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(54) Title: CATHETER DEVICES AND METHODS FOR MAKING THEM

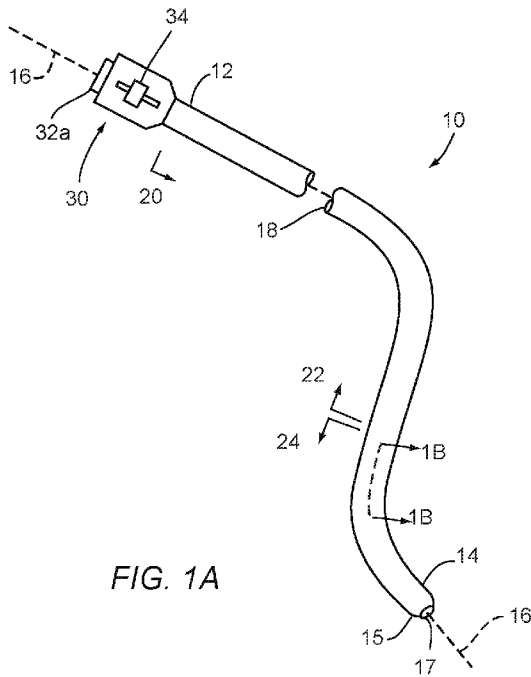


FIG. 1A

(57) Abstract: Catheters, sheaths, or other tubular devices are provided that include a proximal end, a distal end sized for introduction into a patient's body, and a steerable distal portion. The tubular device includes a primary lumen extending between the proximal and distal ends; an auxiliary lumen adjacent the primary lumen; and one or more reinforcement members including windings extending helically along at least the distal portion, at least some of the windings passing between the primary and steering element lumens and at least some of the windings surrounding both the primary and steering element lumens. In one embodiment, a steering element is slidably disposed within the auxiliary lumen. Apparatus and methods for making such tubular devices are also provided.



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CATHETER DEVICES AND METHODS FOR MAKING THEM

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RELATED APPLICATION DATA

[0001] This application claims benefit of co-pending provisional applications Serial Nos. 62/044,327, filed September 1, 2014, and 62/053,188, filed September 21, 2014, the entire disclosures of which are expressly incorporated by reference herein.

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FIELD OF THE INVENTION

[0002] The present invention relates generally to reinforced catheters, sheaths, or other tubular devices including multiple lumens, and, more particularly, to catheters, sheaths, or other tubular devices including braided or other reinforcement configurations and one or more lumens that change position relative to the reinforcement members and/or a central lumen along the length of the tubular devices, and to methods for making such tubular devices.

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BACKGROUND

[0003] Elongate tubular devices, such as diagnostic or treatment catheters or sheaths may be provided for introduction into a patient's body, e.g., the patient's vasculature or other body lumens. For example, a catheter may have a distal portion configured to be introduced into a body lumen and advanced to one or more desired locations within the patient's body by manipulating a proximal end of the catheter.

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[0004] To facilitate introduction of such a catheter, one or more wires, cables, or other steering elements may be provided within the catheter, e.g., that are coupled to the distal portion and may be pulled or advanced from the proximal end to deflect the distal portion. For example, a steering element may be provided that is intended to deflect the distal portion within a predetermined plane and/or into a desired curved shape.

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[0005] Pull wires are a common way to impart deflection ability to such a catheter. However, there are a number of drawbacks associated with such pull wires. For example, a pull wire occupies a significant amount of space within the catheter body. In addition, a pull wire frequently needs to be reinforced, e.g., on the inside and outside of the braid or other reinforcement of the catheter, e.g., to prevent "pull through" or loosening

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when the pull wire is actuated by pushing or pulling, i.e., the resulting bending moment may cause the pull wire to separate layers of or tear at least partially through the wall of catheter, potentially splitting the catheter and/or decreasing the mechanical actuation ability of the pull wire. Further, a pull wire can make the torque properties of the catheter non-

5 homogenous, making it difficult or impossible to torque the catheter when the pull wire is actuated, e.g., within a tortuous pathway. Further, auxiliary lumens, in particular those located in the wall of a large bore sheath, are difficult to manufacture with consistency due to difficulties with alignment, hand assembly, and the like.

[0006] Accordingly, there is a need for improved catheters, sheaths, and other

10 tubular devices and methods of their manufacture.

SUMMARY

[0007] The present invention is directed to reinforced catheters, sheaths, or other tubular devices including multiple lumens. More particularly, the present invention is

15 directed to catheters, sheaths, or other tubular devices, e.g., steerable tubular devices, including braided or other reinforcement configurations and one or more lumens that change position relative to the reinforcement members and/or a central lumen along the length of the tubular devices, and/or to methods for making such catheters, sheaths, or other tubular devices.

[0008] In accordance with one embodiment, a tubular device is provided, e.g., for a catheter or sheath, comprising a proximal end and a distal end sized for introduction into a patient's body. The tubular device may include a central lumen extending between the proximal and distal ends; an auxiliary lumen extending between the proximal and distal ends adjacent the central lumen; and one or more reinforcement members including

25 windings extending around the central lumen between the proximal and distal ends. In addition, one or more layers may surround the one or more reinforcement members and/or the lumens. At one or more locations along the length of the tubular device, the auxiliary lumen may change position relative to the reinforcement members, e.g., may be at least partially braided, woven, or directed into the reinforcement members, between the

30 reinforcement members and the central lumen, and outside the reinforcement members along different portions of the tubular device.

[0009] In accordance with yet another embodiment, a method is provided for making a tubular body that includes directing a primary mandrel along a central axis of a

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braiding apparatus such that the primary mandrel is surrounded by a plurality of horn gears and/or bobbin carriers or other reinforcement carrying elements; and directing a secondary mandrel adjacent to the primary mandrel and offset from the central axis. One or more reinforcement members from the reinforcement carrying elements may be wrapped around the primary mandrel, and an outer jacket may be applied around the primary and secondary mandrels after wrapping the one or more reinforcement members.

[0010] Along a first portion of the primary mandrel, the reinforcement members may be directed such that some windings of the reinforcement members surround the primary mandrel and pass between the primary mandrel and the secondary mandrel, and some windings of the reinforcement members surround both the primary and secondary mandrels. Along a second portion of the primary mandrel, all of the windings of the reinforcement members may surround both the primary mandrel and the secondary mandrel. Optionally, along a third portion of the primary mandrel, the reinforcement members may be wrapped around the primary mandrel such that the secondary mandrel is outside the reinforcement members.

[0011] Alternatively, along a first portion of the primary mandrel, all of the windings of the reinforcement members may surround both the primary mandrel and the secondary mandrel, and along a second portion, the reinforcement members may be directed such that some windings of the reinforcement members surround the primary mandrel and pass between the primary mandrel and the secondary mandrel, and some windings of the reinforcement members surround both the primary and secondary mandrels. Optionally, along a third portion of the primary mandrel, the reinforcement members may be wrapped around the primary mandrel such that the secondary mandrel is outside the reinforcement members.

[0012] In another alternative, along a first portion of the primary mandrel, the reinforcement members may be wrapped around the primary mandrel such that the secondary mandrel is outside the reinforcement members, and along a second portion of the primary mandrel, all of the windings of the reinforcement members may surround both the primary mandrel and the secondary mandrel or the reinforcement members may be wrapped around the primary mandrel such that the secondary mandrel is outside the reinforcement members

[0013] The primary mandrel may be removed to define a primary lumen within the tubular body. In addition, the method may also include removing the secondary

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mandrel to define an auxiliary lumen within the tubular body adjacent the primary lumen. As a result, the position of the auxiliary lumen, e.g., radially and/or circumferentially relative to the primary lumen, may change along the length of the tubular body, e.g., between the first, second, and/or optionally third portions.

5 **[0014]** In accordance with another embodiment, a method is provided for making a tubular body that includes directing a primary mandrel along a central axis of a braiding apparatus such that the primary mandrel is surrounded by a plurality of reinforcement carrying elements; providing a plurality of reinforcement carrying elements in a predetermined configuration relative to the central axis; providing a source of a
10 secondary mandrel at a first location adjacent to the primary mandrel and offset from the central axis; with the secondary mandrel feeding from the source at the first location, wrapping reinforcement members from the reinforcement carrying elements helically around a first portion of the primary mandrel such that some windings of the one or more reinforcement members surround the primary mandrel and pass between the primary
15 mandrel and the secondary mandrel and some windings of the one or more reinforcement members surround both the primary and secondary mandrels; moving the source of secondary mandrel to a second location; with the secondary mandrel feeding from the source at the second location, wrapping reinforcement members from the reinforcement carrying elements helically around a second portion of the primary mandrel such that either
20 a) all of the reinforcement members also surround the secondary mandrel; or b) the second secondary mandrel remains outside the reinforcement members. An outer jacket may be applied around the primary and secondary mandrels after wrapping the one or more reinforcement members therearound; and the primary mandrel may be removed to define a primary lumen within the tubular body.

25 **[0015]** In accordance with still another embodiment, a method is provided for making a tubular body using a braiding apparatus comprising a primary mandrel source configured to direct a primary mandrel along a central axis, a plurality of horn gears rotatably mounted around the central axis in a predetermined arrangement such that the horn gears rotate about respective horn gear axes and carriers travel along a generally circular
30 path around the central axis during operation of the braiding apparatus, and a secondary mandrel source configured to direct a secondary mandrel towards the primary mandrel from one of a plurality of locations comprising a first location disposed adjacent the central axis within the generally circular path, a second location aligned with a horn axis of one of the

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horn gears, and a third location outside the generally circular path. The method may include braiding a first portion of the primary mandrel by: a) directing the primary mandrel along the central axis; b) directing the secondary mandrel from one of the plurality of locations towards the primary mandrel such that the secondary mandrel is disposed adjacent the first
5 portion of the mandrel; and c) wrapping reinforcement members from the carriers around the first portion of the primary mandrel. The method may also include braiding a second portion of the primary mandrel by: a) moving the secondary mandrel source another of the plurality of locations; b) directing the primary mandrel further along the central axis; and c) wrapping reinforcement members from the carriers around the second portion of the
10 primary mandrel. An outer jacket may be applied around the first and second portions of the primary mandrel and the secondary mandrel, and the primary mandrel may be removed to define a primary lumen within the tubular body.

[0016] In accordance with yet another embodiment, a tubular device is provided for a catheter or sheath comprising a proximal end and a distal end sized for introduction
15 into a patient's body that includes a central lumen extending between the proximal and distal ends; an auxiliary lumen extending at least partially between the proximal and distal ends adjacent the central lumen; one or more reinforcement members comprising windings extending helically around the central lumen between the proximal and distal ends; and one or more layers surrounding the one or more reinforcement members, wherein the tubular
20 device comprises a first portion in which at least some of the windings pass between the central and auxiliary lumens and at least some of the windings surround both the central and auxiliary lumens, and a second portion in which either a) all of the windings surround both the central and auxiliary lumens or b) all of the windings surround the central lumen and the auxiliary lumen is disposed outside the windings.

[0017] In accordance with still another embodiment, an apparatus is provided for performing a procedure within a patient's body that includes a tubular member comprising a proximal end, a distal end sized for introduction into a patient's body, a central axis
25 extending therebetween, and a distal portion extending distally from an intermediate portion to the distal end; a primary lumen extending between the proximal and distal ends and surrounding at least a portion of the central axis; a steering element lumen extending at least
30 partially between the proximal and distal ends adjacent the primary lumen; a steering element slidably disposed within the steering element lumen and comprising a distal end fixed to the tubular member distal end and a proximal end adjacent the proximal end of the

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tubular member; and an actuator on the proximal end coupled to the steering element proximal end such that, actuation of the actuator applies axial tension or compression to the steering element, thereby causing the distal portion to bend. One or more reinforcement members comprising windings may extend around the primary lumen between the proximal and distal ends, and one or more layers may surround the one or more reinforcement members, wherein the tubular member comprises a first portion in which at least some of the windings pass between the primary lumen and the steering element lumen and at least some of the windings surrounding both the primary lumen and the steering element lumen, and a second portion in which either a) all of the windings surround both the primary lumen and the steering element lumen or b) all of the windings surround the primary lumen and the steering element lumen is disposed outside the windings.

[0018] Other aspects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0019] The drawings illustrate exemplary embodiments of the invention, in which:

[0020] FIG. 1A is a perspective view of an exemplary embodiment of a catheter, including multiple lumens extending between proximal and distal ends thereof, and including a steerable distal portion.

[0021] FIG. 1B is a cross-sectional side view of the catheter of FIG. 1A, taken along line 1B-1B, showing reinforcement members positioned around primary and auxiliary lumens of the catheter.

[0022] FIG. 2 is a side view of a first example of a catheter including a primary lumen and an auxiliary lumen that changes position along the length of the catheter.

[0023] FIGS. 2A-2D are cross-sectional views of the catheter of FIG. 2 taken at different locations along the length of the catheter.

[0024] FIG. 3 is a side view of a second example of a catheter including a primary lumen and an auxiliary lumen that changes position along the length of the catheter.

[0025] FIGS. 3A-3D are cross-sectional views of the catheter of FIG. 2 taken at different locations along the length of the catheter.

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[0026] FIG. 4A is a schematic of an exemplary embodiment of a braiding apparatus for making a reinforced tubular member including multiple mandrels supported by reinforcement members.

5 [0027] FIG. 4B is a front view of an arrangement of horn gears for creating a braided configuration of reinforcement members that may be included in the braiding apparatus of FIG. 4A and including various locations for sources of mandrels.

[0028] FIG. 4C is a cross-sectional view of a catheter showing the locations of mandrels corresponding to the different locations for the sources of mandrels shown in FIG. 4B.

10 [0029] FIG. 5 is a partial cross-sectional side view of an exemplary embodiment of a catheter including a steering lumen for receiving a steering element.

[0030] FIG. 6 is a partial cross-sectional side view of another embodiment of a catheter including a plurality of electrodes mounted thereon and including a lumen for receiving one or more conductors for coupling to the electrodes.

15 [0031] FIG. 7A is a side view of a portion of a catheter subassembly including a primary mandrel and a secondary mandrel wrapped by reinforcement members and including a section of the secondary mandrel that has been pulled outside the reinforcement members.

[0032] FIG. 7B is a side view of a portion of a catheter resulting from the catheter subassembly of FIG. 7A that includes a discontinuous auxiliary lumen that communicates with side openings in the wall of the catheter.

[0033] FIG. 8A is a side view of a portion of another embodiment of a catheter including an auxiliary lumen that has a variable diameter.

25 [0034] FIG. 8B is a side view of a portion of a steering element that may be received in the auxiliary lumen of the catheter of FIG. 8A.

[0035] FIG. 9 is a side view of a portion of still another embodiment of a catheter including one or more stiffening elements embedded into a wall of the catheter.

[0036] FIG. 9A is a cross-section of the catheter of FIG. 9 taken across 9A-9A.

[0037] FIG. 10 is a side view of a mandrel/reinforcement subassembly including a pair of secondary mandrels partially braided into a length of the subassembly.

30 [0038] FIGS. 10A-10C are cross-sectional views of the subassembly of FIG. 10 taken along sections 10A-10A, 10B-10B, and 10C-10C, respectively.

