view of locator members in an open position.
- [0083] FIG 39 is a view of the locator members of FIG 38 in a closed position.

DETAILED DESCRIPTION OF THE EXAMPLE EMBODIMENTS

[0084] A robotic system such as the system disclosed in US Application 15/029,115 entitled Guide Catheter Control Flexible Track which is incorporated herein by reference in its entirety permits robotic control of a guidewire, a catheter or other elongated medical device and a guide catheter. Referring to Figure 18, robotic catheter system 10 operates proximate a patient bedside system 12 adjacent a patient bed 22. A remote work station 14 includes a controller 16, a user interface 18 and a

display 20. An imaging system 24 may be any medical imaging system that may be used in conjunction with a catheter based medical procedure (e.g., non-digital x-ray, digital x-ray, CT, MRI, ultrasound, etc.). In one embodiment, imaging system 24 is a digital x-ray imaging device that is in communication with workstation 14. Imaging system 24 is configured to take x-ray images of the appropriate area of patient during a particular procedure. For example, imaging system 24 may be configured to take one or more x-ray images of the heart to diagnose a heart condition. Imaging system 24 may also be configured to take one or more x-ray images during a catheter based medical procedure (e.g., real-time images) to assist the user of workstation 14 to properly position a guidewire, guide catheter, and a working catheter such as a stent during a procedure. The image or images may be displayed on display 20 to allow the user to accurately position a distal tip of a guidewire or working catheter into proper position in a patient's vasculature. As used herein the term elongated medical device includes a guidewire, a catheter or any other elongated medical device known in the industry including but not limited to elongated percutaneous devices.

[0085] During certain catheter procedures it may be necessary to exchange one catheter device with another catheter device. As noted above, during a procedure a balloon catheter may be guided to a lesion along a guidewire. After the balloon catheter is inflated the balloon catheter is then removed and a stent catheter is guided to the lesion along the guidewire post dilatation. In one procedure during the exchange of the balloon catheter and the stent catheter the distal end of the guidewire is maintained in a position distal the lesion being treated. However other positions within the vasculature are contemplated. As the balloon catheter is being withdrawn from the vasculature it is desirable to maintain the distal end of the guidewire in a fixed position relative to a lesion or anatomical feature within the vasculature. In the over the wire catheter platform a guidewire 106 is maneuvered either manually or using a robotic drive system to drive a distal end 184 of the guidewire to or beyond a region of interest such as a lesion within a vasculature of a patient. In order to exchange the over the wire catheter the distal end 180 of an over the wire catheter 160 is slid off proximal end 186 of the guidewire 106. In an over the wire platform a proximal end of a guidewire 186 is inserted into a distal end 180 of a lumen in the

catheter or percutaneous device and the catheter is slid along the guidewire along its entire length until the proximal end 186 of the guidewire extends out of the proximal opening 182 in the catheter lumen at a position at the proximal end of the catheter.

The terms distal as used herein referring to a part of a component is the portion of the component that is closer to or within a vasculature during a procedure and the term proximal is the portion that is further from the vasculature when the device is being used during a vasculature procedure. The distal end is generally opposite the proximal end of the component.

[0086] In order to perform an exchange of an over the wire catheter with another over the wire catheter the guidewire needs to be longer than the length of the first catheter. guidewires used for over the wire platforms may be between 270-400 cm. In one technique an assistant applies pressure to the proximal portion of the guidewire to maintain the distal end of the guidewire in a fixed position while the catheter is being pulled off. The fixed position may be relative to one of a y-connector, a hemostasis valve, an introducer, a patient bed, a position within the vasculature, or a specific location on earth. Once the distal end of the catheter clears the patient the guidewire may be held at a position proximate the entry point of the patient to maintain the position of the distal end of the catheter in the vasculature while the catheter is fully pulled off of the proximal end of the guidewire. To load a different or even the catheter on to the guidewire an opening in the catheter lumen on the distal end of the catheter is slide over the proximal end of the guidewire.

[0087] In a rapid exchange catheter platform, a rapid exchange catheter includes a distal end having a distal opening into a guidewire receiving lumen that receives a proximal end of the guidewire. The guidewire receiving lumen extends for a set distance within the catheter and terminates at an exit port. The proximal end of the guidewire is inserted into the catheter guidewire receiving lumen and exits the exit port of the catheter. The distal end of the catheter is then driven along the guidewire until the distal end of the catheter is proximate the lesion to be treated. The distance between the opening of the guidewire receiving lumen and the exit port is referred to as the monorail portion of the catheter and may be between 20-25 cm, though other distances are contemplated.

[0088] Referring to FIG 1 a system 100 includes a movable drive 102 that moves toward and from a y-connector 104 including a hemostasis valve 105. An elongated medical device 106 is received with drive 102 and a percutaneous device 108 such as a stent catheter is removably held on drive 102 with a holding mechanism 110 such as clamp. In one embodiment elongated medical device 106 is a guidewire. The term guidewire will be used in the description. However, it is contemplated that other elongated medical devices may also be used where the term guidewire is used.

[0089] Movable drive 102 includes a base 112 that supports holding mechanism 110. In one embodiment holding mechanism is integrally formed with base 112. Base 112 may be on a slide 122 that is robotically moved away from and toward y-connector 104. In one embodiment y-connector 104 is a hemostasis valve. Movable drive in one embodiment includes a pair of wheels 114 and 116. Wheel 114 may be a drive wheel and 116 may be a driven wheel. Drive wheel 114 is driven by a motor and controlled by a control system.

[0090] In one embodiment an operator positions a distal end of a guidewire 106 distal a lesion of a patient manually or using a robotic system such as the one described in the '115 application referenced above. System 100 is used to exchange a first percutaneous device with a second percutaneous device are guided along guidewire 106. A region near the proximal end of first percutaneous device 108 is secured to movable drive 102. In one embodiment, the distal end of the proximal shaft of the first percutaneous device 108 to be removed from the patient is secured to the holding mechanism 110 when movable drive 102 is in the first position.

[0091] Once the first percutaneous device is secured to movable drive 102 via the holding mechanism 110, the guidewire 106 is placed between wheels 114 and 116. A control system (not shown) moves the movable drive 102 to a second position (See FIG 2) in a direction 124 away from the Y-connector 104. Simultaneous to the movement of the movable drive 102 toward the second position drive wheels 114 and 116 rotate at a speed to feed proximal portion of the guidewire toward the Y-connector. As a result, the distal end of the guidewire does not move relative to the lesion. This is accomplished by moving the guidewire toward the Y-Connector at the same rate that the movable drive base is moving away from the Y-connector.

[0092] Stated another way movable drive 102 maintains the guidewire in a nonmovable or fixed position relative to the patient as the movable drive moves from the first position to the second position. Once the monorail portion 120 of the first percutaneous device is on the side of the Y-connector distal the patient the movable drive can continue to a third position (not shown) in which the proximal terminal end of the guidewire is no longer in the movable drive and the first catheter is pulled completely off of the guidewire. At this point a second catheter device can be thread off the proximal end of the guidewire.

[0093] In one embodiment pair of wheels 114 and 116 form a proximal dynamic guidewire fixation device or a guidewire mechanism that maintains the guidewire in a fixed position as the movable drive 102 moves away from the y-connector. In one embodiment wheels 114 and 116 allow the movable drive 102 and percutaneous device 108 to move along guidewire 106 while maintaining guidewire 106 is a fixed position relative to the y-connector. However other devices are contemplated including but not limited to continuous, discrete or intermittent motion devices. For example, wheels could be replaced with one or a pair of continuous drive belts or as disclosed herein below a pair of clamp members.

[0094] Referring to FIG. 3 – 6 and FIG 7 system 100 percutaneous device 108 is moved away from the y-connector with a catheter drive (not shown). In one embodiment percutaneous device 108 is a rapid exchange device having a monorail portion 120. Monorail portion 120 is formed as part of the percutaneous device 108 and includes a distal opening 126, a lumen portion 128 and a proximal exit opening 130. Rapid exchange devices are well known in the art. The monorail portion 120 is typically 20-25 cm. However, monorail portions of other lengths may also be employed.

[0095] During a first stage of an exchange a first percutaneous device 108 may be initially withdrawn from a patient using a robotic drive mechanism as is known in the art in which a linear drive is acting on the percutaneous device 108 to move the percutaneous device away from the patient. While the linear drive acting to withdraw the percutaneous device a second guidewire linear drive may be acting on the guidewire to assist in maintaining the distal end of the guidewire in a static position

by applying a counter pressure or movement to the portion of the guidewire within the guidewire linear drive to counter any movement of the guidewire resulting from friction of the monorail portion acting against the guidewire as the percutaneous device is being withdrawn. It is also contemplated that the guidewire may be rotated as the percutaneous device 108 is being withdrawn to assist in maintaining the position of the distal end of the guidewire in the vasculature.

[0096] A proximity sensor 132 positioned near the proximal end 134 of y-connector 104 detects when the proximal end 136 of the monorail portion emerges from the y-connector. Proximity sensor 132 may be a mechanical, electro mechanical, or image sensor such as a camera that coupled with hardware or computer software code determines that the proximal end of the monorail portion 120 of percutaneous device 108 has cleared the proximal end of the y-connector and/or hemostasis valve.

Referring to FIG 11 a mechanical proximity sensor 137 include an elongated member extending between the guidewire 106 and percutaneous device 108 between movable drive 102 and the proximal opening 130 of monorail portion 120 of percutaneous device 108. The elongated member is biased out of the way as percutaneous device 108 is moved in a direction away from hemostasis valve 104 along vector 124.

[0097] Once the proximal end of the monorail portion 120 has emerged the guidewire 106 and percutaneous device is placed within movable drive 102. A portion of percutaneous device 108 is operatively secured with a clamp 110 or other means to movable drive 102. Movable drive 102 is then robotically moved along a slide 122 or moved via a robotic arm 138 or other device that robotically moves movable drive 102 away from y-connector 104 in a direction 124. As movable drive 102 is moved in a direction 124 percutaneous device 108 is withdrawn from the vasculature as it rides over the portion of the guidewire within the monorail lumen 128. In order to maintain the distal end of the guidewire in a fixed position within the vasculature drive wheels 114, 116 are rotated in a manner such that moveable drive 102 moves along guidewire 106 and the distal end of guidewire 106 remains in a relatively fixed position within the vasculature.

[0098] Referring to Figures 1-5. Wheel 114 and wheel 116 rotate in opposite directions in a direction such the distal end of the guidewire remains fixed in its

position while the mobile drive 102 moves in a direction 124 away from y-connector 104. The speed in which wheels rotate is related to the speed in which mobile drive moves.

[0099] In one embodiment the movement of mobile drive 102 is a constant velocity and is continuous and the rotation of wheels are also a constant rate and continuous. In one embodiment the movement of mobile drive 102 is done in a series of discrete motions and the rotation of wheels 114 and 116 are also done in a series of discrete motions. In one embodiment the rotation of wheels 114 and 116 are continuous but have a cam non-uniform diameter surface such that the contact with the guidewire is intermittent to match the discrete intermittent movement of the mobile drive 102. In one embodiment other types of drive systems for both the movement of mobile drive 102 in the direction 124 away from y-connector 104 and drive systems related to the movement of the guidewire relative to the mobile drive 102.

[0100] In one embodiment the movement of the guidewire drive relative to the mobile drive 102 imparts a positive pressure on the guidewire in the direction opposite to direction 124 as required to overcome any drag imparted to the guidewire from the movement of percutaneous device 108 as the percutaneous device is moved in the direction 124 away from the y-connector. In one embodiment guidewire drive may vary the speed of the guidewire drive elements such as the wheel 114 and 116 to move the guidewire to or from the y-connector to maintain the distal end of the guidewire in a stationary position relative to a feature such as a lesion or location within the vasculature while the percutaneous device is being withdrawn from the vasculature.

[0101] Referring to FIGS 12A-12G in one embodiment a pair of clamps are used to fix the location of guidewire 106 as percutaneous device 108 is withdrawn from the vasculature and from y-connector 104 in a direction 124 away from the y-connector 104. Referring to FIG 12A a first clamp 140 in a nonclamped orientation is moved along with percutaneous device 108 such that clamp 140 does not interfere with the percutaneous device proximate guidewire exit opening 130. A second clamp 142 located a distance further away from y-connector 104 is clamped to guidewire 106 to fix the location of the guidewire as percutaneous device 108 is being withdrawn such

that a hub 144 of percutaneous device 108 move further away from y-connector 104 with a vector component along direction 124. moved away from y-connector 104. Referring to FIG 12B first clamp 140 moves toward second clamp 142 in the open non-clamped position and once first clamp is proximate second clamp 142 first clamp operatively clamps onto guidewire 106 (See FIG 12C). Second clamp 142 then unclamps from guidewire 106 and moves a distance in the direction 124 and clamps onto guidewire 106 (See FIG 12D). First clamp 140 unclamps from guidewire 106 and moves toward second clamp 144 as percutaneous device 108 is moved further away from y-connector 104 along vector 124. This process is repeated until the distal opening 126 of monorail 120 clears y-connector 104. (See FIGS 12E – 12G).

[0102] In one embodiment first clamp 140 and second clamp 142 are located and operated on a base 146 that is robotically moved away from y-connector 104 and operatively clamps a portion of percutaneous device 108. A schematic of base 146 having a percutaneous clamp member 148 is shown in FIG 12F. First clamp 140 and second clamp 142 are movable relative to base 146 such that the position of the guidewire remains fixed relative to the y-connector 104 and/or vasculature as base 146 is moved along vector 124.

[0103] In one embodiment first clamp 140 and second clamp 142 are supported on a separate structure that operates via a controller in communication with the movement of base 146. In one embodiment one or both of first clamp 140 and second clamp 142 are operated by a robotic arm having one degree of freedom and in one embodiment the robotic arm or arms have more than one degree of freedom.

