



- (51) **International Patent Classification:**
A61M 25/00 (2006.01)
- (21) **International Application Number:**
PCT/US2011/065515
- (22) **International Filing Date:**
16 December 2011 (16.12.2011)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
61/430,303 6 January 2011 (06.01.2011) US
13/326,093 14 December 2011 (14.12.2011) US
- (71) **Applicant (for all designated States except US):** GORE ENTERPRISE HOLDINGS, INC. [US/US]; 551 Paper Mill Road, P.O.Box 9206, Newark, DE 19714-9206 (US).
- (72) **Inventors; and**
- (75) **Inventors/Applicants (for US only):** CULLY, Edward, H. [US/US]; 940 Sinagua Heights Dr., Flagstaff, AZ 86004 (US). DUNCAN, Jeffrey, B. [US/US]; 303 Comanche, Flagstaff, AZ 86001 (US). TRAPP, Benjamin, M. [US/US]; 6860 Bader Road, Flagstaff, AZ 86001 (US).
- (74) **Agents:** CARLETON, Katherine, L. et al.; W.L Gore & Associates, Inc., 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714-9206 (US).

- (81) **Designated States** (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) **Designated States** (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- without international search report and to be republished upon receipt of that report (Rule 48.2(g))

(54) **Title:** METHODS AND APPARATUS FOR AN ADJUSTABLE STIFFNESS CATHETER

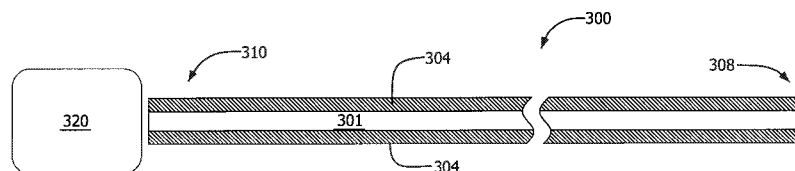


FIG. 3

(57) **Abstract:** Apparatus and methods for an endovascular catheter that can be inserted within tortuous body anatomies and then selectively stiffened and fixed in place. In a particular embodiment, this stiffness is reversible. The stiffness or a comparable mechanical characteristic of the catheter assembly may be adjusted to a relatively low value during insertion (so that it easily navigates a guide wire or the like), and then subsequently adjusted to a relatively high value in situ to keep the catheter assembly substantially fixed in place (i.e., during delivery of an interventional device).



METHODS AND APPARATUS FOR AN ADJUSTABLE STIFFNESS CATHETER

CROSS-REFERENCE TO A RELATED APPLICATION

[0001] This application claims the priority benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 61/430,303 filed on January 6, 2011, the content of which is incorporated herein in its entirety.

TECHNICAL FIELD

[0002] Embodiments of the subject matter described herein generally relate to catheter systems, and more particularly relate to catheters of the type used in the context of tortuous anatomic features.

BACKGROUND

[0003] Catheters are useful in performing a wide range of medical procedures, such as diagnostic heart catheterization, percutaneous transluminal coronary angioplasty, and various endocardial mapping and ablation procedures. It is often difficult, however, to selectively catheterize certain vessels of the human body due to the tortuous paths that the vessels follow. FIG. 1, for example, is a conceptual diagram useful in depicting the human aortic arch 100. As shown, the ascending aorta 110 rises from its origin at the aortic valve (not shown). The right common carotid 104 and the right subclavian 103 branch off of the brachiocephalic artery 102. The left common carotid 105 and the left subclavian artery 106 branch and rise from the aorta just before it turns and descends to the descending aorta 120. Dashed line 170 depicts a typical catheter placement that might be desirable in this context.

[0004] Normal aortic arches such as that shown in FIG. 1 rarely require intervention. Instead, interventionalists most often find themselves viewing and navigating diseased and abnormal aortic pathology, such as that shown in FIGS. 2A-2D, which depict assorted variant conditions of the human aortic arch (201-204). It is clear that navigation from the descending aorta 120, up over the arch, and then back to gain access to the right brachiocephalic artery 102 can be

extremely difficult in such cases, particularly when the arteries are partially occluded with easily displaced and dislodged build-ups of plaque.

[0005] As a result, catheterization procedures often require multiple catheter exchanges – i.e., successively exchanging catheters with different sizes and/or stiffness to "build a rail" through which subsequent catheters can be inserted, eventually resulting in a wire and guide stiff enough to allow delivery of the intended interventional device (e.g., a stent, stent-graft, or the like).

[0006] Flexibility is therefore desirable in a catheter to allow it to track over a relatively flexible guidewire without causing the guidewire to pull out. That is, the "navigability" of the catheter is important. At the same time, the stiffness or rigidity of the same catheter is desirable to allow the guiding catheter to be robust enough to allow a relatively stiff device (such as a stent) to be tracked through the guiding catheter without causing the guiding catheter to lose position (i.e., becoming "dislodged"). If dislodgement occurs, the entire procedure of guide wire and guide catheter exchanges must be performed again from the beginning.

[0007] Often, an optimal balance is sought, such that the distal end of the catheter is flexible, and the proximal end is stiff to enable tracking. However, in order to move the stiff part of a catheter in place, the flexible section typically needs to be buried deep within the anatomy to get "purchase" and to hold position. In many instances, the anatomy does not allow for deep purchase. Accordingly, there is a need for catheter designs and methods that overcome these and other shortcomings of the prior art.

SUMMARY OF THE INVENTION

[0008] The present invention generally relates to a catheter assembly having an adjustable stiffness during, for example, endovascular procedures within the human body. That is, the stiffness or a comparable mechanical characteristic of the catheter assembly may be adjusted to a relatively low value during insertion (so that it easily navigates a guide wire or the like), and then subsequently adjusted to a relatively high value in situ to keep the catheter assembly substantially fixed in place (i.e., during delivery of an interventional device).

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] A more complete understanding of the subject matter may be derived by referring to the detailed description and claims when considered in conjunction with the following figures, wherein like reference numbers refer to similar elements throughout the figures.

[0010] FIG. 1 is a conceptual diagram depicting a human aortic arch useful in describing the present invention;

[0011] FIGS. 2(a)-(d) depict various common aortic pathologies;

[0012] FIG. 3 is a conceptual cross-sectional diagram depicting a catheter apparatus in accordance with one embodiment;

[0013] FIGS. 4 and 5 are qualitative graphs showing the value of a stiffness metric as a function of length for catheters in accordance with various embodiments;

[0014] FIG. 6 depicts a three-point bend test used for measuring a stiffness metric;

[0015] FIGS. 7(a)-(c) depicts an alternate test used for measuring a stiffness metric;

[0016] FIGS. 8(a)-(b) depicts a catheter apparatus in accordance with one embodiment;

[0017] FIG. 9 depicts a catheter apparatus in accordance with one embodiment;

[0018] FIGS. 10 (a)-(b) and 11 depict a catheter apparatus in accordance with one embodiment;

[0019] FIGS. 12-13 depict a catheter apparatus in accordance with one embodiment;

[0020] FIGS. 14-15 depict a catheter apparatus in accordance with one embodiment;

[0021] FIGS. 16-17 depict a catheter apparatus in accordance with one embodiment;

[0022] FIGS. 18(a)-(c) depicts lumen configurations in accordance with various embodiments; and

[0023] FIG. 19 depicts a qualitative graph showing the value of a stiffness metric in accordance with one embodiment.

DETAILED DESCRIPTION

[0024] Overview

[0025] Referring to the longitudinal cross-section shown in FIG. 3, a catheter apparatus (or simply "catheter") 300 in accordance with one embodiment generally includes a generally tubular body (or simply "body") 304 having a delivery lumen (or simply "lumen") 301 defined therein. Catheter 300 extends from a distal end 308 (generally, the end configured to be inserted first within an anatomical feature) and a proximal end 310 opposite distal end 308. A controller 320 communicatively coupled to catheter body 304 and/or lumen 301 will also typically be provided for controlling the operation of catheter 300, as discussed in further detail below.

[0026] An activation means (not illustrated in FIG. 3) is provided for causing body 304 to enter two or more states, which may be discrete states or states that vary continuously, or a combination thereof. The activation means will generally include a variety of mechanical, pneumatic, hydraulic, electrical, thermal, chemical, and or other components as described in connection with the various embodiments presented below, and may be incorporated into body 304, lumen 301, controller 320, or a combination thereof. In various embodiments, controller 320 is one component of the activation means.

[0027] In general, body 304 can be selectably placed in at least two states. In the first state, body 304 has a relatively low stiffness and/or has other mechanical properties selected such that catheter 300 can easily be inserted (e.g., via manual axial force applied at proximal end 310) over a guide wire or the like without substantially disturbing the placement of that guide wire. A variety of conventional, commercially available guide wires are known in the art, and need not be discussed in detail herein. In the second state, body 304 has a relatively high stiffness and/or other has mechanical properties selected such that catheter 300 remains substantially in place within the anatomical feature during subsequent operations, including the removal of any guide wire used during insertion. Stated another way, while in the first state, body 304 has a stiffness metric that is equal to or less than a predetermined "navigability threshold," and while in the second state, body 304 has a stiffness metric that is greater than or equal to a predetermined "rigidity threshold." This is illustrated in FIG. 19, which

qualitatively depicts two states (1902 and 1904) and their corresponding stiffness threshold values (i.e., navigability threshold and rigidity threshold, respectively).

