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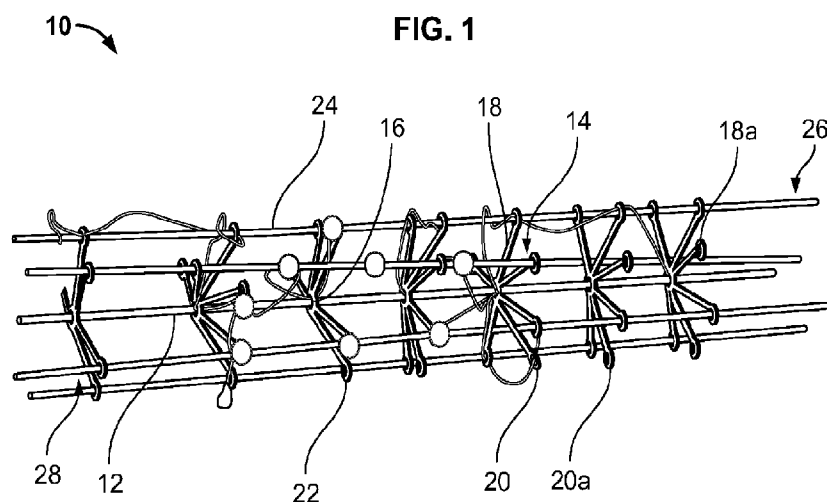
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(54) Title: VARIABLE DIAMETER BOUGIE



(57) Abstract: A method and apparatus for removing strictures, resizing lumens, sizing organs to be divided or sutured, or other activities within body passageways are disclosed herein. An example apparatus disclosed herein includes a central rod operatively coupled to a plurality of struts disposed circumferentially about the central rod at multiple longitudinal positions along the central rod. The example apparatus also includes one or more stringers to couple struts disposed at different longitudinal positions, as well as a mechanical control for moving the central rod and the one or more stringers longitudinally relative to one another, causing the apparatus to transition from a collapsed configuration suitable for insertion into the body passageways to an expanded configuration once inserted.

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VARIABLE DIAMETER BOUGIE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application 62/426,800, filed November 28, 2016, which is incorporated herein by reference in its entirety.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[0002] N/A

BACKGROUND OF THE DISCLOSURE

[0003] The field of the disclosure is related to a device for insertion into body passageways. More particularly, the disclosure relates to a bougie.

[0004] Bougies have several clinical utilities, including aiding surgeons in sizing tissue or organs to be divided or sutured. For example, bougies are used routinely during laparoscopic sleeve gastrectomies, in which a large segment of the stomach is removed, leaving behind a predetermined portion to help with weight loss. Bougies also are used by surgeons when performing anti-reflux operations to help size the tightness of the wrap created to minimize the risk of reflux. They additionally are used to dilate strictures in various passageways or to aid in guiding other instruments through an affected passageway.

[0005] While not limited to oral insertions, a bougie often is introduced through the oral cavity, requiring skill and care to avoid injury to the oropharynx or the esophagus. During such procedures, it often is necessary to exchange a bougie with a nasogastric tube or with bougies of other sizes. These exchanges may be time consuming and also may increase risk of organ injury. Similar concerns exist when bougies are introduced into other passageways.

[0006] Additionally, although bougies have been used for centuries, their design has remained relatively the same during that time. One type of bougie is a generally cylindrical sheath filled with a flowable material. That material often is mercury, despite its well-known toxicity to humans, although other materials may be used. Mercury is used because it remains in a liquid state at body temperatures and because its density provides the bougie with the weight necessary to be guided freely through the passageway and to overcome the compressive forces applied by the passageway generally or by strictures in the passageway specifically. The sheath may be, e.g., a

rubber, plastic, metal, or silicone-based material, in order to provide the bougie with a reduced coefficient of friction (often when coupled with a lubricant) and to provide the bougie with the necessary flexibility to maneuver through body passageways. The sheath may be generally cylindrical when straightened, although it also typically includes a tapered end to aid with insertion.

[0007] Another type of bougie is generally cylindrical with a hollow core extending along a length of the dilator. The core is configured to receive a guide wire having a substantially smaller diameter than the diameter of the bougie, in order to aid with insertion. Specifically, the guide wire may be inserted into the passageway with comparative ease due to its smaller diameter. Once one end of the guide wire is inserted, with the opposite end being fed through the hollow core of the bougie, the bougie then may be inserted into the passageway, following the path laid out by the guidewire. The guidewire may be left in place to assist with resizing of the bougie, although further dilation still requires insertion of one or more additional bougies into the passageway.

[0008] A third type of bougie may include a balloon or other pneumatic dilator positioned at some location along a length of the bougie. This dilator may be inserted to a desired depth such that the balloon is aligned with a stricture or blockage in the passageway. The balloon then is inflated, widening the stricture or removing the blockage. This type of bougie may benefit from only requiring a single device to achieve the desired dilation, but it may require great precision on the part of the practitioner to ensure that the inflatable portion of the bougie is aligned with the stricture or blockage.

[0009] Still other types of bougies are available, as would be appreciated by one of ordinary skill in the art.

SUMMARY OF THE DISCLOSURE

[0010] The present disclosure provides a bougie and a method for using the same in which the bougie is mechanically adjustable at one or more locations along its length in order to vary the diameter of the bougie. In this context, diameter should not be understood as limiting the bougie to a circular cross-section, as bougies having other cross-sections are within the scope of this disclosure.

[0011] An example apparatus disclosed herein includes a central rod, a plurality of hubs disposed longitudinally along the central rod, a plurality of struts extending

radially outwardly from each hub, at least one stringer operatively coupled to a plurality of struts, each strut extending from a different hub, and a mechanical control for transitioning the plurality of struts between an expanded configuration and a collapsed configuration.

[0012] Another example apparatus disclosed herein includes a central rod, a plurality of hubs disposed longitudinally along the central rod, a plurality of struts extending radially outwardly from each hub, at least one stringer operatively coupled to a plurality of struts, each strut extending from a different hub, and a control for moving one or both of the central rod and the at least one stringer longitudinally with respect to one another.

[0013] The foregoing and other aspects and advantages of the examples disclosed herein will appear from the following description. In the description, reference is made to the accompanying drawings which form a part hereof, and in which there is shown by way of illustration example bougies disclosed herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIG. 1 is an isometric partial view of a variable diameter bougie in a fully expanded configuration and without a surrounding external sheath.

[0015] FIG. 2 is an isometric partial view of the variable diameter bougie of FIG. 1 in a partially collapsed configuration and without a surrounding external sheath.

[0016] FIG. 3 is a partial longitudinal section view of another example of a variable diameter bougie in a collapsed configuration.

[0017] FIG. 4 is a section view of the bougie of FIG. 3 in the collapsed configuration.

[0018] FIG. 5 is a partial longitudinal section view of the bougie of FIG. 3 in a fully expanded configuration.

[0019] FIG. 6 is a section view of the expanded bougie of FIG. 5.

[0020] FIG. 7 is a partial longitudinal section view of another example of a variable diameter bougie in a collapsed configuration.

[0021] FIG. 8 is a section view of the bougie of FIG. 7 in the collapsed configuration.

[0022] FIG. 9 is a partial longitudinal section view of the bougie of FIG. 7 in a fully expanded configuration.

