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### SUTURE GUIDE

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#### Abstract

A suture guide for securing a catheter to a patient includes a body and a needle channel extending through the body. The needle channel includes a first passage extending from a first passage inlet to a first passage outlet, and a second passage extending from a second passage inlet a second passage outlet. The first passage is curved toward the second passage as the first passage extends from the first passage inlet to the first passage outlet. The first passage is configured to guide a suture needle from the first passage outlet to the second passage inlet such that the suture needle exits the first passage, traverses skin and tissue of a patient to create a patient suture passage between the first passage and the second passage, and enters the second passage to secure the catheter to the patient.

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## Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This application claims priority to U.S. Provisional Application No. 63/554,837, filed Feb. 16, 2024, the entire contents of which are incorporated herein by reference.

### TECHNICAL FIELD

[0002] The present disclosure relates to a suture guide, for example, for securing a catheter to a patient.

### BACKGROUND

[0003] Intravenous catheters and other devices for subcutaneous access are sutured or adhered to a patient to maintain the catheter or device in the proper location. To suture the device to the patient, suture wings are provided on the catheter to provide location to suture the catheter or device to the patient.

### BRIEF SUMMARY

[0004] A suture guide for securing a catheter to a patient, the suture guide comprising a body having an upper surface, a lower surface, a first side surface extending between the upper surface and the lower surface, and a second side surface extending on an opposing side of the body between the upper surface and the lower surface, and a needle channel extending through the body, the needle channel comprising a first passage extending from a first passage inlet to a first passage outlet, and a second passage extending from a second passage inlet a second passage outlet, wherein the first passage is curved toward the second passage as the first passage extends from the first passage inlet to the first passage outlet, and wherein the first passage is configured to guide a suture needle from the first passage outlet to the second passage inlet such that the suture needle exits the first passage, traverses skin and tissue of a patient to create a patient suture passage between the first passage and the second passage, and enters the second passage to secure the catheter to the patient.

[0005] A catheter assembly comprising a catheter; and a suture guide coupled to the catheter, the suture guide comprising a body having an upper surface, a lower surface, a first side surface extending between the upper surface and the lower surface, and a second side surface extending on an opposing side of the body between the upper surface and the lower surface, and a needle channel extending through the body, the needle channel comprising a first passage on a first side of the catheter and extending from a first passage inlet to a first passage outlet, and a second passage on a second side of the catheter extending from a second passage inlet a second passage outlet, wherein the first passage is curved toward the second passage as the first passage extends from the first passage inlet to the first passage outlet, and wherein the first passage is configured to guide a suture needle from the first passage outlet to the second passage inlet such that the suture needle exits the first passage, traverses skin and tissue of a patient to create a patient suture passage between the first passage and the second passage, and enters the second passage to secure the catheter to the patient.

[0006] A suture guide for securing a catheter to a patient, the suture guide comprising a body having an upper surface, a lower surface, a first side surface extending between the upper surface and the lower surface, and a second side surface extending on a opposing side of the body between the upper surface and the lower surface and a needle channel. The needle channel includes a first passage extending from a first passage inlet to a first passage outlet and a second passage separate from the first passage, the second passage extending from a second passage inlet a second passage outlet. The needle channel is configured to guide a suture needle from the first passage inlet to the second passage outlet such that the suture needle traverses skin and tissue of a patient between the first passage and the second passage and such that a contour of the first passage, a contour of the

second passage, and a contour of the tissue traversed by the suture needle is the same as a contour of the suture needle.

[0007] A catheter assembly comprising a catheter and a suture guide coupled to the catheter, the suture guide having a needle tract configured to guide a suture needle from a first side of the catheter to a second, opposing side of the catheter. The needle tract is configured to guide the suture needle through the suture guide and through a patient's skin to secure the catheter to the patient's skin.

[0008] A method for securing a catheter to a patient, the method comprising locating a suture guide on a skin surface of the patient, inserting a suture needle with suture material affixed thereto into the suture guide, guiding the suture needle from a first side of the suture guide to a second, opposing side of the suture guide, wherein the first side and the second, opposing side are both located above the skin surface of the patient, and securing the suture material such that the suture guide is secured to the skin surface of the patient.

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## **Description**

### **BRIEF DESCRIPTION OF THE DRAWINGS**

[0009] The foregoing and other features and advantages will be apparent from the following, more particular, description of various exemplary embodiments, as illustrated in the accompanying drawings, wherein like reference numbers generally indicate identical, functionally similar, and/or structurally similar elements.

[0010] FIG. 1 illustrates an exemplary catheter, according to the present disclosure.

[0011] FIG. 2A illustrates a cross-sectional view of an exemplary suture guide, taken through a longitudinal centerline axis of the suture guide, according to the present disclosure.

[0012] FIG. 2B illustrates a top view of the suture guide of FIG. 2A, according to the present disclosure.

[0013] FIG. 2C illustrates a bottom view of the suture guide of FIG. 2A, according to the present disclosure.

[0014] FIG. 2D illustrates a cross-sectional view of the suture guide of FIG. 2A with a suture needle partially installed therein, according to the present disclosure.

[0015] FIG. 2E illustrates a cross-sectional view of the suture guide of FIG. 2A with the suture needle of FIG. 2D fully installed therein, according to the present disclosure.

[0016] FIG. 2F illustrates a cross-sectional view of the suture guide of FIG. 2A with the suture material, coupled to the suture needle of FIG. 2E, fully installed therein, according to the present disclosure.

[0017] FIG. 3A illustrates a cross-sectional view of an exemplary suture guide with a suture material installed therein, taken through a longitudinal centerline axis of the suture guide, according to the present disclosure.

[0018] FIG. 3B illustrates the suture guide of FIG. 3A with the suture material secured within the suture guide, according to the present disclosure.

[0019] FIG. 4 illustrates a cross-sectional view of another exemplary suture guide, taken through a longitudinal centerline axis of the suture guide, according to the present disclosure.

### **DETAILED DESCRIPTION**

[0020] Various embodiments are discussed in detail below. While specific embodiments are discussed, this is done for illustration purposes only. A person skilled in the relevant art will recognize that other components and configurations may be used without departing from the spirit and scope of the present disclosure.

