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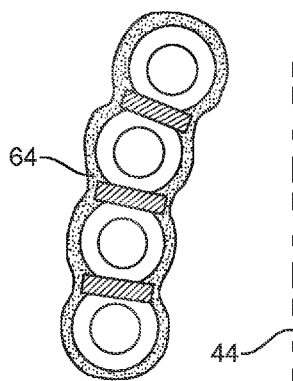


FIG. 10C

(57) Abstract: Articulation devices, systems, methods for articulation, and methods for fabricating articulation structures make use of balloon arrays, with inflation of the balloons locally altering articulation. Inflation fluid may be directed toward the balloons from an inflation fluid source via a series of channels, the balloons and channels included in a helical multi-balloon assembly. The balloons may be supported by encasing the helical balloon assembly in a polymer matrix, such as by winding the balloon assembly onto a mandrel and dip-coating some or all of the assembly in an elastomer such as a silicone, a urethane, or the like. The balloons may be supported by one or more spring, with loops of the spring(s) optionally being inward of the balloons, outward of the balloons, or interspersed between the balloons, and/or a mesh tube, braid, or other compliant materials may be included. Articulation balloon arrays may be disposed in an annular space bordered by inner and outer tubular sheaths, with a portion of one or both sheaths being axially slidable relative to the balloons so as to facilitate elongation and bending.



**MATRIX SUPPORTED BALLOON ARTICULATION SYSTEMS,
DEVICES, AND METHODS
FOR CATHETERS AND OTHER USES**

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of U.S. Provisional Application Serial No. 62/489,864, filed on April 25, 2017, which is incorporated by reference herein in its entirety for all purposes.

FIELD OF THE INVENTION

[0002] In general, the present invention provides structures, systems, and methods for selectively bending or otherwise altering the bend characteristics of catheters and other elongate flexible bodies, the lengths of such bodies, and the like. In exemplary embodiments the invention provides articulated medical systems having a fluid-driven balloon array that can help shape, steer and/or advance a catheter, guidewire, or other elongate flexible structure along a body lumen. Alternative embodiments make use of balloon arrays for articulating (or altering the stiffness of) flexible manipulators and/or end effectors, industrial robots, borescopes, prosthetic fingers, robotic arms, positioning supports or legs, consumer products, or the like.

BACKGROUND OF THE INVENTION

[0003] Diagnosing and treating disease often involve accessing internal tissues of the human body, and open surgery is often the most straightforward approach for gaining access to internal tissues. Although open surgical techniques have been highly successful, they can impose significant trauma to collateral tissues.

[0004] To help avoid the trauma associated with open surgery, a number of minimally invasive surgical access and treatment technologies have been developed, including elongate flexible catheter structures that can be advanced along the network of blood vessel lumens extending throughout the body. While generally limiting trauma to the patient, catheter-based endoluminal therapies can be very challenging. A number of additional minimally invasive surgical technologies have also been developed, including robotic surgery, and robotic systems for manipulation of flexible catheter bodies from outside the patient have also previously been proposed. Some of those prior robotic catheter systems have met with

challenges, in-part because of the difficulties in accurately controlling catheters using pull-wires. While the potential improvements to surgical accuracy make these efforts alluring, the capital equipment costs and overall burden to the healthcare system of these large, specialized systems is a concern.

[0005] A new technology for controlling the shape of catheters has recently been proposed which may present significant advantages over pull-wires and other known catheter articulation systems. As more fully explained in US Patent Publication No. US20160279388, entitled “Articulation Systems, Devices, and Methods for Catheters and Other Uses,” published on September 29, 2016 (assigned to the assignee of the subject application and the full disclosure of which is incorporated herein by reference), an articulation balloon array can include subsets of balloons that can be inflated to selectively bend, elongate, or stiffen segments of a catheter. These articulation systems can use pressure from a simple fluid source (such as a pre-pressurized canister) that remains outside a patient to change the shape of a distal portion of a catheter inside the patient via a series of channels in a simple multi-lumen extrusion, providing catheter control beyond what was previously available often without having to resort to a complex robotic gantry, without pull-wires, and even without motors. Hence, these new fluid-driven catheter systems appear to provide significant advantages.

[0006] Despite the advantages of the newly proposed fluid-driven catheter system, as with all successes, still further improvements would be desirable. In general, it would be beneficial to provide further improved articulation systems and devices, methods of articulation, and methods for making articulation structures. More specifically, it would be beneficial to identify assemblies and fabrication techniques that would facilitate the widespread use of articulation balloon arrays for altering the bending characteristics of catheters and other elongate flexible bodies. It would be particularly beneficial if these new technologies could simplify the overall structures, maintain alignment within balloon-array articulated structures during use, and/or reduce the costs for making and using these new articulated devices.

BRIEF SUMMARY OF THE INVENTION

[0007] The present invention generally provides improved articulation devices, systems, methods for articulation, along with methods for fabricating articulation structures. The articulations structures described herein will often include simple balloon arrays, with

inflation of the balloons locally altering articulation. Liquid or gas inflation fluid may be directed toward the balloons from an inflation fluid source via a series of small channels in a simple extrusion, with the balloons and extrusions often being formed into a helical multi-balloon assembly. Advantageously, the balloons may be supported by encasing the helical balloon assembly in a polymer matrix, such as by winding the balloon assembly onto a mandrel and dip-coating some or all of the assembly in an elastomer such as a silicone, a urethane, or the like. The balloons may be supported by one or more spring, with loops of the spring(s) optionally being radially inward of the balloons, outward of the balloons, or interspersed between balloons (such as by using a flat wire spring having a cross section with a greater radial width than its axial height). In some embodiments, a mesh tube, braid, or other compliant materials may be included instead of or in addition to the spring. Relatively soft matrix materials (such as those having a durometer hardness of less than 30D) may help maintain alignment of the articulation system, and/or a highly elastic matrix (such as those capable of over 500% elongation and having a Shore A durometer hardness of 20 or more) can be used, optionally to help resiliently counteract pressure inside a partially inflated balloon, facilitate balloon deflation, and the like. Articulation balloon arrays may be disposed in an annular space bordered by inner and outer tubular sheaths, with a portion of one or both sheaths being axially slidable relative to the balloons so as to facilitate elongation and bending.

[0008] In a first aspect, the invention provides an elongate articulatable body comprising a first balloon string. The balloon string includes an inflation tube and a first set of balloons distributed along the inflation tube. The inflation tube has a first end and a second end with a first lumen extending therebetween. The balloons of the first set are in communication with the first lumen, and the first balloon string comprises a helical balloon coil having a helical axis. The balloons of the first set are offset from the helical axis along a first lateral bending axis. A first polymer matrix is disposed on the balloon string so as to help maintain alignment between the balloons of the first set when inflation fluid is transmitted through the first lumen and the balloons bend the helical axis laterally.

[0009] A number of optional general features are described herein that can be included, alone or in combinations, in the devices, systems, and methods. Optionally, the inflation tube(s) are integral with the balloons, with the balloons being formed by locally increasing a diameter of the inflation tube so that a relatively small profile segment of the inflation tube extends between adjacent balloons. A multi-lumen shaft may be included in the balloon

string to facilitate inflation of selected subsets of the balloons, and/or multiple balloon strings (typically comprising 2, 3, or 4 strings along at least a portion of the articulatable body, but optionally more) may be included. For example, a second balloon string may be interleaved with the first in a double helix arrangement, with the first set of balloons on the first balloon string being aligned for articulation toward one lateral bending axis, and the second balloon string having a second set of balloons aligned for articulation toward another lateral bending axis; a third balloon string may optionally also be interleaved to provide bending in a third bending axis, and so on. Regardless, the first matrix optionally comprises an elastomeric polymer coating over the first balloon string, with some portion (or all) of first set of balloons and/or the inflation tube being embedded in the first matrix. Such embedding of the balloons and/or inflation tube in the matrix may optionally be performed so that some or all of the balloons, some or all of the inflation tube segments between balloons, or both, are fully encapsulated or encased in the first polymer matrix. Elastomeric matrices that are sufficiently soft to conform and accommodate balloon inflation and associated articulation of the elongate body may be used, with some matrices locally separating from the materials of the balloons, and/or accommodating local matrix fractures while maintaining balloon alignment. Exemplary first matrix materials comprise one or more of a first silicone, latex, polyisoprene, urethane, polyurethane, a thermoplastic, a thermoplastic elastomer, polyether block amide (PEBA) such as a PEBAX™ polymer or a Vestamid™ polymer, and/or a nitrile. The first matrix will often have a Shore durometer hardness of less than 20A, optionally being 10A or less, and in many cases being 5A or less.

[0010] Typically, the balloon coil defines a plurality of circumferential loops, and each balloon of the first set will often be disposed on an associated loop. The first matrix is optionally contiguous between some or all of the adjacent loops. Alternatively, at least one additional helical body may be disposed between adjacent loops of the balloon coil. The additional helical body may have a plurality of other loops, and the first matrix can couple the loops of the balloon coil to adjacent loops of the at least one additional helical body. For example, the first spring can comprise a flat spring disposed axially between loops of the balloon coil.

[0011] In some embodiments, an additional body may be included, with the additional body comprising a first spring supporting the balloon coil so as to bias the axis toward a straight configuration and/or to urge the balloons from a fully inflated state toward an at least partially deflated state. The matrix can help to couple the first spring to the coil. The first

spring can be disposed radially inward of the balloon coil or radial outward of the balloon coil. In fact, the balloon coil can optionally be disposed radially between the first spring and a second spring. The springs may comprise round wire structures, or at least the first spring may comprise a spring member with a flat cross-section having an axial thickness and a radial width greater than the axial thickness, such as a machined spring (optionally being laser cut from a tube), a 3D printed spring, a wound flat wire, or the like. The first spring optionally has a plurality of spring members, such as a multiple start machine spring or the like, particularly where multiple balloon strings are arranged in a double helix, a triple helix, or other multi-helix segments.

[0012] To provide a desired combination of articulation and stiffness characteristics, a second polymer matrix may be disposed over the first matrix. The second matrix will often comprise an elastomeric coating encompassing at least one of the first spring and/or the second spring. The second matrix may comprise a material that is adhereable to, compatible with, structurally similar to (but having a different hardness or other characteristic), or even the same as a material of the first matrix. Typically, the second matrix will be adhered to the first matrix. In many embodiments, the second matrix will have a Shore hardness durometer greater than that of the first matrix, and/or may have an elongation and breaking strength that is higher than that of the first matrix. Optionally, the balloon strings of the articulatable segments described herein may be wound with a first orientation, and one or two springs may be radially offset from the balloon string (with the balloon string often being radially captured between the two). The spring or springs may be wound with a second orientation opposed to the first orientation so that loops of the spring(s) cross loops of the balloon string. This can help the loops of the spring radially restrain radial expansion of the balloon so as to enhance axial elongation of the balloon during inflation, and may thus increase lateral bending articulation. Counter-winding these structures may also help limit unwinding (and associated non-planar articulation) when a subset of balloons along one side of the segment is inflated.

[0013] In another aspect, the invention provides a method for fabricating an articulating catheter. The method comprises fabricating a balloon string including: a) an inflation member having a first end and a second end with at a first lumen extending therebetween; and b) a first set of balloons distributed along the inflation member. The balloons of the first set can be in communication with the first lumen. The balloon string is formed into a helical coil (the coil having a helical axis with the balloons of the first set being laterally offset from the helical axis along a first lateral bending axis). The helical coil is embedded in a first

polymer matrix such that the matrix helps maintain alignment between the balloons of the first set when inflation fluid is transmitted through the first lumen (optionally such that the inflating balloons laterally bend the helical axis laterally toward the first bending axis).

[0014] In another aspect, the invention provides an elongate articulatable body comprising an articulation balloon array having a proximal end, a distal end, and an axis therebetween. The articulation balloon array defines a tubular cross-section having an outer array profile and an inner array profile. An outer sheath has an axial outer sheath lumen, the outer sheath lumen receiving the articulation balloon array therein so that a surface of the outer sheath is adjacent the outer array profile. An inner sheath has an axial lumen, the inner sheath disposed within the articulation balloon array so that a surface of the inner sheath is adjacent the inner array profile. One of the sheaths (and preferably both of the sheaths) have a first portion axially affixed to one of the ends of the articulation balloon array and a second portion axially movable relative to the articulation balloon array so as to facilitate articulation of the articulatable body by the articulation balloon array.

[0015] A number of preferred features can be provided, either individually or in combinations. For example, the articulation balloon array may comprise a helical balloon array distributed along a plurality of helical loops. A helical frame can be disposed between the loops of the balloon array, and the inner and outer sheaths may be radially sealed so as to inhibit radial transmission of any inflation fluid leaking from the balloon array. The inner and outer sheath can be sealed together adjacent the distal end of the articulation balloon array so that any inflation fluid that is contained in an annular balloon array space is directed proximally out of the patient. The surfaces of the inner and outer sheath adjacent the proximal end of the articulation balloon array can be relatively smooth, low friction, and optionally lubricious surfaces so that they can slide axially along the articulation balloon array and the adjacent helical frame proximally of the affixed and sealed distal end. This sliding relative motion between these adjacent components can facilitate axial elongation of the articulatable body and/or lateral bending of the articulatable body, for example, under bending or elongation forces imposed by inflation of some or all of the balloons of the articulation balloon array.

[0016] Additional or alternative refinements may also be included. For example, the helical frame preferably comprises a flat-wire helical spring having axially opposed major surfaces. The frame can be formed with a first wound orientation (such as being a right-hand

spring). The inner sheath optionally comprises a first elastomeric polymer layer having a first surface, with the elastomeric polymer comprising any of the elastomeric polymers described herein. An inner reinforcing coil can be disposed radially inward of the first surface, the inner reinforcing coil having a second wound orientation opposed to the first wound orientation. This can help orient multiple winds of the coil across most or all of the individual articulation balloons, making it easier for the coil to radially constrain the balloon within the frame and inhibiting deleterious radial migration of the balloons out from the desired location between the major surfaces of adjacent loops of the flat spring. Optionally, the outer sheath may include a second elastomeric polymer layer having a second surface and an outer reinforcing coil disposed radially outward of the second surface, the outer reinforcing coil having the second wound orientation.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. 1 is a simplified perspective view of a medical procedure in which a physician can input commands into a catheter system so that a catheter is articulated using systems and devices described herein.

[0018] FIGS. 2A-2C schematically illustrates a catheter having a distal portion with an axial series of articulated segments supporting a prosthetic mitral valve, and show how the segments articulate so as to change the orientation and location of the valve.

