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(54) Title: SYSTEM AND METHOD FOR MANIPULATING AN ELONGATE MEDICAL DEVICE

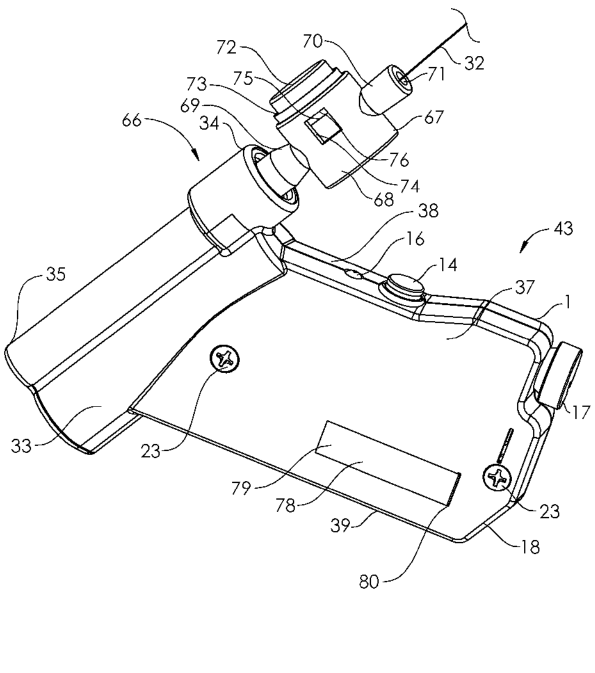

FIG. 7

(57) Abstract: A guidewire manipulation device includes a housing configured to be supported by the hand of a user, the housing having a distal end and a proximal end, the housing configured to allow a guidewire to be placed therethrough and extend between the distal end and proximal end, a drive system carried by the housing and configured to drive rotation of the guidewire, and a manual input module carried by the housing, the manual input module configured to allow one or more fingers of the hand of the user to manually stop or slow the rotation of the guidewire while the housing is supported by the hand of the user.

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SYSTEM AND METHOD FOR MANIPULATING AN ELONGATE MEDICAL DEVICE

FIELD OF THE INVENTION

[0001] The field of the invention generally relates to devices for manipulating a guidewire or other elongate medical device.

BACKGROUND

[0002] The present disclosure generally relates to the maneuvering of a guidewire in medical procedures where an endovascular technique is employed to access vasculature of a patient. A guidewire is typically an elongate probe used as an initial access point for performing an endovascular procedure. The guidewire is twisted (“torqued”), flexed, bent, and otherwise maneuvered through an access vessel in order to position the guidewire tip at or near a location a user (physician, interventionalist, etc.) would like to treat.

[0003] Convention guidewire manipulation methods often involve applying "torque" to the guidewire to aid its passage through tortuous and clogged vessels. This maneuver is performed by quickly and stiffly spinning the wire in one's fingertips. This torque helps curve or manipulate the guidewire through an obstruction or difficult passageway. This technique is also known as "helicoptering", alluding to the spinning blades of a helicopter.

[0004] However, applying torque remains difficult because guidewires are extremely thin in diameter and typically have a low friction surface. Additionally, the gloves of a user are often coated with blood or saline solution, further increasing the slackness of the guidewire. In this respect, helicoptering and similar maneuvers can be time consuming and inefficient. This inefficiency not only frustrates users but also increases procedure times and therefore procedure costs.

[0005] Present guidewire designs attempt to address these problems by providing a torque handle (torquer) that slips over the proximal end of the guidewire and looks in place. The user manipulates this torque device to facilitate rotational motion of the guidewire and grip.

[0006] These current techniques and practices have several problems. First, the current torque devices require a user to concentrate on spinning the guidewire with the attached difficult to learn. Thus, these devices remain inefficient and often highly dependent on the operator skill. Because it is highly desirable to place a guidewire quickly and therefore finish a procedure quickly, a more consistently controllable guidewire placement device that overcomes these disadvantages is desired. This is also true of other, non-guidewire, elongate medical devices that may be used for an interventional procedure.

SUMMARY OF THE INVENTION

[0007] In a first embodiment of the invention, a guidewire manipulation device includes a housing configured to be supported by the hand of a user, the housing having a distal end and a proximal end, the housing configured to allow a guidewire to be placed therethrough and extend between the distal end and proximal end, a drive system carried by the housing and configured to drive rotation of the guidewire, and a manual input module carried by the housing, the manual input module configured to allow one or more fingers of the hand of the user to manually stop or slow the rotation of the guidewire while the housing is supported by the hand of the user.

[0008] In another embodiment of the invention, a method for manipulating an elongate medical device includes providing a guidewire manipulation device including a housing configured to be supported by the hand of a user, the housing having a distal end and a proximal end, the housing configured to allow a guidewire to be placed therethrough and extend between the distal end and proximal end, a drive system carried by the housing and configured to drive rotation of the guidewire, and a manual input module carried by the housing, the manual input module configured to allow one or more fingers of the hand of the user to manually stop or slow the rotation of the guidewire while the housing is supported by the hand of the user, securing an elongate medical device to at least a portion of the guidewire manipulation device, grasping the guidewire manipulation device in a hand, and causing the elongate medical device to change a rotation speed by input from one or more finger of the hand.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] FIG. 1 is a perspective view of a guidewire manipulation device according to a first embodiment of the disclosure.

[0010] FIG. 2 is an exploded view of the guidewire manipulation device of FIG. 1.

[0011] FIG. 3 is a side view of the guidewire manipulation device of FIG. 1.

[0012] FIG. 4 is a side view of the guidewire manipulation device of FIG. 1 held in the hand of a user.

[0013] FIG. 5 is a side view of a guidewire manipulation device according to a second embodiment of the disclosure.

[0014] FIG. 6 is the guidewire manipulation device of FIG. 5 held in the hand of a user.

[0015] FIG. 7 is a perspective view of a guidewire manipulation device according to a third embodiment of the disclosure.

[0016] FIG. 8 is an exploded view of the guidewire manipulation device of FIG. 7.

[0017] FIG. 9 is a side view of the guidewire manipulation device of FIG. 7.

[0018] FIG. 10 is a side view of the guidewire manipulation device of FIG. 7 held in the hand of a user.

DETAILED DESCRIPTION

[0019] The present disclosure includes embodiments of systems for manipulating elongate medical devices, such as guidewires, thrombectomy devices, including brushes, beaters, rooter-type apparatus, drills, or atherectomy devices. Standard guidewires range from 0.009 inches (0.229 mm) in diameter to 0.038 inches (0.965 mm) in diameter. Guidewires for use in coronary arteries are often between about 0.010 inches (0.254 mm) and about 0.018 inches (0.457 mm). The systems for manipulating elongate medical devices may be configured to lock onto and rotate the elongate medical device on one direction or in two different directions. The systems for manipulating elongate medical devices may instead (or also) be configured to longitudinally displace, or piston, the elongate medical device backward and forward (proximally and distally). A number of different speeds may be used, depending on the particular material being acted upon.

[0020] Some embodiments presented in the present disclosure are designed to clamp or otherwise engage onto a guidewire, including standard guidewire diameters, in order to however, the systems presented in the embodiments could also be used to increase pushability or trackability of a guidewire. In additional, an oscillating linear motion may be incorporated into the systems. Once the system for manipulating a medical device is engaged with the guidewire, the system will be capable of being activated to rotate the guidewire in one or both of a clockwise (CW) direction and a counter-clockwise (CCW) direction. In addition, the speed of rotation (e.g., revolutions per minute) may be adjusted by the user with a control knob carried by the system. In some embodiments, the system comprises a handle having a “reverse gun handle” shape, which, among other things, allows one or more fingers of the user to have access to one or more control elements (buttons, knobs, etc.) without having to regrip the handle. The system may also be configured to allow the user to apply manual input. For example, the rotation of the guidewire which is applied by the system may be slowed down or completely stopped by manual input from one or more fingers of the user. For clarity purposes, the thumb is considered a finger, as are the other digits of the hand. When discussing a finger herein, for example a finger that is contacting a surface, it is intended to encompass both an uncovered finger and a covered (e.g., gloved) finger. The system may also be configured to allow the user to apply manual input via one or more fingers, to impart rotation on a non-rotating guidewire, or to increase rotation speed of a rotating guidewire.