[0021] As used herein, the terms “first,” “second,” and “third” may be used interchangeably to distinguish one component from another and are not intended to signify location or importance of

the individual components.

[0022] The terms “upper,” “lower,” “left,” and “right” refer to relative positions of a sensor pod with respect to a ground surface, as viewed from a position forward of the sensor pod. For example, “upper” refers to a position vertically above a “lower” position. For example, “left” refers to a position laterally to the left of a “right” position.

[0023] The term “side” as used herein may refer to a surface, wall, edge, border, boundary, etc., or simply to a general position or location with respect to the described component (e.g., not referring to any physical component).

[0024] The terms “coupled,” “fixed,” “attached,” “connected,” and the like, refer to both direct coupling, fixing, attaching, or connecting as well as indirect coupling, fixing, attaching, or connecting through one or more intermediate components or features, unless otherwise specified herein.

[0025] The singular forms “a,” “an,” and “the” include plural references unless the context clearly dictates otherwise.

[0026] The suture guide of the present disclosure provides a system and method for securing a catheter to a skin surface of a patient. The suture guide of the present disclosure simplifies and enhances the safety of securing vascular catheters to the skin surface of a patient. Prior art methods and devices include providing two separate sutures on either side of a catheter hub using suture wings. This is difficult for the operator, particularly, where the available skin space is small such that placing the two sutures correctly is difficult, can take longer than the process of putting the catheter in, and engenders a significant risk of a fingerstick while threading the suture needle while holding the catheter in place.

[0027] Accordingly, the suture guide of the present disclosure provides an attachment or addition to the back of the catheter or catheter hub that has a channel (referred to herein as a passage) to receive the suture needle. The channel, by the nature of the shape of the channel, directs the suture needle from a first passage of the channel, under the skin behind the catheter hub, to the corresponding second passage of the channel on the opposite side of the catheter. The suture guide of the present disclosure thus has a predetermined angle and shape of the channel and openings to the channel that will create a needle tract of the appropriate depth below the skin surface. In addition, the back end of the suture material may be pre-knotted, or have a bumper, so that at least the first side requires no further fixation (e.g., the operator does not need to secure or knot the suture material at a first end). The needle end of the suture would be clipped above the catheter hub surface, in some examples, this may be a small, vascular-type clip applied to the free end of the suture material, followed by the removal of the excess suture material.

[0028] FIGS. **1** to **4** illustrate exemplary suture guides to achieve the aforementioned function, however, the present disclosure is not limited to the appearance of the suture guide illustrated and other shapes, orientations, sizes, contours, curves, angles, etc., are contemplated. The suture guide of the present disclosure provides a track for a suture needle from one side of the catheter to the other. In some examples, the present disclosure provides a two-part device: the suture guide and the catheter. In such an example, the suture guide may be first secured to the skin surface, and then attached or snapped onto the back of the catheter. In another example, the suture guide is integral with and unitary to the catheter hub.

[0029] Referring to FIG. **1**, a catheter **10** includes an elongated catheter shaft **12** having a tip **13** and a catheter hub **14** that may admit one or more fluid access lines **18** through the catheter shaft **12** and into a patient (not shown) in a conventional manner. During use of the catheter **10**, and prior to any procedure being performed on the patient, the tip **13** is inserted into the patient and the catheter **10** is secured to the outer surface (e.g., skin) of the patient, typically with one or more sutures. In FIG. **1**, a suture guide **16** is associated with the catheter **10** to allow for securing of the catheter **10** to the patient. The suture guide **16** has a longitudinal centerline axis **17**. In practice, a suture material is inserted through the openings of the suture guide **16** to secure the suture guide **16** (and, therefore,

also the catheter hub **14** and catheter shaft **12**) to the patient.

[0030] FIGS. 2A to 2F illustrate schematic views of an exemplary suture guide **100** that may be employed as the suture guide **16** in FIG. 1. The suture guide **100** may be integrally and unitarily formed with the catheter **10** or may be separately formed and attached to the catheter **10**. For example, when integrally formed with the catheter **10**, the suture guide **100** and the catheter **10** may be molded or manufactured together as a single unitary component. When coupled or connected, the catheter **10** and the suture guide **100** may be attached in any number of manners, including snap connections, adhesive, and other coupling types. As illustrated in FIG. 1, the suture guide **100** may be integral with or coupled to the catheter hub **14**, however, other locations along the catheter shaft **12** are contemplated.

[0031] The suture guide **100** of FIG. 2A is illustrated from a side, cross-sectional view, taken at a longitudinal centerline axis **101** of the suture guide **100**. The suture guide **100** includes a body **102** having the longitudinal centerline axis **101** and a vertical centerline axis **103** that is normal to the longitudinal centerline axis **101**. The body **102** is shown schematically in FIG. 2A and is not limited to the generally u-shaped and rectangular shape shown. Other shapes, such as polygonal, curved, ovular, circular, etc., are contemplated. The body **102** includes a groove **104** for receiving the catheter shaft **12** (FIG. 1) or the catheter hub **14** (FIG. 1) to couple the suture guide **100** to the catheter **10**. The groove **104** is optional and may be omitted (e.g., as described with respect to the suture guide **300** of FIGS. 3A and 3B). The body **102** includes a first portion **106**, a second portion **108**, and a third portion **110**. The third portion **110** extends between the first portion **106** and the second portion **108**. The first portion **106** and the second portion **108** protrude outwardly from the third portion **110**. That is, the first portion **106** and the second portion **108** are raised with respect to the third portion **110**. The raised or protruding nature of the first portion **106** and the second portion **108** form the groove **104**. Although the first portion **106** and second portion **108** are shown as rectangular, other shapes are contemplated. Likewise, the shape of the groove **104** may be different than shown. For example, the sides **104a**, **104b**, **104c** of the groove **104** may be curved or otherwise of a conforming or mating shape to a body of the catheter **10** (FIG. 1) to allow for a mating connection or interface between the catheter **10** and the suture guide **100**.

[0032] FIG. 2A further illustrates a channel, also referred to as a needle channel **111**, in the body **102** of the suture guide **100**. The needle channel **111** has a first passage **112** and a second passage **114**. The first passage **112** extends between an upper surface **102a** of the body **102** to a lower surface **102b** of the body **102**. In the example shown in FIG. 2A, the portion of upper surface **102a** through which the first passage **112** extends is an upper surface **106a** of the first portion **106**. The second passage **114** extends between the upper surface **102a** of the body **102** to the lower surface **102b** of the body **102**. In the example shown in FIG. 2A, the portion of upper surface **102a** through which the second passage **114** extends is an upper surface **108a** of the second portion **108**.