[0028] The term "stiffness metric" as used herein refers to a dimensionless or dimensional parameter that may be defined in various ways, as described in further detail below. However, regardless of the nature of the stiffness metric, the navigability threshold and rigidity threshold define the primary modes of operation of catheter 300. In this regard, note that "stiffness metric" is often used herein to refer to an actual stiffness metric *value*.

[0029] **Stiffness Metric and Thresholds**

[0030] FIG. 4 presents a qualitative graphical representation of a stiffness metric (S) as a function of distance along catheter 300 from its proximal end to its distal end. FIG. 4 corresponds to the case where the stiffness metric is substantially uniform along its length, but as will be seen below, the invention is not so limited. Dashed line 412 indicates the navigability threshold, and dashed line 410 represents the rigidity threshold for a given stiffness metric. While in the first state (during insertion) catheter 300 has a stiffness metric 402 that is equal to or less than navigability threshold 412. Similarly, while in the second state, catheter 300 has a stiffness metric 410 that is greater than or equal to rigidity threshold 410.

[0031] In one embodiment, the stiffness metric corresponds to the flexural modulus of catheter 300 -- i.e., the ratio of stress to strain during bending, as is known in the art. This value may be determined empirically, for example, using a three-point bend test as shown in FIG. 6, wherein catheter 300 (or a portion of catheter 300) is placed on a pair of supports 602 and 604 that are a known distance apart, and a downward (radial) force 608 is applied to catheter 300 via a third structure 606 that is situated between supports 602 and 604.

[0032] In another embodiment, the stiffness metric corresponds to an empirical measurement that more closely models the actual operation of catheter 300. For example, FIGS. 7(a)-(c) depict a "dislodgment" test that simulates the placement of a catheter 300 placed at approximately a 90-degree angle (although this angle may vary depending upon the test). More particularly, stationary supports 702, 704, and 706 are positioned in a predetermined geometric relation such that catheter 300 (or a short segment cut from catheter 300) must bend to fit

between supports 702 and 704 while contacting support 706. Additional supports (not illustrated) may also be used to assist in placing catheter 300.

[0033] During the start of the test, a probe 702 is inserted within one end of catheter 300 as shown (FIG. 7(a)). Probe 702 might be configured to approximate the stiffness of a typical stent-graft or the like. As probe 702 is further inserted into the lumen 301 of catheter 300, it makes contact with the inner surface of the lumen 301 and causes end 308 to move with respect to support 702. Ultimately, when probe 702 is inserted with a sufficient force, catheter 300 will be released entirely from between supports 702 and 704 as shown. The force necessary to dislodge catheter 300 in this way then becomes the stiffness metric. The test is advantageously conducted at approximately 37°C (body temperature). Further, the test may be initiated with an exemplary guide wire in place, thereby allowing the navigability threshold to be determined.

[0034] **Stiffness Metric Variation**

[0035] While FIG. 4 depicts the stiffness metric as being invariant over the length of catheter 300, the invention is not so limited. FIG. 5 presents a qualitative graphical representation of stiffness metric (S) as a function of distance along catheter 300 from its proximal end to its distal end; however, in this embodiment, catheter 300 includes two "zones" or segments, each having a corresponding stiffness metric while in the second state. That is, in zone 520, the stiffness metric in the second state (504) is substantially the same as the stiffness metric in the first state (502) (i.e., is generally below the navigability threshold 412). Within zone 522, the stiffness metric in the second state (504) is above the rigidity threshold 410.

[0036] Catheter 300 may include any number of such zones. Furthermore, the stiffness metric within each zone may be constant or vary continuously. In a particular embodiment, a first zone is adjacent to the distal end of catheter 300, and a second zone is adjacent to the first zone, wherein the stiffness metric of the first zone is less than the stiffness metric of the second zone while in the second state.

[0037] In an alternate embodiment, catheter 300 has one stiffness metric value along a first curvature axis and another stiffness metric value along a second curvature axis that is orthogonal to the first curvature axis.

[0038] **Catheter Body**

[0039] Catheter body 304 may have any suitable structure, and be fabricated using any suitable combination of materials capable of achieving the selectable stiffness metric described above. For example, in one embodiment, catheter body 304 includes a helical (spiral) channel formed within its exterior and/or its interior. The channel effectively weakens body 304 such that the stiffness metric in the first state is lower than it would be if the body 304 were perfectly tubular. In another embodiment, catheter body 304 includes a plurality of ring-shaped channels formed circumferentially therein. In a particular embodiment, the plurality of ring-shaped channels are distributed irregularly along the tubular body. Such an embodiment allows the baseline stiffness metric to vary in a specified way along the length of catheter 300.

[0040] Catheter body 304 may comprise a variety of materials. Typical materials used to construct catheters can comprise commonly known materials such as Amorphous Commodity Thermoplastics that include Polymethyl Methacrylate (PMMA or Acrylic), Polystyrene (PS), Acrylonitrile Butadiene Styrene (ABS), Polyvinyl Chloride (PVC), Modified Polyethylene Terephthalate Glycol (PETG), Cellulose Acetate Butyrate (CAB); Semi-Crystalline Commodity Plastics that include Polyethylene (PE), High Density Polyethylene (HDPE), Low Density Polyethylene (LDPE or LLDPE), Polypropylene (PP), Polymethylpentene (PMP); Amorphous Engineering Thermoplastics that include Polycarbonate (PC), Polyphenylene Oxide (PPO), Modified Polyphenylene Oxide (Mod PPO), Polyphenylene Ether (PPE), Modified Polyphenylene Ether (Mod PPE), Polyurethane (PU), Thermoplastic Polyurethane (TPU); Semi-Crystalline Engineering Thermoplastics that include Polyamide (PA or Nylon), Polyoxymethylene (POM or Acetal), Polyethylene Terephthalate (PET, Thermoplastic Polyester), Polybutylene Terephthalate (PBT, Thermoplastic Polyester), Ultra High Molecular Weight Polyethylene (UHMW-PE); High Performance Thermoplastics that include Polyimide (PI, Imidized Plastic), Polyamide Imide (PAI, Imidized Plastic), Polybenzimidazole (PBI, Imidized Plastic); Amorphous High Performance Thermoplastics that include Polysulfone (PSU), Polyetherimide (PEI), Polyether Sulfone (PES), Polyaryl Sulfone (PAS); Semi-Crystalline High Performance Thermoplastics that include Polyphenylene Sulfide (PPS), Polyetheretherketone (PEEK); and Semi-Crystalline High

Performance Thermoplastics, Fluoropolymers that include Fluorinated Ethylene Propylene (FEP), Ethylene Chlorotrifluoroethylene (ECTFE), Ethylene, Ethylene Tetrafluoroethylene (ETFE), Polychlorotrifluoroethylene (PCTFE), Polytetrafluoroethylene (PTFE), Expanded Polytetrafluoroethylene (ePTFE), Polyvinylidene Fluoride (PVDF), Perfluoroalkoxy (PFA). Other commonly known medical grade materials include elastomeric organosilicon polymers, polyether block amide or thermoplastic copolyether (PEBAX), Kevlar, and metals such as stainless steel and nickel/titanium (nitinol) alloys.

[0041] The material or materials selected for catheter body 304 may depend upon, for example, the nature of the activation means used to effect a transition from the first state to the second state of operation. Catheter body 304 may be manufactured, for example, using conventional extrusion methods or film-wrapping techniques as described in U.S. Pat. App. No. 2005/0059957, which is hereby incorporated by reference. Additional information regarding the manufacture of catheters may be found, for example, at U.S. Pat. No. 5,324,284, U.S. Pat. No. 3,485,234, and U.S. Pat. No. 3,585,707, all of which are hereby incorporated by reference.

[0042] **Activation Means (Generally)**

[0043] Catheter 300 includes activation means for causing body 304 to enter two or more states as detailed above. The activation means may make use of a variety of physical phenomenon and be composed of any number of components provided within and/or communicatively coupled to catheter 300, including for example, controller 320 as illustrated in FIG. 1. The change of state may be accomplished, for example, via mechanical activation, electrical activation, pneumatic activation, chemical activation, and/or thermal activation. Typically, activation will occur subsequent to catheter placement -- i.e., in situ. Various specific types of activation means will now be discussed below in conjunction the exemplary embodiments.

[0044] **Embodiment 1: Thermal Activation**

[0045] In one embodiment, the activation means includes a controller 320 communicatively coupled to body 304 as well features within body 304 that are

together adapted to place the body in the second state by subjecting at least a portion of the catheter 300 to a reduction or change in temperature.

[0046] Referring now to FIGS. 8 (a)-(b) in conjunction with FIG. 1, a catheter 300 in accordance with one embodiment generally includes two auxiliary lumens or channels 802 and 804 that are interconnected (e.g., fluidly coupled near a distal end) such that the coolant travels through body 304. The channels 804 and 802 are separated, for example, by a membrane (such as an ePTFE membrane) 806.

[0047] After delivery of catheter 300 (during which it is in the first state), a coolant 805 such as liquid nitrogen is supplied to channel 804 (e.g., via a coolant delivery system within controller 320), where it travels parallel to lumen 301 along the length of (or a portion of) body 304. As the changes from liquid to gas at membrane 806, it cools body 304 as well as membrane 806. The materials for catheter body 304 and/or membrane 806 are selected that their stiffness increases as the temperature is reduced. Exemplary materials include, for example, urethane and the like. As channel 804 is significantly smaller than channel 802, compressed gas 803 is allowed to expand as it passes through membrane 806 into channel 802.

