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Anchor instrumentation and methods

Abstract

Some embodiments of a medical device anchor system include an anchor sleeve that receives a catheter (or other medical instrument) though a working channel of the anchor sleeve. The anchor sleeve may include a first actuator that controls the extension of one or more subcutaneous tines into the subcutaneous region under the skin. The anchor sleeve can also include a second actuator that can cause the anchor sleeve to lock onto an outer portion of the catheter (or other medical instrument) arrange in the working channel.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS (1) This is a continuation of U.S. application Ser. No. 17/078,579, filed on Oct. 23, 2020, which is a continuation of U.S. application Ser. No. 16/051,709, filed on Aug. 1, 2018 (now U.S. Pat. No. 10,814,105), which is a continuation of U.S. application Ser. No. 15/404,514 filed Jan. 12, 2017 (now U.S. Pat. No. 10,058,682), which

is a continuation of U.S. application Ser. No. 14/059,640 filed on Oct. 22, 2013 (now U.S. Pat. No. 9,545,503), which is a continuation of U.S. application Ser. No. 13/405,499, filed on Feb. 27, 2012 (now U.S. Pat. No. 8,585,654) by Michael S. Rosenberg et al. and entitled “Anchor Instrumentation And Methods,” which is a continuation of U.S. application Ser. No. 12/243,229, filed on Oct. 1, 2008 (now U.S. Pat. No. 8,147,459) by Michael S. Rosenberg et al. and entitled “Anchor Instrumentation And Methods,” which claims priority to U.S. Application Ser. No. 60/978,900, filed on Oct. 10, 2007 by Michael S. Rosenberg et al. and entitled “Anchor Instrumentation And Methods,” the contents of these earlier applications being fully incorporated herein by reference.

TECHNICAL FIELD

(1) This document relates to anchor instrumentation, such as an anchor device for use in placement of a catheter or other medical instrument.

BACKGROUND

(2) Venous, arterial, and body fluid catheters are commonly used by physicians. For example, such catheters may be used to gain access to the vascular system for dialysis, for introducing pharmaceutical agents, for nutrition or fluids, for hemodynamic monitoring, and for blood draws. Alternatively, catheters can be used for drainage of fluid collections and to treat infection. Following introduction into the patient, the catheter is secured to the patient. In conventional practice, the catheter is commonly secured to the patient using an adhesive tape patch or by suturing an attached hub to the patient's skin.

SUMMARY

(3) Some embodiments of a medical device anchor system include an anchor sleeve that receives a catheter (or other medical instrument) though a working channel of the anchor sleeve. The anchor sleeve may include a first actuator that controls the extension of one or more subcutaneous tines into the subcutaneous region under the skin. The anchor sleeve can also include a second actuator that can cause the anchor sleeve to lock onto the outer body of the catheter (or other medical instrument) arrange in the working channel.

(4) In some embodiments, an anchor sleeve device may include an elongate body that defines at least one working channel extending from a proximal opening to a distal tip opening so as to receive a catheter. The anchor sleeve device may also include a subcutaneous anchor mechanism coupled to the elongate body. The subcutaneous anchor mechanism may have one or more flexible anchors that extend away from the body wall when in a deployed orientation in a subcutaneous layer. The anchor sleeve device may include a first actuator that is adjustable relative to the elongate body so as to shift the flexible anchors to the deployed orientation. The anchor sleeve device may further include a locking device that releasably engages to the catheter when the catheter is received in the working channel. The anchor sleeve device may include a second actuator that is adjustable relative to the elongate body so as to urge the locking device to compress at least a portion of an outer surface of the catheter when the catheter is received in the working channel.

(5) Some embodiments can include a method of delivering a catheter device to an internal body site. The method may include advancing an anchor sleeve through a percutaneous opening so that one or more subcutaneous anchor tines are disposed adjacent to a subcutaneous region. The method may also include advancing a catheter device though a working channel of the anchor sleeve and toward a targeted body site. The catheter device may define at least one lumen that extends to a catheter tip. The method may further include operating a first actuator to deploy the subcutaneous anchor tines into the subcutaneous region. Also, the method may include operating a second actuator to deploy the subcutaneous anchor tines into the subcutaneous region to urge a locking device to compress at least a portion of an outer surface of the catheter when the catheter is received in the working channel.

