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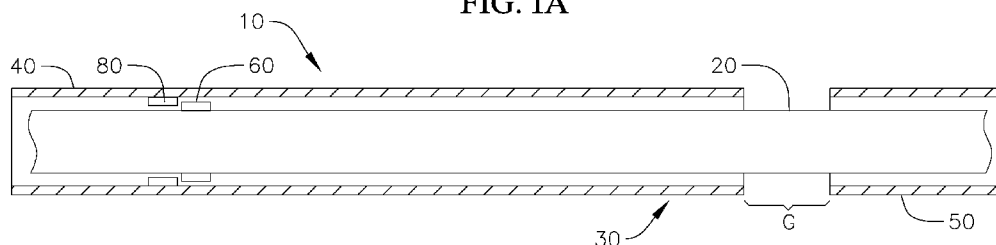
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FIG. 1A



(57) Abstract: A guidewire including a thin elongated structure and an outer shell around at least a portion of the thin elongated structure. The outer shell includes a first portion and a second portion. The first portion and the second portion of the outer shell are each coupled to the thin elongated structure. The first portion is spaced from the second portion by a gap. The guidewire is configured to move between a flexible state and a rigid state. The gap has a first distance when the guidewire is in the flexible state and the gap has a second distance greater than the first distance when the guidewire is in the rigid state.



## GUIDEWIRE

### CROSS-REFERENCE TO RELATED APPLICATION(S)

**[0001]** This application claims priority to and the benefit of U.S. Provisional Application No. 62/540,504, filed August 2, 2017, the entire contents of which are incorporated herein by reference.

### FIELD

**[0002]** The present disclosure generally pertains to medical devices, and more particularly to medical guidewires such as intravascular guidewires and mechanisms for tensioning guidewires.

### BACKGROUND

**[0003]** Guidewires are commonly used in conjunction with intravascular devices, for example intravascular catheters or other such devices, to facilitate navigation through the vasculature of a patient. The vasculature of a patient may be very tortuous. It is often desired that certain portions of a guidewire have lateral flexibility characteristics as well as pushability characteristics. It is also desirable that the guidewire be able to achieve a rigid state from a flexible state, to achieve a shape-locked configuration, and to revert to a flexible state from the rigid state.

### SUMMARY

**[0004]** The present disclosure is directed to various embodiments of a guidewire. In one embodiment, the guidewire includes a thin elongated structure, and an outer shell around at least a portion of the thin elongated structure. The outer shell includes a first portion and a second portion each coupled to the thin elongated structure. The first portion is spaced from the second portion by a gap. The guidewire is configured to move between a flexible state and a rigid state. The gap has a first distance when the guidewire is in the flexible state and the gap has a second distance greater than the first distance when the guidewire is in the rigid state.

**[0005]** The first distance may be substantially zero.

**[0006]** The second distance may be at least approximately 1 cm.

**[0007]** The guidewire may include an outer stop coupled to the thin elongated structure.

**[0008]** The guidewire may also include an inner stop coupled to the first portion of the outer shell. The inner stop is configured to engage the outer stop when the

1 guidewire is in the flexible state to maintain a minimum distance of the gap between the first portion and the second portion of the outer shell.

[0009] The outer stop may extend into the gap between the first portion and the second portion of the outer shell. The outer stop is configured to engage a proximal end of the first portion of the outer shell when the guidewire is in the flexible state to maintain a minimum distance of the gap between the first portion and the second portion of the outer shell.

[0010] The outer shell may include a spring.

[0011] The thin elongated structure may be a wire or a cable.

10 [0012] The present disclosure is also directed to various embodiments of a system. In one embodiment, the system includes a guidewire and a tensioning mechanism. The guidewire includes a thin elongated structure and an outer shell around a first portion of the thin elongated structure. A second portion of the thin elongated structure is exposed outside the thin elongated structure. The tensioning mechanism is configured to engage the second portion of the thin elongated structure to move the guidewire between a flexible state and a rigid state.

15 [0013] The tensioning mechanism may include a body portion defining a central opening having threads, and a flange portion extending from the body portion.

[0014] The thin elongated structure may include screw threads along at least a portion of the second portion, and the threads in the central opening of the tensioning mechanism may be configured to threadedly engage the screw threads of the thin elongated structure.

20 [0015] Rotating the tensioning mechanism in a first direction may move the guidewire from the flexible state to the rigid state, and rotating the tensioning mechanism in a second direction opposite the first direction may move the guidewire from the rigid state to the flexible state.

25 [0016] The system may also include an inwardly-extending flange at a proximal end of the outer shell, and an outer stop on the second portion of the thin elongated structure configured to engage the inwardly-extending flange when the guidewire is in the flexible state.

30 [0017] A length of an inner surface of the flange portion may be longer than a length of an outer surface of the outer stop.

[0018] An inner diameter of the flange portion may be larger than an inner diameter of central opening.

35 [0019] The tensioning mechanism may further include a taper extending between the inner surface of the flange portion and an inner surface of the central opening.

[0020] The present disclosure is also directed to various embodiments of a method of operating a guidewire comprising a thin elongated structure and an outer

1 shell around at least a portion of the thin elongated structure. In one embodiment, the method includes moving the guidewire from a flexible state to a rigid state by pulling the thin elongated structure proximally.

5 **[0021]** The outer shell of the guidewire may include a first portion and a second portion each coupled to the thin elongated structure, and moving the guidewire from the flexible state to the rigid state may include increasing a length of a gap between the first portion of the outer shell and the second portion of the outer shell.

10 **[0022]** A second portion of the thin elongated structure may be exposed outside of the outer shell, and moving the guidewire from the flexible state to the rigid state may include threading a tensioning mechanism onto the second portion of the thin elongated structure.

15 **[0023]** The tensioning mechanism may include a body portion and a flange portion extending distally from the body portion, and the flange portion may engage a proximal end of the outer shell while moving the guidewire from the flexible state to the rigid state.

20 **[0024]** This summary is provided to introduce a selection of features and concepts of embodiments of the present disclosure that are further described below in the detailed description. This summary is not intended to identify key or essential features of the claimed subject matter, nor is it intended to be used in limiting the scope of the claimed subject matter. One or more of the described features may be combined with one or more other described features to provide a workable device.

#### BRIEF DESCRIPTION OF THE DRAWINGS

25 **[0025]** These and other features and advantages of embodiments of the present disclosure will become more apparent by reference to the following detailed description when considered in conjunction with the following drawings. In the drawings, like reference numerals are used throughout the figures to reference like features and components. The figures are not necessarily drawn to scale.

30 **[0026]** FIG. 1A is a side view of a portion of a guidewire according to one embodiment of the present disclosure;

**[0027]** FIG. 1B is a side view of a portion of a guidewire according to another embodiment of the present disclosure;

35 **[0028]** FIG. 2 is a side view of a portion of a guidewire according to another embodiment of the present disclosure, the guidewire including a series of flexure members between a thin elongated structure and an outer shell;

**[0029]** FIG. 3 is a perspective view of the flexure member of the embodiment of the guidewire illustrated in FIG. 2;

1     **[0030]**     FIG. 4 is a perspective view of the flexure member surrounding the thin elongated structure according to the embodiment of the guidewire illustrated in FIG. 2;

5     **[0031]**     FIG. 5 is a side view of the embodiment of the guidewire illustrated in FIG. 2 with the series of flexure members engaging each other;

**[0032]**     FIG. 6 is a side view of a series of flexure members according to another embodiment of the present disclosure;

**[0033]**     FIG. 7 is a side view of the embodiment of the flexure members illustrated in FIG. 6 showing the flexure members engaging each other;

10    **[0034]**     FIG. 8A is a side view of a tensioning mechanism configured to apply and release tension from a guidewire according to one embodiment of the present disclosure;

**[0035]**     FIG. 8B is a side view of a tensioning mechanism configured to apply and release tension from a guidewire according to another embodiment of the present disclosure;

15    **[0036]**     FIG. 8C is a side view of a tensioning mechanism according to another embodiment of the present disclosure configured to apply and release tension from a guidewire, where the tensioning mechanism is in an "open" configuration and the guidewire is in a flexible state;

20    **[0037]**     FIG. 8D is a side view of the embodiment of the tensioning mechanism illustrated in FIG. 8C, where the tensioning mechanism is in a "closed" configuration and the guidewire is in a rigid state;

**[0038]**     FIG. 9 is a side view of a tensioning mechanism configured to apply and release tension from a guidewire according to another embodiment of the present disclosure;

25    **[0039]**     FIG. 10 is a side view of a tensioning mechanism configured to apply and release tension from a guidewire according to a further embodiment of the present disclosure;

30    **[0040]**     FIGS. 11A-11C are cross-sectional views of a tensioning mechanism configured to apply and release tension from a guidewire according to a further embodiment of the present disclosure;

**[0041]**     FIGS. 12A-12C are cross-sectional views of a tensioning mechanism configured to apply and release tension from a guidewire according to another embodiment of the present disclosure;

35    **[0042]**     FIGS. 13A-13B are cross-sectional views of a guidewire according to another embodiment of the present disclosure; and

**[0043]**     FIGS. 14A-14B are cross-sectional views of a guidewire and a tensioning mechanism according to a further embodiment of the present disclosure.

## DETAILED DESCRIPTION

**[0044]** The present disclosure is directed to various embodiments of a guidewire configured to move between a flexible state and a rigid state. The present disclosure is also directed to various embodiments of a tensioning mechanism configured to move the guidewire between the flexible and rigid states. Medical intervention inside a patient's blood vessel includes advancing a rigid device (e.g., a balloon catheter, a stent, an atherectomy device, or an intravascular ultrasound probe) over a guidewire. These rigid devices must navigate acute angles in the patient's blood vessel. As the rigid device is advanced through an acute angle, the rigid device can puncture the blood vessel and cause fatal bleeding. Conventionally, a flexible guidewire that is not prone to puncturing the blood vessel is first advanced into the patient's blood vessel and then the flexible guidewire is exchanged with a relatively stiffer guidewire over a soft catheter. The rigid device can then be passed over the stiffer guidewire to navigate acute angles without puncturing the blood vessel. However, each exchange of a relatively flexible guidewire for a relatively stiffer guidewire creates the risk of complications. For instance, each exchange increases the risk that the patient's blood vessel will be punctured by the guidewire. Additionally, exchanging the flexible guidewire for the relatively stiffer guidewire increases surgical time, and thus increases fluoroscopy exposure time for the patient and the attending medical staff. The present disclosure, which is directed to various embodiments of a guidewire configured to selectively move between a flexible state and a rigid state, is configured to reduce the number of exchanges that must occur during a medical intervention and thereby improve patient outcomes.

**[0045]** FIG. 1 shows a side view of a portion of a guidewire 10 in accordance with one example embodiment. The guidewire 10 includes a thin elongated structure 20 (e.g., a wire or a monofilament). An outer shell 30 including a first portion 40 and a second portion 50 surrounds the thin elongated structure 20. The outer shell 30 may have any suitable configuration, such as a spiral configuration (e.g., a coil spring), as is known in the art. A portion (e.g., a tip portion) of the first portion 40 of the outer shell 30 is coupled (e.g., welded) to a portion (e.g., a tip portion) of the thin elongated structure 20, as is well known in the art. Additionally, in one or more embodiments, the second portion 50 of the outer shell 30 is coupled (e.g., welded) to a portion of the thin elongated structure 20. In FIG. 1, a distal end 51 of the second portion 50 is spaced apart from a proximal end 41 of the first portion 40 (e.g., by a gap G). In one or more embodiments, the gap G exposes a portion of the thin elongated structure 20.

**[0046]** Additionally, in the embodiment shown, the guidewire 10 includes an outer stop (e.g., lock) 60 formed on the thin elongated structure 20. The outer stop 60

1 extends outward from the thin elongated structure 20 toward the first portion 40 of  
the outer shell 30. Additionally, in the illustrated embodiment, the guidewire 10  
includes an inner stop (e.g., lock) 80 on the outer shell 30 configured to engage the  
5 outer stop 60. The inner stop 80 extends inward from the first portion 40 of the outer  
shell 30 toward the thin elongated structure 20. In the illustrated embodiment, the  
inner stop 80 is positioned between the outer stop 60 and the tip portions of the thin  
elongated structure 20 and the first portion 40 of the outer shell 30. The engagement  
10 between the outer stop 60 and the inner stop 80 is configured to keep the first  
portion 40 and second portion 50 of the outer shell 30 spaced apart by the gap G  
(e.g., the inner and outer stops 80, 60 are configured to prevent the gap G from  
completely closing).

**[0047]** In one or more embodiments, the guidewire 10 may be provided without  
the outer stop 60 (e.g., the guidewire 10 may be provided with only the inner stop 80  
on the thin elongated structure 20). For instance, in the embodiment illustrated in  
15 FIG. 1B, the guidewire 10 is provided with only the inner stop 80 on the thin  
elongated structure 20, and the inner stop 80 extends into the gap G between the  
first portion 40 and the second portion 50 of the outer shell 30 (e.g., the inner stop 80  
may be provided on a portion of the thin elongated structure 20 that is aligned with  
the gap G between the first portion 40 and the second portion 50 of the outer shell  
20 30). Additionally, in the embodiment illustrated in FIG. 1B in which the inner stop 80  
extends into the gap G between the first portion 40 and the second portion 50 of the  
outer shell 30, contact between the inner stop 80 and the proximal end 41 of the first  
portion 40 and/or the distal end 51 of the second portion 50 is configured to keep the  
first portion 40 and second portion 50 of the outer shell 30 spaced apart by the gap  
25 G (e.g., the contact between the inner stop 80 and the proximal end 41 of the first  
portion 40 of the outer shell 30 and/or the distal end 51 of the second portion 50 of  
the outer shell 30 is configured to prevent the gap G from completely closing).  
Additionally, in the illustrated embodiment, the proximal end 41 of the first portion 40  
includes an inwardly extending flange 42 configured to engage the inner stop 80 on  
30 the thin elongated structure 20. In the illustrated embodiment, an outer surface 81 of  
the inner stop 80 is recessed below an outer surface 43 of the first portion 40 of the  
outer shell 30 (e.g., the outer surface 81 of the inner stop 80 is between the outer  
surface 43 and an inner surface 44 of the first portion 40 of the outer shell 30). In one  
or more embodiments, recessing the outer surface 81 of the inner stop 80 below the  
35 outer surface 43 of the first portion 40 is configured to enable a tensioning  
mechanism, described in detail below, to extend into the gap G and move the first  
and second portions 40, 50 of the outer shell 30 toward and away from each other.

1     **[0048]**     The thin elongated structure 20 may be any suitable structure for use as a thin elongated structure, as will be understood by those of skill in the art and others. For example, the thin elongated structure 20 can be a wire or a cable. The thin elongated structure 20 can have a solid cross-section, but in some embodiments, 5     can have a hollow cross-section. In yet other embodiments, the thin elongated structure 20 can include a combination of areas having solid cross-sections and hollow cross-sections.

10    **[0049]**     The guidewire 10 is configured to move between a flexible configuration in which the guidewire 10 has lateral flexibility, and a rigid configuration (e.g., a shape-locked configuration) in which the guidewire 10 has relatively less lateral flexibility than when the guidewire 10 is in the flexible configuration. In one or more 15    embodiments, when the guidewire 10 is in the flexible state, a distal end portion of the thin elongated structure 20 (e.g., a tip portion of the thin elongated structure 20) has a greater degree of flexibility than a remaining portion of the thin elongated structure 20. In one embodiment, the guidewire 10 may be moved from the flexible configuration to the rigid configuration by moving the first and second portions 40, 50 of the outer shell 30 away from each other such that the gap G between the first and second portions 40, 50 increases. In one or more embodiments, the gap G may be increased by advancing the first portion 40 of the outer shell 30 away from the 20    second portion 50 of the outer shell 30 and/or retracting the second portion 50 away from the first portion 40 of the outer shell 30. As the first and second portions 40, 50 of the outer shell 30 are moved away from each other, the first portion 40, which is coupled to the thin elongated structure 20, pulls on the thin elongated structure 20 and thereby applies tension to the thin elongated structure 20. The tension applied to the thin elongated structure 20 by the first portion 40 of the outer shell 30 maintains the guidewire 10 in the rigid configuration. As the first and second portions 40, 50 of the outer shell 30 are moved toward each other such that the gap G between the first and second portions 40, 50 decreases, the thin elongated structure 20 relaxes (e.g., the tension supplied to the thin elongated structure 20 by the first portion 40 of the 25    outer shell 30 is reduced), which returns the guidewire 10 to the flexible configuration. Accordingly, the guidewire 10 according to one embodiment of the present disclosure may be moved between the flexible configuration and the rigid configuration by moving the first portion 40 of the outer shell 30 away from and toward the second portion 50 of the outer shell 30 to increase and decrease, 30    respectively, the gap G between the first and second portions 40, 50 of the outer shell 30. In one or more embodiments, the length of the gap G when the guidewire is in the flexible configuration may be zero or substantially zero. In one or more embodiments, the length of the gap G when the guidewire is in the rigid configuration

1 may be at least approximately 0.5 cm. In one or more embodiments, the length of the gap G when the guidewire is in the rigid configuration may be at least approximately 1 cm.