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[0039] FIGS. 11A-11J show an exemplary method for making a steerable catheter including a lapped braid with a pull wire ring.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

5 [0040] Turning to the drawings, FIGS. 1A and 1B show an exemplary embodiment of an apparatus 10 for introduction into a body lumen (not shown), e.g., for performing a diagnostic and/or therapeutic procedure within a patient's body. In exemplary embodiments, the apparatus 10 may be a guide catheter, a sheath, a procedure catheter, e.g., an imaging catheter, an ablation and/or mapping catheter, a balloon catheter, or other
10 tubular device sized for introduction into a body lumen, such as a vessel within a patient's vasculature, a passage within a patient's gastrointestinal tract, urogenital tract, reproductive tract, respiratory tract, lymphatic system, and the like (not shown). In exemplary embodiments, the apparatus 10 may have a length between about ten and one hundred thirty centimeters (10-130 cm), and an outer diameter between about four and twenty-four French
15 (4-24 Fr or 1.33-8.0 mm).

[0041] Generally, the apparatus 10 is an elongate tubular member including a proximal end 12, a distal end 14 sized for insertion into a body lumen, a central longitudinal axis 16 extending between the proximal and distal ends 12, 14, and one or more lumens 18 extending between the proximal and distal ends 12, 14. For example, as shown in FIG. 1B,
20 the apparatus 10 may include a central or primary lumen 18a, e.g., sized for receiving or carrying one or more instruments or other elements (not shown). In exemplary embodiments, the central lumen 18a may be sized for receiving or carrying a guide wire, procedure catheter, balloon catheter, ablation catheter, cardiac lead, needle, or other instrument (not shown), one or more wires or other conductors, one or more optical fibers,
25 one or more tubes or accessory lumens, one or more mechanical elements, one or more sensors, and/or sized for delivering and/or removing fluids or other flowable agents or materials therethrough.

[0042] In one embodiment, shown in FIG. 1A, the central lumen 18a may exit at or communicate with an outlet 17 in the distal end 14, e.g., to allow a guidewire or other
30 instrument (not shown) to pass therethrough and/or for delivering or aspirating fluid therethrough. Alternatively, the central lumen 18a may be enclosed, e.g., terminating within or adjacent the distal end, e.g., by an electrode, cap, or other component (not shown)

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to isolate the central lumen 18a and/or elements carried therein from the environment outside the apparatus 10.

[0043] Returning to FIG. 1B, in addition to the central lumen 18a, the apparatus 10 includes an auxiliary lumen 18b, e.g., extending adjacent the central lumen 18a, e.g.,
5 substantially parallel to and radially offset relative to the central axis 16. For example, in FIG. 5, an exemplary embodiment of a catheter 110 is shown in which the auxiliary lumen 118b may be a steering element lumen configured to receive a pull wire or other steering element 136 therein, e.g., to bend or otherwise deflect a distal portion of the catheter 110, as described further below. In FIG. 6, an exemplary embodiment of a catheter 210 is shown in
10 which the auxiliary lumen 218b may receive one or more wires or conductors 236 for coupling to one or more electrodes 238 mounted on the distal portion of the catheter 210, also as described further below.

[0044] With continued reference to FIGS. 1A and 1B, optionally, the apparatus 10 may include one or more additional lumens (not shown), e.g., one or more additional
15 steering element lumens, conductor lumens, inflation lumens (e.g., if the apparatus 10 includes one or more balloons, not shown on the distal end 14), and/or accessory lumens. For example, a pair of auxiliary lumens may be provided (not shown) on opposite sides of the apparatus 10, e.g., offset about one hundred eight degrees (180°) around the circumference of the apparatus 10.

[0045] Optionally, the auxiliary lumen(s) may have a variety of cross-sectional shapes and/or sizes, e.g., a substantially circular shape, an elliptical or oval shape, a substantially rectangular shape, a triangular shape, a pair of overlapping circles shape, and the like, e.g., similar to the devices disclosed in U.S. Publication No. 2014/ 0323964, the entire disclosure of which is expressly incorporated by reference herein. The shape and/or
20 size of the auxiliary lumen(s) may be substantially uniform along the length of the apparatus 10 or may vary at different locations, as described elsewhere herein.

[0046] The auxiliary lumen 18b is generally radially offset from the central axis 16 substantially along the length of the apparatus 10, e.g., entirely from the distal end 14 to the proximal end 12. In addition, the radial and/or circumferential position of the auxiliary
30 lumen 18b may change relative to the primary lumen 18a and/or other components of the apparatus 10 at various locations along the length of the apparatus 10, as described elsewhere herein.

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[0047] Returning to FIG. 1A, the distal end 14 may include a tapered, rounded, or otherwise shaped distal tip 15, e.g., to provide a substantially atraumatic tip and/or to facilitate advancement or navigation through various anatomy. In addition or alternatively, the distal end 14 may include one or more therapeutic and/or diagnostic elements, e.g., one or more balloons, stents, sensors, electrodes, ablation elements, thermocouples, steering mechanisms, imaging devices, helical anchors, needles, and the like (not shown), depending upon the particular intended application for the apparatus 10. Further, in addition or alternatively, the distal end 14 may include one or more markers or other features to enhance radiopacity and/or visibility under ultrasound, MRI or other imaging modalities, e.g., by mounting one or more platinum elements on the distal end 14, doping one or more regions of the distal end 14 with tungsten or barium sulfate, and/or other methods known in the art.

[0048] Optionally, as shown in FIG. 1A, the proximal end 12 may include a handle or hub 30, e.g., configured and/or sized for holding and/or manipulating the apparatus 10 from the proximal end 12. In addition, the handle 30 may include one or more ports, e.g., port 32a communicating with the central lumen 18a, or other respective lumens (not shown). Optionally, the port 32a may include one or more valves, e.g., a hemostatic valve (also not shown), which may provide a substantially fluid-tight seal, while accommodating insertion of one or more instruments or fluids into the central lumen 18a. Optionally, a side port (not shown) may be provided on the handle 30, e.g., for delivering fluid into and/or aspirating fluid from the primary lumen 18a, e.g., around an instrument inserted into the primary lumen 18a. Optionally, the handle 30 and/or proximal end 12 may include one or more connectors, such as luer lock connectors, electrical connectors, and the like, for connecting other devices (not shown) to the apparatus 10, such as syringes, displays, controllers, and the like (also not shown).

[0049] In addition, the handle 30 may include one or more actuators, such as sliders, buttons, switches, rotational actuators, and the like, e.g., for activating and/or manipulating components (also not shown) on the distal end 14 or otherwise operating the apparatus 10. For example, as shown in FIG. 1A, an actuator 34 may be provided that is coupled to a proximal end of a steering element (not shown) within the auxiliary lumen 18b, e.g., similar to the embodiment shown in FIG. 5, as described further elsewhere herein.

[0050] Generally, with particular reference to FIG. 1B, the apparatus 10 may include an inner liner 40, e.g., at least partially or entirely surrounding or otherwise defining

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the central lumen 18a, a reinforcement layer 42 surrounding the inner liner 40, and an outer jacket 44 surrounding and/or encasing the reinforcement layer 42, each of which may extend at least partially between the proximal and distal ends 12, 14 of the apparatus 10.

5 The reinforcement layer 42 and/or outer jacket 44 may be attached to the inner liner 40, e.g., by laminating, adhering, adhesive bonding, ultrasonic welding, reflowing or other heating, and the like, as described elsewhere herein.

[0051] In an exemplary embodiment, the central lumen 18a is defined by an inner liner 40a including an inner surface 41a. The inner liner 40a may be formed from lubricious material, e.g., PTFE, to provide a lubricious inner surface 41a. Alternatively, the
10 inner liner 40 may be formed from one or more layers of thermoplastic or other polymeric material including one or more coatings on the inner surface 41a having desired properties, e.g., a hydrophilic and/or lubricious coating, e.g., similar to the liners disclosed in U.S. Patent Nos. U.S. Patent Nos. 7,550,053 and 7,553,387, and U.S. Publication No. 2009/0126862, the disclosures of which are expressly incorporated by reference herein.

15 [0052] Optionally, as shown in FIG. 1B, an inner liner 40b may also at least partially surround the auxiliary lumen 18b, which may be formed from a lubricious material and/or may include one or more coatings on its inner surface 41b, similar to the inner liner 40a. The inner surface 41b of the auxiliary lumen 18b may have a substantially uniform cross-section, as shown in FIG. 1B. Alternatively, the inner surface 41b of the auxiliary
20 lumen 18b may have a textured or other variable cross-section along, e.g., along its length and/or about its circumference (not shown).

[0053] Optionally, any or all of the inner liner 40a, reinforcement layer 42, and/or outer jacket 44 may be formed from multiple layers of like or different materials (not shown), e.g., to provide desired material properties in the different portions of the apparatus
25 10. In an exemplary embodiment, the outer jacket 44 may be formed from PEBAX, nylon, urethane, and/or other thermoplastic material, e.g., such that the material of the outer jacket 44 may be heated and reflowed and/or otherwise formed around the components defining the lumens 18, e.g., as described elsewhere herein.

[0054] In one embodiment, one or more of the layers of the apparatus 10 may
30 have a substantially homogenous construction between the proximal and distal ends 12, 14. Alternatively, the construction may vary along the length of the apparatus 10 to provide desired properties, e.g., between proximal, intermediate, and distal portions 20, 22, 24. For example, a proximal portion 20 of the apparatus 10 adjacent the proximal end 12 may be

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substantially rigid or semi-rigid, e.g., providing sufficient column strength to allow the distal end 14 of the apparatus 10 to be pushed or otherwise manipulated from the proximal end 12, while the distal portion 24 may be substantially flexible. As described further below, the distal portion 24 of the apparatus 10 may be steerable, i.e., may be bent, curved, or otherwise deflected substantially within a steering plane, as described further below.

5 [0055] Returning to FIG. 1B, the reinforcement layer 42 may include one or more reinforcing members, e.g., wound in a braided or other helical configuration around the inner liner 40a, e.g., using a braiding apparatus such as that shown in FIGS. 4A and 4B, and the outer jacket 44 may include one or more tubular layers surrounding the
10 reinforcement layer 42 and/or between the reinforcement layer 42 and the inner liner 40a. In an exemplary embodiment, the reinforcement layer 42 may include one or more, or a plurality of, round or flat (e.g., rectangular, elliptical, or flat oval) wires, filaments, strands, or other reinforcement members 43, e.g., formed from metal, such as stainless steel, plastic, such as PEEK, glass, woven or twisted fibers, such as aramid, and the like, or composite
15 materials.

[0056] In one embodiment, a plurality of reinforcement members 43 may be braided around the inner liner 40a, e.g., with each reinforcement member 43 having the same material and/or shape. Alternatively, the reinforcement members 43 may have different sizes and/or shapes, e.g., a first size or shape extending helically in a first direction
20 and a second size or shape (different than the first) extending helically in a second direction (e.g., opposite the first direction).

[0057] The reinforcement layer 42 may be configured to substantially transfer torsional forces between the proximal and distal ends 12, 14, e.g., to allow the apparatus 10 to be twisted from the proximal end 12 to rotate the distal end 14 about the longitudinal axis
25 16 within a patient's body. In addition, the reinforcement layer 42 may allow the distal end 14 of the apparatus 10 to be advanced or otherwise manipulated within a patient's body from the proximal end 12 without substantial risk of buckling and/or kinking. The pitch of the reinforcement layer 42 may be varied along the length of the apparatus 10, e.g., in order to optimize mechanical properties of various segments or portions of the apparatus 10.

30 [0058] In addition, the location of the reinforcement layer 42 may vary relative to the central lumen 18a and/or auxiliary lumen 18b, e.g., as the auxiliary lumen 18b transitions to different radial locations within the wall of the apparatus 10. For example, FIG. 2 shows an example of a catheter 10A that includes a central lumen 18A-a that extends

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substantially along a central axis 16A and is surrounded by a reinforcement layer 42, which may be similar to any of the embodiments described elsewhere herein. In addition, the catheter 10A includes an auxiliary lumen 18A-b that extends between proximal and distal ends 12A, 14A of the catheter 10A adjacent the central lumen 18A-a at different radial and/or circumferential locations. As shown in FIG. 2A, along a proximal portion, the auxiliary lumen 18A-b may be braided into the reinforcement layer 42, while, as shown in FIG. 2B, at an intermediate portion, the auxiliary lumen 18A-b may transition outside the reinforcement layer 42. Further, as shown in FIG. 2C, the auxiliary lumen 18A-b may transition to a location closer to the central lumen 18A-a such that the reinforcement layer 42 surrounds both lumens 18A-a, 18A-b. Finally, as shown in FIG. 2D, the auxiliary lumen 18A-b may transition again and be braided into the reinforcement layer 42 along a distal portion to the distal end 14A.

[0059] With continued reference to FIGS. 2 and 2A-D, in an exemplary embodiment, a deflectable catheter shaft may be constructed wherein one or more auxiliary lumens 18A-b (e.g., a single auxiliary lumen or two auxiliary lumens spaced approximately one hundred eighty degrees (180°) apart) may be braided into or within the reinforcement layer 42 as shown in FIG. 2D at an intermediate portion (e.g., corresponding to FIG. 2 sections B and/or C) while the auxiliary lumen 18A-b may transition outside the reinforcement layer 42 as shown in FIG. 2B at a distal and proximal location (e.g., corresponding to FIG. 2 sections A and D). Additionally, the auxiliary lumen(s) 18A-b may pass through a jacket layer (as described elsewhere herein) overlying the reinforcement layer at or near the point(s) of transition from within to outside of the reinforcement layer 42.

[0060] In a further exemplary embodiment, the auxiliary lumen(s) 18A-b may pass through a jacket layer at or near the proximal transition(s) from within to outside the reinforcement layer and may terminate under or within the jacket layer at or near the distal transition(s) from within to outside the reinforcement layer, e.g., such that an actuator wire ring (not shown) with actuator wire(s) (not shown) attached may be positioned adjacent the distal point(s) of transition with actuator wire(s) travelling through the auxiliary lumen(s) 18A-b over the intermediate portion, the actuator wire ring being positioned under the jacket adjacent the distal transition and the actuator wire(s) exiting the a wall of the shaft through the jacket adjacent the proximal transition(s). A handle, such as that shown in FIG.

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1, may be positioned around the proximal exit(s) that includes one or more actuators attached or otherwise coupled to the actuator wires at this position.

[0061] With continued reference to FIG. 2 and 2A-D, in another exemplary embodiment, a deflectable catheter shaft may be constructed wherein one or more auxiliary lumens 18A-b (e.g., a single auxiliary lumen or two auxiliary lumens spaced approximately one hundred eighty degrees (180°) apart) may be braided under the reinforcement layer 42 as shown in FIG. 2C at an intermediate portion (e.g., corresponding to FIG. 2 sections B and/or C) while the auxiliary lumen 18A-b may transition outside the reinforcement layer 42 as shown in FIG. 2B at a distal and proximal location (e.g., corresponding to FIG. 2 sections A and D). Additionally, the auxiliary lumen(s) 18A-b may pass through a jacket layer (as described elsewhere herein) overlying the reinforcement layer at or near the point(s) of transition from under to outside of the reinforcement layer 42.

