GUIDEWIRE-MANAGEMENT DEVICES AND METHODS THEREOF

PRIORITY

[0001] This application claims the benefit of priority to U.S. Patent Application No. 62/989,371, filed March 13, 2020, which is incorporated by reference in its entirety into this application.

BACKGROUND

[0002] A catheter is typically placed in a blood vessel of a patient using the Seldinger technique, which involves inserting a hollow needle into the blood vessel, inserting a guidewire into the needle, advancing the guidewire into the blood vessel, and removing the needle from the blood vessel leaving the guidewire in place. The catheter is then advanced over the guidewire until it is suitably placed with the patient's vasculature. The guidewire is then removed from the patient.

[0003] Guidewires for use in accordance with the Seldinger technique are typically packaged in a coiled-tube dispenser to keep the guidewires sterile and make handling the guidewires less cumbersome. However, inserting such a guidewire from a dispenser into a hollow needle requires two hands. In particular, one hand is required to hold both the needle and an engagement piece configured to guide the guidewire into the needle, while another hand is required to grip the guidewire and direct the guidewire from the dispenser into the needle. The more the guidewire is handled, the more opportunity for contamination or damage to the guidewire. In view of the foregoing, there is a need for better guidewire management in medical procedures such as those requiring the Seldinger technique.

[0004] Disclosed herein are guidewire-management devices and methods thereof that address the foregoing.

SUMMARY

[0005] Disclosed herein is a guidewire-management device including, in some embodiments, a guidewire, a first sleeve, and a second sleeve. The first sleeve is configured for distally feeding the guidewire out of the guidewire-management device. The first sleeve is also configured for proximally feeding the guidewire into the guidewire-management device. The second sleeve is proximal of the first sleeve in the guidewire-management device. The

second sleeve is configured for feeding the guidewire in concert with the first sleeve. At least a length of the guidewire extending between the first sleeve and the second sleeve is disposed within a sterile barrier configured to maintain sterility of the guidewire. The sterile barrier is a splittable casing configured to split off the guidewire while distally feeding the guidewire out of the guidewire-management device.

[0006] In some embodiments, the first sleeve has a distal portion configured as a male connector with a Luer taper for connecting the first sleeve to a complementary female connector.

[0007] In some embodiments, the first sleeve is configured to straighten the guidewire when proximally feeding the guidewire into the guidewire-management device.

[0008] In some embodiments, the first sleeve includes a seal configured to block fluid from entering or escaping the guidewire-management device when proximally feeding the guidewire into the guidewire-management device.

[0009] In some embodiments, the first sleeve has a proximal portion including a bore configured to house a distal portion of the sterile barrier.

[0010] In some embodiments, the second sleeve has a distal portion including a bore configured to house a proximal portion of the sterile barrier.

[0011] In some embodiments, the second sleeve has a proximal portion including another bore configured to stop an end of the guidewire from completely passing through the second sleeve.

[0012] In some embodiments, the guidewire has a distal portion including a 'J'-shaped tip configured to straighten as the tip of the guidewire enters the first sleeve when proximally feeding the guidewire into the guidewire-management device.

[0013] In some embodiments, the guidewire has a proximal portion including a ball end configured to stop the guidewire from completely passing through the second sleeve.

[0014] In some embodiments, the guidewire-management device is configured to redispose the splittable casing over the guidewire while proximally feeding the guidewire into of the guidewire-management device.

[0015] Also disclosed herein is a guidewire-management device including, in some embodiments, a handle, a guidewire, a first sleeve formed in a distal portion of the handle, a second sleeve formed in a proximal portion of the handle, and a thumb wheel disposed under the guidewire between the first sleeve and the second sleeve. At least a length of the guidewire extending between the first sleeve and the second sleeve is disposed within a sterile barrier configured to maintain sterility of the guidewire. The sterile barrier is a splittable casing configured to split off the guidewire while distally feeding the guidewire out of the guidewire-management device. The thumb wheel is configured to assist in distally feeding the guidewire out of the guidewire-management device by way of the first sleeve. The thumb wheel is also configured to assist in proximally feeding the guidewire into the guidewire-management device by way of the first sleeve.

[0016] In some embodiments, the first sleeve has a distal portion configured as a male connector with a Luer taper for connecting the first sleeve to a complementary female connector.

[0017] In some embodiments, the first sleeve is configured to straighten a 'J'-shaped tip in a distal portion of the guidewire as the tip of the guidewire enters the first sleeve when proximally feeding the guidewire into the guidewire-management device.

[0018] In some embodiments, the second sleeve has a proximal portion including a bore with a constriction configured to capture a ball end of the guidewire and stop the guidewire from completely passing through the second sleeve.

[0019] In some embodiments, the splittable casing is over an entirety of the guidewire excepting that within or distal to the first sleeve.

[0020] In some embodiments, the guidewire-management device further includes a guidewire conduit coupled to the second sleeve and a casing conduit coupled to both a first split sleeve in the distal portion of the handle and a second split sleeve in the proximal portion of the handle. The guidewire conduit is configured to distally feed the guidewire into the second sleeve. The casing conduit is configured to collect therein the splittable casing that splits off the guidewire while distally feeding the guidewire out of the guidewire-management device.

[0021] In some embodiments, the handle includes a channel configured to hold the guidewire conduit therein when the guidewire conduit is in a coiled configuration.

[0022] In some embodiments, the guidewire-management device further includes a guidewire-casing conduit coupled to both the second sleeve and a first split sleeve in the distal portion of the handle. The guidewire-casing conduit is configured to distally feed the guidewire into the second sleeve. The guidewire-casing conduit is also configured to collect therein by way of the first split sleeve the splittable casing that splits off the guidewire while distally feeding the guidewire out of the guidewire-management device.

