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(54) **Title**: CATHETERS, CATHETERS FOR USE IN ULTRASOUND GUIDED PROCEDURES, AND RELATED METHODS

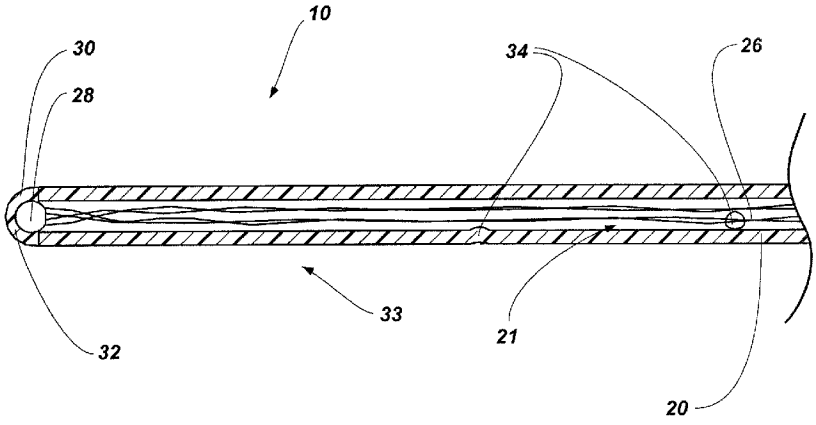

FIG. 3

(57) **Abstract**: Catheters include a catheter tube and an echogenic structure extending from a proximal portion of the catheter tube to a distal end of the catheter tube where a portion of the echogenic structure is at least partially formed in the distal end of the catheter tube. Such catheters may exhibit improved echogenicity. Methods of forming a tool for a clinical procedure performed upon a subject utilizing ultrasound guidance include forming a catheter and forming a portion of an echogenic structure within a distal end of the catheter. Methods of ultrasound guidance for a clinical procedure performed upon a subject may include such catheters.

TITLE

CATHETERS, CATHETERS FOR USE IN ULTRASOUND GUIDED PROCEDURES, AND RELATED METHODS

TECHNICAL FIELD

The disclosure relates generally to the field of medical devices and related methods. In particular, the disclosure relates to catheters for use proximate portions of the nervous system of a subject, catheters having improved echogenic properties, methods for utilizing ultrasound to guide such catheters, and methods of forming such catheters.

BACKGROUND

As described in U. S. Patent 6,019,724 to Gronningsaeter et al. (Feb. 1, 2000), the disclosure of which is hereby incorporated herein in its entirety by this reference, ultrasound can provide useful feedback to a clinician during a clinical procedure.

With the advent of ever more sophisticated ultrasound equipment (*e.g.*, a SONOSITE® NANOMAXX®, S Series, MICROMAXX®, or M-TURBO® device, details available on the internet at sonosite.com) having ever improved resolution, the ability of a clinician to optimally place and use a tool, such as a cutting or resecting device, coagulating device, stapler, biopsy forceps, needle, cannula, *etc.* increases.

For example, improper placement of a catheter for delivering anesthesia can result in 20% to 40% secondary block failure. *See, e.g.*, Tui & Bhargava, *Atlas of Ultrasound and Nerve Stimulation-Guided Regional Anesthesia*, 16.1 (2007).

Unfortunately, however, with the utilization of tools in the tightest crevices of the body nearby vital organs and tissues, comes the added risk associated with guiding and positioning the tools within the body and the added risk associated with unexpected tool failure.

DISCLOSURE OF THE INVENTION

Described are catheters that may be utilized with ultrasound guidance and exhibit improved echogenic properties, methods of utilizing such catheters, and methods of forming such catheters. Such catheters may include one or more structures therein that increase the echogenicity of the catheter (*e.g.*, for improved ultrasound guidance). In some embodiments, the catheters may be used to transport fluid (*e.g.*, a medication) to locations proximate (*e.g.*, adjacent) one or more portions of the nervous system of a subject (*e.g.*, proximate the spinal cord or peripheral nervous system of a subject). For example, the catheter may be placed adjacent to neural structures of the peripheral nervous system of a subject to form a nerve block.

In some embodiments, the present disclosure includes a catheter including a catheter tube comprising a proximal end, a distal end, and a lumen formed therebetween. An echogenic structure extends from a proximal portion of the catheter tube to a distal portion of the catheter tube, a distal end of the echogenic structure being at least partially formed in the catheter tube proximate the distal end of the catheter tube.

In some embodiments, the echogenic structure may comprise an enlarged distal end having a diameter that is greater than a cross-sectional diameter of the echogenic structure and the enlarged distal end may be at least partially formed in the catheter tube proximate the distal end of the catheter tube.

In some embodiments, the distal end of the catheter tube may comprise a solid, distal end.

In additional embodiments, the present disclosure includes a catheter having improved echogenicity including a catheter tube having an open proximal end in communication with a lumen and a distal end. An echogenic structure extends through the lumen from the proximal end to proximate the distal end of the catheter tube. The echogenic structure terminates in a weld bead at least partially embedded within a distal portion of the catheter tube proximate the distal end of the catheter tube. The echogenic structure and the weld bead may provide improved imaging by an ultrasound sensor used to guide placement of the catheter and means for removing broken portions of the catheter during use.

In yet additional embodiments, the present disclosure includes a catheter, comprising a catheter tube including a proximal end, a distal end, and a lumen

formed therebetween. The catheter tube having a plurality of apertures formed in a sidewall of the catheter tube at a distal portion of the catheter tube enabling fluid transported by the catheter to pass therethrough. The catheter further includes at least two discrete sets of wires where each set comprising a twisted pair of wires extending from a proximal portion of the catheter tube to a distal portion of the catheter tube. The at least two discrete sets of wires comprise an enlarged terminal end having a diameter that is greater than a cross-sectional diameter of at least one wire of the at least two discrete sets of wires where the enlarged terminal end is at least partially formed in the catheter tube proximate the distal end of the catheter tube. A remaining portion of each set of the at least two discrete sets of wires extends through the catheter tube separate from at least another set of the at least two discrete sets of wires.

In yet additional embodiments, the present disclosure includes a method of forming a tool for a clinical procedure performed upon a portion of a peripheral nervous system of a subject utilizing ultrasound guidance comprising forming a catheter having a lumen extending from a proximal end of the catheter to a solid distal end of the catheter, disposing an echogenic structure within the lumen of the catheter extending from a proximal portion of the catheter to a distal portion of the catheter, and forming an enlarged end of the echogenic structure within the catheter proximate solid distal end of the catheter.

Also disclosed are methods of and utilizing a catheter according to the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 depicts an embodiment of the disclosure associated with a catheter connector hub.

FIG. 2 depicts the embodiment of the preceding figure with a portion of a catheter connector hub shown in cross-section.

FIG. 3 depicts an enlarged, partial cross-sectional view of a distal portion of the catheter of the embodiment of the preceding two figures.

FIG. 4 depicts an enlarged, partial cross-sectional view of a distal portion of a catheter in accordance with another embodiment of the disclosure.

FIG. 5 depicts an enlarged, partial cross-sectional view of a distal portion of a catheter in accordance with yet another embodiment of the disclosure.

FIG. 6 depicts an enlarged, partial cross-sectional view of a distal portion of a catheter in accordance with yet another embodiment of the disclosure.

FIG. 7 depicts an enlarged, partial cross-sectional view of a distal portion of a catheter in accordance with yet another embodiment of the disclosure

FIG. 8 depicts an enlarged, partial cross-sectional view of a distal portion of a catheter in accordance with yet another embodiment of the disclosure

FIG. 9 depicts an enlarged, partial cross-sectional view of a distal portion of a catheter in accordance with yet another embodiment of the disclosure

FIG. 10 is a cross-sectional view of an embodiment of a catheter inserted within a subject.

MODE(S) FOR CARRYING OUT THE INVENTION

Illustrations presented herein are not meant to be actual views of any particular catheter or clinical procedure tool, but are merely idealized representations, which are employed to describe embodiments of the disclosure. Additionally, elements common between figures may retain the same numerical designation.

