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VASCULAR ACCESS DEVICES WITH INTEGRATED SAFETY FEATURES

Abstract

Provided herein are vascular access devices having integrated safety features configured to prevent unintended migration of guidewires into a patient's body. Also provided are safety guidewires that provide a tactile and/or visual indicator of insertion length. Also provided are introducer sets including the same.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATION [0001] This application claims the benefit of priority under 35 U.S.C. § 119(e) of U.S. Ser. No. 62/848,878, filed May 16, 2019, the entire content of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION
Field of the Invention
[0002] The invention relates generally to vascular access devices and more specifically to vascular access devices having integrated safety features configured to prevent unintended migration of guidewires into a patient's body.
Background Information
[0003] Over 5 million central venous catheters are inserted every year in the United States alone (N ENGL J MED 2003; 348:1123-33, McGee,DC, Gould, MK. Preventing Complications of Central Venous Catheterization). An over-the-wire or Seldinger Technique is standard for such procedures. However, this technique is associated with guidewire retention at a rate of approximately 1:3,291 procedures (ANAES ANALG 2013; 117:102-8, Vanucci, A, Jeffcoat, A, Ifune,C, Salinas, C, Duncan, JR, Wall,M. Retained Guidewires after Intraoperative Placement of Central Venous Catheters). Guidewire retention can cause arrhythmias, thrombosis, cardiac perforation, cardiac tamponade, and death. (J ASSOC VASC ACCESS 2014; 19:29-34, Williams, TL, Bowdle, AT, Winters, BD, Pavkovic, SD, Skekendi, MK). Guidewires Unintentionally Retained During Central Venous Catheterization). Thus, a need exists for a reliable means of preventing the inadvertent retention of catheter guidewires.
SUMMARY OF THE INVENTION
[0004] The present invention relates to vascular access devices having integrated safety features configured to prevent unintended migration of guidewires into a patient's body. Accordingly, in an exemplary aspect, the invention provides an internal sheath inserted into a vascular catheter. The sheath includes an elongated body having an inner surface forming a lumen along an axis and a safety device disposed within the elongated body. The safety device may include one or more protrusions extending from the inner surface of the elongated body toward the axis thereof (e.g., towards the opposing inner wall of the internal sheath), wherein when the elongated body is inserted over a guidewire, each of the one or more protrusions applies frictional force onto the guidewire to prevent unintended migration thereof. In various embodiments, each of the one or more protrusions is in compressive contact with adjacent protrusions and/or the opposing wall of the inner sheath to close or substantially close the lumen of the elongated body. Thus, in various embodiments, each of the one or more protrusions may apply one or more of frictional, compressive, and interlocking force onto the guidewire to prevent unintended migration thereof. In various embodiments, each of the one or more protrusions may be substantially perpendicular to the axis or may be angled inward toward the axis of the elongated body. In various embodiments, each of the one or more protrusions contacts a textured coating of the guidewire, wherein frictional force increases between the one or more protrusions and the textured coating. In various embodiments, each of the one or more protrusions is disposed equidistantly along the inner surface of the elongated body. In various embodiments, each of the one or more protrusions further comprises a corresponding deformable flexure extending toward the axis of the lumen. In various embodiments, each deformable flexure comprises one or more teeth protruding therefrom, wherein