(6) Some or all of the embodiments described herein may provide one or more of the following

advantages. First, some embodiments of the anchor sleeve may include subcutaneous anchors that retain the anchor sleeve in the subcutaneous region. For example, the anchors may comprise adjustable tines comprising a material that exhibits superelasticity when used in a human body (e.g., Nitinol or the like). The anchors can be deployed in the subcutaneous region so as to at least temporarily retain the anchor sleeve in engagement with the patient's body.
(7) Second, some embodiments of the anchor sleeve may include a first actuator device (e.g., a slider device in particular embodiments) that can be actuated to control the extension of the anchors into the subcutaneous region. As such, the anchor tines can be in a retracted position (e.g., retracted into the sleeve body) during passage through the skin surface. Thereafter, the anchor tines can be controllably shifted to the extended position under the skin and in the subcutaneous region so as to anchor the sleeve body to the skin insertion site.
(8) Third, some embodiment of the anchor sleeve may include a second actuator (e.g., a twist device in particular embodiments) that causes the anchor sleeve to releasably lock with the catheter (or other medical instrument) after the catheter has been advanced through the sleeve device toward a targeted location. In some circumstances, the locking device can also form a seal around the catheter when connected thereto. In particular, the locking device may comprise a polymeric seal member (e.g., a silicon cylindrical member or the like) that is compressed upon an outer surface of the catheter device in response to the adjustment of the second actuator.
(9) Fourth, because some embodiments of the anchor sleeve include a first actuator to deploy the anchors and a second actuator to cause the locking engagement, the anchor sleeve can be equipped to isolate these two functions and provide the proper amount of force for each function. For example, the force required to releasably lock the anchor sleeve with the catheter device may be substantially greater than the force required to deploy the anchors in the subcutaneous region. As such, the second actuator can be configured to provide a mechanical advantage for the user so that the locking force is applied in a suitable manner. Also, the first actuator can be configured to deploy the anchors without using an unnecessarily high level of force.
(10) The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

Description

DESCRIPTION OF DRAWINGS
(1) FIG. **1** is a perspective view of an anchor sleeve being advanced into a subcutaneous region and having a catheter device passing therethrough, in accordance with some embodiments.
(2) FIGS. **2-4** are perspective views of an anchor sleeve in accordance with some embodiments.
(3) FIGS. **5-7** are bottom views of the anchor sleeve of FIGS. **2-4**.
(4) FIGS. **8-10** are cross-sectional views of the anchor sleeve of FIGS. **2-4**.
(5) FIG. **11** is a perspective exploded view of adjustable anchor tines and a first actuator of an anchor sleeve, in accordance with some embodiments.
(6) FIG. **12** is a cross-sectional view of the adjustable anchor tines and the first actuator of FIG. **11**.
(7) Like reference symbols in the various drawings indicate like elements.
DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS
(8) Some embodiments of a medical device anchor system **10** include an anchor sleeve **100** and a catheter device **50** (or other medical instrument) to advance though a working channel **112** of the anchor sleeve **100**. The anchor sleeve **100** may include an elongate body **110**, into which the catheter device **50** can be inserted. The anchor sleeve **100** includes a distal tip portion **115** that may penetrate through a skin entry site **22** and into the subcutaneous layer **24** adjacent to the skin **20**. Also, the sleeve device **100** includes a proximal portion **116** that can remain external to the skin **20**

so as to provide an insertion path for the catheter device **50** or other medical instrument. The catheter device **50** is movable relative to the anchor sleeve **100**, so the catheter tip **52** can be advanced through the anchor sleeve **100**, into a patient's blood vessel **25** (or other body lumen), and toward a targeted body site inside the patient's body. In such circumstances, the anchor sleeve **100** can be used to retain the catheter device **50** at the skin entry site **22** on the patient's skin **20**. In particular, the elongate body **110** can releasably house one or more anchors **160**. As described in more detail below, the anchors **160** may comprise flexible tines that are deployable into a subcutaneous region **24** under the skin **20** so as to retain the position of the anchor sleeve **100** relative to the skin entry point **22**.

(9) In this embodiment, the anchor sleeve includes a first actuator **130** that adjusts the anchors from a non-deployed position to the deployed position depicted in FIG. **1**. The first actuator **130** can be a slider mechanism that reciprocates along a portion of the elongate body **110** between a distal position and a proximal position. A user may insert the elongate body **110** through the skin insertion site **22** so that anchor deployment ports (FIG. **5**) are arranged under the skin **20** the subcutaneous region **24**. For example, the anchor sleeve **100** may penetrate the skin **20** through a small incision made by a physician. In some cases a dilation instrument may be used to assist in advancing the anchor sleeve **100** through the incision. After insertion, the distal tip portion **115** of the anchor sleeve **100** can be advanced into a targeted blood vessel **25** or other body lumen. When the anchor sleeve **100** is arranged in the desired position, the user can pull upon the first actuator **130** so as to slide the first actuator from a distal position to the proximal position shown in FIG. **1**. As described in more detail below, the adjustment of the first actuator **130** causes the anchor tines **160** to shift from the non-deployed position to the deployed position shown in FIG. **1**.