5 **[0050]** In one or more embodiments in which the first portion 40, or at least a portion thereof, of the outer shell 30 has a spiral wound configuration (e.g., a coil spring), the first portion 40 is a resilient member configured to bias the guidewire 10 into the flexible configuration. For instance, in one or more embodiments, the resilient first portion 40 of the outer shell 30 is configured to bias the first portion 40 toward the second portion 50 such that the gap G between the first and second  
10 portions 40, 50 has a minimal length (e.g., the resiliency of the first portion 40 is configured to bias the first portion 40 toward the second portion 50 of the outer shell 30 such that the outer stop 80 contacts the inner stop 60, as illustrated in FIG. 1A, or the inner stop 60 contacts the proximal end 41 of the first portion 40, as illustrated in FIG. 1B).

15 **[0051]** FIG. 2 illustrates another example embodiment of a guidewire 10 including a plurality of flexure members (or flexure sections) 70 interposed between the thin elongated structure 20 and the outer shell 30. In at least some embodiments, the flexure members 70 are cylinders. In at least some embodiments, each of the flexure members 70 is a separate and discrete structure spaced from any adjacent  
20 segment or segments (e.g., independent from any adjacent segment or segments). Each of the flexure members 70 is adapted and configured to be movable to contact with one or more segments that are adjacent thereto, as illustrated in FIG. 5. This allows lateral flexure (e.g., flexibility) of the guidewire 10. FIG. 3 shows an individual flexure member 70 containing an inner lumen 90 configured to surround the thin  
25 elongated structure 20. FIG. 4 illustrates the thin elongated structure 20 disposed through the inner lumen 90 of the flexure members 70.

**[0052]** In one or more embodiments, the number of flexure members 70 used in the guidewire 10 is dependent upon the desired length and/or flexibility characteristics of the guidewire 10. In one or more embodiments, the length of each  
30 flexure member can be varied dependent upon the desired length and/or flexibility characteristics of the guidewire 10. In one or more embodiments, all of the flexure members 70 within a guidewire 10 can be of generally uniform length, or can vary in length to achieve variable stiffness characteristics of a guidewire 10.

35 **[0053]** In one or more embodiments, each of the flexure members 70 is a hollow or generally tubular segment. Additionally, in one or more embodiments, each of the flexure members 70 includes engagement features to connect to another flexure member. Such engagement features can include any structure generally known to provide such a connection function. For example, each of the flexure members 70

1 can include side surfaces including engagement means (e.g., engagement  
structure), for example, crenations, teeth, serrations, bends, grooves, protrusions,  
notches, tongue and groove arrangements, or other arrangements, and the like, that  
5 are adapted and configured to mate with each other such that side surfaces of  
adjacent segments connect in a mechanical or frictional manner in relation to one  
another.

**[0054]** In the embodiment illustrated in FIGS. 6-7, each of the flexure members  
70 include opposing side surfaces 72 and 74. The side surfaces 72 include a male  
shape, and the side surfaces 74 include a female shape therein (e.g. convex and  
10 concave, etc.). The side surfaces 72 are adapted and configured to mate with the  
side surfaces 74 to provide a mechanical connection between adjacent segments  
70. As seen in FIGS. 6-7, the side surfaces 72 and 74 of the multiple flexure  
members 70 are generally in line with each other along the length of the guidewire  
10. FIG. 7 shows the flexure members 70 of FIG. 6, in a connected position. The  
15 connecting construction allows for movement into a rigid configuration.

**[0055]** In the illustrated embodiment, the outer shell 30 is disposed about at least  
a portion of the plurality of flexure members 70. In some embodiments, the outer  
shell 30 is also disposed about at least a portion of the thin elongated structure 20.  
The outer shell 30 is disposed over the plurality of flexure members 70, and can  
20 encapsulate the flexure members 70, yet allow the thin elongated structure 20 to flex  
and bend laterally. The outer shell 30 can be a spring or similar structure known to  
those skilled in the art.

**[0056]** When tension is applied to the thin elongated structure 20, the flexure  
members 70 mate with each other to provide a mechanical connection between  
25 adjacent segments. The guidewire 10 therefore goes from soft e.g., resting form to  
rigid (e.g., stiff) form and shape-locked in this configuration.

**[0057]** Now with reference to FIGS. 8A-8B, tensioning mechanisms are described  
wherein guidewire 10 is disposed at rest in the flexible (e.g., soft) configuration. In  
the embodiment illustrated in FIG. 8A, a tensioning mechanism 100 includes a fixed  
30 leg 110, a pivot leg 120, and a handle 130 all arranged around a central pivot 140,  
enclosed within a box 150. The box 150 has slits 160 formed thereon through which  
the guidewire 10 extends.

**[0058]** In order to transition the guidewire 10 from the flexible configuration to the  
rigid configuration, the fixed leg 110 is detachably engaged to a portion of the  
35 guidewire 10, such as at the second portion 50 of the outer shell 30. The fixed leg  
110 is held stationary while the handle 130 is advanced. Pivot leg 120 rotates in the  
same direction as the handle 130 around the central pivot 140 and engages the  
guidewire 10, such as at the first portion 40 of the outer shell 30, and the pivot leg

1 120 applies force in the direction of the arrow shown in FIG. 8A, thereby increasing  
the gap G between the first and second portions 40 and 50 of the outer shell 30.  
Therefore, tensioning the guidewire 10 transitions the guidewire 10 to the rigid  
configuration and shape-locking in this configuration. To return the guidewire 10 to  
5 the flexible configuration, the handle 130 is released or returned, which causes the  
pivot leg 120 to cease applying force to the guidewire 10.

**[0059]** In FIG. 8B, the tensioning mechanism 100 has been modified, such that  
the fixed leg 110 is modified to become a pivot leg 122. As the handle 130 is  
advanced, the pivot legs 120 and 122 engage the guidewire 10 at the first portion 40  
10 and the second portion 50 of the outer shell 30 and apply force in the direction of the  
arrows shown in FIG. 8B, thereby increasing the gap G between the first and second  
portions 40 and 50 of the outer shell 30. Therefore, tensioning the guidewire 10  
transitions the guidewire 10 to the rigid configuration and shape-locking in this  
configuration. To return the guidewire 10 to the flexible configuration, the handle 130  
15 is released or returned, which causes the pivot legs 120 and 122 to cease applying  
force to the guidewire 10.

**[0060]** In FIGS. 8C and 8D, the tensioning mechanism 100 has further been  
modified to add an additional handle 132 around the central pivot 140. In the  
configuration shown in FIG. 8C, the guidewire 10 is in a resting state. The handles  
20 130 and 132 of the tensioning mechanism are in an "open" configuration. As the  
handles 130 and 132 are rotated towards each other, as shown in the arrows in FIG.  
8D, the pivot legs 120 and 122 engage the guidewire 10 at first portion 40 and  
second portion 50, respectively, of the outer shell 30 and apply force in the direction  
of the arrows shown in FIG. 8D, thereby tensioning the guidewire 10 to the rigid  
25 configuration and shape-locking in this configuration. To return the guidewire 10 to  
the flexible configuration, the handles 130 and 132 are released or returned, which  
causes the pivot legs 120 and 122, respectively, to cease applying force to the  
guidewire 10.

**[0061]** A tensioning mechanism 200 according to another embodiment is  
30 illustrated in FIG. 9. In the illustrated embodiment, the tensioning mechanism 200  
includes a rack 201 having a series of teeth 202, a pinion 203 having a series of  
teeth 204 engaging the teeth 202 of the rack 201, and a motor 205 coupled to the  
pinion 203. In the illustrated embodiment, the rack 201 is coupled to the first portion  
40 of the guidewire 10, although in one or more embodiments, the rack 201 may be  
35 coupled to the second portion 50 of the guidewire 10. Additionally, in the illustrated  
embodiment, the tensioning mechanism 200 includes a box 206 defining a slit 207  
configured to accommodate a portion of the guidewire 10 extending through the slit  
207.

1     **[0062]**     Actuation of the motor 205 in a first direction (arrow 208) (e.g., clockwise) is configured to rotate the pinion 202 in the first direction (arrow 208), and rotation of the pinion 203 in the first direction (arrow 208) is configured to slide the rack 201 in a first direction (arrow 209), which causes the first portion 40 of the guidewire 10 to  
5     move away from the second portion 50 of the guidewire 10 and thereby moves the guidewire 10 into the rigid state (e.g., actuation of the motor 205 in the first direction (arrow 208) increases the gap G between the first and second portions 40, 50 of the outer shell 30 and thereby moves the guidewire 10 into the rigid state). Actuation of the motor 205 in a second direction (arrow 210) (e.g., counterclockwise) opposite the  
10    first direction is configured to rotate the pinion 202 in the second direction (arrow 210), and rotation of the pinion 203 in the second direction (arrow 210) is configured to slide the rack 201 in a second direction (arrow 211), which causes the first portion 40 of the guidewire 10 to move toward the second portion 50 of the guidewire 10 and thereby moves the guidewire 10 into the flexible state (e.g., actuation of the motor  
15    205 in the second direction (arrow 210) decreases the gap G between the first and second portions 40, 50 of the outer shell 30 and thereby moves the guidewire 10 into the flexible state).

20    **[0063]**     To transition the guidewire 10 from the flexible configuration to the rigid configuration, the guidewire 10 is inserted through the slit 207 in the box 206. In one or more embodiments, the box 206 is then connected to a portion of the guidewire 10, such as at the second portion 50 of the outer shell 30. The motor 205 is then actuated in the first direction 208 (e.g., clockwise), which moves the first portion 40 of the guidewire 10 away from the second portion 50 of the guidewire 10 and thereby moves the guidewire 10 into the rigid state in which the guidewire 10 is shape-  
25    locked. To return the guidewire 10 to the flexible configuration, the motor 205 is actuated in the second direction 210 (e.g., counterclockwise), which moves the first portion 40 of the guidewire 10 toward the second portion 50 of the guidewire 10 and thereby moves the guidewire 10 into the flexible state in which the guidewire 10 is laterally flexible.

30    **[0064]**     FIG. 10 depicts a tensioning mechanism 300 according to another embodiment of the present disclosure. In the illustrated embodiment, the tensioning mechanism 300, or at least a portion thereof, is positioned in or proximate to the gap G between the first and second portions 40, 50 of the outer shell 30. In the illustrated embodiment, the tensioning mechanism 300 includes a thumbwheel 301. Actuation  
35    of the thumbwheel 301 (e.g., rotation of the thumbwheel 301 with the user's thumb) in a first direction (arrow 302) is configured to move the first and second portions 40, 50 further apart from each other (e.g., rotation of the thumbwheel 301 in the first direction 302 is configured to increase the length of the gap G between the first and

1 second portions 40, 50 of the outer shell 30), and thereby move the guidewire 10 into  
the rigid state. Actuation (e.g., rotation) of the thumbwheel 301 in a second direction  
(arrow 303) opposite to the first direction is configured to move the first and second  
portions 40, 50 closer to each other (e.g., rotation of the thumbwheel 301 in the  
5 second direction 303 is configured to decrease the length of the gap G between the  
first and second portions 40, 50 of the outer shell 30), and thereby return the  
guidewire 10 to the flexible state. The thumbwheel 301 may be operably to any  
suitable mechanism or mechanism for increasing and decreasing the length of the  
gap G between the first and second portions 40, 50 of the outer shell 30. For  
10 instance, in one or more embodiments, the thumbwheel 301 may be operably  
coupled to a linear actuator 304 (e.g., a telescoping linear screw) that is coupled at  
opposite ends to the first and second portions 40, 50 of the outer shell 30. In the  
illustrated embodiment, the linear actuator 304 is a telescoping linear screw including  
a first segment 305 and a second segment 306 at least partially telescopically  
15 housed in the first segment 305. The first segment 305 of the telescoping linear  
screw is coupled to the second portion 50 of the outer shell 30, and the second  
segment 306 of the telescoping linear screw is coupled to the first portion 40 of the  
outer shell 30. In one or more embodiments, actuation of the thumbwheel 301 in the  
first direction (arrow 302) is configured to lengthen (arrow 307) the telescoping linear  
20 screw 304 (e.g., actuation of the thumbwheel 301 in the first direction (arrow 302) is  
configured to extend (arrow 307) the second segment 306 further out of the first  
segment 305 of the telescoping linear screw) and thereby increase the length of the  
gap G between the first and second portions 40, 50. Additionally, in one or more  
embodiments, actuation of the thumbwheel 301 in the second direction (arrow 303)  
25 is configured to shorten (arrow 308) the telescoping linear screw 304 (e.g., actuation  
of the thumbwheel 301 in the second direction (arrow 303) is configured to retract  
(arrow 308) the second segment 306 further into the first segment 305 of the  
telescoping linear screw) and thereby decrease the length of the gap G between the  
first and second portions 40, 50 of the outer shell 30. In this manner, the thumbwheel  
30 301 and the telescoping linear screw 304 are configured to move the guidewire 10  
between the flexible state and the rigid state. In one or more embodiments, the  
thumbwheel 301 may be operably coupled to a motor configured to increase and  
decrease the length of the gap G between the first and second portions 40, 50 of the  
outer shell 30 to move the guidewire 10 between the flexible and rigid states.

35 **[0065]** FIGS. 11A-11C depict a tensioning mechanism 400 according to another  
embodiment of the present disclosure. In the illustrated embodiment, the tensioning  
mechanism 400 includes a body 401 defining a central opening 402 (e.g., a blind  
bore hole or a through hole). In the illustrated embodiment, the body 401 of the

1     tensioning mechanism 400 is tubular (e.g., a hollow cylindrical member), although in  
one or more embodiments, the body 401 may have any other suitable shape. In the  
illustrated embodiment, the body 401 includes a sidewall 403 (e.g., a cylindrical  
sidewall) having a distal end 404 and a proximal end 405 opposite the distal end  
5     404, and an end wall 406 at the proximal end 405 of the sidewall 403. Together, the  
sidewall 403 and the end wall 406 define the central opening 402. Additionally, in the  
illustrated embodiment, the central opening 402 is a blind bore terminating at the end  
wall 406. In one or more embodiments, the body 401 may be provided without the  
end wall 406 and the central opening 402 may be a through hole that extends  
10    completely through the body 401. Additionally, in the illustrated embodiment, the  
distal end 404 of the body 401 is open such that the guidewire 10 may be inserted  
into the central opening 402.

**[0066]**   In the embodiment illustrated in FIGS. 11A-11C, the tensioning  
mechanism 400 also includes a first pad 407 and a second pad 408 movably  
15    coupled to the sidewall 403 of the body 401. In the illustrated embodiment, the first  
and second pads 407, 408 are spaced apart from each other along the lengthwise  
direction of the sidewall 403 such that the tensioning mechanism 400 includes a  
relatively distal pad 407 and a relatively proximal pad 408. In the illustrated  
embodiment, the first pad 407 is proximate to the distal end 404 of the sidewall 403  
20    and the second pad 408 is proximate to the proximal end 405 of the sidewall 403. In  
the illustrated embodiment, the first pad 407 and the second pad 408 are both  
annular members (e.g., a snap ring or a retaining ring).

**[0067]**   In one or more embodiments, the first pad 407 and the second pad 408  
are each configured to move (arrows 409, 410, respectively) between a retracted  
25    position (shown in FIG. 11A) and an extended position (shown in FIGS. 11B-11C). In  
the illustrated embodiment in which the sidewall 403 is cylindrical, the first and  
second pads 407, 408 are configured to move radially (arrows 409, 410) inward and  
outward between the retracted and extended positions. In the extended position, the  
first and second pads 407, 408 extend a greater distance into the central opening  
30    402 than when the first and second pads 407, 408 are in the retracted position. In  
one or more embodiments, the first and second pads 407, 408 may not extend into  
or may substantially not extend into the central opening 402 when the first and  
second pads 407, 408 are in the retracted position.

