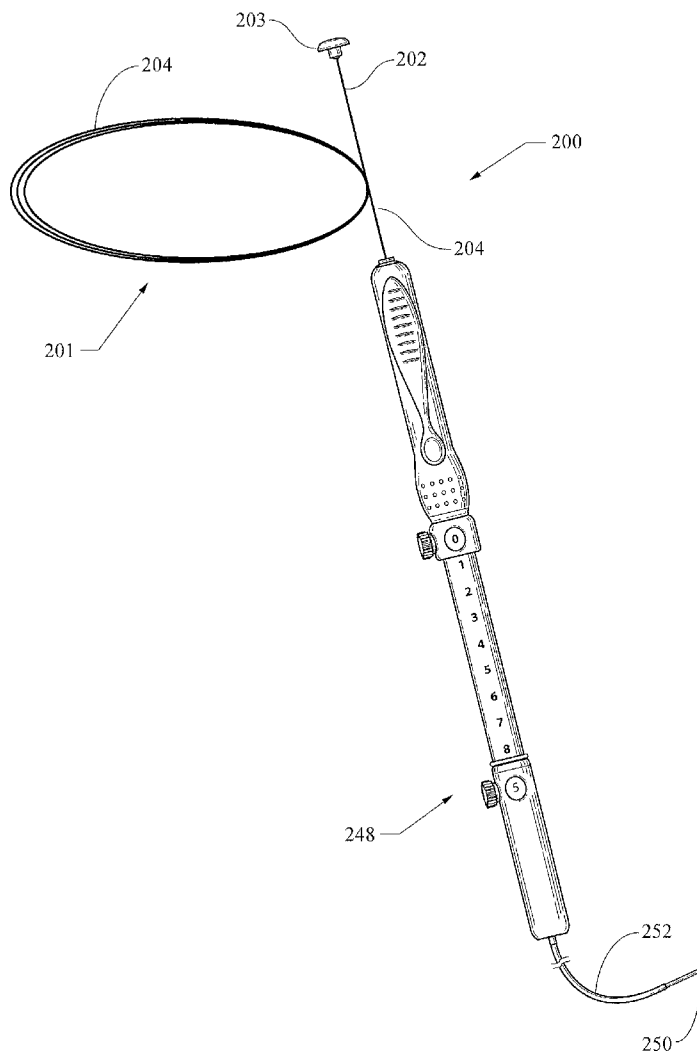


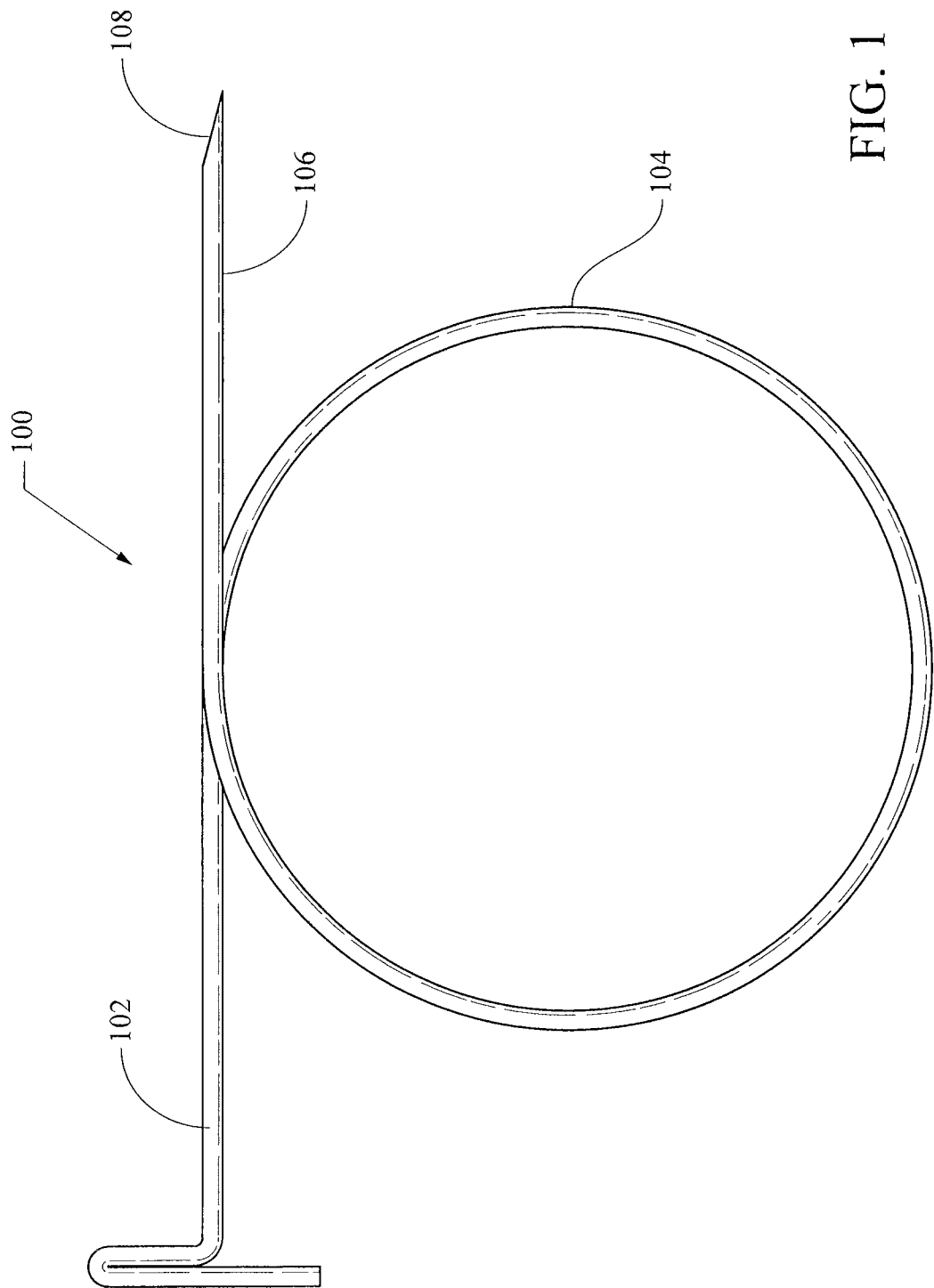


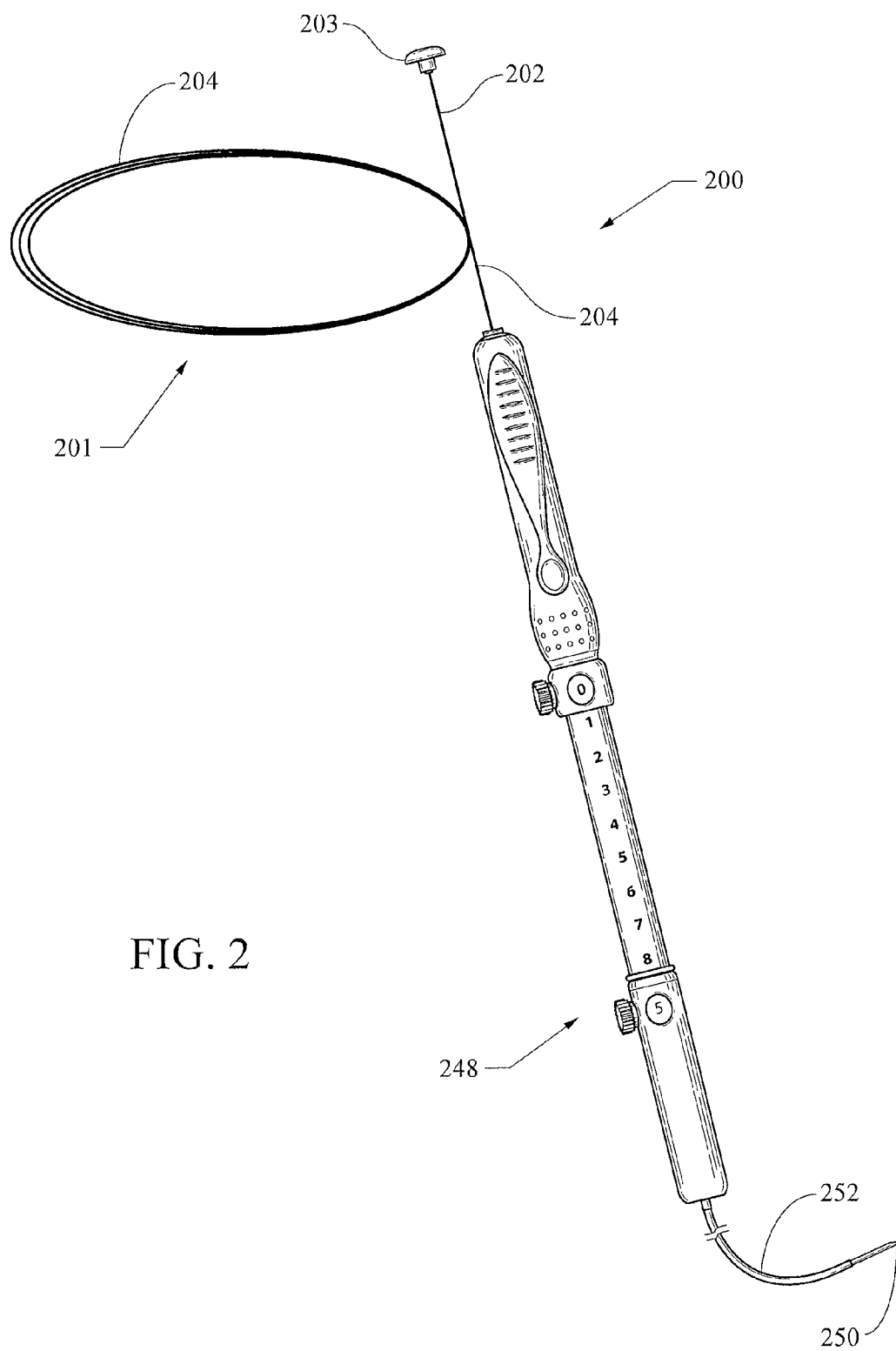
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**Irwin et al.**(10) **Pub. No.: US 2014/0114255 A1**(43) **Pub. Date: Apr. 24, 2014**(54) **SELF-COILING STYLET NEEDLE DEVICE****Publication Classification**(71) Applicant: **Cook Medical Technologies LLC**,  
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USPC ..... **604/164.06**; 604/164.01; 604/530(73) Assignee: **Cook Medical Technologies LLC**,  
Bloomington, IN (US)(21) Appl. No.: **14/055,249**(22) Filed: **Oct. 16, 2013****Related U.S. Application Data**(60) Provisional application No. 61/716,002, filed on Oct.  
19, 2012.(57) **ABSTRACT**

A medical device includes an elongate single-wire memory-metal body with a complete length that includes a proximal stylet length, an intermediate self-coiling stylet length, and a distal stylet length that is generally straight and non-self-coiling. The moment of force of the self-coiling stylet length is less than the moment of force of the medical endoscopy needle that is resistant to the stylet's self-coiling force. The device may further include being incorporated into an endoscopy needle system where the single-wire stylet body is disposed through a lumen of a medical endoscopy needle.