- [0023]** FIG. 10 is a section view of the expanded bougie of FIG. 9.
- [0024]** FIG. 11 is a partial longitudinal section view of another example of a variable diameter bougie in a collapsed configuration, the bougie having a plurality of sections and being configured to permit dilation of one or more of those sections.
- [0025]** FIG. 12 is a section view of the bougie of FIG. 11 in the collapsed configuration.
- [0026]** FIG. 13 is a partial longitudinal section view of the bougie of FIG. 11, with one section in a fully expanded configuration.
- [0027]** FIG. 14 is a section view of the expanded bougie of FIG. 13.
- [0028]** FIG. 15 is a partial longitudinal section view of another example of a variable diameter bougie in a collapsed configuration, the bougie having a plurality of sections and being configured to permit dilation of one or more of those sections.
- [0029]** FIG. 16 is a section view of the bougie of FIG. 15 in the collapsed configuration.
- [0030]** FIG. 17 is a partial longitudinal section view of the bougie of FIG. 16, with one section in a fully expanded configuration.
- [0031]** FIG. 18 is a section view of the expanded bougie of FIG. 17.
- [0032]** FIG. 19 is a plan view of the internal structure of a variable diameter bougie in a fully expanded configuration.
- [0033]** FIG. 20 is an isometric view of the internal structure of FIG. 15 in a partially collapsed configuration.
- [0034]** FIG. 21 is a graph depicting the relationship between relative longitudinal displacement of the central rod of the bougie of FIGS. 19 & 20 to the stringers vs. diameter at various locations along a length of the bougie.

DETAILED DESCRIPTION

[0035] A variable diameter bougie and method for using the same are disclosed herein. Various aspects are described, although in each aspect, the bougie is configured with a mechanical control or actuator to permit tailored adjustment of at least a portion of the bougie while in place and without the need for a formal exchange with another bougie.

[0036] FIG. 1 depicts one example of a variable diameter bougie 10 in a fully expanded configuration. As seen in this figure, the bougie 10 includes a central rod 12

pivotaly coupled to a plurality of flowers 14. Alternatively, one or more flowers 14 may be fixedly coupled to the central rod 12. Each flower 14 includes a hub 16 disposed around the central rod 12 with a plurality of struts 18 extending radially outward there from. Distal ends 20 of each strut 18 may include or be coupled to a secondary hub 22. One or more stringers 24 may extend along a length of the bougie 10, connecting a plurality of secondary hubs 22 on consecutive flowers 14. A sheath (not shown) may encase the bougie 10 in order to facilitate insertion and removal of the bougie 10 within the desired body passageway.

[0037] In one aspect, struts 18 connected to a given stringer 24 may be substantially the same length, so that the stringer 24 extends substantially parallel to the central rod 12. In another aspect, struts 18 connected to a given stringer 24 may have varying lengths, resulting in longitudinal (as opposed to radial) curvature of the outer surface of the bougie.

[0038] As seen in FIG. 1, flowers 14 may be generally equidistantly spaced along a length of the central rod 12. In one aspect, flowers 14 may be longitudinally spaced apart a distance greater than a length of struts 18. In another aspect, flowers 14 may be spaced apart approximately the same distance as a length of struts 18. In still another aspect, flowers 14 may be spaced apart a distance less than a length of struts 18, such that struts 18 of one flower 14 may overlap longitudinally with portions of one or more adjacent flowers 14 when the bougie 10 is collapsed. Alternatively, one or more regions may be more or less longitudinally densely packed with flowers 14 than other portions of the bougie 10.

[0039] Similarly, struts 18 may be generally equidistantly spaced circumferentially about a hub 16, although one or more flowers 14 may include struts 18 that are concentrated circumferentially around one or more portions of the flower 14. In one aspect, about 8 struts 18 may be provided about each hub 16, although a greater or smaller number of struts 18 per hub 16 is possible. For example, a flower 14 may have between about 3 and about 20 struts 18, preferably between about 4 and about 20 struts 18.

[0040] Each strut 18 may be coupled to a respective stringer 24 at a respective secondary hub 22. In another aspect, however, one or more struts 18a may not be coupled to a stringer, as seen in FIG. 1. Distal ends 20a of those struts 18a (with or without secondary hubs 22) may provide radial support to the bougie sheath, in order

to help it retain its desired shape and to provide adequate pressure against the passageway walls.

[0041] Turning now to FIG. 2, the bougie 10 is depicted with one of the stringers 24 collapsed closer to the central rod 12, and it will be appreciated that similar couplings and motion are possible with respect to the other stringers. Collapsing of the stringer 24 may occur prior to insertion of the bougie 10 into the passageway, in order to minimize the diameter of the bougie 10. Collapsing may be accomplished by pulling the stringer 24 towards a rearward end 26 of the bougie 10. Secondary hubs 22 and stringers 24 may be fixedly coupled to one another, and hubs 16 may be restricted from longitudinal motion relative to the central rod 12, such that the force applied to the stringer 24 may be transmitted to each connected strut 18, causing those struts 18 to act as torsion springs in order to store the introduced energy. When the force applied to the stringers 24 is removed, e.g., when the bougie 10 is located adjacent a stricture, the struts may extend at least partially back outwards, removing the stricture. Spring loading on each strut 18 may be modified by varying a thickness, material, and/or shape of the strut 18, and each strut 18 may be configured to exert adequate force to remove strictures or otherwise be adapted to the use for which the bougie 10 is employed.

[0042] Each stringer 24 may be operatively coupled to a single actuation control, such that all stringers 24 may be collapsed upon implementation of the actuation control. For example, the actuation control may comprise a cable, a wire, a chain, a lever, or another pull mechanism coupled to each stringer 24. Alternatively, the actuation control may comprise separate cables, wires, chains, levers, or other pull mechanisms coupled to separate stringers 24 and then coupled to one another. The actuation control also may include a rotational actuator operatively coupled to the pull mechanism, such that rotation of the actuator causes linear motion of the pull mechanism. In one example, this may be achieved by causing the pull mechanism to wind and unwind around the rotational actuator. In another example, the rotational actuator and pull mechanism may have teeth to act as a rack and pinion. In another example, the rotational actuator and pull mechanism may be operatively coupled to form a slider crank. In still another example, the rotational actuator and pull mechanism may include interfacing screw threads. In yet another example, the rotational actuator and pull mechanism may act as a scotch and yoke. Still other types of mechanisms to convert rotational motion to linear motion are possible, as would be appreciated by one of

ordinary skill in the art.

[0043] In one aspect, the actuation control may be semi-rigid in order to avoid buckling when a compressive force is applied. As such, the bougie 10 may rely on the resistive spring force of the struts 18, either by itself or in combination with user applied force, to expand the bougie 10 after insertion. In any event, the actuation control may be configured to provide continuous adjustment of the stringers 24 along the full range of motion of the stringers 24. By extension, the actuation control also may be configured to provide continuous adjustment of the struts 18. Accordingly, as opposed to the limited, discrete, and approximate sizing that is possible with prior fixed diameter bougies, the bougie 10 may be infinitely adjustable within its range of adjustment in order to permit the user to customize the degree of adjustment to the desired situation.

[0044] The actuation controls preferably are disposed internal to the perimeter formed by the sheathing along the portions of the bougie that are to be disposed within the passageway and may remain internally disposed or may be disposed external to the perimeter at some point rearward of those portions. In another aspect, stringers 24 may be coupled to separate, disconnected actuation controls so that different stringers 24 are independently actuatable from one another, which may provide the user with greater flexibility in determining whether and to what degree one or more sides of the bougie are expanded.

[0045] In still another aspect, the actuation control may be operatively coupled to the central rod 12 rather than the one or more stringers 24 in order to cause the relative movement between the rod and stringers, thereby achieving substantially the same effect of expanding and collapsing the struts 18 to change the diameter of the bougie 10.

[0046] The bougie also may include one or more external indicators to visually inform the user of the degree of rotation of an actuator, the length of insertion of the bougie, the amount of longitudinal movement of the central rod 12 or stringers 24, and/or the diameter at one or more locations along a length of the bougie. The indicators may include, e.g., a series of tick marks with one or more numerical values indicating the properties previously enumerated, although other indicators are possible, as would be appreciated by one of ordinary skill in the art.