**[0068]**   Additionally, in the illustrated embodiment, the first pad 407 is slidably  
35    coupled (arrow 411) to the sidewall 403 of the body 401 such that first pad 407 is  
configured to slide along the sidewall 403 toward and away (arrow 411) from the  
second pad 408. In the illustrated embodiment, the first pad 407 is configured to  
slide (arrow 411) between a first position in which the first pad 407 is spaced apart

1 from the second pad 408 by a first length  $L_1$  along a lengthwise direction of the  
sidewall 403 of the body 401 to a second position in which the first pad 407 is  
spaced apart from the second pad 408 by a second length  $L_2$  along the lengthwise  
5 direction of the sidewall 403 of the body 401 that is greater than the first length  $L_1$ . In  
the illustrated embodiment, the first pad 407 is at least partially slidably  
accommodated in a track 412 in an inner surface 413 of the sidewall 403.

**[0069]** Although in the illustrated embodiment the tensioning mechanism 400  
includes two pads 407, 408, in one or more embodiments, the tensioning mechanism  
400 may include any other suitable number of pads. For instance, in one or more  
10 embodiments, the first pad 407 may include a series of first pad segments arranged  
around the inner circumference of the sidewall 403, and the second pad 408 may  
include a series of second pad segments arranged around the inner circumference  
of the sidewall 403. In one or more embodiments, the first pad 407 may include at  
least a pair of opposing first pad segments (e.g., two pairs of opposing first pad  
15 segments), and the second pad 408 may include at least a pair of opposing second  
pad segments (e.g., two pairs of opposing second pad segments).

**[0070]** Additionally, in the illustrated embodiment, the tensioning mechanism 400  
includes an actuator 414 coupled to the body 401 and operably coupled to the first  
and second pads 407, 408. The actuator 414 is configured to move (arrows 409,  
20 410) the first and second pads 407, 408 between the retracted and extended  
positions (e.g., the actuator 414 is configured to move the pads 407, 408 radially  
inward and outward). In the illustrated embodiment, the actuator 414 is also  
configured to slide (arrow 411) the first pad 407 toward and away from the second  
pad 408. As described in more detail below, moving the pads into the extended  
25 positions is configured to connect the first pad to the first portion of the guidewire and  
the second pad to the second portion of the guidewire, and moving the first pad  
toward and away from the second pad is configured to decrease and increase,  
respectively, the length of the gap G between the first and second portions 40, 50 of  
the outer shell 30 and thereby move the guidewire 10 between the flexible state and  
30 the rigid state.

**[0071]** In the illustrated embodiment, the actuator 414 includes a switch 415 and  
a button 416. Additionally, in the illustrated embodiment, the switch 415 is coupled to  
a cam 417, the first pad 407 is coupled to the cam 417 by a first linkage 418 (e.g., a  
first lever), and the second pad 408 is coupled to the cam 417 by a second linkage  
35 419 (e.g., a second lever). In one embodiment, a first end 420 of the first linkage 418  
is fixedly coupled to the first pad 407 and a second end 421 of the first linkage 418  
opposite the first end 420 is rotatably coupled to the cam 417 (e.g., by a hinge pin).  
Additionally, in the illustrated embodiment, a first end 422 of the second linkage 419

1 is fixedly coupled to the second pad 408 and a second end 423 of the second linkage 419 opposite the first end 422 is rotatably coupled to the cam 417 (e.g., by a hinge pin).

5 **[0072]** Depressing (arrow 424) the button 416 relative to the sidewall 403 is configured to move (arrows 409, 410) the first and second pads 407, 408 from the retracted position to the extended position. In the illustrated embodiment, depressing (arrow 424) the button 416 is configured to move the cam 417 toward the inner surface 413 of the sidewall 403, and the movement of the cam 417 is configured to move the first and second linkages 418, 419, which moves the first and second pads 10 407, 408, respectively, into the extended positions. In one or more embodiments, the button 416 may include a spring-loaded lock mechanism configured to retain the button 416 in the depressed position until the button 416 is pressed again, which returns the button 416 to the initial position.

15 **[0073]** Rotation (arrows 425, 426) of the switch 415 is configured to slide (arrow 411) the first pad 407 along the sidewall 403 toward and away from the second pad 408 (e.g., rotation of the switch 415 in the first direction 425 is configured to separate the first and second pads 407, 408 further from each other, and rotation of the switch 415 in the second direction 426 and draw the first and second pads 407, 408 closer to each other). In the illustrated embodiment, rotation of the switch 415 in the first direction (arrow 425) rotates the cam 417 in a first direction (arrow 427), which causes the first end 420 of the first linkage 418, and the first pad 407 coupled thereto, to move toward the distal end 404 of the sidewall 403 and thereby increase the distance between the first and second pads 407, 408 along the sidewall 403. In the illustrated embodiment, rotation of the switch 415 in the second direction (arrow 25 426) rotates the cam 417 in a second direction (arrow 428), which causes the first end 420 of the first linkage 418, and the first pad 407 coupled thereto, to move toward the proximal end 405 of the sidewall 403 and thereby decrease the distance between the first and second pads 407, 408 along the sidewall 403.

30 **[0074]** In one or more embodiments, the tensioning mechanism 400 may include a lock 433 configured to lock the switch 415 into the desired position. In the illustrated embodiment, the lock 433 is rotatably coupled to the body 401 of the tensioning mechanism 400 and the lock 433 is configured to rotate between a stowed position (shown in FIGS. 12A-12B) in which the lock 433 is not engaging the switch 415 and an engaged position (shown in FIG. 12C) in which the lock 433 engages the switch 415 to prevent rotation (arrows 425, 426) of the switch 415. In one or more embodiments, the lock 433 may have any other suitable configuration. Accordingly, in one or more embodiments, the switch 415 may be rotated (arrow 425 or 426) to achieve the desired amount of tension in, and the rigidity of, the guidewire 35

1 10 and then the lock 433 may be moved into the engaged position (e.g., activated) to  
lock the switch 415 into the set position to maintain the desired tension and rigidity in  
the guidewire 10. The lock 433 may be moved into the stowed position (e.g.,  
released) to adjust the tension in, and the rigidity of, the guidewire 10 (e.g., the lock  
5 433 may be released to allow the switch 415 to be rotated (arrow 426) to return the  
guidewire 10 to the flexible configuration).

**[0075]** Although in the illustrated embodiment the tensioning mechanism 400  
includes a single actuator 414 configured to both move (arrow 409, 410) the first and  
second pads 407, 408 into the extended position and slide (arrow 411) the first pad  
10 407 along the sidewall 403 toward and away from the second pad 408, in one or  
more embodiments, the tensioning mechanism 400 may include separate actuators  
for moving the first and second pads 407, 408 into the extended position and sliding  
the first pad 407 along the sidewall 403 toward and away from the second pad 408  
(e.g., the tensioning mechanism 400 may include a first actuator configured to move  
15 the first and second pads 407, 408 into the extended position and a second actuator  
configured to slide the first pad 407 along the sidewall 403 toward and away from the  
second pad 408).

**[0076]** In operation, a proximal end of the guidewire 10 may first be inserted into  
the central opening 402 in the tensioning mechanism 400. In one or more  
20 embodiments in which the central opening 402 is a blind bore, the guidewire 10 may  
be inserted into the central opening 402 until the proximalmost end of the guidewire  
10 contacts the end wall 406. Providing the end wall 406 on the tensioning  
mechanism 400 is configured to ensure proper alignment between the guidewire 10  
and the tensioning mechanism 400. In the illustrated embodiment, the depth of the  
25 central opening 402 is selected such that the first pad 407 at least partially overlaps  
(e.g., completely overlaps) the first portion 40 of the outer shell 30 of the guidewire  
10 and the second pad 408 at least partially overlaps (e.g., completely overlaps) the  
second portion 50 of the outer shell 30 of the guidewire 10 when the guidewire 10 is  
fully inserted into the central opening 402 in the tensioning mechanism 400 such that  
30 the proximalmost end of the guidewire 10 contacts the end wall 406. In one or more  
embodiments in which the central opening 402 in the tensioning mechanism 400 is a  
through hole, the guidewire 10 may be inserted into the central opening 402 until the  
first pad 407 overlaps with the first portion 40 of the outer shell 30 and the second  
pad 408 overlaps with the second portion 50 of the outer shell 30. In one or more  
35 embodiments, the outer shell 30 of the guidewire 10 may include visual indicia (e.g.,  
one or more markings) to aid in alignment between the guidewire 10 and the  
tensioning mechanism 400.

1 **[0077]** Once the guidewire 10 has been inserted into the central opening 402 of  
the tensioning mechanism 400, the tensioning mechanism 400 may be secured to  
the guidewire 10. In the illustrated embodiment, the tensioning mechanism 400 may  
be secured to the guidewire 10 by depressing (arrow 424) the button 416 of the  
5 actuator 414. As described above, depressing the button 416 of the actuator 414  
moves the first and second pads 407, 408 into the extended positions. In the  
illustrated embodiment, when the first and second pads 407, 408 are in the extended  
positions, an inner surface 429 of the first pad 407 engages an outer surface 42 of  
the first portion 40 of the outer shell 30 and an inner surface 430 of the second pad  
10 408 engages an outer surface 52 of the second portion 50 of the outer shell 30. The  
engagement between the inner surfaces 429, 430 of the first and second pads 407,  
408 and the outer surfaces 42, 52 of the first and second portions 40, 50 of the outer  
shell 30 are configured to secure the tensioning mechanism 400 to the guidewire 10.

**[0078]** In one or more embodiments, the inner surfaces 429, 430 of the first and  
15 second pads 407, 408 may include one or more friction-inducing features 431, 432,  
respectively, such as, for instance, projections (e.g., a knurled surface) and/or  
depressions (e.g., grooves, striations, and/or dimples). Additionally, in one or more  
embodiments, portions of the first and second portions 40, 50 of the outer shell 30  
that are configured to be engaged by the first and second pads 407, 408 may be  
20 solid (e.g., the portions of the first and second portions 40, 50 of the outer shell 30  
that are configured to be engaged by the first and second pads 407, 408 may be  
solid and remaining portions of first portion 40 and the second portion 50 may be a  
coil spring). Additionally, the outer surfaces 42, 52 of the first and second portions  
40, 50 of the outer shell 30 may include one or more friction-inducing features 43,  
25 53, respectively, such as, for instance, projections (e.g., a knurled surface) and/or  
depressions (e.g., grooves, striations, and/or dimples).

**[0079]** In the illustrated embodiment, when the first and second pads 407, 408  
are in the retracted positions shown in FIG. 12A, the inner surface 429 of the first  
pad 407 and the inner surface 430 of the second pad 408 each have a diameter  $D_1$   
30 that is greater than an outer diameter  $D$  of the outer shell 30 of the guidewire 10,  
which permits the guidewire 10 to be inserted into the central opening 402 of the  
tensioning mechanism 400. When the first and second pads 407, 408 are in the  
extended positions, the inner surface 429 of the first pad 407 and the inner surface  
430 of the second pad 408 each have a diameter  $D_2$  less than the diameter  $D_1$ . In  
35 one or more embodiments, the diameter  $D_2$  of the inner surfaces 429, 430 of the first  
and second pads 407, 408 when the first and second pads 407, 408 are in the  
extended position is equal to or less than the outer diameter  $D$  of the outer shell 30.  
Accordingly, in one or more embodiments, when the first and second pads 407, 408

1 are in the extended positions, the first and second pads 407, 408 engage the first and second portions 40, 50, respectively, of the outer shell 30 with an interference fit or a friction fit.

5 **[0080]** Once the tensioning mechanism 400 is secured to the guidewire 10 (e.g., by the first and second pads 407, 408 engaging the first and second portions 40, 50, respectively, of the outer shell 30), the tensioning mechanism 400 may be operated to move the guidewire 10 between the flexible state and the rigid (e.g., shape-locked) state. In the illustrated embodiment, the switch 415 may be rotated in the first direction (arrow 425) to move the guidewire 10 into the rigid state. As described  
10 above, rotating the switch 415 in the first direction (arrow 425) is configured to cause the first pad 407 to slide (arrow 411) along the sidewall 403 away from the second pad 408. This sliding movement of the first pad 407 moves the first portion 40 of the outer shell 30 away from the second portion 50 of the outer shell 30, due to the engagement between the inner surface 429 of the first pad 407 and the outer surface  
15 42 of the first portion 40 of the outer shell 30, thereby increasing the length of the gap G between the first and second portions 40, 50 and moving the guidewire 10 into the rigid state. To return the guidewire 10 to the flexible state, the switch 415 may be rotated in the second direction (arrow 426) opposite the first direction. In the illustrated embodiment, rotating the switch 415 in the second direction (arrow 426)  
20 causes the first pad 407 to slide (arrow 411) along the sidewall 403 toward the second pad 408, and this sliding movement of the first pad 407 moves the first portion 40 of the outer shell 30 toward the second portion 50 of the outer shell 30 and reduces the length of the gap G between the first and second portions 40, 50 thereby moving the guidewire 10 into the flexible state.

25 **[0081]** In one or more embodiments, the first and second pads 407, 408 may be configured to extend into the gap G between the first and second portions 40, 50 of the outer shell 30 to move the guidewire 10 between the flexible and rigid states, as illustrated, for instance, in the embodiment shown in FIGS. 12A-12C. To operate the tensioning mechanism 400 illustrated in FIGS. 12A-12C, a proximal end of the  
30 guidewire 10 may first be inserted into the central opening 402 in the tensioning mechanism 400 when the first and second pads 407, 408 are both in the retracted position. In the illustrated embodiment, when the first and second pads 407, 408 are in the retracted positions shown in FIG. 12A, the inner surface 429 of the first pad 407 and the inner surface 430 of the second pad 408 each have a diameter  $D_1$  that  
35 is greater than an outer diameter D of the outer shell 30 of the guidewire 10, which permits the guidewire 10 to be inserted into the central opening 402 of the tensioning mechanism 400. In one or more embodiments in which the central opening 402 is a blind bore, the guidewire 10 may be inserted into the central opening 402 until the

1 proximalmost end of the guidewire 10 contacts the end wall 406. Providing the end  
wall 406 on the tensioning mechanism 400 is configured to ensure proper alignment  
between the guidewire 10 and the tensioning mechanism 400. In the illustrated  
embodiment, the depth of the central opening 402 is selected such that the first pad  
5 407 and the second pad 408 are both aligned with the gap G between the first and  
second portions 40, 50 of the outer shell 30 when the guidewire 10 is fully inserted  
into the central opening 402 in the tensioning mechanism 400 such that the  
proximalmost end of the guidewire 10 contacts the end wall 406. In one or more  
embodiments in which the central opening 402 in the tensioning mechanism 400 is a  
10 through hole, the guidewire 10 may be inserted into the central opening 402 until the  
first pad 407 and the second pad 408 are both aligned with the gap G between the  
first and second portions 40, 50 of the outer shell 30. In one or more embodiments,  
the outer shell 30 of the guidewire 10 may include visual indicia (e.g., one or more  
markings) to aid in alignment between the guidewire 10 and the tensioning  
15 mechanism 400.

**[0082]** Once the guidewire 10 has been inserted into the central opening 402 of  
the tensioning mechanism 400, the button 416 of the actuator 414 may be  
depressed (arrow 424) to move (arrows 409, 410) the first and second pads 407,  
408 into the extended positions. In the embodiment illustrated in FIG. 12B, when the  
20 first and second pads 407, 408 are in the extended positions, the diameters  $D_2$  of the  
inner surfaces 429, 430 of the first and second pads 407, 408, respectively, are less  
than the outer diameter D of the outer shell 30, and the inner surfaces 429, 430 of  
the first and second pads 407, 408, respectively, extend into the gap G between the  
first and second portions 40, 50 of the outer shell 30. Accordingly, in the illustrated  
25 embodiment, when the first and second pads 407, 408 are in the extended positions,  
at least a portion of the first pad 407 overlaps in a radial direction with the first  
portion 40 of the outer shell 30 and at least a portion of the second pad 408 overlaps  
in a radial direction with the second portion 50 of the outer shell 30. In one or more  
embodiments, the first and second pads 407, 408 may partially extend into the gap  
30 G between the first and second portions 40, 50 of the outer shell 30 when the button  
416 is depressed (arrow 424) and the first and second pads 407, 408 are in the  
extended positions illustrated in FIG. 12B. In one or more embodiments, the first and  
second pads 407, 408 may completely or substantially completely extend into the  
gap G between the first and second portions 40, 50 of the outer shell 30 when the  
35 button 416 is depressed (arrow 424) and the first and second pads 407, 408 are in  
the extended positions.