As a result of heat transfer from the coolant, the coolant (in the case of liquid nitrogen) changes to a gas phase and exits through channel 802. In other embodiments, the coolant remains in liquid form during operation. Suitable coolants include, for example, chilled saline, liquid CO₂, liquid N₂, and the like. Other approved medical chilling methods may also be employed.

[0048] **Embodiment 2: Axial Compression**

[0049] Referring now to FIGS. 16 and 17 in conjunction with FIG. 1, in one embodiment, the activation means includes controller 320 communicatively coupled to the body 304 and components within body 304 that are adapted to place body 304 in the second state by subjecting it to an increase in axial compression.

[0050] As shown in FIG 16, one or more tension lines 1602 may be used to selectively apply a compressive force to body 304. The tension lines 1602 are attached at the distal end 308 of catheter 300 and are slideably received by corresponding accessory lumens 1402 that pass through a series of body

segments 1605. The accessory lumens 1402 are preferably sized to allow the free axial movement of tension lines 1602. Depending upon the particular design, body segments 1605 will typically be separated by a small interstitial gaps 1607.

[0051] The tension lines 1602 are subjected to approximately zero tension (i.e., are generally "slack") while navigating the anatomy during the first state; however, when stiffening of all or a portion of catheter 300 is desired, tension lines 1602 are pulled substantially simultaneously as depicted in FIG. 17. Gaps and the orientation between body segments 1605 may be optimized to reduce (and/or increase the repeatability of) the foreshortening that occurs when tension is applied. In one embodiment, tension wires 1602 are attached to a floating gimbal mechanism incorporated into controller 320. Once tension is applied, the compressive force tends to bind the catheter; thereby decreasing its flexibility in that section. Reduction in the axial length may accompany the application of tension. That is, as illustrated, the interstitial gaps 1607 may be reduced.

[0052] The tension lines may be made of any suitably strong and flexible material, such as polymeric or metallic filaments or ribbons. The force necessary to place catheter 300 in the second state may vary depending upon the length, material, and cross-section of tension lines 1602, as well as the structural characteristics of body 304.

[0053] Any number of tension lines 1602 and accessory lumens 1402 may be used. FIGS. 18(a)-(c) present a cross-sectional view of various designs for catheter body 304, including three equidistant accessory lumens 1402 (FIG. 18(a)), two equidistant accessory lumens 1402 (FIG. 18(b)), and four equidistant accessory lumens (FIG. 18(c)). In addition, equidistant accessory lumens may be distributed in any arbitrary fashion, and need not be symmetrical or equidistant as illustrated.

[0054] In one embodiment, the column stiffness of body 304 is modified to allow for tracking, then increased to deployment without foreshortening during stiffening.

[0055] **Embodiment 3: Radial Compression**

[0056] In one embodiment, the activation means includes controller 320 communicatively coupled to the body 304 and adapted to place the body 304 in the second state by subjecting at least a portion of the tubular body to an

increase in radial compression. For example, body 304 may include two fluid impermeable layers defining a pressure-responsive chamber and at least one interstitial structure provided within the pressure-responsive chamber. The controller is configured to cause a change in internal pressure within the pressure-responsive chamber; and the interstitial structure is adapted to exhibit radial compression in response to the change in internal pressure.

[0057] Referring now to FIG. 9, in the illustrated embodiment catheter 300 includes an accessory lumen 902 extending from chambers 906 to a hub 302. Hub 302 in this embodiment is configured as a standard "Y" fitting, wherein negative pressure (i.e., a reduction from some baseline pressure) is applied by attaching a syringe to luer fitting 910. When negative pressure is applied, chambers 906 collapse and apply pressure to corresponding body segments 904 (as illustrated in FIGS. 12 and 13). The pressure is preferably great enough to cause a change in stiffness metric of the affected portion of catheter 300.

[0058] In an alternate embodiment shown in FIGS. 10A and 10B, the body 304 comprises a layered structure 1002 (i.e., an interstitial component) positioned between two or more layers of an air-impermeable chamber 1004. To facilitate the use of negative pressure, the chamber 1004 includes a flexible polymeric material configured to be non-permeable while in the bloodstream. The flexible polymeric comprise, for example, Polyethylene Terephthalate (PET), Polyurethane, Fluorinated Ethylene Propylene (FEP), Nylons or Fluoropolymers, including Polytetrafluoroethylene (PTFE) or Expanded Polytetrafluoroethylene (ePTFE), or combinations thereof.

[0059] At atmospheric pressure, bending causes the individual components of layers 1002 to slide across each other with minimum friction. When the individual layers are allowed to slide and act individually, the resulting stiffness metric is very low. Upon application of negative pressure, however, a normal (i.e., radial) force 1008 is created within structure 1002 by the collapse of the flexible polymeric material 1004. This normal force is translated through the layers, increasing the layer-to-layer friction and limiting their ability to slide with respect to each other. As a result, the stiffness metric of the structure is increased. In an alternate embodiment, the pressure is increased in an adjacent pressure chamber, thereby causing that chamber to press the adjacent layered structure.

[0060] The layered structure 1002 of the present invention may be manufactured using a variety of processes, including, for example, tape wrapping, braiding, serving, coiling, and manual layup. Suitable materials include, include, fibers/yarns (Kelvar, nylon, glass, etc), wires (flat or round, stainless steel, nitinol, alloys, etc), and/or thin slits of film (Polyester, Nylon, Polyimide, Fluoropolymers including PTFE and ePTFE, etc.) In this embodiment, the change in stiffness metric is easily reversed by allowing the chamber pressure to increase (e.g., by relaxation of a syringe attached to luer fitting 910), thereby decreasing the applied normal force.

[0061] In an alternate embodiment depicted in FIG. 11, multiple discrete air chambers 1102 are distributed along the length of catheter 300 and can be toggled independently. Chambers 1102 may be composed of differentiated layered structures, such as layers of slit, thin film 1104. The distal air chambers may be controlled independently through lumen 1109, while the proximal air chamber is controlled through lumen 1108. This allows the operator to control the segments independently to varying degrees of stiffness change. The lumens 1108 and 1109 may be constructed in a variety of conventional ways, including evacuation through the annular space of the chamber, or individual lumens of tubing such as polyimide that either have an open end in communication with the hub, or holes through the sidewall allowing for unobstructed evacuation.

[0062] **Embodiment 4: Torsional Activation**

[0063] In one embodiment, the activation means includes a controller rotatably coupled to at least two body segments (i.e., portions of body 304), wherein controller 320 is configured to apply a relative rotational force between the body segments to cause the tubular body to enter the second state. In one embodiment, two body segments includes an outer layer, an inner layer, and a torsionally-responsive structure provided therebetween. In one embodiment, for example, the torsionally-responsive structure comprises a substantially cylindrical braided structure.

[0064] **Embodiment 5: Solidifying Material/Membrane**

[0065] In one embodiment, body 304 includes at least one inner chamber, a selectably solidifiable material provided within the inner chamber; and a controller

fluidly coupled to the at least one inner chamber. The solidifiable material is adapted to substantially solidify in response to, for example, UV radiation, the introduction of a catalyst within the inner chamber, a temperature change, the introduction of water (in the case of hydrophilic particles), acoustic energy (in the case of an acoustically-active polymer), or an electrical current or field (in the case of an electroactive polymer).

[0066] FIGS. 14 and 15 depict an exemplary embodiment incorporating a selectively solidifiable material to effect transition to the second state. As shown in FIG. 14, body 304 is at least partially filled with a medium 1404 (for example, within individual chambers as illustrated) that together can alter the stiffness metric of catheter 300. In this embodiment, the medium 1404 is injected through accessory lumens 1402. Medium 1404 may be a substance that hardens relatively quickly, such as a silicone or polyurethane. If medium 1404 requires a catalyst to activate, that catalyst may already reside within the walls of the body 304 or within the material of catheter 300 itself.

[0067] In one embodiment, medium 1404 is a slurry of particles suspended in solution as depicted in FIG. 15. In this case, the walls of body 304 (or membranes provided therein) may be selectively permeable so to allow a carrier liquid to escape (e.g., the chamber and/or catheter body walls) while confining the particles themselves. Once these particles build up and “pack” into the chamber they cause an increased stiffness metric in that section. A variety of suitable particle materials and sizes can be used. In one embodiment, the particle possesses neutral buoyancy in the selected carrier liquid. A hydrophilic particle is advantageous in that it swells during hydration, causing additional binding and increased catheter stiffness.

[0068] **Embodiment 6: Memory Metal**

[0069] In one embodiment, the activation means includes at least one metallic structure having shape-memory properties provided within body 304 and communicatively coupled to a power source (e.g. a voltage and/or current source located within controller 320). In one embodiment, the shape-memory metallic structure comprises a Ni/Ti alloy (nitinol).