[0047] In one aspect, a channel may extend along a length of the bougie 10. The

channel may serve one or more of a variety of purposes, including providing access for a guide wire to assist in positioning the bougie 10. Alternatively, the channel may be connected to or provide a pathway for an external suction and/or irrigation device in order to provide suction and/or irrigation within the body passageway. (See, e.g., FIGS. 7-10.) The channel preferably is disposed longitudinally within the central rod 12, although it alternatively may be disposed adjacent to the central rod 12, within an interior of the bougie 10.

[0048] Turning to FIGS. 3-6, one example of a bougie 110 is depicted in both a collapsed and an expanded state. (In this example, as well as in subsequent examples, features similar to those described above may be numbered the same as previously enumerated but with a different numerical prefix, e.g., bougie 110 instead of bougie 10.) As with the previous example, bougie 110 includes a central rod 112 with a plurality of flowers 114 disposed circumferentially about the central rod 112 and spaced generally equidistantly along a length thereof. Each flower 114 includes a plurality of struts 118. As shown in these figures, struts 118 may angle acutely with respect to a rearward end 126 in a collapsed configuration and may expand to no more than perpendicular to the central rod 112 in a fully expanded configuration. Bougie 110 includes a forward end 128 that tapers radially inwardly in order to aid with insertion. Bougie 110 also may include a central channel 130, which may be used with a guide wire or with suction or irrigation tools, as discussed above. The bougie 110 of these figures may be sized and otherwise adapted for use in the treatment of strictures, such that the bougie 110 may permit precise control over a diameter of bougie 110 while avoiding repetitive exchange of bougies during a clinical procedure, saving time and minimizing trauma of insertion.

[0049] Turning to FIGS. 7-10, another example of a bougie 210 is depicted, also in both a collapsed and an expanded state. The bougie 210 of this example may resemble the bougie 110 of the previous example, although it may not necessarily include a tapered forward end. Bougies of this type may be used to assist in sizing residual lumens of the GI tract, which may be accomplished by placing the bougie 210 in the nasogastric tract to decompress the GI tract while, at the same time or subsequently, accurately measuring and resecting a specific segment of interest. When used in this application, the central rod 212 may include or permit passage of a suction and/or irrigation mechanism 234, and unclogging during suctioning or at other times may be

accomplished by repeated expansion and contraction of the struts 218 of the bougie 210. In conjunction with the inclusion of the suction and/or irrigation mechanism 234 within the central rod 212, the forward end 228 of the bougie 210 may form the end of that mechanism 234 or otherwise may be configured to permit unrestricted positioning and use of the mechanism 234.

[0050] Turning now to FIGS. 11-14, still another example of a bougie 310 is depicted, again in both a collapsed and expanded state. Bougie 310 may be configured to expand one or more segments 332 while keeping a remainder of the bougie 310 in a substantially collapsed configuration. In one aspect, this may be accomplished by locating flowers 314 coupled to actuation control only in the area to be expanded while either locating uncoupled flowers in other regions of the bougie 310 or by omitting expandable flowers from the other regions. Alternatively, the actuation control may comprise a plurality of separate actuators configured to actuate separate segments of the bougie 310, providing the user with the flexibility to select the one or more segments to expand. In this latter case, instead of a stringer extending along a length of the bougie 310 and coupling each flower along that length, the bougie 310 may include a plurality of stringers 324a, 324b, 324c coupling subsets of flowers 314a, 314b, 314c, where the stringers 324a, 324b, 324c may be radially and circumferentially aligned with one another or offset from one another. Bougies of this type may be used in various applications, although they may be particularly well-suited to tamponade of bleeds, including GI bleeds arising from esophageal varices, trauma, or other causes. By applying localized pressure, the bougie 310 may be able to stop the bleed without causing damage to other portions of the GI tract or other passageway.

[0051] In yet another aspect, the central rod, struts, or stringers may not be substantially linear but instead may be curved or have another non-linear shape. Alternatively, the central rod, struts, or stringers may be linear in a collapsed configuration, but one or more components may be flexible and non-linear when in an expanded configuration. For example, in conjunction with a flexible central rod and stringers, the bougie 410 of FIGS. 15-18 may have struts that are shorter along at least a portion of the length than struts on an opposing side of the central rod. As such, when expanded, bougie 410 may have an arcuate-type shape similar to the shape of a banana, which may result in more accurate placement of the bougie 410. One such implementation includes placement of the bougie along the lesser curve of the stomach.

In such implementations, the bougie preferably remains relatively flexible during insertion, i.e., when collapsed, and takes on its curved configuration during expansion. Deflection of the distal end of the bougie 410 during expansion may be between about 15 degrees and about 45 degrees, and in one example, about 30 degrees.

[0052] In still another aspect, obtaining the desired curvature may be accomplished by forming the bougie with longitudinally consecutive struts that connect to a common stringer, the struts having differing radial lengths. For example, a first strut followed by a shorter, second strut closer to the forward end of the bougie may cause the bougie to bend toward the shorter strut. Additionally, a third strut closer to the forward end of the bougie that is longer than the second strut may cause increased curvature. Modifications to other struts, including to struts coupled to other stringers also are possible in order to modify the expanded shape of the bougie.

[0053] In each of the examples provided above, the central rod and stringers may be made of strong yet bendable materials. Exemplary materials include spring steel, aluminum, stainless steel, nylon, polyurethane, polypropylene, acrylonitrile butadiene styrene (ABS), and combinations thereof. Hubs, struts, and secondary hubs may be made of materials that also are flexible, e.g., spring steel, nylon, or polypropylene. These components, particularly the secondary hubs, may be manufactured using a process that creates a substantially smooth exterior so as to avoid snagging, tearing, or otherwise compromising the sheath. For example, electrical discharge machining (EDM) may be used to fabricate these components. In another aspect, one or more of the central rod, stringers, and struts may include an electrically active material such as an electroactive polymer, whereby application of a current to the active material results in actuation of those components, i.e., transition from the expanded to the collapsed state.

[0054] Bougie sheath may be made of a durable material with a relatively low coefficient of sliding friction, e.g., silicone, polyether block amide (which may be sold under the trademark PEBAX), polyurethane, other thermoplastic elastomers, or shape memory alloys. The sheath preferably is bonded to the internal frame components, e.g., the secondary hubs and/or the stringers, using a biocompatible adhesive. The choice of materials used also may depend on the function to be achieved. For example, the shape memory alloys mentioned previously or other materials may be selected to aid in actuation of the device. Additionally or alternatively, conductive fibers, optical fibers, or other materials may be incorporated into the bougie sheath for one or more sensing

purposes. These materials also may be incorporated into other elements of the bougie. For example, the stringers may include conductive fibers, optical fibers, or include embedded sensors in order to monitor one or more operative properties, such strain, stress, temperature, etc., during use of the bougie. Still further, other materials may be used for additional integrated functionality, e.g., the sheath may be impregnated with chemical stimulants that are released after the bougie is inserted, or heating elements may be integrated into the sheath to warm the body passageway after insertion.

[0055] Turning now to FIGS. 19 and 20, testing of the bougie design of FIG. 1 was performed to determine the effect of relative longitudinal motion between the central rod 12 and the stringers 24 on diameter of the bougie 10. The bougie was placed on an optical bench with a stage having a micrometer adjustment. The central rod 12 was attached to a micrometer to measure longitudinal movement of the central rod 12, while the stringers 24 were inhibited from lateral movement in order to accurately measure relative longitudinal movement between the two sets of elements. Calipers also were used to measure the diameter of the bougie 10 at each of the flowers for various degrees of longitudinal displacement. The rearward end 26 of the bougie 10 is the end proximate the end plate, with the forward end 28 being opposite the rearward end 26. Results of this testing are depicted in the following table.