**[0083]** Once the button 416 has been depressed (arrow 424) to move (arrows  
409, 410) the first and second pads 407, 408 into the extended positions extending

1 into the gap G between the first and second portions 40, 50 of the outer shell 30, the  
tensioning mechanism 400 may be operated to move the guidewire 10 between the  
flexible state and the rigid (e.g., shape-locked) state. In the embodiment illustrated in  
FIG. 12C, the switch 415 may be rotated in the first direction (arrow 425) to move the  
5 guidewire 10 into the rigid state. As described above, rotating the switch 415 in the  
first direction (arrow 425) is configured to cause the first pad 407 to slide (arrow 411)  
along the sidewall 403 away from the second pad 408. This sliding movement of the  
first pad 407 moves the first portion 40 of the outer shell 30 away from the second  
portion 50 of the outer shell 30 due to the engagement between the first pad 407 and  
10 the proximal end 41 of the first portion 40 of the outer shell 30, thereby increasing  
the length of the gap G between the first and second portions 40, 50 and moving the  
guidewire 10 into the rigid state. Additionally, in the illustrated embodiment, the  
second pad 408 engages the distal end 51 of the second portion 50 and thereby  
holds the second portion 50 in place as the first pad 407 engages the proximal end  
15 41 of the first portion 40 and moves the first portion 40 away from the second portion  
50 of the outer shell 30. To return the guidewire 10 to the flexible state, the switch  
415 may be rotated in the second direction (arrow 426) opposite the first direction. In  
the illustrated embodiment, rotating the switch 415 in the second direction (arrow  
426) causes the first pad 407 to slide (arrow 411) along the sidewall 403 toward the  
20 second pad 408, and this sliding movement of the first pad 407 permits the first  
portion 40 of the outer shell 30 to move toward the second portion 50 of the outer  
shell 30, thereby reducing the length of the gap G between the first and second  
portions 40, 50 and moving the guidewire 10 into the flexible state. In one or more  
embodiments, the first portion 40 may move toward the second portion 50 of the  
25 outer shell 30 due to the resiliency of the first portion 40 (e.g., the resiliency of the  
coil spring of the first portion 40 of the outer shell 30) as the first pad 407 slides  
(arrow 411) toward the second pad 408.

**[0084]** With reference now to FIGS. 13A-13B, a guidewire 510 according to  
another embodiment of the present disclosure includes a thin elongated structure  
30 520 (e.g., a wire or a monofilament) and an outer shell 530 surrounding the thin  
elongated structure 520. In the illustrated embodiment, the outer shell 530 includes a  
first portion 540 and a second portion 550. The first portion 540 and the second  
portion 550 of the outer shell 530 may have any suitable configuration. For instance,  
in one or more embodiments, at least a portion of the first portion 540 and at least a  
35 portion of the second portion 550 may each have a spiral wound configuration (e.g.,  
a coil spring). In one or more embodiments, at least a portion of the first portion 540  
and at least a portion of the second portion 550 may each be solid. In one or more  
embodiments, the first portion 540 and/or the second portion 550 include both a solid

1 portion and a spiral wound (e.g., coil spring) portion. In the illustrated embodiment, a  
portion (e.g., a tip portion) of the first portion 540 of the outer shell 530 is coupled  
(e.g., welded) to a portion (e.g., a tip portion) of the thin elongated structure 520.  
Additionally, in the illustrated embodiment, a portion of the second portion 550 of the  
5 outer shell 530 is coupled to a portion (e.g., a proximal portion) of the thin elongated  
structure 520. In the illustrated embodiment, a proximal end portion 521 of the thin  
elongated structure 520 extends through an opening 551 in the second portion 550  
of the outer shell 530, and the proximal end portion 521 of the thin elongated  
structure 520 includes an enlarged portion 522 (e.g., a flange) configured to prevent  
10 the thin elongated structure 520 from withdrawing from the opening 551 and  
disengaging the second portion 550 of the outer shell 530.

**[0085]** In the illustrated embodiment, an inner surface 552 of the second portion  
550 of the outer shell 530 includes threads 553, and an outer surface 523 of the thin  
elongated structure 520 includes screw threads 524 configured to threadedly engage  
15 the threads 553 in the second portion 550 of the outer shell 530. In one or more  
embodiments, the screw threads 524 may be provided only along a portion of the  
thin elongated structure 520 that is configured to be engaged by the threads 553 in  
the second portion 550 of the outer shell 530.

**[0086]** The guidewire 510 is configured to move between a flexible state (flexible  
20 configuration), illustrated in FIG. 12A, in which the guidewire 510 has lateral  
flexibility, and a rigid state (rigid configuration) (e.g., a shape-locked configuration),  
illustrated in FIG. 12B, in which the guidewire 510 has relatively less lateral flexibility.  
In the flexible state illustrated in FIG. 12A, a proximal end 541 of the first portion 540  
of the outer shell 530 is spaced apart from a distal end 554 of the second portion 550  
25 of the outer shell 530 by a gap G having a length  $l_1$ . In the rigid state illustrated in  
FIG. 12B, the gap G between the proximal end 541 of the first portion 540 of the  
outer shell 530 and the distal end 554 of the second portion 550 of the outer shell  
530 has a length  $l_2$  greater than the length  $l_1$  of the gap G when the guidewire 510 is  
in the flexible state. In one or more embodiments, the length  $l_1$  of the gap G when the  
30 guidewire 510 is in the flexible configuration may be zero or substantially zero. In  
one or more embodiments, the length  $l_2$  of the gap G when the guidewire 510 is in  
the rigid configuration may be at least approximately 0.5 cm. In one or more  
embodiments, the length  $l_2$  of the gap G when the guidewire 510 is in the rigid  
configuration may be at least approximately 1 cm.

**[0087]** In one embodiment, the guidewire 510 may be moved from the flexible  
35 configuration to the rigid configuration by rotating, relative to the thin elongated  
structure 520, the second portion 550 of the outer shell 530 in a first direction (arrow  
555) (e.g., counterclockwise). In the illustrated embodiment, the passage of the

1 proximal end 521 of the thin elongated structure 520 through the opening 551 in the  
second portion 550 is configured to prevent the rotation of the second portion 550  
from twisting the thin elongated structure 520 (e.g., rotation of the second portion  
550 of the outer shell 530 is not imparted to the thin elongated structure 520). As the  
5 second portion 550 of the outer shell 530 is rotated (arrow 555) relative to the thin  
elongated structure 520, the engagement between the screw threads 524 on the thin  
elongated structure 520 and the threads 553 of the second portion 550 causes the  
second portion 550 to move (arrow 556) away from the first portion 540 of the outer  
shell 530 such that the gap G between the first and second portions 540, 550  
10 increases. As the second portion 550 moves away from the first portion 540 of the  
outer shell 530, the first portion 540, which is coupled to the thin elongated structure  
520, pulls on the thin elongated structure 520 and thereby applies tension to the thin  
elongated structure 520. The tension applied to the thin elongated structure 520 by  
the first portion 540 of the outer shell 530 maintains the guidewire 510 in the rigid  
15 configuration.

**[0088]** To return the guidewire to the flexible configuration, the second portion  
550 of the outer shell 530 may be rotated, relative to the thin elongated structure  
520, in a second direction (arrow 557) (e.g., clockwise) opposite to the first direction  
(arrow 555). As the second portion of the outer shell is rotated (arrow 557) relative to  
20 the thin elongated structure 520, the engagement between the screw threads 524  
and the threads 553 causes the second portion 550 of the outer shell 530 to move  
(arrow 558) toward the first portion 540 of the outer shell 530. As the second portion  
550 of the outer shell 530 moves (arrow 558) toward the first portion 540 of the outer  
shell 530, the length of the gap G between the first and second portions 540, 550  
25 decreases and the thin elongated structure 520 relaxes (e.g., the tension supplied to  
the thin elongated structure 520 by the first portion 540 of the outer shell 530 is  
reduced), which returns the guidewire 510 to the flexible configuration. Accordingly,  
the guidewire 510 according to one embodiment of the present disclosure may be  
moved between the flexible configuration and the rigid configuration by rotating  
30 (arrow 555, 556) the second portion 550 of the outer shell 530 to move the second  
portion 550 away from and toward, respectively, the first portion 540 of the outer  
shell 530 to increase and decrease, respectively, the length of the gap G between  
the first and second portions 540, 550 of the outer shell 530.

**[0089]** Additionally, in one or more embodiments, a tensioning mechanism 560  
35 may be provided to aid in rotation (arrows 555, 557) of the second portion 550 of the  
outer shell 530 to move the guidewire 510 between the flexible and rigid  
configurations. In the illustrated embodiment, the tensioning mechanism 560 is  
provided on an outer surface 559 of the second portion 550 to increase the effective

1 outer diameter of the second portion 550, which facilitates a user ergonomically grasping the tensioning mechanism 560 (e.g., between the user's thumb and forefinger) and rotating the tensioning mechanism 560 to rotate (arrows 555, 557) the second portion 550 of the outer shell 530 in the desired direction to achieve the  
5 desired tension or flexibility in the guidewire 510. In one or more embodiments, the tensioning mechanism 560 may be a thumbwheel that engages the outer surface 559 of the second portion 550. In one or more embodiments, the tensioning mechanism 560 may be any other suitable device configured to aid in rotation (arrows 555, 557) of the second portion 550 of the outer shell 530 (e.g., the  
10 tensioning mechanism 560 may be any other device fit over the outer surface 559 of the second portion 550 of the outer shell 530).

**[0090]** In one or more embodiments, the guidewire 510 may include one or more stops configured to maintain a minimum length of the gap G between the first portion 540 and the second portion 550 of the outer shell 530. The configuration of the one  
15 or more stops may be the same as or similar to the configuration of the inner and outer stops 60, 80 illustrated in FIG. 1A. In one or more embodiments, the configuration of the one or more stops may be the same as or similar to the configuration of the inner stop 60 illustrated in FIG. 1B.

**[0091]** With reference now to FIGS. 14A-14B, a guidewire 610 according to  
20 another embodiment of the present disclosure includes a thin elongated structure 620 (e.g., a wire or a monofilament) and an outer shell 630 surrounding a portion of the thin elongated structure 620. In the illustrated embodiment, the outer shell 630 includes a single portion (e.g., the outer shell 630 is monolithic), although in one or more embodiments outer shell 630 may include two or more separate portions (e.g.,  
25 two portions separated by a gap). The outer shell 630 may have any suitable configuration. For instance, in one or more embodiments, at least a portion of the outer shell 630 may have a spiral wound configuration (e.g., at least a portion of the outer shell 630 may be a coil spring). In one or more embodiments, at least a portion of the outer shell 630 may be solid. In one or more embodiments, the outer shell 630  
30 may include both a solid portion and a spiral wound (e.g., coil spring) portion. In the illustrated embodiment, a portion (e.g., a tip portion) of the outer shell 630 is coupled (e.g., welded) to a portion (e.g., a tip portion) of the thin elongated structure 620.

**[0092]** In the illustrated embodiment, the guidewire 610 also includes an outer stop 660 extending outward (e.g., radially outward) from an outer surface 621 of the  
35 thin elongated structure 620. In one or more embodiments, the outer stop 660 may be integrally formed with the thin elongated structure 620 or the outer stop 660 may be formed separately from the elongated structure 620 and coupled to the thin elongated structure 620 by any suitable process, such as welding. In the illustrated

1 embodiment, the outer stop 660 is an annular member (e.g., a ring) extending  
circumferentially around the thin elongated structure 620. In one or more  
embodiments, the outer stop 660 may not be an annular member (e.g., the outer  
stop 660 may include a series of protrusions arranged around the circumference of  
5 the thin elongated structure 620). Additionally, in the illustrated embodiment, the  
outer stop 660 is provided on a proximal end portion 622 of the thin elongated  
structure 620 that is exposed outside (e.g., not surrounded by) the outer shell 630.

**[0093]** In the illustrated embodiment, a proximal end 631 of the outer shell 630  
includes an inwardly-extending flange 632 (e.g., an inwardly-turned flange 632  
10 extending inward toward the thin elongated structure 620) configured to engage the  
outer stop 660 on the thin elongated structure 620. The engagement between the  
outer stop 660 and the inwardly-extending flange 632 is configured to prevent the  
outer shell 630 from completely covering the thin elongated structure 620, which  
might otherwise occur, for example, due to the resiliency of the coil spring of the outer  
15 shell 630 (e.g., the engagement between the outer stop 660 and the inwardly-  
extending flange 632 is configured to maintain the proximal end portion 622 of the  
thin elongated structure 620 exposed outside of the outer shell 630).

**[0094]** Additionally, in the illustrated embodiment, an outer surface 661 of the  
outer stop 660 is recessed below an outer surface 633 of the outer shell 630. In one  
20 or more embodiments, recessing the outer surface 661 of the outer stop 660 below  
the outer surface 633 of the outer shell 630 is configured to enable a tensioning  
mechanism 700, described in detail below, to engage the proximal end 631 of the  
outer shell 630 to move the guidewire 610 between a flexible configuration, shown in  
FIG. 14A, and a rigid configuration, shown in FIG. 14B.

**[0095]** In the illustrated embodiment, the outer surface 621 of the thin elongated  
structure 620 includes screw threads 623. In one or more embodiments, the screw  
threads 623 may be provided only along the proximal end portion 622 (or a portion  
thereof) of the thin elongated structure 620. As described in more detail below, the  
screw threads 623 on the thin elongated structure 620 are configured to be  
30 threadedly engaged by the tensioning mechanism 700 to move the guidewire 610  
between the flexible and rigid configurations.

**[0096]** With continued reference to the embodiment illustrated in FIGS. 14A-14B,  
the tensioning mechanism 700 includes a body portion 701 having a distal end 702  
and a proximal end 703, and a flange portion 704 extending distally from the distal  
35 end 702 of the body portion 701. In one or more embodiments, the body portion 701  
and the flange portion 704 are both annular members. Additionally, in the illustrated  
embodiment, the flange portion 704 includes a proximal end 705 connected to the  
distal end 702 of the body portion 701 and a free, distal end 706 opposite to the

1 proximal end 705. In the illustrated embodiment, the body portion 701 of the  
tensioning mechanism 700 has a central opening 707 (e.g., a hole) and an inner  
surface 708 of the central opening 707 defines threads 709 configured to engage the  
screw threads 623 on the thin elongated structure 620. In the illustrated embodiment,  
5 the central opening 707 is a through hole extending completely through the body  
portion 701 (e.g., the central opening 707 extends from the distal end 702 to the  
proximal end 703 of the body portion 701).

**[0097]** In the illustrated embodiment, the size of an inner surface 710 of the  
flange portion 704 in transverse cross-section is larger than the size of the inner  
10 surface 708 of the central opening 707 in transverse cross-section (e.g., an inner  
diameter of the flange portion 704 is larger than an inner diameter of the central  
opening 707). Additionally, in the illustrated embodiment, the tensioning mechanism  
700 includes a taper 711 (e.g., a draft or a chamfer) extending from the inner surface  
710 of the flange portion 704 to the inner surface 708 of the central opening 707.  
15 The taper 711 tapers from a relatively wider end 712 at a proximal end 713 of the  
inner surface 710 of the flange portion 704 to a relatively narrower end 714 at a  
distal end 715 of the inner surface 708 of the central opening 707. The taper 711 is  
configured to aid in guiding the tensioning mechanism 700 onto the proximal end  
portion 622 of the thin elongated structure 620 (e.g., the taper 711 is configured to  
20 guide the proximal end portion 622 of thin elongated structure 620 into the central  
opening 707 in the body portion 701 as the tensioning mechanism 700 is attached to  
the proximal end portion 622 of the thin elongated structure 620). In one or more  
embodiments, the tensioning mechanism 700 may be provided without the taper 711  
(e.g., the tensioning mechanism 711 may include a step between the inner surface  
25 708 of the flange portion 704 and the inner surface 708 of the central opening 707).

**[0098]** The inner surface 710 of the flange portion 704 may have any suitable  
length L depending, for instance, on the distance the tensioning mechanism 700 is  
configured to pull the thin elongated structure 620 proximally relative to the outer  
shell 630 to move the guidewire 610 into the rigid configuration. In the illustrated  
30 embodiment, the length L of the inner surface 710 of the flange portion 704 is longer  
than the length I of the outer surface 661 of the outer stop 660 in a longitudinal  
direction of the thin elongated structure 620. In one or more embodiments, the  
tensioning mechanism 700 is configured to pull the thin elongated structure 620  
proximally relative to the outer shell 630 up to a distance equal to the difference  
35 between the length L of the inner surface 710 of the flange portion 704 and the  
length I of the outer surface 661 of the outer stop 660. For instance, in one or more  
embodiments, the length L of the inner surface 710 of the flange portion 704 may be  
longer than length I of the outer surface 661 of the outer stop 660 by at least 0.5 cm

1 or approximately 0.5 cm. In one or more embodiments, the length L of the inner surface 710 of the flange portion 704 may be longer than length I of the outer surface 661 of the outer stop 660 by at least 1 cm or approximately 1 cm (e.g., in a range from 1 cm or approximately 1 cm to 2 cm or approximately 2 cm).