[0104] Referring to FIG 13A a first clamp 150 and a second clamp 152 operate to maintain guidewire 106 in a fixed position relative to y-connector 104 and/or to maintain a distal end of guidewire 106 in a set position with a vasculature. As percutaneous device 108 is withdrawn from the vasculature and y-connector 104 with a movable drive clamps 150 and 152 operate to maintain guidewire 106 in a fixed position. Referring to FIG 13A first clamp 150 is in an open unclamped configuration in which clamp 150 is not clamping guidewire 106. Second clamp 152 is in a closed clamped configuration in which guidewire 106 is clamped thereto. Referring to FIG 13A – 13C as the proximal opening of the monorail lumen moves away from y-

connector 104 and approaches first clamp 150, first clamp 150 is moved to a position beyond second clamp 152. Stated another way second clamp 152 is moved from a position in which it is intermediate second clamp 152 and y-connector 104 to a position in which second clamp 152 is intermediate first clamp 150 and y-connector 104. First clamp is then moved from the open unclamped configuration to a closed clamped configuration in which first clamp 150 clamp guidewire 106. Second clamp 150 is then moved to an open position from the closed position to unclamp second clamp 150 from guidewire 106. The leap frog movement of first clamp 150 and second clamp 152 continues until the distal end of the monorail portion clears the y-connector 104 or stated another way until the distal end of the monorail is intermediate the proximal end of the y-connector 104 and the percutaneous movable drive. In one embodiment a percutaneous movable drive 154 includes a base 156 having a clamp to secure percutaneous member 108 thereto. Base 156 may be robotically moved on a slide member or a robotic arm in a linear direction 124.

[0105] In one embodiment first clamp 150 and second clamp 152 are supported on a separate structure that operates via a controller in communication with the movement of base 156. In one embodiment one or both of first clamp 150 and second clamp 152 are operated by a robotic arm having one degree of freedom and in one embodiment the robotic arm or arms have more than one degree of freedom. In one embodiment first clamp 150 and second clamp 152 are supported on the base having a mechanical linkage to provide leap frog movement that moves the first clamp 150 and second clamp 152 in a synchronized movement as base 156 moves away from y-connector 104 in the direction along vector 124.

[0106] Referring to FIG 4 proximity sensor 132 detects that the distal end of percutaneous device 108 has cleared the proximal end of y-connector 104 and sends a signal to a controller. Controller sends a signal to a proximal clamp 118 to clamp onto guidewire 106 between the distal end 126 of percutaneous device 108 and y-connector 104. In one embodiment y-connector includes a robotically controlled homeostasis valve that is activated to clamp onto guidewire 106 with sufficient force to maintain the position of the guidewire to the hemostasis valve as the percutaneous device 108 is removed completely from guidewire 106. Once proximal clamp 118

clamps onto guidewire 106, the wheels 114 and 116 release guidewire 106 and drive 102 continues to move along a path to remove the mono rail portion 120 off of the proximal end of guidewire 106. Once percutaneous device 108 has been removed from guidewire 106 it is possible to then guide a second percutaneous device 108 onto the proximal end of guidewire 106 either manually or robotically as described herein below.

[0107] In one embodiment, the first percutaneous device is removed from the guidewire robotically while the distal end of the guidewire is maintained in fixed position relative to the patient. In one embodiment the robotic system monitors guidewire movement during the removal of the first percutaneous device to ensure that the distal end remains stationary relative to the lesion. Adjustments may be made to the speed of the roller wheels relative to the linear movement of the movable drive 102 to ensure the distal end of the guidewire remains fixed with respect to the lesion. The distal end of the guidewire may be monitored using an imaging system or a portion of the guidewire external to the patient may be monitored for appropriate movement either through a visual imaging system or an electrical - mechanical interface.

[0108] Although the description describes a rapid exchange percutaneous device (monorail). System 100 is contemplated to be used both for a rapid exchange monorail type system and an over the wire system.

[0109] Referring to FIG 14 an over the wire percutaneous device 160 is secured to a clamp 162 proximal end hub 164. Clamp 162 is operatively secured to a drive 166 that moves clamp 162 and a guidewire mechanism 170. Drive 166 is moved in a direction 168 away from a y-connector and/or hemostasis valve on a slide member, robotic arm or other translation device as discussed above with respect to drive mechanism 102. Referring to FIG 15 clamp 162 includes a clamp portion 170 that releasably clips percutaneous device 160 to clamp 162.

[0110] Monorail Detection: In one embodiment after therapy is delivered and the balloon catheter is in the guide catheter, the balloon catheter is rapidly utilizing retracted until the monorail is detected as it exits the y-connector. In one embodiment, the monorail portion is detected, and a signal is sent to the control

system for either further manual manipulation or robotic manipulation. In one embodiment balloon catheter is robotically withdrawn via a signal from the controller with a percutaneous linear drive mechanism as is known in the art. The proximal end of the monorail portion is detected utilizing a proximity sensor 132 as discussed herein above. Once a proximal end of the monorail is detected in order to avoid damage to the balloon catheter the controller sends a signal to the percutaneous linear drive mechanism to stop so that that the guidewire and balloon catheter may be switched to the movable drive 102 as discussed above.

[0111] Proximal Dynamic Guidewire Fixation: In one embodiment, the guidewire is continuously held proximal to the balloon catheter's monorail while the monorail is advanced into or retracted from the y-connector and/or hemostasis valve. This arrangement is in place whenever the distal guidewire clamp would interfere with the balloon catheter.

[0112] Guidewire Distal Clamp: In one embodiment, a second clamp 118 is positioned on the proximal side of the y-connector (the side of the y-connector further away from the patient). The second clamp 118 operatively clamps on to the guidewire after the monorail clears the Y-connector on the proximal side. The second clamp is maintained onto the guidewire until a monorail of second percutaneous device is ready to advance into the y-connector.

[0113] Auto Backload: Proximal end of guidewire is held with respect to either the first or second percutaneous device to load one of the percutaneous devices onto the guidewire. In one embodiment a guiding structure robotically guides the monorail of the percutaneous device over the guidewire to automatically backload guidewire. The guidewire is continuously held distal to the balloon catheter distal tip while the monorail is fully advanced onto the guidewire. And/or guidewire is driven into monorail until it guidewire is past the monorail's guidewire exit port.

[0114] Motorized y-connector as described in US patent application No. 15/029,115 and incorporated herein by reference in its entirety: The motorized opening and closing of the y-connector valves allow for reduced friction between the portion of the percutaneous device that is coated and the y-connector. This is to minimize any damage to the coated portion of the percutaneous device as it travels through the y-

connector. This feature is in addition to fixate devices and control bleedback. Percutaneous devices with coated devices include a drug coated balloon or a drug eluting stent. The motorized opening and closing of the valve in the y-connector may be used as a clamp to secure the guidewire relative to the y-connector and/or hemostasis valve when the distal end of the percutaneous device 108 is past the proximal end of the y-connector in a direction away from patient.

[0115] Referring to FIG 19 and FIG 20 an automated percutaneous device exchange system 200 includes a loading module 202 and a drive module 208. Once a first percutaneous device 108 has been removed from the guidewire 106 a second percutaneous device 210 can be loaded onto guidewire 106. The system 200 may be used in conjunction with the system 100 as described herein above. Drive module 208 may be the same as movable drive 102 or may be the cassette drive mechanism that robotically controls the guidewire and a percutaneous device. In one embodiment a separate drive module 208 is used in the loading of the second percutaneous device 210 onto a guidewire. However, it is also contemplated that system 200 is used to load a first percutaneous drive member onto the guidewire as well. Once the first catheter or percutaneous device 108 is removed from guidewire 106, the proximal end of the guidewire is positioned within loading module 202. Loading module 202 is moved into a position between the proximal end of the guidewire and the hemostasis valve 104. As discussed herein below loading module may be formed from two components that move toward and away from one another to capture a portion of guidewire 106 within a drive mechanism 230. A clamp member 220 secures a portion of the guidewire proximal the hemostasis valve to fix the location of the distal end of the guidewire relative to one of a position with a vasculature, a patient, a patient bed, introducer, or the earth. As discussed above clamp member 232 may be the same as clamp member 118 or may be the robotic closing of the hemostasis valve.

[0116] Loading module 202 includes a guidewire drive 234 that operatively moves guidewire 106 along a vector 236. In one embodiment guidewire drive 234 includes a pair of roller members such as wheels that are robotically rotated to move guidewire 106 toward hemostasis valve 104. As guidewire 106 is moved toward hemostasis valve 104 a portion 228 of the guidewire 106 will need to be managed in a non-linear manner. In one embodiment the portion 228 of the guidewire 106 will be coiled. In one embodiment portion 228 may be robotically moved such that portion 228 forms a u-shaped loop. guidewire 106 is moved toward hemostasis valve 104 until a proximal end of the guidewire 106 is positioned within loading module 202.

[0117] Referring to FIGS 21 automated percutaneous device exchange system 200 includes a loading module 202 that supports a distal end of a percutaneous device 210 and threads the proximal end of a guidewire 106 into the monorail portion of percutaneous device 210. Clamp 220 pinches a portion of guidewire 106 on the proximal side of the y-connector 104. After loading module 202 moves into place a proximal end of guidewire 106 is thread into loading module 202. A pair of wheels robotically drive the proximal end of guidewire 106 in a direction away from y-connector 206. In the initial loading position a drive module 208 is positioned away from the loading module 202. The guidewire proximal tip is positioned to a known location within loading module 202 so that the tip is aligned to be inserted into the monorail portion of the percutaneous device.

[0118] Referring to FIG 23 the percutaneous device 210, which as illustrated is a balloon / stent catheter is loaded into loading module 202 such that the distal end of the monorail is adjacent the proximal end of the guidewire. The percutaneous device 210 is then clamped in both the loading module 202 and the drive module 208.

Referring to FIG 23 the loading module 202 drive wheels 218 drive the guidewire proximal tip through the monorail portion of the percutaneous device 210. Magnets may assist maintaining the guidewire on the correct path as it exits the monorail portion of the percutaneous device.

[0119] Referring to FIG 24 loading module 202 releases the percutaneous device 210 and the guidewire 106 and moves out of the way so that drive module 208 may move toward the y-connector. As explained above with respect to FIG 1 and FIG 2 drive wheels 224 on the drive module 102 maintain the guidewire 106 in a fixed location with respect to the patient as the drive module moves toward the y-connector. In one embodiment drive module 102 may be replaced with drive module 208 having a pair of wheels 226 act to both clamp the percutaneous device to the drive module 208 as well as to drive the percutaneous device into and out of the y-connector and patient.

[0120] Referring to FIG 25 the drive module 208 is adjacent the y-connector and operates to provide axial drive of both the percutaneous device and the guidewire.

[0121] Referring to FIG 21 loading module 202 includes a percutaneous device locator 238 that will be described in further detail below. The distal end 240 of

percutaneous device 210 is moved into device locator 238 by movement of drive module 208 toward loading module 202. In one embodiment device locator 238 is in an open configuration as distal end 240 is moved into loading module 202. Referring to FIG 22 once distal end 240 is in a loading position device location 238 moves to the closed configuration to hold and align percutaneous device 210. Referring to FIG 23 once the proximal end of the guidewire 106 and the distal end of the percutaneous device 210 are properly aligned guidewire 106 is inserted into a lumen of percutaneous device 210 by guidewire drive 234. In one embodiment the proximal end of guidewire 106 enters into and extends through drive module 208. Referring to FIG 24 once portion 228 of guidewire 106 is back to a linear path drive module 208 moves toward hemostasis valve 104 loading module 206 is moved from the path between drive module 208 and hemostasis valve 104. Referring to FIG 25 drive module 208 includes a guidewire drive 242 that operates to maintain guidewire 106 in a fixed location as drive module 208 moves towards hemostasis valve 104. In this manner percutaneous device 210 is moved along guidewire 106.

[0122] Referring to FIG 26 loading module 206 includes a guidewire drive 234 include a pair of roller wheels 243, 244 that operatively drive guidewire 106 toward and away from hemostasis valve 104. In one embodiment loading module 206 includes a base 245 formed from a first portion 246 and a second portion 248 that move toward and away from one another. In one embodiment first and second portion 246, 248 moves along a vector 252 substantially perpendicular to a longitudinal axis 250 of hemostasis valve 104 and a portion of guidewire 106. A first wheel 243 is positioned on first portion 246 and second wheel 244 is positioned on second portion 248. In one embodiment one of wheels 246, 248 is a drive wheel that is robotically controlled by a controller in a remote control station. guidewire drive 234 drives proximal end of guidewire 106 into the distal opening of the guidewire receiving lumen of percutaneous device 210.

[0123] Percutaneous device is positioned within device locator 238. In one embodiment device locator 238 forms a channel to positively position the percutaneous device 210 such that the distal opening of the guidewire lumen is positioned to receive the proximal end of the guidewire. In one embodiment a

longitudinal axis of the distal portion of the guidewire lumen and a longitudinal axis of the proximal portion of the guidewire are coaxial. In one embodiment the longitudinal axis of the distal portion of the guidewire lumen and the longitudinal axis of the proximal portion of the guidewire are at an obtuse angle relative to one another to assist in inserting the proximal end of the guidewire into the distal opening of the guidewire lumen of the percutaneous device 210 as is known in the art.

[0124] In one embodiment device location 238 includes a plurality of locating members 260 that operate to positively position the distal portion of the percutaneous device in a fixed position relative to base 245. In one embodiment a number of locating members 260 are positioned on first portion 246 and a number of locating members are positioned on second portion 248. Referring to FIGS 27-29 and 30 locating members each include a locating feature 262 such as a recess that positively positions the longitudinal axis of the distal portion of the percutaneous device relative to base 245. In one embodiment a first group of locating members 260 and a second group of locating members are moved toward and away from one another with a rack and pinion mechanism to form a channel that positively receives and positions the distal portion of the percutaneous device.

[0125] Referring to FIG 27 and FIG 28 In one embodiment a sensor 254 detects the location of the proximal tip of guidewire 106 and the distal end of percutaneous device 210. In one embodiment sensor 254 is a camera operatively coupled to an imaging system to identify the relative locations of the proximal end of the guidewire and the distal end of the percutaneous device and or more specifically to the opening to the guidewire lumen of the percutaneous device. It is also contemplated that sensor 254 be one of a magnetic sensor, inductive sensor, ultrasound sensor, tactile sensor or other sensors known in the art. In one embodiment a controller send a control signal to at least one operatively connected to members 260 to move members 260 based on an offset of the proximal end of guidewire and the distal end of the percutaneous device. In one embodiment members 260 are moved in at least two degrees of freedom. Referring to FIG 26 and FIG 28 sensor 254 may be mounted on base 245 or may be supported in a position by a holder other than base 245. In one embodiment sensor 254 is a 3-d sensor to identify the proximal end of the guidewire and the distal

end of the percutaneous device in three dimensional space. In one embodiment percutaneous device 210 has more than one lumen opening proximate the distal end of the percutaneous device and sensor 254 identifies the guidewire lumen opening and the controller directs the motor or motors to align the proximal end of the guidewire with the guidewire lumen opening of the percutaneous device.