[0070] **Conclusion**

[0071] What has been described are methods and apparatus for an endovascular catheter that can be inserted within tortuous body anatomies and then selectively stiffened and fixed in place. In a particular embodiment, this stiffness is reversible. In this regard, the foregoing detailed description is merely illustrative in nature and is not intended to limit the embodiments of the subject matter or the application and uses of such embodiments. As used herein, the word “exemplary” means “serving as an example, instance, or illustration.” Any implementation described herein as exemplary is not necessarily to be construed as preferred or advantageous over other implementations. Thus, although several exemplary embodiments have been presented in the foregoing description, it should be appreciated that a vast number of alternate but equivalent variations exist, and the examples presented herein are not intended to limit the scope, applicability, or configuration of the invention in any way. To the contrary, various changes may be made in the function and arrangement of the various features described herein without departing from the scope of the claims and their legal equivalents.

[0072] Techniques and technologies may be described herein in terms of functional and/or logical block components, and with reference to symbolic representations of operations, processing tasks, and functions that may be performed by various computing components or devices.

[0073] While at least one exemplary embodiment has been presented in the foregoing detailed description, it should be appreciated that a vast number of variations exist. It should also be appreciated that the exemplary embodiment or embodiments described herein are not intended to limit the scope, applicability, or configuration of the claimed subject matter in any way. Rather, the foregoing detailed description will provide those skilled in the art with a convenient road map for implementing the described embodiment or embodiments. It should be understood that various changes can be made in the function and arrangement of elements without departing from the scope defined by the claims, which includes known equivalents and foreseeable equivalents at the time of filing this patent application.

CLAIMS

What is claimed is:

1. A catheter apparatus comprising:
a tubular body having a distal end, a proximal end, and a lumen defined therein; and
activation means for selectably causing the tubular body to enter a first state and a second state;
wherein, in the first state, the tubular body has a first value of a stiffness metric that is below a predetermined navigability threshold; and
wherein, in the second state, the tubular body has a second value of the stiffness metric that is above a predetermined rigidity threshold value.
2. A catheter apparatus comprising:
a tubular body having a distal end, a proximal end, and a lumen defined therein; and
activation means for selectably causing the tubular body to enter a first state and a second state;
wherein, in the first state, the tubular body has a first value of a stiffness metric;
wherein, in the second state, the tubular body has a second value of the stiffness metric that is greater than the first value; and
wherein the activation means includes a controller communicatively coupled to the tubular body and adapted to place the tubular body in the second state by subjecting at least a portion of the catheter apparatus to a reduction or change in temperature.

3. A catheter apparatus comprising:
a tubular body having a distal end, a proximal end, and a lumen defined therein; and
activation means for selectably causing the tubular body to enter a first state and a second state;
wherein, in the first state, the tubular body has a first value of a stiffness metric;
wherein, in the second state, the tubular body has a second value of the stiffness metric that is greater than the first value; and
wherein the activation means includes a controller communicatively coupled to the tubular body and adapted to place the tubular body in the second state by subjecting at least a portion of the tubular body to an increase in axial compression.
4. The catheter apparatus of claim 3, wherein the tubular body comprises a plurality of axial segments responsive to the increase in axial compression.
5. The catheter apparatus of claim 4, wherein the controller includes at least one linkage component mechanically coupled to at least one of the plurality of axial segments and extending to the proximal end of the tubular body.
6. The catheter apparatus of claim 5, wherein the tubular body includes an auxiliary lumen provided therein, and wherein the at least one linkage component includes at least one wire component extending through the auxiliary lumen.
7. The catheter apparatus of claim 6, wherein the tubular body includes at least two auxiliary lumens distributed symmetrically within the tubular body.
8. The catheter apparatus of claim 7, wherein the at least one wire includes two or more wires, and the controller includes a gimble component coupled to the two or more wires, the gimble component configured to apply substantially equal tension on the two or more wires.
9. The catheter apparatus of claim 8, wherein the two or more wires includes four three wires.

10. A catheter apparatus comprising:
a tubular body having a distal end, a proximal end, and a lumen defined therein; and
activation means for selectably causing the tubular body to enter a first state and a second state;
wherein, in the first state, the tubular body has a first value of a stiffness metric;
wherein, in the second state, the tubular body has a second value of the stiffness metric that is greater than the first value; and
wherein the activation means includes a controller communicatively coupled to the tubular body and adapted to place the tubular body in the second state by subjecting at least a portion of the tubular body to an increase in radial compression.
11. The catheter apparatus of claim 10, wherein:
the tubular body includes at least two fluid impermeable layers defining a pressure-responsive chamber;
the tubular body includes at least one interstitial structure provided within the pressure-responsive chamber;
the controller is configured to cause a change in internal pressure within the pressure-responsive chamber; and
the at least one interstitial structure is adapted to exhibit radial compression in response to the change in internal pressure.
12. The catheter apparatus of claim 11, wherein the at least one interstitial structure includes a plurality of laminar members configured to be substantially slideable with respect to each other during the first state, and be substantially non-slideable with respect to each other during the second state.
13. The catheter apparatus of claim 12, wherein the plurality of laminar members comprise a braid or a helically wrapped structure.

14. The catheter apparatus of claim 10,
wherein the tubular body includes an outer layer, an inner layer, and one or more interstitial structures provided therebetween; and
wherein the controller includes at least one linkage component mechanically coupled to at least one of the interstitial structures and configured to cause the at least one linkage component to expand and contract radially.
15. The catheter apparatus of claim 12, wherein the at least one interstitial component comprises a substantially cylindrical braided structure.
16. The catheter apparatus of claim 12, wherein the at least one interstitial component comprises a helically-wrapped structure.
17. A catheter apparatus comprising:
a tubular body having a distal end, a proximal end, and a lumen defined therein; and
activation means for selectably causing the tubular body to enter a first state and a second state;
wherein, in the first state, the tubular body has a first value of a stiffness metric;
wherein, in the second state, the tubular body has a second value of the stiffness metric that is greater than the first value; and
wherein the tubular body includes at least two body segments,
the activation means includes a controller rotatably coupled to the at least two body segments, and the controller is configured to apply a relative rotational force between the at least two body segments to cause the tubular body to enter the second state.
18. The catheter apparatus of claim 17, wherein the at least two body segments includes an outer layer, an inner layer, and a torsionally-responsive structure provided therebetween.
19. The catheter apparatus of claim 18, wherein the torsionally-responsive structure comprises a substantially cylindrical braided structure.

20. A catheter apparatus comprising:
a tubular body having a distal end, a proximal end, and a lumen defined therein; and
activation means for selectably causing the tubular body to enter a first state and a second state;
wherein, in the first state, the tubular body has a first value of a stiffness metric;
wherein, in the second state, the tubular body has a second value of the stiffness metric that is greater than the first value; and
wherein the tubular body includes at least one inner chamber, a selectably solidifiable material provided within the inner chamber; and a controller fluidly coupled to the at least one inner chamber.
21. The catheter apparatus of claim 20, wherein the solidifiable material is adapted to substantially solidify in response to UV radiation.
22. The catheter apparatus of claim 20, wherein the solidifiable material is adapted to substantially solidify in response to introduction of a catalyst within the inner chamber.
23. The catheter apparatus of claim 20, wherein the solidifiable material is a polymer adapted to substantially solidify in response to a temperature change.
24. The catheter apparatus of claim 20, wherein the solidifiable material includes hydrophilic particles configured to expand when contacting water, and the controller is configured to introduce a volume of water into the inner chamber.
25. The catheter apparatus of claim 24, further including a perfusion lumen provided within the inner chamber, the perfusion lumen fluidly coupled to the controller.
26. The catheter apparatus of claim 20, wherein the solidifiable material is an acoustically-active polymer.

27. The catheter apparatus of claim 20, wherein the solidifiable material is an electroactive polymer (EAP).

28. A catheter apparatus comprising:

a tubular body having a distal end, a proximal end, and a lumen defined therein;

activation means for selectably causing the tubular body to enter a first state and a second state; and

a controller adapted to selectably dispense an aqueous mixture;

wherein, in the first state, the tubular body has a first value of a stiffness metric;

wherein, in the second state, the tubular body has a second value of the stiffness metric that is greater than the first value;

wherein the tubular body includes a chamber fluidly coupled to the controller and at least partially bounded by a membrane; and

wherein the membrane is configured to be permeable to a liquid portion of the aqueous mixture and impermeable to a solid portion of the aqueous mixture.

29. The catheter apparatus of claim 28, wherein the aqueous mixture is a saline mixture.

30. A catheter apparatus comprising:

a tubular body having a distal end, a proximal end, and a lumen defined therein;

activation means for selectably causing the tubular body to enter a first state and a second state; and

a controller comprising a voltage source;

wherein, in the first state, the tubular body has a first value of a stiffness metric;

wherein, in the second state, the tubular body has a second value of the stiffness metric that is greater than the first value; and

wherein the activation means includes at least one shape-memory metallic structure provided within the tubular body and communicatively coupled to the voltage source.