[0019] FIGS. 3A-3C schematically illustrate input command movements to change the orientation and location of the valve, with the input commands corresponding to the movements of the valve so as to provide intuitive catheter control.

[0020] FIG. 4 is a partially see-through perspective view of an exemplary fluid drive manifold system for articulating a balloon array so as to control the shape of a valve delivery catheter or other elongate flexible body.

[0021] FIG. 5 is a simplified schematic illustration of components of a helical balloon assembly, showing how an extruded multi-lumen shaft can be assembled to provide fluid to laterally aligned subsets of the balloons.

[0022] FIGS. 6A-6C schematically illustrate helical balloon assemblies supported by flat springs and embedded in an elastomeric polymer matrix, and show how selective inflation of subsets of the balloons can elongate and laterally articulate the assemblies.

[0023] FIGS. 7A and 7B are cross-sections schematically illustrating a polymer dip coat supporting helical balloon assemblies with the balloons nominally inflated and fully inflated, respectively.

[0024] FIG. 8 is a schematic cross-sections illustrating a helical balloon assembly having fully deflated balloons, and showing how balloon folding can impact efficiency of articulation.

[0025] FIG. 9 is an alternative schematic cross-sections illustrating an alternative balloon folding arrangement, and showing radially inner and outer sheaths with the matrix and balloon assemblies disposed therebetween.

[0026] FIGS. 10A-10C are cross-sections schematically illustrating a dip-coated helical balloon assembly having a flat spring between axially adjacent balloons in an uninflated state, a nominally inflated state, and a fully inflated state, respectively, with the dip coating comprising a soft elastomeric matrix.

[0027] FIGS. 11A and 11B are schematically illustrations of an alternative dip-coated helical balloon assembly showing a cross-section of a flat spring sandwiched between adjacent balloons, and a cross-section of the assembly between balloons, respectively.

[0028] FIG. 12 is a cross-section schematically illustrating yet another alternative dip-coated helical balloon assembly embedded within a relatively soft polymer matrix, with support coils disposed radially inward and outward of the balloon assemblies and dip-coated in a different, relatively hard polymer matrix.

[0029] FIGS. 13A-13E schematically illustrate frame systems having axially opposed elongation and contraction balloons for locally elongating and bending a catheter or other elongate flexible body.

[0030] FIGS. 14A-14E schematically illustrate frame systems having axially opposed elongation and contraction balloons similar to those of FIGS 13A-13E, with the frames comprising helical structures.

[0031] FIG. 15 is a cross-section schematically illustrating an elongation-contraction frame similar to those of FIGS. 13A-14E, showing a soft elastomeric polymer matrix supporting balloon assemblies within the frames.

[0032] FIGS. 16A-16C schematically illustrate cross-sections of balloons dip-coated in a low-strength polymer matrix while deflated and folded, and then at least partially embedded

in an elastically distensible dip-coat polymer matrix so as to allow expansion and subsequent controlled deflation to a small-profile configuration.

[0033] FIG. 17 schematically illustrate a simplified cross-section of a helical frame within an annular space bordered by an inner reinforced polymer sheath and an outer reinforced polymer sheath, in which a proximal portion of one or both sheath(s) can slide axially relative to a balloon array within the annular space to facilitate articulation.

DETAILED DESCRIPTION OF THE INVENTION

[0034] The present invention generally provides fluid control devices, systems, and methods that are particularly useful for articulating catheters and other elongate flexible structures. The structures described herein will often find applications for diagnosing or treating the disease states of or adjacent to the cardiovascular system, the alimentary tract, the airways, the urogenital system, and/or other lumen systems of a patient body. Other medical tools making use of the articulation systems described herein may be configured for endoscopic procedures, or even for open surgical procedures, such as for supporting, moving and aligning image capture devices, other sensor systems, or energy delivery tools, for tissue retraction or support, for therapeutic tissue remodeling tools, or the like. Alternative elongate flexible bodies that include the articulation technologies described herein may find applications in industrial applications (such as for electronic device assembly or test equipment, for orienting and positioning image acquisition devices, or the like). Still further elongate articulatable devices embodying the techniques described herein may be configured for use in consumer products, for retail applications, for entertainment, or the like, and wherever it is desirable to provide simple articulated assemblies with multiple degrees of freedom without having to resort to complex rigid linkages.

[0035] Embodiments provided herein may use balloon-like structures to effect articulation of the elongate catheter or other body. The term “articulation balloon” may be used to refer to a component which expands on inflation with a fluid and is arranged so that on expansion the primary effect is to cause articulation of the elongate body. Note that this use of such a structure is contrasted with a conventional interventional balloon whose primary effect on expansion is to cause substantial radially outward expansion from the outer profile of the overall device, for example to dilate or occlude or anchor in a vessel in which the device is located. Independently, articulated medial structures described herein will often have an

articulated distal portion, and an unarticulated proximal portion, which may significantly simplify initial advancement of the structure into a patient using standard catheterization techniques.

[0036] The catheter bodies (and many of the other elongate flexible bodies that benefit from the inventions described herein) will often be described herein as having or defining an axis, such that the axis extends along the elongate length of the body. As the bodies are flexible, the local orientation of this axis may vary along the length of the body, and while the axis will often be a central axis defined at or near a center of a cross-section of the body, eccentric axes near an outer surface of the body might also be used. It should be understood, for example, that an elongate structure that extends “along an axis” may have its longest dimension extending in an orientation that has a significant axial component, but the length of that structure need not be precisely parallel to the axis. Similarly, an elongate structure that extends “primarily along the axis” and the like will generally have a length that extends along an orientation that has a greater axial component than components in other orientations orthogonal to the axis. Other orientations may be defined relative to the axis of the body, including orientations that are transverses to the axis (which will encompass orientation that generally extend across the axis, but need not be orthogonal to the axis), orientations that are lateral to the axis (which will encompass orientations that have a significant radial component relative to the axis), orientations that are circumferential relative to the axis (which will encompass orientations that extend around the axis), and the like. The orientations of surfaces may be described herein by reference to the normal of the surface extending away from the structure underlying the surface. As an example, in a simple, solid cylindrical body that has an axis that extends from a proximal end of the body to the distal end of the body, the distal-most end of the body may be described as being distally oriented, the proximal end may be described as being proximally oriented, and the surface between the proximal and distal ends may be described as being radially oriented. As another example, an elongate helical structure extending axially around the above cylindrical body, with the helical structure comprising a wire with a square cross section wrapped around the cylinder at a 20 degree helix angle, might be described herein as having two opposed axial surfaces (with one being primarily proximally oriented, one being primarily distally oriented). The outermost surface of that wire might be described as being oriented exactly radially outwardly, while the opposed inner surface of the wire might be described as being oriented radially inwardly, and so forth.

[0037] Referring first to FIG. 1, a first exemplary catheter system 1 and method for its use are shown. A physician or other system user U interacts with catheter system 1 so as to perform a therapeutic and/or diagnostic procedure on a patient P, with at least a portion of the procedure being performed by advancing a catheter 3 into a body lumen and aligning an end portion of the catheter with a target tissue of the patient. More specifically, a distal end of catheter 3 is inserted into the patient through an access site A, and is advanced through one of the lumen systems of the body (typically the vasculature network) while user U guides the catheter with reference to images of the catheter and the tissues of the body obtained by a remote imaging system.

[0038] Exemplary catheter system 1 will often be introduced into patient P through one of the major blood vessels of the leg, arm, neck, or the like. A variety of known vascular access techniques may also be used, or the system may alternatively be inserted through a body orifice or otherwise enter into any of a number of alternative body lumens. The imaging system will generally include an image capture system 7 for acquiring the remote image data and a display D for presenting images of the internal tissues and adjacent catheter system components. Suitable imaging modalities may include fluoroscopy, computed tomography, magnetic resonance imaging, ultrasonography, combinations of two or more of these, or others.

[0039] Catheter 3 may be used by user U in different modes during a single procedure. More specifically, at least a portion of the distal advancement of catheter 3 within the patient may be performed in a manual mode, with system user U manually manipulating the exposed proximal portion of the catheter relative to the patient using hands H1, H2. In addition to such a manual movement mode, catheter system 1 may also have a 3-D automated movement mode using computer controlled articulation of at least a portion of the length of catheter 3 disposed within the body of the patient to change the shape of the catheter portion, often to advance or position the distal end of the catheter. Movement of the distal end of the catheter within the body will often be provided per real-time or near real-time movement commands input by user U. Still further modes of operation of system 1 may also be implemented, including concurrent manual manipulation with automated articulation, for example, with user U manually advancing the proximal shaft through access site A while computer-controlled lateral deflections and/or changes in stiffness over a distal portion of the catheter help the distal end follow a desired path or reduce resistance to the axial movement. Additional details regarding modes of use of catheter 3 can be found in US Patent Publication

No. US20160279388, entitled “Articulation Systems, Devices, and Methods for Catheters and Other Uses,” published on September 29, 2016, assigned to the assignee of the subject application, the full disclosure of which is incorporated herein by reference.

[0040] Referring now to FIGS. 2A-3C, devices and methods are shown for controlling movement of the distal end of a multi-segment articulated catheter 12 using a movement command input device 14 in a catheter system similar system 1 (described above). Multi-segment catheter 12 is shown in FIG. 2A extending within a heart 16, and more specifically with a distal portion of the catheter extending up to the heart via the inferior vena cava, with a first, proximal articulatable segment 12a bending within a right atrium of the heart toward a trans-septal access site. A second, intermediate articulatable segment 12b traverses the septum, and a third, distal articulatable segment 12c has some bend inside the left atrium of the heart 16. A tool, such as a prosthetic mitral valve, is supported by the distal segment 12c, and the tool is not in the desired position or orientation for use in the image of FIG. 2A. As shown in FIG. 3A, input device 14 is held by the hand of the user in an orientation that, very roughly, corresponds to the orientation of the tool (typically as the tool is displayed to the user in the display of the image capture system, as described above).

[0041] Referring to FIGS. 2A, 2B, 3A, and 3B, to change an orientation of the tool within the heart the user may change an orientation of input device 14, with the schematic illustration showing the input command movement comprising a movement of the housing of the overall input device. The change in orientation can be sensed by sensors supported by the input housing (with the sensors optionally comprising orientation or pose sensors similar to those of smart phones, tablets, game controllers, or the like). In response to this input, the proximal, intermediate, and distal segments 12A, 12B, and 12C of catheter 12 may all change shape so as to produce the commanded change in orientation of the tool. The changes in shapes of the segments will be calculated by a robotic processor of the catheter system, and the user may monitor the implementation of the commanded movement via the image system display. Similarly, as can be understood with reference to FIGS. 2B, 2C, 3B, and 3C, to change a position of the tool within the heart the user may translate input device 14. The commanded change in position can again be sensed and used to calculate changes in shape to the proximal, intermediate, and distal segments 12A, 12B, and 12C of catheter 12 so as to produce the commanded translation of the tool. Note that even a simple change in position or orientation (or both) will often result in changes to shape in multiple articulated segments of

the catheter, particularly when the input movement command (and the resulting tool output movement) occur in three dimensional space within the patient.

[0042] Referring to FIG. 4, an exemplary articulated catheter drive system 22 includes a pressurized fluid source 24 coupled to catheter 12 by a manifold 26. The fluid source preferably comprises a receptacle for and associated disposable canister containing a liquid/gas mixture, such as a commercially available nitrous oxide (N₂O) canister. Manifold 26 may have a series of valves and pressure sensors, and may optionally include a reservoir of a biocompatible fluid such as saline that can be maintained at pressure by gas from the canister. The valves and reservoir pressure may be controlled by a processor 28, and a housing 30 of drive system 22 may support a user interface configured for inputting of movement commands for the distal portion of the catheter, as more fully explained in co-pending US Patent Application Serial No. 15/369,606, entitled “INPUT AND ARTICULATION SYSTEM FOR CATHETERS AND OTHER USES,” filed on December 5, 2016 (the full disclosure of which is incorporated herein by reference).

[0043] Regarding processor 28 and the other data processing components of drive system 22, it should be understood that a variety of data processing architectures may be employed. The processor, pressure or position sensors, and user interface will, taken together, typically include both data processing hardware and software, with the hardware including an input (such as a joystick or the like that is movable relative to housing 30 or some other input base in at least 2 dimensions), an output (such as a sound generator, indicator lights, and/or an image display, and one or more processor board. These components are included in a processor system capable of performing the rigid-body transformations, kinematic analysis, and matrix processing functionality associated with generating the valve commands, along with the appropriate connectors, conductors, wireless telemetry, and the like. The processing capabilities may be centralized in a single processor board, or may be distributed among the various components so that smaller volumes of higher-level data can be transmitted. The processor(s) will often include one or more memory or storage media, and the functionality used to perform the methods described herein will often include software or firmware embodied therein. The software will typically comprise machine-readable programming code or instructions embodied in non-volatile media, and may be arranged in a wide variety of alternative code architectures, varying from a single monolithic code running on a single processor to a large number of specialized subroutines being run in parallel on a number of separate processor sub-units.

[0044] Referring now to FIG. 5, the components of, and fabrication method for production of, an exemplary balloon array assembly, sometimes referred to herein as a balloon string 32, can be understood. A multi-lumen shaft 34 will typically have between 2 and 18 lumens. The shaft can be formed by extrusion with a polymer such as a nylon, a polyurethane, a thermoplastic such as a Pebax™ thermoplastic or a polyether ether ketone (PEEK) thermoplastic, a polyethylene terephthalate (PET) polymer, a polytetrafluoroethylene (PTFE) polymer, or the like. A series of ports 36 are formed between the outer surface of shaft 34 and the lumens, and a continuous balloon tube 38 is slid over the shaft and ports, with the ports being disposed in large profile regions of the tube and the tube being sealed over the shaft along the small profile regions of the tube between ports to form a series of balloons. The balloon tube may be formed using any compliant, non-compliant, or semi-compliant balloon material such as a latex, a silicone, a nylon elastomer, a polyurethane, a nylon, a thermoplastic such as a Pebax™ thermoplastic or a polyether ether ketone (PEEK) thermoplastic, a polyethylene terephthalate (PET) polymer, a polytetrafluoroethylene (PTFE) polymer, or the like, with the large-profile regions preferably being blown sequentially or simultaneously to provide desired hoop strength. The shaft balloon assembly 40 can be coiled to a helical balloon array of balloon string 32, with one subset of balloons 42a being aligned along one side of the helical axis 44, another subset of balloons 44b (typically offset from the first set by 120 degrees) aligned along another side, and a third set (shown schematically as deflated) along a third side. Alternative embodiments may have four subsets of balloons arranged in quadrature about axis 44, with 90 degrees between adjacent sets of balloons.