As described in U.S. Patent 5,490,845 to Racz (Feb. 13, 1996), the disclosure of which is hereby incorporated herein in its entirety by this reference, "Small diameter catheters are used to introduce medication into the spinal canal, spinal space, epidural space, blood vessels, body cavities and the like. Due to their uni-wall construction when undergoing repetitive movement while being subjected to body heat, such small diameter catheters have a tendency to migrate to other body cavities or to kink thereby preventing the flow of medication therethrough. Such problems can be particularly troublesome when a catheter is used within the spinal canal. In the event of migration of the catheter any kinking of the catheter will preclude aspiration and seeing evidence of such migration due to the closure of the lumen of the catheter and the attendant inability to withdraw blood or spinal fluid. Typical prior art catheter placement units for small diameter catheters are shown in U.S. Patent Nos. 3,856,009; 4,518,383; 4,650,472; 5,084,022; 5,106,376; 5,129,889; 5,213,578; and 5,232,442 (the disclosure of each of which is hereby incorporated

herein in its entirety by this reference). Another problem associated with the use of such small diameter catheters is their susceptibility to breaking and, possibly, leaving portions thereof remaining in a body cavity. Removal of such broken portions of the catheter may be difficult or impossible."

These problems were addressed in U.S. Patent 5,490,845 by preventing occlusion of the catheter to allow the flow of fluids therethrough and allowing the removal of broken portions thereof from the spinal canal, spinal space, epidural space, blood vessels, body cavities and the like during use. Specifically, as described by U.S. Patent 5,899,891 to Racz (May 4, 1999), the disclosure of which is hereby incorporated herein in its entirety by this reference, U.S. Patent 5,490,845 disclosed a flexible catheter which includes a catheter tube containing an intraluminal cord member (cord) extending along the tube's length and protruding out of the tube's distal and proximal ends. The thus placed cord helps to prevent collapse of the tube during fluid administration, and the portion of the cord extending out of the tube's distal end also aids in the retention and removal of parts of the tube, which might break off during use of the catheter.

The incorporated U.S. Patent 5,899,891 goes on to describe "catheters which utilize a flexible tube that has been modified at either one end or both ends. Such modifications generally involve strengthening the interior of a tube end by increasing its break strength and possibly its rigidity, but do not generally involve decreasing the tip's flexibility. In one embodiment, the tube end modifications involve special placement of an intraluminal cord contained within the tube."

The disclosure includes catheters and related methods wherein the catheter tube has been modified in such a way as to be echogenic and to enhance the ability to create an echo (*i.e.*, return a signal in an ultrasound procedure). The catheters may include one or more structures that increase the echogenicity of the catheter placed at least partially within the tube. In some embodiments, the echogenic structure placed within the catheter tube may also act to support and reinforce portions of the catheter tube in such a manner that the reinforced portion of the catheter tube remains flexible. In some embodiments, the echogenic structure of the catheter may include a cord (*e.g.*, a wire, a ribbon, or combinations thereof) running therethrough. The cord may be attached at the catheter or to additional echogenic structure such as, for example, an enlarged end (*e.g.*, a ball or spherical member).

In some embodiments, the echogenic structure may extend into the distal portion of the catheter (*e.g.*, proximate to the distal tip of the catheter). Such placement may enhance ultrasound imaging and may improve structural integrity of the catheter. In some embodiments, the echogenic structure may enable fluid (*e.g.*, a medication such as, for example, a anesthetic, a analgesic, or combinations thereof) to pass therethrough in order to fluidly couple the lumen of the catheter tube with openings formed in the catheter tube (*e.g.*, at the sidewalls or distal end thereof).

In use, the echogenic structure acts to increase the echogenicity of the catheter for better detection by ultrasound, to increase the rigidity of the catheter (while maintaining flexibility). Where the echogenic structure is implemented as at least one of a cord and ball structure, the echogenic structure may be utilized to collect a portion of the tube that has broken off in a procedure.

As shown in FIGS. 1 and 2, a catheter 10 may be used in conjunction with, for example, a catheter connector hub 24. In some embodiments, the catheter connection hub 24 may be similar to, for example, the catheter connection hubs described in U.S. Patent 8,038,667, issued October 18, 2011, the disclosure of which is hereby incorporated herein in its entirety by this reference. As shown, the catheter 10 includes a hollow cylindrical member such as a catheter tube 20. In some embodiments, the catheter tube 20 may, for example, have a length from about twenty-five (25) centimeters (9.8 inches) to about ninety (90) centimeters (about 35.4 inches) (*e.g.*, sixty-one (61) centimeters (about 24 inches)). In some embodiments, the catheter tube 20 may, for example, have a diameter of about 0.762 millimeter (about 0.03 inch).

Referring to FIG. 2, the connector hub 24 is shown in conjunction with the catheter tube 20. The proximal portion 36 of the catheter tube 20 is securable within a catheter-receiving portion 27 of the catheter hub 24 using, for example, a deformable member 35 that may selectively constrict and expand in response to relative rotation of first and second portions 27 and 29 of the catheter hub 24.

In some embodiments, the catheter 10 may include a plurality of depth indicators 23 located on the catheter tube 20. The depth indicators 23 are configured to indicate to a user the depth of insertion of a distal end 32 of the catheter 10, and are typically located a positions corresponding to depths of insertion for certain procedures (*e.g.*, depths relative to a flexible introducer cannula (FIC)).

FIG. 3 depicts an enlarged, partial cross-sectional view of the distal portion 33 of the catheter 10 shown in FIGS. 1 and 2. Referring to FIG. 3, an echogenic structure may be placed at least partially within the catheter tube 20. For example, one or more wires 26 may be placed at least partially within the catheter tube 20. The wires 26 may extend through the catheter tube 20 and terminate proximate to the distal end 32 of the catheter tube 20 (*e.g.*, in the distal portion 33). In some embodiments, the wires 26 may be one or more sets of twisted wires (*e.g.*, one or more twisted pairs) forming a cord. For example, the wires 26 may include two or more sets (*e.g.*, sets of twisted pairs). The sets of wires 26 may be configured to extend through the lumen 21 of the catheter 10 at least partially spaced from one another. For example, the sets of wires 26 may be configured to be spaced along a portion (*e.g.*, a majority) of the catheter 10. Stated in other way, the sets of wires 26 may be substantially discrete except for, for example, being connected (*e.g.*, directly or indirectly) at the distal end of the wires 26 to a common structure (*e.g.*, to the catheter tube 20 or an enlarged end as discussed below) and/or at a proximal end of the wires 26 to another common structure (*e.g.*, to a portion of the catheter 10 or to a catheter connection hub 24 (FIG. 2)). The discrete sets of wires 26 may extend separately (*e.g.*, unattached) through a middle portion of the lumen 21. In other words, one set of wires 26 may not be connected with another set of wires 26 in the lumen 21 at locations between the distal and proximal ends of the wires 26. Such spacing of the sets of wires 26 in lumen 21 may enhance the echogenicity of the catheter 10. For example, as shown in FIG. 3, the spaced sets of wires 26 may occupy relatively more portions of a cross-sectional area of the lumen 21 as compared to a single wire or a tightly wound set of wires, thereby, enhancing the ability of the lumen 21 be identified in an ultrasound procedure.

The wires 26 may extend through the lumen 21 of the catheter tube 20, and be free to move within the lumen 21 of the catheter tube 20. Referring also back to FIG. 2, in embodiments where the wires 26 are not somehow affixed to the proximal portion 36 of the catheter tube 20, the wires 26 may be secured in the catheter connector hub 24.

The wires 26 for use with catheters such as those disclosed herein may include a cable having several wound metal wires (*e.g.*, stainless steel wires). The wires 26 can also be a braided line including at least three optionally braided cables.

Such cords are strong, hypoallergenic, and flexible. In other embodiments, the wires 26 may be made of a single metal wire, other electrically conductive material, plastic (*e.g.*, nylon), other polymers, silk, or other suitable material. In some embodiments, the wires 26 have a diameter of about 0.23 millimeter (about 0.009 inch). In some embodiments, the wires 26 may be manufactured to contain anti-thrombogenic agents or other materials, so as to prevent, for example, occlusion of the catheter during longer term use. In additional embodiments, other chemical agents may be introduced such as, for example, antiseptics and anesthetics.