[0021] A first embodiment of a guidewire manipulation device 31 is illustrated in FIGS. 1-4. A housing 33 includes a first housing half 1 and a second housing half 18, which are configured to hold a number of components, and to provide an interface with the hand of a user. The first housing half 1 and the second housing half 18 are secured to one another by screws 23. The housing 33 has a distal end 34 and a proximal end 35 and a longitudinal axis 36 though which a guidewire 32 may be placed, to extend between the distal end 34 and the proximal end 35. A chuck 7 is rotatably mounted on the housing 33 and is configured to releasably engage a guidewire. The chuck 7 has an unlocked mode in which it is not engaged with the guidewire 32, and thus the guidewire 32 can be slid longitudinally with respect to the housing 33 and the chuck 7. The chuck 7 also has a locked mode in which it is engaged with the guidewire 32, thus maintaining the longitudinal position of the guidewire 32 in relation to the housing 33 (and in relation to the chuck 7). In the locked mode, the guidewire 32 and the chuck 7 are rotationally coupled, and can be rotated together, in relation to the housing. Turning to FIG. 2, One or more batteries 25 are held within the housing 33 and covered by a battery cover 26, which is secured to the first half 1 of the housing 33 with screws 22. Two one or both halves 1, 18 of the housing 33 such that the batteries 25 (two are shown in this embodiment) electrically couple with the contacts 19, 20. The contacts 19, 20 are electrically coupled to a circuit board 21 by conductor wires (not shown), for example, by soldering, or other comparable methods. The circuit board 21 includes an on/off switch 44, which is configured to provide power to a motor 11. The motor 11 is also electrically coupled to the circuit board 21 by standard methods. The motor 11 may be a standard or brushless electric motor, and may include a gear module 45. The motor 11, may also be configured to serve as a stepper motor, whose particular rotational orientation is controlled by a controller 46 on the circuit board 21. The motor 11 may include a thermally insulative and/or physically protective covering disposed over a portion of its outer surface. In some embodiments, the covering may comprise Kapton® (polyimide) tape. In some embodiments, the speed of the motor 11 may be varied by a potentiometer 47. When the motor 11 is activated (e.g., by the on/off switch 44), the circuit board 21 lights an LED (light emitting diode) 48, which is thus configured to indicate motor activity. The LED may be a green color to provide a feeling of "on" to the user, but other colors may be used. The motor 11 rotates the guidewire, reducing the physical requirements on the user, who otherwise would only be able to rotate the guidewire manually, and would thus likely to be subject to fatigue.

[0022] A handle 37 extends in a generally radial direction in relation to the longitudinal axis 36. In the embodiment of FIGS. 1-4, the handle 37 includes a distally facing surface 38 and a proximally facing surface 39. Generally, at least a portion of the proximally facing surface 39 is configured to either rest within a portion of the palm of the hand, or at least to be adjacent to the portion of the palm of the hand between the thumb and the index finger. In some cases, the user may grip the handle 37 such that the proximally facing surface 39 is cradled or cushioned within the fleshy portion of the hand between the thumb and the index finger. The guidewire manipulation device 31, including the handle 37, is configured to fit at least partially in the hand of the user in order to allow complete operation of the guidewire manipulation device 31 by this single hand. Generally, at least a portion of the distally facing surface 38 is configured to provide one or more controls 43, and to allow access for the ends of one or more finger of the user's hand. The controls 43 may include an activation button 14 and a control knob 17. The activation button 14 extends from the housing 33 on one side and engages with the on/off switch 44 at the other side, such that the user may operate the on/off switch 44 by pressing the activation button 14 while holding the handle 37 in one hand. An o-ring 15 may be carried by the activation button 14 within a circumferential groove on the to keep external contamination (water, dirt, etc.) from entering the housing 33. The hole 50 is shown in FIG. 2 as comprising two semi-circular holes in each of the two housing halves 1, 18 which come together to make a circular hole. A light pipe 16 is attached to the housing 33 with an external portion on the outside of the housing 33 and an internal portion adjacent the LED 48 of the circuit board 21. The activity of the motor 11 is thus visible by the user, as the light pipe 16 is illuminated via the LED when the motor 11 is in operation. The control knob 17 may be configured to select two or more different rotational settings. For example, the controller 43 of the circuit board 43 may include different routines for rotating a guidewire (eight rotations in one direction, followed by eight rotations in the opposite direction, repeated, etc.). This will be subsequently discussed in more detail. Alternatively, the control knob 17 can be rotationally coupled with the rotatable portion 49 of the potentiometer 47, such that the user may turn the control knob 17 with one or more finger of the hand that grips the handle 37, to change the speed of the motor 11, and thus increase or decrease the rotational speed of the guidewire 32. Some rotation speeds that may be used include a rotation speed that is adjustable between about 1,000 RPM (rotations per minute) and about 10,000 RPM. In other embodiments, the rotation speed may be adjustable between about 2,000 RPM (rotations per minute) and about 5,000 RPM. Individual exemplary rotation speeds may include 2,500 RPM or 4,000 RPM, but may include higher or lower rotational speed settings, depending on the medical application, and the type of elongate medical device being rotated by the guidewire manipulation device 31. Other controls 43 may include a mode control, which may be configured to switch the motor 11 (e.g., via the controller 46) into different rotational modes, which may include simple continuous rotation in a single rotational direction, back and forth rotation, or stop and start of rotation in a particular rotational direction. The controller 46 may comprise a microcontroller

[0023] The motor 11 is coupled to the chuck 7 as follows. An output shaft 51 of the motor 11 is rotationally coupled to a sleeve 12 onto which a drive gear 13 is press fit or bonded (adhesive, epoxy, hot melt, heat fused). The motor 11, output shaft 51, sleeve 12, and drive gear 13 all have a motor axis 52. A driven gear 3 is carried by the housing 33 and is rotatable around the longitudinal axis 36. The driven gear 3 is configured to mesh with and be driven by the drive gear 13. In some embodiments, a lubricant may be used between the drive gear 13 and the driven gear 3. Some potential lubricants include Krytox® or silicone oil. In the embodiment of FIG. 2, the motor axis 52 is substantially parallel and non-co-linear with the longitudinal axis 36. In alternative embodiments, the motor axis 52 may be angled in rotationally coupled to a rotatable drive tube 2, which rotates around the longitudinal axis 36. The drive tube 2 is rotationally held and maintained longitudinally within the housing 33 by a bearing 9 and a spacer 4. The bearing 9 is held within a cavity 53 and the spacer abuts a flange 54. The driven gear 3 abuts a bearing 5. The work "chuck" is intended to broadly describe any component which is capable of gripping or holding a guidewire 32 or other elongate medical device. The chuck 7 of FIGS 1-4 is rotationally coupled to the drive tube 2 and includes a collet holder 6, a collet 24, and a compression cap 55, which is threadingly coupled to the collet holder 6. When the compression cap 55 is tightened to the collet holder 6, the collet 24 is forced closed, gripping the guidewire. The compression cap 55 includes a gripping portion 62. The gripping portion 620 may alternatively be carried on any other external surface of the chuck 7. The collet 24 may be made from brass, bronze, or other metals which do not unacceptably damage the guidewire 32 (or other elongate medical devices). A seal 8 serves to seal the collet holder 6 within the housing 33 even as the collet holder 6 rotates. A luer lock 10 is bonded to the housing 33 or the drive tube 2, and may be used to couple a syringe (with or without an extension tube), so that the interior of the housing around the guidewire 32 may be flushed prior to, after, or during a medical procedure. Though a male luer lock is shown in FIGS. 1-4, alternatively, a female luer lock or a non-locking male or female luer may be used. Though the guidewire 32 is shown in FIGS. 1 and 4 extending a small amount proximally from the housing 33, in use, the guidewire need not extend at all.

[0024] Alternatively, the luer lock 10 may be attached to the drive tube 2 instead of the housing 33, for example at the distal end of the drive tube 2, in order to be rotated by the drive tube 2. In this embodiment, the luer lock 10 is configured to be coupled to the proximal luer hub of a catheter, which may include a microcatheter, or a sheath. The motor 11 may then be configured to rotate the catheter or sheath to allow the distal end of the catheter or sheath to more easily be tracked through tortuous vasculature, or through an occlusion or stenosis. The catheter or sheath may also be operated as a drilling member or coring member to cannulate a thrombus or lesion. In the tracking application, the rotational speed setting may even be significantly less than 1,000 RPM, and in the drilling operation, the rotational speed may even be greater than 10,000 RPM.