[0062] In a further embodiment, the auxiliary lumen(s) 18A-b may pass through a jacket layer at or near the proximal transition(s) from under to outside the reinforcement layer and may terminate under or under the jacket layer at or near the distal transition(s) from under to outside the reinforcement layer, e.g., such that an actuator wire ring (not shown) with actuator wire(s) (not shown) attached may be positioned adjacent the distal point(s) of transition with actuator wire(s) travelling through the auxiliary lumen(s) 18A-b over the intermediate portion, the actuator wire ring being positioned under the jacket adjacent the distal transition and the actuator wire(s) exiting the a wall of the shaft through the jacket adjacent the proximal transition(s). A handle, such as that shown in FIG. 1, may be positioned around the proximal exit(s) and one or more actuators may be attached or otherwise coupled to the actuator wires at this position.

[0063] FIG. 3 shows another example of catheter 10B, similar to that shown in FIG. 2 except that the auxiliary lumen 18B-b may extend along a proximal portion close to the central lumen 18B-a surrounded by the reinforcement layer 42 (as shown in FIG. 3A), may then transition and extend along an intermediate portion outside the reinforcement layer 42 (as shown in FIG. 3B), may again transition to a location surrounded by the reinforcement layer 42 (as shown in FIG. 3C), and finally may transition to a location outside the reinforcement layer 42 along a distal portion (as shown in FIG. 3D).

[0064] Thus, again with general reference to FIGS. 1A and 1B, in any of the apparatus and methods herein, it will be appreciated that the location of the auxiliary lumen 18b and/or reinforcement members 43 of the reinforcement layer 42 may be changed along

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the length of the apparatus 10 to provide desired mechanical and/or other performance characteristics for the final apparatus.

[0065] For example, with reference to FIG. 5, an apparatus 110 is shown in which a distal portion 124 of the apparatus 10 is steerable, e.g., using one or more pull
5 wires, cables, fibers, threads, filaments, or other steering elements, such as a pull wire 136 slidably received within auxiliary lumen 118b. The steering element 136 generally includes a proximal end (not shown) coupled to an actuator, e.g., such as the actuator 34 on the handle 30 shown in FIG. 1, and extends from a proximal portion (not shown) through an intermediate portion 122 and into the distal portion 124. A distal end 136b of the steering
10 element 136 may be fixed or otherwise coupled to the distal end 114, e.g., to a component defining or adjacent the distal tip (not shown).

[0066] The steering element 136 may be formed from materials capable of substantially transferring any axial forces applied at the proximal end to the distal end 114, as is known in the art. Optionally, the steering element 136 may include a coating, e.g.,
15 PTFE, parylene, silicone, or other lubricious material, an outer sleeve, e.g., formed from HDPE, PTFE, and the like, to reduce friction between the steering element and the wall of the auxiliary lumen 18b. Alternatively or in addition, the inner surface of the auxiliary lumen 118b may be formed from lubricious material and/or may include one or more coatings, as described elsewhere herein. Alternatively or in addition, the auxiliary lumen
20 18b may include one or more incompressible elements, e.g., a tightly wound coil therearound, e.g., to prevent compression, which may otherwise lead to creating a bending moment along at least part of its length.

[0067] During use, the actuator may be activated, e.g., directed proximally or distally relative to the handle and/or the proximal end (not shown), to apply an axial force to
25 the steering element 136, e.g., tension (when the steering element is pulled) or compression (when the steering element is advanced). Because the steering element 136 is slidable within the auxiliary lumen 118b, the axial force is translated and applied to the distal end 136b coupled to the distal end 114. Further, because the auxiliary lumen 118b is offset from the central axis 116 along at least the distal portion 124, the axial force applies a
30 bending moment, thereby causing the distal portion 124 to curve or otherwise bend in a desired plane or other manner. Optionally, the proximal and intermediate portions 122 of the apparatus 110 may be constructed to prevent or minimize bending forces caused by actuation of the steering element 136.

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[0068] In the configuration shown in FIG. 5, along the distal portion 124, a second segment 118b-2 of the auxiliary lumen 118b may be surrounded by the reinforcement layer 142, e.g., immediately adjacent the central lumen 118a (e.g., similar to the location shown in FIG. 3A), and then may transition such that a first segment 118b-1 of the auxiliary lumen 118b is outside the reinforcement layer 142, e.g., closer to an outer surface of the apparatus 110 along at least the intermediate portion 122 (and/or optionally along the proximal portion to the proximal end and/or handle, not shown). Alternatively, the second segment 118b-2 may be braided into the reinforcement layer 142 (e.g., similar to the location shown in FIG. 2A).

10 [0069] Locating the second segment 118b-2 surrounded by the reinforcement layer 142 may enhance performance properties of the steering element 136 and/or may reduce the risk of the steering element 136 tearing through the wall of the distal portion 124, e.g., when a proximal force or tension is applied to the steering element 136. Locating the first segment 118b-1 outside the reinforcement layer 142 may facilitate accessing the auxiliary lumen 118b, e.g., during manufacturing and/or assembly, to couple the proximal end of the steering element 136 to an actuator and/or other components (not shown) at the proximal end of the apparatus 110.

[0070] Conversely, if the apparatus 110 were intended to include one or more sensors, actuators, electrodes, imaging element, or other components on the distal portion, the configuration could be reversed. For example, the location of the second segment 118b-2 of the auxiliary lumen 118b may extend from a proximal end of the apparatus 110 to a distal portion and then may transition to the location of the first segment 118b-1, e.g., outside the reinforcement layer 142 along the distal portion. This configuration may facilitate accessing the auxiliary lumen 118b at the distal portion, e.g., to couple one or more wires or conductors disposed within the second segment 118b-2 of the auxiliary lumen 118b to the sensors, actuators, electrodes, imaging elements, and/or other components, e.g., since the auxiliary lumen 118b is closer to the outer surface of the apparatus 10. Along the proximal and/or intermediate portions, the auxiliary lumen 118b and consequently the conductor(s) may be disposed deeper within the apparatus 110, e.g., beneath and/or within the reinforcement layer 142, which may at least partially shield or otherwise protect the conductor(s).

30 [0071] Turning to FIG. 6, in another embodiment, an apparatus 210 may be provided that includes a plurality of sensors, actuators, electrodes, imaging elements, and/or

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or other components 238 on a distal portion 224 of the catheter 210, which may be coupled to one or more wires or conductors 236 extending through an auxiliary lumen 218b proximally from the distal portion 224, e.g., to one or more connectors and/or electronics at the proximal end (not shown) of the apparatus 210.

5 **[0072]** In the exemplary embodiment shown, the auxiliary lumen 218b may extend generally along the distal portion 224 braided into the reinforcement layer (e.g., similar to the location shown in FIG. 2A) or completely surrounded by the reinforcement layer (e.g., similar to the location shown in FIG. 3A) as represented by segments 218b-1, but may transition to segments 218b-2 that are positioned outside the reinforcement layer
10 (e.g., similar to the location shown in FIG. 3B) for a relatively short distance, e.g., under the locations intended for the electrodes 238. With the auxiliary lumen 218b closer to the outer surface at the short segments 218b-2, any wires or conductors within the auxiliary lumen 218b may be easily accessed during manufacturing or assembly, e.g., to expose and couple the electrodes 238 to the conductor(s) when the electrodes 238 are mounted to the distal
15 portion 224. Otherwise, the conductor(s) may be located relatively deep within the apparatus 210.

[0073] Alternatively, the lumen configuration shown in FIG. 6 may be adapted to provide a series of side ports in the distal portion 224 in fluid communication with a proximal portion of the catheter (not shown) by way of an unoccupied auxiliary lumen
20 218b, e.g., such that fluid may delivered through the auxiliary lumen 218b and out the side ports and/or aspirated into the auxiliary lumen 218b through the side ports from a location outside the distal portion 224.

[0074] In yet another embodiment, shown in FIGS. 7A and 7B, an apparatus 310 may be provided that includes a discontinuous auxiliary lumen 318b adjacent a central
25 lumen 318a. For example, as shown in FIG. 7B, a first segment 318b-1 of the auxiliary lumen 318b may extend proximally from a predetermined location, e.g., to a proximal portion of the apparatus 310 and a second segment 318b-2 may extend distally from the predetermined location such that both segments communicate with side openings 319 disposed adjacent one another. The auxiliary lumen 318b may be braided into a
30 reinforcement layer 342, e.g., as shown in FIG. 7A, or disposed at other positions relative to the central lumen 318a, as described elsewhere herein.

[0075] Turning to FIGS. 4A-4C, various methods may be used for manufacturing and/or assembling any of the embodiments described herein. For example,

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FIG. 4A shows an exemplary embodiment of an apparatus 50 for making one or more tubular bodies, such as catheters and/or components for catheters, sheaths, or other tubular devices 8. Generally, the apparatus 50 includes a plurality of sources 52, 54 of mandrels 2 and/or liners 4, a guide 60, a source 70 of reinforcement members 6, a drive mechanism 80, and, optionally, a source 90 of jacket material 7.

[0076] While mandrels, liners, and/or jackets may be provided in discrete segments (not shown), the apparatus 50 may allow for substantially continuous fabrication of tubular bodies, e.g., wrapping a liner material 4a around a primary mandrel 2a (or the primary mandrel 2a may include a tubular or other liner material provided around it on the source 52, e.g., similar to the liners disclosed in the references incorporated by reference elsewhere herein), positioning an auxiliary mandrel 2b (with optional liner material, not shown) adjacent the primary mandrel 2a, braiding a plurality of reinforcement members 4 around the mandrels 2, and optionally, applying outer jacket material 7 around the reinforced mandrels, as described further below.

[0077] As used herein, “substantially continuous” means that the apparatus 50 and/or method may operate indefinitely, i.e., to make as few as one or as many as hundreds or thousands of tubular bodies 8, e.g., by substantially simultaneously feeding components of the tubular bodies 8 from sources 52, such as reels, through components of the apparatus 50 until the sources 52 are depleted, whereupon new source(s) may be loaded onto the apparatus 50 and the process continued. Alternatively, the apparatus 50 may be used to create discrete lengths of tubular devices, e.g., if the mandrels and/or liners are provided in specific lengths corresponding to one or more individual tubular devices (not shown). In a further alternative, some of the operations may be performed substantially continuously, while other operations are performed on components intended for one or more individual tubular devices.

[0078] Thus, the apparatus 50 and methods herein may be used to make one or more relatively long tubular bodies 8, e.g., that are substantially longer than finished catheters or other tubular devices. For example, one resulting tubular body 8 may be collected, e.g., on a take-up reel or container (not shown), or may be separated into individual shorter tubular bodies, e.g., using a cutter or other tool (not shown), that may be incorporated into individual catheters or other tubular devices, e.g., as described elsewhere herein and/or as disclosed in U.S. Publication No. 2009/ 0126862, the entire disclosure of which is expressly incorporated by reference herein.

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[0079] With particular reference to FIG. 4A, the apparatus 50 may include one or more sources 52 of mandrels 2 and, optionally, one or more sources 54 of liner material 4, which may be fed into a guide 60 to define lumens of the tubular bodies 8. For example, a first reel 52a may include an elongate primary mandrel 2a, e.g., shaped and/or configured to define a primary or central lumen (not shown) of the tubular bodies 8. Similarly, a second reel 52b may include an elongate auxiliary mandrel 2b, e.g., shaped and/or configured to define a secondary or auxiliary lumen (also not shown) of the tubular bodies 8. As described further below, the second reel 52b or other source of auxiliary mandrel may be located at one of a plurality of available locations during operation to configure the tubular bodies 8 in a desired manner. Optionally, if additional lumens are desired for the tubular bodies 8, one or more additional auxiliary mandrels may be provided (not shown), which may also be moved to one or more locations.

[0080] The mandrels 2 may have desired cross-sectional shapes and/or sizes corresponding to the desired cross-sections of the lumens, e.g., substantially circular or other shapes, as described elsewhere herein. The mandrels 2 may be a solid or hollow wire or other cylindrical member having a diameter (or other cross-section) corresponding to the diameter of the lumen to be lined by the strip 24, e.g., between about 0.005-0.300 inch (0.125-7.5 mm), 0.014-0.092 inch (0.35-2.3 mm), or 0.014-0.045 inch (0.35-1.15 mm). In an exemplary embodiment, the auxiliary mandrel 2b may have a substantially smaller diameter or other cross-section than the primary mandrel 2a. In exemplary embodiments, the mandrels 2 may be formed from beading or monofilament material, for example, lubricious material, e.g., PTFE or other fluoropolymer, silicone-treated Acetal, PTFE-coated stainless steel, Parylene-coated stainless steel, silver coated copper, and the like, having sufficient flexibility to allow the mandrels 2 to be wound onto a source reel 52 and/or onto a take-up reel (not shown) after being incorporated into a tubular body 8.

[0081] Alternatively or in addition, the mandrels 2 may have a tubular liner predisposed about them, e.g. a fluoropolymer sleeve or coating or other tubular material which may facilitate removal of the mandrel 2 and/or be left behind upon removal of the mandrel 2 to form a liner. Further alternatively, a shim (not shown) may be positioned over a mandrel 2 and/or within a tubular or strip liner such that the shim (not shown) may facilitate creation of a lumen that is larger than the mandrel 2 with or without ultimate removal of the mandrel 2. For example, a PTFE tube or strip shim (not shown) may be positioned around a mandrel 2 and inside of a strip or tubular liner. The mandrel/shim/liner

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assembly may then be incorporated into a braided shaft or finished apparatus. The shim (not shown) may be subsequently removed, e.g. after braiding, lamination, etc. to leave a lumen larger than the mandrel. After this, the mandrel may remain in place, for example in the case of the auxiliary mandrel 2b to serve as a pull wire, or simply removed with less
5 force.

[0082] In an alternative embodiment, the mandrels 2 may be formed from material that substantially maintains its size and shape during fabrication of the tubular bodies, yet may be reduced in cross-section after fabrication to facilitate removal. For example, silver-coated copper wire, PTFE beading, or other malleable metals or polymers
10 may be used for the mandrels 2 that, after fabrication of the tubular body 8, may be necked down before and/or during removal. For example, after fabricating a tubular body 8, the mandrels 2 (or the entire tubular body) may be pulled at one or both ends, thereby causing the mandrels 2 to plastically elongate and thereby reduce their outer cross-section slightly, which may reduce friction between the mandrels 2 and the surrounding liners,
15 reinforcement members, and/or other materials, and thereby facilitate removal. Further alternatively, the mandrels 2 may include a rolled strip with inherent radial strength capable of supporting a lumen during braiding and/or lamination and/or other processing, but may subsequently be constrained, stretched, or otherwise removed. Further alternatively, the mandrels 2 may be constructed from material having relatively high thermal expansion such
20 that during heating, lamination, and/or reflow, the mandrels 2 expand and upon cooling contract, thereby creating a lumen larger than the original mandrel 2.

[0083] In yet another alternative, the mandrels 2 may be formed from materials that may be dissolved, e.g., after fabrication, leaving the surrounding materials intact to define the lumens.

[0084] In still another alternative, tubular mandrels may be used that have sufficient hoop strength to resist deformation under the forces encountered during braiding and/or other fabrication and/or heating or other processing parameters experienced during fabrication. In this alternative, the tubular mandrels may remain substantially within the tubular bodies 8 after fabrication, e.g., to define the auxiliary lumen. For example, a
30 relatively thick walled PTFE, a lined or bare polyimide tube, or other tubular mandrel may be used. Alternatively, the inner diameter of such a tubular mandrel may be temporarily supported by a temporary supporting mandrel (not shown), e.g. during braiding, and the temporary supporting mandrel may be removed prior to subsequent fabrication and/or

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heating or other processing steps, e.g., if the tubular mandrel is to remain as a permanent component of the tubular bodies.