Together, the first passage **112** and the second passage **114** form the needle channel **111** through which a suture needle and a suture material are installed to secure the suture guide **100** (and thus the catheter **10**) to the patient, as described in more detail with respect to FIGS. 2D to 2F.

[0033] Referring to FIGS. 2A to 2C, the first passage **112** extends from a first passage inlet **112a** to a first passage outlet **112b**. The first passage inlet **112a** extends through the upper surface **102a** of the body **102** and the first passage outlet **112b** extends through the lower surface **102b** of the body **102**. The first passage **112** provides guidance for a suture needle **200** (FIG. 2D) to extend from the first passage inlet **112a** to the first passage outlet **112b**. Thus, the first passage inlet **112a**, the first passage **112**, and the first passage outlet **112b** are sized and shaped as a guide for the suture needle **200**. The shape, contour, or profile of the first passage **112** may be the same or similar as that of the suture needle **200**, but larger than the outer diameter of the suture needle to accommodate passage therethrough. By having the same or similar shape, contour, or profile, the first passage **112** acts as a guide for the suture needle **200** causing the suture needle **200** to proceed through the first passage **112** along a predetermined pathway (defined by the shape and curvature of the first passage **112**).

In this manner, the suture needle **200** will be caused to exit the first passage outlet **112b** and enter the patient at a predetermined location (e.g., the inlet to the second passage **114**, as discussed in more detail to follow). In this manner, the suture needle **200** is obligated to move from the first passage **112** to the second passage **114** due to the contouring of the first passage **112**.

[0034] With continued reference to FIGS. 2A to 2C, the second passage **114** extends from a second passage inlet **114a** to a second passage outlet **114b**. The second passage inlet **114a** extends through the lower surface **102b** of the body **102** and the second passage outlet **114b** extends through the upper surface **102a** of the body **102**. The second passage **114** provides guidance for the suture needle **200** (FIG. 2D) to extend from the second passage inlet **114a** to the second passage outlet **114b**. Thus, the second passage inlet **114a**, the second passage **114**, and the second passage outlet **114b** are sized and shaped as a guide for the suture needle **200**. As with the first passage **112**, the shape of the second passage **114** may be the same or similar shape, contour, or profile as the suture needle **200**, but larger than the outer diameter of the suture needle to accommodate passage therethrough. This may result in the first passage **112** and the second passage **114** being mirror images of each other. In particular, the first passage **112** is arcuate. The first passage **112** is curved toward the second passage **114** as the first passage **112** extends from the first passage inlet **112a** to the first passage outlet **112b**. Thus, a distance from the first passage outlet **112b** to the vertical centerline axis **103** is less than a distance from the first passage inlet **112a** to vertical centerline axis **103**. In other words, the first passage outlet **112b** is closer to the vertical centerline axis **103** (and to the second passage **114**) than the first passage inlet **112a**.

[0035] Similarly, the second passage **114** is arcuate. The second passage **114** is curved away from the first passage **112** as the second passage **114** extends from the second passage inlet **114a** to the second passage outlet **114b**. Thus, a distance from the second passage inlet **114a** to vertical centerline axis **103** is less than a distance from the second passage outlet **114b** to the vertical centerline axis **103**. In other words, the second passage inlet **114a** is closer to the vertical centerline axis **103** (and to the first passage **112**) than the second passage outlet **114b**. In this way, the first passage **112** and the second passage **114** are convex. By having the same or similar shape, contour, or profile, the second passage **114** acts as a guide causing the suture needle **200** to proceed through the second passage **114** along a predetermined pathway defined by the shape and curvature of the second passage **114**. In this manner, once inserted into the first passage **112**, the suture needle **200** is caused or forced to follow through from the first passage **112** to the second passage **114** due to the mating profile. In this way, the first passage **112** curves the suture needle **200** and directs the suture needle **200** through a patient **50** (e.g., tissue of the patient **50**) and to the second passage **114**, as detailed further below.

[0036] As illustrated in FIGS. 2B and 2C, the first passage inlet **112a**, the first passage outlet **112b**, the second passage inlet **114a**, and the second passage outlet **114b** each the same dimension (e.g., diameter) of opening. In some examples, the first passage outlet **112b** may have a larger dimension (e.g., diameter) than the first passage inlet **112a** and the second passage inlet **114a** may have a larger dimension (e.g., diameter) than the second passage outlet **114b**. In the examples where the inlets and outlets have differing dimensions (e.g., diameters), the passages may also increase (the first passage **112**) or decrease (the second passage **114**) in dimension from inlet to outlet. Such an increase or decrease in dimension of passage and passage inlet/outlet facilitates guiding and exiting of the suture needle **200** from the body **102**. Although illustrated and described with circular cross-sections, the passage inlets **112a**, **114a**, the passages **112**, **114**, and the passage outlets **112b**, **114b** may have other shape cross-sections, such as, for example, but not limited to ovals and polygons. Regardless of the size, structure, shape, or dimension of the passage, passage inlets, or passage outlets, the passages are arranged to facilitate capture of the suture needle **200** during installation of the suture material.

[0037] In some examples, the first passage inlet **112a** and the second passage outlet **114b** are identical and the first passage outlet **112b** and the second passage inlet **114a** are identical. In such

an example, the suture guide **100** is symmetric about the vertical centerline axis **103** extending from the upper surface **102a** to the lower surface **102b**. In this example, therefore, the second passage outlet **114b** may operate as an inlet and the first passage inlet **112a** may operate as an outlet such that a suture guide may be inserted from either side of the suture guide **100**. In other examples, the suture guide **100**, passages, protruding portions (e.g., first portion **106**, second portion **108**), groove, or any combination thereof may be arranged such the suture guide **100** is not symmetric about the vertical centerline axis **103** extending from the upper surface **102a** to the lower surface **102b**.