[0025] The handle 37 may have a first side 41 and a second side 42 extending between the distally facing surface 38 and the proximally facing surface 39. In some embodiments, both sides 41, 42 may be substantially flat, and in other cases, both sides 41, 42 may have hand. In other embodiments, the one of the two sides 41, 42 may have a different shape than the other of the two sides 41, 42, which may be done in order to provide either a left hand only device or a right hand only device.

[0026] Turning to FIG. 3, the distally facing surface 38 extends at an angle α that is distally oriented in relation to a plane 56 cutting through the guidewire manipulation device 31 and perpendicular to the longitudinal axis 36. In some embodiments, the angle α may be between about 25° and about 45°, and in some embodiments, the angle α may be between about 30° and about 40°. In some embodiments, the angle α may be about 35°. At these values of angle α, the user is able to grip the handle 37 of the guidewire manipulation device 31 while the fingers of the user's gripping hand maintain easy access to the controls 43 of the guidewire manipulation device 31. The location of the chuck 7 (and thus the location of placement of the guidewire 32) towards the top of the housing 33, above the handle 37, allows the guidewire 32 to pass through the guidewire manipulation device 31 and the user's hand without interruption. The location of the controls 43 below the longitudinal axis 36 is another factor that gives the user easy access to the controls with one or more fingers of the hand that is gripping the handle 37. As an example, in FIG. 4, the user's hand 57 is shown grasping the handle 37. In this position, the activation button 14 is easily accessible with the middle finger 58 of the user's hand 57, while at the same time the control knob 17 is easily accessible with the pinky 59 of the user's hand 57. Thus, without regripping the handle 37, the user may continually turn the motor 11 on and off as needed by pushing the activation button 14 with the middle finger 58 while also changing the rotational pattern and/or increasing or decreasing the speed of the motor 11 by turning the control knob 17 in one direction or the other with the pinky 59. Alternatively, the control knob 17 may be turned using the thumb 60 and pinky 59 together, or the thumb 60 and ring finger 65 together. The location of the chuck 7 distal to the housing 33, or distal to at least the majority of the housing 33, and distal to the handle 37, enables a user to have easy access for providing manual input to the chuck 7 with one or more fingers of the hand that is gripping, supporting, or cradling the handle 37. The user may also be able to reach distally of the chuck 7 and actually grip the guidewire 32 directly with one or more fingers of the hand, to manually stop or slow the rotation of the guidewire 32 while the housing 33 is supported by the hand of the user, or to initiate rotation or increase rotation speed of the guidewire 32. The handle 37 also allows the user leverage on the guidewire, in case it needs to be pushed or pulled.

fingers of the hand 57 of the user. With the user's hand 57 in the same gripping position, the thumb 60 and the index finger 61 are located on substantially opposite sides of the gripping portion 62 of the chuck 7. With the guidewire 32 actively being rotated by the motor 11, the user may use both the thumb 60 and the index finger 61 together to place substantially opposite normal forces on the chuck 7, for example, on the gripping portion 62, in order to slow down the rotation of the guidewire 32, or even to stop the rotation of the guidewire 32. The user may even use the thumb 60 and the middle finger 58 instead of the thumb 60 and index finger 61. In some cases, the user may even use the thumb 60, index finger 61, and the middle finger 58 together. The motor 11 and/or gear module 45 can be configured to stall at a particular stall torque. For example, the stall torque of the motor 11 (or motor 11 and gear module 45) may be a torque that can be overcome by pressure that can be applied by most users, using one or more of their fingers on the chuck 7. In some embodiments, the overall stall torque is configured to be about 24 ounce-inches or less. In other embodiments, the overall stall torque is configured to be between about 0.1 ounce-inches and about 24 ounce-inches (about 7.06×10^{-4} newton-meter to about 0.169 newton-meter). In other embodiments, the overall stall torque is configured to be between about 1.5 ounce-inches and about 24 ounce-inches (about 0.010 newton-meter to about 0.169 newton-meter). The ability of the user to manually override the guidewire manipulation device 31 at any time increases the overall safety profile of the device. For example, in the event of a circuit board failure or motor failure, of the guidewire 32 is still being rotated, the user is nevertheless able to manually stop guidewire rotation. This is a particularly important feature, because scenarios may occur wherein any further rotation of the guidewire 32 within a blood vessel or other location in a patient's body could potentially cause damage. By having the motor 11 on at all times and slowing, stopping, and/or starting and speeding up the rotation of the guidewire by manual input alone, the procedure is very much in the control of a single hand of the user. Additionally, the procedure is simplified, as the circuit board 21 remains simply in an "on" mode, and is not required for the manual speed changes. The user is able to switch back and forth between motorized control and manual control at will. The fingers of the user are always in position to manipulate the chuck 7 (to change the speed of the guidewire) and to operate any of the controls 43, without any need to change the grip on the handle 37 of the guidewire manipulation device 31. The same grip may be maintained while advancing or retracting the guidewire in the patient.

finger 61, alternatively, the user may choose to apply a one-sided normal force on the chuck 7 from only one of the thumb 60 or index finger 61 to slow or stop the motor 11 rotation. The gripping portion 62 is shown with a series of circumferentially-arrayed, radially-protruding, longitudinally-lying ribs. However, in alternative embodiments, the gripping portion 62 may be knurled or comprise a series of bumps. In other alternative embodiments, the gripping portion 62 may comprise a tacky surface, which, due to its relatively high coefficient of friction, may even be a smooth cylindrical shape.

[0029] Returning to FIG. 3, proximally facing surface 39 is shown extending at an angle β that is also distally oriented in relation to plane 56. Alternatively, the proximally facing surface 39 may be contoured in other shapes to conform to the shape of typical hands of users.

[0030] In some embodiments, the controller 46 may be configured, or configured to be programmed, such that a number of different rotation schemes are applied to the guidewire 32. These different schemes may be selected by the user by turning the control knob 17 to a different orientation or different detents. For example, the motor 11 may be commanded to rotate the guidewire 32 a certain number of turns in a first rotational direction, and then to rotate the guidewire in a certain number of turns in a second, opposite direction. In other embodiments, the motor 11 may be commanded to rotate the guidewire 32 at a series of different speeds, or at accelerating and/or decelerating speeds. For example, in a particular embodiment, the motor 11 is commanded to rotate the guidewire 32 in a first rotational direction at a first rotational speed, and then in a second, opposite rotational direction at a second rotational speed, different from the first rotational speed. In yet another embodiment, the motor 11 may be commanded to rotate the guidewire 32 in a first rotational direction at a varying rotational speed and then in a second, opposite, rotational direction at a varying rotational speed. The varying rotational speed may include: a speed that is increasing with time; a speed that is decreasing with time; or a speed that includes different finite speeds which begin and end at different time periods. Certain body tissue characteristics or geometry may respond better to one speed more than another, and so the varying of speeds may aid in finding the more effective speed for a particular tissue and/or geometry condition. The same can be said about different rotational directions and/or numbers of rotations. Additional designs and schemes for rotating and/or longitudinally actuating a guidewire which may be incorporated into any of the embodiments described herein can be found in U.S. Patent No. 9,119,941, entitled “Method and Apparatus for Manipulating a Surgical Guidewire,” which

“Guidewire Manipulation Device,” which issued to Rollins et al. on September 1, 2015.