each of the one or more teeth are inclined relative to the flexure. Thus, each deformable flexure engages corresponding teeth or notches of the guidewire to form a one-way mechanism similar to a "zip-tie" mechanism. In various embodiments, the one-way mechanism may be a leaflet. In various embodiments, the guidewire may include unidirectional protrusions (e.g., barbs, needles, pins, cones, etc.). In various embodiments, the guidewire may include a curved end that creates a "J" tip.
[0005] In various embodiments, the sheath may further include a luer-lock, screw, or tapered mechanism disposed at a proximal end of the elongated body. In various embodiments, the elongated body and the safety device are formed as a single unit. In various embodiments, the elongated body and the safety device are formed separately and permanently bonded to one another. In various embodiments, the safety device is integrated into a vascular access device.
[0006] In another exemplary aspect, the invention provides a safety guidewire. The safety guidewire includes a guidewire having a length and a first "J" tip disposed at a distal end thereof, and a textured coating disposed over a portion of the length of the guidewire. In various embodiments, the textured coating provides a tactile indication of insertion length and/or depth within a patient. In various embodiments, the guidewire may be colored for visual indication of insertion length and/or depth into a patient. In various embodiments, about 8-11 centimeters of the distal end of the guidewire is not coated by the textured coating. In various embodiments, the textured coating is disposed over the proximal end, wherein the textured coating is configured to increase engagement of one or more protrusions of a safety device through which the guidewire is traversed. In various embodiments, the textured coating is a polymer coating. In various embodiments, the safety guidewire may also include a second "J" tip disposed at a proximal end of the guidewire. The second "J" tip may be easily straightened by a user. In various embodiments the guidewire itself may provide a one-way mechanism via the "J" tip and/or one or more extensions disposed at a proximal end of the guidewire and extending outward from a central axis of the guidewire. In various embodiments, the guidewire may engage the protrusions of the safety sheath to create the one-way mechanism to prevent unwanted migration of the guidewire into a patient's body. In various embodiments, the extensions are disposed radially, helically, or randomly along a length of the guidewire. In various embodiments, the extensions are disposed linearly along a length of the guidewire. In various embodiments, the extensions are formed equidistant around a circumference of the guidewire. In various embodiments, each of the plurality of extensions has different length and/or thickness relative to one another.
[0007] In another exemplary aspect, the invention provides an introducer set. The introducer set includes at least a catheter, a guidewire, and the sheath described above. In various embodiments, the guidewire is the safety guidewire described above.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0008] FIG. **1**A is a pictorial diagram showing a side view of an exemplary safety sheath or safety catheter with an integrated safety device in accordance with one or more embodiments of the present disclosure.
[0009] FIG. **1**B is a pictorial diagram of a cross-sectional view, taken along line **1**B-**1**B of FIG. **1**A, showing the exemplary safety sheath or safety catheter with the integrated safety device in accordance with one or more embodiments of the present disclosure.
[0010] FIG. **2**A is a pictorial diagram of a partial cross-sectional view, taken along line **1**B-**1**B of FIG. **1**A, showing the exemplary safety sheath or safety catheter with integrated safety device in a resting position in accordance with one or more embodiments of the present disclosure.
[0011] FIG. **2**B is a pictorial diagram of a partial cross-sectional view, taken along line **1**B-**1**B of FIG. **1**A, showing the safety sheath or safety catheter with an exemplary integrated safety device in

an engaged position in accordance with one or more embodiments of the present disclosure.
[0012] FIG. **3**A is a pictorial diagram of a cross-sectional view, taken along line **3**A-**3**A of FIG. **2**A, showing the safety device closing the lumen of the safety sheath or safety catheter in accordance with one or more embodiments of the present disclosure.
[0013] FIG. **3**B is a pictorial diagram of a cross-sectional view, taken along line **3**A-**3**A of FIG. **2**A, showing an alternative embodiment of the same exemplary safety device in accordance with one or more embodiments of the present disclosure.
[0014] FIGS. **4**A and **4**B are pictorial diagrams showing various views of an exemplary safety sheath with an alternative exemplary embodiment of the safety device and corresponding guidewire in accordance with one or more embodiments of the present disclosure.
[0015] FIGS. **5**A and **5**B are pictorial diagrams showing various views of an exemplary safety sleeve with an alternative exemplary embodiment of a safety device in accordance with one or more embodiments of the present disclosure.
[0016] FIGS. **6**-**9** are pictorial diagrams showing side views of exemplary guidewires in accordance with one or more embodiments of the present disclosure.
[0017] FIG. **10** is a pictorial diagram showing an exemplary introducer set in accordance with one or more embodiments of the present disclosure.
[0018] Embodiments of the present invention and their advantages are best understood by referring to the detailed description that follows. It should be appreciated that like reference numerals are used to identify like elements illustrated in one or more of the figures.

DETAILED DESCRIPTION OF THE INVENTION

[0019] The present invention relates to vascular access devices having integrated safety features configured to prevent unintended migration of guidewires into a patient's body.
[0020] Before the present invention and methods are described, it is to be understood that the terminology used herein is for purposes of describing particular embodiments only, and is not intended to be limiting, since the scope of the present invention will be limited only in the appended claims.
[0021] As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include plural references unless the context clearly dictates otherwise. Thus, for example, references to “the method” includes one or more methods, and/or steps of the type described herein which will become apparent to those persons skilled in the art upon reading this disclosure and so forth.
[0022] The term “comprising,” which is used interchangeably with “including,” “containing,” or “characterized by,” is inclusive or open-ended language and does not exclude additional, unrecited elements or method steps. The phrase “consisting of” excludes any element, step, or ingredient not specified in the claim. The phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristics of the claimed invention. The present disclosure contemplates embodiments of the invention compositions and methods corresponding to the scope of each of these phrases. Thus, a composition or method comprising recited elements or steps contemplates particular embodiments in which the composition or method consists essentially of or consists of those elements or steps.
[0023] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the invention, the preferred methods and materials are now described.
[0024] Guidewires are typically used to facilitate insertion of a medical device, such as a catheter, into a body lumen, such as, for example, a blood vessel. The classic or modified Seldinger technique is a common way to deploy the medical device over the guidewire. Briefly, catheter insertion using the Seldinger technique can include one or more of the following steps: administer