Displacement (mm)	Diameter (mm)		
	Flower closest to forward end 28	Central flower	Flower closest to rearward end 26
Start (0 mm)	27.58	27.61	27.62
3 mm	26.95	27.15	27.13
5 mm	26	27	27
10 mm	25.53	25.69	26
15 mm	22.69	22.93	23.37

[0056] As these results show, and as seen in FIG. 20, relative longitudinal displacement of the central rod 12 causes the diameter at each flower 14 to decrease, with the diameter being smallest at the flower closest the forward end 28 and expanding slightly more with each progressively more-rearward flower. Thus, in this example, the forward end may be tapered in comparison to the rest of the bougie 10,

further aiding insertion.

[0057] Additionally, the values in the above table were graphed and are provided in FIG. 21, which shows that the rate of contraction of the bougie is generally linear over the first 10 mm of displacement and then increases significantly thereafter (i.e., the diameter gets smaller more quickly). Recalling that the bougie is inserted in a collapsed configuration, this means that the bougie can be expanded quickly from that collapsed configuration while permitting more fine adjustment when approaching the fully expanded configuration, permitting the user to achieve the desired diameter more accurately. The range of diameter variation may vary between about 16 Fr to about 60 Fr, preferably between about 16 Fr to about 40 Fr.

[0058] Although a single size bougie may permit a wide range of expansion and contraction, a plurality of differently-sized bougies, e.g., small, medium, large, extra-large, may be available to provide the user with more choice and accuracy in selecting a bougie appropriately sized for the desired application. Despite the potential availability of multiple sizes, it will be appreciated that only a single one of those bougies may be necessary for the desired application, thereby eliminating a need to remove a first bougie and insert a second one to achieve a desired passageway diameter.

[0059] Although some example apparatus have been disclosed herein, many equivalents, alternatives, variations, and/or modifications, aside from those expressly stated, are employed in other examples and are within the scope of the present disclosure.

CLAIMS

1. An interventional medical apparatus, comprising:
 - a central rod;
 - a plurality of hubs disposed longitudinally along the central rod;
 - a plurality of struts extending radially outwardly from each hub;
 - at least one stringer operatively coupled to a plurality of struts, each strut extending from a different hub; and
 - a mechanical control for transitioning the plurality of struts between an expanded configuration and a collapsed configuration.
2. The apparatus of claim 1, wherein the expanded configuration comprises the struts being substantially perpendicular to the central rod, and wherein the collapsed configuration comprises the struts being angled acutely rearwardly with respect the central rod.
3. The apparatus of claim 1, wherein the central rod and the at least one stringer are bendable, and wherein the stringers are configured such that, in the expanded configuration, the apparatus generally conforms to a shape of an organ into which the apparatus is designed to be inserted.
4. The apparatus of claim 1, further comprising a sheath surrounding the central rod, the plurality of hubs, the plurality of struts, and the at least one stringer.
5. The apparatus of claim 1, wherein the at least one stringer comprises a plurality of stringers.
6. The apparatus of claim 5, wherein the plurality of stringers are circumferentially offset from one another.
7. The apparatus of claim 5, wherein the plurality of stringers are circumferentially aligned with one another.

8. The apparatus of claim 7, wherein the mechanical control includes an actuator for adjusting each stringer independent of the other stringers.
9. The apparatus of claim 7, wherein the mechanical control includes a control for collectively adjusting two or more of the plurality of stringers.
10. The apparatus of claim 1, further comprising a tapered forward end.
11. The apparatus of claim 1, wherein the apparatus is configured for insertion into a passageway of an animal in the collapsed configuration and further is configured to transition to the expanded configuration while disposed in the animal.
12. The apparatus of claim 1, wherein the central rod includes a hollow core configured to receive a suction or irrigation device.
13. A variable diameter bougie, comprising:
 - a central rod;
 - a plurality of hubs disposed longitudinally along the central rod;
 - a plurality of struts extending radially outwardly from each hub;
 - at least one stringer operatively coupled to a plurality of struts, each strut extending from a different hub; and
 - a control for moving one or both of the central rod and the at least one stringer longitudinally with respect to one another.
14. The variable diameter bougie of claim 13, wherein relative longitudinal movement between the central rod and the at least one stringer changes an angle formed by the central rod and the plurality of struts coupled to the at least one stringer.
15. The variable diameter bougie of claim 13, wherein relative longitudinal movement between the central rod and the at least one stringer changes a diameter of at least a portion of the bougie.

16. The apparatus of claim 13, wherein the central rod and the at least one stringer are bendable, and
wherein the stringers are configured such that, in an expanded configuration, the apparatus generally conforms to a shape of an organ into which the apparatus is designed to be inserted.
17. The variable diameter bougie of claim 13, wherein the struts are pivotally coupled to the central rod.
18. The variable diameter bougie of claim 13, wherein the plurality of struts are fixedly coupled to the at least one stringer.
19. The variable diameter bougie of claim 13, the central rod defining an orifice extending along a length of the central rod.
20. The variable diameter bougie of claim 13, wherein the at least one stringer comprises a plurality of stringers.
21. The variable diameter bougie of claim 20, wherein the plurality of stringers are circumferentially offset from one another.
22. The variable diameter bougie of claim 20, wherein the plurality of stringers are circumferentially aligned with one another.
23. The variable diameter bougie of claim 22, wherein the control includes a drive for adjusting each stringer independent of the other stringers.
24. The variable diameter bougie of claim 22, wherein the control includes drive for collectively adjusting two or more of the plurality of stringers.
25. The variable diameter bougie of claim 13, wherein the control includes at least one cable, wire, chain, lever, or other pull mechanism.

26. The variable diameter bougie of claim 13, wherein the control includes a rotational actuator operatively coupled to at least one cable, wire, chain, lever, or other pull mechanism, such that rotation of the actuator causes longitudinal motion of the central rod or at least one stringer.

27. The variable diameter bougie of claim 13, wherein the central rod includes a hollow core configured to receive a suction or irrigation device.

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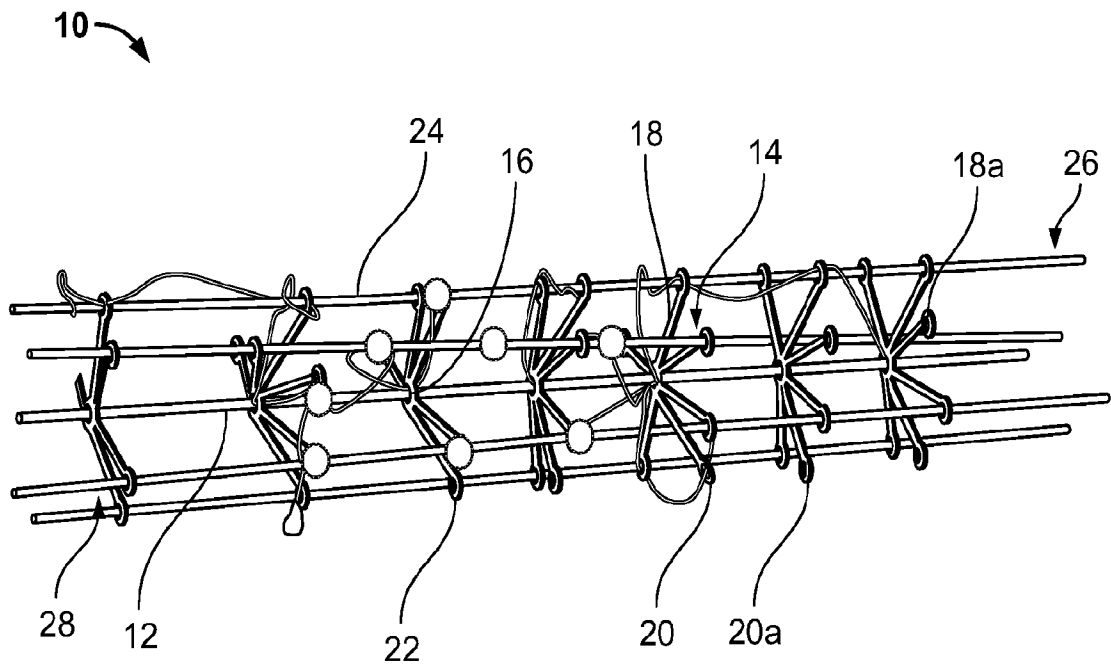