[0045] Referring now to FIGS. 6A, 6B, and 6C, an articulated segment assembly 50 has a plurality of helical balloon strings 32, 32' arranged in a double helix configuration. A pair of flat springs 52 are interleaved between the balloon strings and can help axially compress the assembly and urge deflation of the balloons. As can be understood by a comparison of FIGS. 6A and 6B, inflation of subsets of the balloons surrounding the axis of segment 50 can induce axial elongation of the segment. As can be understood with reference to FIGS. 6A and 6C, selective inflation of a balloon subset 42a offset from the segment axis 44 along a common lateral bending orientation X induces lateral bending of the axis 44 away from the inflated balloons. Variable inflation of three or four subsets of balloons (via three or four channels of a single multi-lumen shaft, for example) can provide control over the articulation of segment 50 in three degrees of freedom, i.e., lateral bending in the +/-X orientation and the +/-Y

orientation, and elongation in the +Z orientation. As noted above, each multilumen shaft of the balloon strings 32, 32' may have more than three channels (with the exemplary shafts having 6 lumens), so that the total balloon array may include a series of independently articulatable segments (each having 3 or 4 dedicated lumens of one of the multi-lumen shafts, for example).

[0046] Referring still to FIGS. 6A, 6B, and 6C, articulated segment 50 includes a polymer matrix 54, with some or all of the outer surface of balloon strings 32, 32' and flat springs 52 that are included in the segment being covered by the matrix. Matrix 54 may comprise, for example, a relatively soft elastomer to accommodate inflation of the balloons and associated articulation of the segment, with the matrix optionally helping to urge the balloons toward an at least nominally deflated state, and to urge the segment toward a straight, minimal length configuration. Advantageously, matrix 54 can maintain overall alignment of the balloon array and springs within the segment despite segment articulation and bending of the segment by environmental forces.

[0047] Segment 50 may be assembled by, for example, winding springs 52 together over a mandrel and restraining the springs with open channels between the axially opposed spring surfaces. Balloon strings 32, 32' can be wrapped over the mandrel in the open channels. The balloons may be fully inflated, partially inflated, nominally inflated (sufficiently inflated to promote engagement of the balloon wall against the opposed surfaces of the adjacent springs without driving the springs significantly wider apart than the diameter of the balloon string between balloons), deflated, or deflated with a vacuum applied to locally flatten and maintain 2 or 4 opposed outwardly protruding pleats or wings of the balloons. The balloons may be pre-folded, gently pre-formed at a moderate temperature to bias the balloons toward a desired fold pattern, or unfolded and constrained by adjacent components of the segment (such as the opposed surfaces of the springs and/or other adjacent structures) urge the balloons toward a consistent deflated shape. When in the desired configuration, the mandrel, balloon strings, and springs can then be dip-coated in a pre-cursor liquid material of polymer matrix 54, with repeated dip-coatings optionally being performed to embed the balloon strings and springs in the matrix material and provide a desired outer coating thickness. Alternatively, matrix 54 can be over-molded onto, sprayed or poured over, brushed onto or otherwise applied to the balloon strings and springs, with the balloons and other assembly components optionally being supported by a spinning mandrel, or the like. The liquid material can be evened by rotating the coated assembly, by passing the assembly through an aperture, by manually

troweling matrix material over the assembly, or the like. Curing of the matrix may be provided by heating (optionally while rotating about the axis), by application of light, by inclusion of a cross-linking agent in the matrix, or the like. The polymer matrix may remain quite soft in some embodiments, optionally having a Shore A durometer hardness of 2-30, typically being 3-25, and optionally being almost gel-like. Other polymer matrix materials may be somewhat harder (and optionally being used in somewhat thinner layers), having Shore A hardness durometers in a range from about 20 to 95, optionally being from about 30 to about 60. Suitable matrix materials comprise elastomeric urethane polymers, polyurethane polymers, silicone polymers, latex polymers, polyisoprene polymers, nitrile polymers, plastisol polymers, thermoplastic elastomers, polyether block amide polymers (such as PEBAX™ polymers or Vestamid™ polymers), or the like. Regardless, once the polymer matrix is in the desired configuration, the balloon strings, springs, and matrix can be removed from the mandrel. Optionally, flexible inner and/or outer sheath layers may be added.

[0048] Referring now to FIGS. 7A and 7B, a simple articulated segment 60 includes a single balloon string 62 supported by a polymer matrix 64 in which the balloon string is embedded. A multilumen shaft of balloon string 62 includes 3 lumens, and the balloons of the balloon string are shown in a nominally inflated state in FIG. 7A, so that the opposed major surfaces of most of the balloons of each subset are disposed between and adjacent balloons of that subset on adjacent loops, such that pressure within the subset of balloons causes the balloons to push away from each other (see FIG. 7B). Optionally, the balloons of the subset may directly engage each other across much or all of the balloon/balloon force transmission interface, particularly when the balloons are dip-coated when in the nominally inflated state. Alternatively, a layer of matrix 64 may be disposed between some portion or all of the adjacent force-transmission balloon wall surfaces of the subset, for example, if the balloon strings are dip-coated in a deflated state (see FIGS. 8 and 9). As can be understood with reference to FIG. 7B, inflation of one or more subsets of the balloons may separate adjacent loops of the balloon string between balloons, along the tapering balloon ends, and the like. Elastic elongation of matrix 64 may accommodate some or all of this separation, or the matrix may at least locally detach from the outer surface of the balloon string to accommodate the movement. In some embodiments, localized fracturing of the polymer matrix in areas of high elongation may help to accommodate the pressure-induced articulation, with the overall bulk and shape of the relatively soft matrix material still helping to keep the balloons of the helical balloon array in the desired alignment. Bending in

different orientations may optionally be induced by transmitting balloon inflation fluid through different channels of the multi-lumen shaft toward different subsets of balloons (each subset being in fluid communication via a common channel and aligned for bending in an associated lateral bending orientation, as described above). In alternative arrangements, a plurality of balloon strings can wind in parallel around axis 44, with the first string including a first subset of balloons that are aligned for bending in a first bending axis (see FIG. 6C). In such systems, the balloons may push axially (directly or indirectly, such as via the matrix) against the balloon tube 38 between balloons (see FIG 5), rather than the balloons pushing against each other. Two, three, four, or more strings of balloons may be interleaved, with or without multi-lumen shafts, to provide the desired degrees of freedom.

[0049] Referring now to FIGS. 8 and 9, shape-setting of balloon string 62 can help to improve articulation performance and uniformity along the axial length of the segment. In the embodiment of FIG. 8, the balloon have been urged toward a 4-wing “H” shaped folded balloon configuration by, for example, winding the balloon string within a helical channel of a substantially cylindrical mandrel, such as by using a threaded acme rod as the mandrel and winding the balloon string within the roughly square thread of the rod, and then heat-setting the balloons at a moderate temperature for sufficient time to maintain the balloon fold shape. In the illustrated embodiment, the major surfaces of the “H” folded shape are oriented radially; in other embodiments, the major surfaces may be oriented axially so as to increase balloon/balloon force transmission efficiency. Still other configurations may be used, including a 2-wing balloon fold configuration 66 of FIG. 9, in which the wings have been wrapped circumferentially about the multi-lumen shaft within the balloon. Other optional configurations include a 3-wing balloon fold, and any of these configurations may optionally comprise asymmetric folds, with one or more folds disposed on a radially inward portion of the balloon (relative to the helical axis) having a different amount of balloon wall material than one or more folds along a radially outward portion of the balloon. A vacuum may be applied to the balloons via the multi-lumen shaft as the balloons are folded, and may be maintained during shape setting and/or the embedding of the balloon in matrix 64. Local detachment of matrix 64 from an outer surface of the balloon string, and/or local fracture of the polymer matrix, adjacent the wings of the balloons during initial inflation may facilitate articulation. Note that a flexible radially inner sheath 68 and a flexible outer sheath 70 may support the segment, provide desirable inner and outer surface characteristics (such as low friction, etc.), and/or may optionally radially constrain the balloons during inflation

sufficiently to enhance axial balloon expansion and the associated articulation range of motion available from each balloon of the subset.

[0050] Referring now to FIGS. 10A-10C, an alternative segment 80 has a single balloon string 62 interleaved with a flat spring 52, and both the balloon string and spring are coated by an elastomeric polymer matrix 64. Shape setting of the balloons may be optionally be omitted, as axial compression of spring 52 can help induce at least rough organization of deflated balloons 62 (as shown in FIG. 10A). Local inclusion of some matrix material 64 between the balloon walls and adjacent spring surface (see FIG. 10B) may not significantly impact overall force transmission and articulation, particularly where the balloons are generally oriented with major surfaces in apposition, as the pressure force can be transmitted axially through the soft matrix material. Alternatively, the balloons may be nominally inflated during application of the matrix material, as noted above, providing a more direct balloon wall/spring interface (see FIG. 10C). As with the other embodiments of segments described herein, flexible (and often axially resilient) radially inner and/or outer sheaths may be included, with the sheaths optionally comprising a coil or braid to provide radial strength and accommodate bending and local axial elongation, such inner and/or outer sheaths often providing a barrier to inhibit release of inflation fluid from the segment should a balloon string leak.

[0051] Many of the embodiments described above include soft elastomeric polymer matrices that help maintain alignment between subsets of balloons in an articulation balloon array, with the matrix optionally filling spaces between balloons. Referring now to FIGS. 11A and 11B, an alternative segment 90 includes a polymer matrix layer 92 that may be quite thin, typically being less than a half millimeter, often being 0.25 mm thick or less in at least some areas, and which flexibly adheres the balloons of the balloon string in the desired alignment without filling the spaces between balloons or the like. Matrix layer 92 may again comprise an elastomeric polymer, but may have a significantly higher hardness than the soft, space-filling matrices described above. The articulation performance of segment 90 may benefit from coating of balloon string 62 and spring 52 while the balloons are in nominally inflated state (with detachment of polymer matrix from the balloon string and/or localized failure of the matrix between the small-profile region of string 62 and spring, as can be understood with reference to FIG. 11B) facilitates initial articulation. Alternatively, the balloon may be in a partially or fully inflated state when the matrix is applied so that the

coating on the balloon string between balloons and coating on the spring surfaces are separate, as can also be understood with reference to FIG. 11B.

[0052] Referring now to FIG. 12, an exemplary segment 100 was fabricated with an intermediate sub-assembly including balloon string 102 embedded in an intermediate matrix 104. An inner sheath is formed radially inward of (and optionally prior to the assembly of) the intermediate sub-assembly by embedding an inner spring 106 within an inner matrix 108. An outer sheath is formed radially outward of (and optionally after assembly of) the intermediate assembly, with the outer sheath including an outer spring 110 and an outer matrix. Segment fabrication parameters and characteristics are summarized in Table 1.

TABLE 1

<i>Fabrication processing parameters and characteristics</i>		
Characteristic / Parameter	Condition	Comment
<i>Inside Spring</i>		
Wire Material	304V SS Spring Temper Wire	
Wire Diameter	0.014"	
ID	0.140"	
OD	0.168"	
Pitch	0.045	measure gap (target = .031") spacing with gage pin
Wind Direction	Right Hand	
<i>Outside Spring</i>		
Wire Material	304V SS Spring Temper Wire	
Wire Diameter	0.014"	
ID	0.245"	
OD	0.273"	
Pitch	0.045	

Wind Direction	Right Hand	
Spring Constant - k	TBD	
<i>Balloon Coil (Middle)</i>		
Tube Material	Pebax 63D	
Tube ID	0.016"	
Tube OD	0.026"	
Balloon Spacing	TBD	measurement of proximal end of 1 balloon to the proximal end of next balloon
Inflation Pressure (Hot air station)	90psi	
Balloon Mold Diameter	0.075"	
Number of Balloons	5	
Nitinol Coring Wire Diameter	0.014"	wire used during balloon wind shape set
Shape Setting Spring Specifications	Gap between coils - 0.046"; Pitch - 0.084"; Wire Diameter - 0.038"; Wind Direction - Left Hand	Tool used for balloon chambers flattening mitigation during shape set processing
Wind Shape Set Temperature	100 Celsius	
Wind Shape Set Time	TBD	
Wind Direction	Left Hand	
Balloons per Revolution	1	
Inflation Multi-lumen Shaft Included	No	
<i>Inside, Middle and Outside Silicone Layers</i>		
Type	Dragon Skin 10 Medium	

Manufacturer	Smooth-On, Inc.	
Durometer	10 Shore A	
Viscosity	23,000 cps	
Elongation at Break %	1000%	
Pot Life	20 minutes	
Cure Time @ ambient	5 hours	
Dip Withdraw Rate	0.5 in/min	
Wall Thickness	~0.009"	

Measurements of the assembled components are provided in Table 2.

TABLE 2

Prototype measurements

Layers of Prototype from ID to OD		Actual OD (in)
1	Inside Spring	0.168
2	Inside Silicone	~0.186
3	Balloon Coil	~0.220
4	Middle Silicone	0.240
5	Outside Spring	0.272
6	Outside Silicone	0.290
	ID of Prototype	0.140

Note that as in this embodiment, it will often be beneficial for any inner or outer spring to be counterwound relative to the balloon string. First, when the loops of the springs cross the balloons it may help inhibit radial protrusion of the balloons through the coils. Second, it may help to counteract rotational unwinding of the balloon coil structure with balloon inflation, and thereby inhibit non-planar articulation of the segment form inflation of a single balloon subset. Alternative embodiments may benefit from harder matrix materials encompassing the inner or outer springs (or both), from replacing the inner or outer springs

(or both) with a braid, multiple layers of threads, fine wire or polymer lines, eliminating the springs altogether, or the like.