[0023] In some embodiments, a distal end of the splittable casing that splits off the guidewire is configured to chase a proximal end of the guidewire around the guidewire-casing conduit while distally feeding the guidewire out of the guidewire-management device.

[0024] In some embodiments, the handle includes a channel configured to hold the guidewire-casing conduit therein when the guidewire-casing conduit is in a coiled configuration.

[0025] In some embodiments, the guidewire-management device further includes a flexible membrane extending from the distal portion of the handle, over the thumb wheel, and to the proximal portion of the handle. The flexible membrane is configured to be pressed down onto the thumb wheel for distally feeding the guidewire out of the guidewire-management device or proximally feeding the guidewire into the guidewire-management device.

[0026] These and other features of the concepts provided herein will become more apparent to those of skill in the art in view of the accompanying drawings and following description, which describe particular embodiments of such concepts in greater detail. In addition, this application is related to U.S. Patent Application No. 17/079,320, filed October 23, 2020, which is incorporated by reference in its entirety into this application.

DRAWINGS

[0027] FIG. 1 provides an isometric view of a first guidewire-management device in accordance with some embodiments.

[0028] FIG. 2 provides a longitudinal cross section of the first guidewire-management device in accordance with some embodiments.

[0029] FIG. 3 provides an isometric view of a second guidewire-management device in accordance with some embodiments.

[0030] FIG. 4 provides a longitudinal cross section of the second guidewire-management device in accordance with some embodiments.

[0031] FIG. 5 provides a detailed view a ball end of a guidewire distal to a plug in a guidewire conduit in accordance with some embodiments.

[0032] FIG. 6 provides a side view of a third guidewire-management device in accordance with some embodiments.

[0033] FIG. 7 provides an isometric view of a handle of a fourth guidewire-management device in accordance with some embodiments.

[0034] FIG. 8 provides a longitudinal cross section of the fourth guidewire-management device in accordance with some embodiments.

[0035] FIG. 9 provides a side view of a handle of a fifth guidewire-management device in accordance with some embodiments.

[0036] FIG. 10 provides the handle of a fifth guidewire-management device with a guidewire partially advanced out of the guidewire-management device in accordance with some embodiments.

[0037] FIG. 11 provides the handle of the fifth guidewire-management device with the guidewire partially advanced out of the guidewire-management device farther than that shown in FIG. 10.

[0038] FIG. 12 provides a side view of a handle of a sixth guidewire-management device in accordance with some embodiments.

[0039] FIG. 13 provides an isometric view of a seventh guidewire-management device in accordance with some embodiments.

[0040] FIG. 14 provides a side view of the seventh guidewire-management device in accordance with some embodiments.

[0041] FIG. 15 provides an isometric view of an eighth guidewire-management device in accordance with some embodiments.

[0042] FIG. 16 provides a side view of the eighth guidewire-management device in accordance with some embodiments.

[0043] FIG. 17 provides a side view of the eighth guidewire-management device coupled with a catheter assembly in accordance with some embodiments.

DESCRIPTION

[0044] Before some particular embodiments are disclosed in greater detail, it should be understood that the particular embodiments disclosed herein do not limit the scope of the concepts provided herein. It should also be understood that a particular embodiment disclosed herein can have features that can be readily separated from the particular embodiment and optionally combined with or substituted for features of any of a number of other embodiments disclosed herein.

[0045] Regarding terms used herein, it should also be understood the terms are for the purpose of describing some particular embodiments, and the terms do not limit the scope of the concepts provided herein. Ordinal numbers (e.g., first, second, third, etc.) are generally used to distinguish or identify different features or steps in a group of features or steps, and do not supply a serial or numerical limitation. For example, "first," "second," and "third" features or steps need not necessarily appear in that order, and the particular embodiments including such features or steps need not necessarily be limited to the three features or steps. Labels such as "left," "right," "top," "bottom," "front," "back," and the like are used for convenience and are not intended to imply, for example, any particular fixed location, orientation, or direction. Instead, such labels are used to reflect, for example, relative location, orientation, or directions. Singular forms of "a," "an," and "the" include plural references unless the context clearly dictates otherwise.

[0046] With respect to "proximal," a "proximal portion" or a "proximal end portion" of, for example, a catheter disclosed herein includes a portion of the catheter intended to be near a clinician when the catheter is used on a patient. Likewise, a "proximal length" of, for example, the catheter includes a length of the catheter intended to be near the clinician when the catheter is used on the patient. A "proximal end" of, for example, the catheter includes an end of the catheter intended to be near the clinician when the catheter is used on the patient. The proximal portion, the proximal end portion, or the proximal length of the catheter can include the proximal end of the catheter; however, the proximal portion, the proximal end

portion, or the proximal length of the catheter need not include the proximal end of the catheter. That is, unless context suggests otherwise, the proximal portion, the proximal end portion, or the proximal length of the catheter is not a terminal portion or terminal length of the catheter.

[0047] With respect to "distal," a "distal portion" or a "distal end portion" of, for example, a catheter disclosed herein includes a portion of the catheter intended to be near or in a patient when the catheter is used on the patient. Likewise, a "distal length" of, for example, the catheter includes a length of the catheter intended to be near or in the patient when the catheter is used on the patient. A "distal end" of, for example, the catheter includes an end of the catheter intended to be near or in the patient when the catheter is used on the patient. The distal portion, the distal end portion, or the distal length of the catheter can include the distal end of the catheter; however, the distal portion, the distal end portion, or the distal length of the catheter need not include the distal end of the catheter. That is, unless context suggests otherwise, the distal portion, the distal end portion, or the distal length of the catheter is not a terminal portion or terminal length of the catheter.