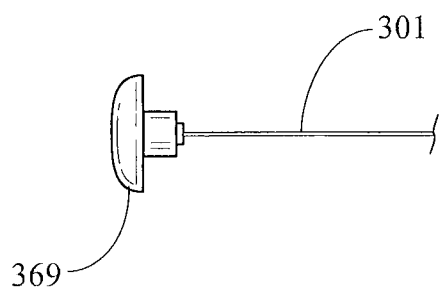


FIG. 3A

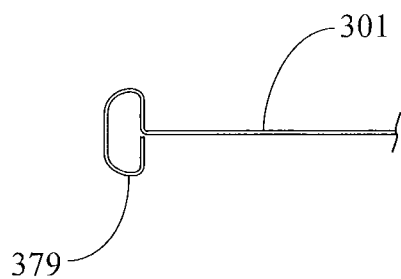


FIG. 3B

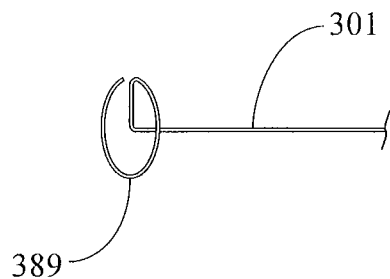


FIG. 3C

## SELF-COILING STYLET NEEDLE DEVICE

### CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application is a non-provisional application which claims priority to U.S. provisional application Ser. No. 61/716,002, filed Oct. 19, 2012, which is incorporated by reference herein in its entirety.

### TECHNICAL FIELD

**[0002]** Embodiments disclosed herein generally relate to a medical endoscopic needle and stylet system. More particularly, the disclosed embodiments relate to a self-coiling stylet.

### BACKGROUND

**[0003]** Fine needle aspiration (FNA) and fine needle biopsy are diagnostic biopsy procedures used to obtain a sample from a target site in a patient body. A fine needle (e.g., 19-gauge to 25-gauge) is directed to a target site, and suction is applied to the proximal end of a lumen of the needle to aspirate cells through its distal end. The procedure typically is far less invasive than other biopsy techniques, whether performed percutaneously (e.g., to sample a suspected breast tumor or subcutaneous lesion) or endoscopically (e.g., to sample a suspected cholangiocarcinoma via a duodenoscope). Moreover, advances in endoscopic ultrasound (EUS) technology have helped physicians and patients by providing enhanced ability of a physician to visualize a biopsy needle to obtain a sample of material from a target site without requiring an open incision or use of large-bore needles and/or percutaneous trocars.

**[0004]** In order to provide desirable pushability and trackability for these small-bore sample-collection needles, and to prevent inadvertent (e.g., early and/or late) collection of tissue in one or more distal needle openings, a stylet is typically provided through the length of the needle lumen. After the distal end opening(s) of the needle is/are directed to a target location via a medical endoscope such as a duodenoscope or other minimally-invasive endoscope device, the stylet is withdrawn and a syringe or other modality is attached to the proximal needle end for generating vacuum through the needle lumen to facilitate sample collection by drawing sample material into the distal end opening(s) of the needle. Stylet-management may pose challenges during such procedures.

**[0005]** Specifically, a nurse or other person assisting the physician conducting the endoscopic sample collection must typically use both hands to withdraw the stylet from the needle lumen. Because the stylet may be nearly 2 meters in length and is non-sterile after having been inside the patient, it is usually wound up by nurse as it is withdrawn. However, the default configuration/orientation of existing stylets is generally straight, which is to say that their default configuration is to lie along an uncurved line in all longitudinal planes. As such, stylets are biased to become unwound. This can pose a sharps injury risk due to a sharp distal tip when a stylet springs loose from a wound-up position, and/or it can become contaminated by contacting other non-sterile surfaces. For this reason, the nurse must often clip or otherwise secure the wound-up stylet. In the event that the stylet must be reintroduced into the needle, both hands of the nurse are required to control unwinding and to feed the distal stylet portion back into the needle lumen. If the wound-up stylet escapes the clip

or other constriction, it may contact the floor or another contaminating surface and have to be replaced by a sterile stylet—increasing procedure time and expense.

**[0006]** Thus, it may be desirable to provide a stylet configuration that will reduce procedure time, reduce the manual manipulation required during a stylet/needle procedure such as endoscopic sample collection (e.g., FNA, FNB), and that will reduce other risks associated with loss of stylet control during such a procedure.