[0038] The first passage **112** and the second passage **114** are separate, with separate inlets and outlets. The first passage **112** and the second passage **114** do not intersect. The first passage inlet **112a** of the first passage **112** is on the same surface as the second passage outlet **114b** of the second passage **114**, though that surface may be non-planar. The first passage outlet **112b** of the first passage **112** is on the same surface as the second passage inlet **114a** of the second passage **114**, though that surface may be non-planar. Although shown on the upper surface and lower surface, the inlets and outlets of the passages may be on different surfaces, such as shown and described with respect to FIG. 4.

[0039] FIGS. 2D to 2F illustrate insertion of the suture needle **200** and a suture material **202**, such as a suture thread, into the suture guide **100** to secure the suture guide **100** (and thus the catheter **10**) to the patient **50**. Since the first passage **112** has the same or similar shape or contour as the suture needle **200**, when the suture needle **200** is inserted through the first passage inlet **112a** by the user, the suture needle **200** is caused to travel through the first passage **112**, as shown in FIG. 2D, at the predetermined contour of the first passage **112** and exit the first passage **112** from the first passage outlet **112b** into the patient **50** at a predetermined location. The contour or shape of the first passage **112** also causes the suture needle **200** to continue through the patient **50** and into the second passage inlet **114a** of the second passage **114** at the same predetermined contour. In particular, the first passage **112** directs the suture needle **200** from the first passage inlet **112a** into the patient **50** through the first passage outlet **112b**. Once the suture needle **200** has been inserted into the patient **50**, the curvature of the first passage **112** directs the suture needle **200** into the patient **50** and then to the second passage inlet **114a** of the second passage **114**. The second passage **114** directs the suture needle **200** from the second passage inlet **114a** out of the second passage **114** through the second passage outlet **114b**.

[0040] As illustrated in FIG. 2E, the suture needle **200** is sized such that an end protrudes from the first passage inlet **112a** of the first passage **112** at the same time as a tip protrudes from the second passage outlet **114b** of the second passage **114**. The suture needle **200** must be sized longer than the total passage length (e.g., the length of passages **112**, **114** and the portion of the patient **50** traversed) in order for the user to be able to push the end of the suture needle **200** through the first passage **112** and the second passage **114**. Once the suture needle **200** exits the second passage **114**, the tip of the suture needle **200** is exposed and the user can grab the tip to pull the suture needle **200** out of the suture guide **100**. The suture guide **100** therefore provides a predetermined pathway through the patient **50** for the suture needle **200** to secure the suture guide **100** to the patient with a single suture thread or single suture material **202**.

[0041] FIG. 2F illustrates the suture needle **200** removed and the suture material **202** fully inserted into both the suture guide **100** and the patient **50**. As shown in FIG. 2F, the suture material **202** has the same contour as the suture needle **200** and the passages **112**, **114**. Once the suture needle **200** is removed and the suture material **202** is inserted, a tool **250** may grab an end (e.g., a second end **210**) and tension applied to suture material **202** (due to a first securing device **206** at a first end **208**). With the suture material **202** under tension, a clip (such as a clip **318** in FIG. 3B), may be secured to the second end **210** the suture material **202**. The clip and the first securing device **206** secure the suture guide **100** to the patient **50**, and, thus, secure the catheter **10** (FIG. 1) to the patient **50**.

[0042] As illustrated in FIGS. 2D to 2F, the suture material **202** is coupled to the suture needle **200** and extends through the patient **50** (this may be the skin of the patient **50** or other organ to which the suture is being applied). The suture needle **200** and suture material **202** are guided through the patient **50** (e.g., through a contour, also referred to as a patient suture passage **52**). Accordingly, the first passage **112**, the second passage **114**, and the patient suture passage **52** through the patient **50** provide a tract or contour, also referred to as a needle tract, for guiding the suture needle **200** from a first side **150** (e.g., the inflow side) of the suture guide **100** to a second side **160** (e.g., the outflow side) of the suture guide **100**. The patient suture passage **52** through the patient **50** is not a preformed passage or channel within the patient **50**. Rather, the patient suture passage **52** is the pathway the suture needle **200** is caused to travel due to the contour and shape of the first passage **112** and the second passage **114**. The patient suture passage **52** has a contour that is the same as the suture needle **200**. In this way, the contour of the patient suture passage **52** is the same as the contour of the first passage **112** and the second passage **114**.

[0043] The suture guide **100**, by way of the passages **112** and **114**, allows for the suture needle **200** to be inserted in the first side **150** of the suture guide **100** (e.g., the first passage inlet **112a**) and exit the other, second side **160** of the suture guide **100** (e.g., the second passage outlet **114b**) with a single action by the operator. That is, the user need only insert the suture needle **200** into the first passage inlet **112a** and the suture needle **200** is automatically guided from the first passage inlet **112a**, through the patient **50**, and to the second passage outlet **114b**. The automatic guidance is due to the shape and size of the passages, inlets, and outlets. In this manner, a single suture is created to secure the suture guide **100** (and any device connected thereto) to the patient **50**.

[0044] Since the suture material **202** is attached to the suture needle **200**, the suture material **202** is guided through the suture guide **100** along with the suture needle **200**. Thus, once the suture needle **200** and the suture material **202** have exiting the second passage **114**, the suture guide **100** is attached to the patient **50** by way of the suture material **202**. The suture material **202** is secured at both the first passage inlet **112a** (with first securing device **206** at a first end **208**) and the second passage outlet **114b** (with a clip at a second end **210**) to secure the suture guide **100** to the patient **50** and prevent removal of the suture guide **100** from the patient **50**. As noted previously, a device, such as a catheter, may be located within the groove **104** (FIG. 2A) of the suture guide **100**. Accordingly, once the suture guide **100** is secured to the patient **50**, the catheter **10** may be secured to the patient **50** by locating the catheter in the groove **104** (either before securing of the suture guide **100** to the patient **50** or after securing of the suture guide **100** to the patient **50**).