[0048] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by those of ordinary skill in the art.

[0049] As set forth above, there is a need for better guidewire management in medical procedures such as those requiring the Seldinger technique. Disclosed herein are guidewire-management devices and methods thereof that address the foregoing.

Guidewire-management devices

[0050] FIGS. 1-16 illustrate various guidewire-management devices, namely guidewire-management devices 100, 300, 600, 700, 900, 1200, 1300, and 1500. For expository expediency, guidewire-management devices 100, 300, 600, and 700 are initially described below with an emphasis on features in common with each other and many other guidewire management devices set forth herein. Such features can be identified among the various guidewire-management devices by identical reference numbers (e.g., guidewire 102), similar reference numbers (e.g., first sleeve 110, first sleeve 610, first sleeve 710, or the like, where the leading digits of the reference numbers are different to reflect the figures or embodiments associated with the features), description, or a combination thereof. Indeed, features in common among any group of guidewire-management devices of the various guidewire-management devices 100, 300, 600, 700, 900, 1200, 1300, and 1500 can be similarly identified. Subsequent

to the initial description for the guidewire-management devices 100, 300, 600, and 700, the guidewire-management devices 100, 300, 600, 700, 900, 1200, 1300, and 1500 are individually or collectively described below with respect to some of the unique features thereof.

[0051] As shown, the guidewire-management device 100, 300, 600, or 700 includes a guidewire 102, a first sleeve 110, 610, or 710, and a second sleeve 120, 620, or 720.

[0052] The first sleeve 110, 610, or 710 is configured with a lumen for distally feeding, or advancing, the guidewire 102 out of the guidewire-management device 100, 300, 600, or 700. The first sleeve 110, 610, or 710 has a distal portion configured as a male connector with a Luer taper for connecting the first sleeve 110, 610, or 710 to a complementary female connector such as that of a hub of a hollow needle or a catheter. The male connector is configured such that when coupled to such a complementary female connector of, for example, the foregoing catheter, the guidewire-management device 100, 300, 600, or 700 forms a single unit with the catheter, thereby enabling the single unit to be held with one hand for guidewire management (e.g., distally feeding the guidewire 102 out of the guidewire-management device 100, 300, 600, or 700 into the catheter). (*See* FIG. 17.) The first sleeve 110, 610, or 710 also has a proximal portion including a bore 112, 612 (not shown), or 712 into which the lumen of the first sleeve 110, 610, or 710 opens. The bore 112, 612, or 712 is configured to house a distal portion of a sterile barrier 104 or 304 or collect the distal portion of the sterile barrier 104 or 304 when distally feeding the guidewire 102 out of the guidewire-management device 100, 300, 600, or 700.

[0053] The first sleeve 110, 610, or 710 is also configured for proximally feeding, or withdrawing, the guidewire 102 into the guidewire-management device 100, 300, 600, or 700. The first sleeve 110, 610, or 710 is configured to straighten the guidewire 102 such as a 'J'-shaped tip thereof when proximally feeding the guidewire 102 into the guidewire-management device 100, 300, 600, or 700. (*See* FIGS. 7 and 8 for the 'J'-shaped tip of the guidewire 102 in accordance with some embodiments.) The first sleeve 110, 610, or 710 can include a seal such as an 'O'-ring 114, 614 (not shown), or 714 configured to block fluid (e.g., blood) from entering the guidewire-management device 100, 300, 600, or 700 when proximally feeding the guidewire into the guidewire-management device 100, 300, 600, or 700. The seal, for example, the 'O'-ring 114, 614, or 714, is also configured to block fluid (e.g., air) from escaping the guidewire-management device 100, 300, 600, or 700 when proximally feeding the guidewire

into the guidewire-management device 100, 300, 600, or 700, thereby minimizing or obviating risk of air embolism.

[0054] The second sleeve 120, 620, or 720 is proximal of the first sleeve 110, 610, or 710 in the guidewire-management device 100, 300, 600, or 700 such that at least a length of the guidewire 102 extends between the first sleeve 110, 610, or 710 and the second sleeve 120, 620, or 720. At least the length of the guidewire 102 extending between the first sleeve 110, 610, or 710 and the second sleeve 120, 620, or 720 is disposed within the sterile barrier 104 or 304.

[0055] The second sleeve 120, 620, or 720 is configured with a lumen for feeding the guidewire 102 in concert with the first sleeve 110, 610, or 710 such as distally feeding the guidewire 102 out of the guidewire-management device 100, 300, 600, or 700. The second sleeve 120, 620, or 720 has a proximal portion optionally including a bore 122 into which the lumen of the second sleeve 120, 620, or 720 opens. For example, the second sleeve 120 has the proximal portion including the bore 122, whereas the second sleeve 620 or 720 has the proximal portion without such a bore. Whether or not the second sleeve 120, 620, or 720 includes such a bore, the second sleeve 120, 620, or 720 further includes a constriction 124, a recess 724, or a similar stopping means for stopping an end of the guidewire 102 such as a ball or slug end thereof from completely passing through the second sleeve 120, 620, or 720 when distally feeding the guidewire 102 out of the guidewire-management device 100, 300, 600, or 700. Since the constriction 124, the recess 724, or the similar stopping means is configured to stop the end of the guidewire 102 from completely passing through the second sleeve 120, 620, or 720, the constriction 124, the recess 724, or the similar stopping means is also configured to stop the guidewire from completely passing through the guidewire-management device 100, 300, 600, or 700 and into a patient where the guidewire 102 can be lost.