31. The catheter apparatus of claim 30, wherein the shape-memory metallic structure comprises a Ni/Ti alloy.
32. The catheter apparatus of claim 30, wherein the stiffness metric is a measurement of the bending stiffness of the tubular body.
33. The catheter apparatus of claim 30, wherein the stiffness metric is a catheter pull-out metric.
34. The catheter apparatus of claim 30, wherein the tubular body has a plurality of zones, each zone having a corresponding stiffness metric while in the second state.
35. The catheter apparatus of claim 34, wherein, within a first zone, the stiffness metric of the tubular body varies continuously along its length while in the second state.
36. The catheter apparatus of claim 35, wherein a first zone is adjacent the distal end of the tubular body, and a second zone is adjacent the first zone, further wherein the corresponding stiffness metric of the first zone is less than the corresponding stiffness metric of the second zone while in the second state.
37. The catheter apparatus of claim 30, wherein, while in the second state, the tubular body has the second stiffness value along a first curvature axis and a third stiffness value along a second curvature axis that is orthogonal to the first curvature axis.
38. The catheter apparatus of claim 30, wherein the activation means is coupled to a controller provided at the proximal end of the tubular body.
39. The catheter apparatus of claim 30, wherein the activation means is communicatively coupled to a controller configured to be slideably inserted within the lumen.

40. The catheter apparatus of claim 30, wherein the activation means is coupled to a controller that is remote from the tubular body.

41. The catheter apparatus of claim 30, wherein the tubular body includes a helical channel formed therein.

42. The catheter apparatus of claim 30, wherein the tubular body includes a plurality of ring-shaped channels formed circumferentially therein.

43. The catheter apparatus of claim 42, wherein the plurality of ring-shaped channels are distributed irregularly along the tubular body.