[0045] The first securing device **206** may be a knot, a bumper, a protrusion, or other device or means that is part of or coupled to the suture material **202** and that prevents removal of the suture material **202** from the suture guide **100** (e.g., by preventing a first end **208** of the suture material **202** from being pulled out of the suture guide **100** by tension of a second end **210** of the suture material **202** at the second (outflow) side **160**). The first securing device **206** may be pre-formed, pre-tied, or pre-attached to the suture material **202** such that the suture material **202** is provided with the first securing device **206** before securing of the suture guide **100** to the patient **50** and before inserting the suture needle **200** into the suture guide **100**. Once the suture material **202** is extended through the first passage **112** and the second passage **114**, a second securing device (not shown, such as clip **318**) be applied to the second end **210** of the suture material **202**. The second end **210** is outside of the second passage **114** and above the upper surface **102a** (FIG. 2B) of the suture guide **100**. The second securing device at the second end **210** prevents the suture material **202** from being removed from the suture guide **100** (e.g., by preventing the second end **210** of the suture material **202** from being pulled out of the suture guide **100** by tension of the first end **208** of the suture material **202** at the first (inflow) side **150**). With securing device at each of the first end **208** and the second end **210**, the suture material **202** is prevented from being removed from the suture guide **100**. Thus, the suture guide **100**, and attached catheter **10**, is secured to the patient **50**.

[0046] In some examples, the suture guide **100** and the catheter **10** are simultaneously secured to



the patient **50**. In some examples, the catheter **10** is removably connected to the suture guide **100**. In such examples, the catheter **10** may be inserted into the groove **104** before securing of the suture guide **100** on the patient **50** or after securing of the suture guide **100** on the patient **50**.

[0047] As discussed, the shape and structure of the suture guide **100** is exemplary. Other shapes, dimensions, and sizes are contemplated so long as the passage through the suture guide allows for a suture needle to be guided from an upper surface on a first side of the suture guide, through the lower surface at a first location, through the patient, into the lower surface at a second location and out the upper surface on a second side (e.g., an opposing side of the suture guide from the first side, where a device may be coupled to the suture guide therebetween).

[0048] Accordingly, schematic views of another exemplary suture guide **300** that may be employed as the suture guide **16** in FIG. **1** are illustrated in FIGS. **3A** and **3B**. FIG. **3A** illustrates a condition with the suture material **402** inserted within the suture guide **300** but not yet secured therein. FIG. **3B** illustrates a condition with the suture material **402** secured within the suture guide **300**. The same variations and alternatives described above with respect to the suture guide **100** of FIGS. **2A** to **2F** apply to the suture guide **300** as well. Likewise, the function, operation, and securement of the suture guide **300** is the same as the suture guide **100**, unless otherwise noted in the description to follow. FIGS. **3A** and **3B** illustrate a cross-sectional view of the suture guide **300**. A series of three openings **350** are illustrated in the suture guide **300**. These openings **350** represent the fluid access lines **18** (FIG. **1**). Therefore, the suture guide **300** illustrates a unitary suture guide **300** and catheter **10**, however, as discussed previously, the catheter **10** may be separate from the suture guide **300** and may be coupled thereto.

[0049] The suture guide **300** includes a body **302**. The body **302** is shown schematically in FIG. **3A** and is not limited to the polygonal shape shown. Other polygonal shapes, such as curved, ovular, circular, etc., are contemplated. The body **302** includes a protrusion **304**, which is the integral portion of the catheter **10**. Alternatively, a groove, such as the groove **104**, may be provided to receive the catheter **10**. The protrusion **304** is optional and may be omitted. The body **302** includes a first portion **306**, a second portion **308**, and a third portion **310**. The third portion **310** extends between the first portion **306** and the second portion **308**. The third portion **310** may include the protrusion **304**. Although the first portion **306**, the second portion **308**, and the third portion **310** are shown as rectangular, other shapes are contemplated.

[0050] Similar to the suture guide **100**, the suture guide **300** includes a needle channel **311** formed of a first passage **312** and a second passage **314** in the body **302** of the suture guide **300**. The first passage **312** extends between an upper surface **302a** of the body **302** to a lower surface **302b** of the body **302**. The second passage **314** extends between the upper surface **302a** of the body **302** to the lower surface **302b** of the body **302**. As in the suture guide **100**, the first passage **312** extends from a first passage inlet **312a** to a first passage outlet **312b** and the second passage **314** extends from a second passage inlet **314a** to a second passage outlet **314b**. Therefore, the related description is not repeated but is understood to apply to the suture guide **300**. The first passage **312** and the second passage **314** are, therefore, shaped, dimensioned, and contoured to provide guidance of a suture needle (not shown) from a first side of the suture guide **300** to a second side of the suture guide **300** to secure the suture guide **300** and any attached device to a patient.

[0051] Insertion of a suture material **402** is the same as described with respect to the suture material **202** described with respect to FIGS. **2D** to **2F** and will therefore not be repeated. In the example of the suture guide **300**, a first end **408** of the suture material **402** includes a first securing device **406**, which may be the same or similar as the first securing device **206**. In the example of FIGS. **3A** and **3B**, the first securing device **406** is a bumper. The suture guide **300** includes a second securing device at a second end **410** of the suture material **402**. The second securing device may be a wedge **316** that is embedded into the suture guide **300**. As shown in FIG. **3B**, when the suture material **402** is extended through the suture guide **300** (e.g., and tension is applied with a tool **450**), instead of tying a knot or applying a bumper to the second end **410**, the wedge **316** may be depressed, pushed,

or otherwise moved to intersect the second passage **314** and the suture material **402** therein. In this manner, the suture material **402** is secured within the second passage **314** and is prevented from movement. Additionally, or alternatively, the second securing device may be a clip **318** to prevent movement of the suture material **402** at the second end **410**. Any of a knot, bumper, clip, or pre-embedded wedge may be applied to the suture material at the second end as the second securing device, in either or both of the suture guide **300** or the suture guide **100**.

[0052] In other words, the second side of the suture material **402** (or the suture material **202**), e.g., the outflow side, having traversed both passages **312**, **314** of the channel and the subcutaneous passage (e.g., the patient suture passage **52** within the patient **50**), can be secured in a number of manners. The securing of the outflow side occurs once the suture material **402** is pulled taut so that the first securing device **406** is seated at the first side, e.g., the inflow side. At that point, either a clip could be attached producing the desired level of tension of the suture material **402**, or a pre-embedded wedge is advanced in a way that crimps the suture material within the channel, also providing the appropriate level of suture tension.