local anesthetic: locate vein using finder needle connected to a syringe: remove syringe once needle is appropriately situated in body lumen: confirm placement of needle (e.g., using hemodynamic monitoring such as central venous pressure, color, or absence of pulsatile blood flow, for example): advance guidewire through needle lumen into the target vessel: hold guidewire in place, remove needle: enlarge cutaneous puncture site (e.g., via a scalpel): insert dilator over the guidewire to further enlarge site: remove dilator: thread tip of catheter over the guidewire: grasp catheter near skin and advance into vein with a slight twisting motion: remove guidewire: place caps on input ports to reduce risk of air embolism: aspirate catheter ports to remove air: flush ports, e.g., with saline or heparin.

[0025] A potential life-threatening complication with the use of central venous catheters is migration of the guidewire with the intravascular fragment or migration of the entire guidewire centrally as a foreign body embolus, such as when the operator may not be fully attentive to the guidewire. It has been estimated that this complication occurs with a frequency of approximately 1/1000- 2/1000. Most often, an intravascular fragment of a guidewire or a complete guidewire becomes lodged within the right heart where it may produce an arrhythmia or compromise a valve. Less frequently, the intravascular guidewire lodges more distally within a pulmonary artery with the risk of causing a pulmonary infarction.

[0026] There is also a risk of undesired guidewire migration at any step where the guidewire is at least partially in the body, after the guidewire is advanced through the needle lumen into the target vessel. It is often inconvenient to necessitate a second operator to be present and “sterile” for the sole purpose of holding onto the proximal end of the guidewire for preventing unwanted guidewire migration during a catheter insertion or exchange procedure. Furthermore, other methods of preventing unwanted guidewire migration, such as clamping the proximal end of the guidewire with a hemostat to lock the guidewire in place can undesirably damage the guidewire.

[0027] While guidewires are more commonly used to cannulate a vein or an artery, other body lumens including a lymphatic vessel, biliary tree, etc., can also be cannulated and embodiments described herein can be used to prevent guidewire migration in systems and methods thereof, and for that matter, any procedure in which a guidewire is used to deliver a medical or non-medical device.

[0028] Accordingly, the present invention provides a safety feature (also referred to herein as a “safety device”) for incorporation into a vascular access device (e.g., sheath or catheter). More specifically, a safety device may be integrated into a sheath of a vascular access catheter (e.g., the sheath may be a removeable inner safety sleeve of a catheter) used for accessing a lumen of a patient's body. In various embodiments, the inner safety sleeve may extend beyond the body of the catheter to also act as a dilator. Referring now to the drawings, wherein the showings are for purposes of illustrating embodiments of the present invention only and not for the purposes of limiting the same, FIGS. **1**A and **1**B show a side view and a cross-sectional side view (taken along line **1**B-**1**B of FIG. **1**A), respectively, of a sheath **100** with an integrated safety device **10**, in accordance with one or more embodiments of the present disclosure. As shown in FIGS. **1**A and **1**B, the safety device **10** is disposed within a sheath **100** and includes a one-way mechanism. The sheath **100** includes an elongated body **60** having a lumen **40** defined by an inner surface **105** and extending along a longitudinal center axis X. The elongated body **60** has opposing first and second ends, such as a distal end **20** (i.e., the end of the sheath **100** that is closest to the patient during insertion of the sheath **100** over a guidewire and into a lumen of a patient's body) and a proximal end **30** (i.e., the end of sheath **100** that is farthest from the patient during insertion of sheath **100**). In various embodiments, the proximal end **30** of the elongated body **60** may be formed to include a connector **32** (e.g., a conventional luer-lock, screw connector, or other suitable connectors, adapters, or hubs).