(10) Still referring to FIG. **1**, the anchor sleeve is configured to permit the catheter device **50** to be delivered through the working channel **112** either before the anchor tines **160** are deployed or after the anchor tines **160** are deployed. For example, the first actuator **130** can be shifted to cause the deployment of the anchors **160** without necessarily acting upon the catheter device **50**. As such, the catheter device **50** can be advanced through the working channel **112** of the anchor sleeve **100** to deliver the catheter tip portion **52** to a targeted site inside the patient's body. When the catheter device **50** is delivered to the targeted site, the user can initiate a second actuator motion that causes the anchor sleeve **100** to releasably lock with the catheter device **50**. For example, the anchor sleeve **100** may include a second actuator **140** that is at least partially rotatable relative to the elongate body **110**. Thus, the user can impart a twisting motion to the second actuator **140** so as to cause the anchor sleeve **100** to retain the portion of the catheter device **50** that is arranged in the working channel **112**. In some embodiments, the second actuator **140** may act upon a locking device (FIGS. **8-10**) that comprises a polymeric seal member (e.g., a silicon seal). The polymeric seal member (FIGS. **8-10**) can be compressed upon an outer surface of the catheter device **50** in response to the adjustment of the second actuator **140**.

(11) In these embodiments, the operation of first actuator **130** (to deploy the anchors **160**) can be independent from the operation of the second actuator **140** (to cause the locking engagement between the anchor sleeve **100** and the catheter device **50**). Accordingly, the anchor sleeve **100** can be equipped to isolate these two functions. For example, the first actuator **130** can be adjusted to deploy the anchor tines **160** without impeding the insertion or retraction of the catheter device **50**. Also, the second actuator **140** can be operated to lock the anchor sleeve **100** in engagement with the catheter device without restricting the deployment or retraction of the anchor tines **160**. Furthermore, the anchor sleeve **100** can be equipped to provide the proper amount of force for achieving each function. In some embodiments, the force required to releasably lock the anchor sleeve **100** with the catheter device **50** may be substantially greater than the force required to deploy the anchors **160** in the subcutaneous region **24**. As such, the second actuator **140** can be configured to provide a mechanical advantage for the user so that the locking force is applied in a suitable manner. Also, the first actuator **130** can be configured to deploy the anchors **160** without

transmitting an unnecessarily high level of force to the anchor tines **160**.
(12) Still referring to FIG. **1**, the anchor sleeve **100** includes one or more subcutaneous anchors **160** for use in the temporary anchoring of at least a portion of elongate body **110** in the subcutaneous layer **24** under the skin **20**. In some embodiments, the subcutaneous anchors **160** may comprise a material that exhibits superelasticity when used in the patient's body. As such, the subcutaneous anchors **160** can flexibly shift from a non-deployed position (FIG. **2**) to a deployed position (FIG. **1**) when in the subcutaneous layer **24**. For example, the anchors **60** may be formed from a length of nitinol wire or from a sheet of nitinol material, which has been processed to exhibit superelasticity below or at about a normal human body temperature, such as below or at about 37 degrees C. The nitinol material may comprise, for example, Nickel Titanium (NiTi), Niobium Titanium (NbTi), or the like. Alternatively, the subcutaneous anchors **160** may comprise a metal material such as stainless steel, spring steel, titanium, MP35N and other cobalt alloys, or the like. In these embodiments, the subcutaneous anchors **160** can be formed from a material or materials that allow them to be adjustable from the non-deployed position to the deployed position as shown in FIG. **1**.
(13) In some embodiments, the subcutaneous anchors **160** can be flexed to a stressed condition when in the non-deployed position (e.g., prior to placement of the sleeve device **100** in a patient). For example, as described below in connection with FIG. **2**, the subcutaneous anchors **160** may be retracted into an internal space of the elongate body **110** when in the non-deployed position. When deployed, as shown in FIG. **1**, the subcutaneous anchors **160** can return to a shape (e.g., by exhibiting superelastic characteristics) that allows the subcutaneous anchors **160** to at least temporarily retain a portion or all of the body **110** in the subcutaneous region **24** for a period of time until the treatment with the catheter device **50** is completed.
(14) As shown in FIG. **1**, the subcutaneous anchors **160** may be designed with a curvature that facilitates the transition from the non-deployed to the deployed position. Furthermore, the curvature of the anchors **160** may be configured to eliminate or reduce the potential damage to the skin during deployment of the anchors **160**. For example, the anchors **160** may include a convex curvature that abuts against the underside of the skin in a manner that prevents the tips of the anchors **160** from piercing through the underside of the skin **20**. When the anchors **160** extend from the anchor deployment ports **162** (refer to FIGS. **5-7**), which are positioned immediately under the skin **20** in the subcutaneous region **24**, the curved shape of the anchors **160** can allow them to deploy adjacent to the skin **20** without tearing or otherwise damaging it. When deployed, the anchors **160** can serve to retain the elongate body **110** of the sleeve device **100** relative to the skin entry site **22**. In some embodiments, the anchors **160** may provide a holding force of about 1 lb. or greater, depending upon the medical procedure being performed, the materials comprising the anchors **160**, the geometry of the anchors **160**, and/or other factors. For example, the anchors **160** may provide a holding force of about 0.5 lbs or more, about 1 lb to about 20 lbs, about 1 lb to about 5 lbs, or about 2 lbs to about 3 lbs.
(15) In use, the subcutaneous anchors **160** can be shifted to the non-deployed position (refer, for example, to FIG. **2**) prior to insertion so as to minimize resistance and possible damage to the skin **20** when inserted through the skin entry site **22**. When the anchor sleeve **100** has been inserted to the intended depth inside the subcutaneous layer **24**, the anchors **160** can be shifted to the deployed position (refer, for example, to FIG. **1**) to provide at least temporary anchoring for the anchor sleeve **100**. When removal of the anchor sleeve device **100** is desired, the subcutaneous anchors **160** can be shifted back to the non-deployed position (e.g., by adjustment of the first actuator **130**) prior to removal to minimize resistance and possible damage to the skin **20** and subcutaneous region **24**.
(16) Referring now to FIGS. **2-4**, some embodiments of the anchor sleeve **100** can be configured to deploy the anchors **160** in an operation that is separate from the operation of locking the anchor sleeve **100** with the catheter device **50** (not shown in FIGS. **2-4**, refer to FIG. **1**). As shown in FIG. **2**, the anchor sleeve **100** is in a non-deployed and non-locked configuration. In particular, the