5 **[0099]** In the illustrated embodiment, an outer surface 722 of the tensioning mechanism 700 includes one or more friction-inducing features 723, such as, for instance, projections (e.g., a knurled surface) and/or depressions (e.g., grooves, striations, and/or dimples) configured to aid a user in grasping the tensioning mechanism 700 and rotating the tensioning mechanism 700 to move the guidewire 610 between the rigid and flexible states, as described in more detail below. Additionally, in the illustrated embodiment, the outer surface 722 of the tensioning mechanism 700 is larger in transverse cross-section than the outer surface 633 of the outer shell 630 in transverse cross-section (e.g., the outer diameter of the tensioning mechanism 700 is larger than the outer diameter of the outer shell 630), which is configured to aid a user in ergonomically grasping the tensioning mechanism 700 and rotating the tensioning mechanism 700 to move the guidewire 610 between the rigid and flexible states. In one or more embodiments, the outer surface 722 of the tensioning mechanism 700 may have any other suitable size relative to the outer surface 633 of the outer shell 630 (e.g., the outer diameter of the tensioning mechanism 700 may be the same or substantially the same as the outer diameter of the outer shell 630).

15 **[00100]** In the illustrated embodiment, the guidewire 610 also includes a device 634 connected to the outer shell 630 to aid the user in grasping the guidewire 610 during rotation of the tensioning mechanism 700 to move the guidewire 610 between the rigid and flexible states, as described in more detail below. In one or more embodiments, an outer surface 635 of the device 634 includes one or more friction-inducing features 636, such as, for instance, projections (e.g., a knurled surface) and/or depressions (e.g., grooves, striations, and/or dimples). In the illustrated embodiment, the device 634 is provided on the outer shell 630 proximate to the proximal end 631 of the outer shell 630, although in one or more embodiments, the device 634 may be provided at any other suitable location along the length of the outer shell 630. In one or more embodiments, the device 634 may be an annular member (e.g., a donut-shaped device or a slotted ring) fit around the outer surface 633 of the outer shell 630. In one or more embodiments, at least the portion of the outer shell 630 along which the device 634 is provided is solid. Additionally, in one or more embodiments, the outer shell 630 may be configured to prevent the device 634 from rotating (e.g., slipping) relative to the outer shell 630. For instance, in one or more embodiments, the portion of the outer shell 630 along which the device 634 is

1 provided may be non-circular (e.g., the portion of the outer shell 630 at which the  
device is provided may have a square transverse cross-section shape) and an inner  
surface of the device 634 engaging the outer shell 630 may have a mating (e.g.,  
corresponding) configuration (e.g., a square transverse cross-sectional shape). In  
5 the illustrated embodiment, the portion of the outer shell 630 along which the device  
634 is provided may include one or more flat surfaces 637 engaging one or more  
corresponding flat surfaces 638 on the device 634. The device 634 may be made out  
of any suitable material.

**[00101]** In operation, the tensioning mechanism 700 may first be connected to the  
10 guidewire 610. In the illustrated embodiment, the tensioning mechanism 700 may be  
connected to the guidewire 610 by inserting the proximal end portion 622 of the thin  
elongated structure 620 into the central opening 707 in the body portion 701 of the  
tensioning mechanism 700 and threading the threads 709 of the tensioning  
mechanism 700 onto the screw threads 623 of the thin elongated structure 620. In  
15 one or more embodiments, the taper 711 of the tensioning mechanism 700 aids in  
guiding the proximal end portion 622 of the thin elongated structure 620 into the  
central opening 707 of the tensioning mechanism 700.

**[00102]** Once the tensioning mechanism 700 is connected to the guidewire 610,  
the tensioning mechanism 700 may be operated to move the guidewire 610 between  
20 the flexible and rigid configurations. In one embodiment, the guidewire 610 may be  
moved from the flexible configuration to the rigid configuration by rotating, relative to  
the thin elongated structure 620, the tensioning mechanism 700 in a first direction  
(arrow 716) (e.g., clockwise). In one embodiment, the tensioning mechanism 700  
may be rotated by grasping the guidewire 610 (e.g., the device 634) with one hand  
25 (e.g., grasping the guidewire 610, such as the device 63, between the thumb and  
index finger of the user's left hand) and grasping the tensioning mechanism 700 with  
the user's other hand (e.g., grasping the tensioning mechanism 700 between the  
thumb and index finger of the user's right hand). As the tensioning mechanism 700 is  
rotated (arrow 716) relative to the thin elongated structure 620, the engagement  
30 between the threads 709 in the central opening 707 of the tensioning mechanism  
700 and the screw threads 623 on the outer surface 621 of the thin elongated  
structure 620 moves (arrow 717) the tensioning mechanism 700 distally toward the  
proximal end 631 of the outer shell 630 (e.g., as the tensioning mechanism 700 is  
rotated (arrow 716), the engagement between the threads 709, 623 moves (arrow  
35 717) the tensioning mechanism 700 distally along the thin elongated structure 620).  
Additionally, as the tensioning mechanism 700 is rotated (arrow 716) further, the  
flange portion 704 of the tensioning mechanism 700 passes over the outer stop 660  
and an abutment surface 718 at the distal end 706 of the flange portion 704 engages

1 (e.g., contacts) the proximal end 631 of the outer shell 630 (e.g., the inwardly-  
extending flange 632). In the illustrated embodiment, the inner surface of the 710 of  
the flange portion 704 of the tensioning mechanism 700 is larger in transverse cross-  
section than the outer surface 661 of the outer stop 660 in transverse cross-section  
5 (e.g., the inner diameter of the flange portion 704 of the tensioning mechanism 700  
is larger than the outer diameter of the outer stop 660). Accordingly, in the illustrated  
embodiment, a recess 719 (e.g., a cavity) is defined between the inner surface 710  
of the flange portion 704, the outer surface 621 of the thin elongated structure 620,  
and the outer surface 661 of the outer stop 660, which accommodates the outer stop  
10 660 on the thin elongated structure 620 and allows the flange portion 704 to pass  
over the outer stop 660 and contact the proximal end 631 of the outer shell 630.

**[00103]** Continued rotation (arrow 716) of the tensioning mechanism 700 after the  
abutment surface 718 of the tensioning mechanism 700 engages the proximal end  
631 of the outer shell 630 pulls (arrow 624) the thin elongated structure 620  
15 proximally relative to the outer shell 630 such that a greater extent of the proximal  
end portion 622 of the thin elongated structure 620 extends through the central  
opening 707 in the tensioning mechanism 700. Pulling (arrow 624) the thin elongated  
structure 620 proximally applies tension to the thin elongated structure 620 because  
the thin elongated structure 620 is coupled to the outer shell 630 (e.g., at the distal  
20 tip). As the thin elongated structure 620 moves proximally (arrow 624) relative to the  
outer shell 630, the thin elongated structure 620, which is coupled to the outer shell  
630 (e.g., at the distal tip), pulls proximally on the outer shell 630 and thereby  
compresses the outer shell 630. The compression applied to the outer shell 630 by  
the thin elongated structure 620 and the tension applied to the thin elongated  
25 structure 620 by the tensioning mechanism 700 maintains the guidewire 610 in the  
rigid configuration.

**[00104]** To return the guidewire to the flexible configuration, the tensioning  
mechanism 700 may be rotated, relative to the thin elongated structure 620, in a  
second direction (arrow 720) (e.g., counterclockwise) opposite to the first direction  
30 (arrow 716), as illustrated in FIG. 14B. As the tensioning mechanism 700 is rotated  
(arrow 720) relative to the thin elongated structure 620, the engagement between the  
screw threads 623 and the threads 709 causes the tensioning mechanism 700 to  
move (arrow 721) proximally away from the proximal end 631 of the outer shell 630.  
As the tensioning mechanism 700 moves (arrow 721) proximally relative to the outer  
35 shell 530, the thin elongated structure 620 moves distally (arrow 625) relative to the  
outer shell 630 such that a lesser extent of the proximal end portion 622 of the thin  
elongated structure 620 extends through the central opening 707 in the tensioning  
mechanism 700, which reduces the tension in the thin elongated structure 620 (e.g.,

1 relaxes the thin elongated structure 620) and thereby returns the guidewire 610 to  
the flexible configuration. Accordingly, the guidewire 610 according to one  
embodiment of the present disclosure may be moved between the flexible  
configuration and the rigid configuration by rotating (arrow 716, 720) the tensioning  
5 mechanism 700 to move the thin elongated structure 620 proximally and distally  
(arrows 624, 625) relative to the outer shell 630.

**[00105]** While certain embodiments of the present invention have been illustrated  
and described, it is understood by those of ordinary skill in the art that certain  
modifications and changes can be made to the described embodiments without  
10 departing from the spirit and scope of the present invention as defined by the  
following claims, and equivalents thereof. Although relative terms such as "outer,"  
"inner," "upper," "lower," and similar terms have been used herein to describe a  
spatial relationship of one element to another, it is understood that these terms are  
intended to encompass different orientations of the various elements and  
15 components of the invention in addition to the orientation depicted in the figures.  
Additionally, as used herein, the term "substantially," "about," and similar terms are  
used as terms of approximation and not as terms of degree, and are intended to  
account for the inherent deviations in measured or calculated values that would be  
recognized by those of ordinary skill in the art. Moreover, the tasks described above  
20 may be performed in the order described or in any other suitable sequence.  
Additionally, the methods described above are not limited to the tasks described.  
Instead, for each embodiment, one or more of the tasks described above may be  
absent and/or additional tasks may be performed. Furthermore, as used herein,  
when a component is referred to as being "on" another component, it can be directly  
25 on the other component or components may also be present therebetween.  
Moreover, when a component is referred to as being "coupled" to  
another component, it can be directly attached to the other component or intervening  
components may be present therebetween.

**[00106]** Furthermore, although discussed with specific reference to guidewires, the  
30 invention may be applicable to other medical devices having a need for a distal  
portion with characteristic of lateral flexibility. For example, the present invention may  
be applicable for use in intravascular catheters (e.g., rapid exchange balloon  
catheters, stent delivery catheters, etc.) or intravascular rotational devices  
(atherectomy catheters, IVUS catheters, etc.).

1 WHAT IS CLAIMED IS:

1. A guidewire comprising:

a thin elongated structure; and

5 an outer shell around at least a portion of the thin elongated structure, the outer shell comprising a first portion and a second portion, the first portion and the second portion each being coupled to the thin elongated structure,

wherein the first portion is spaced from the second portion by a gap,

10 wherein the guidewire is configured to move between a flexible state and a rigid state,

wherein the gap has a first distance when the guidewire is in the flexible state, and

15 wherein the gap has a second distance greater than the first distance when the guidewire is in the rigid state.

2. The guidewire of claim 1, wherein the first distance is substantially zero.

3. The guidewire of claim 2, wherein the second distance is at least approximately 1 cm.

25 4. The guidewire of claim 1, further comprising an outer stop coupled to the thin elongated structure.

30 5. The guidewire of claim 4, further comprising an inner stop coupled to the first portion of the outer shell, wherein the inner stop is configured to engage the outer stop when the guidewire is in the flexible state to maintain a minimum distance of the gap between the first portion and the second portion of the outer shell.

35 6. The guidewire of claim 4, wherein the outer stop extends into the gap between the first portion and the second portion of the outer shell, and wherein the outer stop is configured to engage a proximal end of the first portion of the outer

1 shell when the guidewire is in the flexible state to maintain a minimum distance of  
the gap between the first portion and the second portion of the outer shell.

5 7. The guidewire of claim 1, wherein the outer shell comprises a spring.

8. The guidewire of claim 1, wherein the thin elongated structure  
comprises a wire or a cable.

10 9. A system comprising:

a guidewire comprising:

a thin elongated structure; and

15 an outer shell around a first portion of the thin elongated  
structure, wherein a second portion of the thin elongated structure is exposed  
outside the thin elongated structure; and

a tensioning mechanism configured to engage the second portion of  
the thin elongated structure to move the guidewire between a flexible state and a  
20 rigid state.

10. The system of claim 9, wherein the tensioning mechanism comprises:

25 a body portion defining a central opening, the central opening having  
threads; and

a flange portion extending from the body portion.

11. The system of claim 10, wherein:

30 the thin elongated structure further comprises screw threads along at  
least a portion of the second portion, and

the threads in the central opening of the tensioning mechanism are  
configured to threadedly engage the screw threads of the thin elongated structure.

35 12. The system of claim 11, wherein rotating the tensioning mechanism in  
a first direction moves the guidewire from the flexible state to the rigid state, and

1 wherein rotating the tensioning mechanism in a second direction opposite the first  
direction moves the guidewire from the rigid state to the flexible state.

5 13. The system of claim 12, further comprising:  
an inwardly-extending flange at a proximal end of the outer shell; and  
an outer stop on the second portion of the thin elongated structure  
configured to engage the inwardly-extending flange when the guidewire is in the  
flexible state.

10 14. The system of claim 13, wherein a length of an inner surface of the  
flange portion is longer than a length of an outer surface of the outer stop.

15 15. The system of claim 14, wherein an inner diameter of the flange portion  
is larger than an inner diameter of central opening.

20 16. The system of claim 15, wherein the tensioning mechanism further  
comprises a taper extending between the inner surface of the flange portion and an  
inner surface of the central opening.

25 17. A method of operating a guidewire comprising a thin elongated  
structure and an outer shell around at least a portion of the thin elongated structure,  
the method comprising:  
moving the guidewire from a flexible state to a rigid state by pulling the thin  
elongated structure proximally.

30 18. The method of claim 17, wherein the outer shell of the guidewire  
comprises a first portion and a second portion each coupled to the thin elongated  
structure, and wherein the moving the guidewire from the flexible state to the rigid  
state comprises increasing a length of a gap between the first portion of the outer  
35 shell and the second portion of the outer shell.

19. The method of claim 17, wherein a second portion of the thin elongated  
structure is exposed outside of the outer shell, and wherein the moving the guidewire

1 from the flexible state to the rigid state comprises threading a tensioning mechanism  
onto the second portion of the thin elongated structure.

20. The method of claim 19, wherein the tensioning mechanism comprises  
5 a body portion and a flange portion extending distally from the body portion, and  
wherein the flange portion engages a proximal end of the outer shell during the  
moving the guidewire from the flexible state to the rigid state.