[0029] In other embodiments, the safety sheath **100** does not have a connector and must therefore be removed from an inserted catheter prior to use of the catheter. For example, the sheath **100** may

be disposed inside a catheter (e.g., as an inner safety sleeve) such that the sheath **100** and catheter are simultaneously inserted over a guidewire into a lumen of a patient's body so that the sheath **100** engages the guidewire (as discussed further herein). The sheath **100** and the engaged guidewire may thereafter be removed from the catheter, and thus, removed from the lumen of the patient, leaving the catheter positioned within the lumen of the patient. The connector of the catheter may then be connected to, for example, a syringe or intravenous fluid line. In various embodiments, the safety device **10** includes a one-way mechanism and is disposed within the elongated body **60**. For example, the safety device **10** may be located within the lumen **40** at the distal end **20**, or within close proximity to the distal end **20**, of the elongated body **60**. Thus, when the sheath **100** is inserted over a guidewire (e.g., guidewire **70** as shown in FIGS. **2**A-**2**B), the one-way mechanism of the safety device **10** engages the guidewire, thereby preventing unwanted migration of the guidewire into the patient even with minimal guidewire insertion into the sheath **100**.

[0030] FIGS. **2**A and **2**B show partial cross-sectional side views of an exemplary safety device **10** in a resting position and in an engaged position, respectively, in accordance with one or more embodiments of the disclosure. In various embodiments, the safety device **10** may be conically-shaped and may include one or more protrusions **12**, as discussed further herein. While the safety device **10** is shown as being disposed at the distal end **20** of the elongated body **60**, it should be understood that the safety device **10** may be located anywhere within the lumen **40** of the elongated body **60**, and that the one-way mechanism may be configured for compressive, frictional, and/or interlocking engagement with a guidewire **70**.

[0031] As shown in FIG. **2**A, the sheath **100** may be inserted over the guidewire **70**, as indicated by directional arrow **15**, such that at least a portion of the guidewire **70** traverses through an opening **24** of elongated body **60** and into lumen **40**, for example, in a direction indicated by directional arrow **17**. As shown in FIG. **2**B, the safety device **10** may then engage the guidewire **70** using compressive clamping force to prevent undesirable movement of the guidewire **70** within lumen **40** of sheath **100** (e.g., in a direction opposite of direction **17**) and/or within a lumen of the patient's body.

[0032] In various embodiments, the one-way mechanism of the safety device **10** may include one or more protrusions **12**, each protrusion **12** extending from the inner surface **105** of the elongated body **60** of the sheath **100** toward the center axis X thereof. In embodiments where the safety device **10** is conically shaped (as shown in FIGS. **2**A-**3**B), the protrusions **12** may be circumferentially oriented along the inner surface **105** and may extend radially toward center axis X. Referring now to FIGS. **3**A and **3**B, the protrusions **12** may be adjoined to an annular ring **18** of the safety device **10**, which may be connected to inner surface **105**, as discussed further herein. In various embodiments, each of the one or more protrusions **12** may be in compressive contact with the adjacent protrusions **12**, thereby forming a closed, one-way mechanism within the lumen **40** of the sheath **100**. As such, when the sheath **100** is inserted over a guidewire **70** along axis X, the protrusions **12** are urged apart from each other, resulting in application of compressive force toward axis X and onto the guidewire **70**, thereby preventing unwanted guidewire migration. In various embodiments, the guidewire **70** may have a textured coating **78** (as shown in FIGS. **7**-**9**) configured to provide a tactile and/or visual indication of insertion length and depth and/or to increase frictional force applied to guidewire **70** resulting from the compressive force applied by the one or more protrusions **12**. The textured coating **78** may be formed from any substance suitable for use in medical devices, such as a polymer, provided that the coating provides a tactile and/or visual indication of insertion length or depth and/or increases the frictional force resulting from the compressive force applied by the one or more protrusions **12**.

[0033] FIGS. **3**A and **3**B illustrate cross-sectional views, taken along line **3**A-**3**A of FIG. **2**A, showing various embodiments of safety device **10** in accordance with one or more embodiments of the present disclosure. In various embodiments, the protrusions **12** may be formed to completely close the lumen **40** (as shown in FIG. **3**A) or may substantially close the lumen **40**, leaving a small

opening through which the guidewire **70** is inserted (as shown in FIG. **3**B). In various embodiments, the protrusions **12** may be substantially perpendicular to the axis X of the sheath **100**, or may be angled, for example, inward toward axis X of the elongated body **60** of the sheath **100** (as shown in FIGS. **2**A and **2**B). For example, each protrusion **12** may provide an inclined surface relative to axis X such that the protrusions **12** are unidirectionally oriented about axis X.

[0034] In various embodiments, the proximal end **30** of the sheath **100** will be formed with or without a typical luer-lock, screw lock, or tapered mechanism (i.e., connector **32**) that allows for attachment of a syringe or intravascular fluid line. As such, when the sheath **100** is formed without a connector **32** at the proximal end **30**, a user will be required to remove the sheath **100** prior to use of the catheter for the procedure. In various embodiments, the sheath **100** will extend beyond a tip of the catheter to act as dilator, thereby eliminating the need for a separate dilation step when inserted into the lumen of a patient.