Referring again to FIG. 3, a distal end of the wires 20 (*e.g.,* terminal end forming the end or extremity of the at last one wire 20) may include an enlarged end 28 (*e.g.*, an end having a cross-sectional dimension, such as, for example, a diameter or thickness that is greater than a cross-sectional dimension of the wires 26). For example, the enlarged end 28 of the wires 26 may be formed as a bead (*e.g.,* a welded bead formed substantially as a ball or spherical member). In such an embodiment, a welding process (*e.g.*, a tungsten inert gas welding process) may be used to form the enlarged end 28 on the wires 26. In embodiments including a plurality of wires 26, the enlarged end 28 may act to couple the distal end of each individual wire 26. It is noted that while the embodiment of FIG. 3 shows the enlarged end 28 of the wires 26 formed as a bead, in other embodiments, the enlarged end may comprise any number of suitable structures (*e.g.,* any structure that may increase the echogenic properties of the catheter 10 or secure a distal end of the wires 26 to the catheter tub 20 such as, for example, the enlarged end 228 discussed below with reference to FIG. 5). As a further example, the enlarged end 28 may comprise any of the echogenic structures described in US Patent Application Publication US2011/0172542 A1, published July 14, 2011, the disclosure of which is hereby incorporated herein in its entirety by this reference. In such embodiments, the enlarged end 28 may comprise one or more of a spring, a structure forming an uneven surface, a braided mesh, and a folded-over cord located within the catheter tube 20.

As further shown in FIG. 3, a portion of the wires 26 may be formed within the catheter tube 20. For example, the enlarged end 28 of the wires 26 may be formed at least partially within the catheter tube 20. In such embodiments, the wires 26 may be secured to the catheter tube 20 at or proximate the distal end 32 of

the catheter 10. Such an embodiment may provide a means for removing broken portions of the catheter 10 from the subject during use. The enlarged end 28 of the wires 26 may be at least partially (*e.g.*, entirely) formed within a solid, distal end 30 of the catheter tube 20. In other embodiments, a terminal portion of the wires 26 that does not include an enlarged end may be formed within the catheter tube 20 such as, for example, as described below with reference to FIG. 4.

The enlarged end 28 of the wires 26 may be, for example, glued, heat formed or melted to the catheter tube 20 to form the enlarged end 28 of the wires 26 at least partially within the catheter tube 20. In other embodiments, the enlarged end 28 of the wires 26 may be otherwise secured within the catheter tube 20. For example, the enlarged end 28 of the wires 26 may be secured to the catheter tube 20 by forcing the enlarged end 28 of the wires 26 into the lumen 21 of the catheter tube 20. The enlarged end 28 of the wires 26 may be sized to be larger than the lumen 21 and the catheter tube 20 may be deformed (*e.g.*, plastically deformed, elastically deformed, or combinations thereof) as the enlarged end 28 of the wires 26 is forced within the relatively smaller lumen 21.

In some embodiments, the enlarged end 28 of the wires 26 may be formed in or otherwise secured to the sidewall of the catheter tube 20 enabling fluid to pass by the enlarged end 28 and out of the distal end 32 of the catheter tube 20 (*e.g.*, as described below with reference to FIG. 5).

A plurality of apertures or openings 34 (*e.g.*, openings about 0.4 millimeter ("mm") (or about 0.015 inch) in diameter) may be formed in the sidewall of the catheter 10 at the distal portion 33 thereof so as to enable the fluid transported by the catheter 10 to pass therethrough. In embodiments where the enlarged end 28 blocks the lumen 21 at the distal end 32 of the catheter tube 20 or where, as in FIG. 3, the distal end of the catheter tube 20 is formed as a solid end 30, the plurality of openings 34 in the distal portion 33 may enable fluid to pass from the lumen 21 of the catheter tube 20 to the openings 34 formed in the sidewall of the catheter tube 20 and from the openings 34 to the lumen 21 (*e.g.*, to delivering fluids to and/or sampling fluids from a subject's body cavity or tissue). It is noted that while the embodiment of FIG. 3 shows the catheter tube 20 as having a solid end 30, in other embodiments, the catheter may include one or more openings at the distal end thereof (*see, e.g.*, FIG. 5). For example, openings similar to the openings 34 in the

sidewall of the catheter may be formed at the distal end of the catheter (*e.g.*, one or more openings extending around the portion of the wires formed within the distal portion of the catheter).

In some embodiments, the wires 26 at the proximal portion 36 of the catheter tube 20 may be associated with (*e.g.*, by adhesion, welding, molding or the like) a coiled member such as, for example, a spring contained within the proximal portion 36 of the catheter tube 20. In other embodiments, the wires 26 may be free-floating (*e.g.*, not attached to the catheter tube 20) at the proximal portion 36 of the catheter tube 20. In some embodiments, the wires 26 may be cut to be substantially flush (or slightly recessed) with respect to the proximal end of the catheter tube 20. In such an embodiment, the wires 26 may be coupled to an additional structure such as, for example, the connector hub 24 (FIG. 2).

FIG. 4 depicts an enlarged, partial cross-sectional view of a distal portion of a catheter 100 in accordance with another embodiment of the disclosure. Catheter 100 may be somewhat similar to catheter 10 discussed above with reference to FIGS. 1 through 3. As shown in FIG. 4, a portion of one or more wires 126 may be formed within a catheter tube 120 of catheter 100. For example, a terminal portion of the wires 126 that does not include an enlarged end may be formed within the solid, distal end 130 of the catheter tube 120. In some embodiments, the portion of the wires 126 proximate the distal end 132 of the catheter 100 may be secured or formed together.

FIG. 5 depicts an enlarged, partial cross-sectional view of a distal portion of a catheter 200 in accordance with yet another embodiment of the disclosure. Catheter 200 may be somewhat similar to catheters 10, 100 discussed above with reference to FIGS. 1 through 4 and, in some embodiments, may include one or more of various components thereof. As shown in FIG. 5, one or more wires 226 may be positioned within a catheter tube 220 of catheter 200 to enable fluid to pass by an enlarged end 228 of the wires 26 and out of a distal end 232 of the catheter tube 220. For example, the enlarged end 228 of the wires 226 may be formed in or otherwise secured to the sidewall of the catheter tube 20 enabling fluid to pass by the enlarged end 228 and out of the distal end 232 of the catheter tube 220. In some embodiments, and as shown in FIG. 5, the enlarged end 228 of the wires 226 may be formed to enable fluid to pass thereby. For example, the enlarged end 228 may be

formed as a cylindrical member (*e.g.*, a hollow cylindrical member such as a sleeve) or a portion of a cylindrical member that is secured to the wires 226 and the catheter tube 220 while still enabling fluid to pass through the lumen 221 to the distal end 232 of the catheter tube 220 (*i.e.*, the enlarged end 228 does not block the distal end 232 of the catheter tube 220). Such an enlarged end 228 may be formed from a similar material as the wires 226 or a dissimilar material. In other embodiments, one or more openings (*e.g.*, similar to openings 34 in the sidewall of the catheter 10 as shown in FIG. 3) may be formed through the catheter tube 220 at the distal end 232 of the catheter 200 enabling fluid to travel around the enlarged end 228 of the wires 226.

FIG. 6 depicts an enlarged, partial cross-sectional view of a distal portion of a catheter 300 in accordance with yet another embodiment of the disclosure. Catheter 300 may be somewhat similar to catheters 10, 100, 200 discussed above with reference to FIGS. 1 through 5 and, in some embodiments, may include one or more of various components thereof. As shown in FIG. 6, an echogenic structure of the catheter 300 may be as a ribbon (*e.g.*, a flat ribbon having a lateral width that is greater than a thickness of the ribbon or, in other words, a rectangular lateral cross section). For example, the ribbon may be formed as a flat, dimpled ribbon 326 having one or more deformities formed therein. In other words, the dimpled ribbon 326 has been deformed along its axis (*e.g.*, by forming circular dimples therein) such that is does not extend linearly along the length of the dimpled ribbon 326 (*e.g.*, extends in more than one direction or dimension). In some embodiments, the dimpled ribbon 326 may be formed from the same materials as the wires as discussed herein. The dimpled ribbon 326 may include an enlarged end 328 (*e.g.*, an end having a cross-sectional dimension that is greater than a cross-sectional dimension of the dimpled ribbon 326). Disposed in (*e.g.*, secured to) the catheter tube 20 that may be similar to the enlarged ends 28, 228 discussed above. As above, one or more of the dimpled ribbon 326 and its enlarged end 328 may enhance the ability of the catheter 300 to create an echo (*i.e.*, return a signal in an ultrasound procedure).