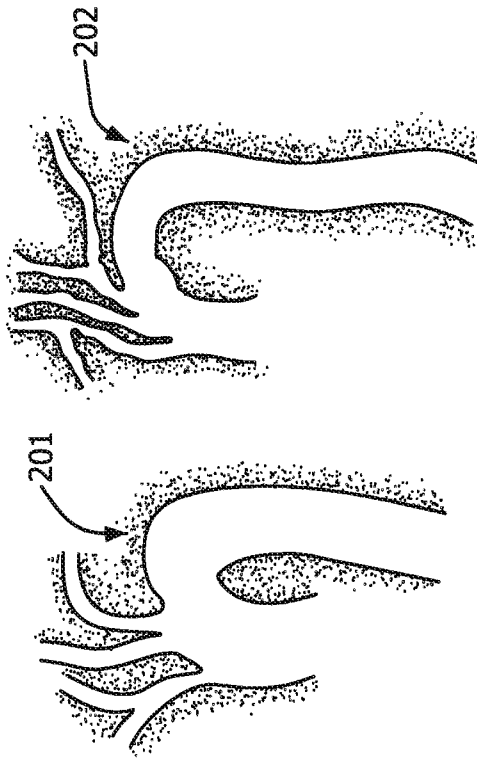


FIG. 2a

FIG. 2b

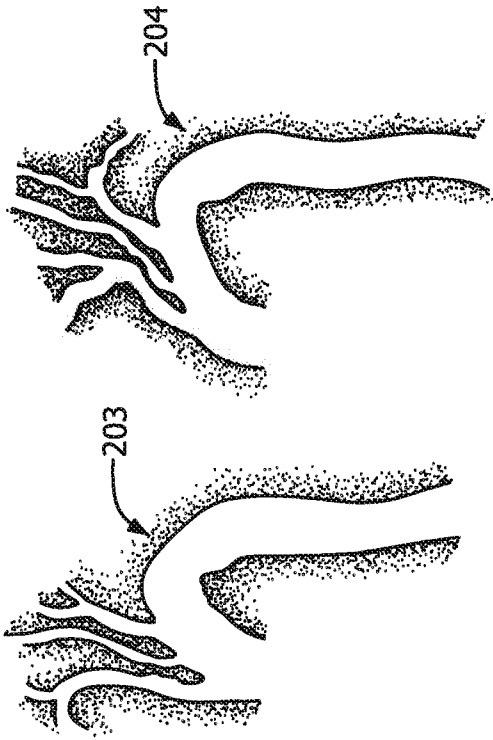


FIG. 2c

FIG. 2d

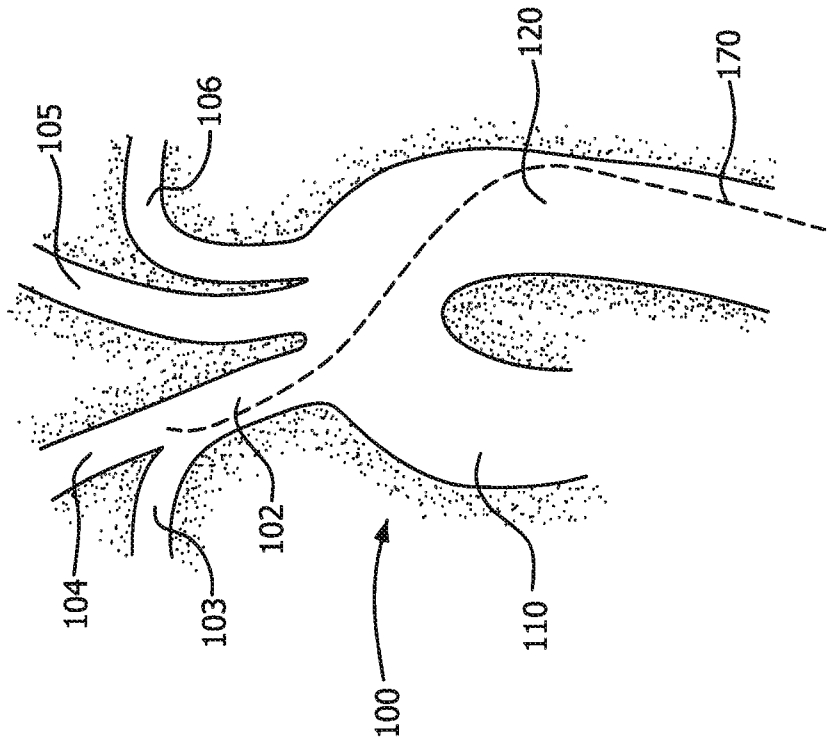


FIG. 1

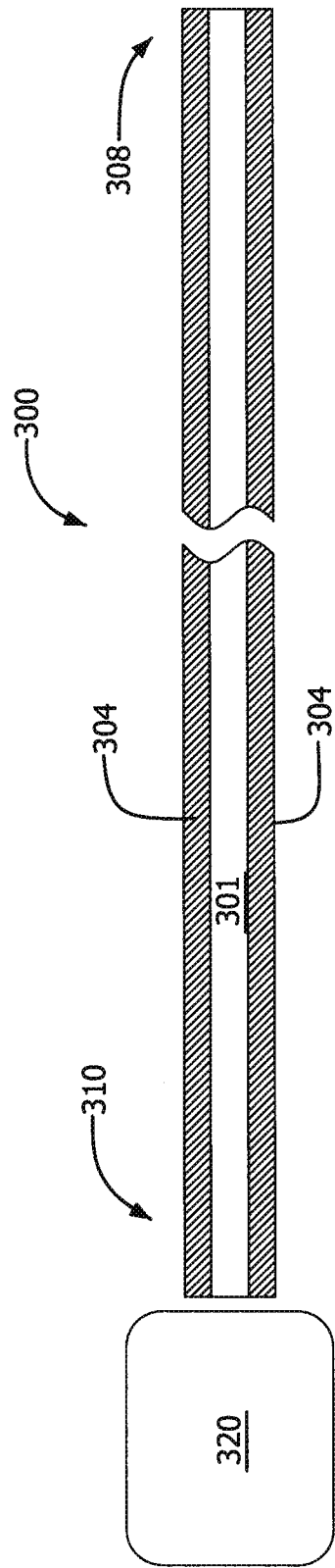


FIG. 3

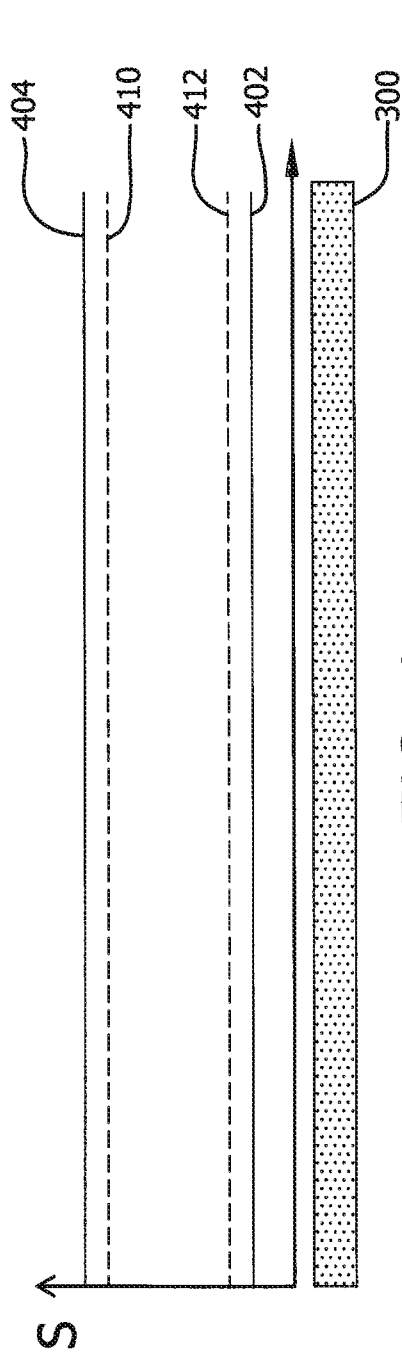


FIG. 4

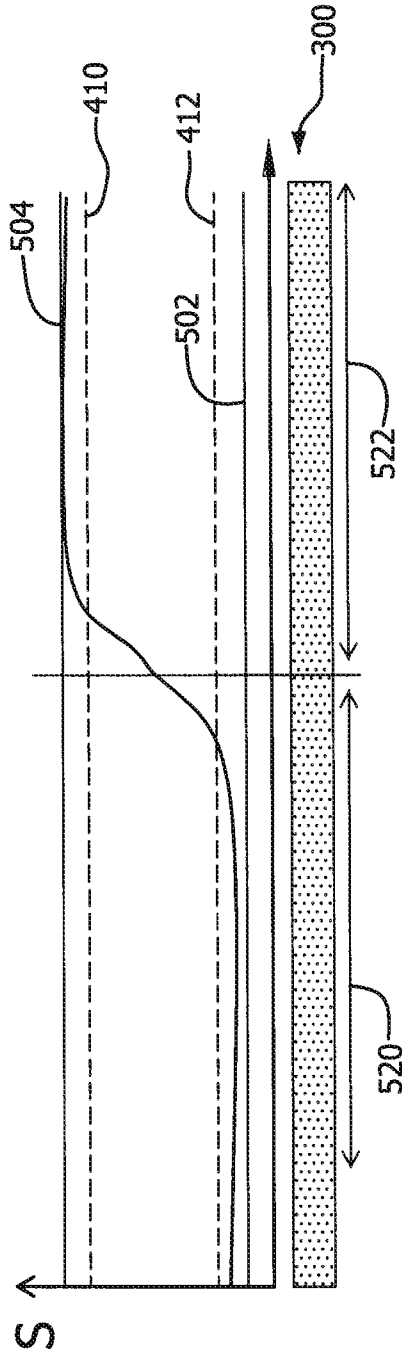


FIG. 5

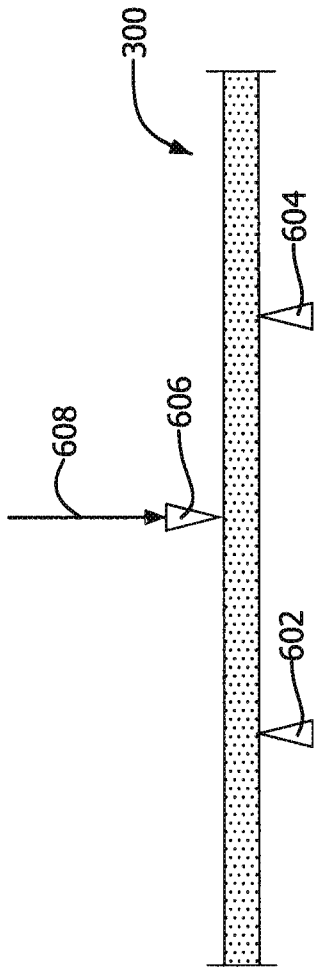


FIG. 6

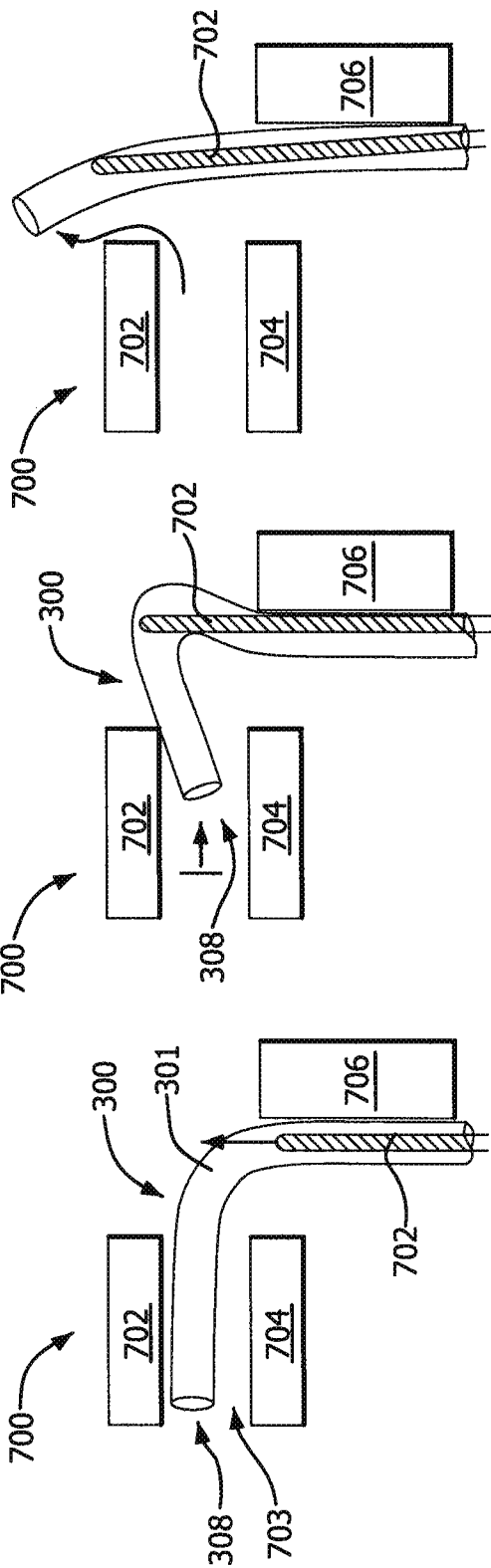