[0053] Referring now to FIGS. 13A-14E, alternative segment structures include opposed balloons disposed within channels of segment frames or skeletons to locally axially elongate or contract the frame, thereby laterally bending the frame or changing the axial length of the frame. Referring first to FIG. 13A, a schematically illustrated frame structure 120 includes an axially interleaved set of frame members, with an inner frame 122 having a radially outwardly open channel, and an outer frame 124 having a radially inwardly open channel. The channels are both axially bordered by flanges, and radially bordered (at an inner or outer border of the channel) by a wall extending along the axis. A flange of the inner frame extends into the channel of the outer frame, and a flange of the outer frame extends into the channel of the inner frame. Axial extension balloons 126 can be placed between adjacent flanges of two inner frames or between flanges of two adjacent outer frames; axial retraction balloons 128 can be placed between a flange of an inner frame and an adjacent flange of an outer frame. As more fully explained in US Patent Publication No. US20160279388, entitled “Articulation Systems, Devices, and Methods for Catheters and Other Uses,” published on September 29, 2016 (assigned to the assignee of the subject application and the full disclosure of which is incorporated herein by reference), inflation of a subset of extension balloons 126 along one side of the frame locally extends the axial length of the frame and can bend the frame away from the balloons of the subset. A subset of retraction balloons 128 is mounted in opposition to that local extension, so that inflation of those retraction balloons (with concurrent deflation of the extension balloons) may move the flanges between the balloons in the opposed direction, locally decreasing the length of the frame and bending the axis of the frame toward the inflating retraction balloons. As can be understood with reference to FIGS. 13B-13E, annular frame segments 120' may have an axially series of ring-shaped inner and outer frames defining the flanges and channels. As shown in FIGS. 14A-14E, helical versions of the frame system may have helical inner and outer frame members 122', 124', with extension balloons 126 and retraction balloons 128 being disposed on multiple helical balloon strings extending along the helical channels.

[0054] Referring now to FIG. 15, embedding the balloons within the helical frames 122', 124' or ring frames described herein within polymer matrix 64 may help maintain alignment of the subsets of balloons despite frame articulation. Articulation performance may be enhanced by the use of soft matrices (with Shore A durometers of 2 to 15), and by inhibiting

adhesion at the frame/matrix interface 152 between the axial wall of the frames and the matrix in the channels. Preferably, a slippery interface 152 is provided by a low-friction surface in the channels of the frames between flanges, such as by coating the axial walls with a mold release agent, a PTFE polymer coating or frame material, or the like. Local friction inhibition between the matrix and the axial wall may be provided by forming the frames from a low-friction polymer (such as PTFE or the like) and selectively enhancing adhesion along the surfaces of the flanges using chemical etching, plasma etching, apertures through the flanges, surface features or roughening along the flanges, or the like.

[0055] Referring now to FIGS. 16A-16C, still further alternative structures 162, 172 can make use of an elastomeric polymer matrix over one or more balloons on a balloon string to provide controlled articulation. In the embodiment of FIG. 16A, balloon 164 is deflated and two wings 166 of the deflated balloon are folded around a multilumen shaft. At least a portion of the deflated balloon is first coated with a thin, low strength layer 168, with the coated portion including the region around the folded wings. A second layer 170 is disposed over the balloon and the first layer, with the second layer being elastomeric and having sufficient elongation to allow inflation of the balloon from the folded configuration of FIG. 16A to the inflated configuration of FIG. 16C. As described above, the low-strength polymer matrix material of first layer 168 may detach from the underlying balloon wall, and/or may fracture locally. This facilitates resilient distention of sufficiently large surface regions of the outer balloon to accommodate movement of the wings and balloon diameter growth, while allowing the outer layer to resiliently contract when inflation fluid flows out of the balloon. An alternative four wing H fold configuration of the balloon is shown in FIG. 16 B. Local voids in the first layer adjacent major surfaces 174 of the balloon may provide a more rigid balloon force transmission interface. Exemplary embodiments may employ low strength, low durometer polymer materials such as soft silicone polymers for first layer 168, and higher strength, high-elongation silicone polymers for second layer 172. Other embodiments may make use of an inner release agent and a silicone, polyurethane, or other elastomer over the release agent. Optionally, the balloons may be folded and coated while the balloon strings remain in a relatively straight configuration (i.e., prior to forming the balloon assembly into a helix). The total coating thickness over the individual balloons, if coated prior to assembly with other components of a segment, will often be less than 0.010", preferably being less than 0.004".

[0056] Referring now to FIG. 17, an alternative articulated assembly 200 has many of the components described above, including a helical balloon array similar to that of FIG. 5. Assembly 200 has a distal end 202 and a proximal portion 204, with the assembly being disposed along a segment of axis 206 so as to allow the user to selectively bend and elongate the segment by directing inflation fluid toward subsets of balloons within a helical balloon array (see FIG. 5; not shown in FIG. 17). The helically balloon array and associated fluid channels are wound between loops of a flat helical spring coil 208. In assembly 200, the balloon array and flat spring have an annular cross section (extending around axis 206) and are disposed within an annular space bordered by an inner sheath 210 and an outer sheath 212.

[0057] As they extend along the articulated portion of the catheter (and may extend proximally or distally beyond the articulated portion, the inner and outer sheath structures will generally have sufficient lateral flexibility to accommodate the desired lateral bending and/or axial elongation of the fluid-driven segment. Additionally, the inner and outer sheaths can be configured to serve some or all of the following functions: inhibiting radial migration of the balloons; inhibiting embolization of any inflation fluid (gas or liquid) that may inadvertently be released from the balloon array; providing a smooth, low friction, and/or lubricious outer surface of the catheter (to facilitate movement of the catheter through surrounding tissues or a surrounding outer guide catheter) or inner surface (to facilitate movement of guidewires and tools relative to the lumen of the inner sheath) or both; enhancing a bending stiffness of at least the articulated segment or portion of the catheter, and the like. To provide the desired combinations of capabilities, each of these sheaths may benefit from a reinforced polymer matrix structure having a combination of materials. Additionally, the overall capabilities of the articulated structure can benefit from configuring the interfacing surfaces so as to allow relative axial motion between one or both of the sheaths and the balloon array and flat helical spring 208. For example, inner sheath 210 may have an inner balloon-restraining surface 214 defined by a polymer layer 216. Inner balloon-restraining surface 214 may be generally smooth, and layer 216 may help limit axial sliding friction against the components contained within the annular space between the sheaths. An inner surface 218 of outer sheath 210 may similarly be configured to accommodate sliding against the balloon array and/or helical spring 208. To maintain overall structural integrity of the articulated portion, inner and outer sheaths 210, 212 may be axially affixed relative to the balloon array and spring 208 adjacent distal end 202 by adhesive 220. However, to

accommodate axial elongation and bending, proximal portion 204 (proximal of the distal end) the balloon array and spring 208 may slide axially against one or both of the sheaths 210, 212. Note that the adjacent radial surface(s) of spring 208 can be provided with a smooth and/or low friction surface to facilitate this axial sliding, such as by coating the spring with a low-friction material such as parylene, PTFE, or the like. The adjacent radial surface(s) of balloon array may optionally also benefit from a low-friction material, even if the engaging axial surfaces of the spring and array are configured to inhibit relative circumferential and/or radial movement (such as being bonded or embedded together in a polymer matrix as described above).

[0058] Regarding the structure of inner sheath 210, a high hoop-strength reinforcing material such as metal or relatively rigid polymer filament can be included, often in the form of a coil or braid. A coil of stainless wire having a diameter from 0.004" to 0.014" can optionally be used with a closed or near-closed pitch. Axial sliding surface 214 will typically be radially outward of the reinforcing material, and the underlying layer 216 may comprise an elastomeric polymer such as PEBAX™ PEBA polymer tube having a hardness in a range from 30D to 60D, an ID of 0.100" to 0.150", and a wall thickness of 0.004" to 0.015", with the layer being urged radially outwardly by the coil therein. Optionally, an inner polymer layer (not shown) is disposed radially within the reinforcing material, and the layers may be fused or bonded together. Low friction coatings (such as PTFE) or lubricious layers (such as commercially available hydrophilic or hydrophobic coatings) may be applied to the inner and/or outer surfaces, with the preferred reinforced matrix materials being very flexible, smooth, and atraumatic. The structure of outer sheath 212 may have many of the properties and structures described above regarding the inner sheath 210, though the sheaths will often have differing composite structures due to the differing loads and strains as the articulated portion of the catheter bends and elongates, and to provide the desired catheter characteristics (pushability, trackability, and crossability) for manual advancement toward the target tissue. The exemplary outer coil 212 includes a stainless coil formed of stainless wire having a pitch and diameter in the ranges described above regarding sheath 210, and a polymer coating of a polymer having a high-elongation (preferably 300 % or more) and low durometer (preferably 60A or less, optionally 30A or less, ideally being 10A) such as a silicone or urethane. Note that the coils are preferably both counterwound relative to the balloon array, and that the reinforcing materials may comprise flat ribbons, braids, and smaller radial dimensions when fused between inner and outer polymers.

[0059] While the exemplary embodiments have been described in some detail for clarity of understanding and by way of example, a variety of modifications, changes, and adaptations of the structures and methods described herein will be obvious to those of skill in the art. For example, while articulated structures may optionally have tension members in the form of pull-wires as described above, alternative tension members in the form of axially slidable tubes in a coaxial arrangement may also be employed. Hence, the scope of the present invention is limited solely by the claims attached hereto.

WHAT IS CLAIMED IS

1. An elongate articulatable body comprising:
a first balloon string including:
an inflation tube having a first end and a second end with at a first lumen extending therebetween; and
a first set of balloons distributed along the inflation tube, the balloons of the first set in communication with the first lumen;
the first balloon string comprising a helical balloon coil having a helical axis with the balloons of the first set being offset from the helical axis along a first lateral bending axis; and
a first polymer matrix disposed on the balloon string so as to help maintain alignment between the balloons of the first set when inflation fluid is transmitted through the first lumen and the balloons bend the helical axis laterally.
2. The articulatable body of claim 1, wherein the first matrix comprises an elastomeric polymer coating over the first balloon string.
3. The articulatable body of claim 1 or 2, wherein the first set of balloons and the inflation tube are embedded in the first matrix.
4. The articulatable body of one of claims 1-3, wherein the first matrix comprises a first silicone.
5. The articulatable body of one of claims 1-3, wherein the first matrix comprises one or more of a latex, a polyisoprene, a urethane, a polyurethane, a polyether block amide, a thermoplastic, a thermoplastic elastomer, and/or a nitrile.
6. The articulatable body of one of claims 1-5, wherein the first matrix has a durometer hardness of less than 20A.
7. The articulatable body of one of claims 1-6, wherein the balloon coil defines a plurality of circumferential loops, each balloon of the first set being disposed on an associated loop, wherein the first matrix is contiguous between the loops.

8. The articulatable body of one of claims 1-6, wherein the balloon coil defines a plurality of circumferential loops, each balloon of the first set being disposed on an associated loop, wherein the articulatable body includes at least one additional helical body having a plurality of other loops, wherein the first matrix couples the loops of the balloon coil to adjacent loops of the at least one additional helical body.

9. The articulatable body of one of claims 1-8, further comprising a first spring supporting the balloon coil so as to bias the axis toward a straight configuration and/or to urge the balloons from a fully inflated state, wherein the matrix helps to couple the first spring to the coil.

10. The articulatable body of claim 9, wherein the first spring is disposed radially inward of the balloon coil or radial outward of the balloon coil.

11. The articulatable body of claim 10, wherein the balloon coil is disposed radially between the first spring and a second spring.

12. The articulatable body of claim 9, wherein the first spring is disposed axially between loops of the balloon coil.

13. The articulatable body of claim 12, wherein the first spring comprises spring member with flat a cross-section having an axial thickness and a radial width greater than the axial thickness.

14. The articulatable body of claim 13, wherein the first spring comprises a machined spring.

15. The articulatable body of claim 14, wherein the first spring has a plurality of spring members.

16. The articulatable body of claim 11, further comprising a second polymer matrix disposed over the first matrix, the second matrix comprising an elastomeric coating encompassing at least one of the first spring and/or the second spring.

17. The articulatable body of claim 12, wherein the second matrix comprises a material that is the same as a material of the first matrix, the second matrix being adhered to the first matrix.

18. The articulatable body of one of claims 1-11, further comprising a second polymer matrix disposed over the first matrix, the second matrix having a durometer greater than that of the first matrix.

19. The articulatable body of one of claims 1-18, wherein the balloon string is wound with a first orientation, wherein a spring is radially offset from the balloon string and is wound with a second orientation opposed to the first orientation so that loops of the spring cross loops of the balloon string, and wherein the loops of the spring radially restrain radial expansion of the balloon so as to enhance axial elongation of the balloon during inflation so as to increase lateral bending articulation.

20. A method for fabricating an articulating catheter, the method comprising:
fabricating a balloon string including:
an inflation member having a first end and a second end with at a first lumen extending therebetween; and
a first set of balloons distributed along the inflation member, the balloons of the first set in communication with the first lumen;
forming the balloon string into a helical coil having a helical axis; and
embedding the helical coil with a first polymer matrix such that the matrix helps maintain alignment between the balloons of the first set when inflation fluid is transmitted through the first lumen.

21. An elongate articulatable body comprising:
an articulation balloon array having a proximal end, a distal end, and an axis therebetween, the articulation balloon array defining a tubular cross-section having an outer array profile and an inner array profile;

an outer sheath having an axial outer sheath lumen, the outer sheath lumen receiving the articulation balloon array therein so that a surface of the outer sheath is adjacent the outer array profile;

an inner sheath having an axial lumen, the inner sheath disposed within the articulation balloon array so that a surface of the inner sheath is adjacent the inner array profile;

one of the sheaths having a first portion adjacent one of the ends of the articulation balloon array and a second portion axially movable relative to the articulation balloon array so as to facilitate articulation of the articulatable body by the articulation balloon array.

22. The articulatable body of claim 21, wherein the articulation balloon array comprises a helical balloon array distributed along a plurality of helical loops, further comprising a helical frame disposed between the loops of the balloon array, wherein the inner and outer sheaths are radially sealed so as to inhibit radial transmission of any inflation fluid leaking from the balloon array, wherein the inner and outer sheath are sealed together adjacent the distal end of the articulation balloon array and are axially slidable relative to the proximal end of the articulation balloon array and adjacent helical frame so as to facilitate axial elongation of the articulatable body and/or lateral bending of the articulatable body by the articulation balloon array.

23. The articulatable body of claim 22, wherein the helical frame comprises a helical spring having axially opposed major surfaces and a first wound orientation,

wherein the inner sheath comprises a first elastomeric polymer layer having a first surface and an inner reinforcing coil disposed radially inward of the first surface, the inner reinforcing coil having a second wound orientation opposed to the first wound orientation; and

wherein the outer sheath comprises a second elastomeric polymer layer having a second surface and an outer reinforcing coil disposed radially outward of the second surface, the outer reinforcing coil having the second wound orientation.