FIG. 7 depicts an enlarged, partial cross-sectional view of a distal portion of a catheter 400 in accordance with yet another embodiment of the disclosure. Catheter 400 may be somewhat similar to catheters 10, 100, 200, 300 discussed

above with reference to FIGS. 1 through 6 and, in some embodiments, may include one or more of various components thereof. As shown in FIG. 7, an echogenic structure of the catheter 300 may be as a ribbon (*e.g.*, a crimped ribbon 426). In other words, the ribbon 426 has been crimped along its length such that is does not extend linearly along the length of the ribbon 426 (*e.g.*, extends in more than one direction or dimension). In some embodiments, the crimped ribbon 426 may be formed from the same materials as the wires as discussed herein. The crimped ribbon 426 may include an enlarged end 428 (*e.g.*, an end having a cross-sectional dimension that is greater than a cross-sectional dimension of the ribbon 426) disposed in (*e.g.*, secured to) the catheter tube 20 that may be similar to the enlarged ends 28, 228 discussed above. As above, one or more of the crimped ribbon 426 and its enlarged end 428 may enhance the ability of the catheter 400 to create an echo (*i.e.*, return a signal in an ultrasound procedure).

FIG. 8 depicts an enlarged, partial cross-sectional view of a distal portion of a catheter 500 in accordance with yet another embodiment of the disclosure. Catheter 500 may be somewhat similar to catheters 10, 100, 200, 300, 400 discussed above with reference to FIGS. 1 through 7 and, in some embodiments, may include one or more of various components thereof. As shown in FIG. 8, an echogenic structure of the catheter 500 may be as a ribbon (*e.g.*, a twisted ribbon 526). In other words, the ribbon 526 has been twisted about its axis such that is does not extend linearly along the length of the ribbon 526 (*e.g.*, extends in more than one direction or dimension). In some embodiments, the twisted ribbon 526 may be formed from the same materials as the wires as discussed herein. The twisted ribbon 526 may include an enlarged end 528 (*e.g.*, an end having a cross-sectional dimension that is greater than a cross-sectional dimension of the ribbon 526) disposed in (*e.g.*, secured to) the catheter tube 20 that may be similar to the enlarged ends 28, 228 discussed above. As above, one or more of the twisted ribbon 526 and its enlarged end 528 may enhance the ability of the catheter 500 to create an echo (*i.e.*, return a signal in an ultrasound procedure).

FIG. 9 depicts an enlarged, partial cross-sectional view of a distal portion of a catheter 600 in accordance with yet another embodiment of the disclosure. Catheter 600 may be somewhat similar to catheters 10, 100, 200, 300, 400, 500 discussed above with reference to FIGS. 1 through 8 and, in some embodiments,

may include one or more of various components thereof. As shown in FIG. 9, an echogenic structure of the catheter 600 may be as one or more wires having one or more deformed portions (*e.g.*, a pressed wire 626). In other words, portions of the pressed wire 626 have been plastically deformed such that portions of the pressed wire 626 are not linear (*e.g.*, extend in more than one direction or dimension). In some embodiments, the pressed wire 626 may be formed from the same materials as the wires as discussed herein. The pressed wire 626 may include an enlarged end 628 (*e.g.*, an end having a cross-sectional dimension that is greater than a cross-sectional dimension of the wire 626) disposed in (*e.g.*, secured to) the catheter tube 20 that may be similar to the enlarged ends 28, 228 discussed above. As above, one or more of the pressed wire 626 and its enlarged end 628 may enhance the ability of the catheter 600 to create an echo (*i.e.*, return a signal in an ultrasound procedure).

In some embodiments, the above-described catheters may be utilized with a clinical procedural tool such as a flexible spinal needle assembly. Such flexible spinal needle assemblies are disclosed in, for example, United States Patent Application Publication US 2008/0065017 A1, which application was filed October 31, 2007 and entitled "Method of Using Flexible Spinal Needle Assemblies," the disclosure of which is hereby incorporated herein in its entirety by this reference. For example, as described in the incorporated US 2008/0065017 A1, a flexible spinal needle assembly may include a catheter such as a flexible needle. The flexible needle may include an echogenic structure such as those described herein within the flexible needle. In some embodiments, the flexible need may include a cord (similar to the cords 26, 126 described herein) comprised of braided wires (*e.g.*, 16 count 0.0254 millimeter (0.001 inch) braided wires) forming an echogenic structure at a distal portion of the flexible needle.

In use, embodiments of the present disclosure may increase echogenicity of the catheter for improved imaging by an ultrasound sensor used to guide placement of the catheter with the wires, the enlarged end of the wires, or the combination of the wires and the enlarged end of the wires. For example, referring to FIG. 10, a catheter tube 20 is shown in use in proximate neural structures 64 of the nervous system (*e.g.*, a neural structure of the peripheral nervous systems) of a subject (*e.g.*, a mammal, such as a human). The catheter 10 may be placed within a subject

through skin 56 and other outer layers 62 (*e.g.,* muscle, fat, *etc.*) using, for example, an introducer needle (*e.g.,* a flexible introducer cannula (FIC)), a flexible needle as discussed above, or any other suitable types of needles. Under ultrasound guidance (sensor not shown), the catheter tube 20 may be advanced into the subject to be positioned proximate (*e.g.,* adjacent) one or more neural structures 64. The proximal portion of the catheter tube 20 is maintained outside the subject's body and may be coupled to any desired tubing, syringe, etc. If any portion of the catheter tube 20 in the subject is broken, it may be retrieved by pulling on the wires 26. In addition, if the catheter tube 20 should become kinked, the wires 26 may allow the flow of fluids through the catheter.

As also can been seen in FIG. 10, an echogenic structure (*e.g.,* the wires 26, 126, 226, 626, the ribbons 326, 426, 526, the enlarged ends 28, 228, 328, 428, 528, 628, or combinations thereof as described above with references to FIGS. 3 and 5 through 10) located in the catheter tube 20 may enhance the ability of portions of the catheter tube 20 (*e.g.,* the distal portion) to create an echo (*i.e.*, to be echogenic and return a signal in an ultrasound procedure). By increasing the ability of the catheter tube 20 to create an echo, the distal portion of the catheter tube 20 may be relatively more easily identified and located during a procedure utilizing ultrasonic guidance to place a catheter within a subject.

Methods of forming catheters having improved echogenicity may include the exemplarily methods and materials such as those discussed above and the following. For example, the catheter tube may be formed from a flexible pre-tapered, pre-holed TECOTHANE® 55D polyurethane tubing (*e.g.,* 0.9 mm (0.035 inch) outer diameter, 0.6 mm (0.025 inch) inner diameter), nylon (*e.g.,* PEBAX® 55D), a polyimide (*e.g.,* a polyimide having a durometer of 72D), *etc.* In other embodiments, it can be made of a synthetic absorbable polymer in a manner similar to that disclosed in U.S. Patent 5,129,889 to Hahn et al. (July 14, 1992), the disclosure of which is hereby incorporated herein in its entirety by this reference. The cord may be, for example, twisted 0.009 inch 304 stainless steel or 0.25 mm (0.010 inch) diameter nylon. The enlarged portion may have a diameter of about 0.86 mm (0.035 inches).

CLAIMS

What is claimed is:

1. A catheter for use with a portion of a nervous system of a subject, comprising:

a catheter tube comprising a proximal end, a distal end, and a lumen formed therebetween; and

a structure disposed within the lumen of the catheter tube and extending from a proximal portion of the catheter tube to a distal portion of the catheter tube, the structure comprising an enlarged distal end having a cross-sectional dimension that is greater than a cross-sectional dimension of the structure, the enlarged distal end being at least partially formed in the catheter tube proximate the distal end of the catheter tube.