[0031] In some embodiments, the controller 46 may be configured to, or configured to be programmed to direct the motor 11 to rotate the guidewire 32 clockwise for about 0.2 seconds, and then switch directions and rotate the guidewire 32 counter-clockwise for about 0.2 seconds. The motor 11 may be commanded by the controller 46 to continuously repeat this pattern. In some embodiments, the controller 46 may be configured to, or configured to be programmed to direct the motor 11 to rotate the guidewire 32 clockwise for about 1.0 second, and then switch directions and rotate the guidewire 32 counter-clockwise for about 1.0 second. The motor 11 may be commanded by the controller 46 to continuously repeat this pattern. In other embodiments, the controller 46 may be configured to, or configured to be programmed to direct the motor 11 to rotate the guidewire 32 only a certain number of degrees in each direction. For example, about 180 degrees in a first direction and then about 180 degrees in the opposite direction. The motor 11 may be commanded by the controller 46 to continuously repeat this pattern. In other embodiments, the controller 46 may be configured to, or configured to be programmed to direct the motor 11 to rotate the guidewire 32 between about one-quarter and about thirty-eight full rotations in a first direction and then between about one-quarter rotation and about thirty-eight full rotations in the opposite direction. The motor 11 may be commanded by the controller 46 to continuously repeat this pattern. In other embodiments, the controller 46 may be configured to, or configured to be programmed to direct the motor 11 to rotate the guidewire 32 between about six and about ten full rotations in a first direction and then between about six and about ten full rotations in the opposite direction. The motor 11 may be commanded by the controller 46 to continuously repeat this pattern. The circuit board 21 may comprise an H-bridge to switch the motor polarity, and thus the motor rotational direction between a first and second direction (e.g., forward and reverse). Any number of different patterns or routines may be programmed into or programmable into the controller 46. In some embodiments, settings may be available in discrete choices, for example, low, medium, or high. In other embodiments, the settings may be adjusted through a continuous range in the particular parameter or parameters.

[0032] In some embodiments, the guidewire manipulation device 31 may include elements that are coupled to any of the rotatable portions (chuck 7, drive tube 2, etc.) which allow for rotation in a first direction, but not in a second, opposite direction. For example, any of these rotatable elements may be coupled to a free wheel, a clutch, or a ratchet.

enable the guidewire manipulation device 31 to be comfortably used with a single hand. The textured surface of the gripping portion 62 of the chuck 7 may be configured, for example, so that one of the ribs has a larger radial protrusion dimension than the other ribs, or in other embodiments, so that there is only one radially-protruding rib. This configuration allows tactile feedback to the user, or more specifically, knowledge of about how fast the guidewire is being rotated from feel only, without having to look at the chuck 7, or at any display. The user, thus, does not have to continually watch the guidewire manipulation device 31 while using it.

[0034] FIGS. 5 and 6 illustrate a guidewire manipulation device 63 that includes most of the features and utility of the guidewire manipulation device 31 of FIGS. 1-4, however, the chuck 7 of the guidewire manipulation device 63 is at least partially within the housing 33. A window 64 in the housing 33 exposes a portion of the gripping portion 62 of the chuck 7, so that, while the user is gripping the handle 37, the gripping portion 62 may be touched by a single finger of the user's hand 57, including the index finger 61, the middle finger 58, the pinky 59, the ring finger 65, or in some cases, even the thumb 60. It should be noted that the though the word "gripping" is being used in the name of the gripping portion 62 of the guidewire manipulation device 63 of FIGS. 5 and 6, in some embodiments the window 64 may be configured in a way that a typical user cannot actually grip two points on the gripping portion 62 (e.g., with two different fingers). However, by placing a normal force (using applied finger pressure) on the gripping portion 62 of the chuck 7, as the index finger 61 is shown being done by the index finger 61 in FIG. 6, the user may still slow or stop the rotation of a guidewire 32 being rotated by the motor 11. Additionally, the user may start rotation or speed up rotational speed of a guidewire 32 that is being rotated by the motor 11, or is not being rotated by the motor 11. Thus, the chuck 7 of the guidewire manipulation device 63 of the embodiment of FIGS. 5-6 can be controlled by finger-based manipulation, much in the same manner as the chuck 7 of the guidewire manipulation device 31 of the embodiment of FIGS. 1-4. In some embodiments, if the window 64 is configured large enough, two or more fingers may have access to place a normal force on the gripping portion 62 of the chuck 7, either in an opposing manner, or together in the same direction (substantially parallel).

[0035] FIGS. 7-10 illustrate a guidewire manipulation device 66 that includes most of the features and utility of the guidewire manipulation device 31 of FIGS. 1-4, however, several components are different. A chuck 67 is configured to grip the guidewire 32 and to be rotated by the motor 11 in order to rotate the guidewire 32, as with the chucks 7 in the embodiments bonded (adhesive, epoxy) to an external diameter of the drive tube 2. The drive tube may comprise stainless steel or other substantially rigid materials. The chuck 67 may comprise any of the gripping configurations and mechanisms of embodiments of a torque device as described in U.S. Patent No. 7,972,282, entitled “Torque Device for a Medical Guidewire,” which issued to Clark et al. on July 5, 2011. The chuck 67 includes a body 68 having a first end 69 and a second end 70. A cavity 71 passes through the body 68 and is configured for the placement of a guidewire 32 (or other elongate medical device). An actuator 72 is telescopically carried within a channel 73, and is spring-loaded (or otherwise biased), so that, when depressed (e.g., in the manner of a push button), a guidewire may pass through, and when released, the guidewire is gripped, as the actuator moves toward its biased position. Thus, a guidewire 32 may be engaged with the chuck 37 or disengaged with the chuck by simply pushing the actuator 72 and removing or inserting the guidewire 32. The actuator 72 may be maintained within the channel 73 of the body 68 (so that it does not fall out) by a catch 75 on the side of the actuator 72, which abuts a ledge 76 in an opening 74 in the body 68. In alternative embodiments a similar chuck 67 may be used which instead of having an actuator 72 that is pushed in order to insert the guidewire 32 and released in order to grip the guidewire 32, instead has an actuator the is pushed in order to grip the guidewire 32, or in other embodiments, and actuator that is pulled in order to grip the guidewire 32. In some embodiments, an additional sleeve, such as a silicone sleeve, is secured to the end of the drive tube 2, in place of the chuck 67. The silicone sleeve rotates in unison with the drive tube and has an internal diameter that is configured to snugly fit around the exterior of a variety of different torque devices (torquers), including any off-the-shelf torque device. Thus, many different torque devices may be used in place of the chuck 67 to rotate the guidewire 32. Instead of a sleeve, a standard chuck or graspers may be used, or a cavity having a set screw, in order to secure one or more torque device to the drive tube 2.

[0036] The drive tube 2 is maintained on one end by a support cap 77, which may or may not be configured to include a luer. A safety element (not shown) may be carried on the handle 37 and may be electrically coupled to the circuit board 21. The safety element may comprise an electrode or coupled surface may serve to couple a terminal of the circuit board 21 to the hand 57 of the user. The safety element may cover a portion of both sides of the handle 37 so that the hand 57 will contact the activation strip whether it is a left hand or a right hand. In some embodiments, the safety element may be capacitive, and in other embodiments, the safety element may be conductive. In some embodiments, the controller 46 the safety element is coupled and/or grounded (to the user).

[0037] An activation strip 78 has a first end 79 that extends out of the second housing half 18 through a slit 80 and a second end 81 that is held between and end (e.g., terminal) of one or more of the batteries 25 (not visible in FIG. 8, see FIG. 2) and one or more of the contacts 19, 20. Prior to using the guidewire manipulation device 66, the user grips the first end 79 of the activation strip 78 and applies a tensile force in order to remove the activation strip 78 completely, thus allowing the end or terminal of the battery 25 to directly contact the contact(s) 19, 20. The activation strip 78 comprises a dielectric material, such as polyimide (e.g., Kapton®) and may have a relatively high material strength. Thus, the activation strip 78 functions to prevent the batteries 25 from discharging while the guidewire manipulation device 66 is on the shelf or stored prior to being used.

[0038] The shape of the chuck 67 has a non-round cross-section and thus allows tactile feedback to the user while it is being rotated by the motor 11. The user, thus, does not have to continuously, or continually, monitor the guidewire manipulation device 66 visually while using the guidewire manipulation device 66 in a medical procedure. Thus the user is able to focus on other aspects of the medical procedure that are important. These may include, patient vital signs (body temperature, pulse rate, respiration rate, blood pressure, etc.) or other characteristics that indicate the effectiveness of the treatment (amount of thrombus removed, fluoroscopic or radiographic image, etc.). In additional, no rotational counter (encoder, etc.) is required to provide rotational feedback during the procedure as the non-round external contour of the chuck 67 provides simple indication of the number of turns and of the general rate of rotation.