[0085] Optionally, a source 54 of liner material 4 may be provided for the one or both mandrels 2. For example, as shown, a source 54a of liner material 4a is provided such that the liner material 4a may be wrapped at least partially around the primary mandrel 2a, e.g., as the primary mandrel 2a and liner material 4a are fed through the guide 60. The liner material 2a may be formed from lubricious material and/or may include one or more coatings (not shown) on an inner surface thereof oriented towards the primary mandrel 2a, which may provide an inner liner for a primary lumen of the resulting tubular bodies 8a.

[0086] For example, the liner material may include a base material, e.g., a relatively thin-walled polymer sheet having a width corresponding to the circumference of the corresponding mandrel, e.g., thermoplastics, such as polyether block amide, urethane, nylon, and the like, fluoropolymers, such as PTFE, FEP, TFE, and the like, thermoset, and thermoform plastics, such as polyimide or polyester, and the like. In exemplary embodiments, the liner material may have a thickness between about 0.0001-0.050 inch (0.0025-1.25 mm), 0.0001-0.003 inch (0.0025-0.076 mm), 0.0001-0.0015 inch (0.0025-0.038 mm), or 0.0005-0.002 inch (0.0125-0.05 mm).

[0087] Optionally, if desired a source of liner material may also be provided for the auxiliary mandrel 2b and/or for other auxiliary mandrels (not shown for simplicity). In this option, a guide (not shown) may be provided for wrapping the liner material around the auxiliary mandrel 2b, e.g., before the auxiliary mandrel 2b is positioned adjacent the primary mandrel 2a. In an alternative embodiment, tubular liner material may be provided on one or both mandrels s when loaded on the source 52, and/or may be fed onto the desired mandrel in discrete segments (not shown) before passing the mandrels 2 through the guide 60 or horn gear 72.

[0088] With additional reference to FIGS. 4A and 4B, the source 70 of reinforcement members 6 may provide one or more, e.g., a plurality of, reinforcement members 6 that may be wrapped around the mandrels 2, e.g., upon exiting the guide 60. In the exemplary embodiment shown in FIG. 4B, the reinforcement source 70 may include an arrangement of horn gears 72, e.g., mounted in a generally circular configuration around the guide 60, for example, to a base or other support structure 76. The horn gears 72 may be free to rotate about their individual central axes but may be substantially fixed translationally relative to one another and the guide 60. The horn gears 72 may pass one or

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more carriers 74 of reinforcement members 6 around the path 78, e.g., in a clockwise and/or counterclockwise direction, e.g., with at least some of the carriers travelling clockwise and some travelling counterclockwise, e.g., to create a braided pattern. The carriers 74 may be loaded onto the horn gears to create a variety of patterns, e.g., one-over-one-under (diamond pattern), two-over-two-under (herring bone pattern), one-over-one-under with two reinforcement members running side by side (tow), and/or other patterns, as are known in the art.

[0089] Alternatively, the horn gears 72 may be rotatable relative to the guide 60 and/or primary mandrel 2a, e.g., around a central axis of the guide 60, e.g., along a path 78 shown in FIG. 4B, while maintaining their same circular configuration, e.g., by rotating the base 76 relative to the guide 60, as described further elsewhere herein.

[0090] In addition, the auxiliary mandrel 2b may be moved to different locations relative to the horn gears 72, e.g., to position the auxiliary mandrel 2b relative to the primary mandrel 2a and/or reinforcement members 6. For example, as shown in FIG. 4B, during operation of the apparatus 50, the source of auxiliary mandrel 2b may be positioned at locations A1, A2, or A3, e.g., for a predetermined time and/or distance along the primary mandrel 2a, and, as desired, moved to one of the other locations one or more times. Thus, in this manner, the location of the auxiliary mandrel 2b may be adjusted, which may result in the location of an auxiliary lumen defined by the auxiliary mandrel 2b being moved to desired locations, as shown in FIG. 4C and as described elsewhere herein.

[0091] For example, in position A1 shown in FIG. 4A, one of the horn gears 72a may include a passage 73a therethrough, e.g., aligned with the central axis of the horn gear 72a, and the auxiliary mandrel 2b may pass through the passage 73a, e.g., from the source 52b towards the primary mandrel 2a where it exits the guide 60. If liner material is wrapped or otherwise disposed around the auxiliary mandrel 2b, a guide (not shown) may be provided before, after, or within the passage 73a to wrap or otherwise dispose the liner material around the auxiliary mandrel 2b. Optionally, if additional auxiliary lumens are to be provided in the tubular bodies 8, one or more additional horn gears may also include such passage(s) and/or guide(s) for guiding corresponding auxiliary mandrel(s) therethrough.

[0092] As described further below, in this location, the auxiliary mandrel 2b may be at least partially braided into the reinforcement members 6 adjacent the primary mandrel 2a, i.e., with some reinforcement members 6 surrounding both the primary mandrel

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2a and the auxiliary mandrel 2b, and some reinforcement members 6 surrounding only the primary mandrel 2a, as identified by auxiliary mandrels A1 shown in FIG. 4C. By comparison, in location A2, i.e., with the auxiliary mandrel 2b directed immediately adjacent the primary mandrel 2a, e.g., through the guide 60, all of the reinforcement members 6 may surround both the primary mandrel 2a and the auxiliary mandrel 2b, thereby positioning the auxiliary mandrel 2b closest to the primary mandrel 2a along the tubular device 8. Finally, in location A3, i.e., with the auxiliary mandrel 2b outside the path of the horn gears 72, e.g., outside the path 78 shown in FIG. 4B, or otherwise directed towards the primary mandrel 2a after the braiding operation, all of the reinforcement members 6 may only surround the primary mandrel 2a and the auxiliary mandrel 2b may remain outside all of the reinforcement members 6, e.g., closest to the outer surface of the tubular device 8 shown in FIG. 4C.

[0093] Optionally, if desired, individual carriers may be loaded with multiple reinforcement members (not shown), e.g., such that multiple reinforcement members are braided adjacent one another in each direction from each carrier. For example, with the auxiliary mandrel 2b directed from location A1, a first set of reinforcement members 43a may travel and be braided in a first direction by the horn gears 72 such that all of the windings of the first set 43a pass between the auxiliary mandrel 2b and the primary mandrel 2a at that specific horn gear. A second set of reinforcement members 43b may travel and be braided in a second opposite direction by the horn gears 72 such that all of the windings of the second set 43b pass over the auxiliary mandrel 2b at that specific horn gear. Otherwise, the reinforcement members may pass over and under one another according to the arrangement of horn gears 72 and carriers 74 loaded onto the reinforcement source 70, which pattern generally alternates at each subsequent horn gear, e.g., as described in U.S. Publication No. 2014/ 0323964, incorporated by reference herein.

[0094] In addition, with the auxiliary mandrel 2b in position A1, one of the horn gears 72a may include a passage 73a therethrough, e.g., aligned with the central axis of the horn gear 72a, and the auxiliary mandrel 2b may pass through the passage 73a, e.g., from the source 52b towards the primary mandrel 2a where it exits the guide 60. If liner material is wrapped or otherwise disposed around the auxiliary mandrel 2b, a guide (not shown) may be provided before, after, or within the passage 73a to wrap or otherwise dispose the liner material around the auxiliary mandrel 2b.

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[0095] Optionally, if additional auxiliary lumens are to be provided in the tubular bodies 8, one or more additional horn gears may also include such passage(s) and/or guide(s) for guiding corresponding auxiliary mandrel(s) therethrough, e.g., to provide auxiliary mandrel(s) in location A1, or additional auxiliary mandrel(s) may be provided at
5 locations A2 and/or A3, as desired.

[0096] With further reference to FIG. 4A, as can be seen, the primary mandrel 2a may exit the guide 60 with the liner material 4a being wrapped substantially around the primary mandrel 2a. With the auxiliary mandrel 2b directed from the desired location, the auxiliary mandrel 2b may be directed towards the primary mandrel 2a such that the
10 auxiliary mandrel 2a is disposed adjacent the primary mandrel 2a, e.g., before braiding (location A2), braided into the reinforcement members 6 (location A1), or after braiding (location A3).

[0097] At any time, the auxiliary mandrel 2b may be moved to a different location than its current one to transition the auxiliary mandrel 2b to the desired position
15 relative to the primary mandrel 2a and/or reinforcement members 6. Thus, in this manner, all of the reinforcement members 6 may surround the primary mandrel 2a, while all, some, or none of windings 43a may surround the auxiliary mandrel 2b, as shown in FIG. 4C. This transition may be performed substantially continuously, e.g. by directing the auxiliary mandrel 2b to the desired location after a predetermined length or portion of the tubular
20 device 7 has been braided in the desired manner. Alternatively, discrete lengths or portions may be braided in the desired manner, e.g., by stopping the apparatus 50, removing and repositioning the auxiliary mandrel 2b to position the auxiliary mandrel 2b to the desired relative to the primary mandrel 2a and/or reinforcement members 6, and then resuming operation for a desired time and/or length. This process may be repeated as many times as
25 desired, e.g., to produce tubular devices, such as the apparatus 10A, 10B shown in FIGS. 2 and 3.

[0098] Returning to FIGS. 4A and 4B, the drive mechanism 80 may include one or more components for pulling or otherwise directing the mandrels 2 through the apparatus 50. For example, the drive mechanism 80 may include a pair of spaced-apart rollers 82
30 coupled to a motor (not shown) that engage the reinforcement-wrapped mandrels 2 and apply sufficient tension to pull the mandrels 2 from their sources 52 through the guide 60 and/or horn gear 72a while the reinforcement members 6 are braided around the mandrels 2. Alternatively, the drive mechanism may be provided before the reinforcement members 6

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are braided around the mandrels 2, e.g., pushing the primary mandrel 2a through the braiding operation and potentially pulling the auxiliary mandrel 2b by the braiding action itself. Optionally, other drive mechanisms and/or tension adjusters (not shown) may be provided for maintaining a desired tension and/or otherwise guiding the mandrels 2, liners 4, reinforcement members 6, and assembled device in a desired manner along the fabrication path.

[0099] Optionally, as shown in FIG. 4A, the jacket source 90 may be provided for applying one or more layers of jacket material around the reinforcement-wrapped mandrels 2. For example, a co-extruder, laminator, or other applicator may be provided that applies melted, uncured, and/or otherwise raw jacket material 7, e.g., from a hopper or other container (not shown), or rolls sheets of jacket material 7 may be wrapped around the reinforcement members 43 and mandrels 2. For example, for thermoplastic or other flowable materials, a heater (not shown) within a co-extruder may melt or otherwise soften the jacket material 7 to allow the jacket material 7 to flow around the reinforcement members 43 and into contact with the liner material 4 surrounding the mandrels 2 (or the mandrels 2 directly if no liner material is provided). Alternatively, the jacket material 7 may be a thermoset plastic or other material such that components of the jacket material 7 may be delivered into the co-extruder, e.g., as a liquid, powder, and the like, and mixed to form a slurry that is delivered around the reinforcement-wrapped mandrels 2. The components may chemically or otherwise react with one another and/or be heat fused to form a solid jacket 7 once cured. Exemplary materials for the jacket material 7 include plastics, e.g., thermoplastics, such as polyether block amide, nylon, or urethanes, thermoset plastics, metals, or composite materials. Alternatively, other processing may be used to bond or otherwise attach the jacket material 7 to the liner material 4 and/or embed the reinforcement members 43 in the jacket material 7, thereby resulting in an integral tubular body 8.

[00100] The resulting tubular body 8 (with or without jacket material 7) may be collected, e.g., on a capture reel or in a container (not shown). Thereafter, the tubular body 8 may be further processed to make a catheter, sheath, or other device. For example, a cutter or other tool (not shown) may separate the tubular body 8 into individual tubular shafts, e.g., before or after removing the mandrels 2. For example, the mandrels 2 may remain within the tubular body 8 when cut into individual devices, and then may be removed, resulting in a primary lumen and an auxiliary lumen, e.g., similar to the apparatus

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10 shown in FIG. 1B. Alternatively, if the friction between the mandrels 2 and the surrounding material is relatively low, the mandrels 2 may be removed before the tubular body 8 is cut into individual devices.

5 [00101] The resulting inner surface 41a of the primary lumen 18a may have a substantially uniform cross-section, e.g., as shown in FIG. 1B. Similar the auxiliary lumen 18b may also have a substantially uniform cross-section, e.g., also as shown in FIG. 1B or may have a variable cross-section, if desired (not shown).

10 [00102] Other components may be added to the individual tubular devices, as desired for the particular application. For example, for a steerable catheter, such as the apparatus 110 shown in FIG. 5, a steering element 136 may be inserted through the auxiliary lumen 118b (created when the auxiliary mandrel 2b is removed). In an alternative embodiment, the auxiliary mandrel 2b may remain within the tubular device to provide the steering element, e.g., if the friction between the outer surface of the auxiliary mandrel 2b and the liner or other material defining the auxiliary lumen are relatively low. A tip or other component (not shown) may be attached to a distal end 114 of the apparatus 110, e.g., after attaching the distal end 136b of the steering element 136 to the tip. The other end of the steering element may be coupled to an actuator of a handle attached to a proximal end of the tubular device, e.g., similar to the embodiment shown in FIG. 1A and described elsewhere herein.

20 [00103] For the apparatus 210 shown in FIG. 6, the auxiliary lumen 218b may be formed by positioning the auxiliary mandrel 2b in location A2 (shown in FIGS. 4B and 4C or optionally in location A1 for at least some portions) and generally braiding the reinforcement material 6 around both the primary and auxiliary mandrels 2a, 2b, except that at the segments corresponding to the locations of the electrodes 238, the auxiliary mandrel 2b may be moved to location A3 and then returned back to location A2 (or A1). After the outer layer 244 has been applied around the reinforcement members 242, the mandrels may be removed to provide an auxiliary lumen with segments 218b-1 braided into or under the reinforcement layer 242 other than segments 218b-2 at the electrode locations.

30 [00104] One or more wires 236 may be directed into the auxiliary lumen 218b (or may be used as the auxiliary mandrel, if desired), and the segments 218b-2 may be accessed, e.g., by cutting into the outer layer 244 to expose the wire(s), which may then be coupled to the electrodes 238 mounted on the apparatus 210.

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[00105] Alternatively, the auxiliary mandrel 2b may remain at location A2 (or A1) for the entire length of the tubular body 8, and a segment of the auxiliary mandrel 2b may be manually (or automatically) pulled out from within the braid of the reinforcement members 6, as shown in FIG. 7A before applying the outer layer 244. In this alternative, the auxiliary lumen 318b may be discontinuous, i.e., communicating with side openings 319. One or more wire(s) may be directed into the auxiliary lumen 318b such that regions of the wire(s) exit and reenter the side openings 319. These regions may then be exposed and/or otherwise coupled to an electrode (not shown) mounted on the apparatus 310.