[0126] Referring to FIGS 31 and 32 the first group of members and the second group of members in a first position are separated by a distance to allow the placement of the guidewire and percutaneous device therebetween. Once the sensor detects the proper position of the guidewire and percutaneous device along at least one direction the members are moved toward one another to positively locate the proximal end of the guidewire with the distal opening of the guidewire lumen of the percutaneous device. In one embodiment members are used to position both the guidewire 106 and catheter 210. A first channel is formed by a first group of members 260 for positioning the guidewire and a second channel is formed by a second group of members 260 for positioning the catheter. In one embodiment certain members 260 form a third channel region 59 that does not contact a portion of the catheter 266 having a therapeutic device such as a balloon, stent or other therapeutic materials.

[0127] Referring to FIG 33 and FIG 34, the distal tips 261 of members 260 in recess 262 have a nonlinear tip. In one embodiment the shape of the tips 261 are arcuate and in one embodiment the tips converge to a vertex. In one embodiment tips 261 are formed of a softer material than the rest of members 260.

[0128] Referring to FIG 35 and 36 first portion 248 and second portion 246 are separate as guidewire and percutaneous device are positioned for loading. Referring to FIG 37 once the distal end of the guidewire and the proximal end of the percutaneous device are positioned a set distance 270 from one another members 260 are then moved to a closed channel position and the distal end of the guidewire is advanced into the guidewire lumen of the percutaneous device.

[0129] Referring to FIG 38 and 39 members 260 may be rotated relative to one another about a pivot 280 to positively position a distal portion of the percutaneous device therein to positively align the distal portion of the percutaneous device with the proximal end of the guidewire. In one embodiment locator members may be

controlled separately or in groups to provide different channel gaps therebetween to accommodate different size percutaneous devices and to accommodate different outer diameters of portions of the percutaneous devices such as a balloon or stent. In one embodiment a subset of the locator members 260 provide a larger diameter channel proximate a sensitive portion of the percutaneous device such as a stent, balloon, or other therapeutic element 266.

[0130] In one embodiment a system for removing a catheter from a percutaneous device includes a hemostasis valve, and a base having a clamp releasably coupling a catheter to the base. A base drive member moves the base relative to the hemostasis valve along a first path. A mechanism maintains the position of the percutaneous device relative to the hemostasis valve while the catheter is being moved in along the first path. The term hemostasis valve includes but is not limited to a hemostasis valve that is part of an introducer sheath, a removable hemostasis valve adapter, a hemostasis valve Y-connector, a touhy-borst hemostasis valve and other hemostasis valves known in the art. In one embodiment the catheter is received directly within the hemostasis valve with no second catheter device extending about the catheter and the hemostasis valve. Or stated another way the catheter is directly in the hemostasis valve where catheter is not positioned within a guide catheter that extends through an introducer sheath's hemostasis valve.

[0131] In an example where a balloon catheter is not directly in the hemostasis valve the balloon catheter is a lumen of a guide catheter and the guide catheter goes through the hemostasis valve. In one embodiment the elongated medical device is a guidewire, but other percutaneous devices are contemplated. In one embodiment at least a portion of the first path is linear. In one embodiment at least a portion of the first path is non-linear.

[0132] In one embodiment the catheter is a guide catheter and the elongated medical device is a guidewire and the hemostasis valve is connected to the introducer sheath.

[0133] It is contemplated that holding mechanism 110 acts as a clamp to releasably couples catheter 108. It is also contemplated in one embodiment holding mechanism 110 may include a linear drive member that functions to releasably couple catheter 108 therein in addition to linearly driving catheter 108 along the longitudinal axis of

the catheter. The longitudinal axis of the catheter is defined as the path through a center portion of the catheter.

[0134] It is contemplated that in one embodiment an integrated exchange system includes the unloading mechanism illustrated in FIGS 1-18 and the loader discussed herein above and illustrated in FIGS 19-39. Further it is contemplated that a robotic drive of a guidewire, elongated medical device such as a catheter and a guide catheter may be robotically operated in conjunction with loading and unloading mechanisms together or separately and controlled via a controller at a remote work station. In one embodiment the catheter loading and catheter unloading devices as discussed herein may move independently between an in-use and non-use position as required to allow proper functioning of all systems.

[0135] Although the present disclosure has been described with reference to example embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the defined subject matter. For example, although different example embodiments may have been described as including one or more features providing one or more benefits, it is contemplated that the described features may be interchanged with one another or alternatively be combined with one another in the described example embodiments or in other alternative embodiments. Because the technology of the present disclosure is relatively complex, not all changes in the technology are foreseeable. The present disclosure described is manifestly intended to be as broad as possible. For example, unless specifically otherwise noted, the definitions reciting a single particular element also encompass a plurality of such particular elements.

WHAT IS CLAIMED IS:

1. An apparatus comprising:
 - a hemostasis valve;
 - a base having a clamp releasably coupling a catheter to the base;
 - a base drive member moving the base relative to the hemostasis valve along a first path;
 - a mechanism maintaining the position of an elongated medical device relative to the hemostasis valve while the catheter is being moved along the first path.
2. The apparatus of claim 1, wherein a portion of the elongated medical device is removably positioned within a lumen of the catheter.
3. The apparatus of claim 1, wherein the first path is a direction that is substantially parallel to both a longitudinal axis of the elongated medical device and a longitudinal axis of the catheter.
4. The apparatus of claim 1, wherein a distal portion of the elongated medical device is maintained in a substantially fixed location relative to an anatomical feature within a patient as the base moves in the first direction, and wherein the distance between the distal portion of the elongated medical device and the base changes as the base moves along the first path.
5. The apparatus of claim 1, wherein at least a portion of the first path is linear.
6. The apparatus of claim 1, wherein at least a portion of the first path is not-linear.
7. The apparatus of claim 1, wherein the base moves along the elongated medical device as the base moves in the first direction.

8. The apparatus of claim 1, wherein the mechanism includes a discrete movement drive mechanism that moves the elongated medical device relative to the base in a series of discrete distances.
9. The apparatus of claim 1, wherein the base drive member moves the base with one or more degrees of freedom.
10. The apparatus of claim 1, wherein the base drive member is being moved by a robotic arm having one or more degrees of freedom.
11. The apparatus of claim 10 wherein the robotic arm moves the base relative to an access site on the patient.
12. The apparatus of claim 10 wherein the robotic arm moves the base relative to a position on a patient bed.
13. The apparatus of claim 1, wherein the catheter is a rapid exchange device having a monorail portion having a lumen therein for a fixed length, the elongated medical device being movably received in the lumen of the monorail portion.
14. The apparatus of claim 12, further including distal clamp removably clamping a portion of the elongated medical device once a distal end of the monorail portion of the catheter is between the distal clamp and the base.
15. The apparatus of claim 14, wherein the distal clamp is positioned between the hemostasis valve and the base.
16. The apparatus of claim 14, wherein the elongated medical device is free to move relative to the mechanism when the distal clamp clamps the elongated medical device thereto.
17. The apparatus of claim 14, wherein the elongated medical device is removed from the mono rail by an elongated medical device removal drive that moves the elongated medical device through the monorail in a second direction such

that the proximal end of the elongated medical device is pulled through the monorail toward the hemostasis valve.

18. The apparatus of claim 1 wherein the mechanism includes a pair of wheels operatively moving the guidewire relative to the base.
19. The apparatus of claim 1 wherein the mechanism includes a first clamp member and a second clamp member moving in direction away from the hemostasis pair of clamp members.
20. The apparatus of claim 19 wherein the first clamp member moves from a first position where the first clamp is intermediate the second clamp and the hemostasis valve and to a second position where the second clamp is intermediate the first clamp and the hemostasis valve.
21. The apparatus of claim 1, wherein the elongated medical device is a guidewire.
22. The apparatus of claim 1, wherein the catheter is an over the wire device having a lumen extending from a proximal end to a distal end of the catheter, the elongated medical device being movably received in the lumen.
23. The apparatus of claim 1, wherein a portion of the elongated medical device is maintained in a substantially fixed location relative to the hemostasis valve as the base moves in the first direction, and wherein the distance between the portion of the elongated medical device and the base changes as the base moves along the first path.
24. An apparatus for loading an elongated medical device through a lumen of a catheter comprising:
 - a catheter support positioning a distal end of a catheter having a catheter lumen;

a drive moving the elongated medical device relative to the catheter inserting a proximal end of the elongated medical device into a distal opening of the catheter lumen.

25. The apparatus of claim 24, wherein the drive moves the proximal end of the elongated medical device to exit through a proximal end of the catheter lumen.
26. The apparatus of claim 24, wherein the catheter support and drive are moveably positioned between an in-use position and a non-use position.
27. The apparatus of claim 24, further including a base having a first base portion supporting a first portion of the drive and a first portion of the catheter support, and a second base portion supporting a second portion of the drive and a second portion of the catheter support.
28. The apparatus of claim 27, wherein the first base portion and second base portion move along a linear path toward and away from the in-use position.
29. The apparatus of claim 27, wherein the first base portion and second base portion move along a non-linear path toward and away from the in-use position.
30. The apparatus of claim 24, wherein the catheter support includes a plurality of regions selectively contacting portions of the catheter.
31. The apparatus of claim 30 wherein the plurality of regions are movably controlled by a controller in one or more degrees of freedom.
32. The apparatus of claim 24 further including an imaging system detecting the location of the distal tip of the elongated medical device and the proximal opening of the catheter lumen.
33. The apparatus of claim 32, further including a control system using information from the imaging system to provide instructions via a controller to

position the drive and the catheter locator to align the proximal tip of the elongated medical device with the opening of the distal end of the catheter lumen.

34. The apparatus of claim 24, wherein the catheter locator includes a portion configured to avoid contact with a therapeutic element positioned on the catheter.
35. The apparatus of claim 24 wherein the catheter support and drive are moved between an in-use and non-use position by one of a robotic arm, linear actuator, movable base and a rotational base.
36. The apparatus of claim 24 wherein the elongated medical device is a guidewire.
37. An apparatus comprising:
 - A hemostasis valve;
 - a loader including:
 - a catheter support positioning a distal end of a catheter having a catheter lumen; and
 - an elongated percutaneous drive moving the elongated medical device relative to the second catheter inserting a proximal end of the elongated medical device into a distal opening of the catheter lumen;
 - and
 - an unloader including:
 - a base having a clamp releasably coupling a first catheter to the base;
 - a base drive member moving the base relative to the hemostasis valve along a first path; and
 - a mechanism maintaining the position of an elongated medical device relative to the hemostasis valve while the catheter is being moved along the first path.

38. An apparatus comprising:
- a hemostasis valve;
 - a base having a clamp releasably coupling a first catheter to the base;
 - a base drive member moving the base relative to the hemostasis valve along a first path;
 - a mechanism maintaining the position of an elongated medical device relative to the hemostasis valve while the catheter is being moved along the first path;
 - a catheter support positioning a distal end of a second catheter having a catheter lumen; and
 - an elongated percutaneous drive moving the elongated medical device relative to the second catheter inserting a proximal end of the elongated medical device into a distal opening of the catheter lumen.

AMENDED CLAIMS
received by the International Bureau on 16 July 2018
(16.07.2018)

1. An apparatus comprising:
 - a hemostasis valve;
 - a base having a clamp releasably coupling a catheter to the base;
 - a base drive member moving the base relative to the hemostasis valve along a first path;
 - a mechanism maintaining the position of an elongated medical device relative to the hemostasis valve while the catheter is being moved along the first path.
2. The apparatus of claim 1, wherein a portion of the elongated medical device is removably positioned within a lumen of the catheter.
3. The apparatus of claim 1, wherein the first path is a direction that is substantially parallel to both a longitudinal axis of the elongated medical device and a longitudinal axis of the catheter.
4. The apparatus of claim 1, wherein a distal portion of the elongated medical device is maintained in a substantially fixed location relative to an anatomical feature within a patient as the base moves in the first direction, and wherein the distance between the distal portion of the elongated medical device and the base changes as the base moves along the first path.
5. The apparatus of claim 1, wherein at least a portion of the first path is linear.
6. The apparatus of claim 1, wherein at least a portion of the first path is non-linear.
7. The apparatus of claim 1, wherein the base moves along the elongated medical device as the base moves in the first direction.

8. The apparatus of claim 1, wherein the mechanism includes a discrete movement drive mechanism that moves the elongated medical device relative to the base in a series of discrete distances.
9. The apparatus of claim 1, wherein the base drive member moves the base with one or more degrees of freedom.
10. The apparatus of claim 1, wherein the base drive member is being moved by a robotic arm having one or more degrees of freedom.
11. The apparatus of claim 10 wherein the robotic arm moves the base relative to an access site on a patient.
12. The apparatus of claim 10 wherein the robotic arm moves the base relative to a position on a patient bed.
13. The apparatus of claim 1, wherein the catheter is a rapid exchange device having a monorail portion having a lumen therein for a fixed length, the elongated medical device being movably received in the lumen of the monorail portion.
14. The apparatus of claim 1, further including a distal clamp removably clamping a portion of the elongated medical device once a distal end of a monorail portion of the catheter is between the distal clamp and the base.
15. The apparatus of claim 14, wherein the distal clamp is positioned between the hemostasis valve and the base.
16. The apparatus of claim 14, wherein the elongated medical device is free to move relative to the mechanism when the distal clamp clamps the elongated medical device thereto.
17. The apparatus of claim 14, wherein the elongated medical device is removed from the mono rail by an elongated medical device removal drive that moves the elongated medical device through the monorail in a second direction such that the

proximal end of the elongated medical device is pulled through the monorail toward the hemostasis valve.

18. The apparatus of claim 1 wherein the mechanism includes a pair of wheels operatively moving a guidewire relative to the base.

19. The apparatus of claim 1, wherein the mechanism includes a first clamp member and a second clamp member moving in a direction away from the hemostasis valve.

20. The apparatus of claim 19 wherein the first clamp member moves from a first position where the first clamp is intermediate the second clamp and the hemostasis valve and to a second position where the second clamp is intermediate the first clamp and the hemostasis valve.