[0056] The second sleeve 120, 620, or 720 is also configured for proximally feeding the guidewire 102 into of the guidewire-management device 100, 300, 600, or 700 in concert with the first sleeve 110, 610, or 710. The second sleeve 120, 620, 720 has a distal portion including a bore 126, 626 (not shown), or 726 into which the lumen of the second sleeve 120, 620, or 720 opens. The bore 126, 626, or 726 is configured to house a proximal portion of the sterile barrier 104 or 304 or collect the proximal portion of the sterile barrier 104 or 304 when proximally feeding the guidewire 102 into of the guidewire-management device 100, 300, 600, or 700.

[0057] The guidewire 102 has a distal portion and a proximal portion.

[0058] The distal portion of the guidewire 102 can include a 'J'-shaped tip configured to straighten as the tip of the guidewire 102 enters the first sleeve 110, 610, or 710 when proximally feeding the guidewire 102 into the guidewire-management device 100, 300, 600, or 700. When distally feeding the guidewire 102 out of the guidewire-management device 100, 300, 600, or 700, the 'J'-shaped tip is configured to reform the 'J' shape upon release from its constriction (e.g., the first sleeve 110, 610, or 710). If the first sleeve 110, 610, or 710 is connected to a complementary female connector such as that of a hub of a hollow needle, the tip of the guidewire 102 does not reform the 'J' shape until the tip is distally beyond the needle such as in a blood vessel.

[0059] The proximal portion of the guidewire 102 can include a ball end configured to stop the guidewire 102 from completely passing through the second sleeve 120, 620, or 720 on account of the constriction 124, the recess 724, or the similar stopping means when distally feeding the guidewire 102 out the guidewire-management device 100, 300, 600, or 700.

[0060] The sterile barrier 104 or 304 is configured to maintain sterility of the guidewire 102 while the guidewire 102 is disposed therein. Importantly, the guidewire never needs to be touched by a clinician during a procedure, thereby preserving the sterility of the guidewire 102 as well as ensuring the clinician remains free from contact with bodily fluids.

[0061] The sterile barrier 104 is a pleated bag. The sterile barrier 104, or the bag 104, is configured to unpleat as it is drawn from the second sleeve 120 of the guidewire-management device 100 or pass through the second sleeve 620 or 720 of the guidewire-management device 600 or 700 while distally feeding the guidewire 102 out of the guidewire-management device 100, 600, or 700. The bag 104 is also configured to pleat as it is inserted into the first sleeve 110, 610, or 710 while distally feeding the guidewire 102 out of the guidewire-management device 100, 600, or 700. Likewise, the bag 104 is configured to unpleat as it is drawn from the first sleeve 110, 610, or 710 while proximally feeding the guidewire 102 into the guidewire-management device 100, 600, or 700. The bag 104 is also configured to pleat as it is inserted into the second sleeve 120 of the guidewire-management device 100 or pass through the second sleeve 620 or 720 of the guidewire-management device 600 or 700 while proximally feeding the guidewire 102 into the guidewire-management device 100, 600, or 700.

[0062] Advantageously, in guidewire-management devices such as the guidewire-management devices 600 and 700, a combination of a length of the bag 104 and a sealed or valved end thereof is configured to stop the end (e.g., ball end) of the guidewire 102 from passing through what would otherwise be an opening in a proximal end of the bag 104. Stopping the end of the guidewire 102 from passing through such an opening prevents the tip of the guidewire 102 from completely passing through the first sleeve 110 and reforming the 'J'-shaped tip when proximally feeding the guidewire 102 into the guidewire-management device 600 or 700.

[0063] A method for distally feeding, or advancing, the guidewire 102 out of the guidewire-management device 100, 600, or 700 is set forth below. A method for proximally feeding, or withdrawing, the guidewire 102 into the guidewire-management device 100, 600, or 700 is also set forth below.

[0064] The sterile barrier 304 is a bellowed boot. The sterile barrier 304, or the boot 304, is configured to iteratively stretch from an equilibrium state and relax back into the equilibrium state while distally feeding the guidewire 102 out of the guidewire-management device 300. Likewise, the boot 304 is configured to iteratively stretch from an equilibrium state and relax back into the equilibrium state while proximally feeding the guidewire 102 into the guidewire-management device 300.

[0065] A method for distally feeding, or advancing, the guidewire 102 out of the guidewire-management device 300 is set forth below. A method for proximally feeding, or withdrawing, the guidewire 102 into the guidewire-management device 300 is also set forth below.

[0066] While not shown for any guidewire-management device of the guidewire-management devices 100, 300, 600, and 700, the sterile barrier 104 or 304 can alternatively be a splittable casing 904 over an entirety of the guidewire 102 or at least most of the guidewire 102, for example, excepting that within or distal to the first sleeve 110, 610, or 710. The splittable casing 904 is configured to split off the guidewire 102 while distally feeding the guidewire 102 out of a guidewire-management device. (*See*, for example, the guidewire-management devices 900, 1200, 1300, and 1500.) Some of the foregoing guidewire-management devices (e.g., the guidewire-management devices 1300 and 1500) are configured to insert the guidewire 102 into the splittable casing 904 while proximally feeding the

guidewire 102 into the guidewire-management devices. The splittable casing 904 can include graduated markings thereon configured to indicate a length of the guidewire 102 from the tip thereof.