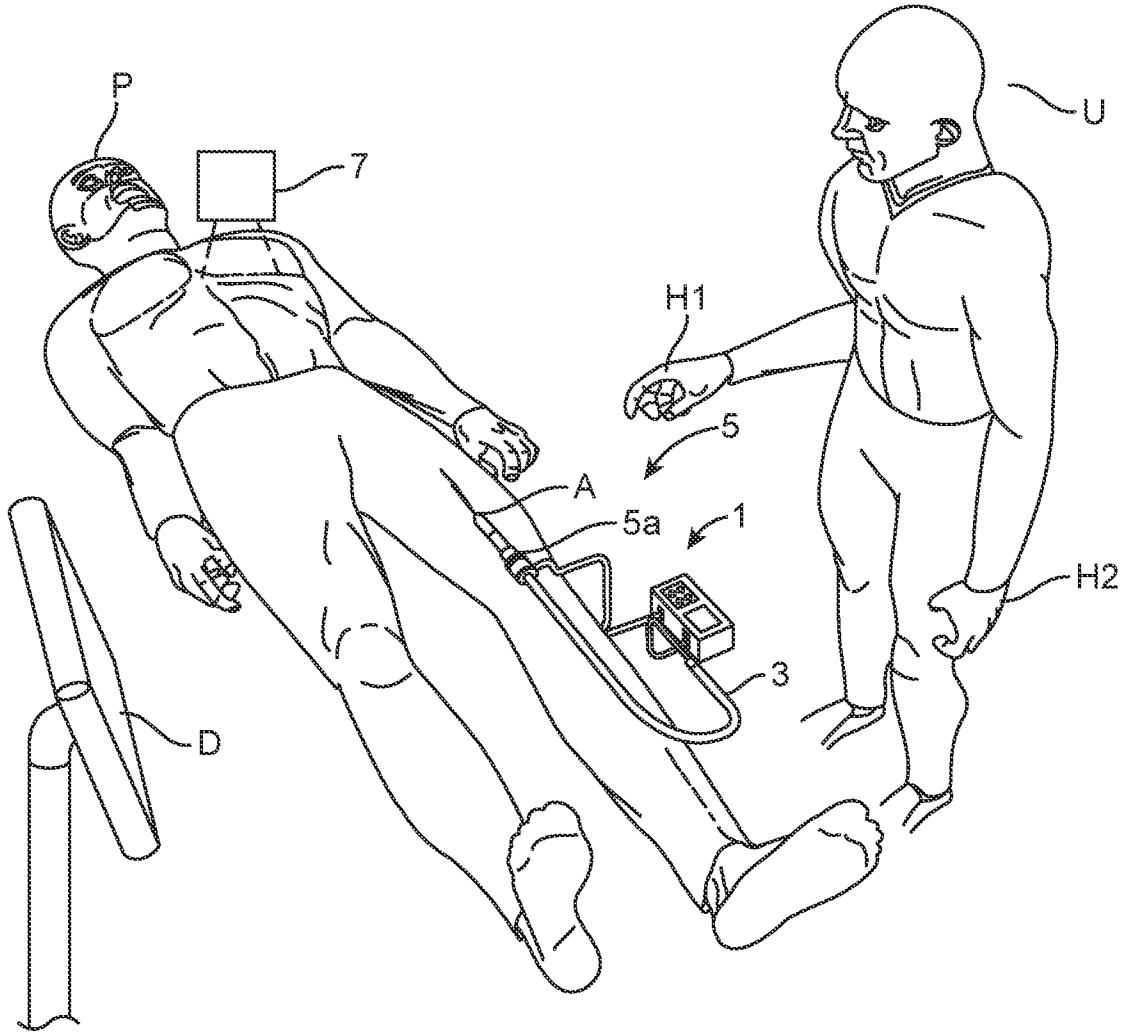


FIG. 1

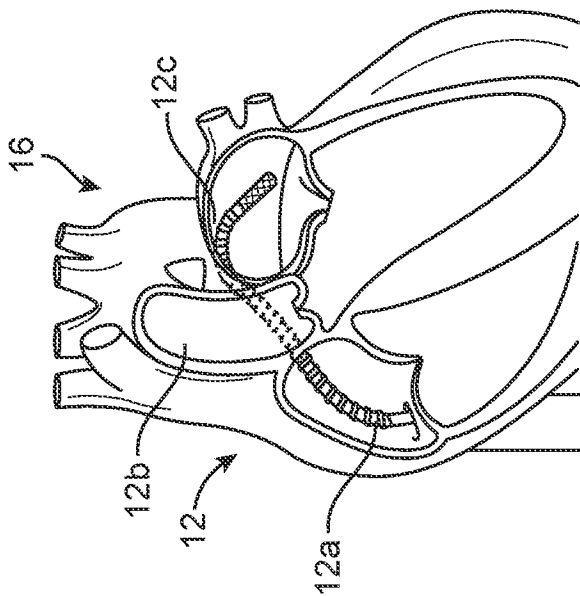


FIG. 2A

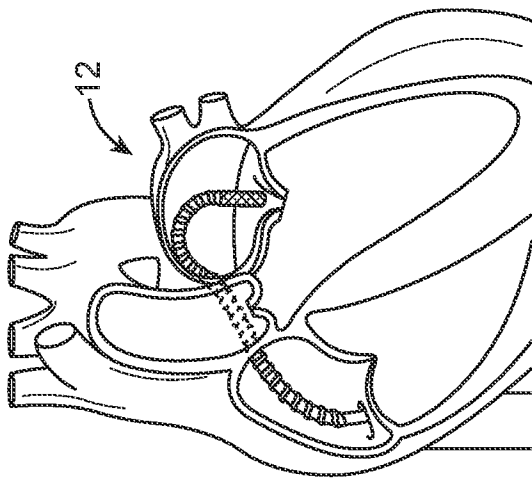


FIG. 2B

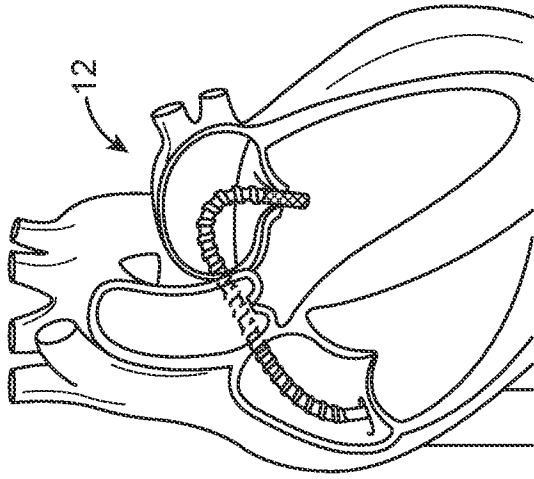


FIG. 2C

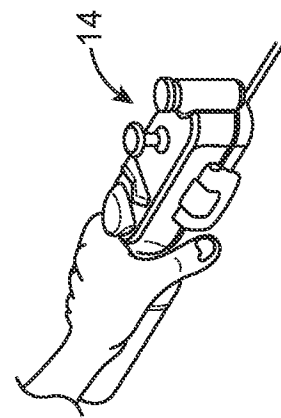


FIG. 3A

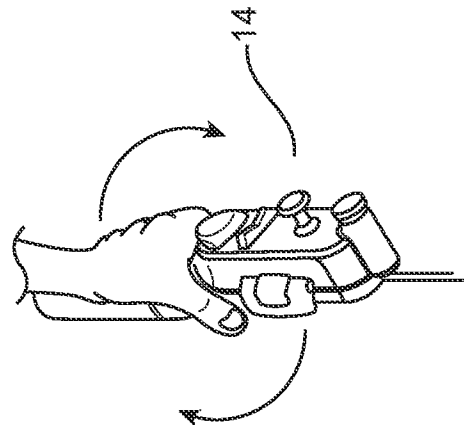


FIG. 3B

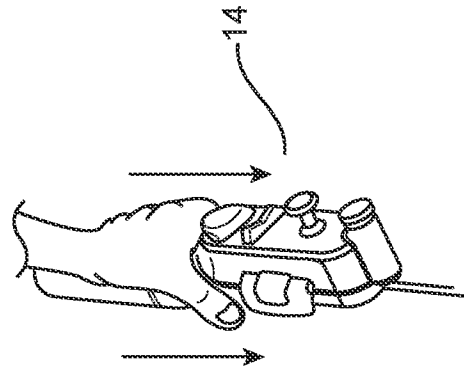


FIG. 3C

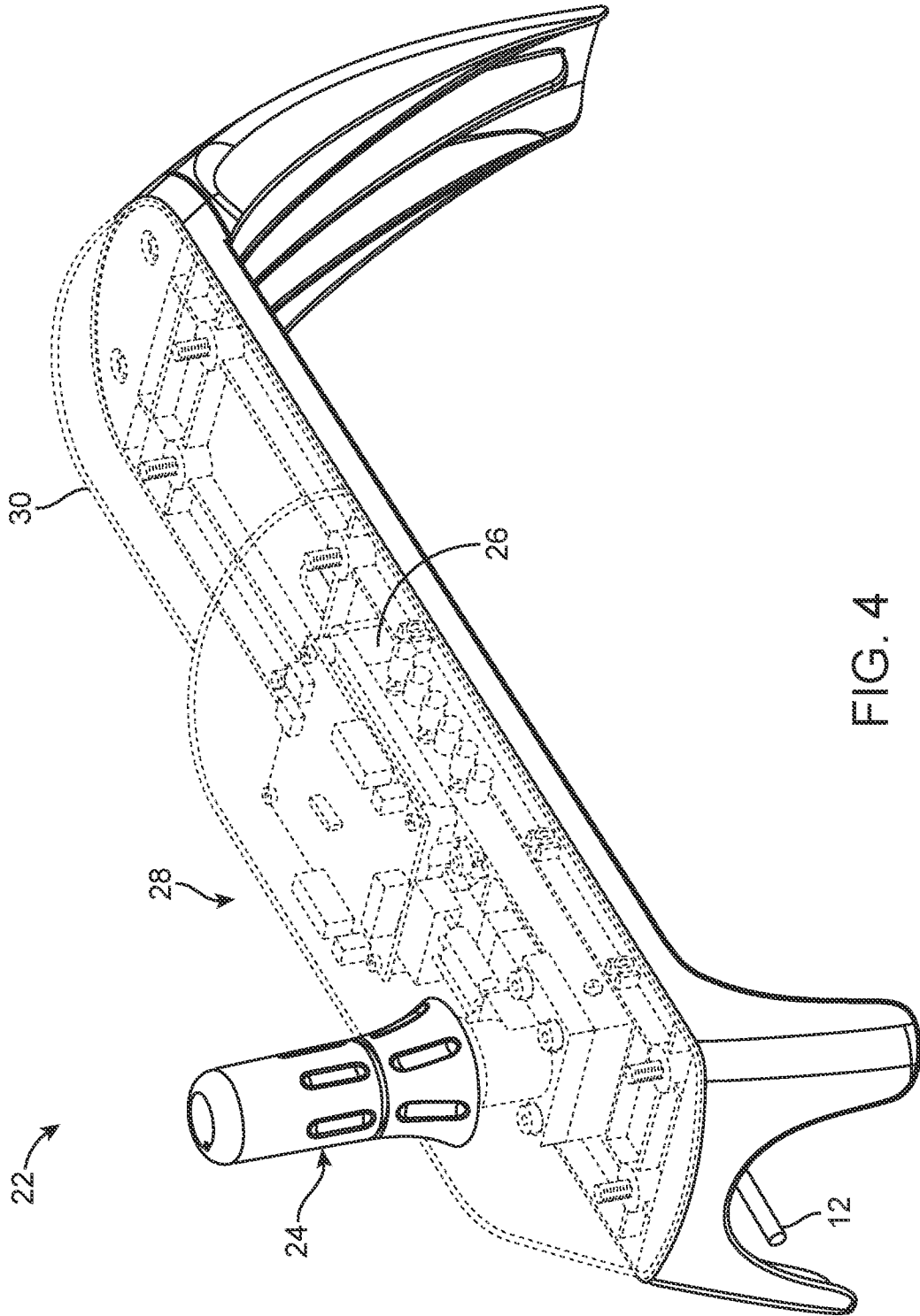


FIG. 4

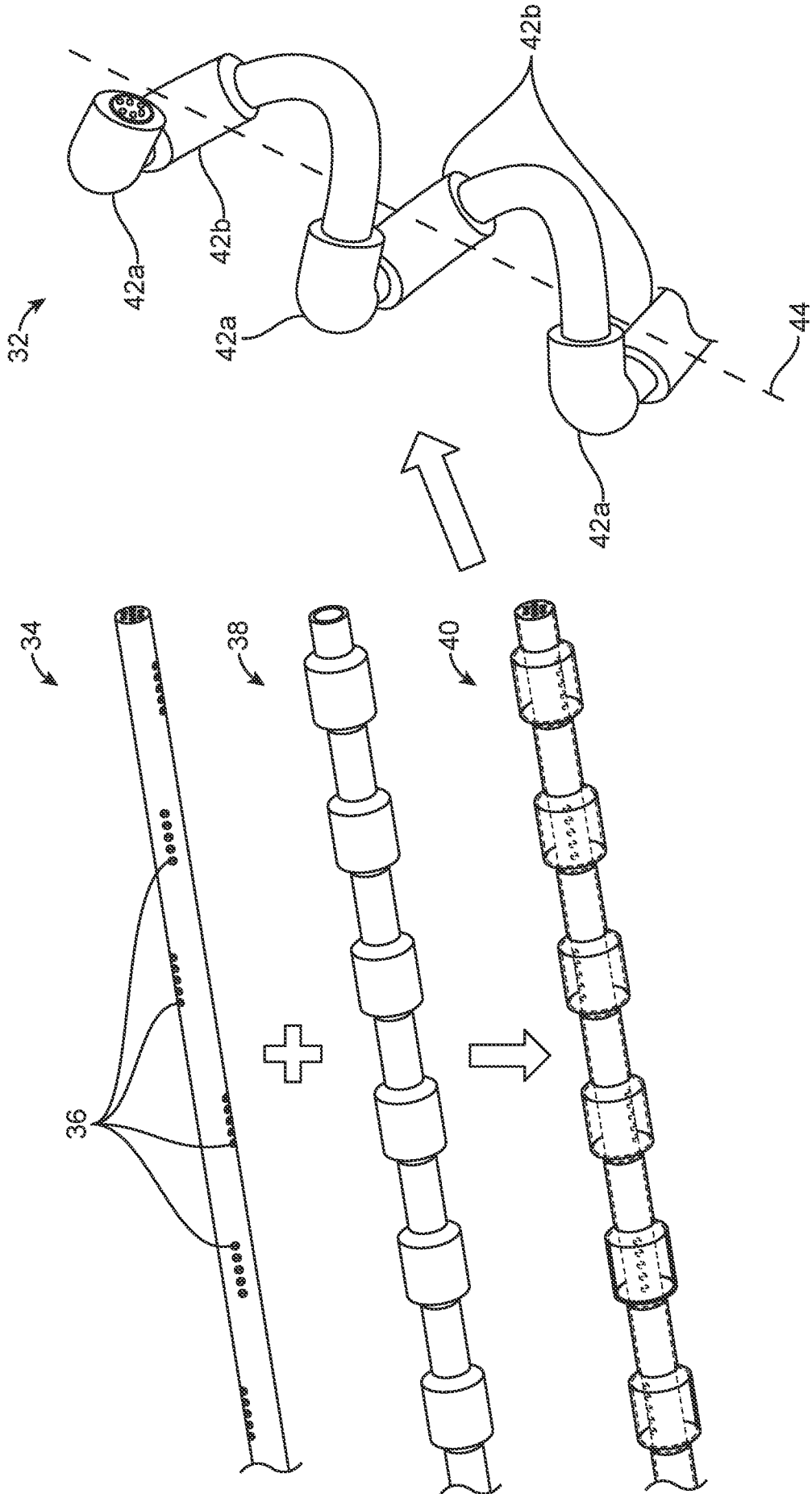


FIG. 5

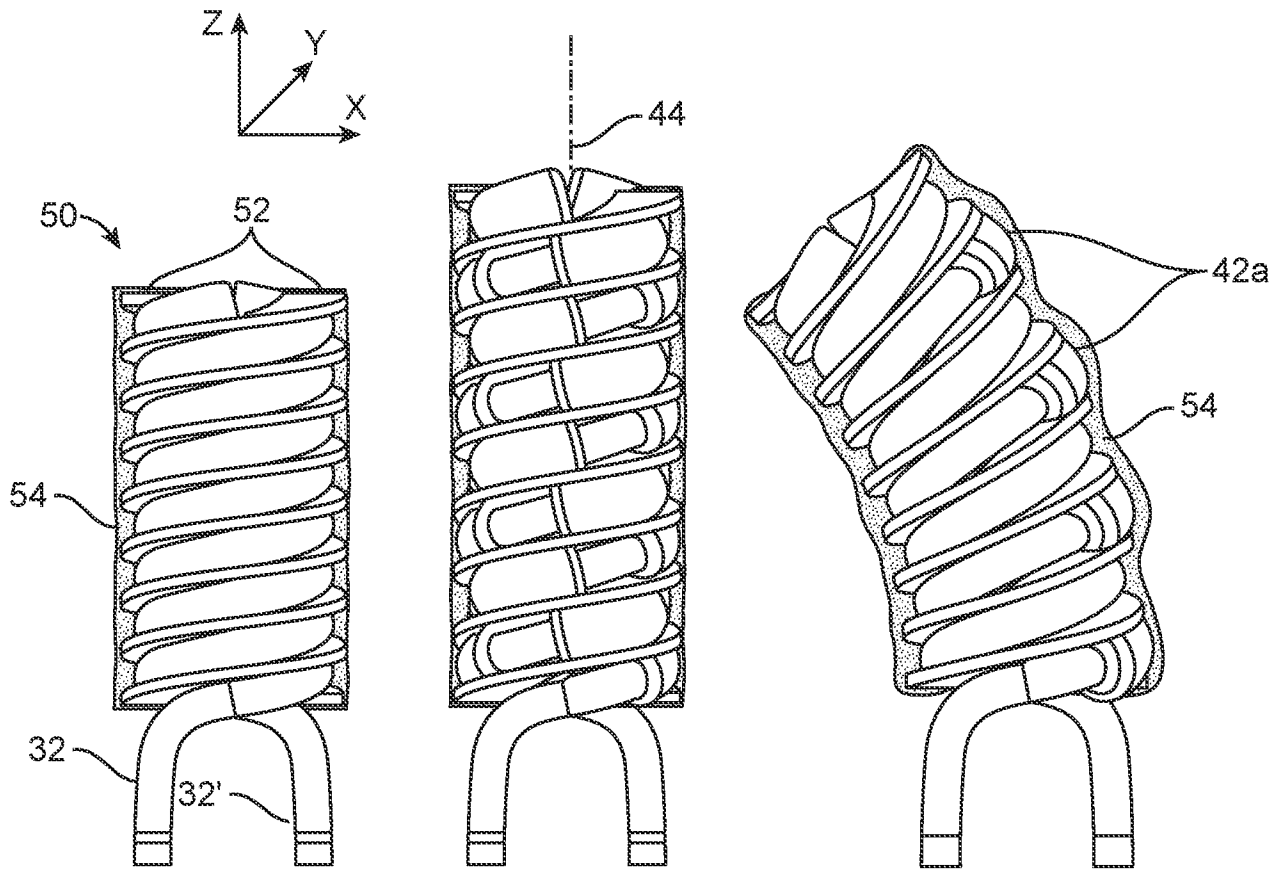


FIG. 6A

FIG. 6B

FIG. 6C

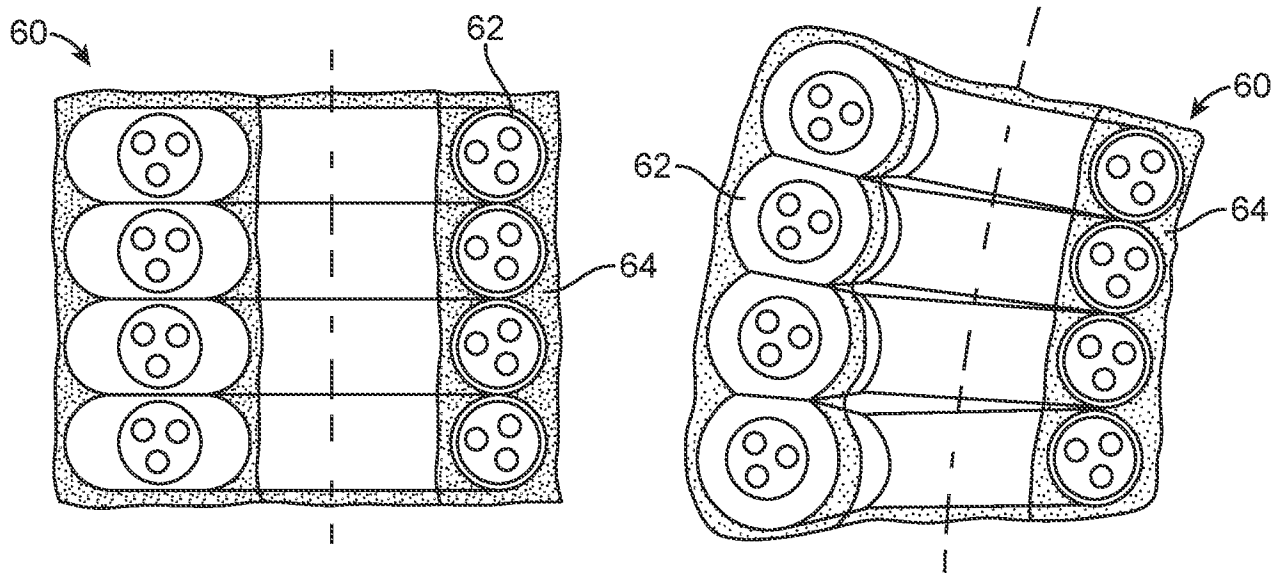


FIG. 7A

FIG. 7B

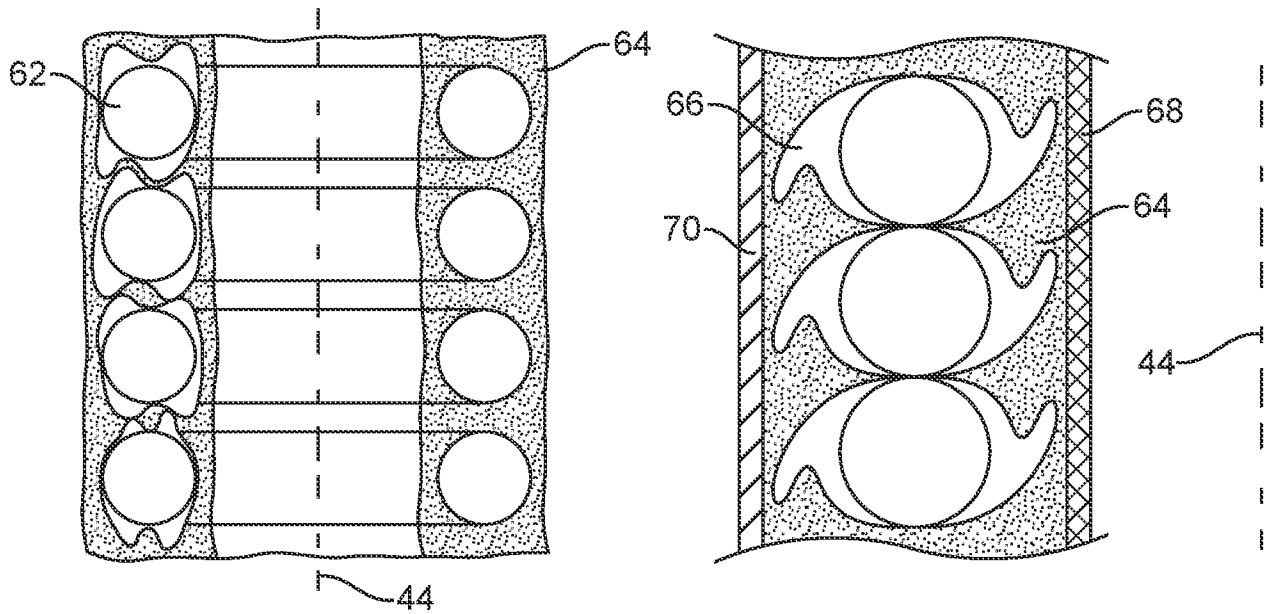


FIG. 8

FIG. 9

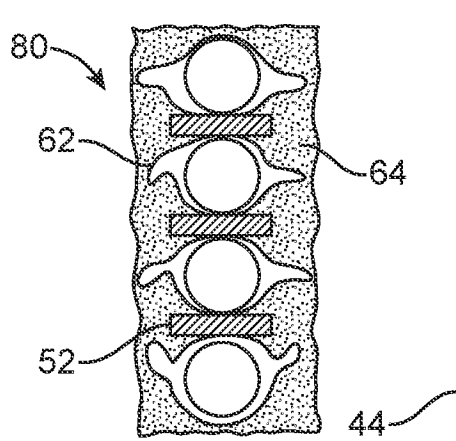


FIG. 10A

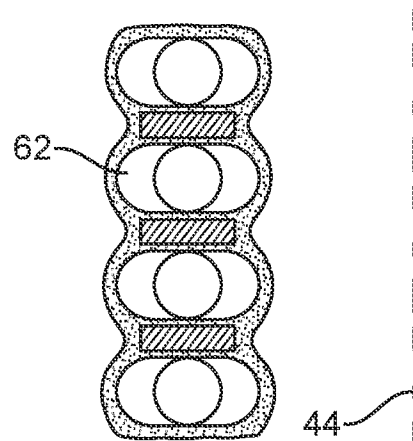


FIG. 10B

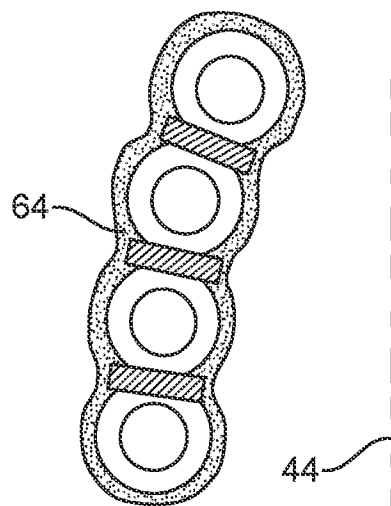


FIG. 10C

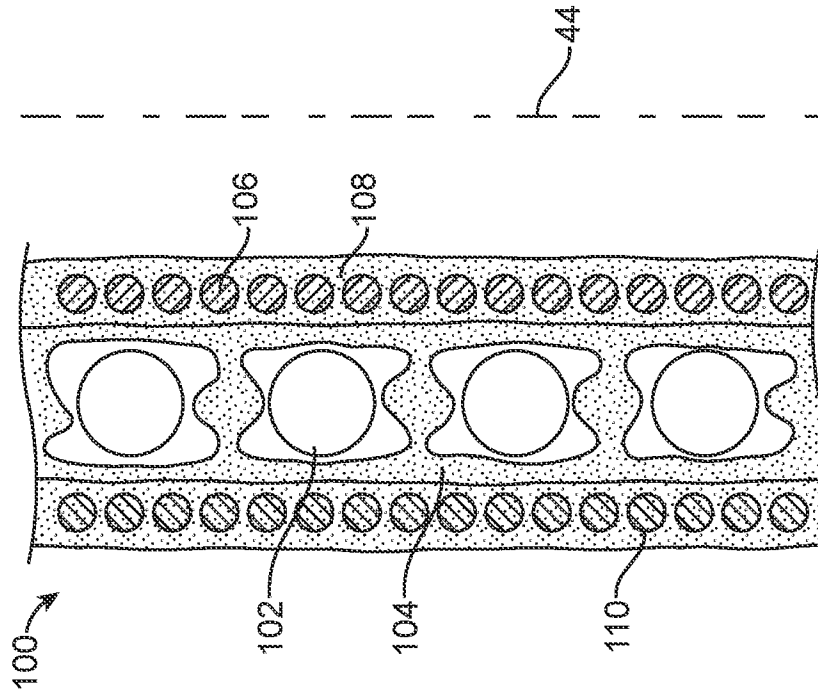


FIG. 12

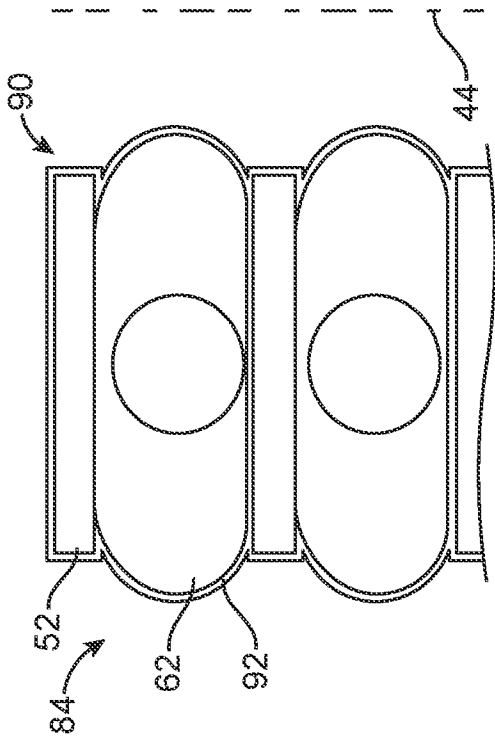


FIG. 11A

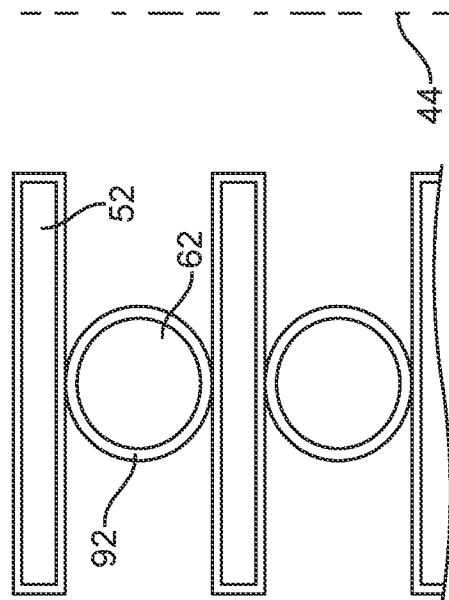


FIG. 11B

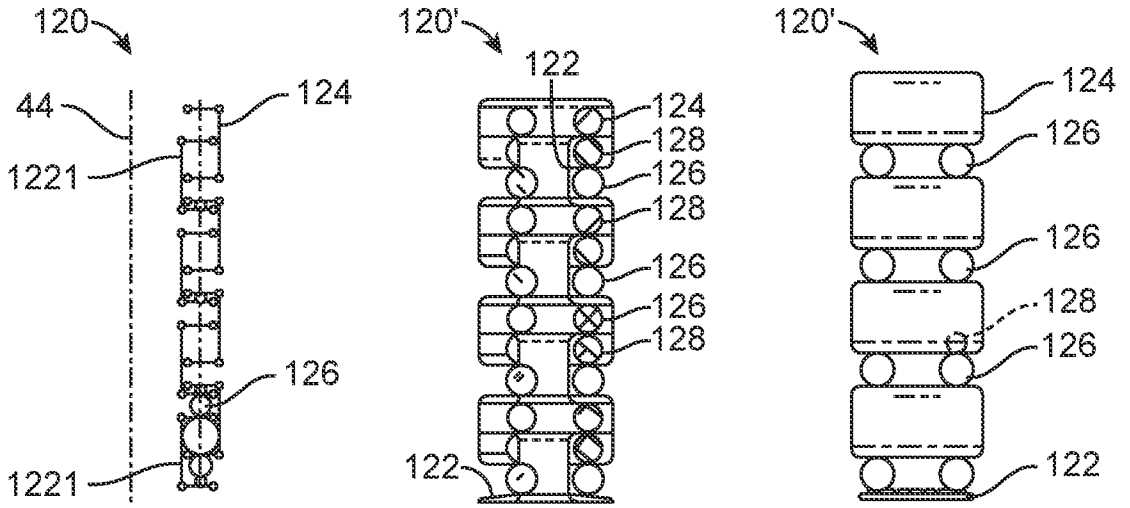


FIG. 13A

FIG. 13B

FIG. 13C

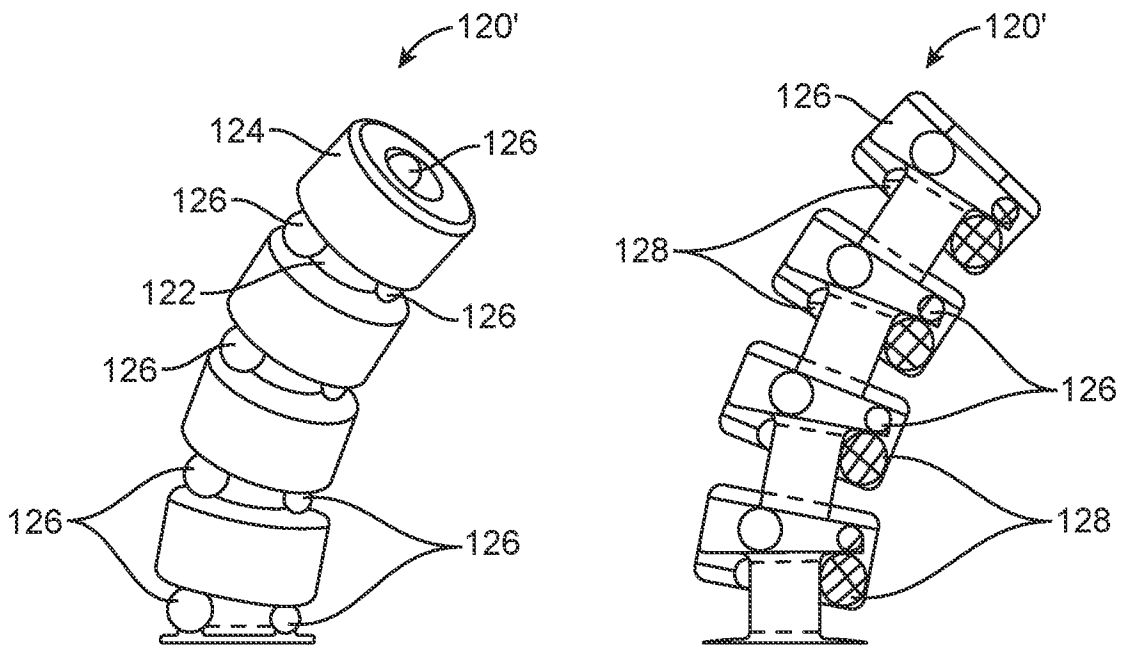


FIG. 13D

FIG. 13E

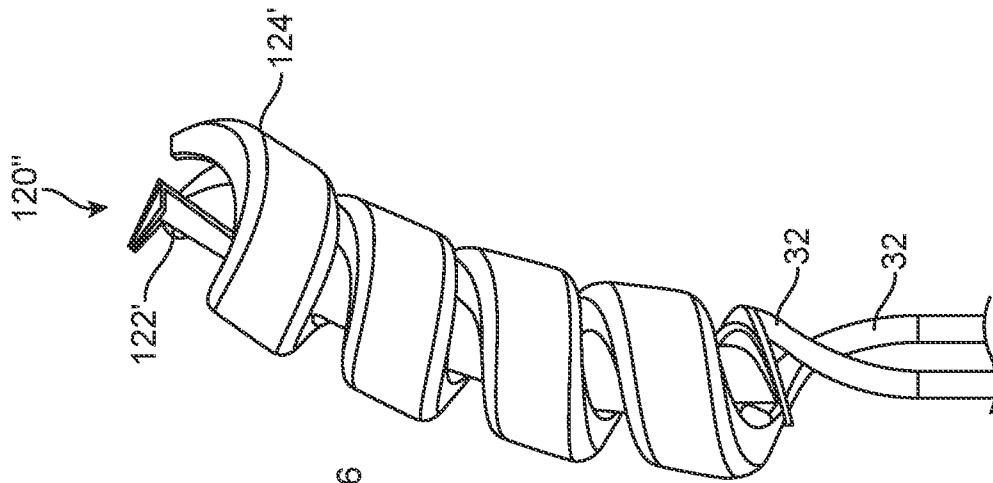


FIG. 14A

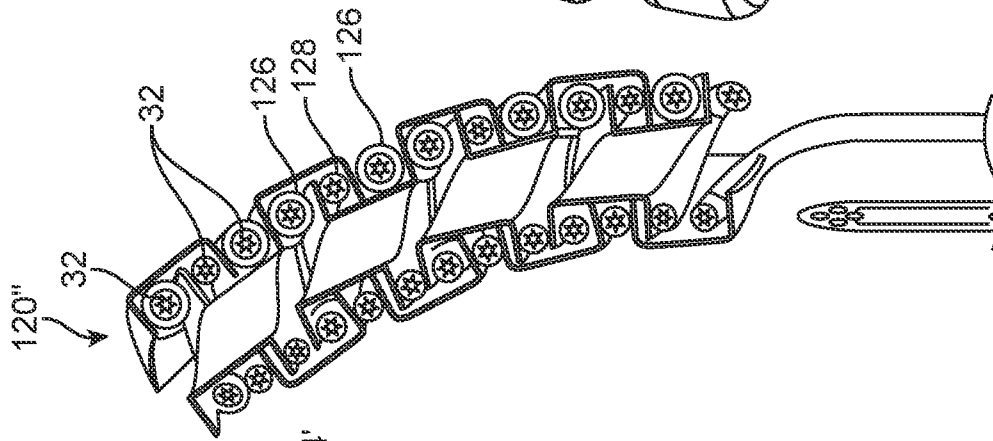


FIG. 14B

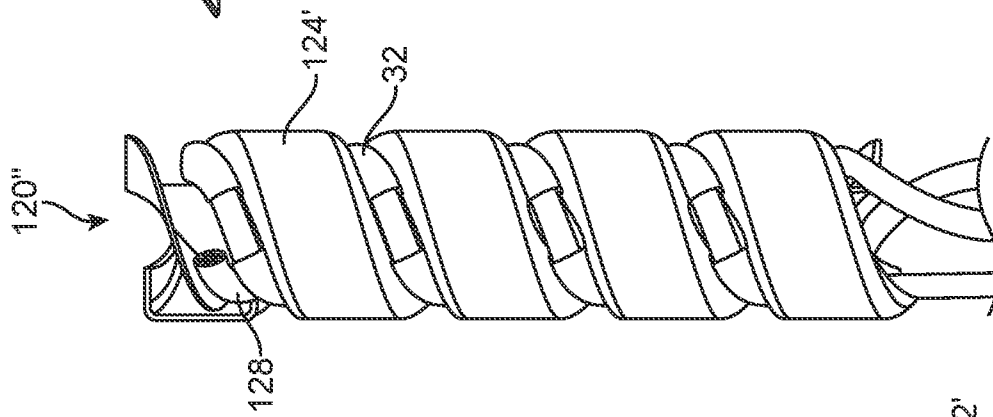


FIG. 14C

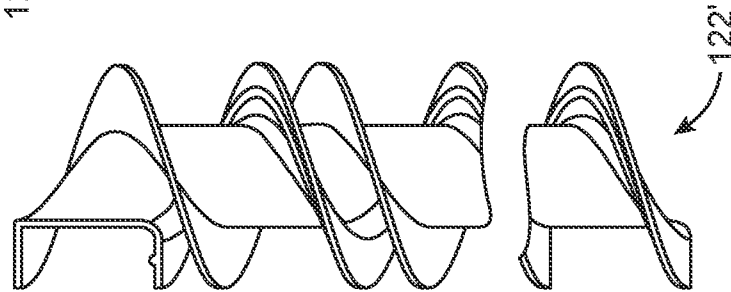


FIG. 14D

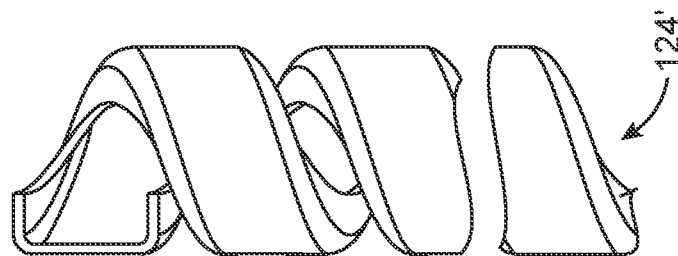


FIG. 14E

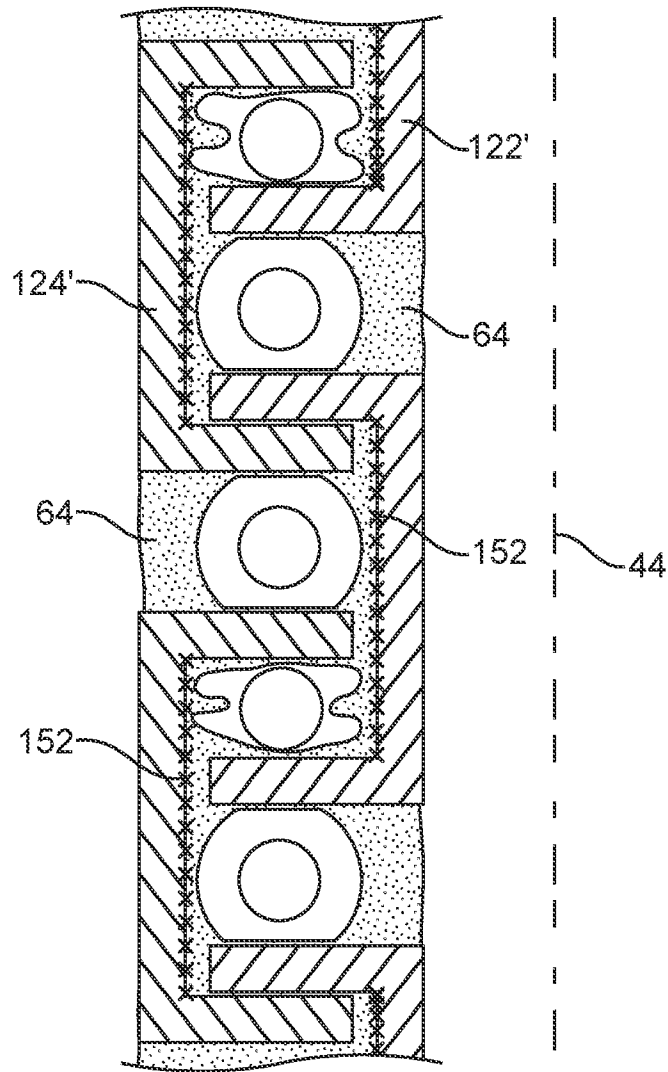


FIG. 15

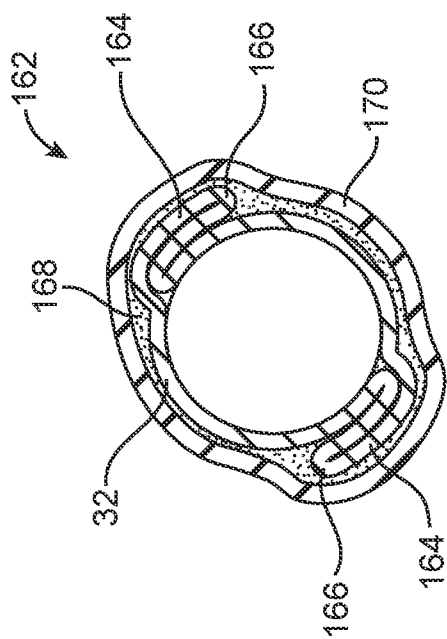


FIG. 16A

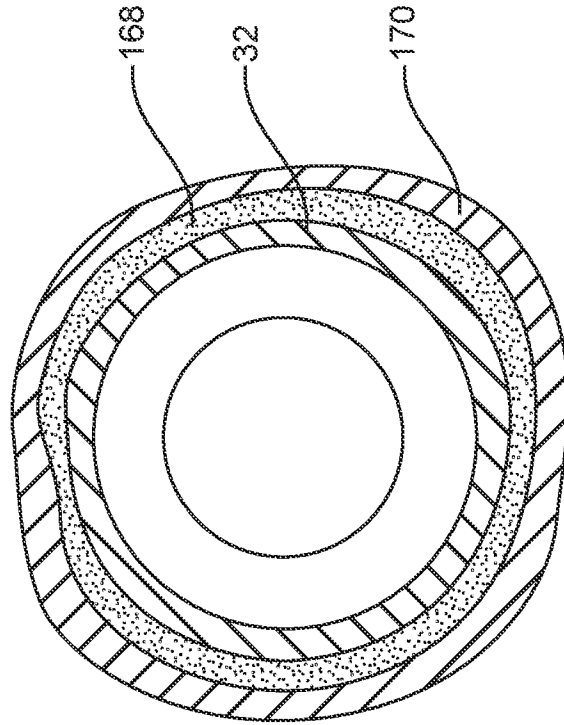


FIG. 16C

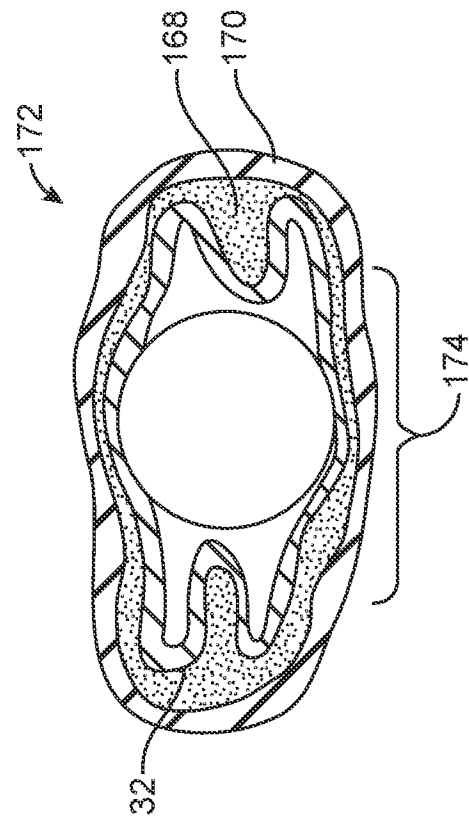


FIG. 16B

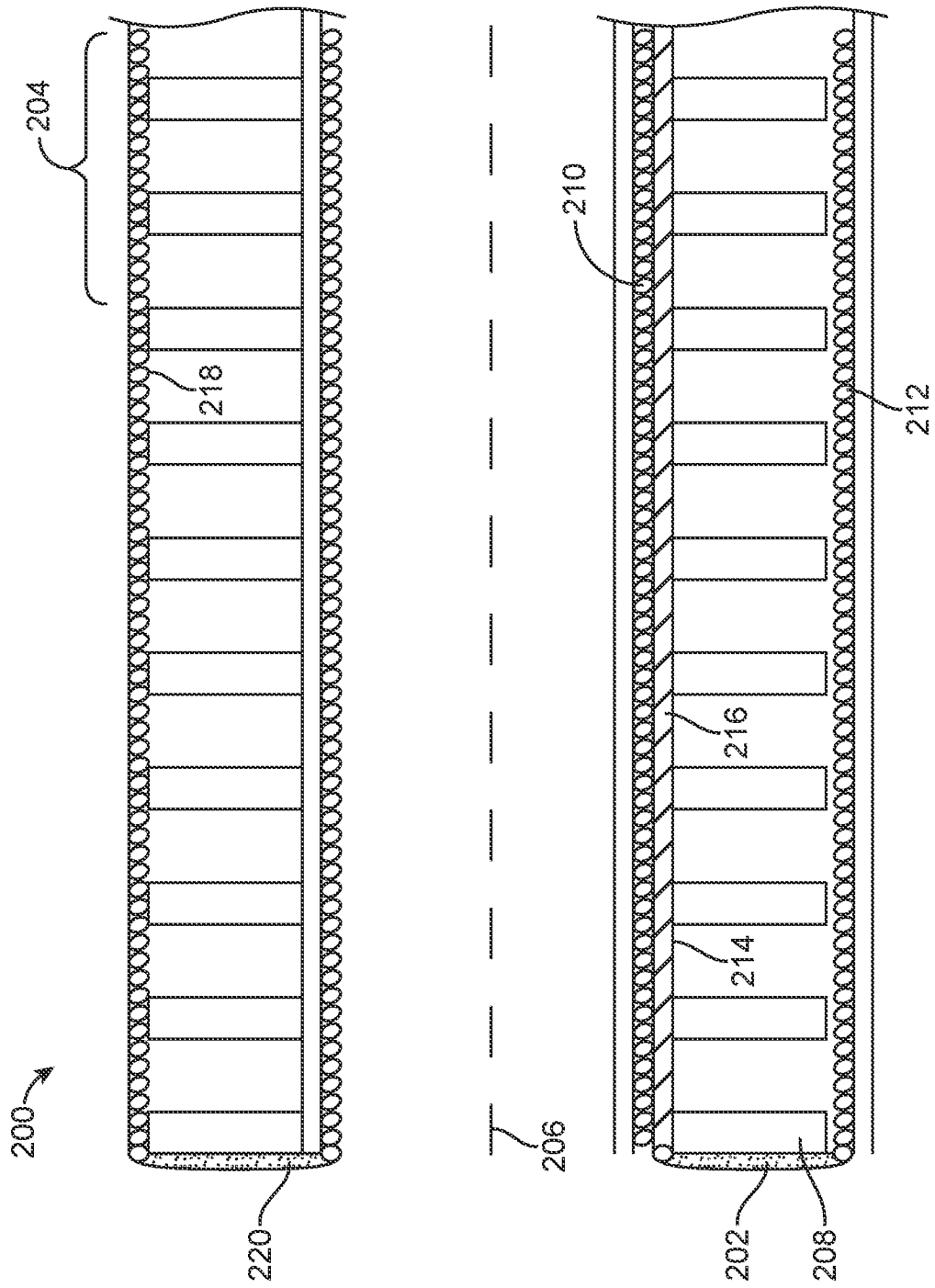


FIG. 17

<p>A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61B 1/00, A61B 17/068, A61B 17/28, A61B 19/00, A61M 25/00 (2018.01) (See Extra Sheet) CPC - A61B 17/02, A61M 25/0105, A61M 25/0138, A61M 25/0147, A61M 2025/015, A61M 2025/0161, Y10S 901/21, A61B 1/008, A61B 17/29, A61B 17/2909, A61B 2017/00477, A61B 2017/291, A61B 2017/2946, A61B 1/0053, A61B 1/0055, A61B 17/072, A61B 17/07207, A61B 2017/00323, A61B 2017/00424, A61B 2017/00438, A61B 2017/2905, A61B 2017/2927, B25J 9/06, B25J 9/104, B25J 13/02</p> <p>According to International Patent Classification (IPC) or to both national classification and IPC</p>																										
<p>B. FIELDS SEARCHED</p> <p>Minimum documentation searched (classification system followed by classification symbols) See Search History Document</p> <p>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched See Search History Document</p> <p>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) See Search History Document</p>																										