21. The apparatus of claim 1, wherein the elongated medical device is a guidewire.

22. The apparatus of claim 1, wherein the catheter is an over the wire device having a lumen extending from a proximal end to a distal end of the catheter, the elongated medical device being movably received in the lumen.

23. The apparatus of claim 1, wherein a portion of the elongated medical device is maintained in a substantially fixed location relative to the hemostasis valve as the base moves in the first direction, and wherein the distance between the portion of the elongated medical device and the base changes as the base moves along the first path.

24. An apparatus for loading an elongated medical device through a lumen of a catheter comprising:

a catheter support positioning a distal end of a catheter having a catheter lumen;

a drive moving the elongated medical device relative to the catheter inserting a proximal end of the elongated medical device into a distal opening of the catheter lumen.

25. The apparatus of claim 24, wherein the drive moves the proximal end of the elongated medical device to exit through a proximal end of the catheter lumen.
26. The apparatus of claim 24, wherein the catheter support and drive are moveably positioned between an in-use position and a non-use position.
27. The apparatus of claim 24, further including a base having a first base portion supporting a first portion of the drive and a first portion of the catheter support, and a second base portion supporting a second portion of the drive and a second portion of the catheter support.
28. The apparatus of claim 27, wherein the first base portion and second base portion move along a linear path toward and away from the in-use position.
29. The apparatus of claim 27, wherein the first base portion and second base portion move along a non-linear path toward and away from the in-use position.
30. The apparatus of claim 24, wherein the catheter support includes a plurality of regions selectively contacting portions of the catheter.
31. The apparatus of claim 30 wherein the plurality of regions are movably controlled by a controller in one or more degrees of freedom.
32. The apparatus of claim 24 further including an imaging system detecting the location of a distal tip of the elongated medical device and the proximal opening of the catheter lumen.
33. The apparatus of claim 32, further including a control system using information from the imaging system to provide instructions via a controller to position the drive and a catheter locator to align the proximal tip of the elongated medical device with the opening of the distal end of the catheter lumen.

34. The apparatus of claim 24, wherein the catheter locator includes a portion configured to avoid contact with a therapeutic element positioned on the catheter.
35. The apparatus of claim 24 wherein the catheter support and drive are moved between an in-use and non-use position by one of a robotic arm, linear actuator, movable base and a rotational base.
36. The apparatus of claim 24 wherein the elongated medical device is a guidewire.
37. An apparatus comprising:
- a hemostasis valve;
 - a loader including:
 - a catheter support positioning a distal end of a catheter having a catheter lumen; and
 - an elongated percutaneous drive moving an elongated medical device relative to a second catheter inserting a proximal end of the elongated medical device into a distal opening of the catheter lumen;
 - and
 - an unloader including:
 - a base having a clamp releasably coupling a first catheter to the base;
 - a base drive member moving the base relative to the hemostasis valve along a first path; and
 - a mechanism maintaining the position of an elongated medical device relative to the hemostasis valve while the catheter is being moved along the first path.
38. An apparatus comprising:

a hemostasis valve;

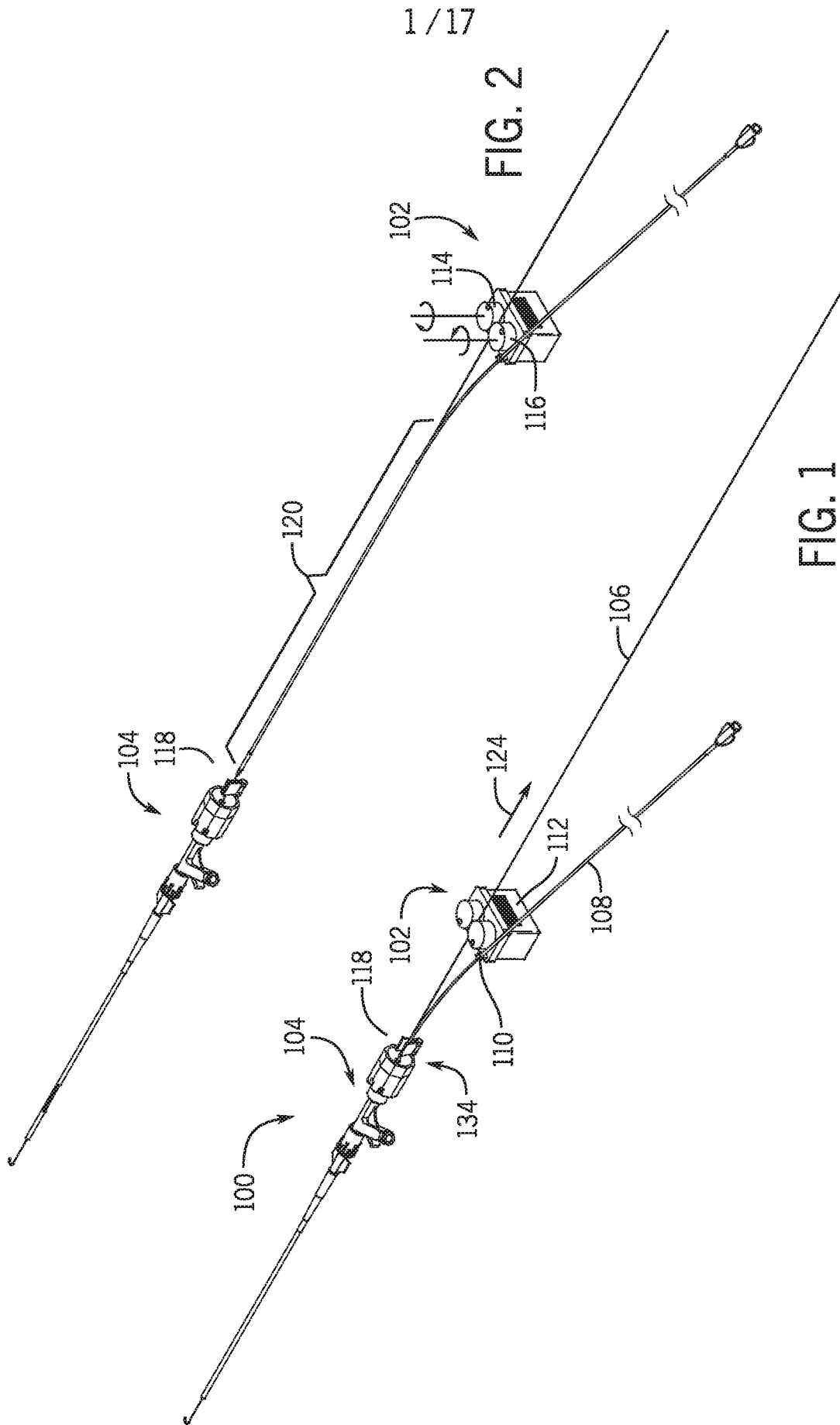
a base having a clamp releasably coupling a first catheter to the base;

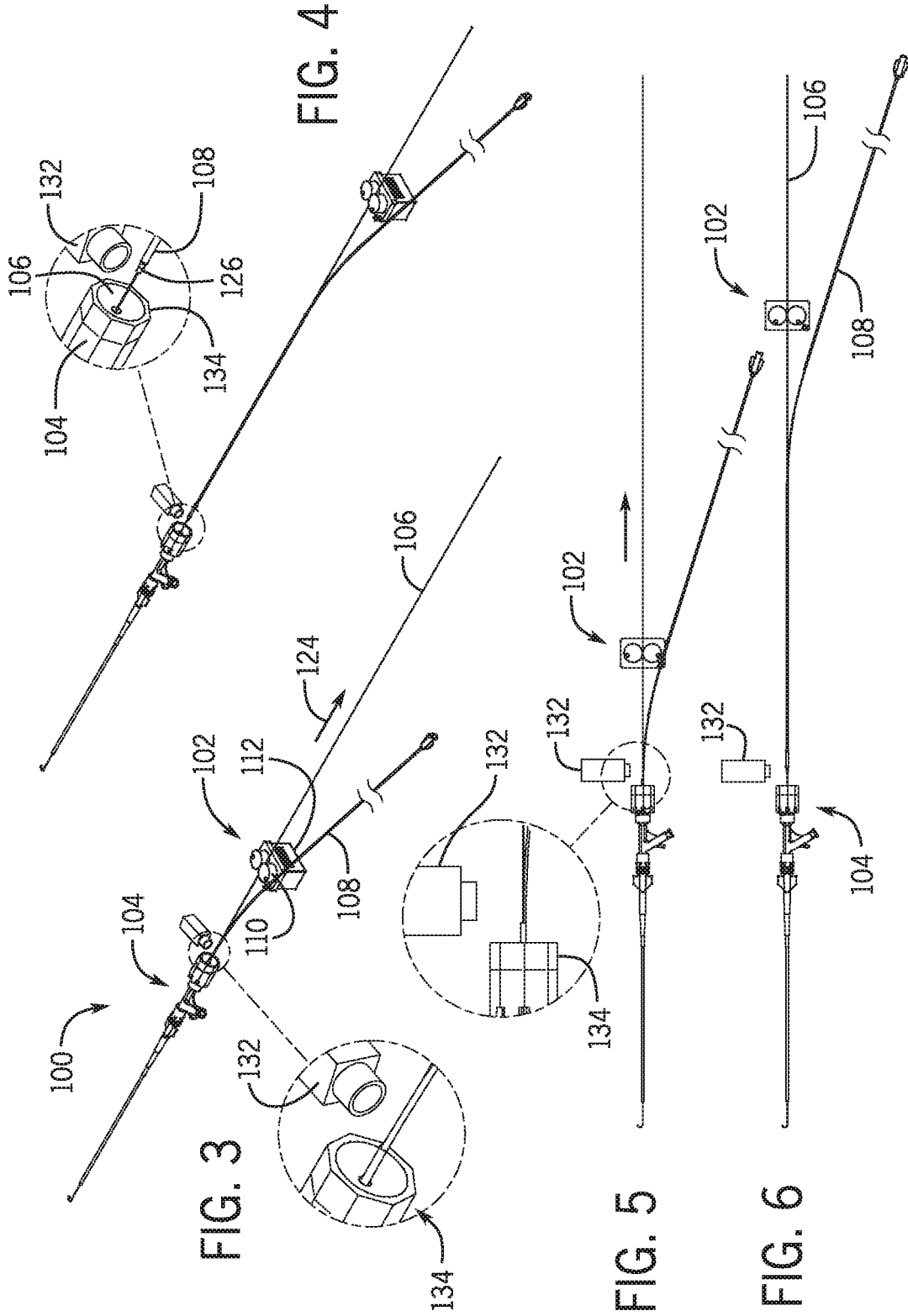
a base drive member moving the base relative to the hemostasis valve along a first path;

a mechanism maintaining the position of an elongated medical device relative to the hemostasis valve while the catheter is being moved along the first path;

a catheter support positioning a distal end of a second catheter having a catheter lumen; and

an elongated percutaneous drive moving the elongated medical device relative to the second catheter inserting a proximal end of the elongated medical device into a distal opening of the catheter lumen.