### BRIEF SUMMARY

**[0007]** The needs described above are met by certain embodiments of the presently described and claimed invention. In one aspect, embodiments disclosed herein include a medical endoscopy sample-collection system including a single-wire memory metal stylet disposed through a needle lumen, as well as methods for using that system. In another aspect, embodiments disclosed herein may include a single-wire memory metal stylet with a self-coiling intermediate length. Additionally, in certain embodiments, a self-coiling single-wire memory metal stylet may include particular patterns of self-coiling that prevent tangling and enhance the ease of manipulating the device.

### BRIEF DESCRIPTION OF THE DRAWINGS

**[0008]** FIG. 1 shows a self-coiling single-wire-body stylet embodiment;

**[0009]** FIG. 2 shows a self-coiling single-wire-body stylet as part of a needle/stylet system embodiment; and

**[0010]** FIGS. 3A-3C show proximal end configuration embodiments of a self-coiling single-wire-body.

### DETAILED DESCRIPTION

**[0011]** Various embodiments are described below with reference to the drawings, in which like elements generally are referred to by like numerals. The relationships and function(s) of the various elements of the embodiments may better be understood by reference to the following detailed description. However, embodiments are not limited to those illustrated in the drawings. It should be understood that the drawings are not necessarily to scale, and in certain instances details may have been omitted that are not necessary for an understanding of embodiments disclosed herein, such as—for example—conventional fabrication and assembly.

**[0012]** The invention is defined by the claims, may be embodied in many different forms, and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey enabling disclosure to those skilled in the art. As used in this specification and the claims, the singular forms “a,” “an,” and “the” include plural referents unless the context clearly dictates otherwise. The terms “proximal” and “distal” are used herein in the common usage sense where they refer respectively to a handle/doctor-end of a device or related object and a tool/patient-end of a device or related object.

**[0013]** As used herein, the term “moment of force” refers to the tendency of a force to coil, twist, or rotate an object and/or to resist coiling, twisting, or rotation. Specifically, the term is used to refer to the self-coiling force of a memory-metal stylet along a length thereof and to refer to the resistance of a needle to that self-coiling force along a corresponding length thereof. The term “single-wire” refers to a structure that,

along the distal operating longitudinal length thereof, includes only a single lengthwise wire with no other parallel, coaxial, or other wires (e.g., differentiating it from the braided, coaxially coiled, and other wire structures used in guidewires, catheter bodies, and other wire-based structures).

**[0014]** One embodiment of a self-coiling stylet is described with reference to FIG. 1, which shows a stylet **100**. The stylet **100** is constructed with an elongate single-wire memory-metal body with a complete length that includes a proximal stylet length **102**, an intermediate self-coiling stylet length **104** including at least one coiled loop—which may include a plurality of coiled loops, and a distal stylet length **106** that is generally straight and non-self-coiling. The distal end tip **108** is configured with a sharp, tissue-piercing beveled geometry. In other embodiment, a piercing tip may be conical or otherwise configured to penetrate and/or cut into/through tissue. In still other embodiments, the tip may be rounded and generally atraumatic, but preferred embodiments are configured to complement the distal piercing/penetrating tip of a needle and/or to extend beyond a needle body to form a leading surface.

**[0015]** The memory metal may include an alloy selected from nickel-titanium, nickel-titanium-cobalt, nickel-titanium-chromium, nickel-titanium-niobium, nickel-titanium-hafnium, nickel-titanium-palladium, nickel-titanium-platinum, nickel-titanium-iron, nickel-titanium plus rare earth elements, iron-manganese-silicon, iron-platinum, iron-nickel, iron-nickel-cobalt, iron-nickel-cobalt-aluminum-tantalum, and any combination thereof. One preferred embodiment includes superelastic nickel-titanium (nitinol) wire. The methods of thermosetting or otherwise imposing a “memorized” shape onto memory-metal alloys are well-known known in the art, and those of skill in the art will be enabled by the present disclosure and contemporary knowledge to configure stylets in keeping with the presently claimed invention embodiments. The intermediate self-coiling stylet length **104** may be configured to form one or more parallel and/or spiraling/concentric loops that have a circular, oval, elliptical, obround, and/or other rounded geometry.