FIG. 1

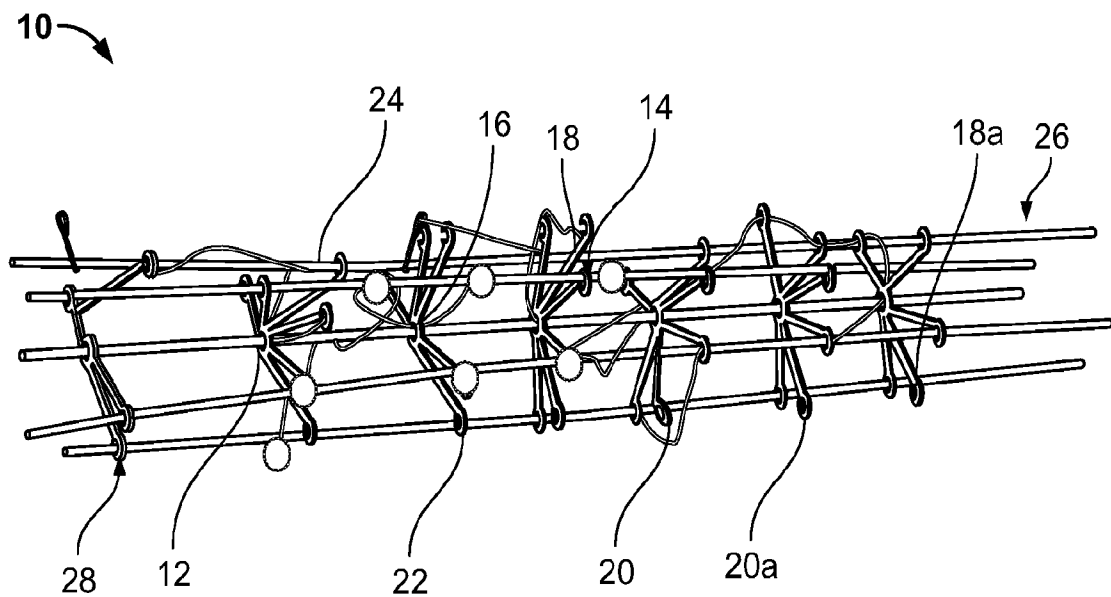


FIG. 2

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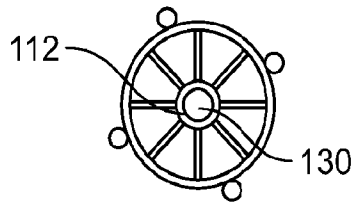


FIG. 4

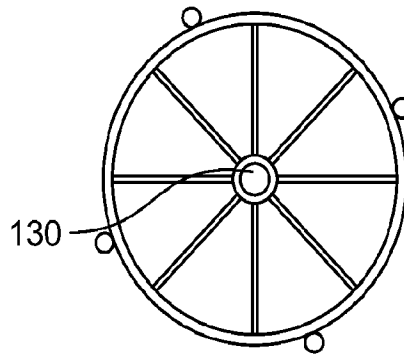


FIG. 6

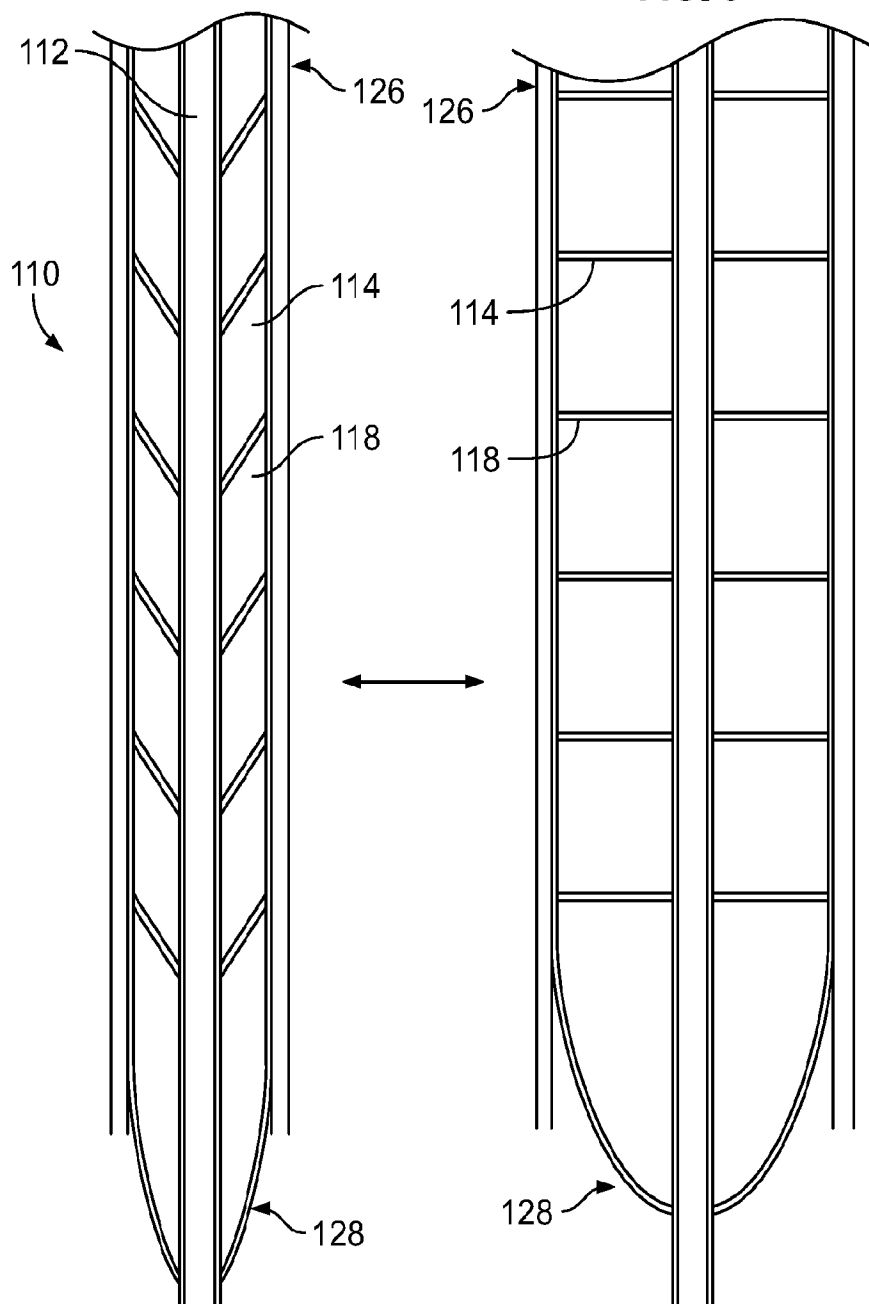


FIG. 3

FIG. 5

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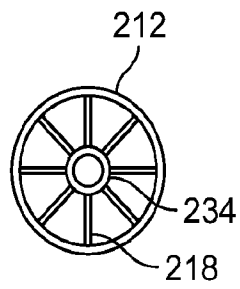