2. The catheter of claim 1, wherein the enlarged distal end of the structure comprises a bead formed on the distal end of the structure.

3. The catheter of claim 1 or claim 2, wherein the distal end of the catheter tube comprises a solid, distal end, and wherein the catheter tube comprises a plurality of apertures formed in a sidewall of the catheter tube at the distal portion of the catheter tube enabling fluid transported by the catheter to pass therethrough.

4. The catheter of claim 3, wherein a majority of the bead formed on the distal end of the structure is embedded in the solid distal end of the catheter tube.

5. The catheter of claim 1, wherein at least a portion of the structure increases echogenicity of a portion of the catheter for improved imaging by an ultrasound sensor used to guide placement of the catheter.

6. The catheter of claim 1, wherein the structure comprises at least one of a wire and a ribbon.

7. The catheter of claim 6, wherein the at least one wire comprises at least two substantially discrete sets of wires.

8. The catheter of claim 7, wherein a distal end of the at least two sets of wires comprises a weld bead, wherein each wire of the at least two sets of wires terminates at the weld bead, and wherein a remaining portion of each set of the at least two set of wires extends separately through the catheter tube.

9. The catheter of claim 1, wherein the structure comprises at least one of at least one deformed wire that extends along the length of the deformed wire in at least two dimensions and a deformed ribbon that extends along the length of the deformed ribbon in at least two dimensions.

10. The catheter of claim 9, wherein the deformed ribbon comprises at least one of a dimpled ribbon, a crimped ribbon, and a twisted ribbon.

11. A catheter having improved echogenicity for use with a portion of a nervous system of a subject, the catheter comprising:

a catheter tube having an open proximal end in communication with a lumen and a distal end; and

an echogenic structure extending through the lumen from the proximal end to proximate the distal end of the catheter tube, the echogenic structure terminating in a weld bead at least partially embedded within a distal portion of the catheter tube proximate the distal end of the catheter tube, wherein the echogenic structure and the weld bead provide improved imaging by an ultrasound sensor used to guide placement of the catheter and means for removing broken portions of the catheter during use.

12. The catheter of claim 11, wherein the distal end of the catheter tube comprises an enclosed distal end defining a terminal end of the lumen.

13. The catheter of claim 11, wherein the distal end of the catheter tube comprises an opening.

14. A catheter configured for at least one of delivering fluid to and sampling fluid from a portion of a nervous system of a subject, the catheter comprising:

a catheter tube comprising a proximal end, a distal end, and a lumen formed therebetween, the catheter tube having a plurality of apertures formed in a sidewall of the catheter tube at a distal portion of the catheter tube enabling fluid transported by the catheter to pass therethrough; and

at least two discrete sets of wires disposed within the lumen of the catheter tube, each set comprising a twisted pair of wires extending from a proximal portion of the catheter tube to a distal portion of the catheter tube, wherein the at least two discrete sets of wires comprise an enlarged terminal end having a diameter that is greater than a cross-sectional diameter of at least one wire of the at least two discrete sets of wires, the enlarged terminal end being at least partially formed in the catheter tube proximate the distal end of the catheter tube, and wherein a remaining portion of each set of the at least two discrete sets of wires extends through the catheter tube separate from at least another set of the at least two discrete sets of wires.

15. A method of forming a tool for a clinical procedure performed upon a portion of a peripheral nervous system of a subject utilizing ultrasound guidance, comprising:

forming a catheter having a lumen extending from a proximal end of the catheter to a solid distal end of the catheter;

disposing an echogenic structure within the lumen of the catheter extending from a proximal portion of the catheter to a distal portion of the catheter; and

forming an enlarged end of the echogenic structure within the catheter proximate the solid distal end of the catheter.

16. The method according to claim 15, further comprising forming the echogenic structure from at least one of at least one deformed wire that extends along the length of thereof deformed wire in at least two dimensions and a deformed ribbon that extends along the length of the deformed ribbon in at least two dimensions.

17. The method according to claim 15, further comprising forming the echogenic structure from at least two twisted pairs of wires.

18. The method according to claim 17, further comprising terminating each wire of the at least two twisted pairs of wires with the enlarged end.

19. The method according to any one of claims 15 through 18, further comprising forming the echogenic structure within the lumen of the catheter to provide a means for removing broken portions of the catheter from the subject during use.

20. The method according to any one of claims 15 through 18, further comprising increasing echogenicity of the catheter for improved imaging by an ultrasound sensor used to guide placement of the catheter with the echogenic structure and the enlarged end.

21. A method of ultrasound guidance for a clinical procedure performed upon a portion of a peripheral nervous system of a subject using the catheter according to any one of claims 1 or 14, the method comprising:

inserting the catheter into the subject; and

guiding placement of the catheter within the subject utilizing an ultrasound sensor and the echogenicity of at least a portion of the structure within the lumen of the catheter.