[0039] When the guidewire manipulation device 31, 63, 66 is used in a back-and-forth mode, wherein the guidewire is turned by the motor 11 in oscillations of a particular number in each direction, the user is also able to visually monitor the type or number of oscillations by viewing the non-round external contour of the rotating chuck 67. The user may even choose to give manual input to slow, speed up, or stop the rotation of the chuck 67 and guidewire 32 in one rotational direction, and not the other. This may be useful in certain situations, such as when the guidewire 32 or other elongate medical device is being tracked around a corner or tortuosity.

[0040] Any of the chucks 7, 67 may be replaced with other guidewire torque devices, including pin vice-type guidewire torquers, sliding friction guidewire torquers, or soft grip devices such as the H_2O Torq™ Device sold by Merit Medical Systems, Inc. of South Jordan, coated with hydrophilic coatings or lubricants such as silicone or silicone oil.

[0041] While embodiments have been shown and described, various modifications may be made without departing from the scope of the inventive concepts disclosed herein.

1. A guidewire manipulation device comprising:

a housing configured to be supported by the hand of a user, the housing having a distal end and a proximal end, the housing configured to allow a guidewire to be placed therethrough and extend between the distal end and proximal end;

a drive system carried by the housing and configured to drive rotation of the guidewire; and

a manual input module carried by the housing, the manual input module configured to allow one or more fingers of the hand of the user to manually stop or slow the rotation of the guidewire while the housing is supported by the hand of the user.

2. The guidewire manipulation device of claim 1, wherein the manual input module is configured to allow one or more fingers of the hand of the user to manually rotate the guidewire when the drive system is not actively rotating the guidewire.

3. The guidewire manipulation device of either of claims 1 or 2, wherein the drive system comprises a motor.

4. The guidewire manipulation device of claim 3, wherein the motor is powered by one or more batteries.

5. The guidewire manipulation device of either of claims 1 or 2, further comprising a locking assembly coupled to the drive system and configured to selectively maintain a longitudinal position of the guidewire in relation to the housing and to transfer rotational movement of the drive system to rotational movement of the guidewire.

6. The guidewire manipulation device of claim 5, wherein the locking assembly comprises a chuck.

7. The guidewire manipulation device of claim 6, wherein the chuck includes a collet.

drive system is configured to rotate the guidewire in a first rotational direction and to inhibit the rotation of the guidewire in a second rotational direction, the second rotational direction opposite the first rotational direction.

9. The guidewire manipulation device of either of claims 1 or 2, wherein the manual input module includes at least one input interface configured to rotate in unison with the guidewire, the at least one input interface including an external surface having non-circular cross-section.

10. The guidewire manipulation device of either of claims 1 or 2, wherein the external surface includes one or more protrusions.

11. The guidewire manipulation device of either of claims 1 or 2, wherein the drive system is configured to apply alternating clockwise motion and counter-clockwise motion to the guidewire.

12. The guidewire manipulation device of either of claims 1 or 2, wherein the drive system is configured to drive rotation of the guidewire at a torque of between about 7.06×10^{-4} newton-meter and about 0.169 newton-meter.

13. The guidewire manipulation device of either of claims 1 or 2, further comprising an activation member carried by the housing and configured to initiate operation of the drive system when activated by the hand of the user.

14. The guidewire manipulation device of claim 13, wherein the manual input module and the activation member are configured to be operable by the hand of the user while the housing is supported by the hand of the user.

15. The guidewire manipulation device of either of claims 1 or 2, wherein the drive system is configured to drive rotation of the guidewire at a plurality of different rotational speeds.

manual input module requires two or more fingers of the hand of the user to manually stop the rotation of the guidewire while the housing is supported by the hand of the user

17. The guidewire manipulation device of claim 1, wherein the one or more fingers of the hand of the user include the index finger of the user.

18. The guidewire manipulation device of any of claims 1, 2, or 17, wherein the housing comprises a longitudinal axis extending between the distal end and the proximal end and a hand grip extending in a generally radial direction in relation to the longitudinal axis, and wherein the hand grip includes a distally facing surface and a proximally facing surface, the distally facing surface extending at a distally-oriented angle in relation to a plane that is perpendicular to the longitudinal axis.

19. The guidewire manipulation device of claim 18, wherein the distally-oriented angle of the distally facing surface is between about 25° and about 45°.

20. The guidewire manipulation device of claim 19, wherein the distally-oriented angle of the distally facing surface is between about 30° and about 40°.

21. The guidewire manipulation device of claim 18, wherein the proximally facing surface extends at a distally-oriented angle in relation to a plane that is perpendicular to the longitudinal axis.

22. The guidewire manipulation device of any of claims 1, 2, or 17, wherein the manual input module is configured to allow two or more fingers of the hand of the user to slow the rotation of the guidewire without stopping the rotation of the guidewire while the housing is supported by the hand of the user.

23. The guidewire manipulation device of any of claims 1, 2, or 17, wherein the manual input module is configured to allow two or more fingers of the hand of the user to manually stop the rotation of the guidewire by overcoming a stall torque of the drive system.

least one manual input module has a first state wherein the at least one manual input module grips the guidewire to rotate in unison therewith, and a second state wherein the at least one manual input module is released from the guidewire such that relative rotation is allowed therebetween.

25. The guidewire manipulation device of claim 24, wherein the at least one manual input module is configured to be moved between the first state and the second state by two or more fingers of the hand of the user.

26. The guidewire manipulation device of any of claims 1, 2, or 17, wherein the manual input module is configured to allow one or more fingers of the hand of the user to manually stop or slow the rotation of the guidewire when the drive system is actively rotating the guidewire.

27. The guidewire manipulation device of any of claims 1, 2, or 17, wherein the manual input module includes a contact surface configured to be directly contacted by the one or more fingers of the hand of the user.

28. A Method for manipulating an elongate medical device, comprising:

providing a guidewire manipulation device comprising:

a housing configured to be supported by the hand of a user, the housing having a distal end and a proximal end, the housing configured to allow a guidewire to be placed therethrough and extend between the distal end and proximal end;

a drive system carried by the housing and configured to drive rotation of the guidewire; and

a manual input module carried by the housing, the manual input module configured to allow one or more fingers of the hand of the user to manually stop or slow the rotation of the guidewire while the housing is supported by the hand of the user;

securing an elongate medical device to at least a portion of the guidewire manipulation device;

grasping the guidewire manipulation device in a hand; and

causing the elongate medical device to change a rotation speed by input from one or more finger of the hand.

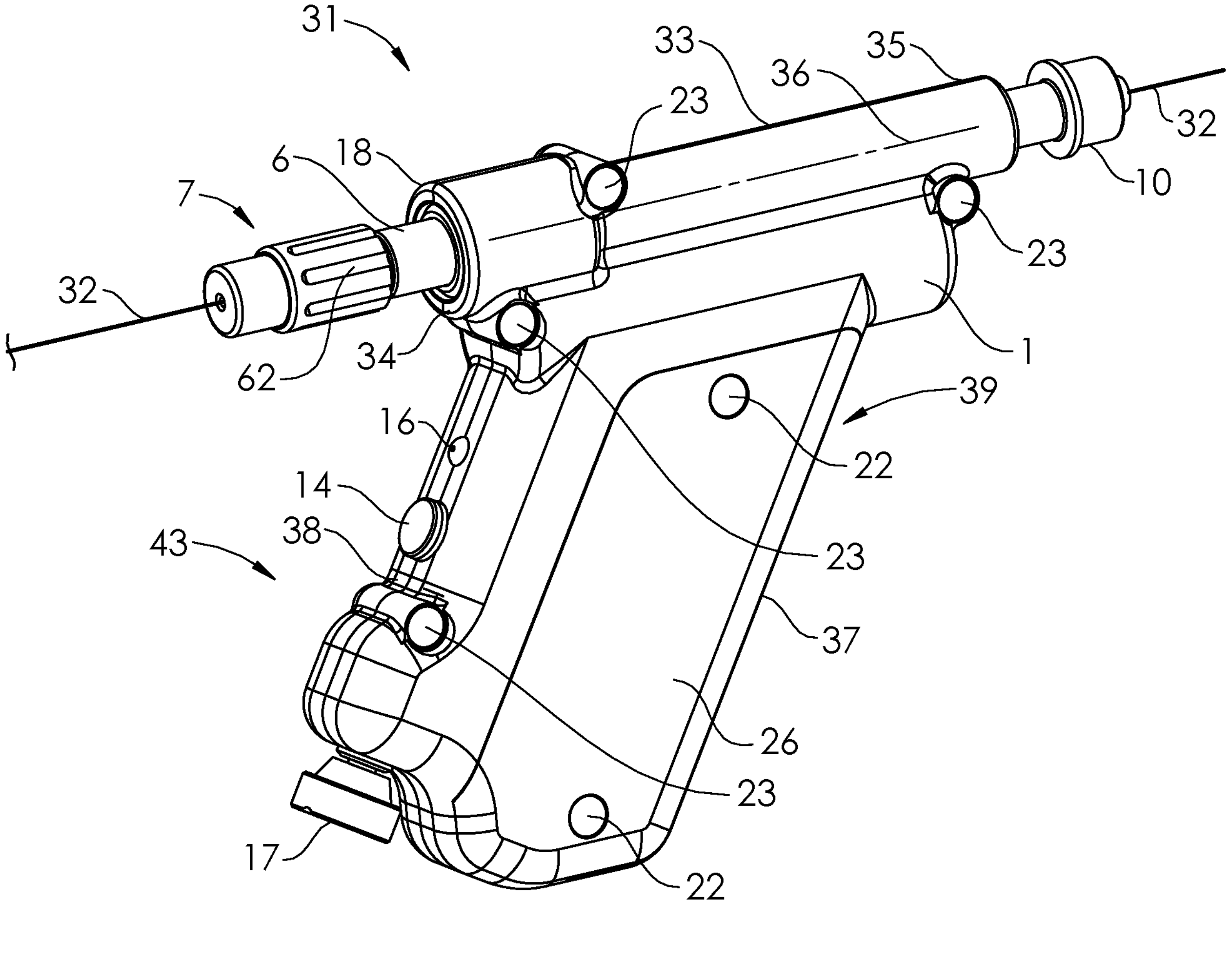
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FIG. 1