anchors **160** are retained inside an internal space of the elongate body **110** in a non-deployed position. The elongate body **110** can include a number of anchor deployment ports **162** through which the anchors can be extended and retracted in response to movement of the first actuator **130**. In this configuration, the first actuator **130** is arranged in a distal position (FIG. **2**) before it is slidably adjusted to a proximal position (FIG. **3**). Also in this configuration, the second actuator **140** is arranged in a first rotational position in which it is oriented transverse to the first actuator **130**. When the anchor sleeve **100** is in the non-deployed and non-locked configuration (FIG. **2**), the distal tip portion **115** can be readily inserted through the skin insertion site **22** (refer to FIG. **1**) without interference from the anchors **160**. Furthermore, the catheter device **50** (refer to FIG. **1**) can be inserted through the working channel **112** of the anchor sleeve **100** when the anchor sleeve **100** is in the non-deployed and non-locked configuration (FIG. **2**). Alternatively, the catheter device **50** can be inserted through the working channel **112** after the anchor tines **160** are deployed (described below in connection with FIG. **3**). As previously described, the catheter device **50** can be advanced through the working channel **112** of the anchor sleeve **100** and into a blood vessel **25** or other body lumen for delivery to a targeted internal site.

(17) As shown in FIG. **3**, the anchor sleeve **100** can be adjusted to a deployed and non-locked configuration. In this configuration, the anchors **160** are deployed from their respective ports **162** so as to extend outwardly from the elongate body **110** of the anchor sleeve **100**. In particular, the subcutaneous anchors **160** are shifted to the deployed position when the first actuator **130** is adjusted to the proximal position via the motion **135** shown in FIG. **3**. The first actuator **130** can be pulled by a user to slide the actuator **130** in the proximal direction along one or more guide rails **132**. The movement of the first actuator **130** transmits a deployment force to the anchor tines **160** (via an actuator rod **164** described in more detail below in connection with FIG. **9** and FIGS. **11-12**) so that the anchor tines **160** at least partially extend out of the ports **162**. As previously described, the anchor tines **160** can include a convexly curved shape that facilitates the transition from the non-deployed to the deployed position and reduces the likelihood of damaging the underside of the skin **20** during deployment in the subcutaneous region **24** (refer to FIG. **1**). In the configuration shown in FIG. **3**, the second actuator **140** is maintained in the first rotational position described above in connection with FIG. **2**. As such, when the anchor tines are deployed as shown in FIG. **3**, the catheter device **50** (refer to FIG. **1**) can be inserted through the working channel **112** of the anchor sleeve **100** for delivery to a targeted internal site.

(18) As shown in FIG. **4**, the anchor sleeve **100** can be adjusted to a deployed and locked configuration. In this configuration, the anchors **160** are deployed to extend outwardly from the elongate body **110**, and an internal locking device **150** (FIGS. **8-10**) is activated to releasably retain the catheter device **50** with the anchor sleeve **100**. As described in more detail below in connection with FIGS. **8-10**, the internal locking device **150** can be activated when the second actuator **145** is at least partially rotated in a movement **145** about a longitudinal axis **111**. In this embodiment, the second actuator **140** is shift from the first rotational position in which it is oriented transversely to the first actuator **130** to a second rotational position shown in FIG. **4**. When in this second rotational position, the second actuator **140** can be oriented in alignment with the first actuator **130**. For example, the second actuator **140** may undergo a rotational movement **145** of approximate 90-degrees about the longitudinal axis **111** so that the second actuator **140** generally aligns with the first actuator **130**. During this rotational movement **145**, the second actuator **140** can urge the internal locking device **150** (FIGS. **8-10**) to act upon a portion of the catheter device **50** arranged in the working channel **112** of the anchor sleeve.