<p>C. DOCUMENTS CONSIDERED TO BE RELEVANT</p> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:10%;">Category*</th> <th style="width:70%;">Citation of document, with indication, where appropriate, of the relevant passages</th> <th style="width:20%;">Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>X</td> <td>US 2016/0279388 A1 (Barrish) 29 September 2016 (29.09.2016), entire document, Figs. 3, 5C, 6A, 6B ; para [0013], [0193], [0201], [0211], [0223]-[0238]</td> <td>1-3, 20</td> </tr> <tr> <td>A</td> <td>US 2009/0112159 A1 (Slattery et al.) 30 April 2009 (30.04.2009), entire document, Fig. 2 , para [0009]</td> <td>1-3, 20</td> </tr> <tr> <td>A</td> <td>US 7,090,637 B2 (Danitz et al.) 15 August 2006 (15.08.2006), entire document</td> <td>1-3, 20</td> </tr> <tr> <td>A</td> <td>US 8,784,476 B2 (Caro et al.) 22 July 2014 (22.07.2014), entire document</td> <td>1-3, 20</td> </tr> <tr> <td>A</td> <td>US 4,762,130 A (Fogarty et al.) 9 August 1988 (09.08.1988), entire document</td> <td>1-3, 20</td> </tr> <tr> <td>A</td> <td>US 2014/0249506 A1 (QMAX, LLC) 4 September 2014 (04.09.2014), entire document</td> <td>1-3, 20</td> </tr> <tr> <td>A</td> <td>US 6,520,933 B1 (Evans et al.) 18 February 2003 (18.02.2003), entire document</td> <td>1-3, 20</td> </tr> </tbody> </table>			Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	X	US 2016/0279388 A1 (Barrish) 29 September 2016 (29.09.2016), entire document, Figs. 3, 5C, 6A, 6B ; para [0013], [0193], [0201], [0211], [0223]-[0238]	1-3, 20	A	US 2009/0112159 A1 (Slattery et al.) 30 April 2009 (30.04.2009), entire document, Fig. 2 , para [0009]	1-3, 20	A	US 7,090,637 B2 (Danitz et al.) 15 August 2006 (15.08.2006), entire document	1-3, 20	A	US 8,784,476 B2 (Caro et al.) 22 July 2014 (22.07.2014), entire document	1-3, 20	A	US 4,762,130 A (Fogarty et al.) 9 August 1988 (09.08.1988), entire document	1-3, 20	A	US 2014/0249506 A1 (QMAX, LLC) 4 September 2014 (04.09.2014), entire document	1-3, 20	A	US 6,520,933 B1 (Evans et al.) 18 February 2003 (18.02.2003), entire document	1-3, 20
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<p><input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.</p>																										