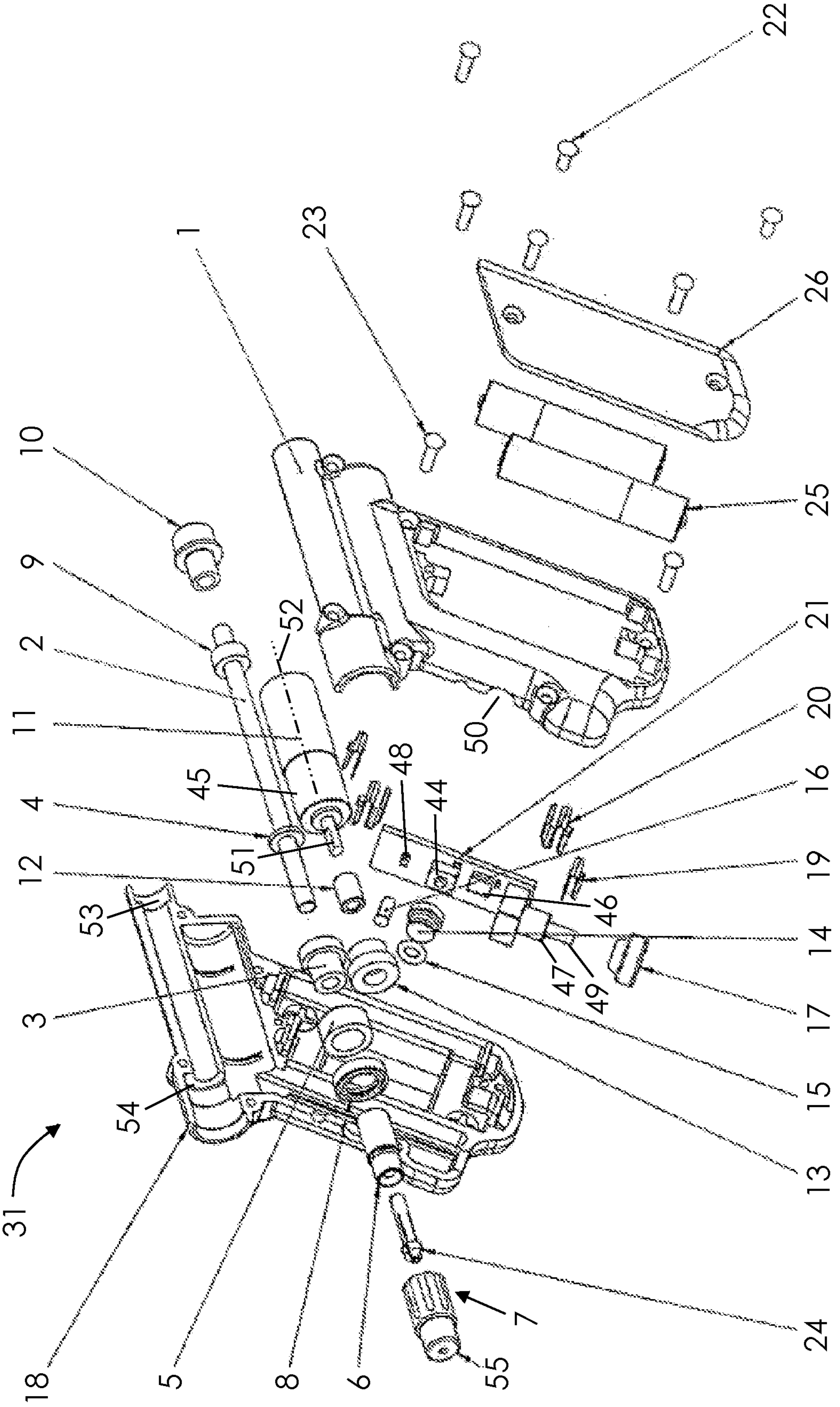
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FIG. 2

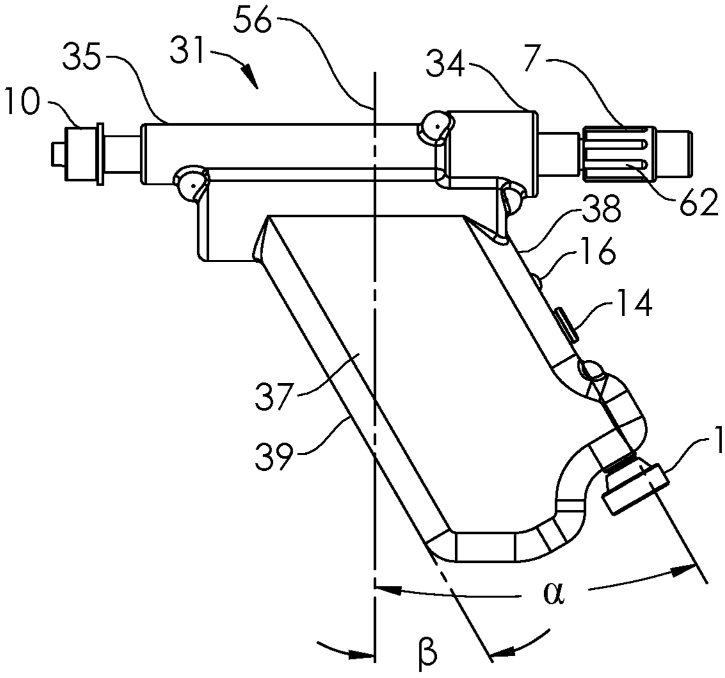
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FIG. 3

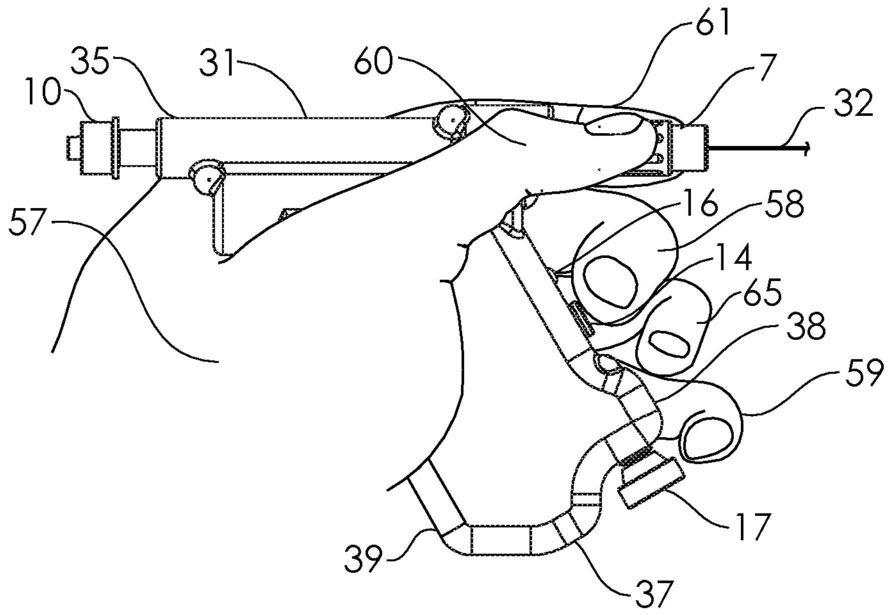
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FIG. 4