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FIG. 1A

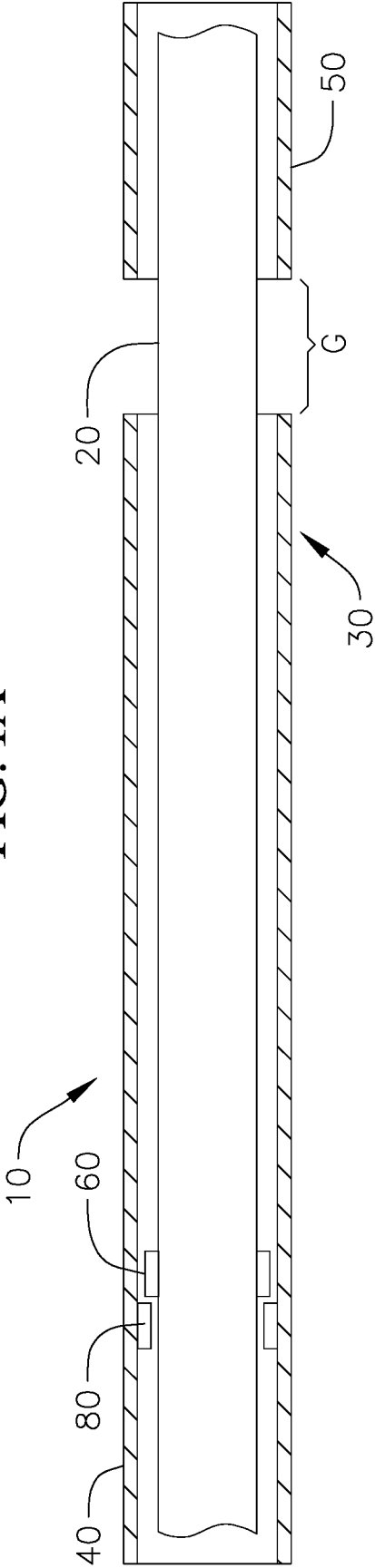


FIG. 1B

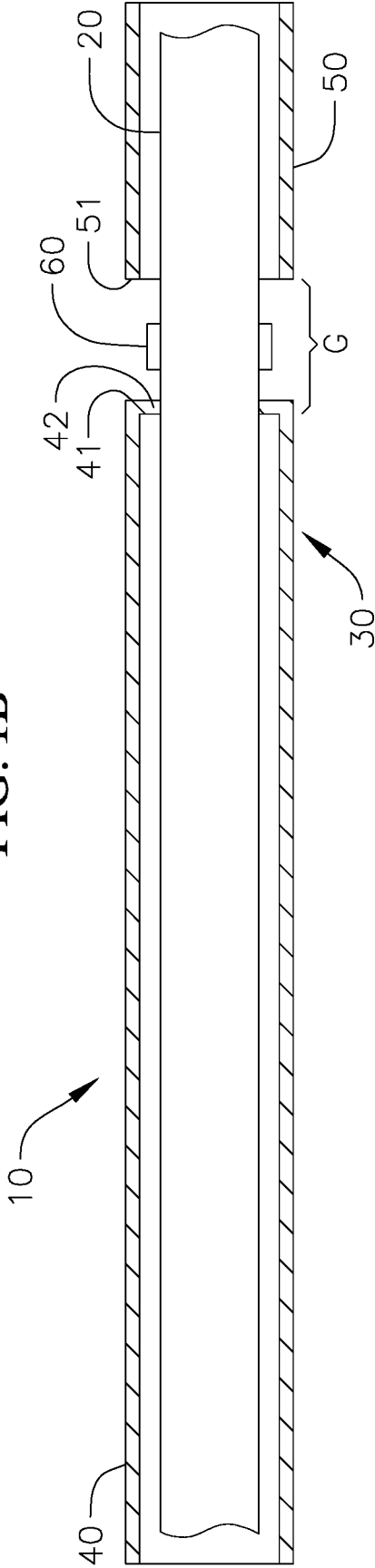


FIG. 2

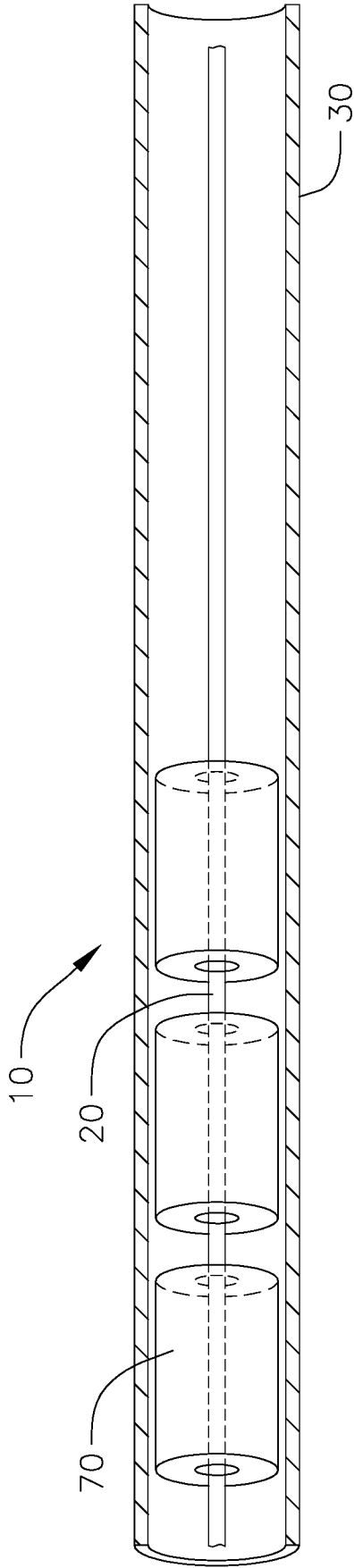


FIG. 4

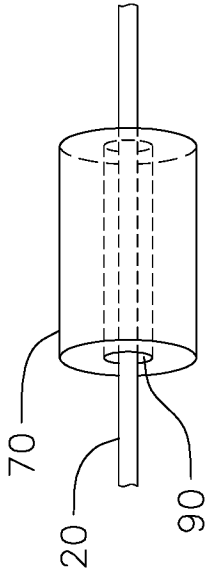
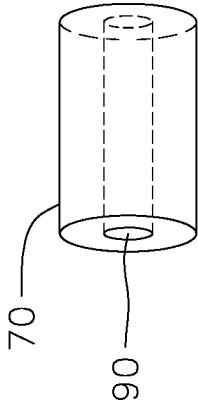
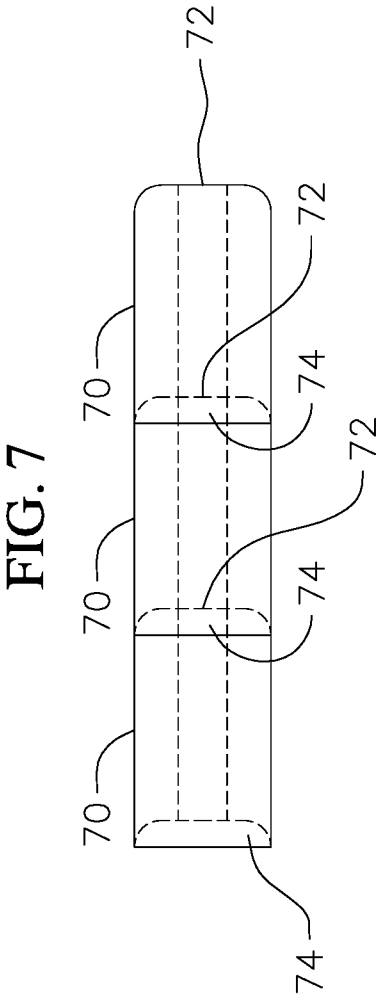
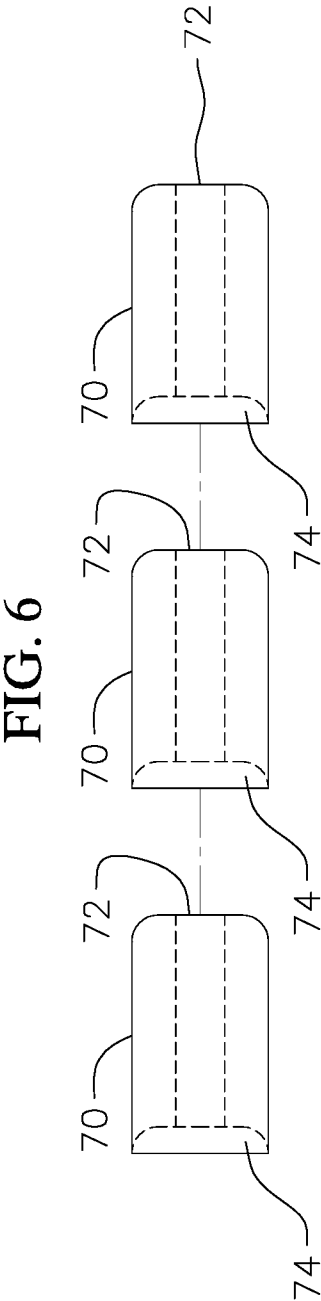
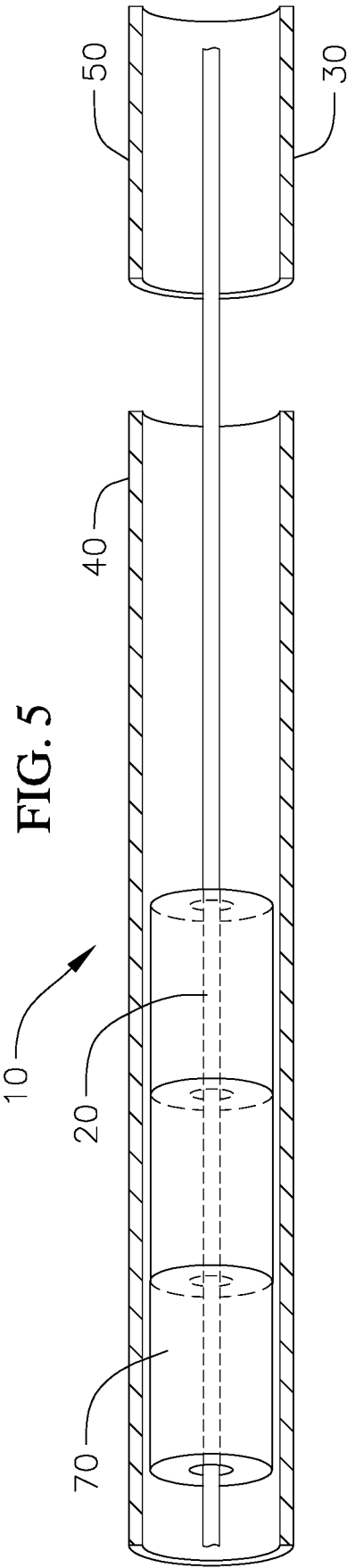
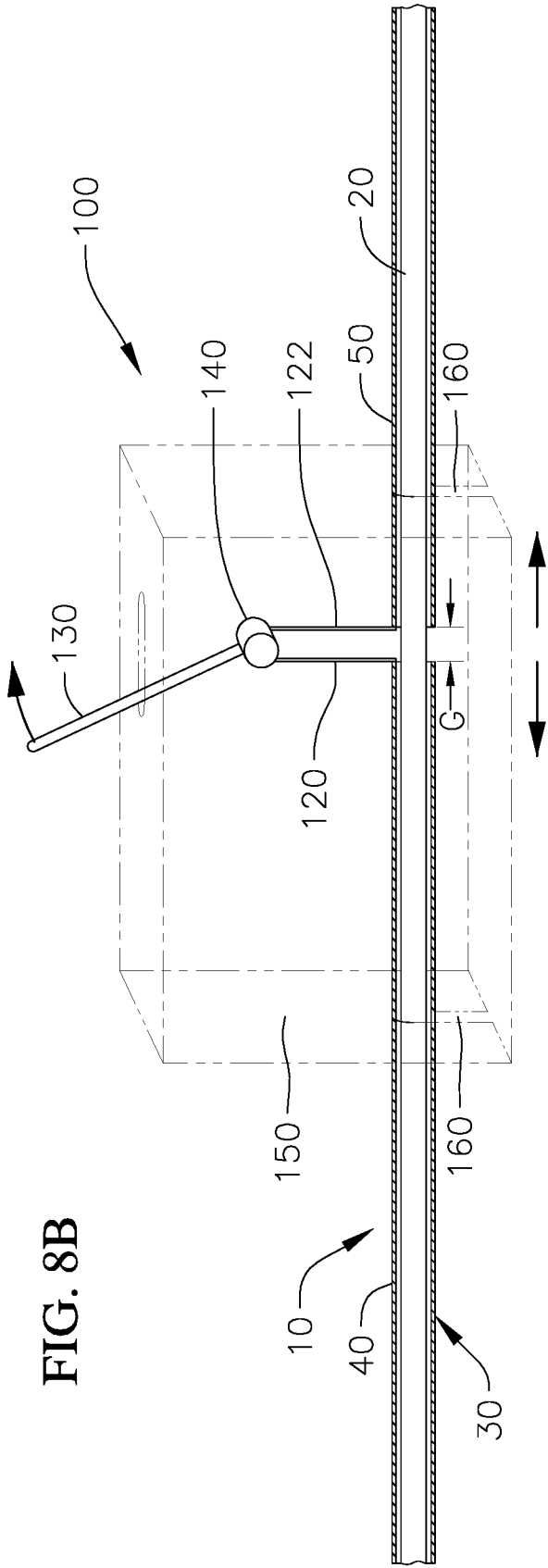
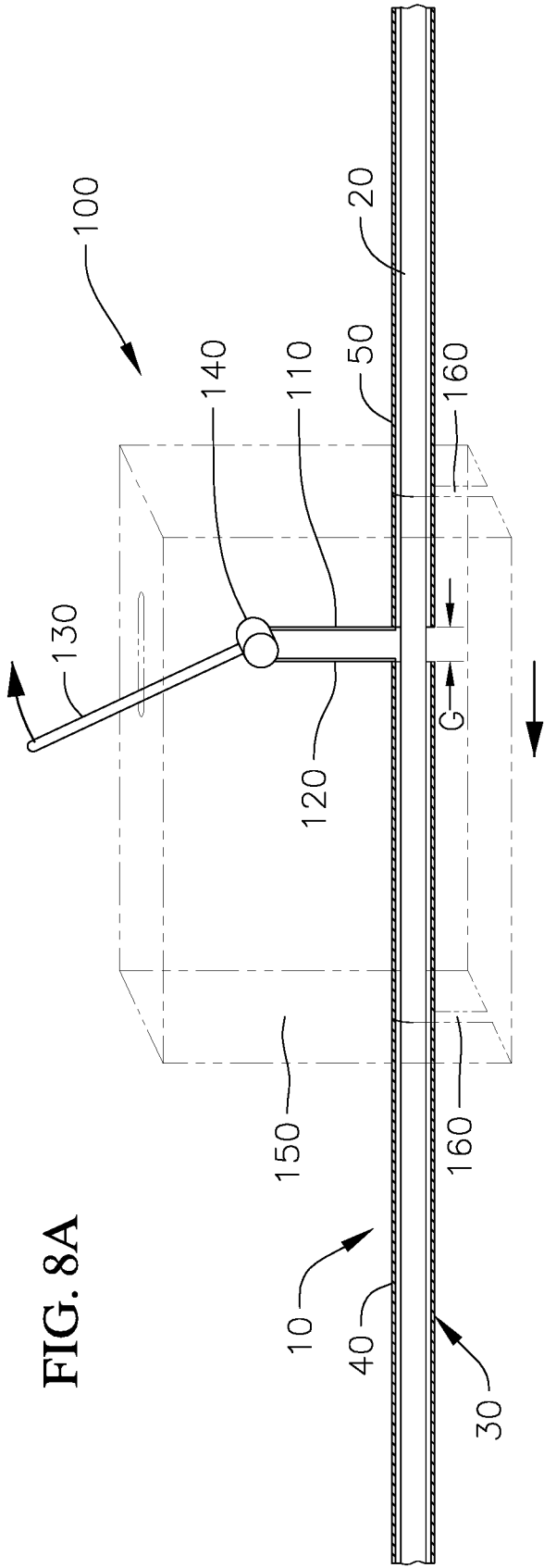