[00106] Turning to FIGS. 8A and 8B, optionally, in any of the embodiments herein, the size of the auxiliary lumen 418b may be varied at desired locations along the apparatus 410, e.g., by using an auxiliary mandrel having a variable diameter or other cross-section (not shown). For example, in the apparatus 410 shown in FIG. 8A, an auxiliary lumen 318b is provided adjacent a central lumen 318a, which may be positioned relative to the central lumen 318a and/or reinforcement members (not shown), similar to other embodiments herein. As shown, the auxiliary lumen 418b includes a first or proximal segment 318b-1 having a first diameter and extending from a side opening 319 along a portion of the apparatus 410. The auxiliary lumen 418b then transitions to a second segment 418b-2 having a second diameter smaller than the first diameter.

[00107] Such an auxiliary lumen 418b may be formed using an auxiliary mandrel having regions corresponding to the first and second diameters and lengths of the segments. As shown in FIG. 8B, a steering element 436 may be provided that has similar diameters and regions (e.g., slightly smaller than the first and second diameters). After removing the auxiliary mandrel, the steering element 436 may be loaded into the auxiliary lumen 418b through the side opening 419 and the distal segment (not shown) may be coupled to the distal end of the apparatus 410, similar to other embodiments herein. Alternatively, the auxiliary mandrel itself may be used as the steering element, also similar to other embodiments herein. This configuration may enhance pushability of the apparatus 410, e.g., since the proximal, larger segment may be relatively stiffer than the distal, smaller segment.

[00108] Optionally, in any of the embodiments herein, one or more stiffening members may be added to desired portions of the apparatus. For example, FIGS. 9A and 9B show an exemplary embodiment of an apparatus 510 including a central lumen 518a and

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auxiliary lumen 518b, which may be surrounded and/or braided into a reinforcement layer 542, similar to other embodiments herein.

[00109] Unlike previous embodiments, a pair of stiffening members 536 have also been braided into the reinforcement layer 542. For example, with reference to the apparatus 50 in FIGS. 4A-4C, at desired portions of the tubular body 8, one or more stiffening members (not shown) may be directed adjacent the primary mandrel 2a, e.g., at positions similar to A1 (to braid the stiffening members into the reinforcement members 6. In this manner, the supported portion(s) may have greater column strength than other unsupported portions of the resulting apparatus 510.

[00110] Turning to FIGS. 10-11J, an exemplary method for making a steerable catheter 610 (best seen in FIG. 11J) that generally includes a proximal end 612, a distal end 614, and one or more lumens 616 extending therebetween, similar to other embodiments herein. For example, as shown in FIG. 11J, the catheter 610 includes a central or primary lumen 616a and a pair of steering lumens 616b slidably receiving respective pull wires 636 coupled to a pull wire ring 638 adjacent the distal end 614. The catheter 610 may be fabricated using similar materials and methods to the previous embodiments, e.g., using a braiding apparatus, similar to that shown in FIGS. 4A and 4B.

[00111] For example, turning to FIG. 10, a mandrel/reinforcement subassembly 640 may be made by braiding a plurality of reinforcement members 643 around a primary mandrel 2a and at least partially around a pair of secondary mandrels 2b, e.g., with the location of the secondary mandrels 2b being changed in a predetermined manner along the length of the subassembly 640. In the exemplary embodiment shown, along a first portion 640a of the subassembly 640, e.g., corresponding to an intermediate and/or proximal portion of the catheter 610, the secondary mandrels 2b are braided into the reinforcement members 643, e.g., such that some of the members 643 are disposed between the primary and secondary mandrels 2a, 2b, and some members surround both the primary and secondary mandrels 2a, 2b, as shown in FIG. 10A.

[00112] At a second portion 640b, e.g., corresponding to a distal portion of the catheter 610, the secondary mandrels 2b transition such all of the reinforcement members 643 are braided around only the primary mandrel 2a, as shown in FIG. 10B. Braiding of the reinforcement members 643 may continue beyond the ends of the secondary mandrels 2b, e.g., as shown in FIG. 10C.

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[00113] One or more outer layers may then be applied around the subassembly 640 to provide the final catheter 610. For example, as shown in FIG. 11A, a plurality of tubular jackets 650 may be applied around the subassembly 640, e.g., having different materials and/or mechanical properties, as desired for the different portions of the catheter 610. The jackets 650 may be sized to have the subassembly 640 inserted into them such that they abut or are otherwise disposed adjacent one another around the subassembly 640. In addition, a tubular jacket and/or shim 652 (where at least the outer part of the shim 652 is ultimately removable) may be positioned around the subassembly 640, e.g., around the portion 640b such that the shim 652 at least partially covers the unconstrained ends of the secondary mandrels 2b.

[00114] Subsequently, the resulting assembly 660 may be reflowed, heated, and/or otherwise laminated, e.g., similar to other embodiments described elsewhere herein. The shim 652 may then be removed, as shown in FIG. 11C, and then the mandrels 2b may also be removed, as shown in FIGS. 11D and 11E. As shown in FIG. 11E, a shoulder 664 (at the right of the assembly 660) remains at the junction between the tubular jackets 650 and the removed shim 652 with the lumens 616b created by removal of the secondary mandrels 2b exiting from the face of the shoulder 664 in a position radially outward from the reinforcement members 643 present in the portion 640b.

[00115] Turning to FIG. 11F, a pull wire ring 638 having pull wires 636 extending from its proximal edge may then be inserted over the portion 640b with the pull wires 636 may be loaded into the lumens 616b. For example, distal ends 636b of the pull wires 636 may be attached to the proximal edge of the ring 638, e.g., by welding, soldering, bonding with adhesive, and the like before the ring 638 is inserted over the portion 640b. This allows the pull wires 636 to be inserted into the auxiliary lumens 616b (not shown in FIG. 11F; see, e.g., FIG. 11E) without taking a substantial bend and the pull wire ring 638 may abut the shoulder 664.

[00116] As shown in FIG. 11G, the reinforcement members 643 may then be trimmed at or near the distal edge of the pull wire ring 638 with the pull wire ring constraining the reinforcement members 643 such that, as shown in FIG. 11I, a subsequent jacket and or tip may be bonded, laminated, reflowed or otherwise attached over and/or beyond the pull wire ring 638 without risk of the reinforcement members 643 rising to or protruding through the surface. Using this method, tip defects may be minimized, stress on

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the pull wire may be minimized, and/or the assembly may be otherwise considerably improved.

[00117] Optionally, the pull wire ring 638 may include one or more features (e.g., holes, slots, etc. not shown) to enhance attachment to the catheter shaft, tip, etc. In addition or alternatively, a thermoplastic liner (e.g., with a coating, similar to other embodiments herein) may be provided on the distal end to enable discrete tip sections to be added and subsequently laminated creating a highly manufacturable device with a completely contiguous/welded liner surface with no edges, discontinuities, or potential for delamination, skiving, leakage, and the like.

10 [00118] Configuring the ring 638 and/or tip jacket components in this manner may provide one or more advantages. For example, lapping the braid or reinforcement layer into and through the ring 638 may eliminate a common kink point that may be a limitation with current devices. In addition, this configuration may eliminate problems with cut end wire protrusions as they are fully constrained within the ring 638. In addition, this
15 configuration may provide locations for pull wire lumens that substantially align with desired positions of pull wires, which may ease assembly, enhance integrity of the tip, and/or improve alignment of pull forces.

[00119] With reference to the previous embodiments, it will be appreciated that lumens and/or mandrels used to create them as described may be replaced by wires,
20 conductors, optical fibers, axial reinforcing elements, e.g., aramid fibers, UHMWPE, or other axial elements. In order to incorporate such elements into the catheter construction for the purpose of achieving desired mechanical or functional performance.

[00120] The foregoing disclosure of the exemplary embodiments has been presented for purposes of illustration and description. It is not intended to be exhaustive or
25 to limit the invention to the precise forms disclosed. Many variations and modifications of the embodiments described herein will be apparent to one of ordinary skill in the art in light of the above disclosure.

[00121] Further, in describing representative embodiments, the specification may have presented the method and/or process as a particular sequence of steps. However, to the
30 extent that the method or process does not rely on the particular order of steps set forth herein, the method or process should not be limited to the particular sequence of steps described. As one of ordinary skill in the art would appreciate, other sequences of steps

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may be possible. Therefore, the particular order of the steps set forth in the specification should not be construed as limitations on the claims.

[00122] While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein
5 described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the scope of the appended claims.

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We claim:

1. A method for making a tubular body, comprising:
 - directing a primary mandrel along a central axis of a braiding apparatus such that the primary mandrel is surrounded by a plurality of reinforcement carrying elements;
 - 5 providing a plurality of reinforcement carrying elements in a predetermined configuration relative to the central axis;
 - providing a source of a secondary mandrel at a first location adjacent to the primary mandrel and offset from the central axis;
 - with the secondary mandrel feeding from the source at the first location, wrapping
10 reinforcement members from the reinforcement carrying elements helically around a first portion of the primary mandrel such that some windings of the one or more reinforcement members surround the primary mandrel and pass between the primary mandrel and the secondary mandrel and some windings of the one or more reinforcement members surround both the primary and secondary mandrels;
 - 15 moving the source of secondary mandrel to a second location;
 - with the secondary mandrel feeding from the source at the second location, wrapping reinforcement members from the reinforcement carrying elements helically around a second portion of the primary mandrel such that either a) all of the reinforcement members also surround the secondary mandrel; or b) the second secondary mandrel remains
20 outside the reinforcement members;
 - applying an outer jacket around the primary and secondary mandrels after wrapping the one or more reinforcement members therearound; and
 - removing the primary mandrel to define a primary lumen within the tubular body.

- 25 2. The method of claim 1, further comprising removing the secondary mandrel to define an auxiliary lumen within the tubular body that extends along a first portion of the tubular body adjacent the primary lumen within a braid of the reinforcement members, and that extends along a second portion of the tubular body either a) adjacent the primary lumen such that all of the reinforcement members surround both the primary and secondary lumens
30 or b) adjacent the primary lumen such that auxiliary lumen is disposed outside the reinforcement members.

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3. The method of claim 2, wherein the secondary mandrel is removed after applying the outer jacket.

4. The method of claim 1, wherein the primary mandrel is removed after
5 applying the outer jacket.

5. The method of claim 1, further comprising wrapping a first liner at least partially around the primary mandrel before directing the primary mandrel along the central axis of the braiding apparatus such that first liner is secured around the primary mandrel
10 when the one or more reinforcement members are wrapped around the primary mandrel.

6. The method of claim 5, wherein the first liner is wrapped at least partially around the primary mandrel such that a coated surface of the first liner contacts the primary mandrel, and wherein the coated surface at least partially defines a lumen of the primary
15 lumen when the primary mandrel is removed.

7. The method of claim 6, wherein the coated surface comprises at least one of a hydrophilic material and a lubricious material.

8. The method of claim 5, further comprising wrapping a second liner at least partially around the secondary mandrel before directing the secondary mandrel substantially parallel to the primary mandrel such that second liner is secured around the secondary mandrel when the one or more reinforcement members are wrapped around the primary
20 mandrel.

9. The method of claim 1, further comprising separating the tubular body into a plurality of tubular shafts for individual catheters or sheaths.

10. The method of claim 9, further comprising:
30 slidably introducing a steering element into the auxiliary lumen of a first tubular shaft;
coupling a distal end of the steering element to a first end of the tubular shaft; and

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coupling a proximal end of the steering element to an actuator on a second end of the tubular shaft.

11. The method of claim 1, wherein applying the outer jacket comprises
5 extruding jacket material around the primary and secondary mandrels after wrapping the one or more reinforcement members therearound.

12. The method of claim 1, wherein directing a primary mandrel through along
the central axis of the braiding apparatus, directing the secondary mandrel substantially
10 parallel to the primary mandrel and offset from the central axis, and wrapping one or more reinforcement members around the primary mandrel are performed substantially continuously.

13. The method of claim 1, wherein wrapping one or more reinforcement
15 members around the primary mandrel comprises:
winding a first set of reinforcement members around the primary mandrel in a first helical direction such that windings of the first set surround the primary mandrel without surrounding the secondary mandrel; and
winding a second set of reinforcement members around the primary mandrel in a
20 second helical direction different than the first helical direction such that windings of the second set surround both the primary mandrel and the second mandrel.

14. The method of claim 1, wherein wrapping reinforcement members with the
secondary mandrel feeding from the source at the first location comprises:
25 winding a first set of reinforcement members around the first portion of the primary mandrel in a first helical direction such that some windings of the first set surround the primary mandrel without surrounding the secondary mandrel and some windings of the first set surround both the primary mandrel and the second mandrel;
winding a second set of reinforcement members around the first portion of the
30 primary mandrel in a second helical direction different than the first helical direction such that some windings of the second set surround the primary mandrel without surrounding the secondary mandrel and some windings of the second set surround both the primary mandrel and the second mandrel.

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15. A method for making a tubular body using a braiding apparatus comprising a primary mandrel source configured to direct a primary mandrel along a central axis, a plurality of horn gears rotatably mounted around the central axis in a predetermined arrangement such that the horn gears rotate about respective horn gear axes and carriers travel along a generally circular path around the central axis during operation of the braiding apparatus, and a secondary mandrel source configured to direct a secondary mandrel towards the primary mandrel from one of a plurality of locations comprising a first location disposed adjacent the central axis within the generally circular path, a second location aligned with a horn axis of one of the horn gears, and a third location outside the generally circular path, the method comprising:

braiding a first portion of the primary mandrel by:

- a) directing the primary mandrel along the central axis;
- b) directing the secondary mandrel from one of the plurality of locations

15 towards the primary mandrel such that the secondary mandrel is disposed adjacent the first portion of the mandrel; and

- c) wrapping reinforcement members from the carriers around the first portion of the primary mandrel;

braiding a second portion of the primary mandrel by:

- a) moving the secondary mandrel source another of the plurality of locations;
- b) directing the primary mandrel further along the central axis; and
- c) wrapping reinforcement members from the carriers around the second portion of the primary mandrel;

25 applying an outer jacket around the first and second portions of the primary mandrel and the secondary mandrel; and

removing the primary mandrel to define a primary lumen within the tubular body.

16. The method of claim 15, further comprising:

30 braiding a third portion of the primary mandrel by:

- a) moving the secondary mandrel source to yet another of the plurality of locations;
- b) directing the primary mandrel further along the central axis; and

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c) wrapping reinforcement members from the horn gears around the third portion of the primary mandrel;

17. The method of claim 15, further comprising:
5 braiding a third portion of the primary mandrel by:

a) moving the secondary mandrel source back to the one of the plurality of locations when the first portion was braided;

b) directing the primary mandrel further along the central axis; and

c) wrapping reinforcement members from the horn gears around the
10 third portion of the primary mandrel.

18. The method of claim 15, wherein the first portion of the primary mandrel is braided with the secondary mandrel source at the first position such that the reinforcement members surround both the primary mandrel and the secondary mandrel along the first
15 portion.

19. The method of claim 15, wherein the first portion of the primary mandrel is braided with the secondary mandrel source at the second position such that some of the reinforcement members surround both the primary mandrel and the secondary mandrel
20 along the first portion and some of the reinforcement members are disposed between the primary mandrel and the secondary mandrel along the first portion.

20. The method of claim 15, wherein the first portion of the primary mandrel is braided with the secondary mandrel source at the third position such that the reinforcement
25 members surround only the primary mandrel and the secondary mandrel remains outside the reinforcement members along the first portion.