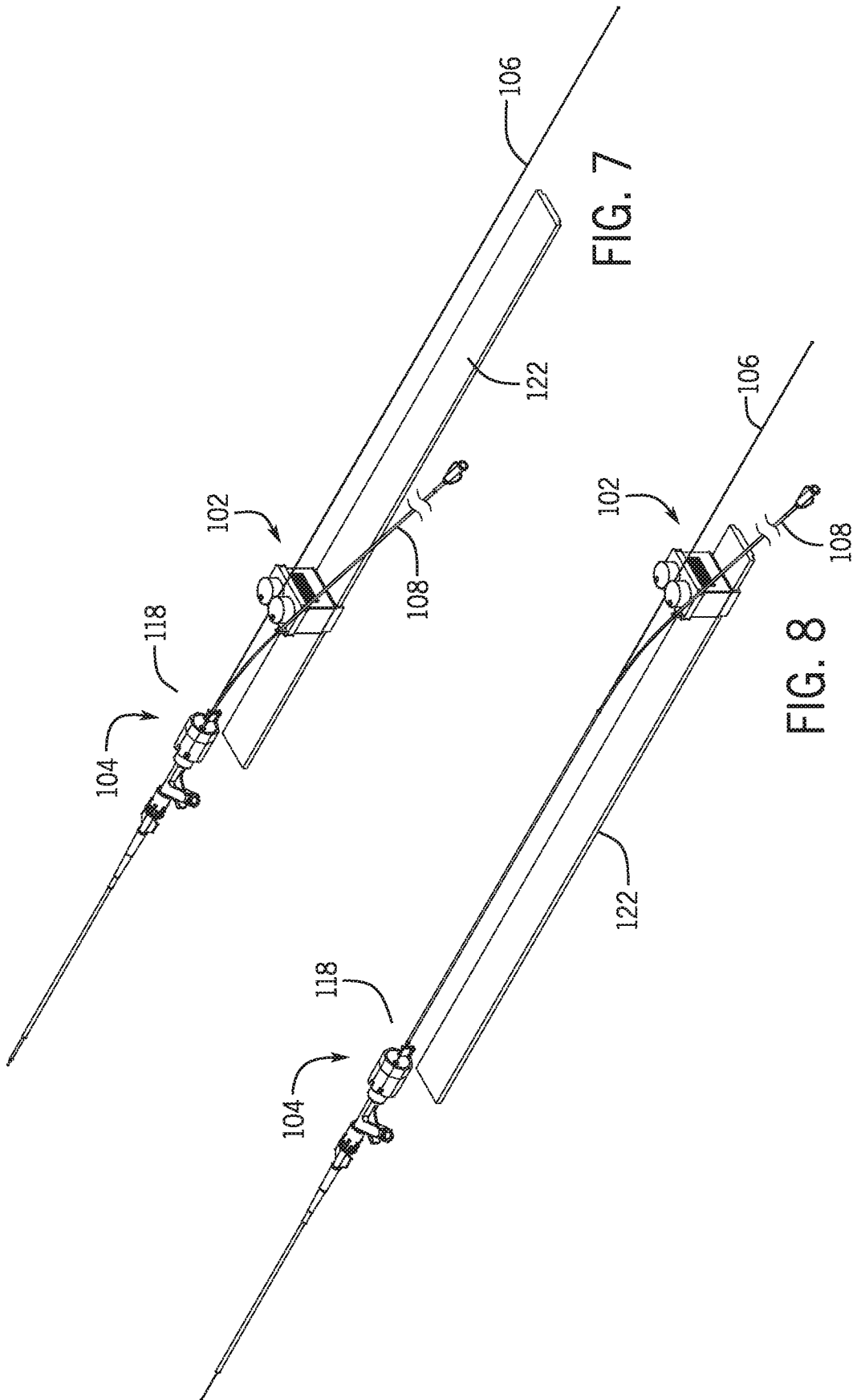


FIG. 7

FIG. 8

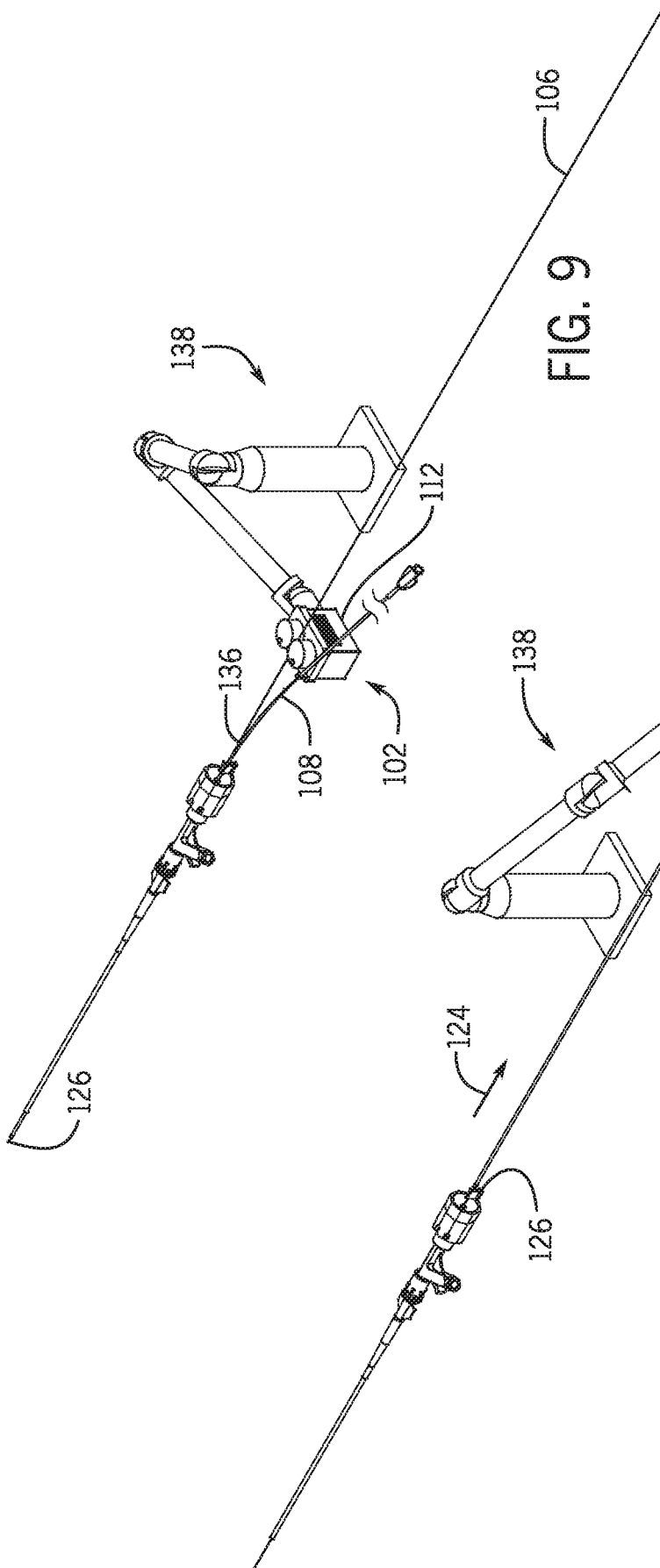


FIG. 9

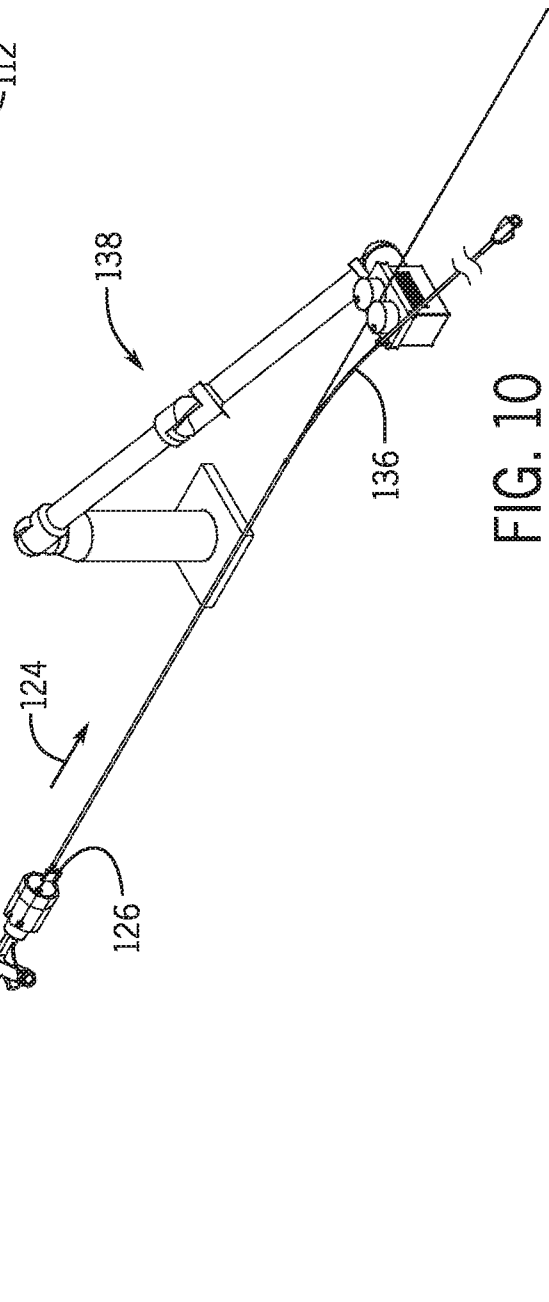


FIG. 10

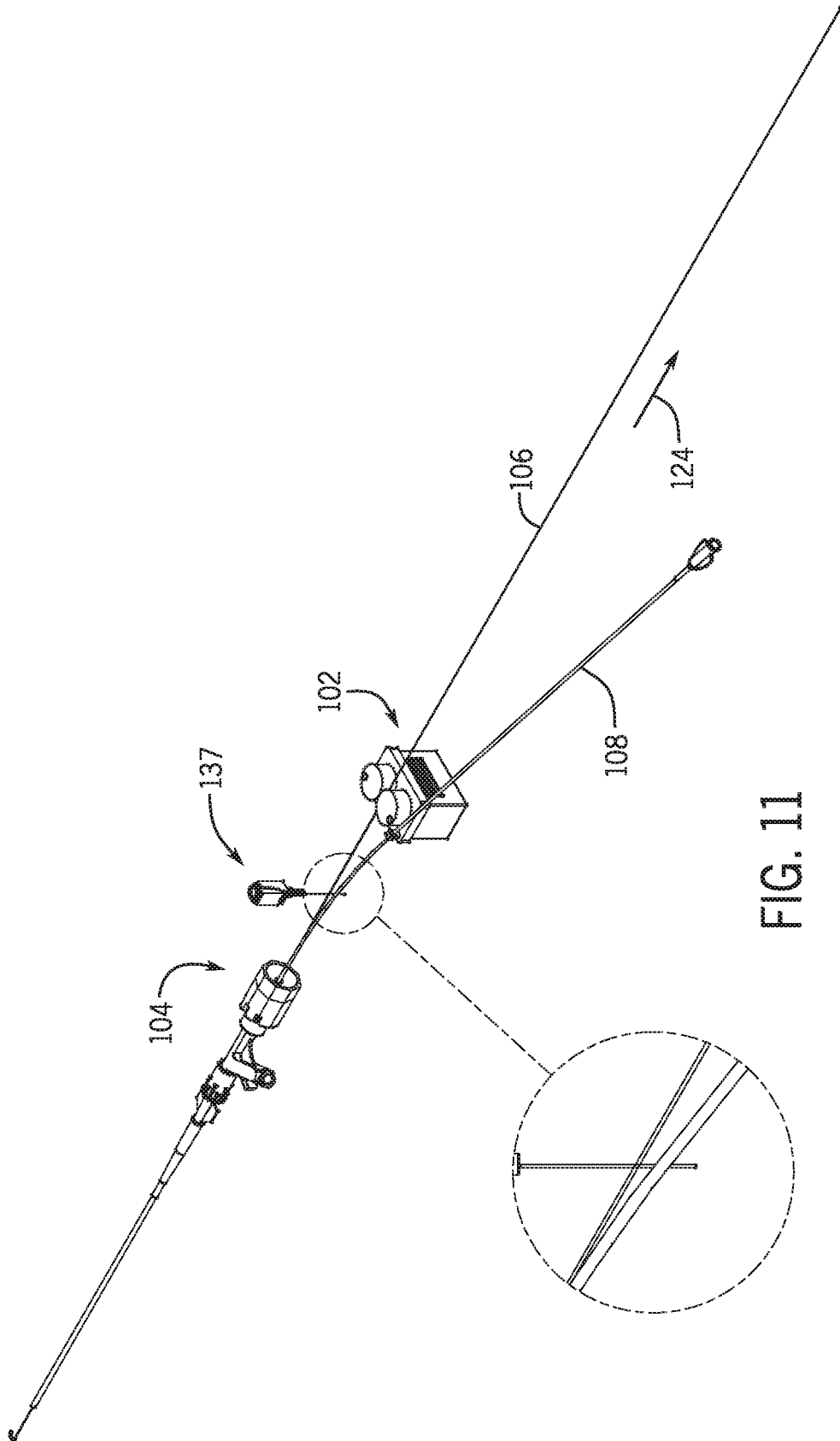
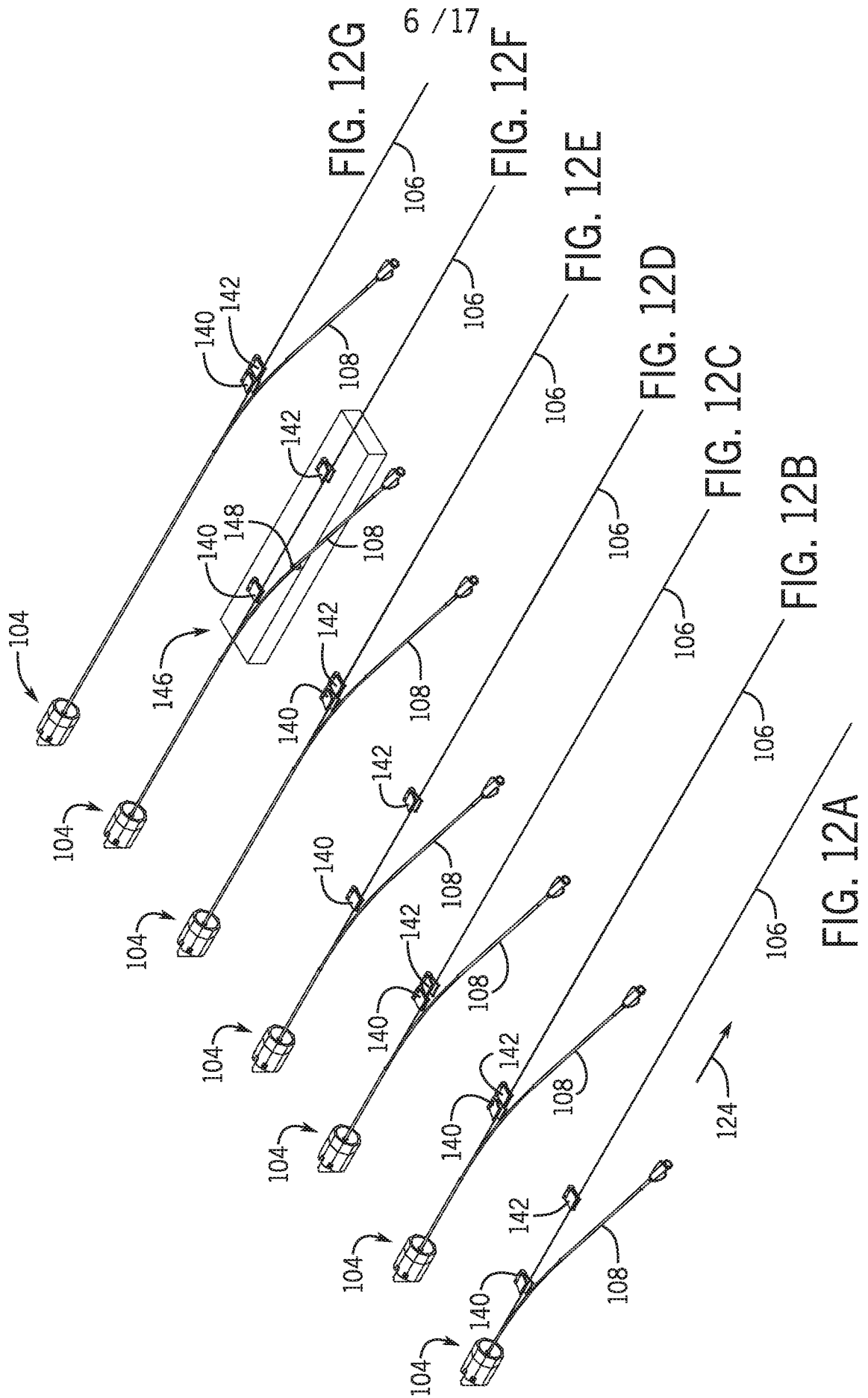
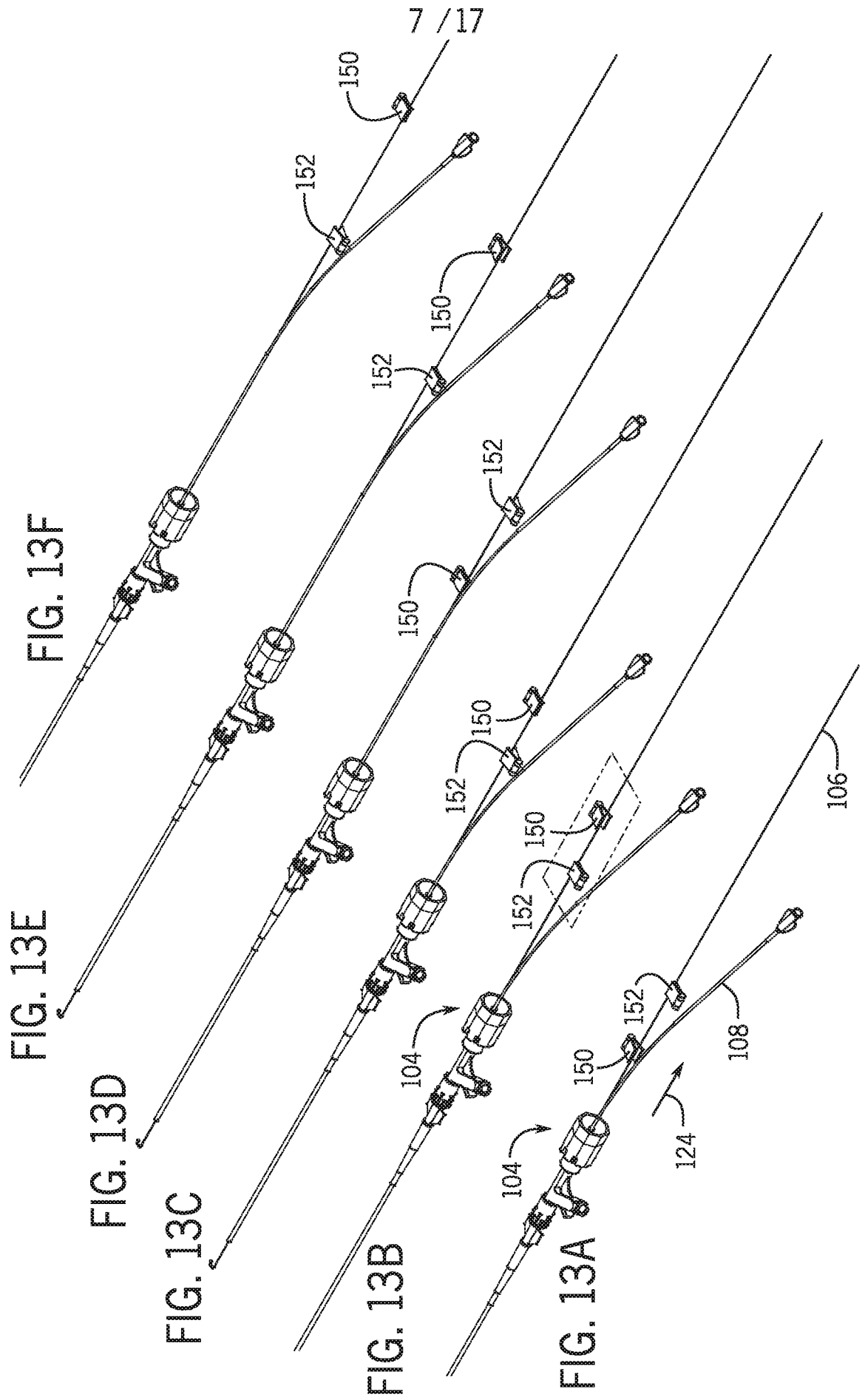