[0067] Adverting to FIGS. 1-4 to describe some of the unique features of least the guidewire-management devices 100 and 300, the guidewire-management devices 100 and 300 include the guidewire 102, a frame 140 including a pair of tubular rails 142, a guidewire conduit 150 threaded through the pair of tubular rails 142, the first sleeve 110 mounted on struts between each rail of the pair of tubular rails 142, and the second sleeve 120 mounted on struts between each rail of the pair of tubular rails 142 proximal of the first sleeve 110. At least a portion of the guidewire 102 is disposed within the guidewire conduit 150.

[0068] The guidewire conduit 150 can be opaque or translucent depending upon a chosen polymeric material. When the guidewire conduit 150 is translucent, the guidewire conduit 150 is configured for viewing the guidewire 102 while distally feeding the guidewire 102 out of the guidewire-management device 100 or 300 or proximally feeding the guidewire 102 into the guidewire-management device 100 or 300.

[0069] FIG. 5 illustrates the ball end of the guidewire 102 distal to a plug 152 in the guidewire conduit 150 in accordance with some embodiments.

[0070] The guidewire conduit 150 has a proximal portion including the plug 152 configured to stop the ball end of the guidewire 102 from passing through what would otherwise be an opening in a proximal end of the guidewire conduit 150. Alternatively, the plug 152 is simply a crimped portion of the guidewire conduit 150 with the same effect. Stopping the ball end of the guidewire 102 from passing through such an opening prevents the tip of the guidewire 102 from completely passing through the first sleeve 110 and reforming the 'J'-shaped tip when proximally feeding the guidewire 102 into the guidewire-management device 100 or 300.

[0071] Adverting to FIGS. 6-16 to describe some of the unique features of at least the guidewire-management devices 600, 700, 900, 1200, 1300, and 1500, the guidewire-management device 600, 700, 900, 1200, 1300, or 1500 includes a handle 640, 740, 940, 1240, 1340, or 1540, the guidewire 102, the first sleeve 610, 710, 910, 1210, 1310, or 1510 formed in a distal portion of the handle 640, 740, 940, 1240, 1340, or 1540, the second sleeve 620, 720, 920, 1220, 1320, or 1520 formed in a proximal portion of the handle 640, 740, 940, 1240,

1340, or 1540, and a thumb wheel 642, 742, 942, 1242, 1342, or 1542 disposed under the guidewire 102 between the first sleeve 610, 710, 910, 1210, 1310, or 1510 and the second sleeve 620, 720, 920, 1220, 1320, or 1520.

[0072] The handle 640, 740, 940, 1240, 1340, or 1540 is ambidextrous in that it is configured to be held in either a right or left hand of a clinician. In addition, the handle 640, 740, 940, 1240, 1340, or 1540 is configured to be held in at least two different modes. The first mode, in which the clinician holds the handle 640, 740, 940, 1240, 1340, or 1540 like a person might hold the handle of a hammer, is a general mode for handling the guidewire-management device 600, 700, 900, 1200, 1300, or 1500. The second mode, in which the clinician repositions his or her thumb over the thumb wheel 642, 742, 942, 1242, 1342, or 1542, is an operational mode for advancing the guidewire 102 out of the guidewire-management device 600, 700, 900, 1200, 1300, or 1500 or withdrawing the guidewire 102 into the guidewire-management device 600, 700, 900, 1200, 1300, or 1500. Notwithstanding the foregoing, some clinicians might find it comfortable to hold the handle 640, 740, 940, 1240, 1340, or 1540 like a person might hold the barrel of a flashlight, thereby accessing both the first and second modes with less hand movement.

[0073] The handle 640, 1340, or 1540 includes a channel 641, 1341, or 1541 configured to hold a conduit therein. As set forth below, the conduit can be the guidewire conduit 1350 of the guidewire-management device 1300, the guidewire-casing conduit 1550 of the guidewire-management device 1500, or the like. Advantageously, such a channel can hold a conduit in a coiled configuration, thereby packing an otherwise elongate conduit into a compact space. While only the handles 640, 1340, and 1540 are shown with channels, any handle of the handles 740, 940, and 1240 can include a channel configured to hold a conduit. In addition, the handle 640, 1340, or 1540 need not include the channel 641, 1341, or 1541.

[0074] Notwithstanding possible differences in one or more design elements, the first sleeve 910, 1210, 1310, or 1510 is similar to the first sleeve 110, 610, or 710 set forth above. As such, the description set forth above for the first sleeves 110, 610, and 710 should be understood to extend to the first sleeves 910, 1210, 1310, and 1510 as if the first sleeves 910, 1210, 1310, and 1510 were included in the description of the first sleeves 110, 610, and 710.

[0075] Notwithstanding possible differences in one or more design elements, the second sleeve 920, 1220, 1320, or 1520 is similar to the second sleeve 120, 620, or 720 set

forth above. As such, the description set forth above for the second sleeves 120, 620, and 720 should be understood to extend to the second sleeves 920, 1220, 1320, and 1520 as if the second sleeves 920, 1220, 1320, and 1520 were included in the description of the second sleeves 120, 620, and 720.

[0076] The thumb wheel 642, 742, 942, 1242, 1342, or 1542 can be rotatably mounted on an axle fixedly coupled to each side of the handle 640, 740, 940, 1240, 1340, or 1540 such that the thumb wheel 642, 742, 942, 1242, 1342, or 1542 rotates relative to both the axle and the handle 640, 740, 940, 1240, 1340, or 1540. Alternatively, the thumb wheel 642, 742, 942, 1242, 1342, or 1542 can include the axle (e.g., as a unitary piece) or be fixedly mounted on the axle, which, in turn, is rotatably coupled to each side of the handle 640, 740, 940, 1240, 1340, or 1540 such that a combination of the thumb wheel 642, 742, 942, 1242, 1342, or 1542 and the axle rotates with respect to the handle 640, 740, 940, 1240, 1340, or 1540. The thumb wheel 642, 742, 942, 1242, 1342, or 1542 is configured to assist in distally feeding the guidewire 102 out of the guidewire-management device 600, 700, 900, 1200, 1300, or 1500 by way of the first sleeve 610, 710, 910, 1210, 1310, or 1510. The thumb wheel 642, 742, 942, 1242, 1342, or 1542 is also configured to assist in proximally feeding the guidewire 102 into the guidewire-management device 600, 700, 900, 1200, 1300, or 1500 by way of the first sleeve 610, 710, 910, 1210, 1310, or 1510.