(19) In an alternative embodiment, the second actuator **140** may include one or more structures that releasably engage the first actuator **130** when the second actuator **140** undergoes the movement **145** to align with the first actuator **130**. For example, the second actuator may include connector arms (not shown in FIGS. **2-4**) that mate with grooves formed in the outer surface of the first actuator **130** when second actuator **140** aligns with the first actuator **130**. In such circumstances, the first

actuator **130** would be locked in its proximal position (with the anchor tines **160** in the deployed position) while the second actuator **140** is in the second rotational position as shown in FIG. **4** (with the anchor sleeve **100** locked with the catheter device **50**). Thus, in this embodiment, the anchor tines **160** could be retracted into the elongate body **110** only after the second actuator **140** is rotated back to the first rotational position (FIGS. **2**-**3**), thereby unlocking the first actuator **130** from the grasp of the second actuator **140** and unlocking the catheter device **50** from the anchor sleeve **100**.

(20) Referring now to FIGS. **5**-**7**, the movements of the first and second actuators **130** and **140** are illustrated from a bottom view that shows the anchor deployment ports **162**. As shown in FIG. **5**, the anchor sleeve **100** can be arranged in the non-deployed and non-locked configuration (as previously described in connection with FIG. **2**). In this configuration, the anchors **160** are retracted into an internal space of the elongate body **110** so that the anchor deployment ports **162** are viewable. The subcutaneous anchors **160** can be arranged in this non-deployed position shown in FIG. **5** prior to insertion of the anchor sleeve **100** so as to minimize resistance and possible damage to the skin **20** when the elongate body inserted through the skin entry site **22**.

(21) As shown in FIG. **6**, the anchor sleeve **100** can be shifted to the deployed and non-locked configuration (as previously described in connection with FIG. **3**). As such, when the anchor sleeve **100** has been inserted to the intended depth inside the subcutaneous layer **24**, the anchors **160** can be shifted to the deployed position to provide at least temporary anchoring for the anchor sleeve **100**. In particular, the subcutaneous anchors **160** are shifted to the deployed position when the first actuator **130** is adjusted to the proximal position via the longitudinal motion **135**. The movement of the first actuator **130** transmits a deployment force to the anchor tines **160** (via an actuator rod described in more detail below in connection with FIGS. **8**-**10**) so that the anchor tines **160** extend out of the ports **162**. In this configuration shown in FIG. **6**, the second actuator **140** may be spaced apart from the first actuator **130** by a gap **136**. This gap **136** can be closed when the second actuator **140** undergoes is partial rotational movement **145**, as described below.

(22) As shown in FIG. **7**, the anchor sleeve **100** can be adjusted to the deployed and locked configuration (as previously described in connection with FIG. **4**). In this configuration, the second actuator **140** is shifted from the first rotational position (FIG. **6**) to the second rotational position (FIG. **7**) by the rotational movement **145** about the longitudinal axis **111**. During this rotational movement **145**, the second actuator **140** also closes the longitudinal gap **136** between the second actuator **140** and the first actuator **130**. For example, the second actuator **140** may be in a threaded engagement with the elongate body **110** or another internal structure so that the rotational movement **145** also translates into a small longitudinal shift to at least partially close the gap **136** (FIG. **7**). In some embodiments, this secondary longitudinal motion of the second actuator **140** can be used to urge the internal locking device **150** (FIGS. **8**-**10**) to act upon a portion of the catheter device **50**. Thus, the user can receive the benefit of the mechanical advantage provide by the twisting action of the second actuator **140** so as to provide a significant force the causes the locking device **150** to retain the catheter device in place. Moreover, the locking device **150** can be used to form a seal around the catheter device, as described in more detail below.

(23) Referring now to FIGS. **8**-**10**, the adjustment of the first actuator **130** and second actuator **140** can cause a number of internal structures to move within the anchor sleeve **100**. In particular, the first actuator **130** can be adjusted to cause an actuation rod **164** to move within an internal actuator channel **113**. Also, the second actuator **140** can be adjusted to cause a locking device **150** to lock with a portion of the catheter device **50** arranged in the working channel **112**. The operation of the locking device **150** is described in more detail below in connection with FIG. **10**. It should be understood from the description herein that the catheter device **50** is removed from view in FIGS. **8**-**10** for purposes of illustrating the working channel **112**.

(24) As shown in FIG. **8**, the anchor sleeve **100** can be arranged in the non-deployed and non-locked configuration so that the anchors **160** are retracted into an internal space of the elongate

body **110** (as previously described in connection with FIG. **2**). The elongate body **110** of the anchor sleeve **100** can comprise a biocompatible material, such as PEEK (polyetheretherketone), polyethylene, polyimide, or the like. The body **110** may have a modified elliptical cross-sectioned shape and may include a taper along the distal portion **115** that facilitates insertion of the anchor sleeve **100** through the skin entry site **22**.