FIG. 11





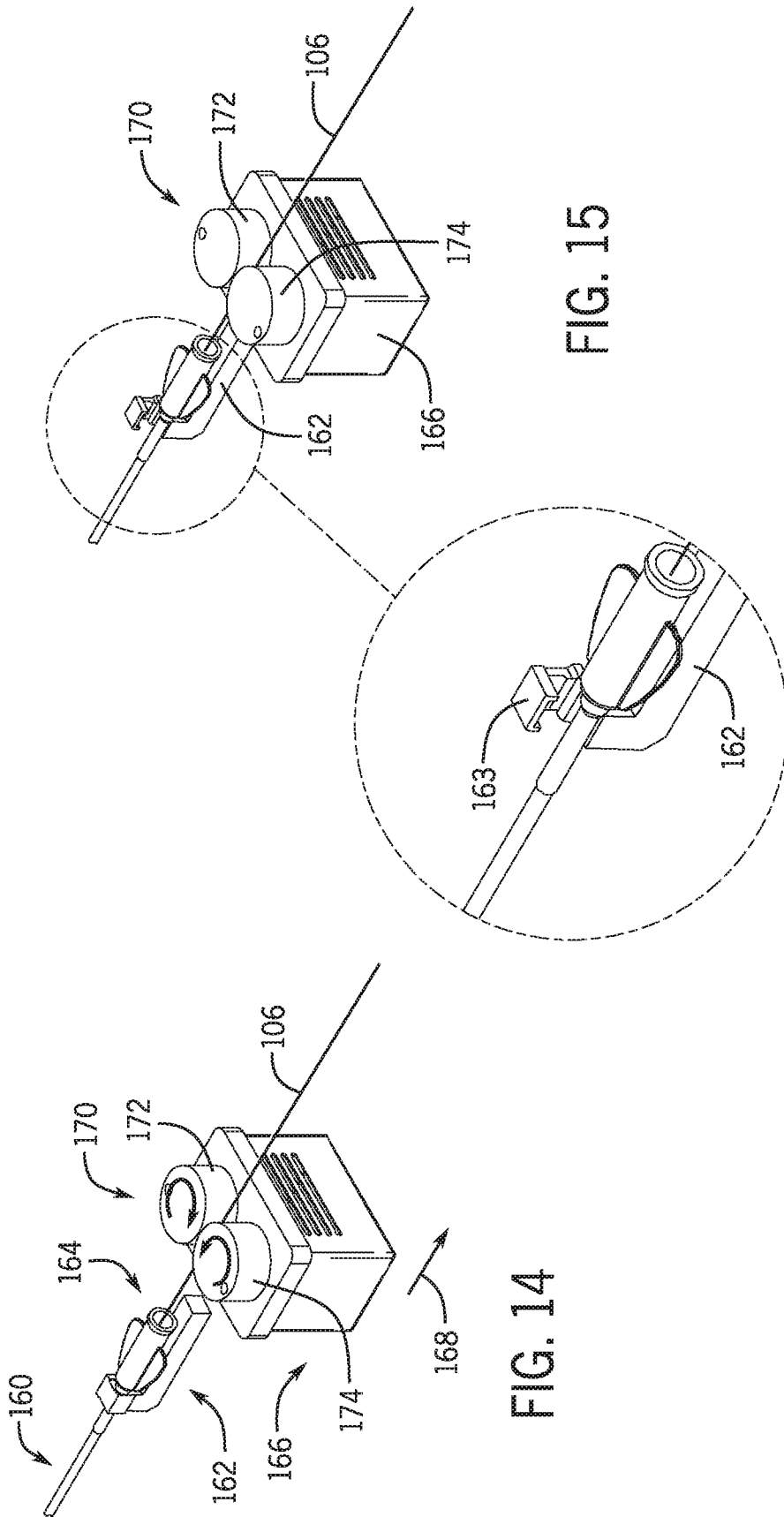


FIG. 15

FIG. 14

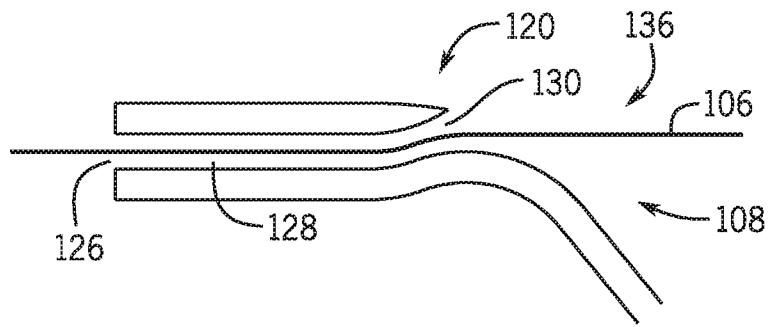


FIG. 16

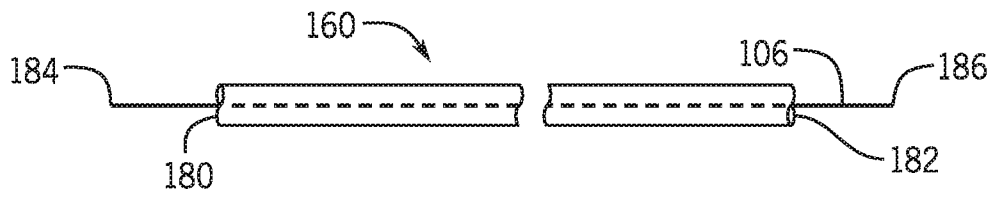


FIG. 17

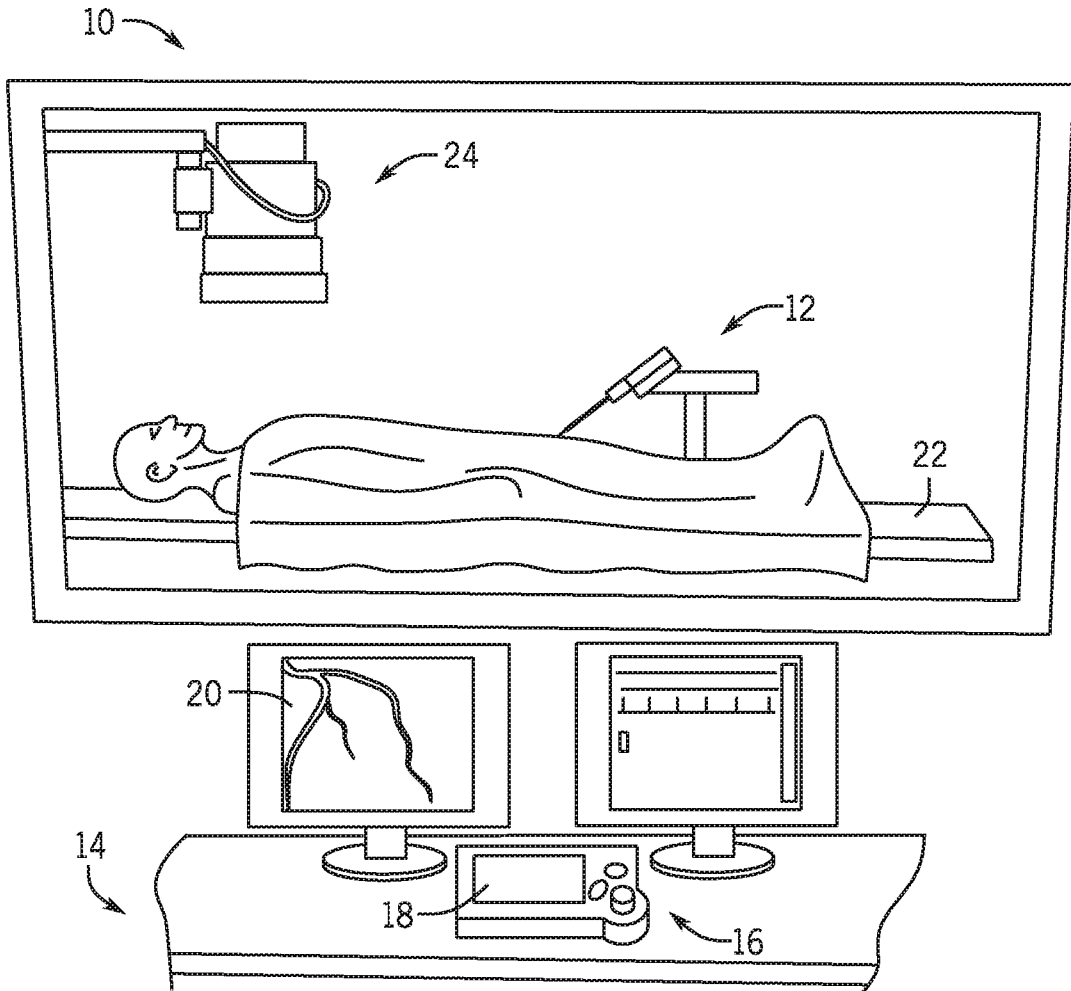


FIG. 18

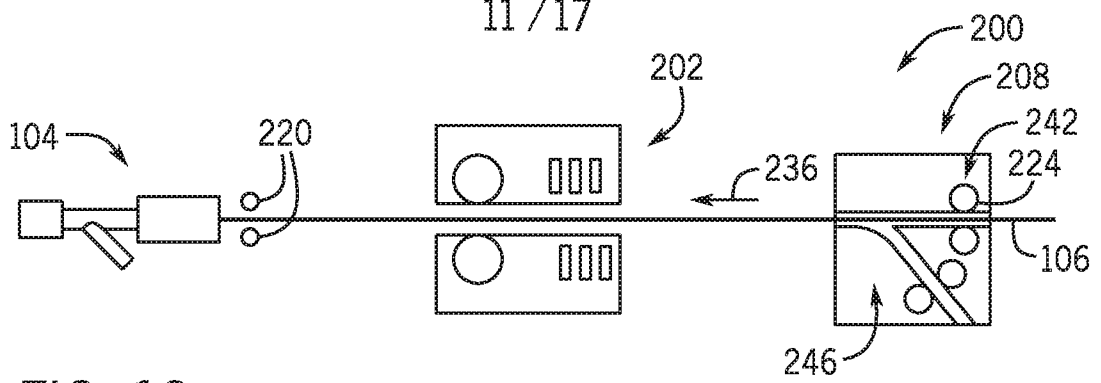


FIG. 19

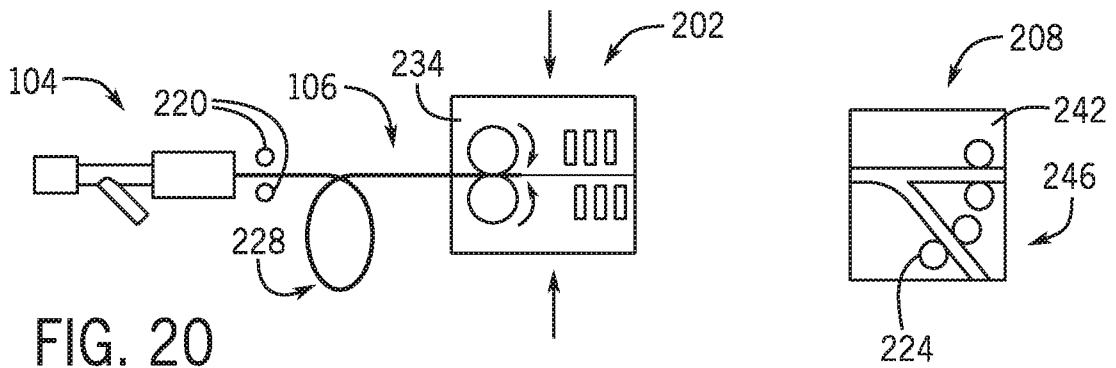


FIG. 20