FIG. 8

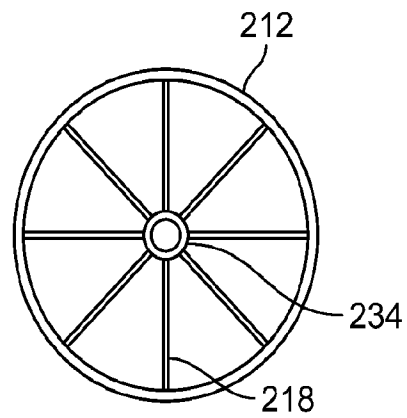


FIG. 10

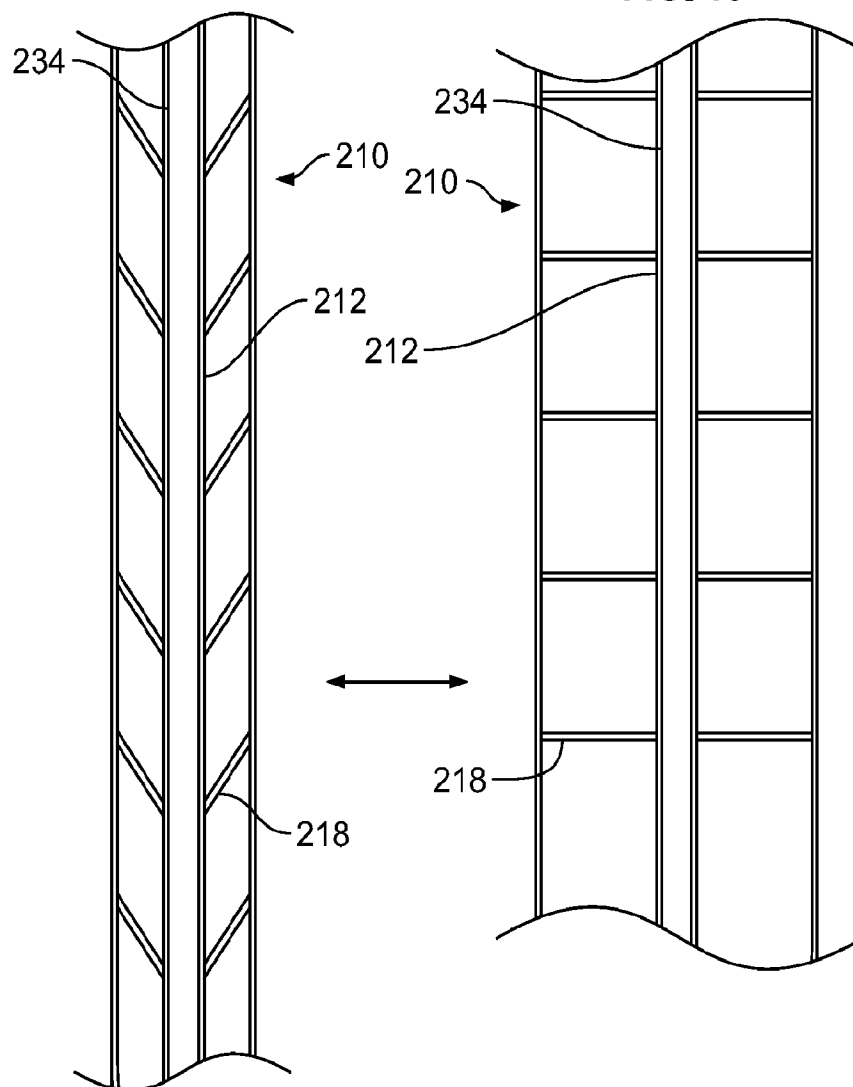


FIG. 9

FIG. 7

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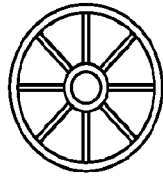


FIG. 12

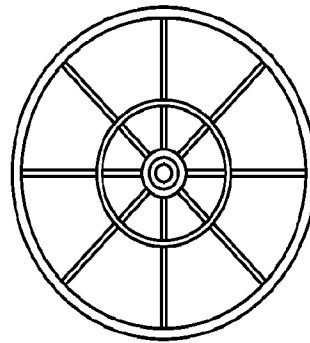


FIG. 14

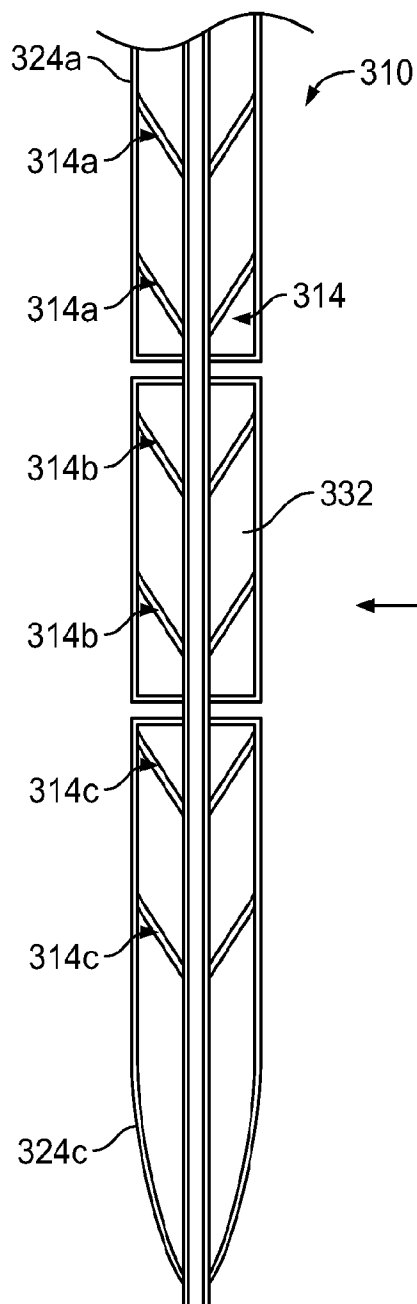


FIG. 11

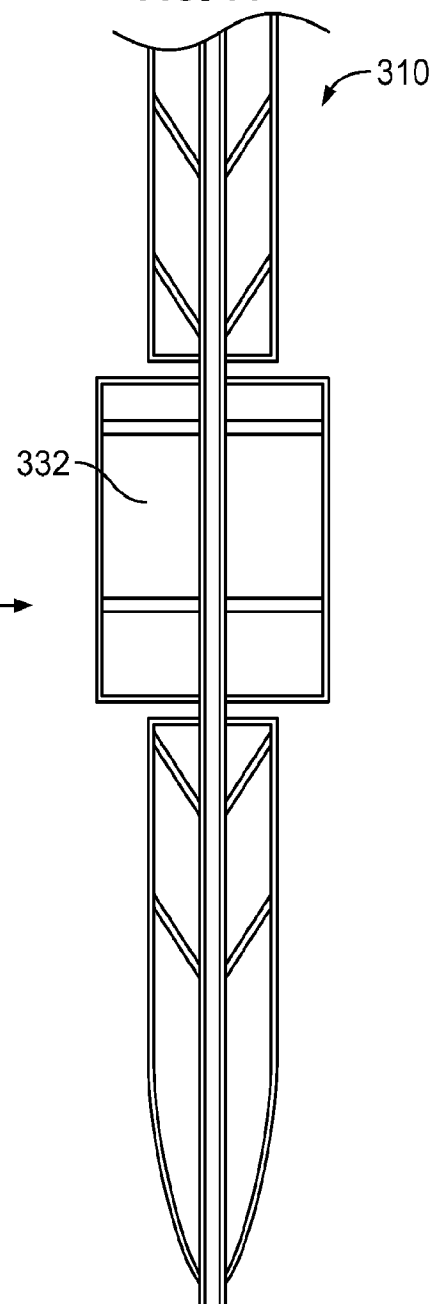


FIG. 13

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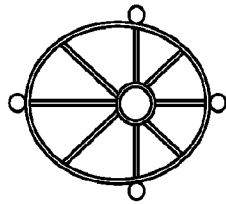