[0077] A method for distally feeding, or advancing, the guidewire 102 out of the guidewire-management device 600, 700, 900, 1200, 1300, or 1500 is set forth below. A method for proximally feeding, or withdrawing, the guidewire 102 into the guidewire-management device 600, 700, 900, 1200, 1300, or 1500 is also set forth below.

[0078] Adverting to FIGS. 9-12 to describe some of the unique features of at least the guidewire-management device 900 or 1200, the guidewire-management device 900 or 1200 includes a first split sleeve 911 or 1211 in the distal portion of the handle 940 or 1240.

[0079] The first split sleeve 911 or 1211 splits off the first sleeve 910 or 1210 in the distal portion of the handle 940 or 1240. Like the lumen of the first sleeve 110, 610, or 710 set forth above, as well as that of the first sleeve 910 or 1210 by extension, the first split sleeve 911 or 1211 is configured with a lumen. Indeed, the lumen of the first split sleeve 911 or 1211 splits or furcates from the lumen of the first sleeve 910 or 1210, thereby forming a bifurcated lumen between the first sleeve 910 or 1210 and the first split sleeve 911 or 1211 in the distal

portion of the handle 940 or 1240. Whereas the first sleeve 910 or 1210 is configured for at least distally feeding the guidewire 102 out of the guidewire-management device 900 or 1200, the first split sleeve 911 or 1211 is configured for discharging the splittable casing 904 that splits off the guidewire 102 while distally feeding the guidewire 102 out of the guidewire-management device 900 or 1200. In fact, the bifurcated lumen between the first sleeve 910 or 1210 and the first split sleeve 911 or 1211 is configured to facilitate splitting the splittable casing 904 off the guidewire 102 while distally feeding the guidewire 102 out of the guidewire-management device 900 or 1200.

[0080] Adverting to FIG. 12 to describe some of the unique features of at least the guidewire-management device 1200, the guidewire-management device 1200 includes a flexible membrane 1206 extending from the distal portion of the guidewire-management device 1200, over the thumb wheel 1242, and to the proximal portion of the guidewire-management device 1200. Indeed, the membrane 1206 can be coupled to a portion of the first sleeve 1210 in the distal portion of the guidewire-management device 1200 and a portion of the second sleeve 1220 in the proximal portion of the guidewire-management device 1200.

[0081] The membrane 1206 is configured for distally feeding the guidewire 102 out of the guidewire-management device 1200 or proximally feeding the guidewire 102 into the guidewire-management device 1200. The membrane 1206 has sufficient flexibility for a medial portion of the membrane 1206 to be pressed down onto a proximal portion of the thumb wheel 1242, distally moved when the thumb wheel 1242 is rolled, and released back into an equilibrium state of the membrane 1206 for one or more additional rounds of the foregoing. Likewise, the membrane 1206 has sufficient flexibility for the medial portion of the membrane 1206 to be pressed down onto a distal portion of the thumb wheel 1242, proximally moved when the thumb wheel 1242 is rolled, and released back into the equilibrium state of the membrane 1206 for one or more additional rounds of the foregoing.

[0082] The membrane 1206 can have a low durometer, a degree of tackiness, or the like to facilitate gripping the guidewire 102 or a combination of the guidewire 102 within the bag 104 or splittable casing 904 for distally feeding the guidewire 102 out of the guidewire-management device 1200 or proximally feeding the guidewire 102 into the guidewire-management device 1200. As shown in FIG. 12, for example, the combination of the guidewire 102 within the splittable casing 904 is disposed between the membrane 1206 and the thumb wheel 1242 of the guidewire-management device 1200. When the medial portion of the

membrane 1206 is pressed down onto the proximal or distal portion of the thumb wheel 1242, the combination of the guidewire 102 within the splittable casing 904 is also pressed down onto the proximal or distal portion of the thumb wheel 1242. When the thumb wheel 1242 is subsequently rolled, the combination of the guidewire 102 within the splittable casing 904 is distally or proximally moved with the medial portion of the membrane 1206. And when the medial portion of the membrane 1206 is released back into the equilibrium state of the membrane 1206, the combination of the guidewire 102 within the splittable casing 904 is also released. In this way, one or more additional rounds of the foregoing can distally feed the guidewire 102 out of the guidewire-management device 1200 or proximally feed the guidewire 102 into the guidewire-management device 1200.

[0083] Adverting to FIGS. 13 and 14 to describe some of the unique features of at least the guidewire-management device 1300, the guidewire-management device 1300 includes a guidewire conduit 1350 coupled to the second sleeve 1320 and a casing conduit 1354 coupled to both a first split sleeve 1311 in the distal portion of the handle 1340 and a second split sleeve 1321 in the proximal portion of the handle 1340.

[0084] Notwithstanding possible differences in one or more design elements, the first split sleeve 1311 is similar to the first split sleeve 911 or 1211 set forth above. As such, the description set forth above for the first split sleeves 911 and 1211 should be understood to extend to the first split sleeve 1311 as if the first split sleeve 1311 were included in the description of the first split sleeves 911 or 1211.