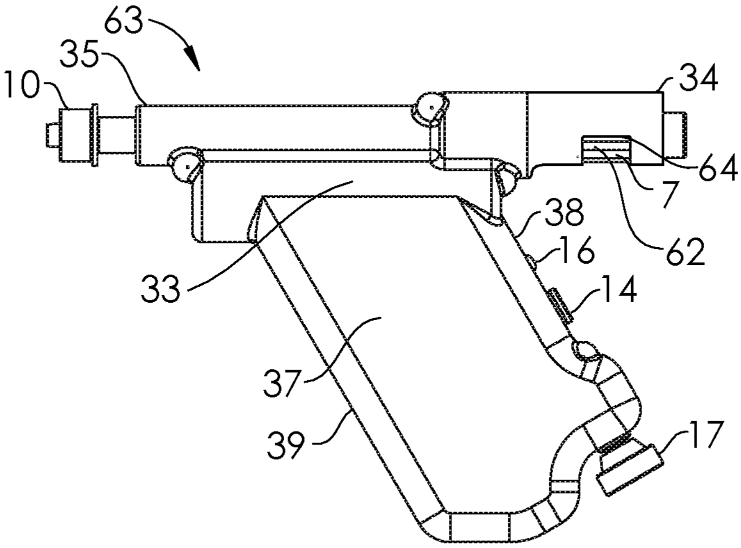
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FIG. 5

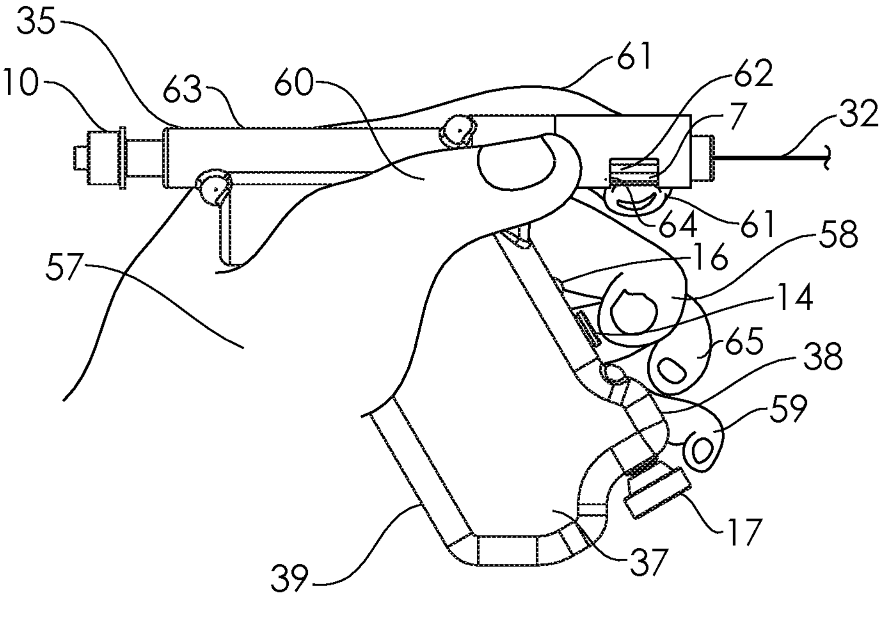
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FIG. 6