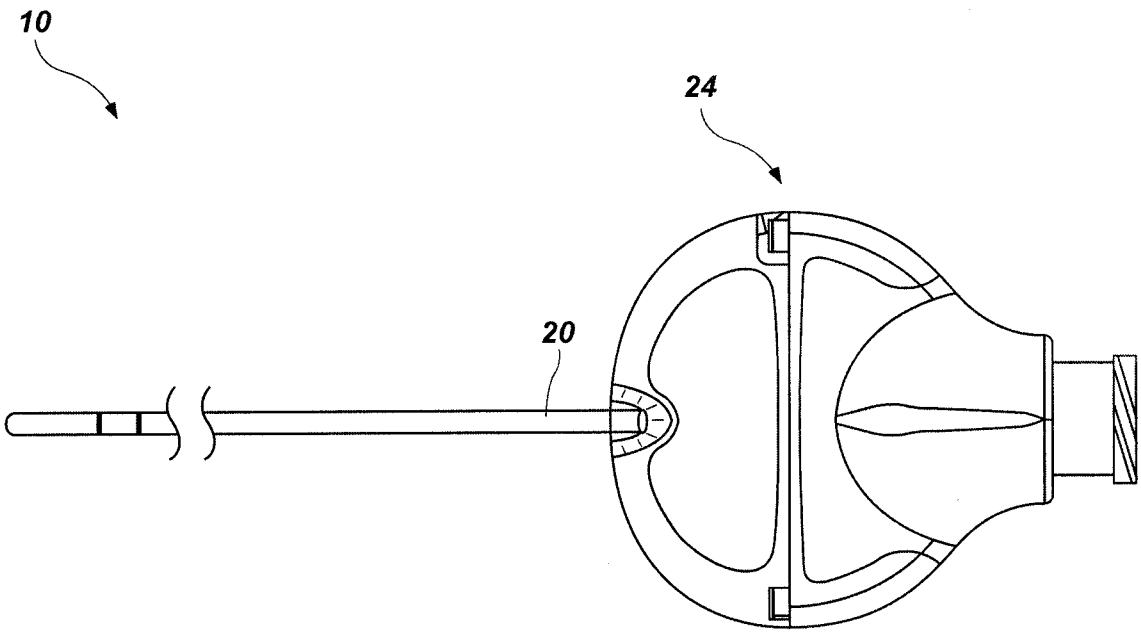

FIG. 1

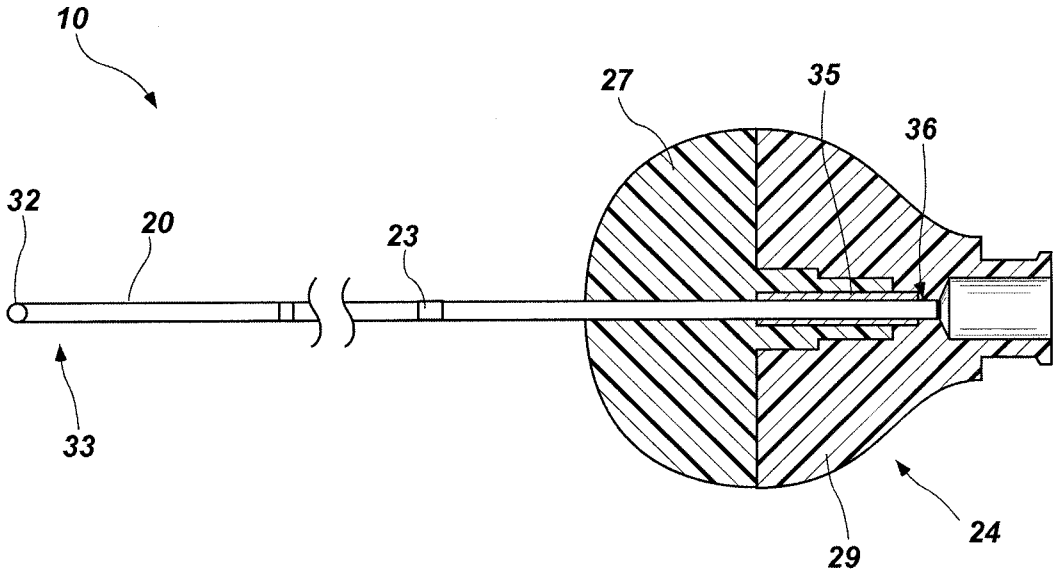

FIG. 2

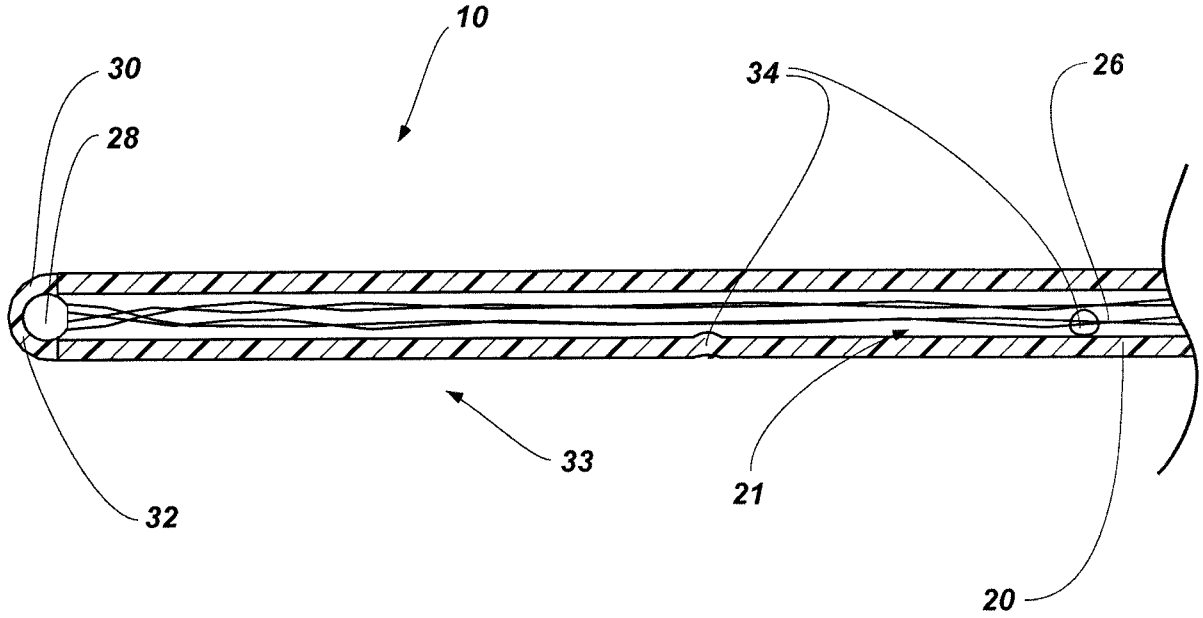

FIG. 3

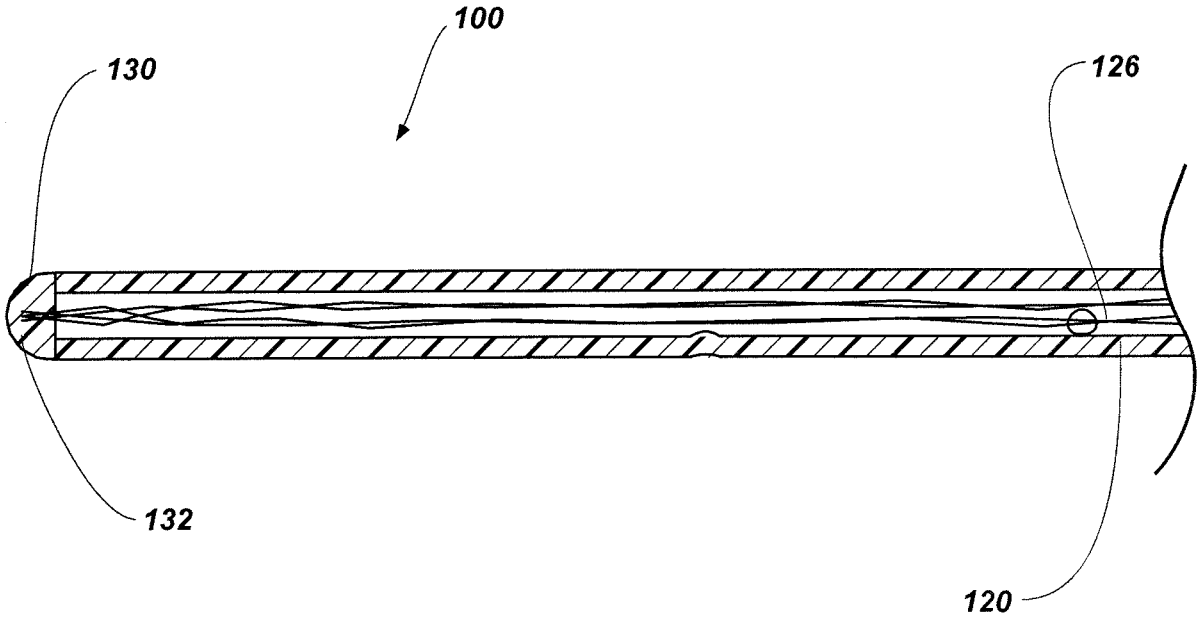

FIG. 4

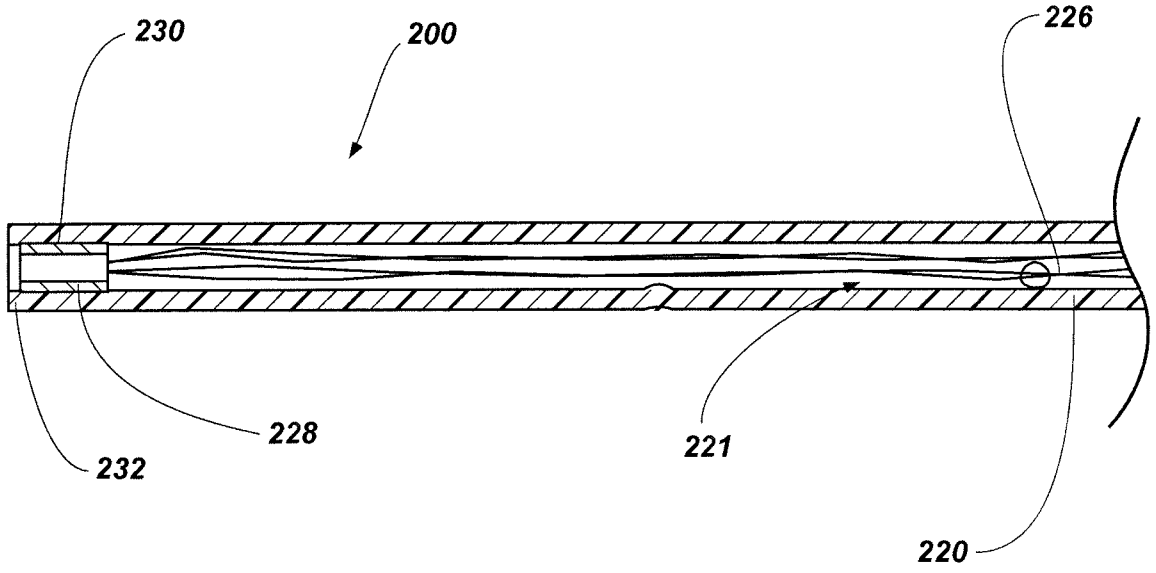

FIG. 5

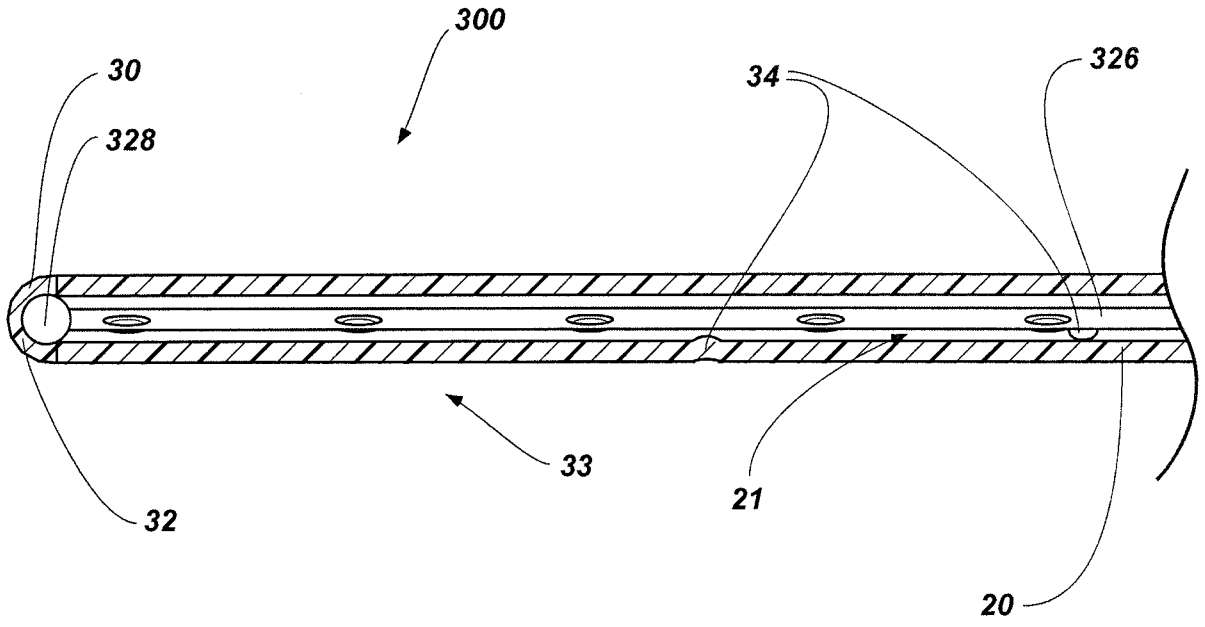

FIG. 6

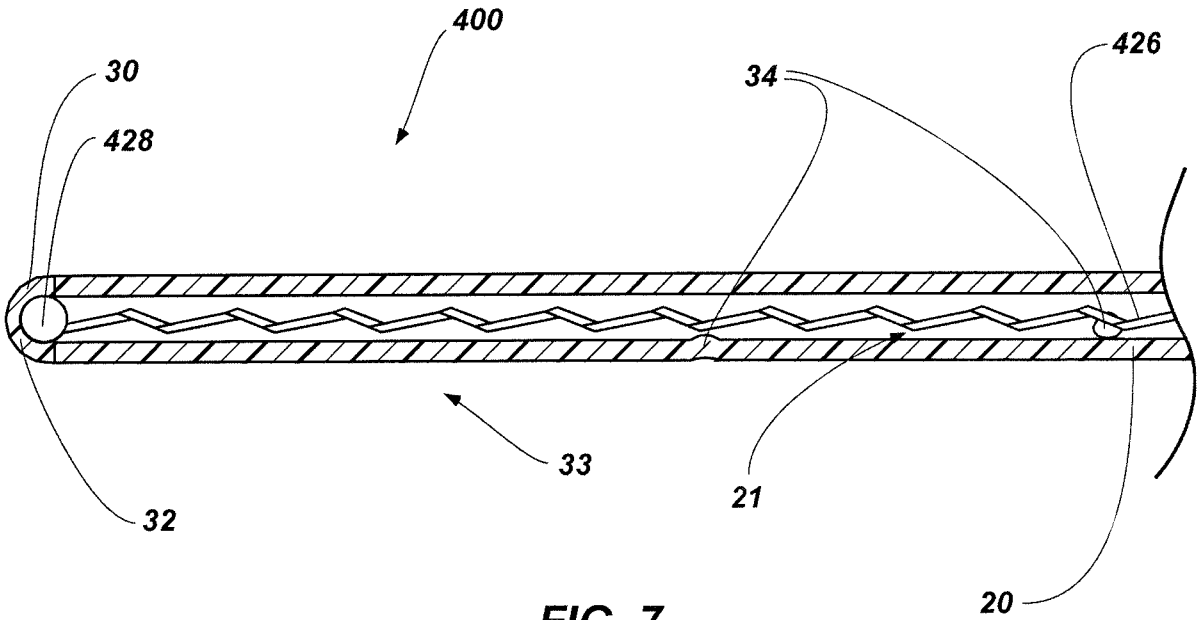

FIG. 7

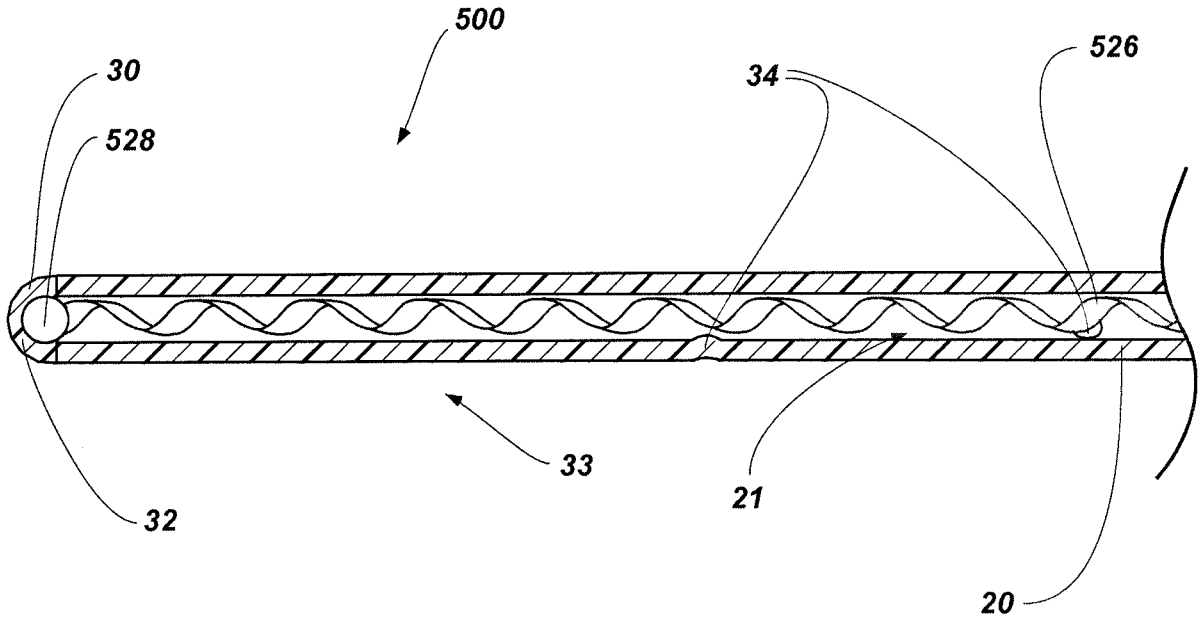

FIG. 8

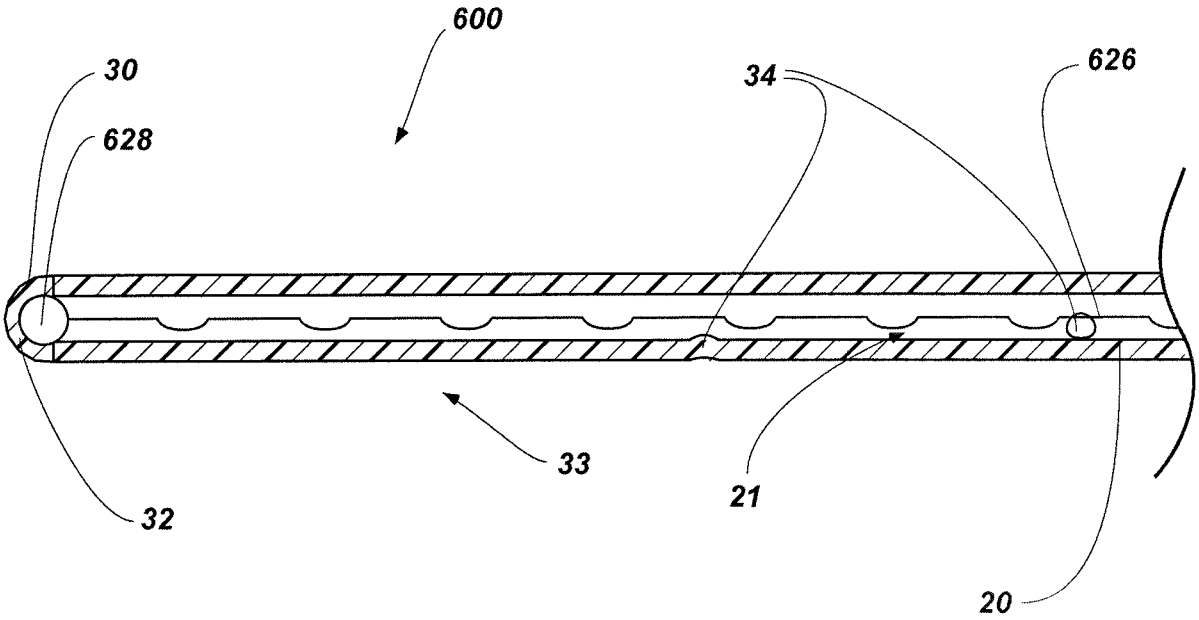

FIG. 9

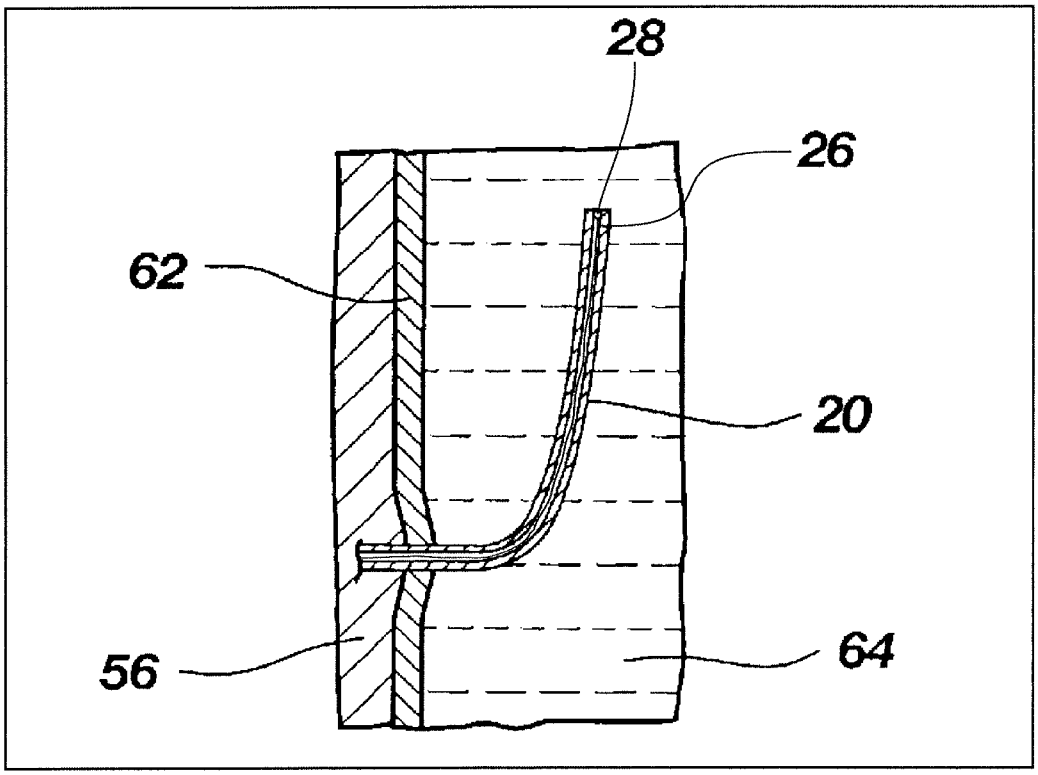

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/025489

A. CLASSIFICATION OF SUBJECT MATTER

A61M 25/088(2006.01)i, A61M 25/09(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M 25/088; A61N 1/30; A61M 5/32; A61M 5/00; B23P 11/00; A61M 25/00; A61B 8/14

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & Keywords: catheter, echogenicity, cord, ultrasound

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011-0172542 A1 (N. SANDOR RACZ) 14 July 2011. See claims 1,2,6,7,9,11; paragraphs [0035],[0038],[0040],[0041],[0057],	1-6,11,12,15,19,20
A	[0062],[0067]; and figs. 2,3.	7-10,13,14,16-18