**[0016]** The intermediate self-coiling stylet length **104** preferably will form the one or more loops with an outer diameter of about 7 cm to about 20 cm. This will provide for the coiled stylet easily to be stored on the surface of one of the carts/trolleys commonly used in endoscopy operating suites without impeding the movement of personnel during the procedure and remaining conveniently accessible for re-use if/as needed.

**[0017]** The exact dimensions and proportions of different stylet embodiments may vary. For example, the length and outer stylet diameter (across a transverse section of the single-wire body) will be constructed and/or selected for compatibility with a particular needle. A stylet being used with a 25-gauge needle will have a different outer diameter than one for a 19-gauge or 22-gauge needle. Common lengths will be about 160 cm to about 170 cm. The outer diameter of the stylet **200** may range from about 0.012 inches (about 0.3 mm) to about 0.036 inches (about 0.9 mm), for stylet lengths ranging from about 850 mm to about 1850 mm.

**[0018]** One exemplary embodiment is a 170 cm long stylet having an outer diameter of about 0.035 inches (about 0.89 mm). This sample stylet embodiment includes an intermediate self-coiling length that is about 154 cm. It also includes a distal straight length of about 16 cm, terminating in a sharp/penetrating beveled tip, and its proximal length is not straight

but is co-terminal with a proximal portion of the self-coiling intermediate length. This configuration provides for a desirable balance between the functional advantages of the unique self-coiling design and the provision of a non-self-coiling distal length that will behave predictably and uniformly (in contrast, for example, with the non-uniform behavior of a guidewire that will have at least a slight distal-end curvature as required for its desired steerability/navigability function). In other embodiments, a proximal length of an exemplary stylet may be straight.

**[0019]** In certain preferred embodiments, a generally straight distal stylet length is no more than about 10% of the complete stylet length. In certain preferred embodiments, the self-coiling intermediate length may include up to about 95% of the complete stylet length. In some embodiments, the self-coiling length may be about 80% to about 92% of the complete stylet length, with about 4% to about 9% of the complete length being a substantially straight distal length, and the remainder (if any) being a substantially straight proximal length.

**[0020]** FIG. 2 shows an embodiment of a medical endoscopy needle and stylet system **200** including a needle **250** extending from a needle sheath **252** workably attached with a needle handle **248**, and a self-coiling stylet **201**. The stylet **201** is constructed with an elongate single-wire memory-metal body with a complete length that includes a proximal stylet length **202** terminating in a cap **203**, a self-coiling intermediate stylet length **204**, and a distal stylet length (not shown, disposed within the needle lumen). The stylet is shown as partially withdrawn from the lumen of the needle **250**. The self-coiling intermediate stylet length **204** is shown as forming a generally oval spiral configuration, where each of the more proximal loops includes an outer diameter about the same as or slightly less than the immediately-more-distal adjacent loop. This configuration will prevent tangling during removal of the stylet **201** from the needle lumen and/or during reintroduction of the stylet **201** into that lumen. Although not shown, the self-coiling intermediate stylet length **204** extends through a significant length of the needle.

**[0021]** Other tangle-prevention features may include that the self-coiling intermediate length is thermoset or otherwise imposed with a shape configured to prevent tangling such as, for example, one or more of a helical construction with a slight pitch imparted to each of the coils, slightly-decreasing or increasing diameters and/or curvatures of each successive coil, and slightly differing shapes of the coils. Stated differently, a coil immediately adjacent to at least a first coil may be disposed at a slight pitch relative thereto, include a different coil diameter in at least one dimension, or any combination thereof effective to prevent—or at least minimize the risk of—tangling. As shown in FIG. 2, the moment of force of the stylet **201** is less than the moment of force of the needle **250**, such that the self-coiling length of the stylet within the needle lumen does not deflect or impose any curvature upon the needle. Specifically, those of skill in the art will appreciate that the needle **250** inherently has a moment of force resisting curvature; this is overcome to varying degrees during use (e.g., navigating the needle through an endoscope working channel), but is—in the presently preferred embodiments—greater than the “pro-curvature/self-curving” moment of force of the stylet **201**. Thus, as illustrated, the stylet **201** is disposed through a longitudinal lumen of the medical endoscopy needle **250**, and the self-coiling stylet length **204** dis-

poses the stylet to coil itself upon removal from the lumen by a person operating the needle system or assisting therewith.