[0053] FIG. **4** illustrates another exemplary suture guide **500**. The suture guide **500** is substantially the same as the suture guide **100** shown in FIGS. **2A** to **2F**. Accordingly, like illustrated items represent the same features and are not discussed further herein, though it is understood that the same description and same alternatives apply to FIG. **4** as well. The suture guide **500** has a body **502** and a needle channel **511** having a first passage **512** and a second passage **514**.

[0054] In the suture guide **500** of FIG. **4**, instead of entering through the top surface (as in FIGS. **2A** to **2F**), the first passage **512** has a first passage inlet **512a** on a side surface **506a** of the suture guide **500**. The first passage **512** has a first passage outlet **512b** at a bottom surface **502b** of the suture guide **500**. Likewise, the second passage **514** has a second passage inlet **514a** on the bottom surface **502b** and a second passage outlet **514b** on a side surface **508a** of the suture guide **500**. Although the shape of the suture guide passages is different as compared to the above examples, the conformance of the suture needle shape and the passage shape is the same such that the suture needle **200** causes the patient suture passage **52** in the patient **50** and is also caused to be advanced through the suture guide **500** in the same manner as described previously.

[0055] In any of the suture guides **100**, **300**, or **500** removal is facilitated by simply pulling on a tail of the suture material extending from the bumper, sufficient to allow the suture material on the deep side of the bumper to be severed, releasing the suture and the suture guide (and thus the catheter) from the skin surface.

[0056] Alternatively, when it is desired to remove the suture guides **100**, **300**, or **500** from the patient, the wedge may be retracted, the clip may be removed, any of the knots or bumpers may be cut or disconnected, or any combination thereof, such that the suture material (e.g., suture material **202** and suture material **402**) can be removed from the passages and, thus, from the patient, to allow the suture guide to be removed from the patient.

[0057] Accordingly, the present disclosure provides a suture guide in which the shape, angle, contour, or configuration of the needle tract (e.g., the passage) guides the suture needle to a specific location. In this description, the specific location is a second side of the suture guide that is on an opposing side of a catheter (or on an opposing side of the location in which the catheter will be secured, if not yet secured). The aforementioned disclosure provides a tract or contour that includes not only the passages provided in the suture guide, but also a portion within the patient. In this sense, the passages (e.g., **112**, **114** or **312**, **314** or **512**, **514**) and the patient suture passage **52** form a needle path. Thus, the needle tract is not entirely within the suture guide. The suture guide of the present disclosure provides a pair of separate needle tracts (e.g., the passages) designed to direct a suture needle in the front, and out of the back of one part of the suture guide, traversing the patient tissue below the skin surface (therefore completely extrinsic to the suture guide), and then re-entering at a specific point in a separate part of the suture guide. The suture guide of the present disclosure is provided entirely above the skin surface of the patient. Thus, the needle channel

comprises a first passage and a second passage that are completely separate and interrupted by a traversal through the patient's tissue.

[0058] Accordingly, the suture guides of the present disclosure provide a needle tract from a first side of the catheter to a second side of the catheter that is free from structure within the patient. That is, there is no structural channel or passage formed by a device within the patient. Instead, the channel formed by the passages above the surface of the patient causes a predetermined path within the patient to be traversed by the suture needle and suture material. In this sense, the pathway through the patient may be considered as a virtual channel, that is, predetermined channel or path caused to be traversed by the needle, but without a structural boundary.

[0059] Aspects of the present disclosure may be appreciated from the following clauses.

[0060] A suture guide for securing a catheter to a patient, the suture guide comprising a body having an upper surface, a lower surface, a first side surface extending between the upper surface and the lower surface, and a second side surface extending on an opposing side of the body between the upper surface and the lower surface, and a needle channel extending through the body, the needle channel comprising a first passage extending from a first passage inlet to a first passage outlet, and a second passage extending from a second passage inlet a second passage outlet, wherein the first passage is curved toward the second passage as the first passage extends from the first passage inlet to the first passage outlet, and wherein the first passage is configured to guide a suture needle from the first passage outlet to the second passage inlet such that the suture needle exits the first passage, traverses skin and tissue of a patient to create a patient suture passage between the first passage and the second passage, and enters the second passage to secure the catheter to the patient.

[0061] The suture guide of the preceding clause, wherein a contour of the first passage is the same as a contour of the suture needle.

[0062] The suture guide of any preceding clause, wherein a contour of the second passage is the same as a contour of the suture needle.

[0063] The suture guide of any preceding clause, wherein a contour of the patient suture passage is the same as a contour of the suture needle.

[0064] The suture guide of any preceding clause, wherein the second passage is curved away from the first passage as the second passage extends from the second passage inlet to the second passage outlet.

[0065] The suture guide of any preceding clause, wherein the first passage outlet and the second passage inlet are located on the lower surface of the body.

[0066] The suture guide of any preceding clause, wherein the first passage inlet and the second passage outlet are located on the upper surface of the body.

[0067] The suture guide of any preceding clause, wherein the first passage inlet is located on the first side surface of the body, and the second passage outlet is located on the second side surface of the body.

[0068] The suture guide of any preceding clause, wherein the suture guide comprises a vertical centerline axis, and the first passage is on a first side of the vertical centerline axis and the second passage is on a second side of the vertical centerline axis.

[0069] The suture guide of any preceding clause, wherein the first passage outlet is closer to the vertical centerline axis than the first passage inlet.

[0070] A catheter assembly comprising a catheter; and a suture guide coupled to the catheter, the suture guide comprising a body having an upper surface, a lower surface, a first side surface extending between the upper surface and the lower surface, and a second side surface extending on an opposing side of the body between the upper surface and the lower surface, and a needle channel extending through the body, the needle channel comprising a first passage on a first side of the catheter and extending from a first passage inlet to a first passage outlet, and a second passage on a second side of the catheter extending from a second passage inlet a second passage outlet, wherein

the first passage is curved toward the second passage as the first passage extends from the first passage inlet to the first passage outlet, and wherein the first passage is configured to guide a suture needle from the first passage outlet to the second passage inlet such that the suture needle exits the first passage, traverses skin and tissue of a patient to create a patient suture passage between the first passage and the second passage, and enters the second passage to secure the catheter to the patient.

[0071] The catheter assembly of the preceding clause, wherein a contour of the first passage is the same as a contour of the suture needle.

[0072] The catheter assembly of any preceding clause, wherein a contour of the second passage is the same as a contour of the suture needle.