<p>* Special categories of cited documents:</p> <table style="width:100%;"> <tr> <td style="width:50%;"> <p>“A” document defining the general state of the art which is not considered to be of particular relevance</p> <p>“E” earlier application or patent but published on or after the international filing date</p> <p>“L” document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>“O” document referring to an oral disclosure, use, exhibition or other means</p> <p>“P” document published prior to the international filing date but later than the priority date claimed</p> </td> <td style="width:50%;"> <p>“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</p> <p>“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</p> <p>“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</p> <p>“&” document member of the same patent family</p> </td> </tr> </table>			<p>“A” document defining the general state of the art which is not considered to be of particular relevance</p> <p>“E” earlier application or patent but published on or after the international filing date</p> <p>“L” document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>“O” document referring to an oral disclosure, use, exhibition or other means</p> <p>“P” document published prior to the international filing date but later than the priority date claimed</p>	<p>“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</p> <p>“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</p> <p>“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</p> <p>“&” document member of the same patent family</p>																						
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<p>Date of the actual completion of the international search</p> <p>20 June 2018</p>		<p>Date of mailing of the international search report</p> <p style="font-size: 24px; font-weight: bold;">20 SEP 2018</p>																								
<p>Name and mailing address of the ISA/US</p> <p>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300</p>		<p>Authorized officer:</p> <p style="text-align: right;">Lee W. Young</p> <p>PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774</p>																								

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 18/29161

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

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

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

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

3. Claims Nos.: 4-19
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-3 and 20, directed to an elongate articulatable body comprising a first set of balloons distributed along the inflation tube, the first balloon string comprising a helical balloon coil having a helical axis.

Group II: Claims 21- 23 directed to an elongate articulatable body comprising an articulation balloon array, an outer sheath, an inner sheath, one of the sheaths having a first portion and a second portion axially movable to facilitate articulation.