FIG. 16

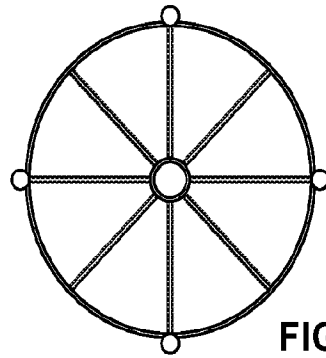


FIG. 18

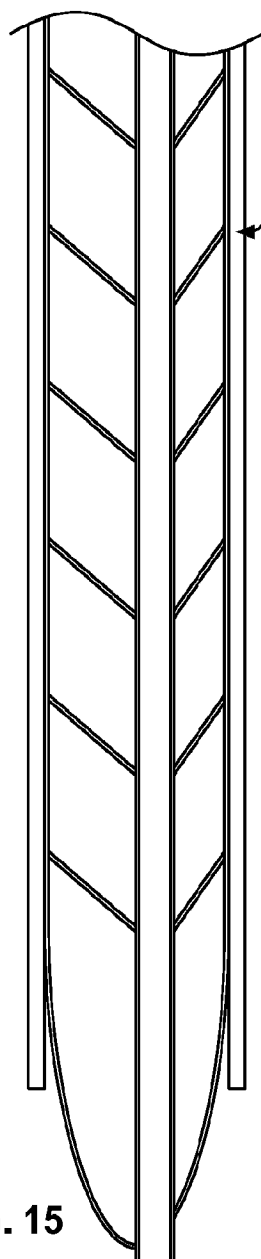
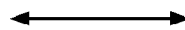


FIG. 15



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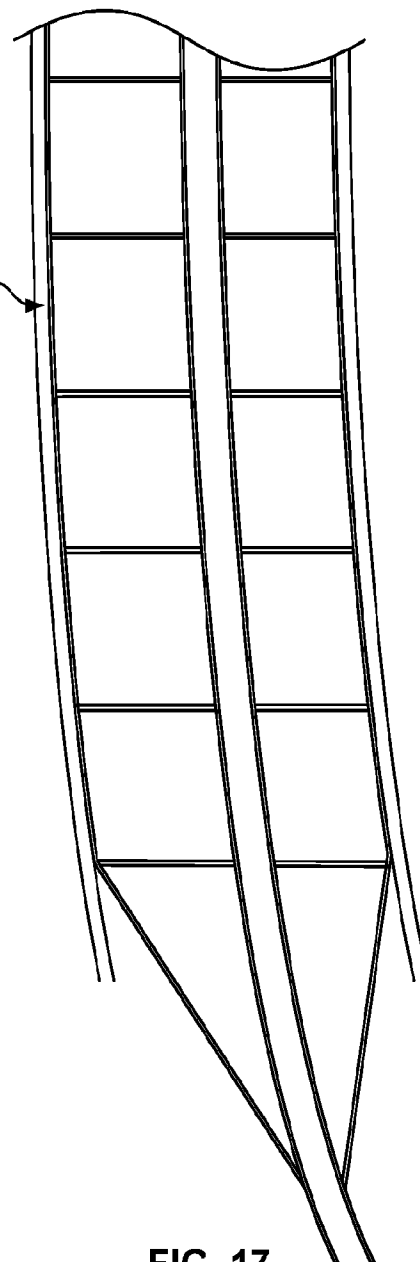


FIG. 17

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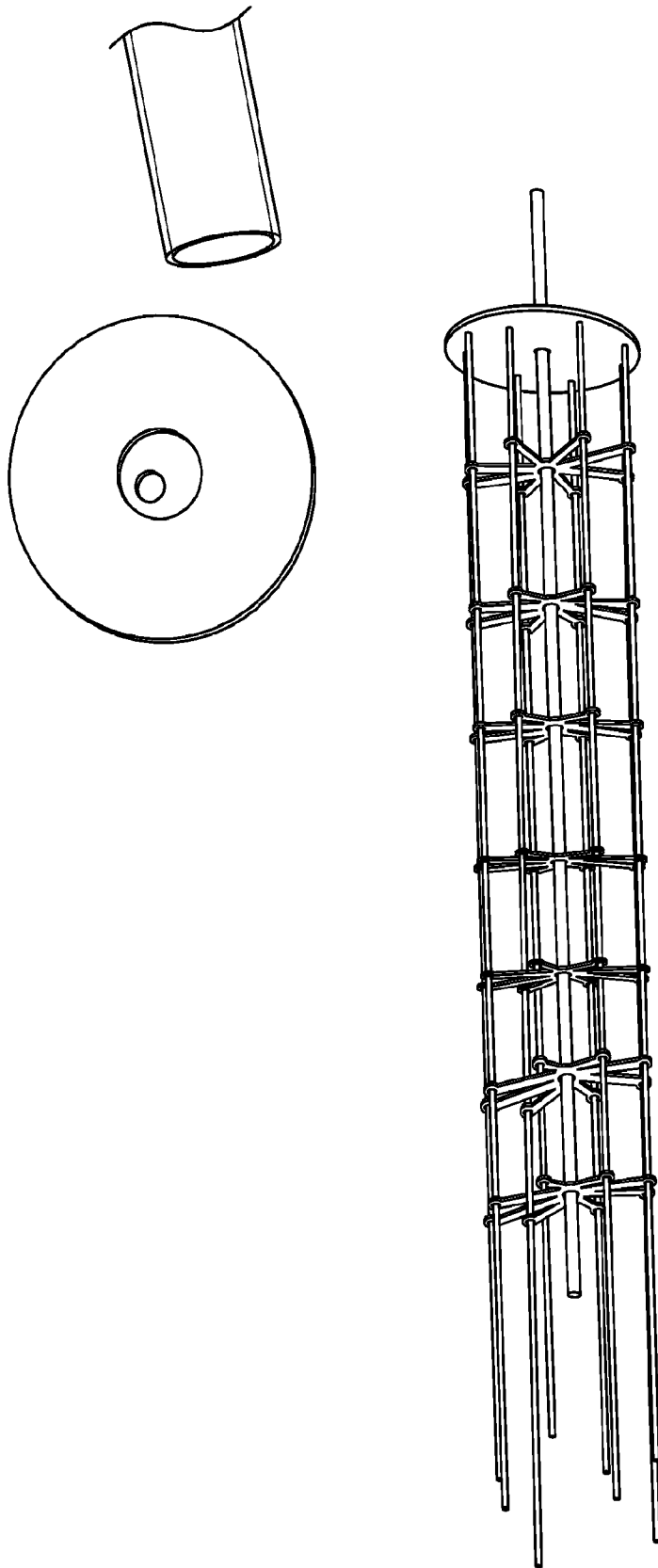