**[0022]** The unique self-coiling feature presents several advantages for the present embodiments over existing stylets. For example, it helps reduce procedure time and activity level, because the nurse or other person who removes the stylet from the needle does not have to manually wind up, then hold, tangle, and/or clip the stylet to prevent it from whipping around, falling to the floor, or otherwise moving in a manner that will allow contamination and/or make it more difficult and time-consuming to reintroduce the stylet to the needle if needed. The presently disclosed configuration also reduces complexity and procedure time if the stylet needs reintroduced into the needle lumen (e.g., for the needle to be repositioned without inadvertent sample collection). In contrast with existing designs that require the handler to manually detangle, unclip, or otherwise unencumber the stylet and utilize both hands to feed the stylet back into the needle lumen, the present embodiments allow one-handed reintroduction into the needle with less time and less risk of the stylet flopping around and/or contacting surfaces that it should not.

**[0023]** FIGS. 3A-3C illustrate configurations for the proximal end terminus of a stylet according to the present embodiments. FIG. 3A shows a configuration currently in use, with a proximal end region of a stylet **301** including a polymer stylet cap **369**. The stylet cap **369** provides a broad proximal terminus for the stylet **301** that provides a handle for withdrawing the stylet **301** and prevents the proximal end of the stylet **301** from traveling into the needle lumen. This and other proximal-end structures may be used with self-coiling stylets of the present disclosure.

**[0024]** For example, as shown in FIG. 3B, a proximal stylet end structure **379** may be constructed as a loop including at least one portion that is generally perpendicular to the longitudinal axis of a stylet **301** and generally coplanar with an immediately adjacent stylet length. This proximal loop **379** may be configured as a handle. In one preferred embodiment, the loop **379** is disposed at a distance from a stylet distal end such that the generally perpendicular transition of the loop **379** to the rest of the stylet **301** will align with the proximal end of a needle (not shown) when the distal stylet end aligns desirably relative to the needle's distal end.

**[0025]** Another example, shown in FIG. 3C, is a proximal stylet end structure **389** be constructed as a loop including at least one portion that is generally perpendicular to the longitudinal axis of a stylet **301**, where the loop portion generally lies along a plane that is not coplanar with an immediately adjacent stylet length, and which plane may be perpendicular/transverse relative to the immediately adjacent stylet length. This proximal loop **389** may be configured as a handle. In one preferred embodiment, the loop handle **389** is disposed at a distance from a stylet distal end such that the generally perpendicular transition of the loop **389** to the rest of the stylet **301** will align with the proximal end of a needle (not shown) when the distal stylet end aligns desirably relative to the needle's distal end.

**[0026]** Those of skill in the art will appreciate that embodiments not expressly illustrated herein may be practiced within the scope of the claims, including that features described herein for different embodiments may be combined with each other and/or with currently-known or future-developed technologies while remaining within the scope of the claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for

purposes of limitation unless specifically defined by context, usage, or other explicit designation. It is therefore intended that the foregoing detailed description be regarded as illustrative rather than limiting. And, it should be understood that the following claims, including all equivalents, are intended to define the spirit and scope of this invention. Furthermore, the advantages described above are not necessarily the only advantages of the invention, and it is not necessarily expected that all of the described advantages will be achieved with every embodiment.

We claim:

**1.** A medical endoscopy needle system with stylet, the stylet comprising:

a medical endoscopy needle; and  
an elongate single-wire memory-metal body with a complete length that includes  
a proximal stylet length,  
an intermediate self-coiling stylet length, and  
a distal stylet length that is generally straight and non-self-coiling;

where the moment of force of the self-coiling stylet length is less than a moment of force inherent to the medical endoscopy needle that is resistant to the stylet's self-coiling force.