*Note: see Note below

-- See Extra Sheet --

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

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

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

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-3, 20

Remark on Protest

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

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 18/29161

Continued from: CLASSIFICATION OF SUBJECT MATTER

IPC(8) B25J 13/02, B25J 15/00, B25J 3/00, B25J 9/10, F16C 1/10, G02B 23/24, A61B 0/00, A61B 17/00 (2018.01)

Continued from:

Box III: Observations where unity of invention is lacking

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a first set of balloons distributed along the inflation tube, the balloons of the first set in communication with the first lumen; the first balloon string comprising a helical balloon coil having a helical axis; and a first polymer matrix so as to help maintain alignment between the balloons of the first set when inflation fluid is transmitted through the first lumen, not required by the claims of Group II.

The invention of Group II includes the special technical feature of a tubular cross-section having an outer array profile and an inner array profile; an outer sheath having an axial outer sheath lumen, the outer sheath lumen receiving the articulation balloon array therein so that a surface of the outer sheath is adjacent the outer array profile; an inner sheath having an axial lumen, the inner sheath disposed within the articulation balloon array so that a surface of the inner sheath is adjacent the inner array profile; one of the sheaths having a first portion adjacent one of the ends of the articulation balloon array and a second portion axially movable relative to the articulation balloon array so as to facilitate articulation of the articulatable body by the articulation balloon array, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of an elongate articulatable body comprising: a first balloon string (generally) having a first end and a second end and an axis therebetween. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2016/0279388 A1 to Barrish, which discloses of an elongate articulatable body (para [0013]; Fig. 3) comprising: a first balloon string (generally) having a first end (left proximal end of 62, Fig. 3) and a second end (right distal end of 62, Fig. 3) and an axis (center of 64, Fig.3) therebetween.

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

*Note: Claims 4-19 are unsearchable because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).