[0035] It should be understood that while the safety device **10** is described as being formed integral to the internal sheath **100**, the present invention also contemplates formation of the safety device **10** as a separate unit from the internal sheath **100**. In such embodiments, the safety device **10** may include an annular ring **18** having an outer surface **22** and an inner surface **28**, where the outer surface **22** is sized for contacting the inner surface **105** of the elongated body **60**. As shown in FIGS. **3**A and **3**B, the one or more protrusions **12** may extend from the inner surface **28** of the annular ring **18** toward the center axis X of sheath **100**. When formed as a separate unit, the annular ring **18** of safety device **10** may be permanently bonded to the inner surface **105** of the sheath **100** by any known means, followed by any known sterilization method suitable for medical or non-medical devices to be inserted into a body lumen. Alternatively, or in addition thereto, annular ring **18** may be permanently bonded to the inner surface **105** of the elongated body **60** under aseptic conditions.

[0036] In various embodiments, the safety device **10** may also be used in conjunction with a catheter to be inserted into a body lumen. For example, the safety device **10** may be incorporated into the distal end of a catheter that is directly inserted over a guidewire **70**, rather than, or in addition to, incorporating the safety device **10** on the internal sheath **100**.

[0037] One common type of catheter inserted over a guidewire is a central venous catheter, which is typically inserted via an internal jugular, subclavian, axillary, or femoral vein approach. A central venous catheter, such as those described, for example, in U.S. Pat. No. 6,206,849, hereby incorporated by reference in its entirety, can include one or more input ports operably connected to a conduit fluidly connected to the catheter body. The catheter may be used for hemodialysis treatment and may also be inserted in a similar fashion into the femoral vein or internal jugular vein, for example. Some non-limiting examples of dialysis catheters that can be used or modified for use herein include Mahurkar™ or Quinton™ catheters, or tunneled catheters such as Hickman™ or Groshong™ catheters.

[0038] As provided herein, the invention may, in action, serve some purposes that are also served by a dilator: however, the invention, in an exemplary form is not intended to be inserted into a patient and then removed prior to the insertion of the vascular access device. Rather the invention may extend beyond the distal end of the catheter to be inserted in order to accomplish the function of a separate dilator, including facilitating the insertion of an otherwise flimsy catheter into a patient lumen, thereby eliminating the need for a separate dilation step.

[0039] Referring now to FIGS. **4**A and **4**B, an alternative exemplary embodiment of safety device **10** is provided in accordance with the disclosure. As shown, the safety device **10** may include one or more protrusions, such as engagement members **212**, configured for one-way engagement of the guidewire **70** (e.g., similar to a ratcheting “zip-tie” mechanism). In various embodiments, the safety device **10** may include one engagement member **212** (as shown in FIG. **4**B) or may include two opposing engagement members **212** (as shown in FIG. **4**A). In various embodiments, safety device **10** may include four, five, six or more protrusions disposed equidistantly along the entirety of the

periphery of the inner surface **105** of the elongated body **60**, and spaced equidistantly from one another about axis X. In various embodiments, each of the engagement members **212** may include a corresponding deformable flexure **208** extending toward axis X of the elongated body **60**. In various embodiments, each of the engagement members **212** may be directly attached to the inner surface **105** of the elongated body **60** or may be formed on a base **210**, which is bonded to the inner surface **105** of the elongated body **60**. In one or more embodiments, each flexure **208** may have one or more teeth **206** protruding therefrom that are inclined relative to the surrounding, adjoining surface of the flexure **208**.

[0040] As such, when guidewire **70** traverses through the lumen **40** and through a channel **202** defined by the flexures **208** of the safety device **10**, the safety device **10** may be configured for ratcheted engagement (i.e., similar to a "zip-tie" mechanism) with the guidewire **70** in that at least a portion of each flexure **208** may translate outward (i.e., away from axis X and toward the inner surface **105** of the sheath **100**). As described above, the teeth **206** protrude from the flexures **208** and extend unidirectionally from each flexure **208** at an angle so that the guidewire **70** may readily traverse through the safety device **10** in a first direction (e.g., direction **217**) when the sheath **100** is inserted over the guidewire **70** (e.g., in direction **215**). Thus, teeth **206** are configured to engage and prevent movement of the guidewire **70** in a second direction (e.g., a direction opposite of direction **217**). In various embodiments, teeth **206** are configured to engage the guidewire **70** using an applied longitudinal force and/or compressive contact, as described above. In various embodiments, the guidewire **70** may have a textured coating **78** configured to increase frictional force applied by the teeth **206** onto guidewire **70**. In another exemplary configuration, guidewire **70** may include complementary circumferential surfaces, such as corresponding threading **204** or recessed notches, that are configured to engage the teeth **206** of the safety device **10**. When so configured, the engagement of teeth **206** of the safety device **10** with corresponding threading **204** or notches of the guidewire prevent movement of the guidewire in the second direction (i.e., the direction opposite of direction **217**).