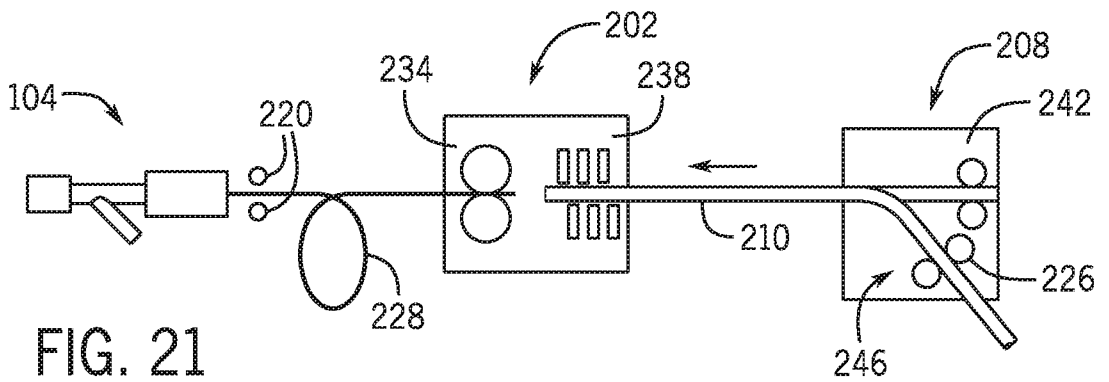


FIG. 21

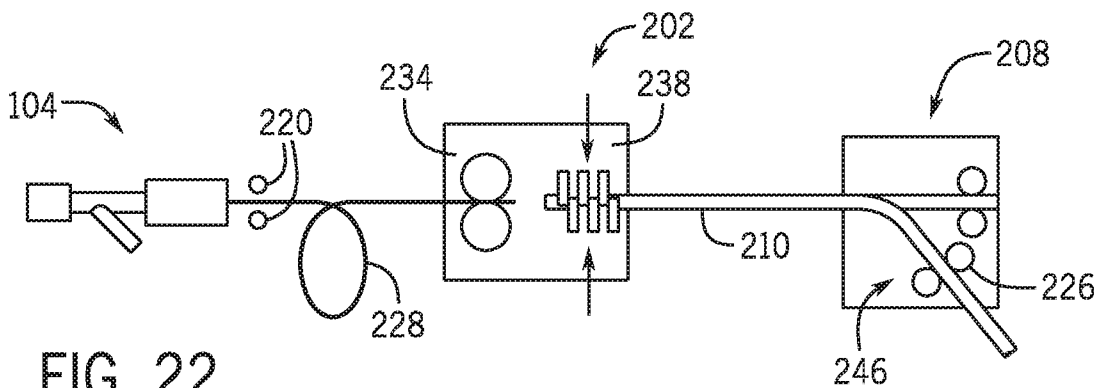
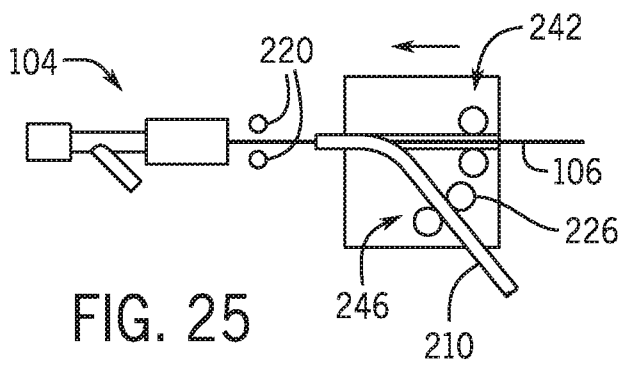
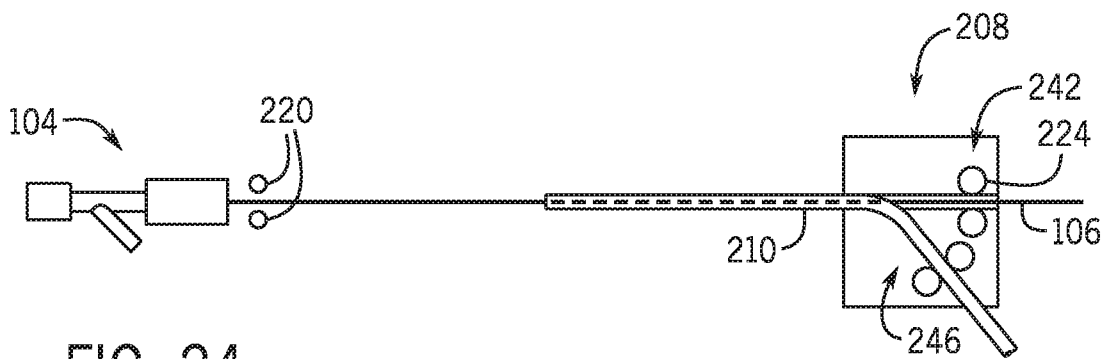
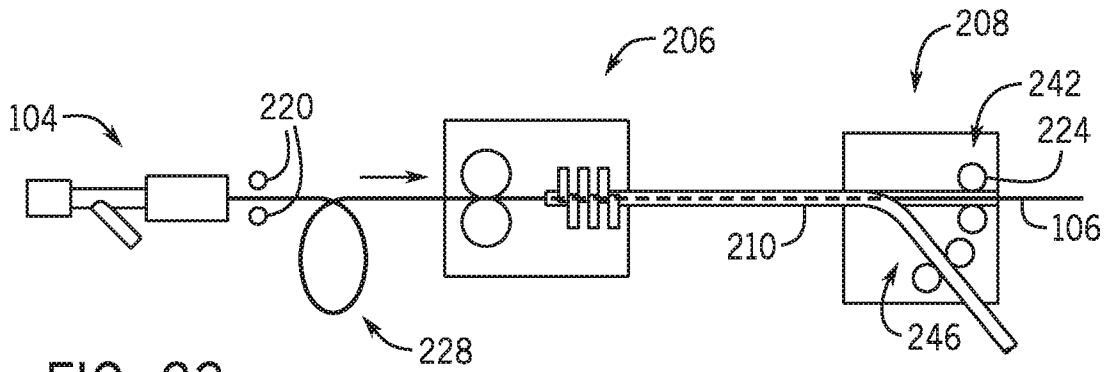
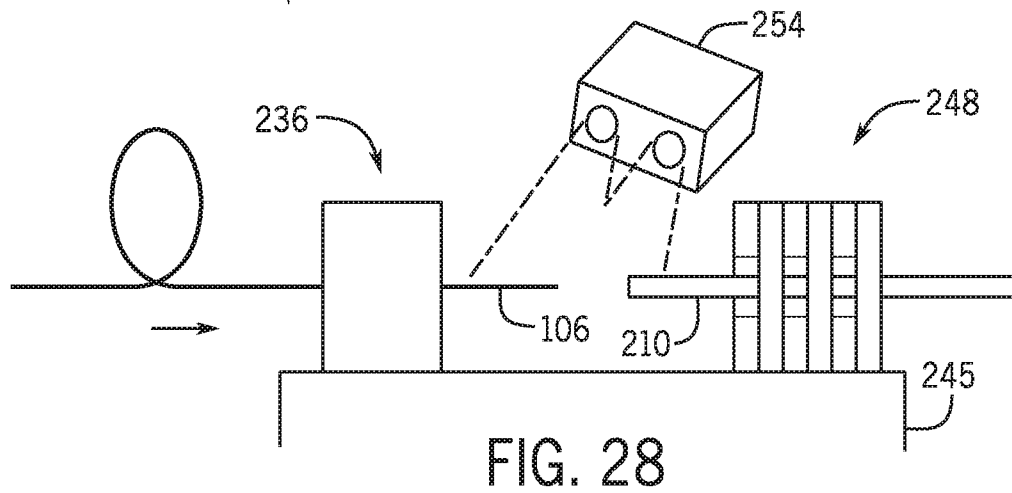
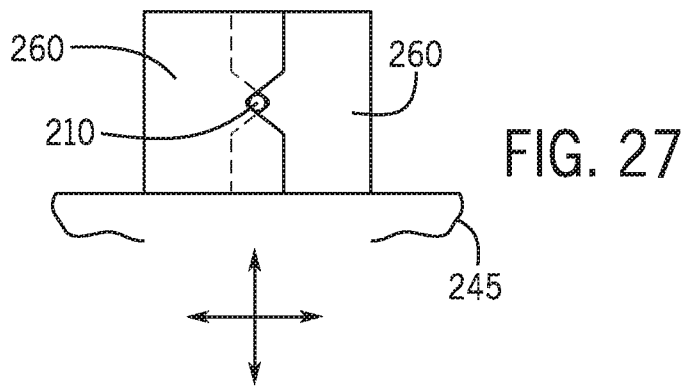
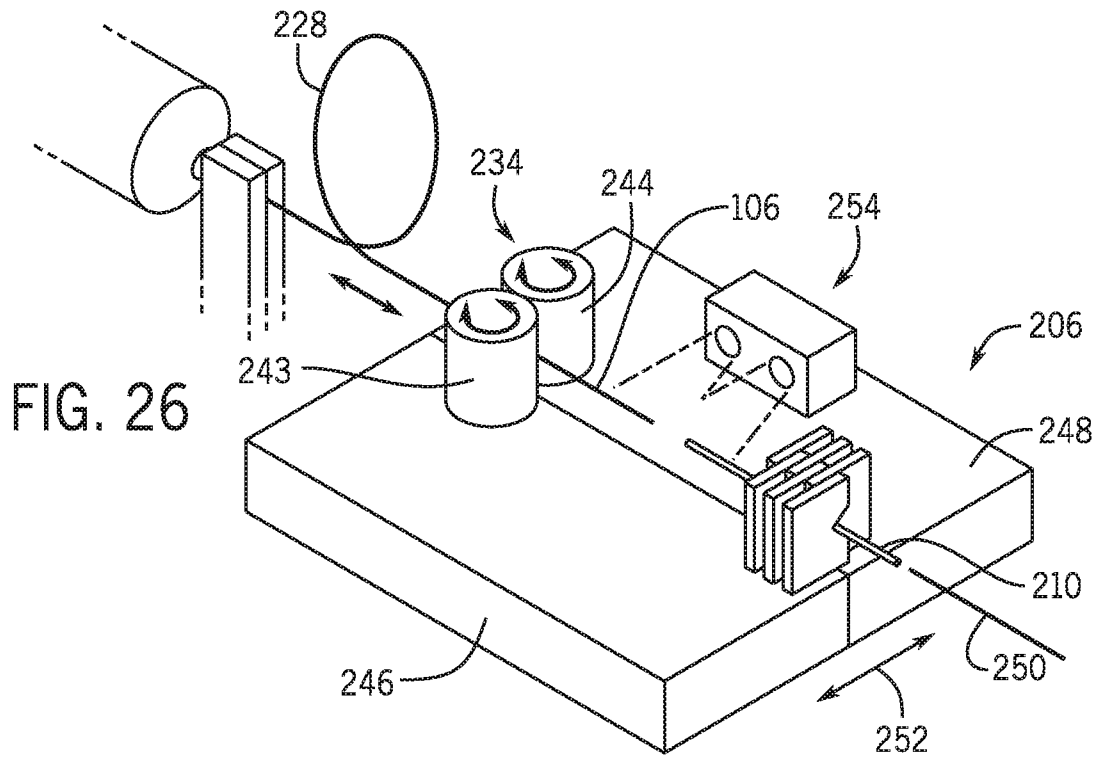