FIG. 7a

FIG. 7b

FIG. 7c

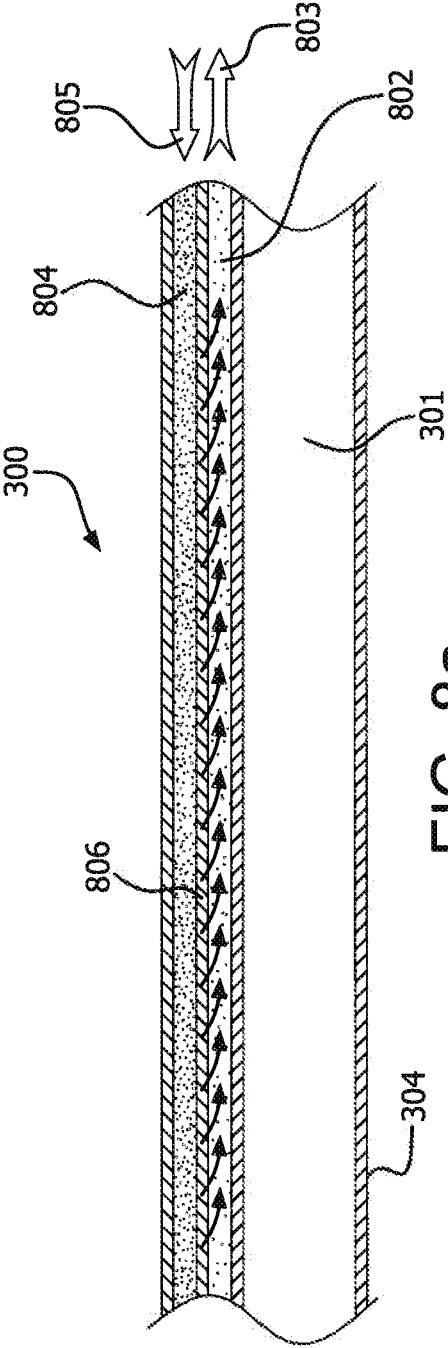


FIG. 8a

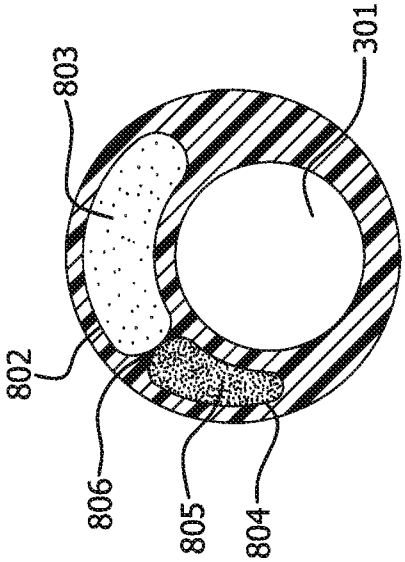


FIG. 8b

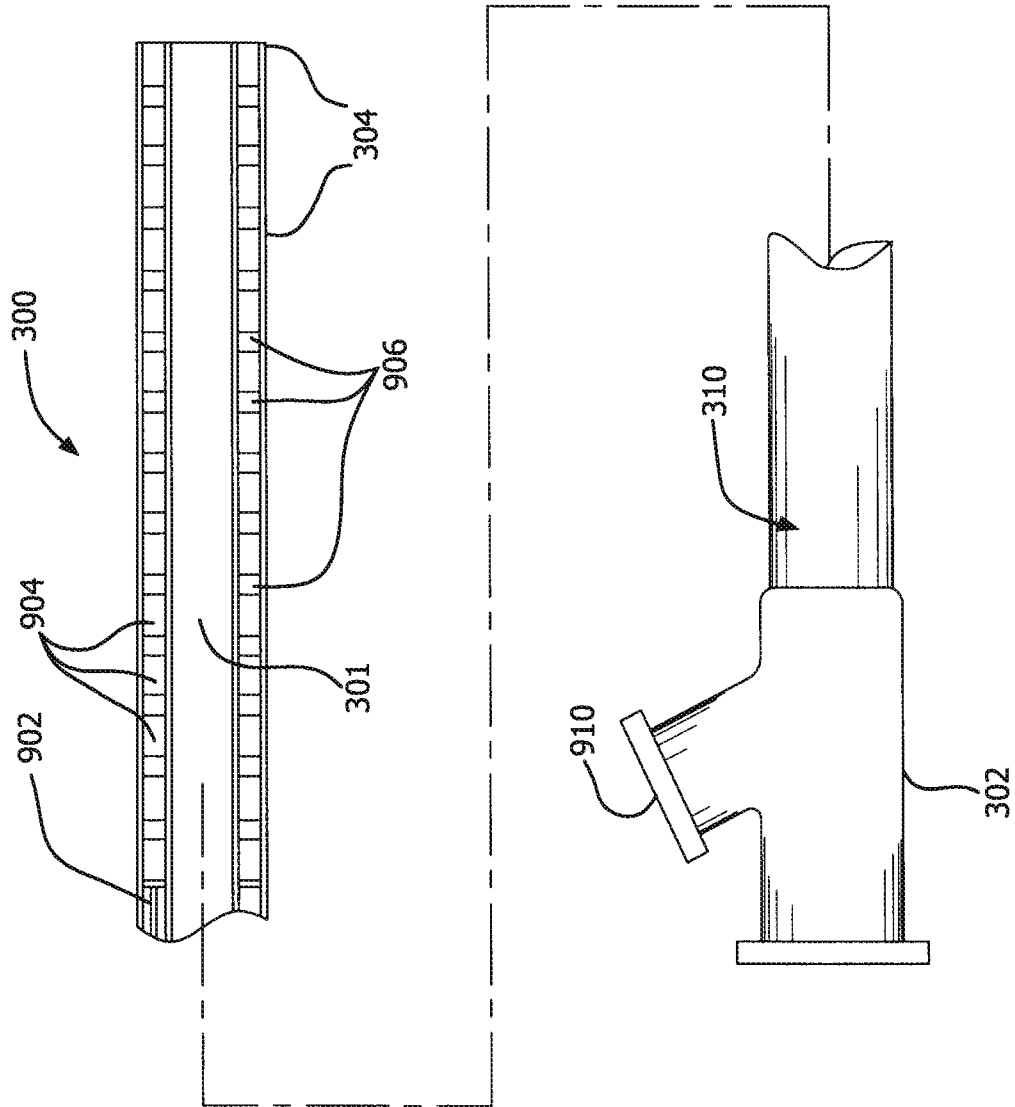


FIG. 9

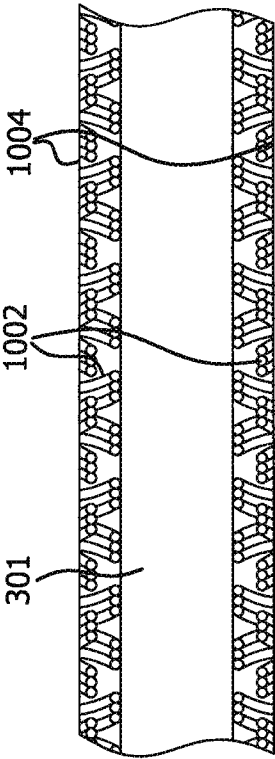


FIG. 10a

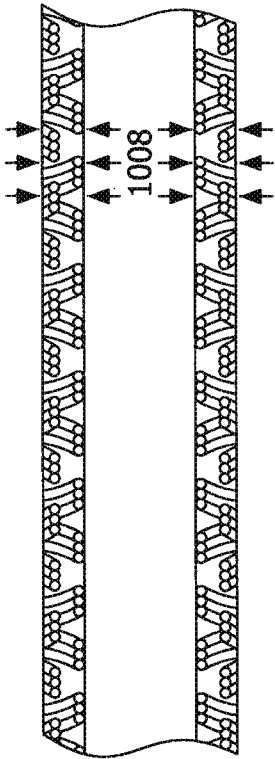


FIG. 10b

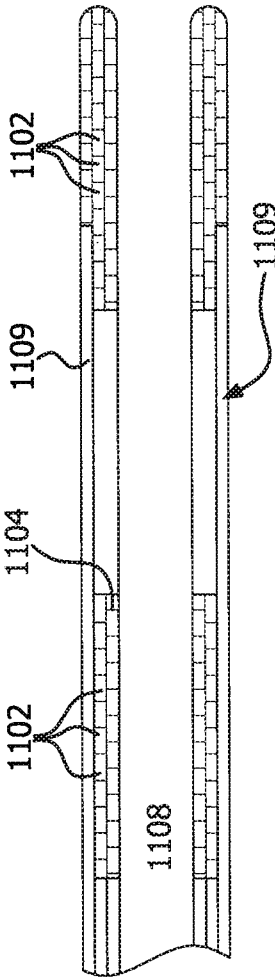
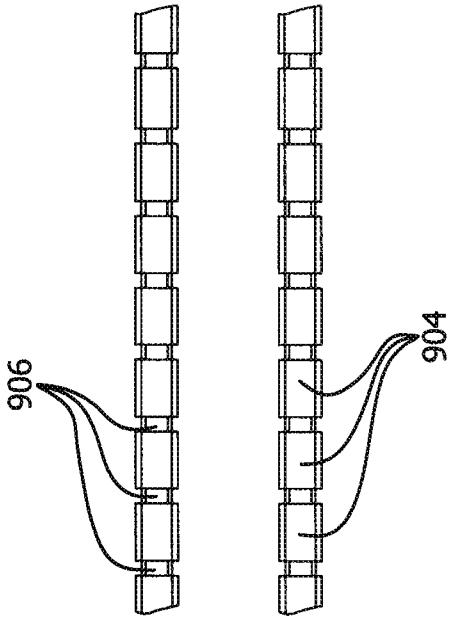
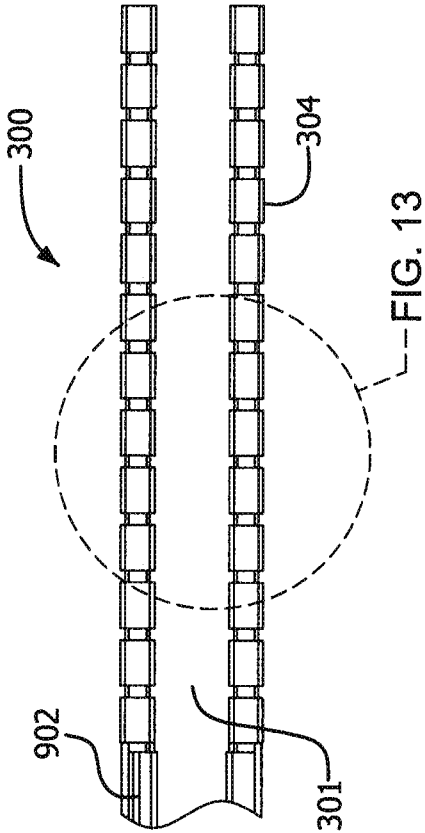