[0041] Referring now to FIGS. **5**A and **5**B, alternative exemplary embodiments of safety device **10** are provided in accordance with the disclosure. As shown, the safety mechanism **10** may include one or more protrusions, such as tabs **312**, formed to resemble circular leaflets (e.g., leaflets that close the lumen **40**) and/or blade-like structures. For example, as shown in FIG. **5**B, the safety device **10** may provide one tab **312** (e.g., a circular leaflet) that is bonded to the inner surface **105** of elongated body **60**, where the tab **312** creates a plane that is angled relative to axis X, thereby closing or substantially closing the lumen **40** of sheath **100**. Upon insertion of the sheath **100** over guidewire **70** (causing guidewire **70** to be inserted into lumen **40** and through safety device **10**), tab **312** flexes toward the adjoining inner surface **105** (as indicated by the curved arrow). In various embodiments, the safety device **10** may include a plurality of tabs **312**, similar to protrusions **12**, as shown in FIG. **5**A. Thus, tabs **312** may be configured to flex and translate outward (i.e., away from axis X) upon insertion of the sheath **100** over the guidewire **70** (as indicated by the arcuate arrows in FIGS. **5**A and **5**B). For example, sheath **100** may be inserted over the guidewire **70** in a direction indicated by arrow **315**, and the guidewire **70** may traverse through the lumen **40** and safety device **10** in a direction indicated by arrow **317** such that tabs **312** may each bend or translate away from axis X and toward their respective adjoining inner surfaces **105** of body **60**.

[0042] As shown in FIGS. **6-9**, the invention also provides a guidewire **70** for reducing the risk of inadvertent passage of the guidewire **70** into the patient and/or insertion beyond a predetermined distance in accordance with one or more embodiments of the present disclosure. As is known in the art, the approximate distance from the sternal angle to the right atrium of the adult human heart is 8-11 centimeters. Thus, medical personnel typically avoid inserting a guidewire more than about 7.5 centimeters to prevent damage to the surrounding organs or vessels. However, a user must also ensure that an adequate length of the guidewire extends outside of the patient for use in inserting the catheter. As such, medical personnel typically leave a length that is at least about **10** centimeters

longer than the vascular catheter that is to be inserted to ensure proper use thereof.
[0043] Accordingly, as briefly discussed above, the present invention provides a guidewire **70** having disposed thereon a textured coating **78** on a portion of its length. The textured coating **78** may thus provide a user with a tactile indicator of sufficient insertion length into the patient and thus prevent over-insertion thereof. In various embodiments, the textured coating **78** may be color-coded to provide a visual indicator of insertion length in addition to the tactile indicator. The textured coating **78** may be formed from any substance suitable for use in medical devices, such as a polymer, provided that the texture is sufficient for use as a tactile indicator of insertion length. In various embodiments, the textured coating **78** may provide additional engagement force with the one or more protrusions **12**. flexures **208**, or tabs **312** of the safety device **10** described above.
[0044] As is known in the art, guidewires **70** are available in movable and fixed core configurations, are typically formed from stainless steel, and may include a “J” tip disposed at an end thereof. Guidewires may also be coated with a polymer coating, such as polytetrafluoroethylene (PTFE) to provide a smooth, slick surface for insertion into a body lumen. As shown in FIG. **6**, the guidewire **70** has a “J” tip **76** disposed at the distal end **72** configured to avoid puncture of surrounding organs or vessels. In various embodiments, the guidewire **70** of the present invention may further include a second, easily straightened, “J” tip **80** disposed at the proximal end **74** thereof to further prevent over-insertion of the guidewire **70** into the patient (FIG. **7**). In various embodiments, the “J” tip **80** may additionally provide frictional force within the safety sheath **100** or even a standard catheter lumen in order to prevent the unintended migration of the guidewire **70** into a patient.
[0045] As shown in FIGS. **4**A, **4**B and **8**, the guidewire **70** may include threading **204** or notches disposed at least at the proximal end **74** thereof. In various embodiments, the threading **204** is configured for ratcheting or frictional engagement with complementary surfaces (e.g., protrusions **12**, teeth **206** or tabs **312**) of the safety device **10** to prevent the guidewire **70** from moving in an undesired direction and/or an undesired distance within the lumen **40** of the sheath **100** (as shown, for example, in FIGS. **4**A and **4**B).
[0046] As shown in FIG. **9**, guidewire **70** may include one or more extensions **304** (e.g., barbs) that extend from at least the proximal end **74** thereof. Each of the one or more extensions **304** may be angled such that the guidewire **70** may readily traverse in one direction (e.g., direction indicated by arrow **317** of FIG. **5**A) through the lumen **40**, but cannot traverse in an opposing direction (e.g., a direction opposite of direction **317**) beyond a predetermined point. Once the guidewire **70** is inserted through the safety device **10** of sheath **100**, extensions **304** may abut and/or engage one or more of the surfaces **302** of the tabs **312** (as shown in FIG. **5**A) to prevent the guidewire **70** from moving in an unwanted direction within the sheath **100**. Thus, tabs **312** may provide a lateral force and/or compressive force to prevent undesired movement of the guidewire **70** within the sheath **100**, or a standard catheter, and a patient's body.
[0047] In various embodiments, the extensions **304** may be barbs, pins, cones, etc. In various embodiments, the extensions **304** are oriented unidirectionally relative to each other. In various embodiments, each of the one or more extensions **304** may have different lengths and/or thicknesses. In various embodiments, the one or more extensions **304** may be uniformly sized and shaped. In various embodiments, the extensions **304** may be positioned linearly along a length of guidewire **70**. In various embodiments, multiple linear arrangements of extensions **304** may be provided on opposing sides of the guidewire **70**. In various embodiments, multiple linear arrangements of extensions **304** may be provided equidistantly and/or randomly around the circumference of guidewire **70** at the proximal end **74** thereof relative to a longitudinal center axis Y thereof. In various embodiments, the extensions **304** may be positioned radially, helically, randomly, and/or positioned in any other various arrangements about at least a portion of the length of the guidewire **70**. As should be understood by one skilled in the art, while certain embodiments of the safety device **10** are described as being used in conjunction with specific embodiments of the