FIG. 22





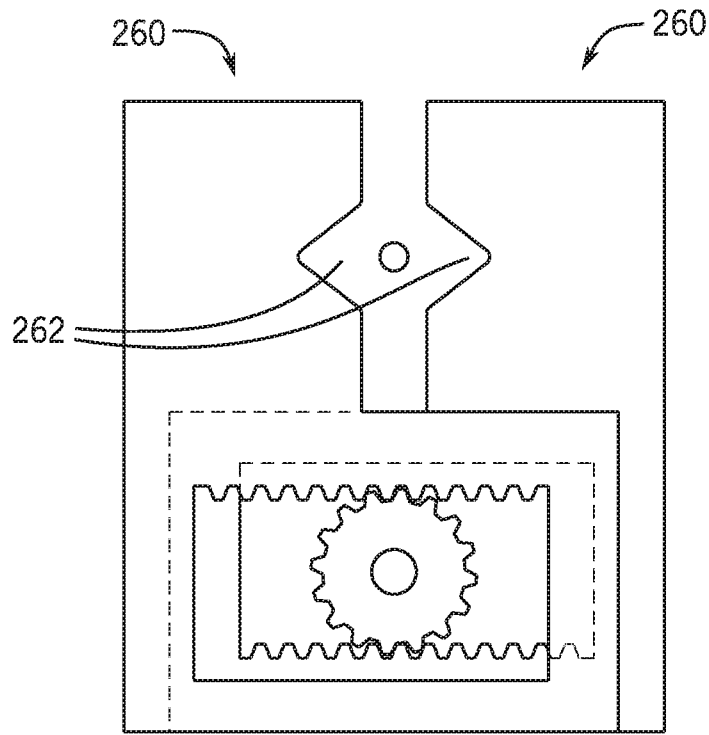


FIG. 29

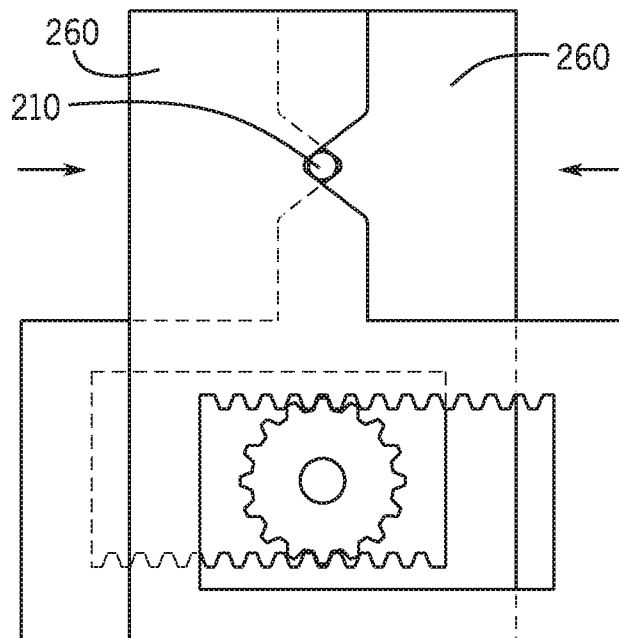


FIG. 30

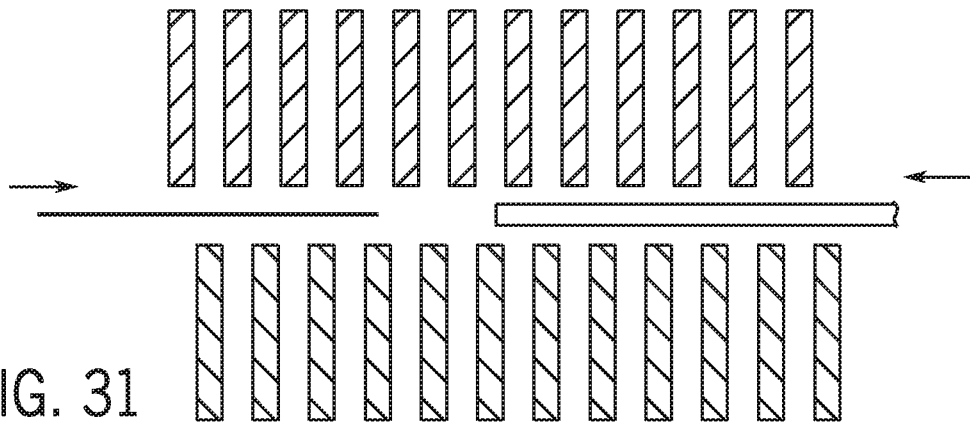


FIG. 31

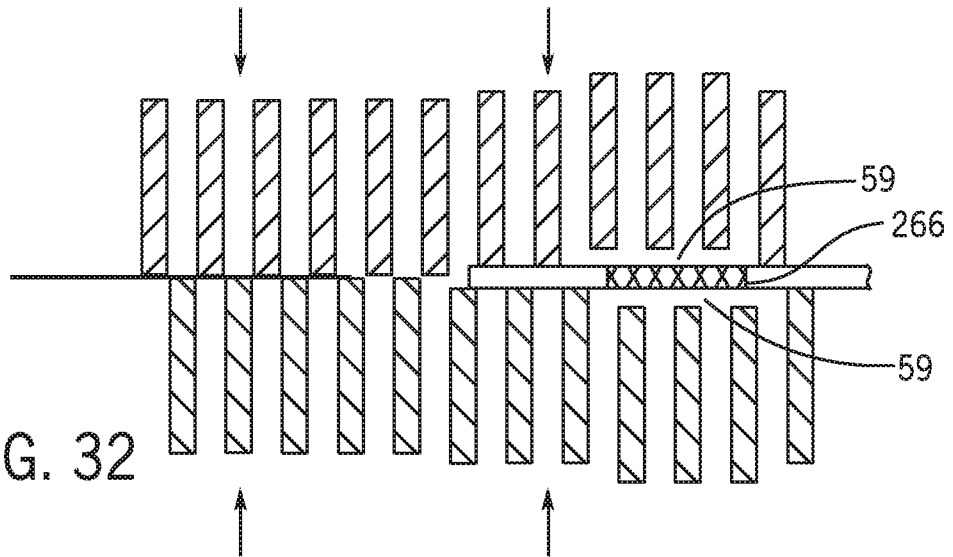


FIG. 32

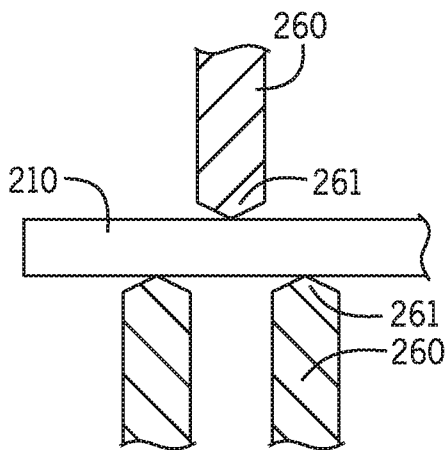


FIG. 33

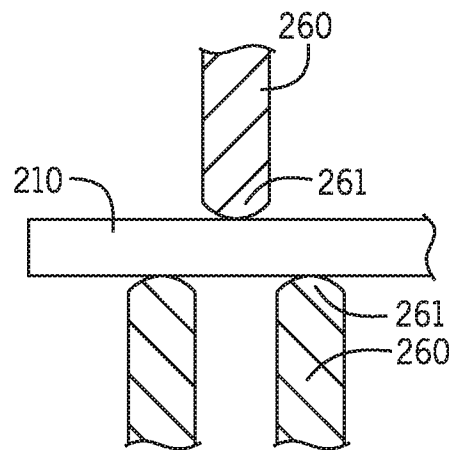


FIG. 34

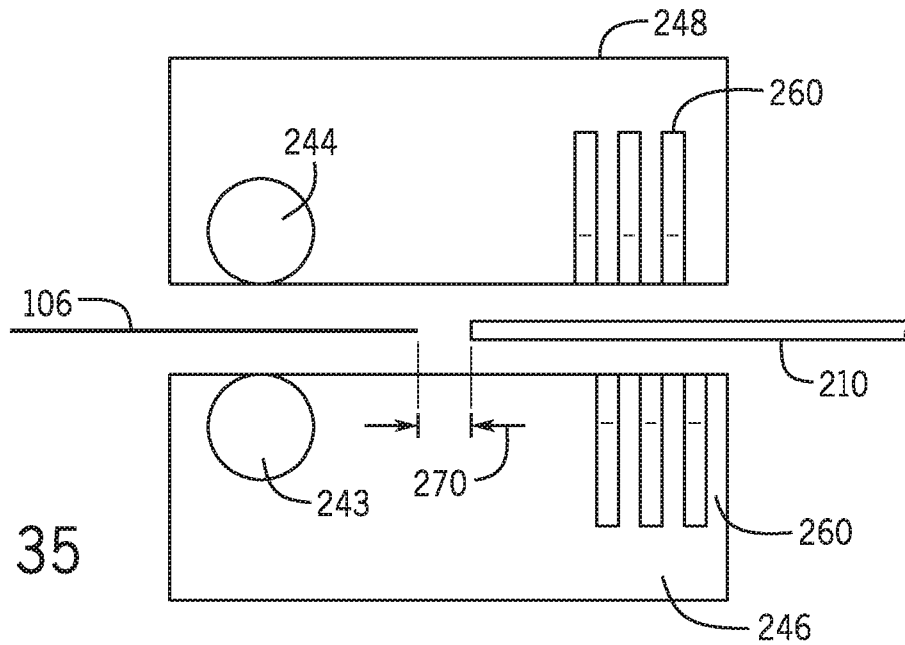


FIG. 35

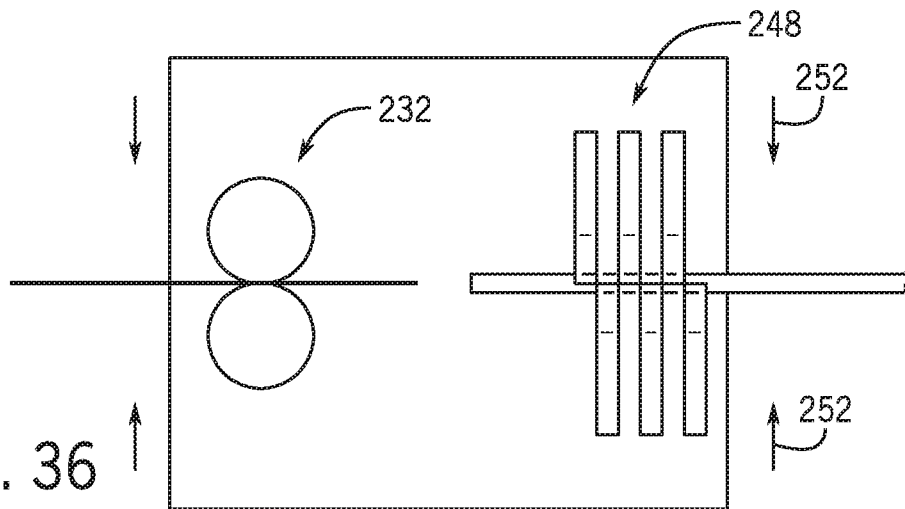


FIG. 36

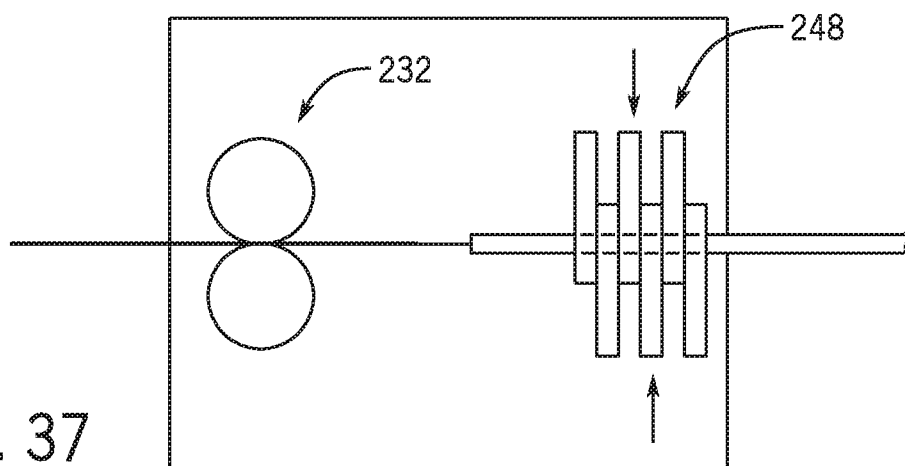


FIG. 37

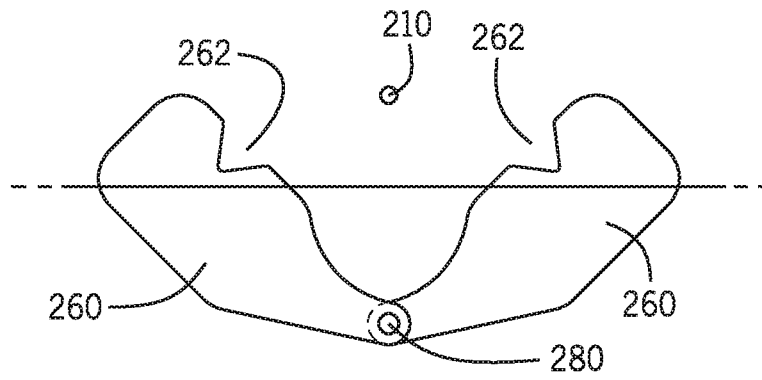


FIG. 38

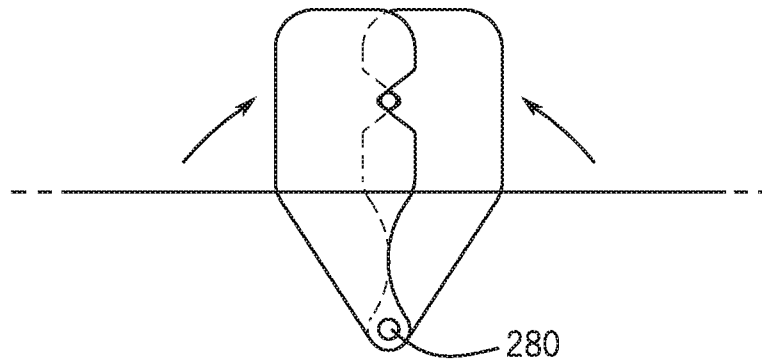


FIG. 39

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US18/21150

A. CLASSIFICATION OF SUBJECT MATTER
 IPC - A61M 25/01, 25/08, 25/082, 25/09 (2018.01)
 CPC - A61M 25/01, 25/0113, 25/0116, 25/0169, 39/06

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)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2006/0041245 A1 (FERRY, SJ et al.) 23 February 2006; abstract; figures 3, 13, 18; paragraphs [0048]-[0050], [0072], [0090]-[0092]	24-26, 30-31, 35-36 ----- 1-13, 18, 21-23, 32
Y	US 5,318,541 A (VIERA, FM et al.) 7 June 1994; figure 3; column 4, lines 47-55; column 5, lines 9-16, 52-55; column 6, lines 35-48, 63-68; column 7, lines 1-20	1-13, 18, 21-23
Y	US 2004/0034311 A1 (MIHALCIK, A) 19 February 2004; abstract; paragraph [0027]	32
Y	US 2014/0148759 A1 (HANSEN MEDICAL, INC.) 29 May 2014; figures 4-5; paragraphs [0083], [0086]	10-12
A	US 5,849,016 A (SUHR, WS et al.) 15 December 1998; abstract; figure 1; column 5, lines 1-20	14-17, 19-20
A	US 2012/0253320 A1 (STEEGERS, A et al.) 4 October 2012; figure 1; paragraph [0082]-[0083], [0021]-[0022]	14-17, 19-20
A	US 2014/0171919 A1 (CORINDUS, INC.) 19 June 2014; paragraphs [0040], [0043], [0044], [0047], [0049]-[0050]	27-29, 37-38
A	US 2012/0184955 A1 (PIVOTTO, LG et al.) 19 July 2012; paragraphs [0010], [0037]	33-34
A	US 5,572,999 A (FUNDA, J et al.) 12 November 1996; abstract; column 3, lines 60-67; column 4, lines 1-3	33-34

 Further documents are listed in the continuation of Box C. See patent family annex.

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"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

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"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

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Date of the actual completion of the international search

19 April 2018 (19.04.2018)

Date of mailing of the international search report

16 MAY 2018

Name and mailing address of the ISA/

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