FIG. 3







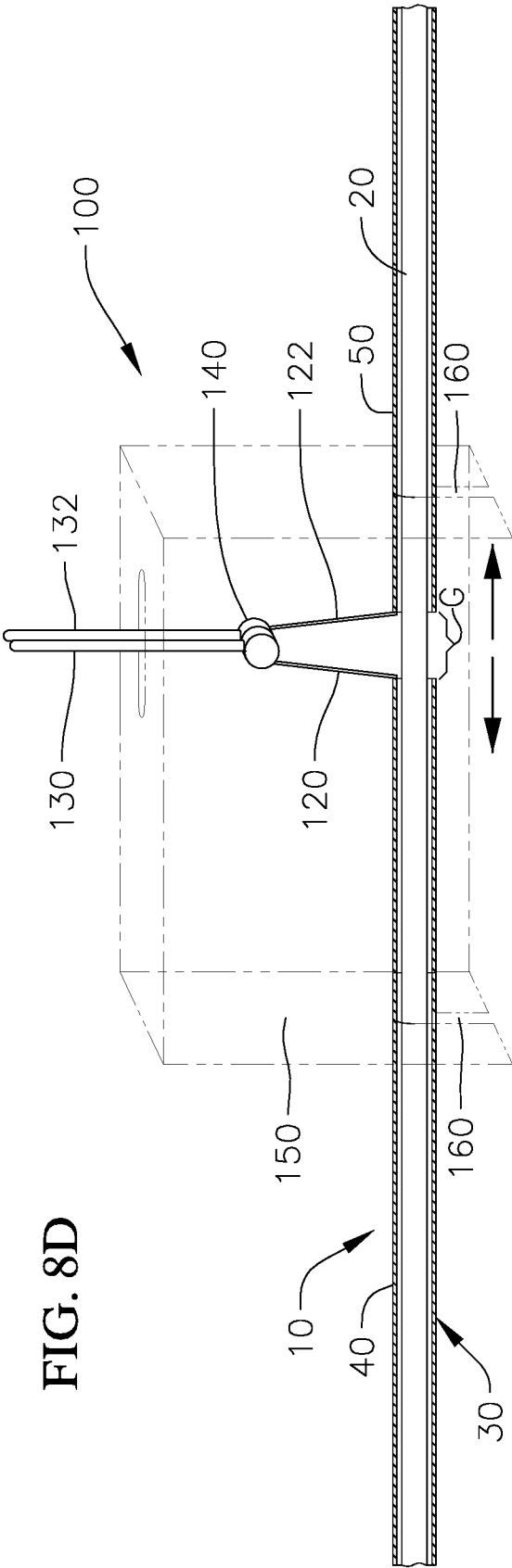
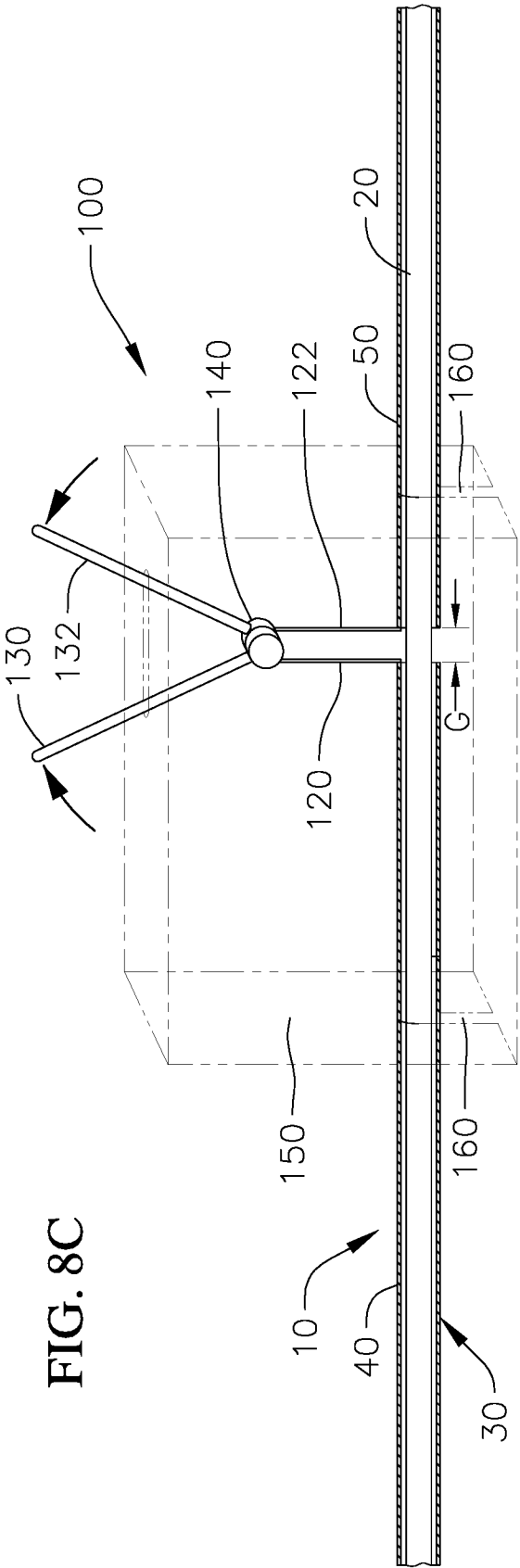


FIG. 9

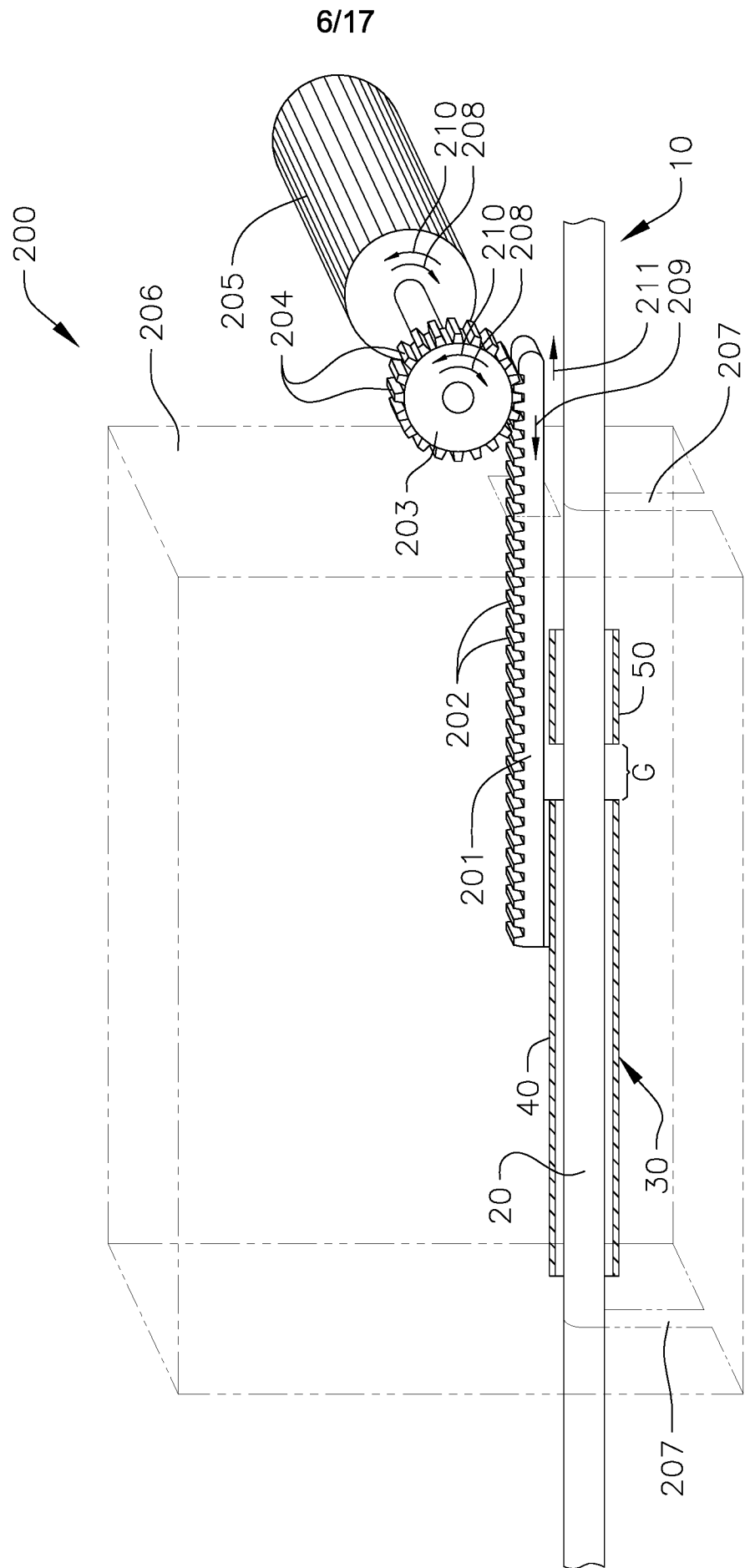


FIG. 10

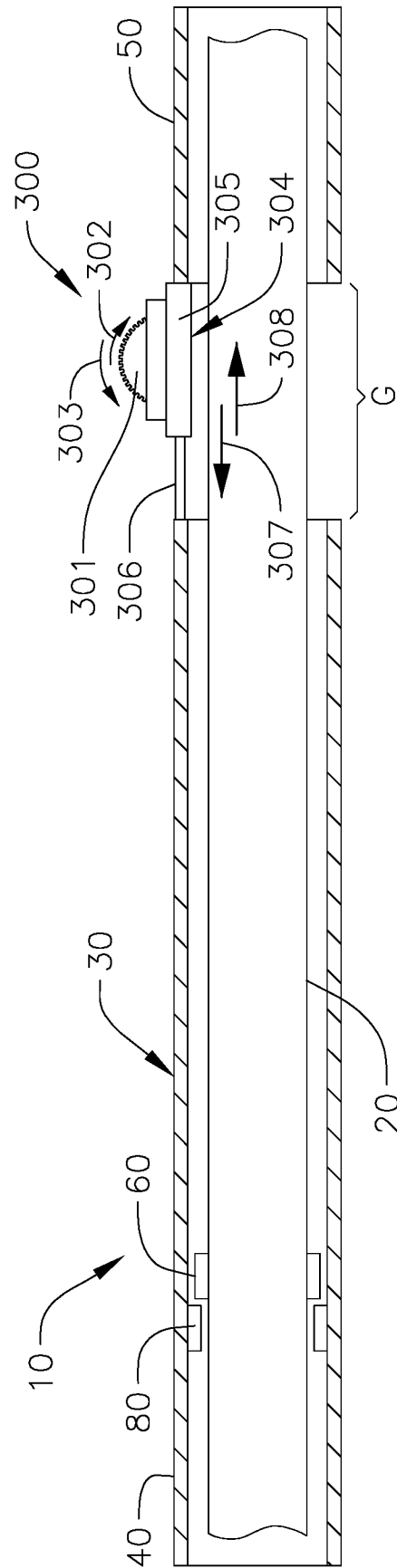
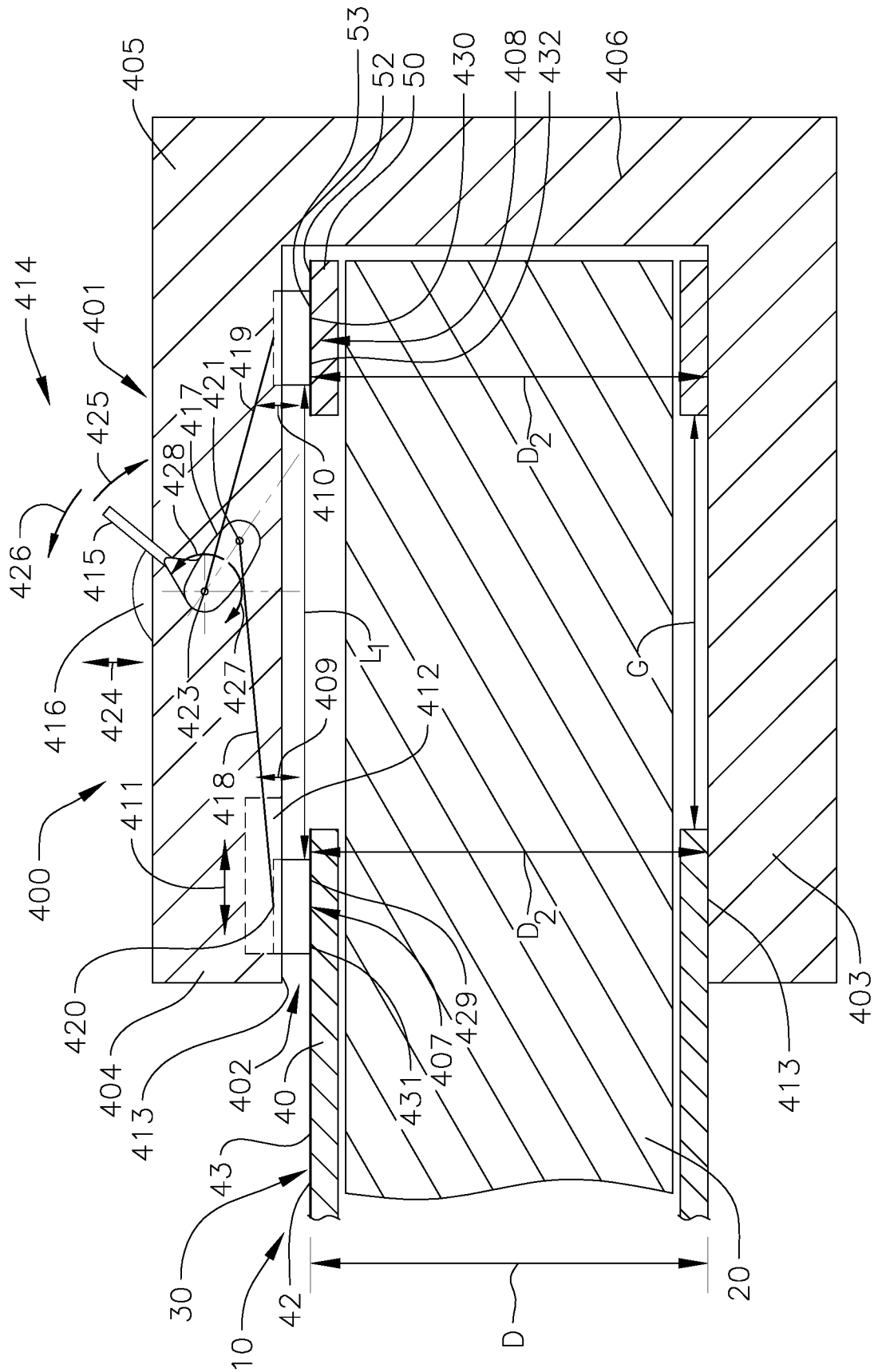






