

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization

International Bureau



(10) International Publication Number

WO 2016/100868 A1

(43) International Publication Date

23 June 2016 (23.06.2016)

(51) International Patent Classification:

A61M 25/00 (2006.01)

(21) International Application Number:

PCT/US2015/066778

(22) International Filing Date:

18 December 2015 (18.12.2015)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/093,750 18 December 2014 (18.12.2014) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: CATHETER PATENCY SYSTEMS AND METHODS

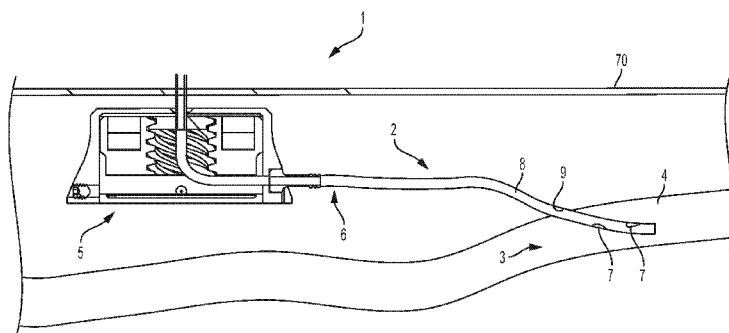


FIG. 1

(57) Abstract: A patency system for maintaining a patency of an indwelling medical device including an elongated shaft configured to be at least partially received within a portion of the indwelling medical device, and at least one cleaner configured to at least partially dislodge debris formed within the indwelling medical device.

CATHETER PATENCY SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims the benefit of the filing date of U.S. provisional patent application serial no. 62/093,750 filed December 18, 2014, the entire disclosure of which is incorporated herein by reference.

FIELD

The present disclosure relates to systems, devices and methods for maintaining catheter patency, and more particularly, systems, devices and method for maintaining patency of indwelling vascular access catheters.

BACKGROUND

Indwelling catheters are used, either alone or in combination with implantable medical devices (such as, but not limited to, implantable access ports) to provide access to the vasculature of a host for delivery of materials (e.g., drugs) and/or for removal/replacement of materials (e.g., blood). Over time, in-growth and clotting may clog indwelling catheters, either reducing fluid flow or completely preventing fluid flow through the catheter.

One method of trying to maintain patency of the catheter includes flushing the catheter with saline or other fluid agents, but these approaches may have only limited success. Once in-growth has begun, the efficacy of flushing alone may become limited, and clogging may ensue. Moreover, material removed from the catheter by the flushing may deposited into the vasculature of the host, particularly elsewhere in the circulatory system.

FIGURES

Features and advantages of the claimed subject matter will be apparent from the following detailed description of some example embodiments consistent therewith, which description should be considered with reference to the accompanying drawings, wherein:

FIG. 1 is a cross-sectional view of an indwelling medical system, and more particularly an indwelling catheter system, consistent with the present disclosure;

FIG. 2 is a cross-sectional view of an embodiment of a catheter patency system disposed within the indwelling catheter system of **FIG. 1**;

5 **FIG. 3** is a cross-sectional view of an embodiment of a catheter patency system consistent with the present disclosure;

FIG. 4 is a cross-sectional view of another embodiment of a catheter patency system in an extended position consistent with the present disclosure;

10 **FIG. 5** is a cross-sectional view of the catheter patency system of **FIG. 4** in a retracted position consistent with the present disclosure;

FIG. 6 is a cross-sectional view of another embodiment of a catheter patency system disposed within an indwelling catheter system;

FIG. 7 is a cross-sectional view of another embodiment of a catheter patency system consistent with the present disclosure;

15 **FIG. 8** is a cross-sectional view of another embodiment of a catheter patency system disposed within an indwelling catheter system;

FIG. 9 is a cross-sectional view of another embodiment of a catheter patency system consistent with the present disclosure;

20 **FIG. 10** is a cross-sectional view of another embodiment of a catheter patency system consistent with the present disclosure;

FIG. 11 is a cross-sectional view of another embodiment of a catheter patency system consistent with the present disclosure;

FIG. 12 is a cross-sectional view of another embodiment of a catheter patency system consistent with the present disclosure;

25 **FIG. 13** is a cross-sectional view of another embodiment of a catheter patency system consistent with the present disclosure;

FIG. 14 is a cross-sectional view of an embodiment of a catheter patency system having a balloon consistent with the present disclosure;

30 **FIG. 15** is a cross-sectional view of an embodiment of a catheter patency system having a balloon disposed within an indwelling catheter system consistent with the present disclosure;

FIG. 16A is a view of an embodiment of a catheter patency system having a balloon consistent with the present disclosure;

FIG. 16B is a cross-sectional view of the catheter patency system of **FIG. 16A** taken along line **XVI-XVI**;

5 **FIG. 17** is a cross-sectional view of another embodiment of a catheter patency system having a balloon consistent with the present disclosure;

FIG. 18 is a cross-sectional view of another embodiment of a catheter patency system having a balloon consistent with the present disclosure;

10 **FIG. 19** is a cross-sectional view of another embodiment of a catheter patency system having a balloon consistent with the present disclosure;

FIG. 20 is a cross-sectional view of another embodiment of a catheter patency system having a balloon consistent with the present disclosure;

FIG. 21 is a cross-sectional view of another embodiment of a catheter patency system having a balloon consistent with the present disclosure;

15 **FIG. 22** is a cross-sectional view of another embodiment of a catheter patency system having a balloon disposed within an indwelling catheter system consistent with the present disclosure;

FIG. 23 is a cross-sectional view of an embodiment of a catheter patency system having a coupler consistent with the present disclosure;

20 **FIG. 24** is a cross-sectional view of an embodiment of a catheter patency system having a light source consistent with the present disclosure; and

FIG. 25 is a cross-sectional view of an embodiment of an indwelling catheter system including an indwelling catheter patency system consistent with the present disclosure.