guidewire **70**, the various embodiments of each may be used alone or in combination with each other while still maintaining the scope of the invention.
[0048] As shown in FIG. **10**, the invention also provides an introducer set **500** incorporating the safety device and/or guidewire described herein. Thus, in various embodiments, the introducer set **500** may include a sheath **100** and guidewire **70** in accordance with one or more embodiments of the disclosure. In various embodiments, the introducer set **500** may be contained in a sterilized, peel-open package **510** intended for one-time use. As can be appreciated, the introducer set **500** may include various components used by physicians and/or medical technicians in, for example, diagnostic and interventional techniques (e.g., techniques known in the art that may be used for placement of vascular access devices). In various embodiments, the introducer set **500** may include a sheath **100** preloaded within an insertable catheter **508** that has, for example, an integral sidearm and corresponding adaptor, valve, and/or stopcock), the guidewire **70**, a vessel dilator **502** (e.g., a dilator with a luer-lock collar), a needle **504**, a scalpel **506**, and/or a syringe (not shown).
[0049] In various embodiments, the introducer set **500** may include: a catheter: a safety guidewire (e.g., guidewire **70**); and/or a safety sheath (e.g., sheath **100**). As described above, the guidewire **70** may have a length and a first "J" tip **76** disposed at a distal end **72** thereof and one or more extensions **304** disposed at a proximal end **74** thereof. In various embodiments, the safety sheath may include an elongated body **100** having an inner surface **105** forming a lumen **40** along an axis X and a safety device **10** disposed anywhere within the elongated body **100**. As described above, the safety device **10** may include one or more protrusions **12**, flexures **208**, or tabs **312** extending from the inner surface **105** of the elongated body **100** toward the axis X thereof or extending toward the opposing wall thereof. In use, as the elongated body **100** is inserted over the guidewire **70** and into a lumen of the patient, each of the one or more protrusions **12**, flexures **208**, or tabs **312** of the safety device **10** engage the one or more extensions **304** of the safety guidewire **70**, thereby preventing unintended migration of the guidewire.
[0050] Although the invention has been described with reference to the above disclosure, it will be understood that modifications and variations are encompassed within the spirit and scope of the invention. Accordingly, the invention is limited only by the following claims.