[0073] The catheter assembly of any preceding clause, wherein a contour of the patient suture passage is the same as a contour of the suture needle.

[0074] The catheter assembly of any preceding clause, wherein the second passage is curved away from the first passage as the second passage extends from the second passage inlet to the second passage outlet.

[0075] The catheter assembly of claim **11**, wherein the first passage outlet and the second passage inlet are located on the lower surface of the body.

[0076] The catheter assembly of any preceding clause, wherein the first passage inlet and the second passage outlet are located on the upper surface of the body.

[0077] The catheter assembly of any preceding clause, wherein the first passage inlet is located on the first side surface of the body, and the second passage outlet is located on the second side surface of the body.

[0078] The catheter assembly of any preceding clause, wherein the suture guide comprises a vertical centerline axis, and the first passage is on a first side of the vertical centerline axis and the second passage is on a second side of the vertical centerline axis.

[0079] The catheter assembly of any preceding clause, wherein the first passage outlet is closer to the vertical centerline axis than the first passage inlet.

[0080] A suture guide for securing a catheter to a patient, the suture guide comprising a body having an upper surface, a lower surface, a first side surface extending between the upper surface and the lower surface, and a second side surface extending on an opposing side of the body between the upper surface and the lower surface and a needle channel. The needle channel includes a first passage extending from a first passage inlet to a first passage outlet and a second passage separate from the first passage, the second passage extending from a second passage inlet to a second passage outlet. The needle channel is configured to guide a suture needle from the first passage inlet to the second passage outlet such that the suture needle traverses skin and tissue of a patient between the first passage and the second passage and such that a contour of the first passage, a contour of the second passage, and a contour of the tissue traversed by the suture needle is the same as a contour of the suture needle.

[0081] The suture guide of the preceding clause, wherein the second passage inlet is configured to guide the suture needle from the skin and tissue of the patient into the second passage.

[0082] The suture guide of any preceding clause, wherein the first passage outlet is configured to guide the suture needle from the first passage, through the skin and the tissue of the patient, and into the second passage.

[0083] The suture guide of any preceding clause, wherein the second passage inlet is larger than the second passage outlet.

[0084] The suture guide of any preceding clause, wherein the first passage inlet and the second passage outlet are both located on the upper surface of the body.

[0085] The suture guide of any preceding clause, wherein the upper surface is non-planar.

[0086] The suture guide of any preceding clause, wherein the first passage outlet and the second passage inlet are both located on the lower surface of the body.

[0087] The suture guide of any preceding clause, wherein the lower surface is non-planar.

[0088] The suture guide of any preceding clause, wherein the first passage and the second passage are both configured to guide the suture needle from the first passage inlet to the second passage outlet.

[0089] The suture guide of any preceding clause, wherein the suture guide comprises a longitudinal centerline extending from the upper surface to the lower surface, and wherein the first passage and the second passage are on opposing sides of the longitudinal centerline.

[0090] The suture guide of any preceding clause, wherein the first passage inlet and the second passage outlet are on opposing sides of the longitudinal centerline.

[0091] The suture guide of any preceding clause, wherein the first passage outlet and the second passage inlet are on opposing sides of the longitudinal centerline.

[0092] The suture guide of any preceding clause, wherein the needle channel is free from structure under the skin of the patient.

[0093] The suture guide of any preceding clause, wherein the needle channel forms a needle tract having the needle channel and a virtual channel between the first passage and the second passage.

[0094] The suture guide of any preceding clause, wherein the needle channel is free from structure between the first passage outlet and the second passage inlet.

[0095] The suture guide of any preceding clause, wherein the first passage outlet and the second passage inlet are located on the same surface of the body.

[0096] The suture guide of any preceding clause, wherein the first passage inlet and the second passage outlet are located on the upper surface of the body.

[0097] The suture guide of any preceding clause, wherein the first passage inlet is located on the first side surface and the second passage outlet is located on the second side surface.

[0098] The suture guide of any preceding clause, wherein the first passage does not enter and exit on the same surface of the body.

[0099] The suture guide of any preceding clause, wherein the second passage does not enter and exit on the same surface of the body.

[0100] A catheter assembly including the suture guide of any preceding clause.

[0101] A catheter assembly includes a catheter and a suture guide coupled to the catheter, the suture guide having a needle tract configured to guide a suture needle from a first side of the catheter to a second, opposing side of the catheter. The needle tract is configured to guide the suture needle through the suture guide and through a patient's skin and tissue to secure the catheter to the patient's skin.

[0102] The catheter assembly of any preceding clause, wherein an inlet to the needle tract and an outlet to the needle tract are on the same surface of the suture guide.

[0103] The catheter assembly of any preceding clause, wherein the needle tract is formed of a first passage, a second passage separate from the first passage, and a space in between the first passage and second passage that is outside of a body of the suture guide and traverses the patient's skin.

[0104] The catheter assembly of any preceding clause, wherein the needle tract includes a virtual channel between the first passage and the second passage.

[0105] The catheter assembly of any preceding clause, wherein the needle tract is free from structure between an outlet of the first passage and an inlet of the second passage.

[0106] The catheter assembly of any preceding clause, wherein the catheter and the suture guide are integrally formed.

[0107] The catheter assembly of any preceding clause, wherein the catheter is removably coupled to the suture guide.

[0108] The catheter assembly of any preceding clause, wherein the catheter is permanently affixed to the suture guide.

[0109] The catheter assembly of any preceding clause, wherein the needle tract is free from structure under the skin of the patient.

[0110] A method of securing a suture guide of any preceding clause.

[0111] A method of inserting a catheter assembly of any preceding clause.

[0112] A method for securing a catheter to a patient includes locating a suture guide on a skin surface of the patient, inserting a suture needle with suture material affixed thereto into the suture guide, guiding the suture needle from a first side of the suture guide to a second, opposing side of the suture guide, wherein the first side and the second, opposing side are both located above the skin surface of the patient, and securing the suture material such that the suture guide is secured to the skin surface of the patient.

[0113] The method of any preceding clause, wherein locating the suture guide on the skin surface comprises placing a lower surface of the suture guide on the skin surface.

[0114] The method of any preceding clause, wherein inserting the suture needle into the suture guide comprises inserting the suture needle into a first passage of the suture guide.