21. A tubular device for a catheter or sheath comprising a proximal end and a distal end sized for introduction into a patient's body, the tubular device comprising:
30 a central lumen extending between the proximal and distal ends;
an auxiliary lumen extending at least partially between the proximal and distal ends adjacent the central lumen;

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one or more reinforcement members comprising windings extending helically around the central lumen between the proximal and distal ends; and

one or more layers surrounding the one or more reinforcement members,

wherein the tubular device comprises a first portion in which at least some of the windings pass between the central and auxiliary lumens and at least some of the windings surround both the central and auxiliary lumens, and a second portion in which either a) all of the windings surround both the central and auxiliary lumens or b) all of the windings surround the central lumen and the auxiliary lumen is disposed outside the windings.

22. The tubular device of claim 21, wherein along the second portion all of the windings surround both the central and auxiliary lumens.

23. The tubular device of claim 22, wherein the tubular device further comprises a third portion adjacent the second portion in which a) at least some of the windings pass between the central and auxiliary lumens and at least some of the windings surround both the central and auxiliary lumens, or b) all of the windings surround the central lumen and the auxiliary lumen is disposed outside the windings.

24. The tubular device of claim 21, wherein along the second portion all of the windings surround the central lumen and the auxiliary lumen is disposed outside the windings.

25. The tubular device of claim 24, wherein the tubular device further comprises a third portion adjacent the second portion in which a) at least some of the windings pass between the central and auxiliary lumens and at least some of the windings surround both the central and auxiliary lumens, or b) all of the windings surround both the central and auxiliary lumens.

26. The tubular device of claim 21, wherein the central lumen is defined by a liner comprising an inner surface substantially surrounding the central lumen.

27. The tubular device of claim 26, wherein the liner comprises a lubricious coating on the inner surface.

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28. The tubular device of claim 21, wherein the auxiliary lumen is defined by a liner comprising an inner surface substantially surrounding the auxiliary lumen.

5 29. The tubular device of claim 21, wherein the auxiliary lumen is smaller than the central lumen.

30. The tubular device of claim 21, wherein the central lumen is substantially aligned around a central longitudinal axis extending between the proximal and distal ends, and wherein the auxiliary lumen is offset radially from the central axis.
10

31. The device of claim 30, further comprising a steering element disposed within the auxiliary lumen and coupled to the distal end, the steering element configured to apply an axial force to a distal portion of the tubular device and thereby generate a bending moment to bend the distal portion.
15

32. An apparatus for performing a procedure within a patient's body, comprising:

a tubular member comprising a proximal end, a distal end sized for introduction into a patient's body, a central axis extending therebetween, and a distal portion extending distally from an intermediate portion to the distal end;
20

a primary lumen extending between the proximal and distal ends and surrounding at least a portion of the central axis;

a steering element lumen extending at least partially between the proximal and distal ends adjacent the primary lumen;
25

a steering element slidably disposed within the steering element lumen and comprising a distal end fixed to the tubular member distal end and a proximal end adjacent the proximal end of the tubular member;

an actuator on the proximal end coupled to the steering element proximal end such that, actuation of the actuator applies axial tension or compression to the steering element, thereby causing the distal portion to bend;
30

one or more reinforcement members comprising windings extending around the primary lumen between the proximal and distal ends; and

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one or more layers surrounding the one or more reinforcement members,
wherein the tubular member comprises a first portion in which at least some of the
windings pass between the primary lumen and the steering element lumen and at least some
of the windings surrounding both the primary lumen and the steering element lumen, and a
5 second portion in which either a) all of the windings surround both the primary lumen and
the steering element lumen or b) all of the windings surround the primary lumen and the
steering element lumen is disposed outside the windings.

33. The apparatus of claim 32, wherein along the second portion all of the
10 windings surround both the central and auxiliary lumens.

34. The apparatus of claim 33, wherein the tubular device further comprises a
third portion adjacent the second portion in which a) at least some of the windings pass
between the primary lumen and the steering element lumen and at least some of the
15 windings surround both the primary lumen and the steering element lumen, or b) all of the
windings surround the primary lumen and the steering element lumen is disposed outside
the windings.

35. The apparatus of claim 32, wherein along the second portion all of the
20 windings surround the primary lumen and the steering element lumen is disposed outside
the windings.

36. The apparatus of claim 35, wherein the tubular device further comprises a
third portion adjacent the second portion in which a) at least some of the windings pass
25 between the primary lumen and the steering element lumen and at least some of the
windings surround both the primary lumen and the steering element lumen, or b) all of the
windings surround both the primary lumen and the steering element lumen.

37. The apparatus of claim 32, wherein the first portion is the distal portion of
30 the tubular member and the second portion is at least a portion of the intermediate portion of
the tubular member.

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38. The apparatus of claim 32, wherein the central lumen is defined by a liner comprising an inner surface substantially surrounding the central lumen.

5 39. The apparatus of claim 38, wherein the liner comprises a lubricious coating on the inner surface.

40. The apparatus of claim 32, wherein the steering element lumen is defined by a liner comprising an inner surface substantially surrounding the steering element lumen.

10 41. The apparatus of claim 32, wherein the steering element lumen is smaller than the primary lumen.

42. The apparatus of claim 32, wherein the primary lumen is substantially aligned around a central longitudinal axis extending between the proximal and distal ends, and wherein the steering element lumen is offset radially from the central axis.
15

43. The apparatus of claim 32, further comprising one or more treatment or diagnostic elements on the distal portion.

20 44. The apparatus of claim 32, wherein the primary lumen communicates with an outlet in the distal end.

45. The apparatus of claim 32, further comprising one or more sensors or electrodes on the distal portion.
25

46. The apparatus of claim 45, further comprising one or more conductors extending through the primary lumen from the tubular member proximal end to the distal portion and coupled to the one or more sensors or electrodes.
30

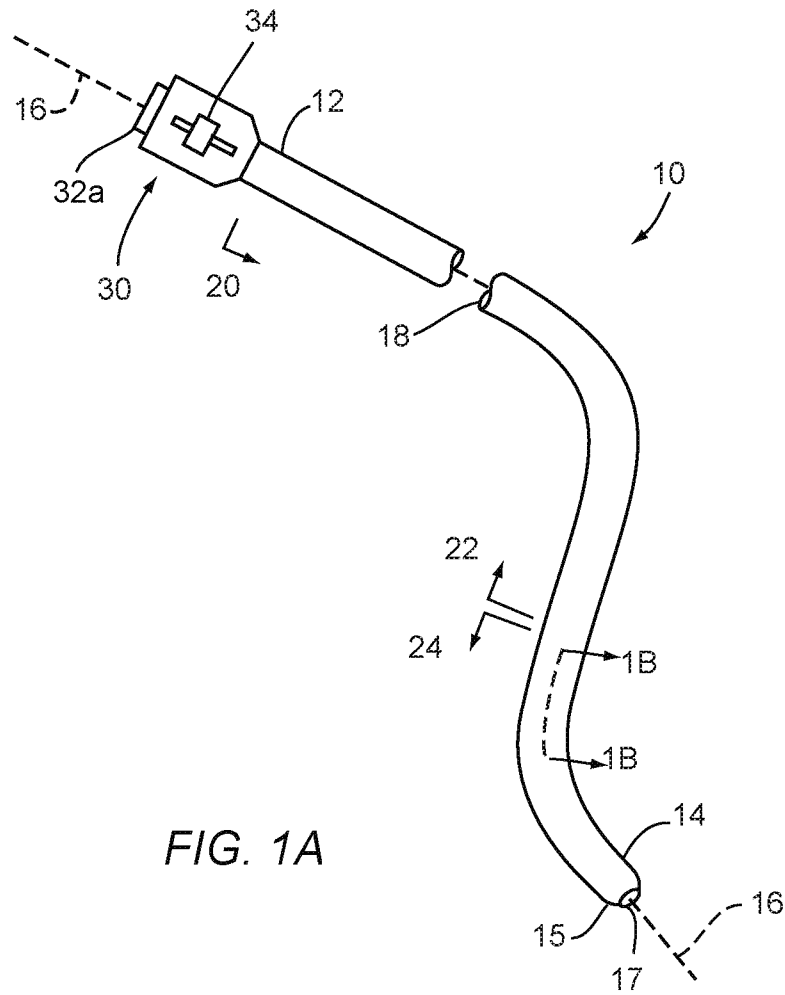


FIG. 1A

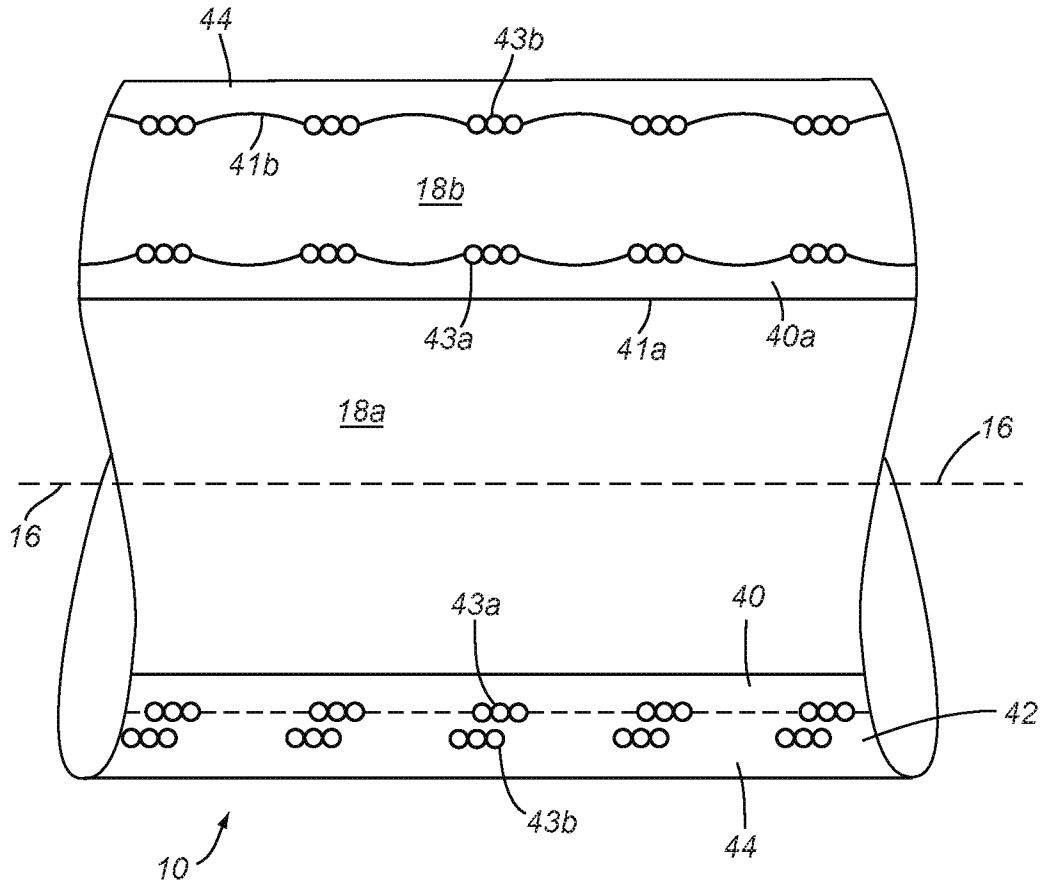


FIG. 1B

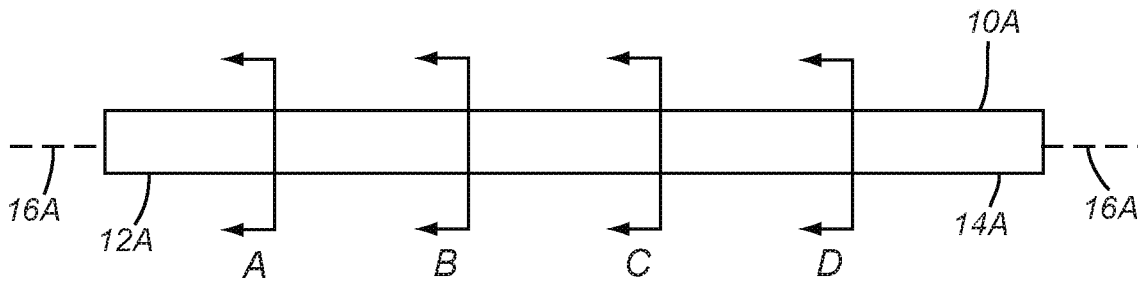


FIG. 2

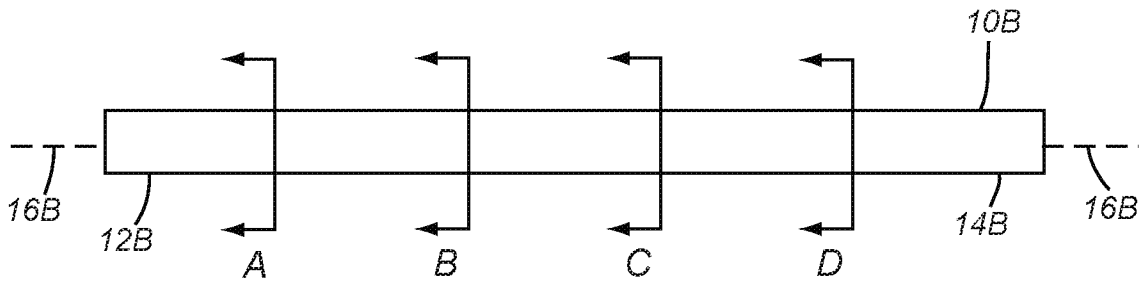
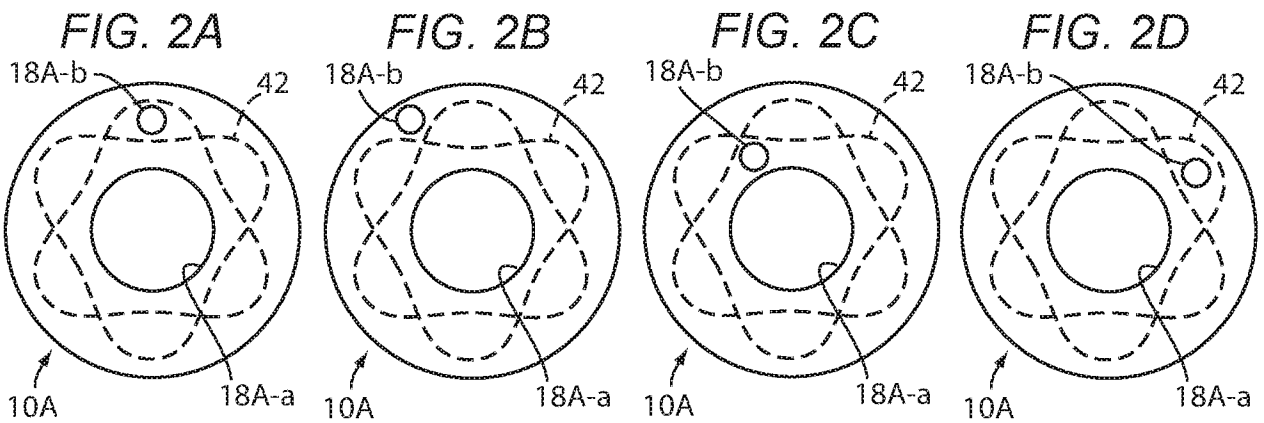
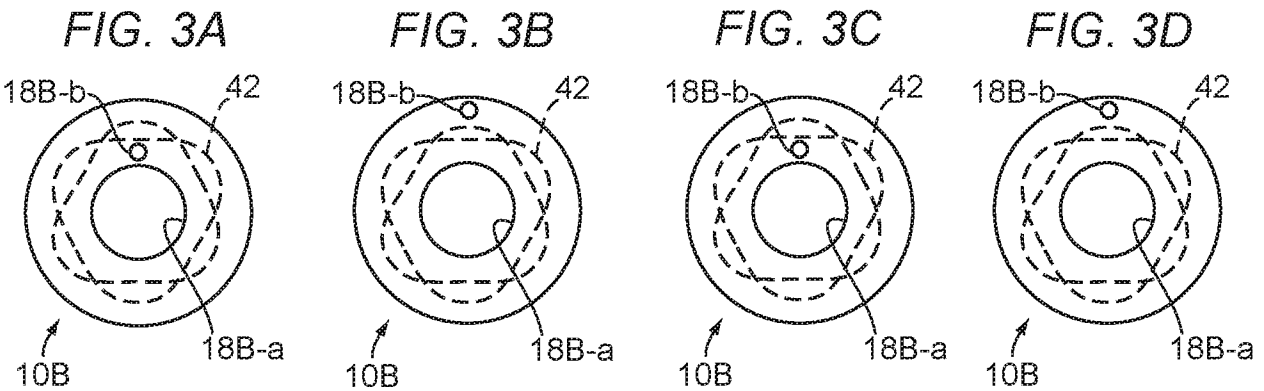