Claims

1. A safety sheath for insertion into a vascular access catheter comprising: (a) an elongated body having an inner surface forming a lumen along an axis: (b) a safety device disposed within the elongated body, the safety device comprising one or more protrusions extending from the inner surface of the elongated body toward the axis or opposing inner surface thereof, wherein, when the elongated body is inserted over a guidewire, each of the one or more protrusions applies one or more of frictional, compressive, and interlocking force onto the guidewire to prevent unintended migration thereof.
2. The safety sheath of claim 1, wherein each of the one or more protrusions is in compressive contact with adjacent protrusions or opposing inner sheath surface to close or substantially close the lumen of the elongated body.
3. The safety sheath of claim 1, wherein the each of the one or more protrusions is angled inward toward the axis or opposing inner sheath surface of the elongated body.
4. The safety sheath of claim 1, wherein each of the one or more protrusions contacts a textured coating of the guidewire, wherein frictional force increases between each of the one or more protrusions and the textured coating.
5. The safety sheath of claim 1, wherein each of the one or more protrusions is disposed equidistantly along the inner surface of the elongated body.
6. The safety sheath of claim 5, wherein each of the one or more protrusions further comprises a corresponding deformable flexure extending toward the axis of the lumen.

7. The safety sheath of claim 6, wherein each deformable flexure comprises one or more teeth protruding therefrom, wherein each of the one or more teeth is inclined relative to the flexure.
8. The safety sheath of claim 7, wherein each deformable flexure engages corresponding teeth or notches of the guidewire.
9. The safety sheath of claim 1, wherein each of the one or more protrusions engages corresponding barbs formed on a surface of the guidewire.
10. The safety sheath of claim 1, further comprising a luer-lock, screw, or tapered mechanism disposed at a proximal end of the elongated body.
11. The safety sheath of claim 1, wherein the elongated body and the safety device are formed as a single unit.
12. The safety sheath of claim 1, wherein the elongated body and the safety device are formed separately and permanently bonded to one another.
13. A safety guidewire comprising: (a) a guidewire having a length and a first “J” tip disposed at a distal end thereof: and (b) a safety coating disposed over a portion of the length of the guidewire.
14. The safety guidewire of claim 13, wherein the safety coating is disposed over the distal end of the guidewire and is textured to provide a tactile indication of insertion length into a patient.
15. The safety guidewire of claim 13, wherein the safety coating is disposed over the distal end of the guidewire and is colored to provide a visual indication of insertion length into a patient.
16. The safety guidewire of claim 13, wherein about a length of about **8-11** centimeters of the distal end of the guidewire is not coated by the safety coating.
17. The safety guidewire of claim 13, wherein the safety coating is disposed over the proximal end and is configured to increase engagement of one or more protrusions of a safety device through which the guidewire is traversed.
18. The safety guidewire of claim 13, wherein the safety coating is a polymer coating.
19. The safety guidewire of claim 13, further comprising a second “J” tip disposed at a proximal end of the guidewire.
20. The safety guidewire of claim 19, wherein the second “J” tip may be straightened by a user.
21. The safety guidewire of claim 13, further comprising one or more extensions disposed at a proximal end of the guidewire, wherein each of the one or more extensions is configured for engagement with a safety device through which the guidewire is traversed or with the inner surface of a standard catheter.
22. The safety guidewire of claim 21, wherein each of the one or more extensions is formed as teeth, notches, barbs, pins, or cones.
23. The safety guidewire of claim 22, wherein the one or more extensions are disposed radially, helically, or randomly along a length of the guidewire.
24. The safety guidewire of claim 22, wherein the one or more extensions are disposed linearly along a length of the guidewire.
25. The safety guidewire of claim 24, wherein the extensions are formed equidistant around a circumference of the guidewire.
26. The safety guidewire of claim 22, wherein each of the one or more extensions has a different length and/or thickness relative to one another.
27. An introducer set comprising: a catheter, a guidewire, and the safety sheath as set forth in claim 1.
28. The introducer set of claim 27, wherein the guidewire is the safety guidewire as set forth in claim 13.
29. An introducer set comprising: (a) a catheter: (b) a safety guidewire, wherein the safety guidewire comprises: (i) a guidewire having a length and a first “J” tip disposed at a distal end thereof: (ii) one or more extensions disposed at a proximal end of the guidewire; and (c) a safety sheath, wherein the sheath comprises: (i) an elongated body having an inner surface forming a lumen along an axis; (ii) a safety device disposed within the elongated body, the safety device

comprising one or more protrusions extending from the inner surface of the elongated body toward the axis thereof; wherein, when the elongated body is inserted over a guidewire, each of the one or more protrusions of the safety sheath engages the one or more extensions of the safety guidewire, thereby preventing unintended migration thereof.

30. The introducer set of claim 29, wherein the one or more extensions are formed as teeth, notches, barbs, pins, or cones.

31. The introducer set of claim 30, wherein the one or more extensions are disposed radially, helically, or randomly along a length of the guidewire.