**2.** The system of claim **1**, where the stylet is disposed through a longitudinal lumen of the medical endoscopy needle, and the self-coiling stylet length disposes the stylet to coil itself upon removal from the lumen.

**3.** The system of claim **1**, where the stylet comprises a rounded generally atraumatic distal end tip.

**4.** The system of claim **1**, where the memory metal comprises an alloy selected from nickel-titanium, nickel-titanium-cobalt, nickel-titanium-chromium, nickel-titanium-niobium, nickel-titanium-hafnium, nickel-titanium-palladium, nickel-titanium-platinum, nickel-titanium-iron, nickel-titanium plus rare earth elements, iron-manganese-silicon, iron-platinum, iron-nickel, iron-nickel-cobalt, iron-nickel-cobalt-aluminum-tin-tantalum, and any combination thereof.

**5.** The system of claim **1**, where the self-coiling length forms one or more coils having an outer diameter of about 7 cm to about 20 cm.

**6.** The system of claim **1**, where the generally straight distal length is no more than about 10% of the complete length.

**7.** The system of claim **1**, where the self-coiling intermediate length comprises up to about 95% of the complete length.

**8.** The system of claim **1**, comprising a stylet with a complete length of about 180 cm, a generally straight distal length of about 2 cm to about 20 cm, and a generally straight proximal length of about 5 cm to about 14 cm.

**9.** The system of claim **1**, where the stylet comprises a tissue-piercing distal end tip.

**10.** The system of claim **9**, where the distal end tip is a sharp, beveled tip.

**11.** The system of claim **1**, where the proximal length includes a proximal end shaped to form a loop including at least one portion that is generally perpendicular to a longitudinal axis of the stylet.

**12.** The system of claim **11**, where the loop is configured for use as a proximal stylet handle and is disposed at a distance from a stylet distal end such that the distal stylet end aligns with a distal needle end when the loop contacts a proximal end of the needle.

**13.** The system of claim 1, where the intermediate self-coiling stylet length, when unconstrained, forms a plurality of coils as a spiral wherein each coil has substantially the same outer diameter.

**14.** The system of claim 1, where the intermediate self-coiling stylet length, when unconstrained, forms a plurality of coils as a spiral wherein each coil has a smaller outer diameter than a more proximal adjacent coil, and the coil diameters decrease likelihood of tangling or binding of the unconstrained stylet length.

**15.** The system of claim 1, where at least one coil of the intermediate self-coiling stylet length, when unconstrained, forms at least one coil shaped as a generally circular, generally elliptical, generally oval, or generally obround shape.

**16.** The system of claim 15, where a coil immediately adjacent to the at least one coil is disposed at a slight pitch relative thereto, includes a different coil diameter in at least one dimension, or any combination thereof.

**17.** A stylet comprising:

an elongate single-wire memory-metal body with a complete length that includes  
a proximal stylet length,  
an intermediate self-coiling stylet length, and

a distal stylet length that is generally straight and non-self-coiling;

where the intermediate self-coiling stylet length comprises no more than 95% of the complete length and, when unconstrained, defaults by a memory-metal-imposed moment of force to form at least one coil with an outer diameter of about 7 cm to about 20 cm.

**18.** The stylet of claim 17, where a distal end tip of the distal stylet length is configured with a sharp beveled end.

**19.** The stylet of claim 17, where at least one coil of the intermediate self-coiling stylet length, when unconstrained, forms at least one coil shaped as a generally circular, generally elliptical, generally oval, or generally obround shape.

**20.** The stylet of claim 17, where the memory metal comprises an alloy selected from nickel-titanium, nickel-titanium-cobalt, nickel-titanium-chromium, nickel-titanium-niobium, nickel-titanium-hafnium, nickel-titanium-palladium, nickel-titanium-platinum, nickel-titanium-iron, nickel-titanium plus rare earth elements, iron-manganese-silicon, iron-platinum, iron-nickel, iron-nickel-cobalt, iron-nickel-cobalt-aluminum-tin-tantalum, and any combination thereof.

\* \* \* \* \*