FIG. 11C



11/17

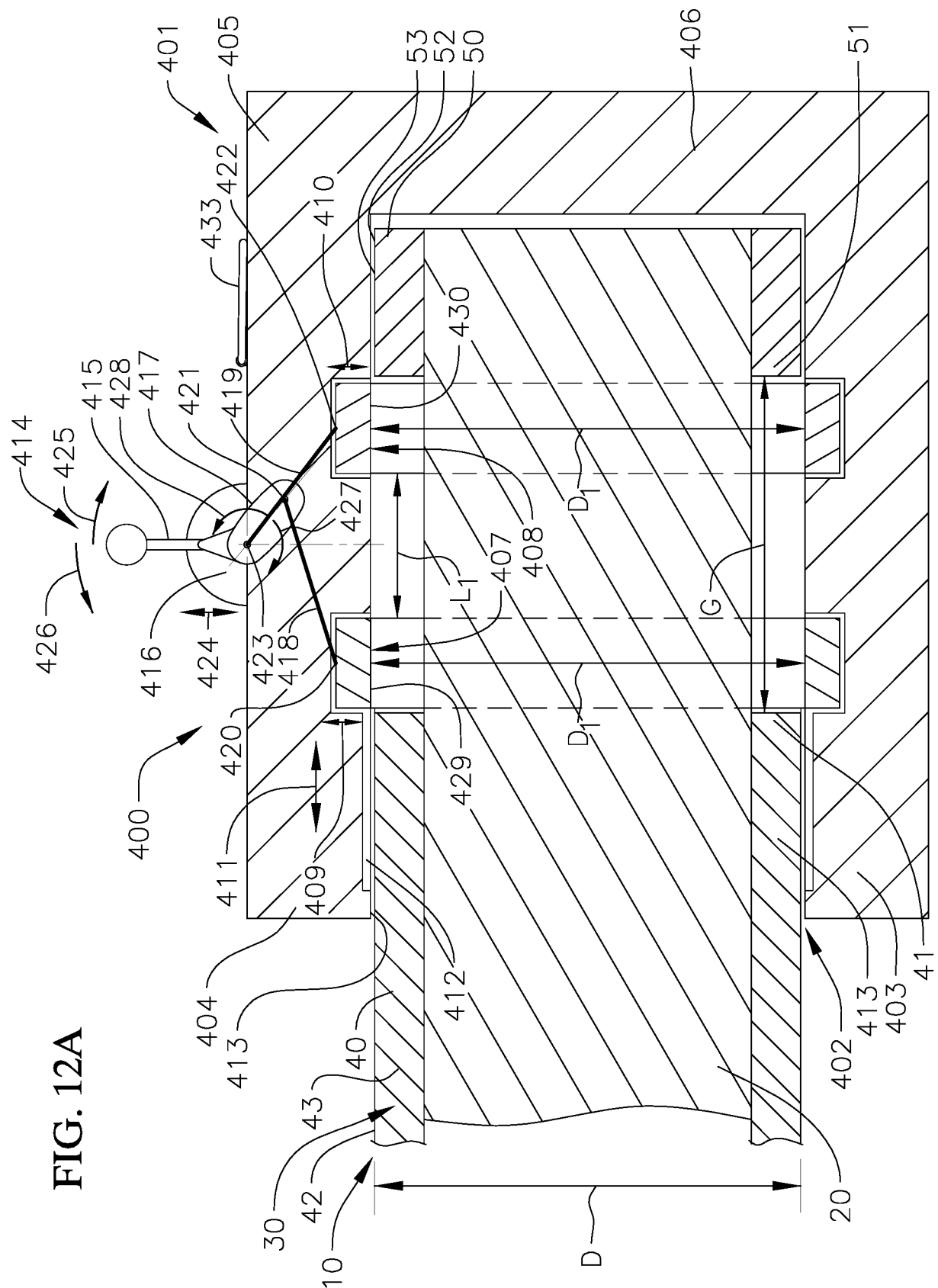


FIG. 12A



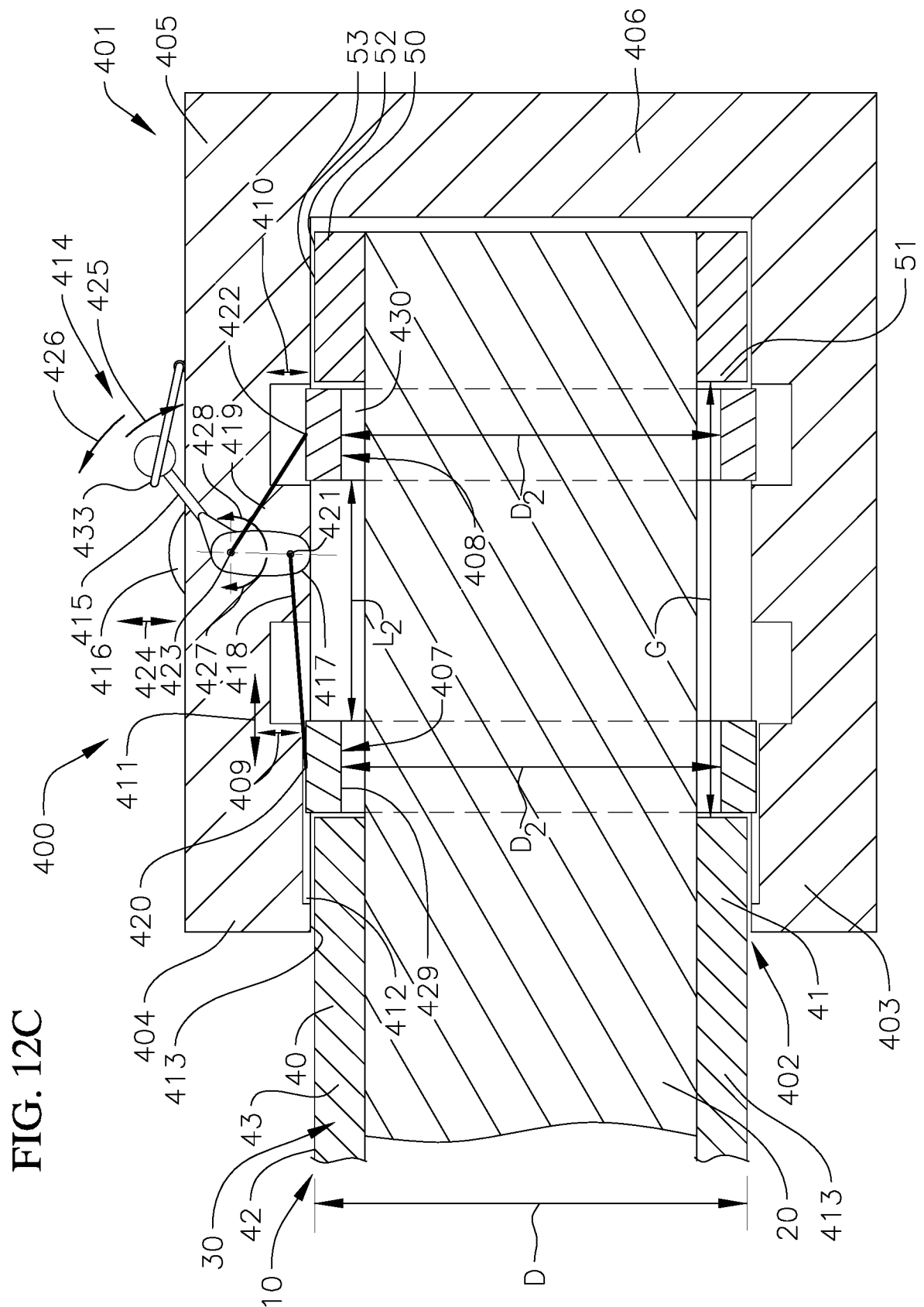
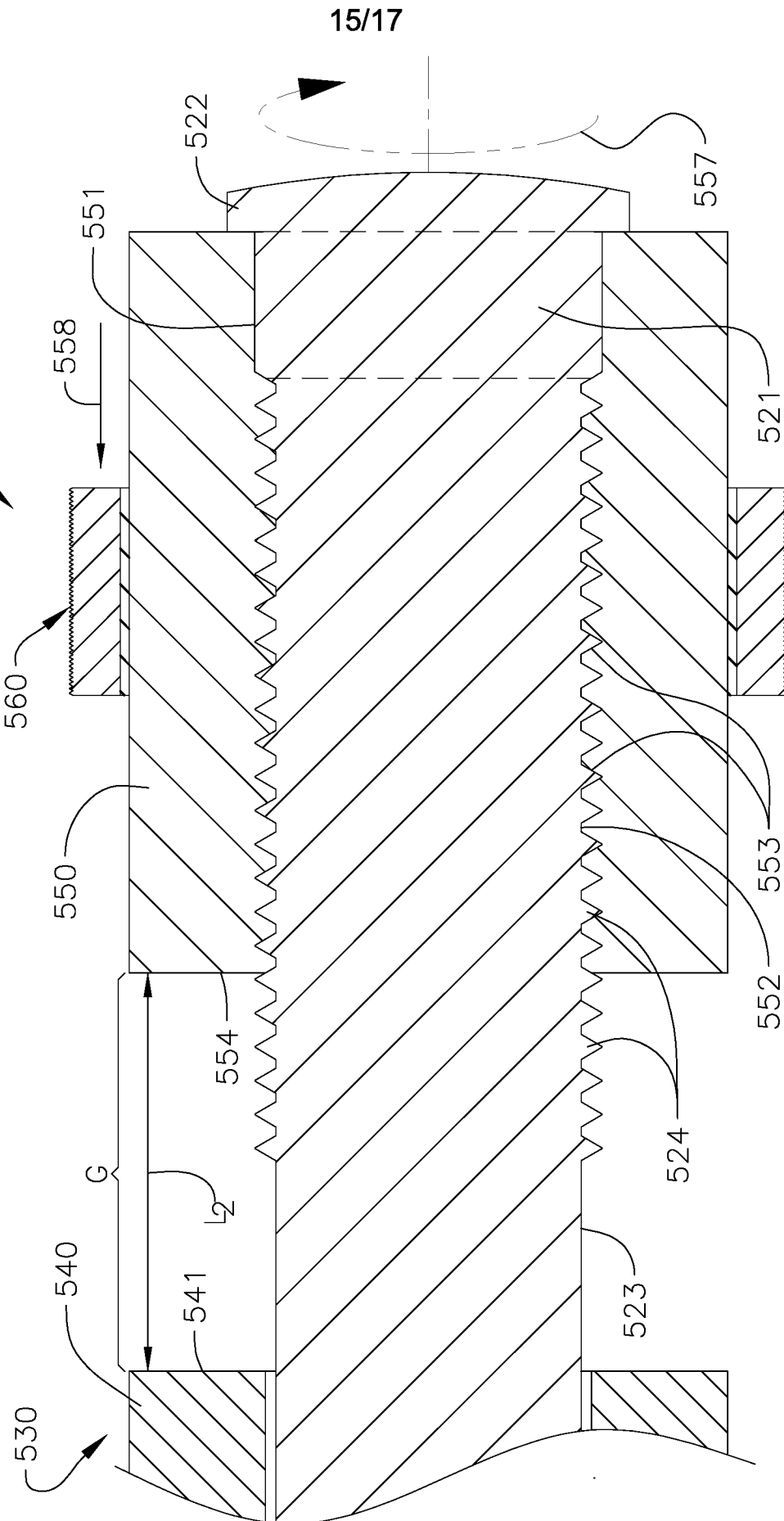
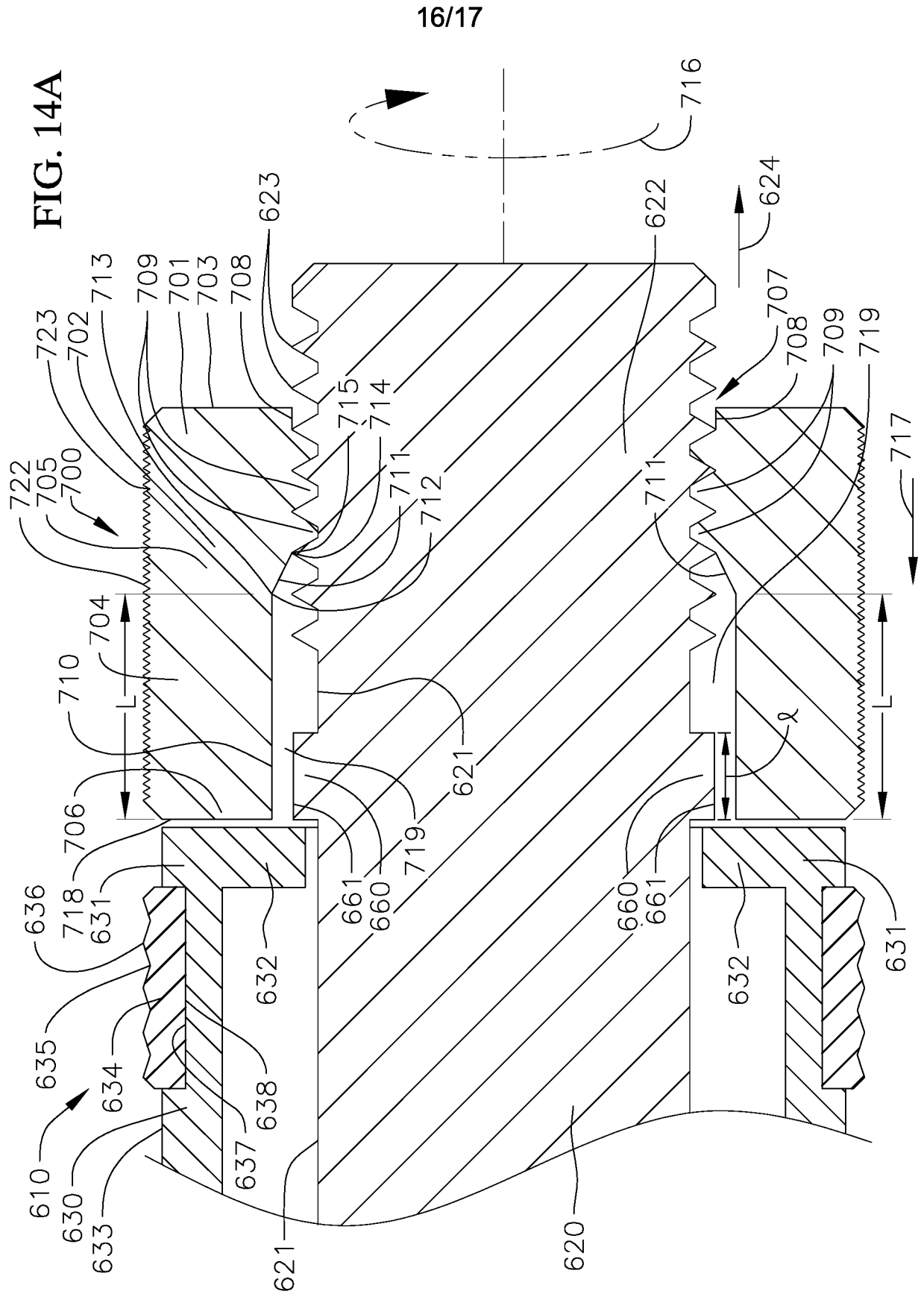




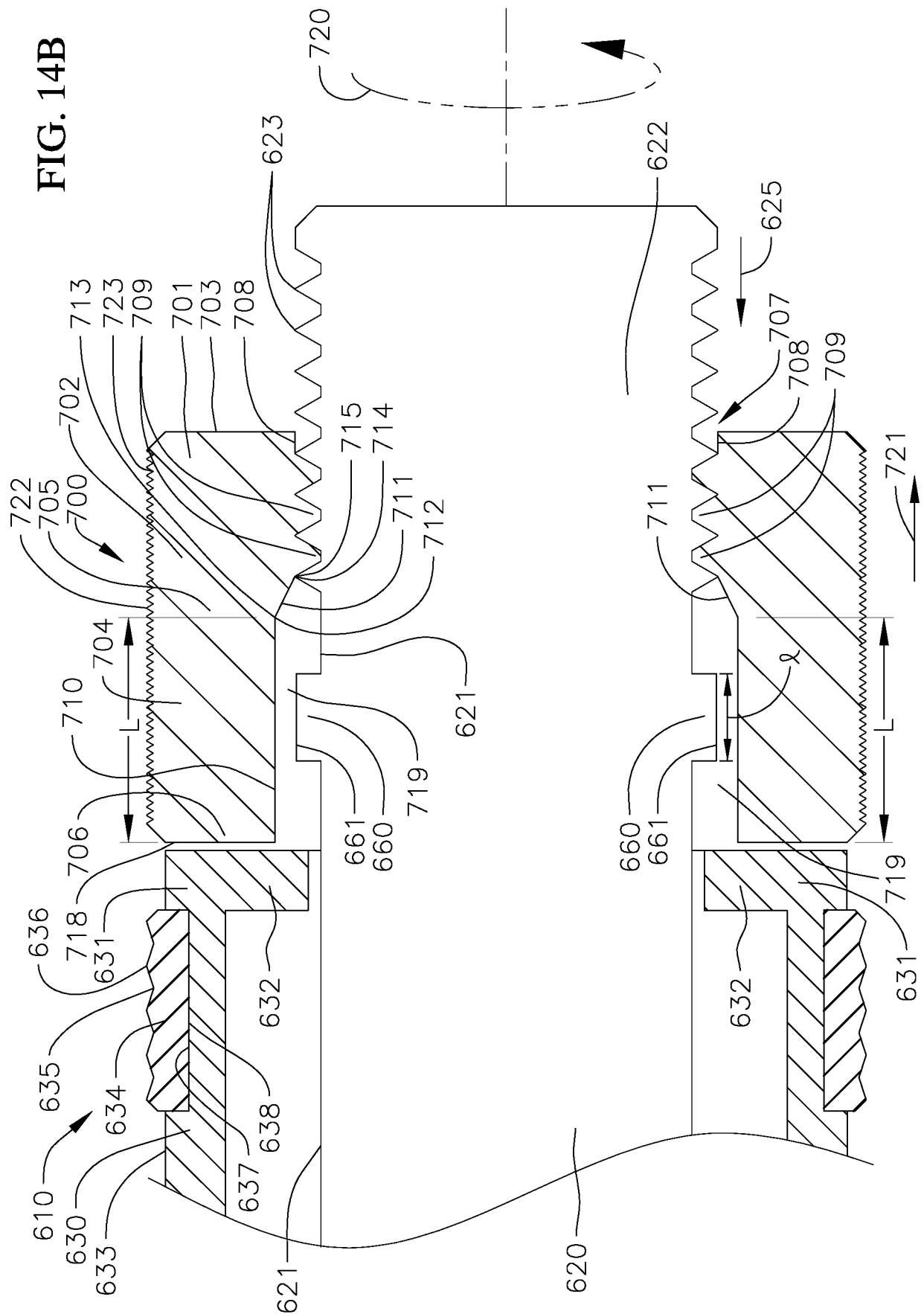
FIG. 13B





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FIG. 14B



## INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/US2018/043750****A. CLASSIFICATION OF SUBJECT MATTER****A61M 25/09(2006.01)i**

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

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

A61M 25/09; A61B 17/00; A61B 6/00; A61M 25/00

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

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

eKOMPASS(KIPO internal) &amp; Keywords: guidewire, thin elongated structure, outer shell, gap, flexible state, rigid state, stop, tensioning mechanism, thread, flange

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                            | Relevant to claim No. |
|-----------|---------------------------------------------------------------------------------------------------------------|-----------------------|
| X         | US 2016-0375226 A1 (TERUMO KABUSHIKI KAISHA) 29 December 2016<br>See paragraphs [0027]-[0085]; figures 1-3.   | 9-17, 19, 20          |
| A         |                                                                                                               | 1-8, 18               |
| X         | US 2007-0149951 A1 (WU, M. et al.) 28 June 2007<br>See paragraphs [0022], [0027], [0029]-[0031]; figures 1-3. | 17                    |
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| A         | US 2012-0041421 A1 (NISHIGISHI, M.) 16 February 2012<br>See the whole document.                               | 1-20                  |
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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 2019 (15.01.2019)

Date of mailing of the international search report

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**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/US2018/043750**

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