(25) In some embodiments, the anchor sleeve **100** can include one or more internal channels **112** and **113**. For example, the anchor sleeve **100** may include the working channel **112** to receive the catheter device **50** or other medical instrument, and may also include an actuator channel **113** to accommodate the actuation of the subcutaneous anchors **160**. The working channel **112** can extend through the entire length of the anchor sleeve **100** from the distal tip portion **115** to the proximal portion **116**. After insertion of at least a portion of the elongate body **110** into the subcutaneous region **24** (FIG. **1**), the working channel **112** can be used to introduce the catheter device **50** or other medical instrument into a patient. Thus, the catheter device **50** can be introduced into the working channel **112** at the proximal portion **116** and advanced through the elongate body **110** until it emerges from the distal tip portion **115**.

(26) In the embodiment depicted in FIGS. **8**-**10**, the anchor sleeve **100** contains a single, round working channel **112**. The working channel **112** is sized to receive at least one catheter device **50** or other medical instrument. In some embodiments, the working channel **112** can have a diameter of about 3 French to about 30 French, and about 5 French to about 20 French, including particular ranges from about 3 French to about 7 French and about 12 French to about 17 French. As such, the working channel **112** can accept a wide range of catheters and medical instruments. In alternate embodiments of the anchor sleeve **100**, the working channel **112** can have a different shape or size. For example, the working channel **112** may have a cross-sectional shape in the form of a square or other polygon that mates with the medical instrument to be passed therethrough. Also, the working channel **112** need not be a single lumen. In alternate embodiments, the anchor sleeve **100** may include multiple working channels, such as adjacent channels or coaxial channels that permit the introduction of multiple medical instruments (e.g., catheters, endoscopes, or the like). Furthermore, the multiple working channels may be selectively sealable so that one working channel could be accessed while another is sealed. In such cases, it would be possible to introduce and secure several catheters at different points in time.

(27) The actuator channel **113** of the anchor sleeve **100** is formed in the elongate body **110** and can movably receive an actuator rod **164**. The actuator channel **113** may be defined by one or more side walls that can slidably engage the actuator rod **164**. Movement of the actuator rod **164** within the actuator channel **113** can urge the anchors **160** to extend from, or retract into, the deployment ports **162**. In this embodiment, the cross-sectional shape of the actuator channel **113** and the actuator rod **164** may be quadrilateral to permit longitudinal movement of the actuator rod **164** while hindering possible rotational movement of the actuator rod **164** about its longitudinal axis.

(28) Referring to FIG. **9**, the first actuator **130** can undergo the previously described movement **135** to cause the actuator rod **164** to move within the actuator channel **113** in a longitudinal direction of the sleeve device **100**. The actuator rod **164** may include a connector **167** that is coupled to the actuator **130** (described below in connection with FIGS. **11**-**12**). As such, movement of the first actuator **130** can be translated to the actuator rod **164**. The actuator rod **164** has a distal end **166** that can be advanced and retracted within the actuator channel **113** in response to the movement of the first actuator **130**. The anchors **160** can be coupled to the actuator rod **164** such that movement of the actuator **130** (and the corresponding translation of the actuator rod **164** within the actuator channel **113**) causes the anchors **160** to shift between the non-deployed position (FIG. **8**) and the deployed position (FIG. **9**).

(29) The actuator channel **113** may not extend fully through the body **110** of the anchor sleeve **100**. For example, the actuator channel **113** may extend distally to a depth that extends to a terminal end **114**. In some embodiments, when the first actuator **130** is shifted to the distal position (FIG. **8**), the

anchor actuator rod **164** is caused to advance within the anchor actuator channel **113** such that the distal end **166** of the actuator rod **164** approaches the terminal end **114** of the actuator channel **113**. In this embodiment, the anchors **160** are coupled to the actuator rod **164** so that the anchors **160** retract into the body **110** as the distal end **166** of the rod **164** approaches the terminal end **114** (shifts to the non-deployed state). In such circumstances, the anchors **160** may be flexed to a stressed condition while retained within the actuator channel **113** or other internal space of the elongate body **110**.

(30) Referring again to FIG. **9**, the first actuator **130** can be pulled to generate the longitudinal movement **135**, and this movement **135** is translated to the actuator rod **164** via the connector portion **167**. The actuator rod **164** slides within the actuator channel **113** so that the distal end **166** of the rod **164** shifts away from the terminal end **114**. This motion of the actuator rod **164** causes the tips of the anchor tines **160** to pass through the deployment ports **162** in an outward movement **165** to extend outwardly from the elongate body **110**. It should be understood from the description herein that, in alternative embodiments, the actuator rod **164** and anchors **160** could be configured so that pulling the first actuator **130** to the proximal position would cause the anchors **160** to transition to their non-deployed state, while pressing the first actuator **130** into the distal position would cause the anchors **160** to transition to the deployed state.