FIG. 3



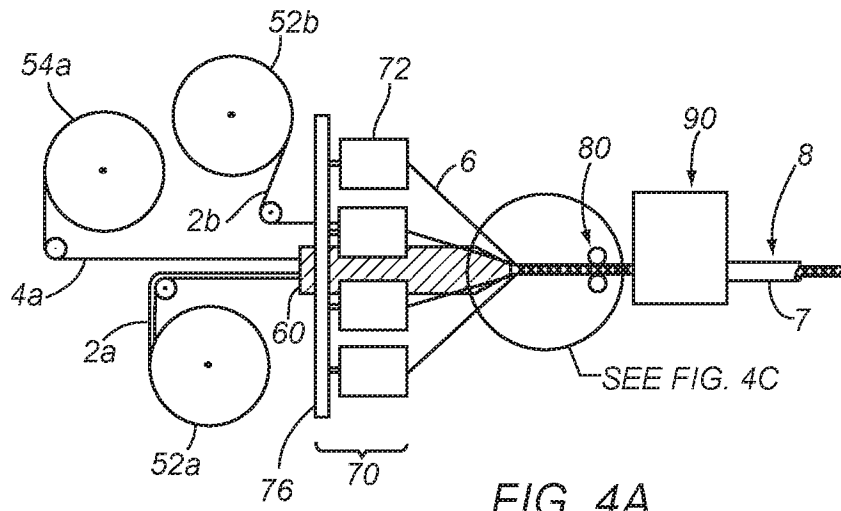


FIG. 4A

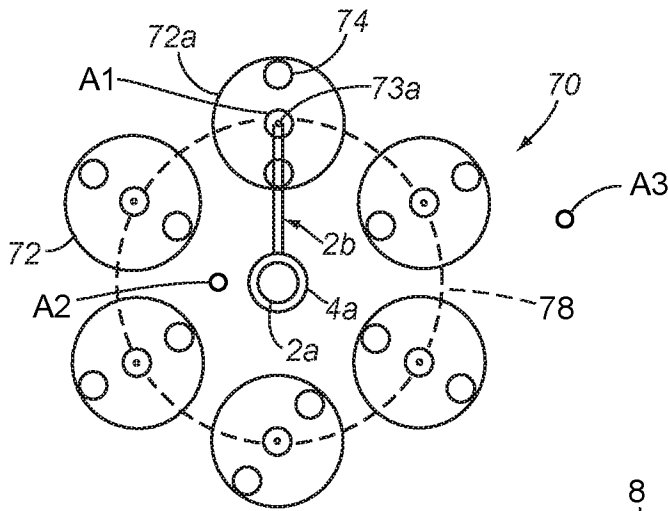


FIG. 4B

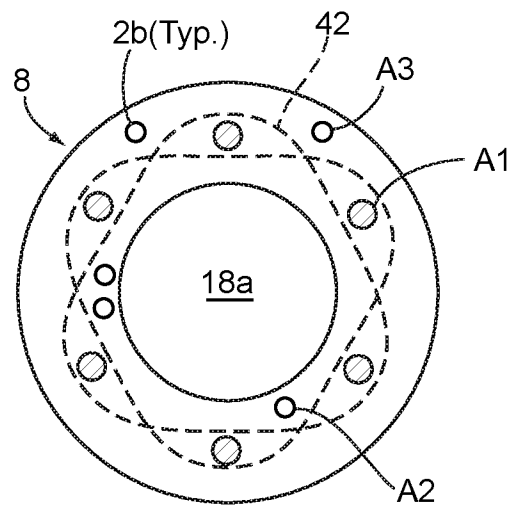


FIG. 4C

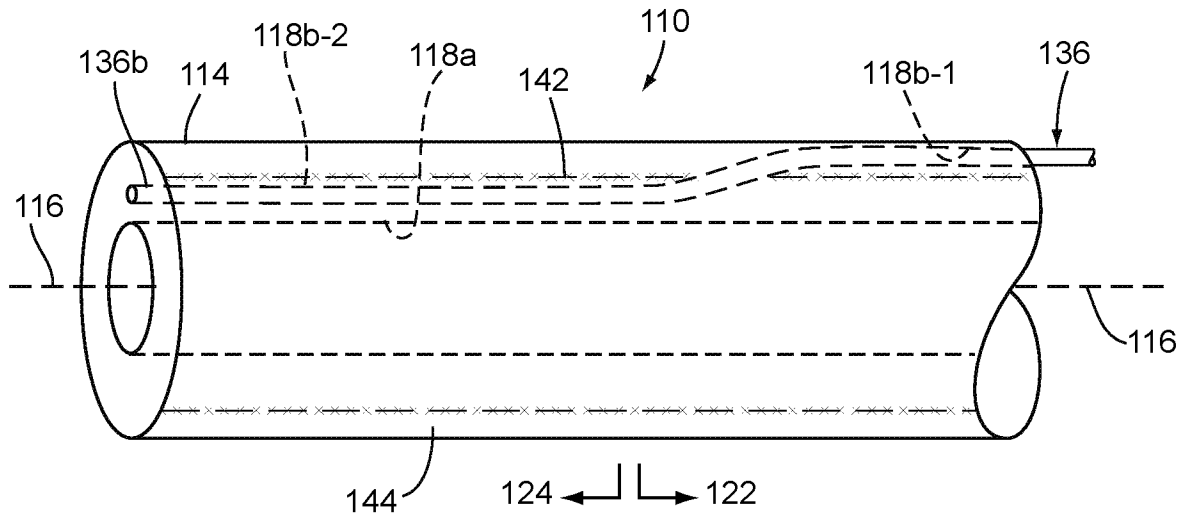


FIG. 5

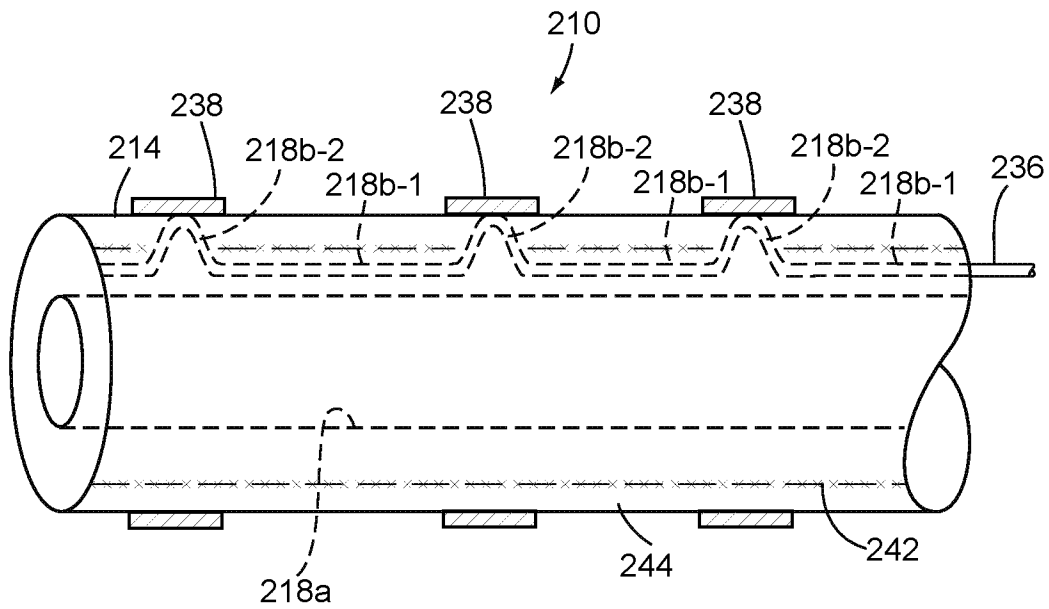


FIG. 6

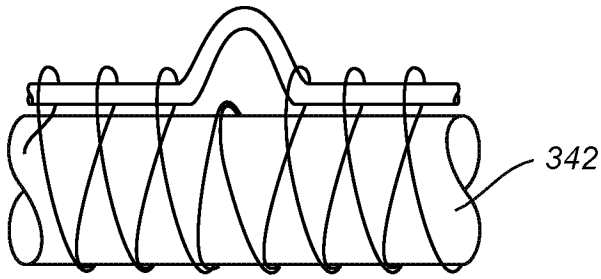


FIG. 7A

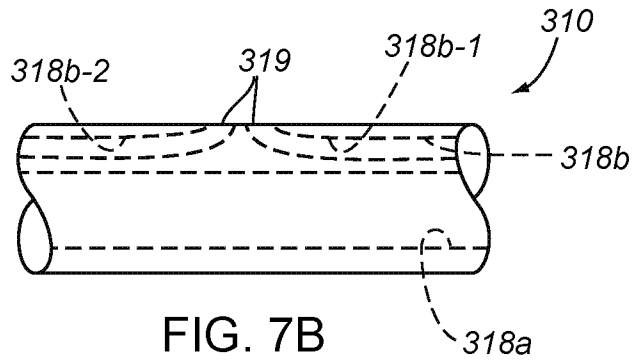


FIG. 7B

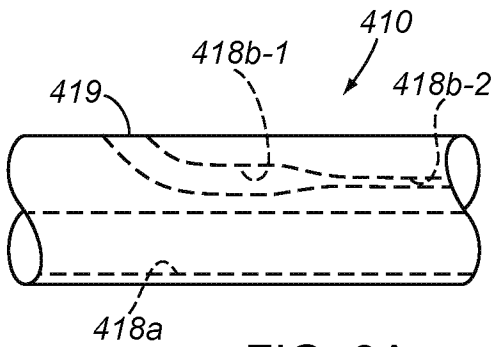


FIG. 8A

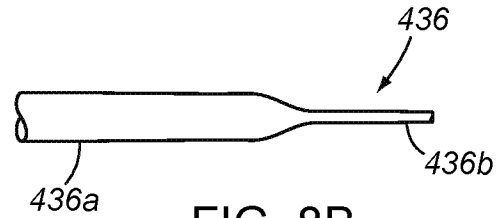


FIG. 8B

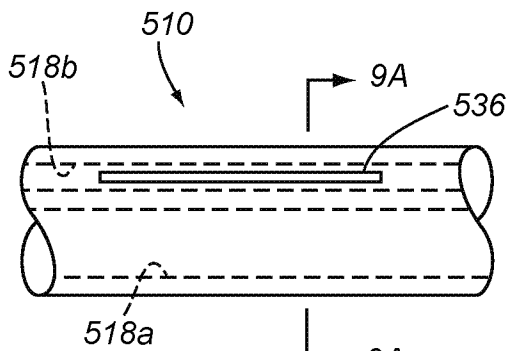


FIG. 9

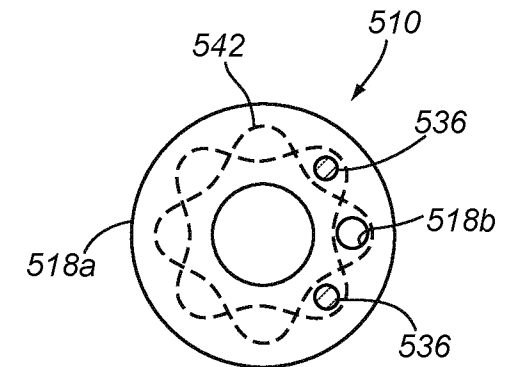


FIG. 9A

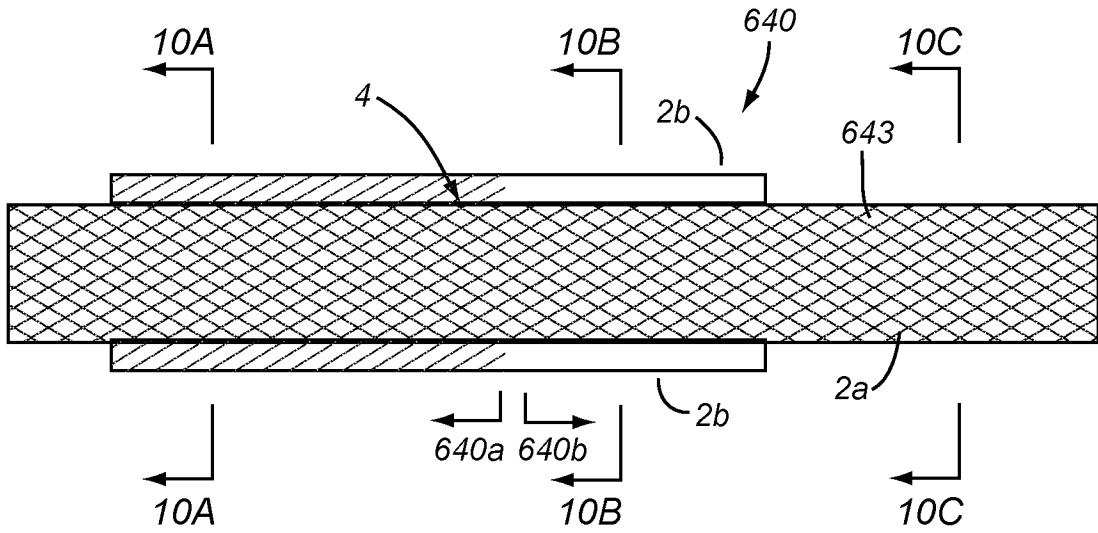


FIG. 10

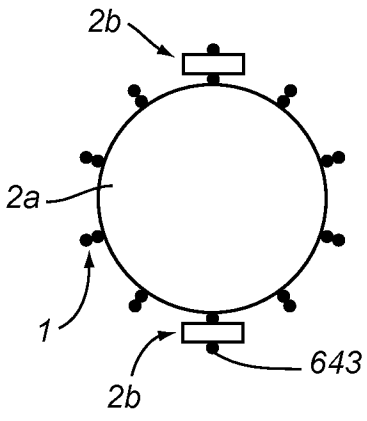


FIG. 10A

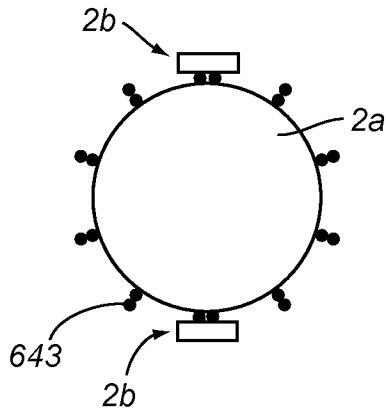


FIG. 10B

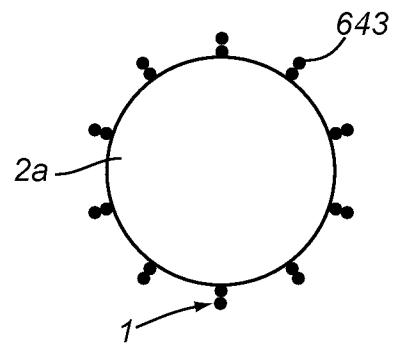
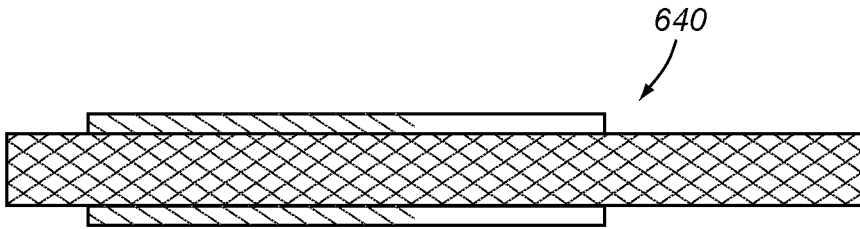