[0115] The method of any preceding clause, further comprising exiting the suture needle from a second passage of the suture guide, the second passage being separate from the first passage.

[0116] The method of any preceding clause, wherein guiding the suture needle comprises inserting the suture needle into a first passage in the suture guide, then extending the suture needle through the skin surface of the patient, and then extending the suture needle into a second passage in the suture guide.

[0117] The method of any preceding clause, wherein the suture needle exits the suture guide from the second passage.

[0118] The method of any preceding clause, wherein the first passage, tissue below the skin surface, and the second passage form a needle tract for the suture needle.

[0119] The method of any preceding clause, wherein securing the suture material comprises securing a first end of the suture material at the first side of the suture guide and securing a second end of the suture material at the second, opposing side of the suture guide.

[0120] The method of any preceding clause, wherein securing the first end of the suture material comprises providing a pre-tied or pre-located bumper on the first end of the suture material.

[0121] The method of any preceding clause, wherein securing the second end of the suture material comprises tying the second end of the suture material.

[0122] The method of any preceding clause, wherein securing the second end of the suture material comprises depressing a wedge to secure the suture material within the suture guide.

[0123] The method of any preceding clause, wherein securing the second end of the suture material comprises attaching a clip to the second end of the suture material.

[0124] Although the foregoing description is directed to the preferred embodiments, it is noted that other variations and modifications will be apparent to those skilled in the art and may be made without departing from the spirit or scope of the disclosure. Moreover, features described in connection with one embodiment may be used in conjunction with other embodiments, even if not explicitly stated above.

## Claims

1. A suture guide for securing a catheter to a patient, the suture guide comprising: a body having an upper surface, a lower surface, a first side surface extending between the upper surface and the lower surface, and a second side surface extending on an opposing side of the body between the upper surface and the lower surface; and a needle channel extending through the body, the needle channel comprising: a first passage extending from a first passage inlet to a first passage outlet; and a second passage extending from a second passage inlet a second passage outlet, wherein the first passage is arcuate and is curved toward the second passage as the first passage extends from the first passage inlet to the first passage outlet, wherein the second passage is arcuate and is curved away from the first passage as the second passage extends from the second passage inlet to the

second passage outlet, and wherein the first passage is configured to guide a suture needle with a suture material from the first passage outlet to the second passage inlet such that the suture needle exits the first passage through the first passage outlet, traverses skin and tissue of a patient to create a patient suture passage between the first passage and the second passage, entirely exits the skin and the tissue of the patient, enters the second passage, and entirely exits the second passage through the second passage outlet while the suture material remains in the skin and the tissue of the patient to secure the catheter to the patient.

**2.** The suture guide of claim 1, wherein a contour of the first passage is the same as a contour of the suture needle.

**3.** The suture guide of claim 1, wherein a contour of the second passage is the same as a contour of the suture needle.

**4.** The suture guide of claim 1, wherein a contour of the patient suture passage is the same as a contour of the suture needle.

**5.** The suture guide of claim 1, wherein the second passage is curved away from the first passage as the second passage extends from the second passage inlet to the second passage outlet.

**6.** The suture guide of claim 1, wherein the first passage outlet and the second passage inlet are located on the lower surface of the body.

**7.** The suture guide of claim 1, wherein the first passage inlet and the second passage outlet are located on the upper surface of the body.

**8.** The suture guide of claim 1, wherein the first passage inlet is located on the first side surface of the body, and the second passage outlet is located on the second side surface of the body.

**9.** The suture guide of claim 1, wherein the suture guide comprises a vertical centerline axis, and the first passage is on a first side of the vertical centerline axis and the second passage is on a second side of the vertical centerline axis.

**10.** The suture guide of claim 9, wherein the first passage outlet is closer to the vertical centerline axis than the first passage inlet.

**11.** A catheter assembly comprising: a catheter extending along a longitudinal centerline axis; and a suture guide coupled to the catheter, the suture guide having a vertical centerline axis and comprising: a body having an upper surface, a lower surface, a first side surface extending between the upper surface and the lower surface, and a second side surface extending on an opposing side of the body between the upper surface and the lower surface; a groove in the body, the catheter disposed in the groove such that the longitudinal centerline axis of the catheter is substantially perpendicular to the vertical centerline axis and the catheter is substantially horizontal with respect to the suture guide; and a needle channel extending through the body, the needle channel comprising: a first passage on a first side of the catheter and extending from a first passage inlet to a first passage outlet, the first passage inlet and the first passage outlet being substantially parallel with the vertical centerline axis; and a second passage on a second side of the catheter extending from a second passage inlet a second passage outlet, the second passage inlet and the second passage outlet being substantially parallel with the vertical centerline axis, wherein the first passage is curved toward the second passage as the first passage extends from the first passage inlet to the first passage outlet, and wherein the first passage is configured to guide a suture needle from the first passage outlet to the second passage inlet such that the suture needle exits the first passage, traverses skin and tissue of a patient to create a patient suture passage between the first passage and the second passage, and enters the second passage to secure the catheter to the patient.

**12.** The catheter assembly of claim 11, wherein a contour of the first passage is the same as a contour of the suture needle.

**13.** The catheter assembly of claim 11, wherein a contour of the second passage is the same as a contour of the suture needle.

**14.** The catheter assembly of claim 11, wherein a contour of the patient suture passage is the same as a contour of the suture needle.

- 15.** The catheter assembly of claim 11, wherein the second passage is curved away from the first passage as the second passage extends from the second passage inlet to the second passage outlet.
- 16.** The catheter assembly of claim 11, wherein the first passage outlet and the second passage inlet are located on the lower surface of the body.
- 17.** The catheter assembly of claim 11, wherein the first passage inlet and the second passage outlet are located on the upper surface of the body.
- 18.** The catheter assembly of claim 11, wherein the first passage inlet is located on the first side surface of the body, and the second passage outlet is located on the second side surface of the body.
- 19.** The catheter assembly of claim 11, wherein the suture guide comprises a vertical centerline axis, and the first passage is on a first side of the vertical centerline axis and the second passage is on a second side of the vertical centerline axis.
- 20.** The catheter assembly of claim 19, wherein the first passage outlet is closer to the vertical centerline axis than the first passage inlet.
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