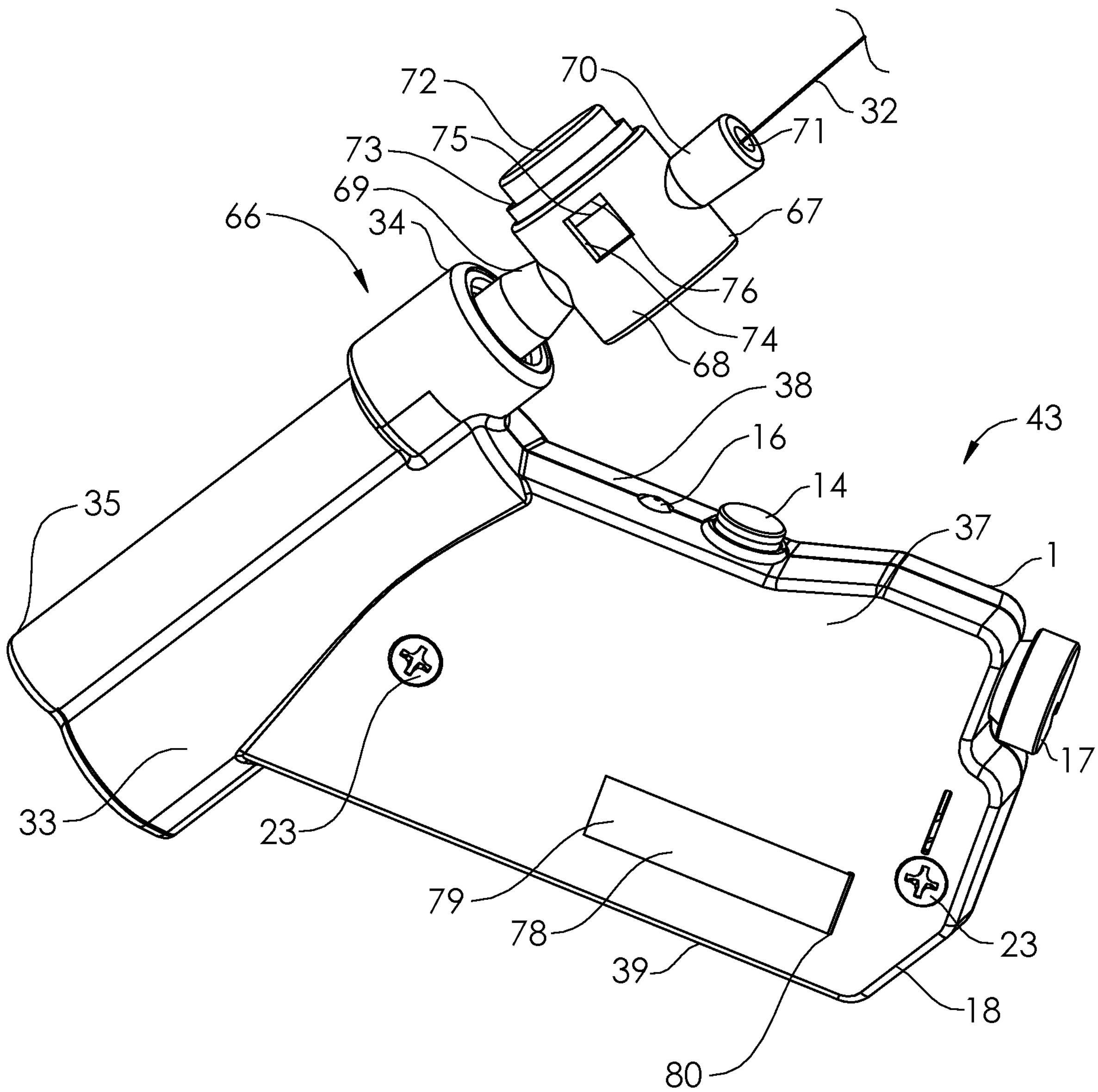

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FIG. 7

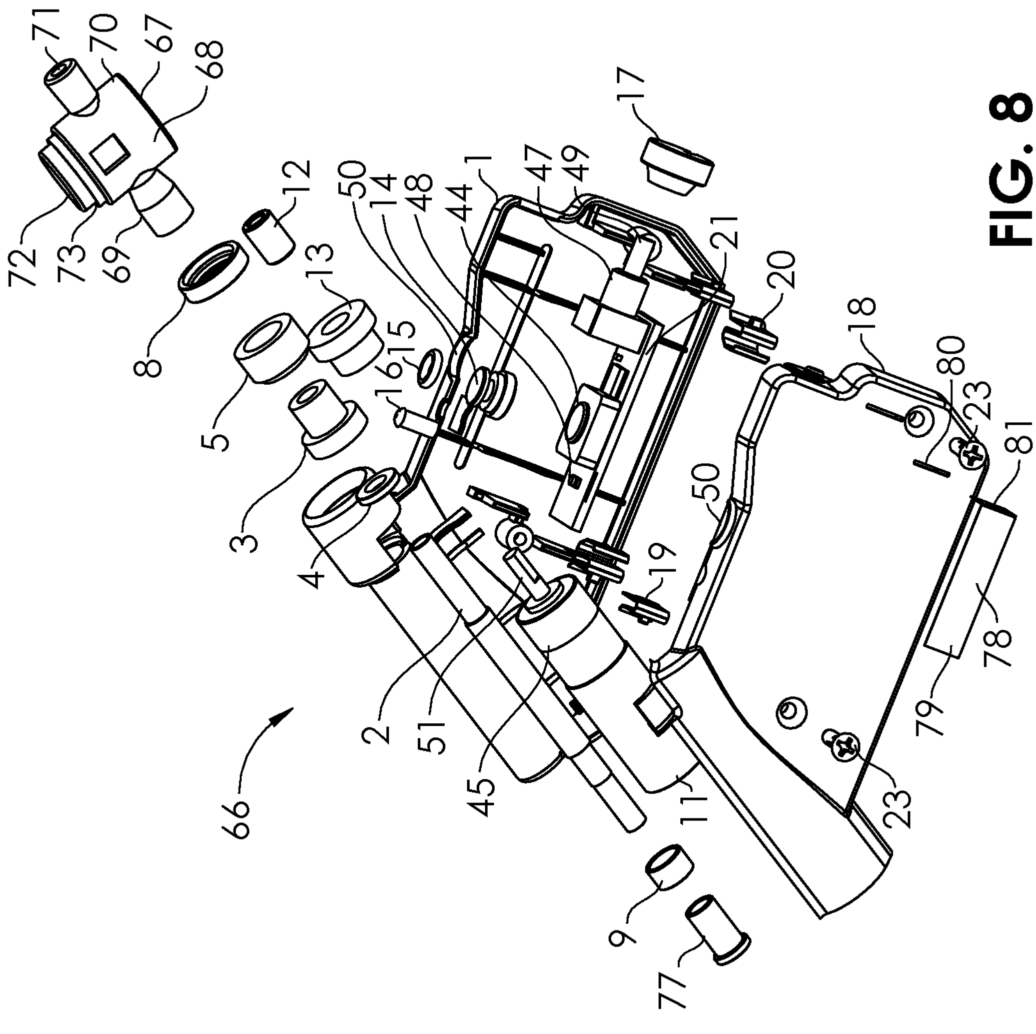
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FIG. 8

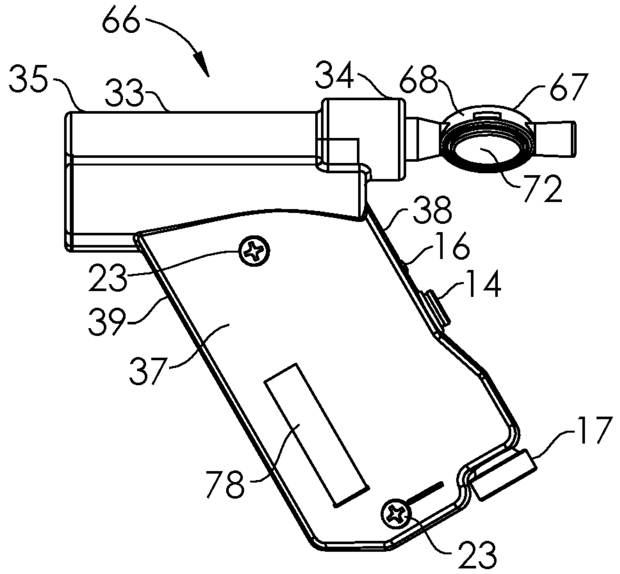
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FIG. 9

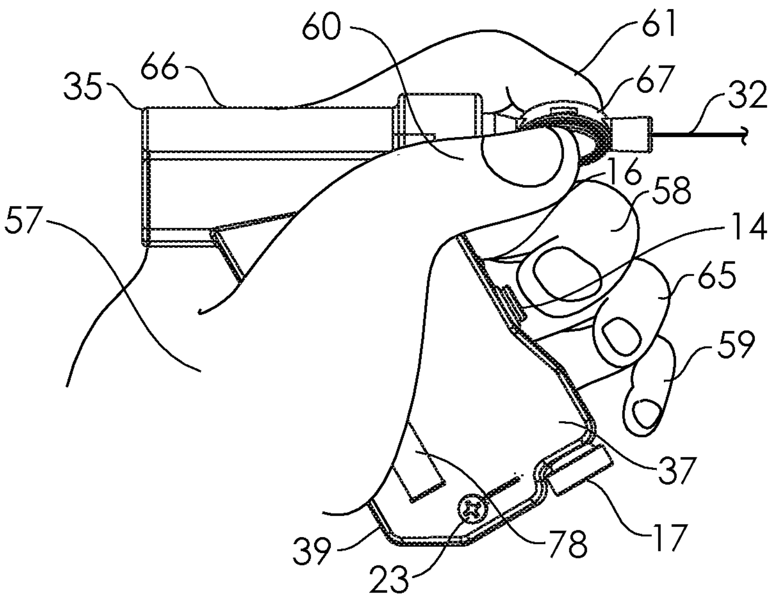
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FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/46877

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 25/09 (2016.01)
CPC - A61M 2025/09116, A61M 25/09041
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)
IPC(8) - A61M 25/09 (2016.01)
CPC - A61M 2025/09116, A61M 25/09041

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
(UPC) 604/528; (CPC) A61M 25/0136; A61M 25/09*, A61M 2025/09*
(Search term limited; see below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest (PGPB, USPT, EPAB, JPAB); Google; PatBase (All);
Search Terms: Guidewire, guide wire, handle, handgrip, grip, pistol, chuck*, manual*, brak*, stop*, torqu*, drive, driving, rotat*, block*, lock*, prevent*, revers*, opposit*, direction, CCW, CW, clockwise, counter, single, one, stall*, slip*, motor*, angle

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 2010/0204613 A1 (ROLLINS et al.) 12 August 2010 (12.08.2010) Entire document, especially Abstract, para[0023]- para[0031] and FIGS. 1-3.	1-7, 9-15, 17, 22, 24-28 -------------------- 8, 16, 18-21, 23
Y	US 6,544,231 B1 (PALMER et al.) 08 April 2003 (08.04.2003) Entire document, especially Abstract, col 8, ln 57- col 9, ln 37.	8
Y	US 2014/0324026 A1 (CHRISMAN) 30 October 2014 (30.10.2014) Entire document, especially Abstract, para[0020]- para[0021] and FIG. 1.	16
Y	US 2009/0264940 A1 (BEALE et al.) 22 October 2009 (22.10.2009) Entire document, especially Abstract, para[0053] and FIG. 3.	18-21
Y	US 2012/0078080 A1 (FOLEY et al.) 29 March 2012 (29.03.2012) Entire document, especially Abstract, para[0094]- para[0095]	23
A	US 2015/0202414 A1 (HWANG) 23 July 2015 (23.07.2015) Entire document.	1-28
A	US 2014/0343527 A1 (SCARPINE et al.) 20 November 2014 (20.11.2014) Entire document.	1-28
A	US 2014/0243734 A1 (EUBANKS et al.) 28 August 2014 (28.08.2014) Entire document.	1-28
A	US 2010/0174233 A1 (KUBAN et al.) 08 July 2010 (08.07.2010) Entire document.	1-28
A	US 2007/0219467 A1 (CLARK et al.) 20 September 2007 (20.09.2007) Entire document.	1-28

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 October 2016	28 OCT 2016

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774