FIG. 10C



+

FIG. 11A



650

652 - JACKET STOP/SHIM

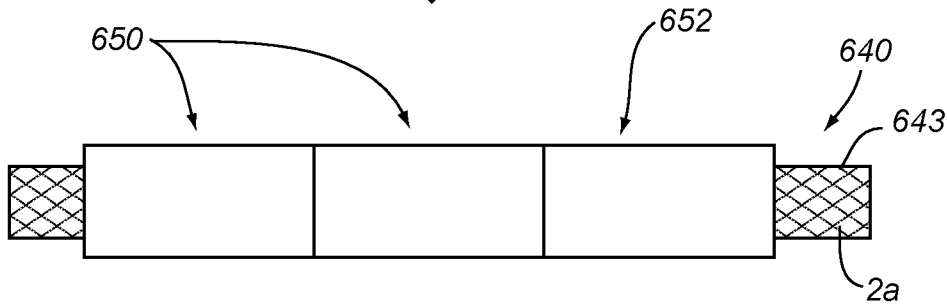


FIG. 11B

LAMINATE
& REMOVE JACKET STOP

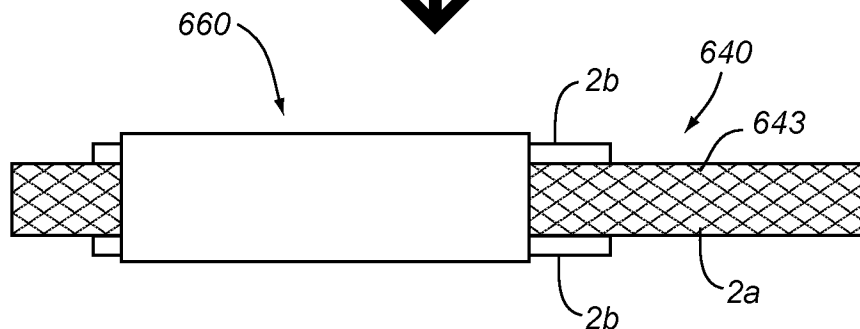


FIG. 11C

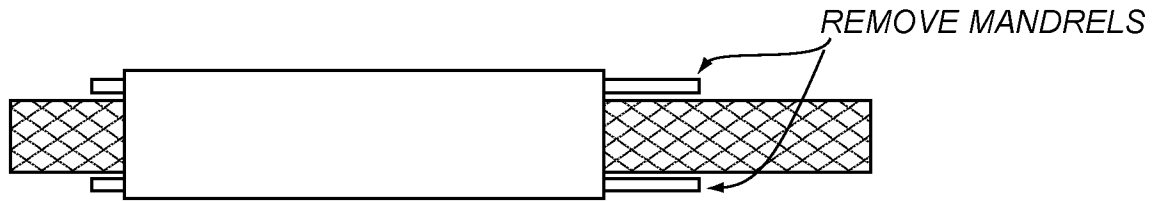


FIG. 11D

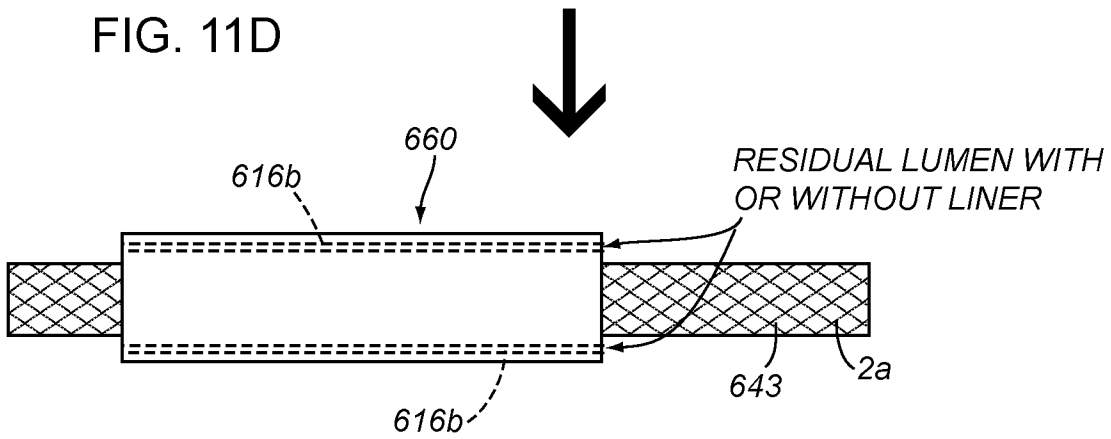


FIG. 11E

ADD PULL WIRE & TRIM BRAID

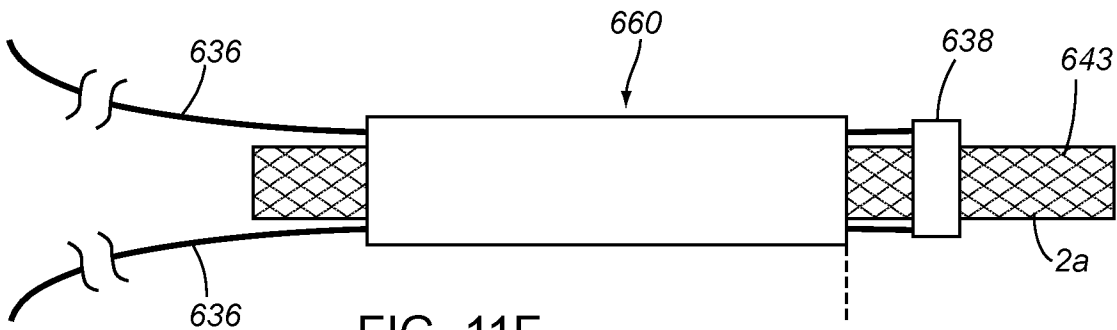


FIG. 11F

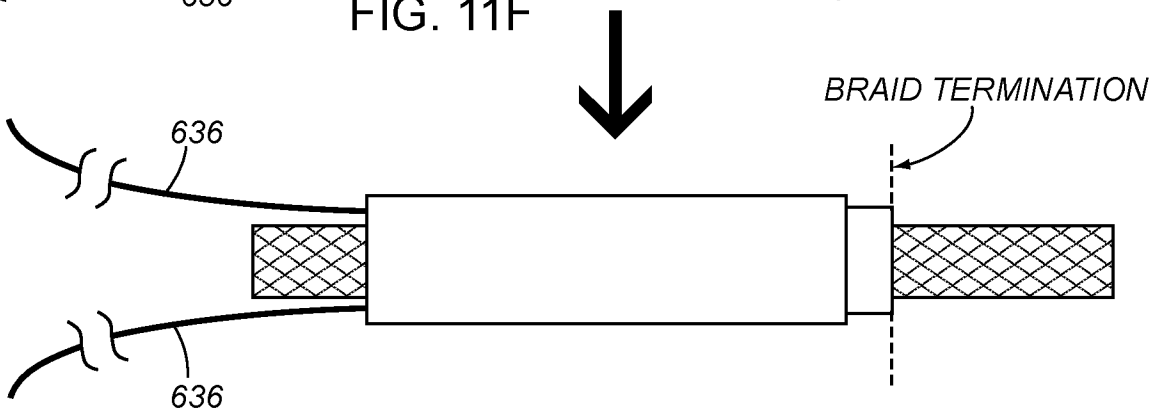


FIG. 11G

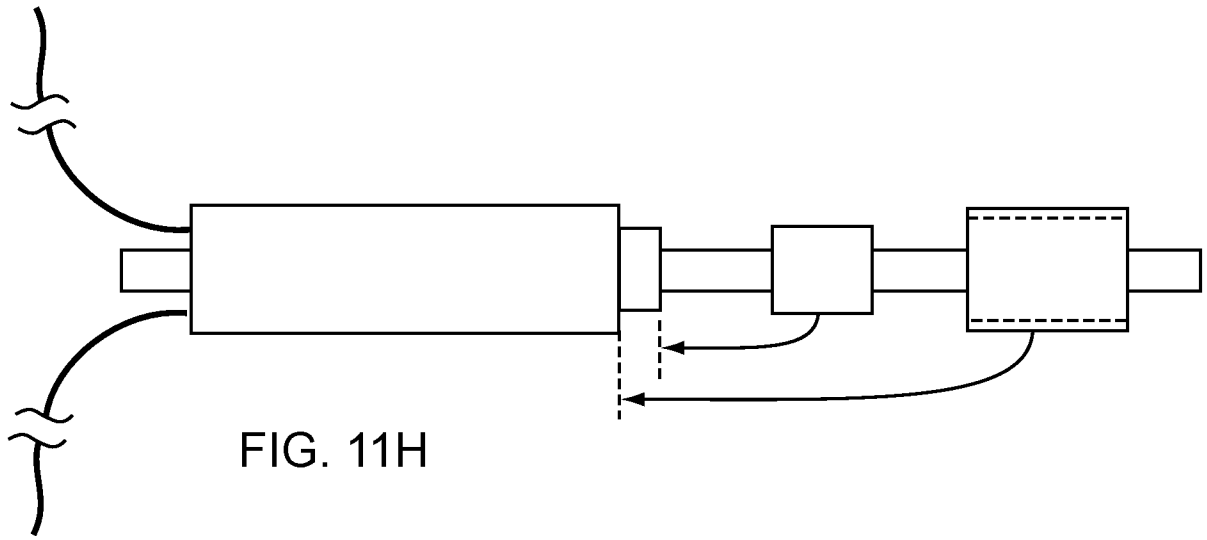


FIG. 11H

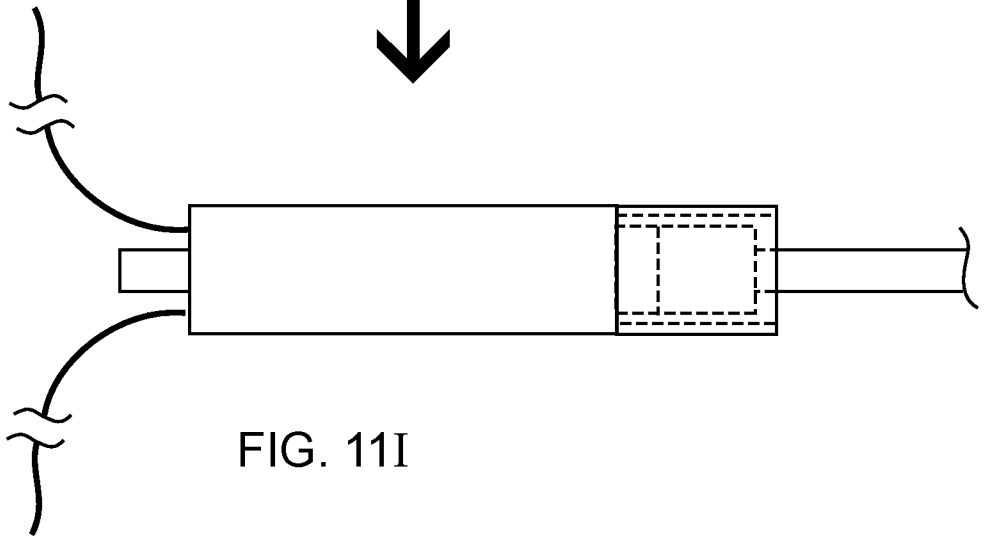


FIG. 11I

LAMINATE, TRIM, FORM, REMOVE
INNER MANDREL

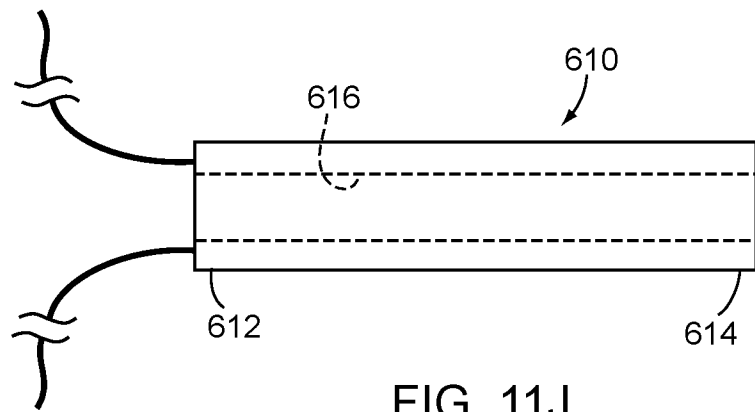


FIG. 11J

A. CLASSIFICATION OF SUBJECT MATTER**A61M 25/00(2006.01)i**

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

B. FIELDS SEARCHEDMinimum documentation searched (classification system followed by classification symbols)
A61M 25/00; B29C 59/00; A61B 18/14; A61B 17/00; B29D 23/00; A61M 25/16; B29C 47/06Documentation 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 modelsElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: tubular, mandrel, braid, lumen, reinforce**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2013-0046298 A1 (KAUFMAN, RALF et al.) 21 February 2013 See abstract; paragraphs [0008], [0028], [0052]; and claim 1.	1-46
A	US 2007-0075452 A1 (LEEFLANG, STEPHEN A. et al.) 05 April 2007 See abstract; claims 1-4; and figure 1.	1-46
A	US 8454578 B2 (LEEFLANG, STEPHEN A. et al.) 04 June 2013 See abstract; claim 1; and figures 1-2.	1-46
A	US 2013-0300036 A1 (WILKOWSKE, ERIC JOHN et al.) 14 November 2013 See abstract; claim 36; and figures 1-3.	1-46
A	US 2010-0059173 A1 (KAMPA, GREG et al.) 11 March 2010 See abstract; claim 1; and figures 1-5.	1-46

 Further documents are listed in the continuation of Box C. See patent family annex.

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"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

16 February 2016 (16.02.2016)

Date of mailing of the international search report

17 February 2016 (17.02.2016)

Name and mailing address of the ISA/KR

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2015/051284

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