A	US 2004-0106891 A1 (JAMES J. LANGAN et al.) 03 June 2004. See paragraphs [0039],[0041],[0042],[0047]; and fig. 3.	1-20
A	US 05490845 A (GABOR J. RACZ) 13 February 1996. See claim 1; column 1,lines 41-48; column 2,lines 26-29, lines 59-62; and fig. 2.	1-20
A	US 05899891 A (N. SANDOR RACZ) 04 May 1999. See claim 1; column 2,lines 31-34; and fig. 2.	1-20

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 JANUARY 2013 (31.01.2013)	**31 JANUARY 2013 (31.01.2013)**

Name and mailing address of the ISA/KR

Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea

Facsimile No. 82-42-472-7140

Authorized officer

CHANG, BONG HO

Telephone No. 82-42-481-3353

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/025489

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 21
because they relate to subject matter not required to be searched by this Authority, namely:
Claim 21 pertains to methods for treatment of the human body by surgery, and thus relates to a subject matter which the International Searching Authority is not required to search, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT.

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2012/025489

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011-0172542 A1	14.07.2011	CA 2726418 A1	12.07.2011
		EP 2343098 A1	13.07.2011
		JP 2011-143245 A	28.07.2011
		KR 10-2011-0083528 A	20.07.2011
US 2004-0106891 A1	03.06.2004	AU 2003-262988 A1	19.03.2004
		WO 2004-020024 A1	11.03.2004
US 05490845 A	13.02.1996	EP 0783336 A1	21.05.2003
		JP 11-508455 A	27.07.1999
		WO 96-09084 A1	28.03.1996
US 05899891 A	04.05.1999	None	

专利名称(译)	导管，用于超声引导程序的导管和相关方法		
公开(公告)号	EP2814554A4	公开(公告)日	2016-03-16
申请号	EP2012868397	申请日	2012-02-16
[标]申请(专利权)人(译)	定制医学应用有限公司		
申请(专利权)人(译)	定制医疗应用，INC.		
当前申请(专利权)人(译)	定制医疗应用		
[标]发明人	RACZ N SANDOR		
发明人	RACZ, N. SANDOR		
IPC分类号	A61M25/088 A61M25/09 A61B8/08 A61B10/00 A61B34/20 A61M25/00 A61M25/01		
CPC分类号	A61B8/0841 A61B10/0045 A61B2010/0077 A61B2090/3925 A61M25/0009 A61M25/007 A61M25/0108 Y10T29/49194		
代理机构(译)	严实，CORNELIS MARINUS		
优先权	PCT/US2012/025489 2012-02-16 WO		
其他公开文献	EP2814554A1		
外部链接	Espacenet		

摘要(译)

导管包括导管管和回声结构，回声结构从导管管的近端部分延伸到导管管的远端，其中回声结构的一部分至少部分地形成在导管管的远端中。这种导管可以表现出改善的回声性。形成用于利用超声引导对受试者进行的临床手术的工具的方法包括形成导管并在导管的远端内形成回声结构的一部分。对受试者进行的临床手术的超声引导方法可包括这种导管。