FIG. 19

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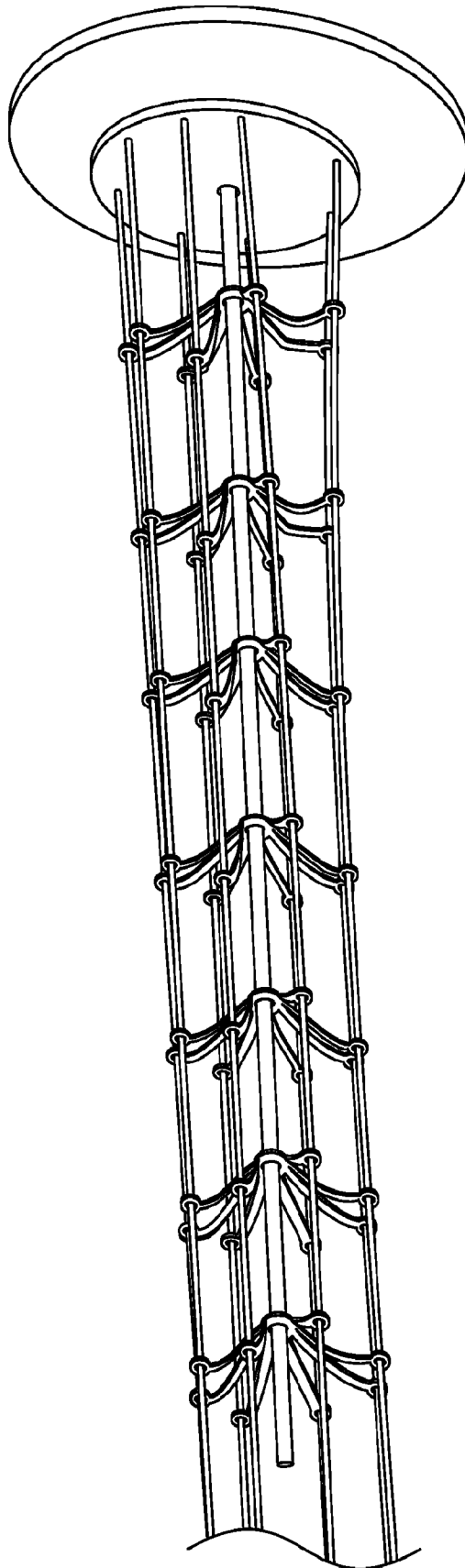


FIG. 20

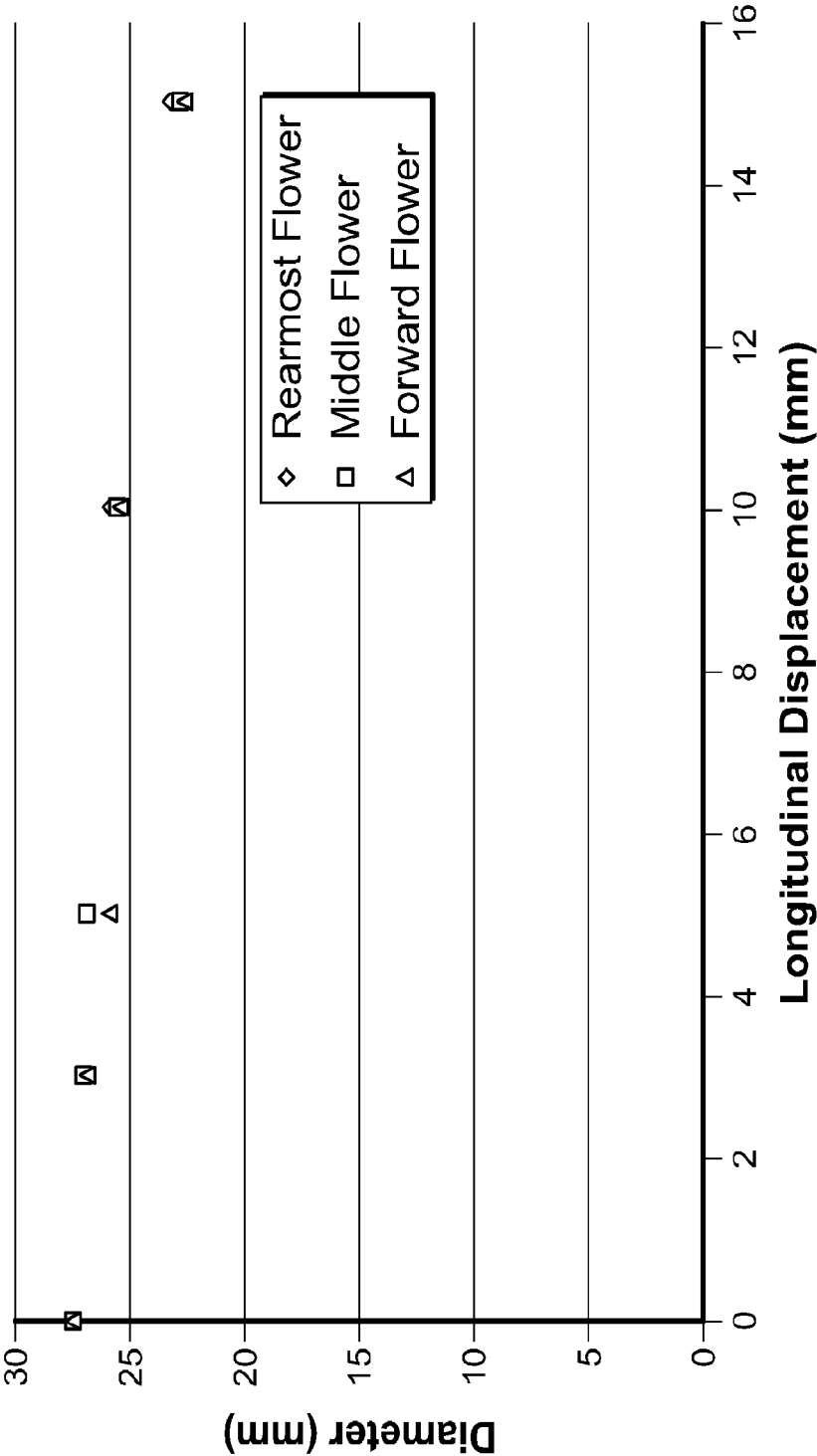


FIG. 21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 17/63477

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 29/00 (2018.01)

CPC - A61M 29/00, A61M 3/0291, A61M 2025/0687, A61B 17/0293

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History Document

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

See Search History Document

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

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y -- A	US 832,201 A (KISTLER) 02 October 1906 (02.10.1906) Entire document, especially Abstract, p1, ln 8-17, p1, ln 28-68 and FIGS. 1-4.	1-2, 5, 7, 9-15, 17-20, 22, 24, 27 ----- 6, 21, 25-26 ----- 3, 8, 16, 23
X	US 2004/0087994 A1 (SUDDABY) 06 May 2004 (06.05.2004) Entire document, especially Abstract, para[0021], [0023] and FIGS. 1-2.	1, 4
X -- A	US 2007/0208366 A1 (PELLEGRINO et al.) 06 September 2007 (06.09.2007) Entire document, especially Abstract, para[0029], [0039] and FIGS. 1-2, 10.	1 ----- 3, 8, 16, 23
Y -- A	US 2013/0231534 A1 (PISKUN et al.) 05 September 2013 (05.09.2013) Entire document, especially Abstract, para[0063]-[0065], [0081] and FIGS. 3.	6, 21, 25-26 ----- 3, 8, 16, 23
A	US 3,774,596 A (COOK) 27 November 1973 (27.11.1973) Entire document.	1-27
A	US 3,968,800 A (VILASI) 13 July 1976 (13.07.1976) Entire document.	1-27
A	US 5,197,971 A (BONUTTI) 30 March 1993 (30.03.1993) Entire document.	1-27
A	US 2013/0053863 A1 (JARAVIC et al.) 28 February 2013 (28.02.2013) Entire document.	1-27



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

15 January 2018

Date of mailing of the international search report

20 FEB 2018

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