[0085] The second split sleeve 1321 splits off the second sleeve 1320 in the distal portion of the handle 1340. Like the lumen of the second sleeve 120, 620, or 720 set forth above, as well as that of the second sleeve 1320 by extension, the second split sleeve 1321 is configured with a lumen. Indeed, the lumen of the second split sleeve 1321 splits or furcates from the lumen of the second sleeve 1320, thereby forming a bifurcated lumen between the second sleeve 1320 and the second split sleeve 1321 in the distal portion of the handle 1340. Similar to the channel 1341 of the handle 1340, which channel 1341 is configured to hold the guidewire conduit 1350 therein, the second split sleeve 1321 is configured to hold the casing conduit 1354 therein.

[0086] As set forth above, the thumb wheel 1342 is configured to assist in distally feeding the guidewire 102 out of the guidewire-management device 1300 by way of the first

sleeve 1310. In concert with the thumb wheel 1342, the guidewire conduit 1350 is configured to distally feed the guidewire 102, or, more specifically, the guidewire 102 disposed in the splittable casing 904, into the second sleeve 1320. The guidewire conduit 1350 can be opaque or translucent depending upon a chosen polymeric material. When the guidewire conduit 1350 is translucent, the guidewire conduit 1350 is configured for viewing the guidewire 102 while distally feeding the guidewire 102 into the second sleeve 1320. In addition, the casing conduit 1354 is configured to collect therein the splittable casing 904 that splits off the guidewire 102 while distally feeding the guidewire 102 out of the guidewire-management device 1300. Like the guidewire conduit 1350, the casing conduit 1354 can be opaque or translucent depending upon a chosen polymeric material. When the casing conduit 1354 is translucent, the casing conduit 1354 is configured for viewing the splittable casing 904 that splits off the guidewire 102 and into the casing conduit 1354 while distally feeding the guidewire 102 out of the guidewire-management device 1300.

[0087] As further set forth above, the thumb wheel 1342 is also configured to assist in proximally feeding the guidewire 102 into the guidewire-management device 1300 by way of the first sleeve 1310. In concert with the thumb wheel 1342, the casing conduit 1354 is configured to feed the splittable casing 904 that split off the guidewire 102 while distally feeding the guidewire 102 out of the guidewire-management device 1300 into the first sleeve 1310 for combination with the guidewire 102 as the guidewire 102 is proximally fed into the guidewire-management device 1300. Again, the casing conduit 1354 can be opaque or translucent. When the casing conduit 1354 is translucent, the casing conduit 1354 is configured for viewing the splittable casing 904 while proximally feeding the splittable casing 904 into the guidewire-management device 1300 for combination with the guidewire 102. The guidewire conduit 1350 is configured to collect therein the combination of the guidewire 102 and splittable casing 904, preferably, the guidewire 102 redisposed in the splittable casing 904, while proximally feeding the guidewire 102 into the guidewire-management device 1300. Again, the guidewire conduit 1350 can be opaque or translucent. When the guidewire conduit 1350 is translucent, the guidewire conduit 1350 is configured for viewing the combination of the guidewire 102 and splittable casing 904 while proximally feeding the guidewire 102 into the guidewire-management device 1300.

[0088] Adverting to FIGS. 15 and 16 to describe some of the unique features of at least the guidewire-management device 1500, the guidewire-management device 1500 includes a

guidewire-casing conduit 1550 coupled to both the second sleeve 1520 and a first split sleeve 1511 in the distal portion of the handle 1540. The handle 1540 can include the channel 1541 configured to hold the guidewire-casing conduit 1550 therein when the guidewire-casing conduit 1550 is in a coiled configuration like that shown.

[0089] Notwithstanding possible differences in one or more design elements, the first split sleeve 1511 is similar to the first split sleeve 911 or 1211 set forth above. As such, the description set forth above for the first split sleeves 911 and 1211 should be understood to extend to the first split sleeve 1511 as if the first split sleeve 1511 were included in the description of the first split sleeves 911 or 1211.

[0090] As set forth above, the thumb wheel 1542 is configured to assist in distally feeding the guidewire 102 out of the guidewire-management device 1500 by way of the first sleeve 1510. In concert with the thumb wheel 1542, the guidewire-casing conduit 1550 is configured to distally feed the guidewire 102, or, more specifically, the guidewire 102 disposed in the splittable casing 904, into the second sleeve 1520. The guidewire-casing conduit 1550 can be opaque or translucent depending upon a chosen polymeric material. When the guidewire-casing conduit 1550 is translucent, the guidewire-casing conduit 1550 is configured for viewing the guidewire 102 while distally feeding the guidewire 102 into the second sleeve 1520. In addition, the guidewire-casing conduit 1550 is configured to collect therein the splittable casing 904 that splits off the guidewire 102 while distally feeding the guidewire 102 out of the guidewire-management device 1500. A distal end of the splittable casing 904 that splits off the guidewire 102 is configured to chase the ball end of the guidewire 102 around the guidewire-casing conduit 1550 while distally feeding the guidewire 102 out of the guidewire-management device 1500. Indeed, when the guidewire-casing conduit 1550 is translucent, the guidewire-casing conduit 1550 is configured for viewing the splittable casing 904 chase the ball end of the guidewire 102 around the guidewire-casing conduit 1550 while distally feeding the guidewire 102 out of the guidewire-management device 1500.