FIG. 11



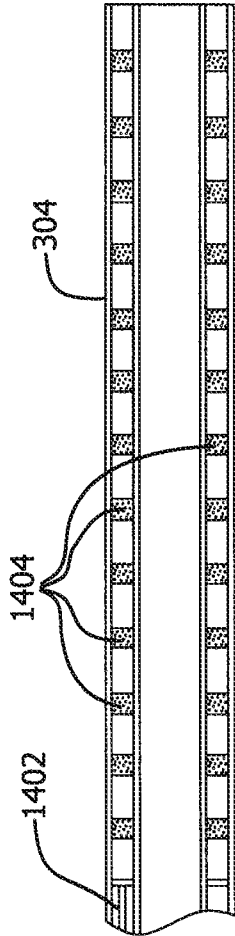


FIG. 14

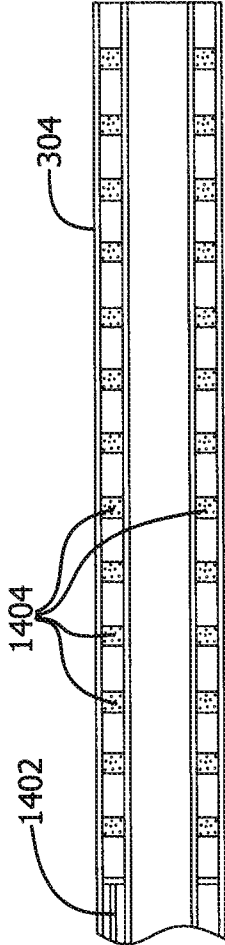


FIG. 15

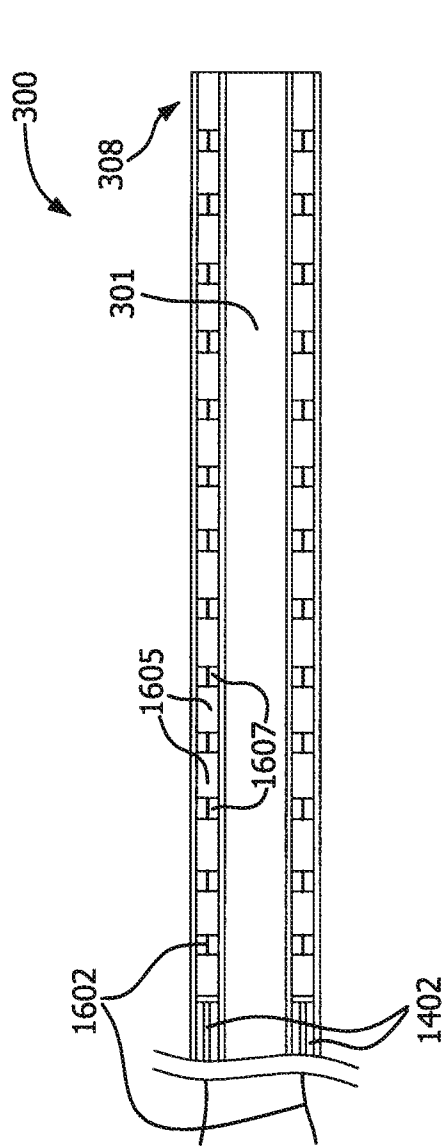


FIG. 16

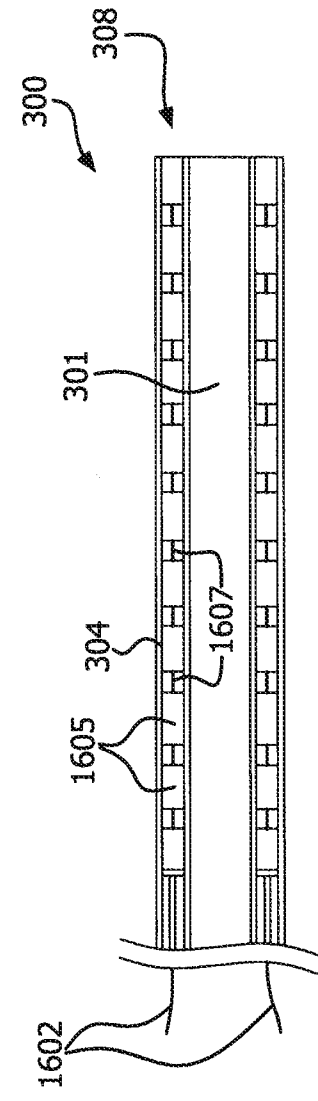


FIG. 17

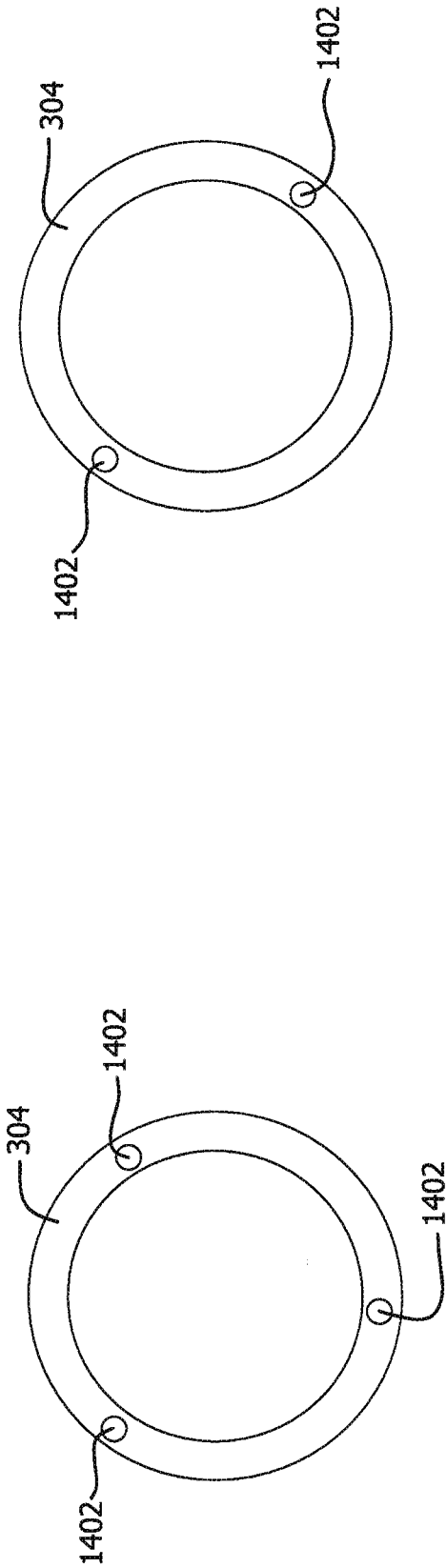


FIG. 18b

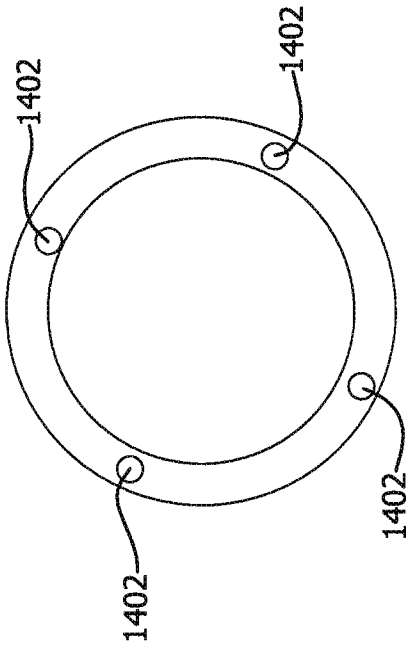


FIG. 18c

12/12

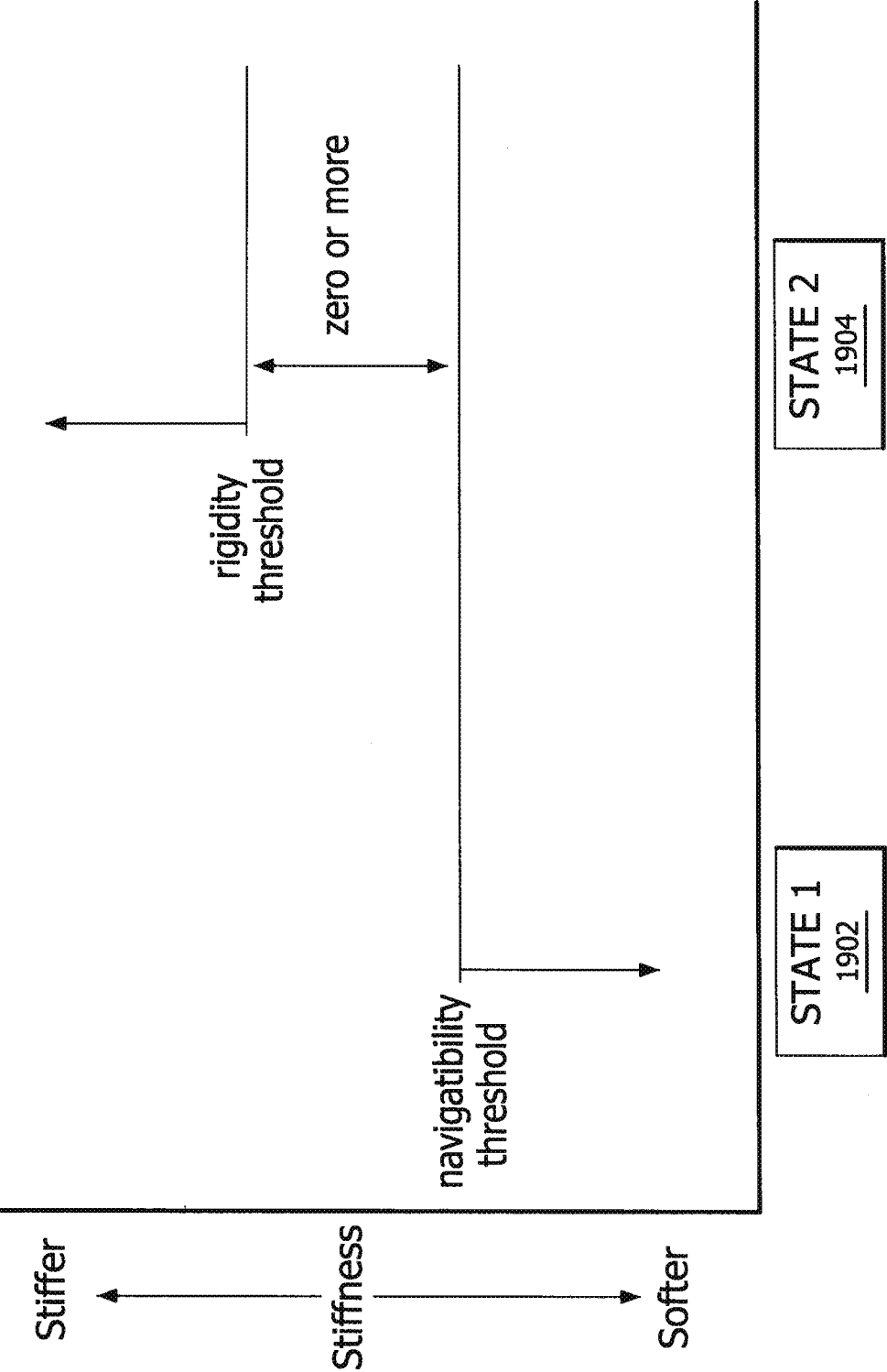


FIG. 19