(31) As shown in FIG. **10**, the anchor sleeve **100** can be adjusted to the deployed and locked configuration (as previously described in connection with FIG. **4**). In this configuration, the second actuator **140** causes the locking device **150** to act upon a portion of the catheter device **50** so as to lock the anchor sleeve to the catheter device **50**. As previously described, the catheter device **50** is removed from view in FIGS. **8-10** for purposes of illustrating the working channel **112**. The second actuator **140** is shifted from the first rotational position (FIGS. **8-9**) to the second rotational position (FIG. **10**) by the rotational movement **145** about the longitudinal axis **111**. During this rotational movement **145**, the second actuator **140** also closes the longitudinal gap **136** (FIG. **9**) between the second actuator **140** and the first actuator **130**. In this embodiment, the second actuator **140** include an internal thread pattern **147** that mates with an external thread pattern **117** on the elongate body **110** or another internal structure. As such, the rotational movement **145** of the second actuator **140** also translates into a small longitudinal movement that closes the gap **136** (FIG. **9**). This secondary longitudinal motion of the second actuator **140** can be used to urge the internal locking device **150** to act upon a portion of the catheter device **50**.

(32) Accordingly, the user an receive the benefit of the mechanical advantage from the twisting action of the second actuator **140** so as to provide a significant force the causes the locking device **150** to be compressed around an outer surface of the catheter device **50**. This compression of the locking device **150** can also form a seal around the catheter device **50**. For example, in some embodiments, the locking device **150** may comprise a cylindrical seal formed of a flexible material, such as silicon. As shown in FIG. **10**, the cylindrical seal **150** can be arranged between an internal surface **148** of the second actuator **140** and an opposing surface **118** of the elongate body **110**. Accordingly, the movement **140** of the second actuator **140** can cause the cylindrical seal to be compressed between the opposing surfaces **148** and **118**. Such compression causes the cylindrical member **150** to flex inwardly (refer to FIG. **10**) and engage the catheter device **50** to thereby compress around an outer surface of the catheter device **50**. Thus, the locking device **150** engages the catheter device **50** to lock it in place relative to the anchor sleeve **100**. Furthermore, the locking device **150** can form a seal around the outer surface of the catheter device **50** when it is compressed around the catheter device **50**.

(33) It should be understood from the description herein that the locking device **150** is not limited to the embodiments of the cylindrical polymer seal. For example, some embodiments of the locking device may include first and second jaws that operate to clamp upon the outer surface of the catheter in response to adjustment of the second actuator **140**. Furthermore, in these embodiments, the locking device may include one or more seal members arranged between the

opposing surfaces of the jaws. For example, a silicone seal having a half-cylinder shape can be affixed to the inner cylindrical face of the first jaw, and an opposing silicone seal having a half-cylinder shape can be affixed to the inner cylindrical face of the second jaw. As such, the opposing seal members would surround and compress the outer surface of the catheter arranged in the working channel **112**.

(34) Referring now to FIGS. **11-12**, the actuation rod **164** and the first actuator **130** can be coupled to one another so that the movement **135** (FIG. **9**) of the first actuator **130** results in a corresponding movement of the actuation rod **164**. In this embodiment, the actuation rod **164** includes a connector **167** that mates with a complementary connector **137** (FIG. **12**) of the first actuator **130**. The connection can be configured to transmit a longitudinal force from the first actuator **130** to the actuation rod **164**, thereby directing the anchor tines **160** to extend from or retract into the elongate body **110** (FIGS. **8-9**). As previously described in connection with FIGS. **8-9**, the anchors **160** are coupled to the actuator rod **164** so that the anchors **160** retract into the elongate body **110** as the distal end **166** of the rod **164** approaches the terminal end **114** (shifts to the non-deployed state). The anchors **160** can be integrally formed with the actuator rod **164** (e.g., formed from a nitinol material or the like). It should be understood from the description herein that, in some embodiments, the anchors **160** can be joined with the actuation rod **220** at a location other than the distal end **224**. For example, in other embodiments, the anchors **160** may be connected to the actuator rod **220** along a middle region of the rod **220**. Also, in alternative embodiments, the anchors **160** may be non-integral with the actuator rod **220**. For example, the anchors may be formed separately from the actuator rod **220** and then mounted to the rod **220** using an adhesive, a weld, a connector, or the like.

(35) A number of embodiments of the invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of the invention. Accordingly, other embodiments are within the scope of the following claims.

Claims

1. An anchor device for securing a catheter to a skin opening, comprising: a retainer body that defines a channel configured to engage with an exterior of a catheter; a first flexible anchor and a second flexible anchor movable from a non-deployed orientation to a deployed orientation in a subcutaneous region under a skin surface in which free ends of the first and second flexible anchors extend oppositely away from one another and outwardly away from a longitudinal axis of the channel of the retainer body; a first actuator that is movable relative to the retainer body so as to shift the first and second flexible anchors from the non-deployed orientation to the deployed orientation; and a second actuator that is movable, independent from the first actuator, relative to the retainer body from a first position to a second position so as to urge a lock device from a non-locked configuration in which the catheter is slidably receivable in the retainer body to a locked configuration in which the lock device is configured to inhibit slidable movement of the catheter in the channel, the second actuator having a surface in slidable engagement with the retainer body, the second actuator having at least one projection configured to engage a corresponding groove formed in the first actuator when the flexible anchors are in the deployed orientation and the lock device is in the locked configuration.