[0091] As further set forth above, the thumb wheel 1542 is also configured to assist in proximally feeding the guidewire 102 into the guidewire-management device 1500 by way of the first sleeve 1510. In concert with the thumb wheel 1542, the guidewire-casing conduit 1550 is configured to feed the splittable casing 904 that split off the guidewire 102 while distally feeding the guidewire 102 out of the guidewire-management device 1500 into the first sleeve 1510 for combination with the guidewire 102 as the guidewire is proximally fed into the

guidewire-management device 1500. Again, the guidewire-casing conduit 1550 can be opaque or translucent. When the guidewire-casing conduit 1550 is translucent, the guidewire-casing conduit 1550 is configured for viewing the splittable casing 904 while proximally feeding the splittable casing 904 into the guidewire-management device 1500 for combination with the guidewire 102. The guidewire-casing conduit 1550 is configured to collect therein the combination of the guidewire 102 and splittable casing 904, preferably, the guidewire 102 redisposed in the splittable casing 904, while proximally feeding the guidewire 102 into the guidewire-management device 1500. When the guidewire-casing conduit 1550 is translucent, the guidewire-casing conduit 1550 is configured for viewing the combination of the guidewire 102 and splittable casing 904 while proximally feeding the guidewire 102 into the guidewire-management device 1500.

[0092] Lastly, FIG. 17 provides a side view of an assembly 1700 of the guidewire-management device 1500 coupled with a catheter assembly 1702 in accordance with some embodiments. With Luer connectors of the guidewire-management device 1500 and the catheter assembly 1702 coupled as shown, single-handed guidewire management while holding the assembly 1700 by the handle 1540 of the guidewire-management device 1500 is enabled.

Methods

[0093] A method of the guidewire-management device 100, 300, or 600 includes a connecting step of connecting the first sleeve 110 or 610 of the guidewire-management device 100, 300, or 600 to a hub of a medical device (e.g., a hollow needle) inserted into an insertion site of a patient.

[0094] The method further includes an advancing step of advancing the guidewire 102 of the guidewire-management device 100, 300, or 600 from the first sleeve 110 or 610 through the hub of the medical device and into the insertion site of the patient. The seal (e.g., the 'O'-ring 114 or 714) in the first sleeve 110 or 610 blocks fluid (e.g., air) from escaping the guidewire-management device 100, 300, or 600 when advancing the guidewire 102 through the hub of the medical device and into the insertion site of the patient.

[0095] The advancing step can include pinching the guidewire 102 within the sterile barrier 104 or 304 and advancing the guidewire 102 into the first sleeve 110 by hand. The advancing can alternatively include pressing the guidewire 102 within the sterile barrier 104

onto the thumb wheel 742 and rolling the thumb wheel 742 to advance the guidewire 102 into the first sleeve 610.

[0096] Indeed, the guidewire 102 can be advanced into the first sleeve 110 or 610 and out of the guidewire-management device 100 or 600 by pinching a combination of the guidewire 102 within the bag 104 or pressing the guidewire 102 within the bag 104 against the thumb wheel 742, advancing the guidewire 102 into the first sleeve 110 by hand or by rolling the thumb wheel 742, releasing the combination of the guidewire 102 within the bag 104, and repeating the foregoing as necessary. The guidewire 102 can be advanced into the first sleeve 110 and out of the guidewire-management device 300 by pinching a combination of the guidewire 102 within the boot 304, advancing the guidewire 102 into the first sleeve 110 by hand, releasing the combination of the guidewire 102 within the boot 304, and repeating the foregoing as necessary.

[0097] The method can further include a ceasing step of ceasing to advance the guidewire 102 into the insertion site of the patient when the ball end of the guidewire 102 is captured in the constriction 124 of the bore 122 in the second sleeve 120 of the guidewire-management device 100 or 300. Likewise, the ceasing step can include ceasing to advance the guidewire 102 into the insertion site of the patient when the ball end of the guidewire 102 is captured in the recess 724 in the second sleeve 620 of the guidewire-management device 600.

[0098] The method further includes withdrawing the guidewire 102 from the insertion site of the patient through the hub of the medical device and into the first sleeve 110 or 610. The seal (e.g., the 'O'-ring 114 or 714) in the first sleeve 110 or 610 blocks fluid (e.g., blood) from entering the guidewire-management device 100, 300, or 600 when withdrawing the guidewire 102 from the insertion site.

[0099] Indeed, the guidewire 102 can be withdrawn into the guidewire-management device 100 or 600 through the first sleeve 110 or 610 by pinching the combination of the guidewire 102 within the bag 104 or pressing the guidewire 102 within the bag 104 against the thumb wheel 742, withdrawing the guidewire 102 from the first sleeve 110 by hand or by rolling the thumb wheel 742, releasing the combination of the guidewire 102 within the bag 104, and repeating the foregoing as necessary. The guidewire 102 can be withdrawn into the guidewire-management device 300 through the first sleeve 110 by pinching the combination of the guidewire 102 within the boot 304, withdrawing the guidewire 102 from the first sleeve

110 by hand, releasing the combination of the guidewire 102 within the boot 304, and repeating the foregoing as necessary.

[0100] The method can further include ceasing to withdraw the guidewire 102 from the insertion site of the patient when the proximal end or the ball end of the guidewire 102 abuts the plug 152 in the proximal portion of the guidewire conduit 150 of the guidewire-management device 100 or 300.

[0101] While some particular embodiments have been disclosed herein, and while the particular embodiments have been disclosed in some detail, it is not the intention for the particular embodiments to limit the scope of the concepts provided herein. Additional adaptations and/or modifications can appear to those of ordinary skill in the art, and, in broader aspects, these adaptations and/or modifications are encompassed as well. Accordingly, departures may be made from the particular embodiments disclosed herein without departing from the scope of the concepts provided herein.