2. The anchor device of claim 1, wherein the first and second actuators are each supported by the retainer body such that operation of the first actuator is independent from operation of the second actuator.

3. The anchor device of claim 1, wherein the at least one projection of the second actuator releasably engages with the corresponding groove of the first actuator when the flexible anchors are in the deployed orientation and the lock device is in the locked configuration.

4. The anchor device of claim 1, the flexible anchors being coupled to the first actuator via a

slidable internal member nonrotatably mounted in the retainer body.
5. The anchor device of claim 1, wherein the lock device has a maximum axial length that is less than a maximum axial length of the second actuator.
6. The anchor device of claim 1, wherein the lock device is housed inside an interior space of the second actuator.
7. The anchor device of claim 1, wherein the first actuator comprises a slider device that reciprocates in a direction substantially parallel to the longitudinal axis of the channel of the retainer body.
8. The anchor device of claim 7, wherein the second actuator comprises a twist device that at least partially rotates about the longitudinal axis of the channel of the retainer body, and wherein a distal end of the lock device remains generally fixed while the second actuator is adjusted to urge the lock device to compress said at least a portion of an outer surface of the catheter when the catheter is received in the channel.
9. The anchor device of claim 8, wherein the surface of the second actuator in slidable engagement with the retainer body includes a first thread pattern that mates with a second thread pattern on an external surface of the retainer body.
10. The anchor device of claim 1, wherein both the first actuator and the second actuator are positioned coaxial with the catheter when the catheter is received in the channel.
11. The anchor device of claim 1, wherein the first and second flexible anchors are retracted into an internal space of the retainer body when in the non-deployed orientation.
12. The anchor device of claim 11, wherein a wall of the retainer body through which the first and second flexible anchors are configured to extend outwardly is defined by a circular outer cross-section.
13. The anchor device of claim 1, wherein the first and second flexible anchors at least temporarily secure the retainer body in engagement with a skin insertion site when the flexible anchors are in the deployed orientation in the subcutaneous region.
14. The anchor device of claim 1, wherein the lock device comprises a polymeric member that is compressed upon the exterior of the catheter in response to adjustment of the second actuator when the catheter is received in the channel.
15. The anchor device of claim 1, wherein a gap separates the first and second actuators when the first and second flexible anchors are in the deployed orientation and the lock device is in the non-locked configuration, and the first actuator abuts the second actuator when the first and second flexible anchors are in the deployed orientation and the lock device is in the locked configuration.
16. The anchor device of claim 1, wherein a force required to urge the lock device to the locked configuration is substantially greater than a force required to deploy the first and second flexible anchors in the subcutaneous region.
17. The anchor device of claim 1, wherein the first actuator comprises a slider device that reciprocates in a direction substantially parallel to the longitudinal axis of the channel of the retainer body, and wherein the second actuator comprises a twist device that at least partially rotates about the longitudinal axis of the channel of the retainer body.
18. The anchor device of claim 17, wherein the twist device travels longitudinally along the longitudinal axis of the channel of the retainer body when the twist device at least partially rotates about the longitudinal axis of the channel of the retainer body.
19. The anchor device of claim 17, wherein a gap separates the first and second actuators when the first and second flexible anchors are in the deployed orientation and the lock device is in the non-locked configuration, and the first actuator abuts the second actuator when the first and second flexible anchors are in the deployed orientation and the lock device is in the locked configuration.
20. An anchor device for securing a catheter to a skin opening, comprising: a retainer body that defines a channel configured to engage with an exterior of a catheter; a first flexible anchor and a second flexible anchor movable from a non-deployed orientation to a deployed orientation in a

subcutaneous region under a skin surface in which free ends of the first and second flexible anchors extend oppositely away from one another and outwardly away from a longitudinal axis of the channel of the retainer body; a first actuator that is movable relative to the retainer body so as to shift the first and second flexible anchors from the non-deployed orientation to the deployed orientation; and a second actuator that is movable, independent from the first actuator, relative to the retainer body from a first position to a second position so as to urge a lock device from a non-locked configuration in which the catheter is slidably receivable in the retainer body to a locked configuration in which the lock device is configured to inhibit slidable movement of the catheter in the channel, the second actuator having a surface in slidable engagement with the retainer body, wherein the first actuator includes an inner surface movably engaged with an outer surface of the retainer body, and the second actuator includes an outer surface that is oriented transversely to an outer surface of the first actuator when the second actuator is in the first position and that is oriented in alignment with the outer surface of the first actuator when the second actuator is in the second position.