25

DETAILED DESCRIPTION

It may be appreciated that the present disclosure is not limited in its application to the details of construction and the arrangement of components set forth in the following description or illustrated in the drawings. The invention(s) herein 30 may be capable of other embodiments and of being practiced or being carried out in various ways. Also, it may be appreciated that the phraseology and terminology used

herein is for the purpose of description and should not be regarded as limiting as such may be understood by one of skill in the art.

Throughout the present description, like reference numerals and letters indicate corresponding structure throughout the several views, and such corresponding structure need not be separately discussed. Furthermore, any particular feature(s) of a particular exemplary embodiment may be equally applied to any other exemplary embodiment(s) of this disclosure as suitable. In other words, features between the various exemplary embodiments described herein are interchangeable as suitable, and not exclusive.

By way of a general overview, the present disclosure may feature systems, devices, and/or methods for maintaining patency of an indwelling medical system. The systems, devices, and/or methods according to at least one embodiment of the present disclosure include a patency system having an elongated shaft and one or more cleaners configured to be at least partially disposed within the indwelling medical system. The cleaners are configured to dislodge debris (e.g. in-growth) forming within the indwelling medical system (e.g., a lumen of an indwelling catheter and/or a vascular access port), and may include one or more cleaners, such as one or more brushes, augers, jets, protrusions and strands. The patency system may optionally include one or more balloons, movable seals and/or valves configured to seal against a portion of the indwelling medical system, such as the indwelling catheter, to prevent dislodged debris from entering into the host's circulatory system or elsewhere in the indwelling catheter. The patency system may also optionally include one or more flushing sources and/or vacuum sources to facilitate the removal of dislodged debris from the indwelling medical system.

The patency system according to the present disclosure may be used to maintain the patency of an indwelling medical system. Referring now to **FIG. 1**, one embodiment of an indwelling medical system 1 according to the present disclosure is generally illustrated, which may comprise one or more medical devices. The indwelling medical system 1 may include a first medical device in the form of an implantable (indwelling) vascular access catheter 2 having a first end 3 configured to be inserted into a lumen 4 of a blood vessel in the tissue of a host (e.g. patient) for

which a fluid is to be delivered (e.g. blood, medication) and/or withdrawn (e.g. blood).

5 Optionally, the indwelling medical system 1 may include a second medical device, such as in the form of a vascular access port 5 coupled to a second end 6 of the indwelling vascular access catheter 2.

Examples of the indwelling medical systems, and tools for use therewith, may include, but are not limited to, those described in U.S. Patent Application Serial No. 10/890,909, filed July 13, 2004; U.S. Patent Application Serial No. 11/234,497, filed October 4, 2005; U.S. Patent Application Serial No. 14/231,392, filed March 31, 10 2014; U.S. Patent Application Serial No. 61/974,807, filed April 3, 2014; U.S. Patent No. 5,906,596; U.S. Patent No. 6,527,754; U.S. Patent No. 7,803,143; U.S. Patent No. 7,803,143; U.S. Patent No. 7,811,266; and U.S. Patent No. 8,377,034, all of which are incorporated herein by reference, to the extent they are consistent with the present disclosure.

15 While the indwelling medical system 1 illustrated in **FIG. 1** is shown to have a single indwelling catheter 2 with a single lumen 8, it should be appreciated that the indwelling catheter 2 may have a plurality of lumens 8, or the indwelling medical system 1 may include a plurality of indwelling catheters 2, with each catheter 2 having one or more lumens 8. Also, the indwelling catheter 2 may form an integral 20 (e.g., unitary or one-piece) component with the vascular access port 5.

For ease of explanation, the patency system will be described in combination with an indwelling medical system 1 having an indwelling catheter 2. As such, the patency system may be referred to as a catheter patency system and the indwelling medical system may be referred to as an indwelling catheter system. It should be 25 appreciated, however, that the patency system according to the present disclosure may be used to maintain the patency of any indwelling medical system and/or medical device with or without a catheter.

As can be seen, in-growth, hereinafter referred to as debris 7, which may include clotting such as fibrin and coagulum, may form within a portion of the 30 indwelling medical system 1 such as, but not limited to, lumen 8. More particularly, the debris 7 may form on the interior surface 9 of the lumen 8 anywhere along the length thereof (i.e. the vascular access port 5 and/or the indwelling catheter 2). The

debris 7, if left untreated, may reduce and/or prevent fluid flow through the lumen 8 of the indwelling medical system 1, and may possibly break loose and enter the host's vasculature. The patency system disclosed herein may be used to remove at least a portion of the debris 7 at any location along the lumen 8 of the indwelling medical system 1, particularly the lumen 8 of either the vascular access port 5 and/or the indwelling catheter 2.

Referring now to **FIG. 2**, one embodiment of a patency system (e.g., catheter patency system) 10 consistent with the present disclosure is generally illustrated disposed within the indwelling medical system (e.g., indwelling catheter system) 1.

10 At least a portion of the catheter patency system 10 is configured to be disposed within at least a portion of the indwelling catheter system 1 (e.g., the lumen 8 of the indwelling catheter 2 and/or the vascular access port 5 and includes at least one cleaner 12. As explained herein, the catheter patency system 10 may be at least partially withdrawn and/or pulled externally generally in the direction of arrow A 15 such that the cleaner 12 at least partially removes debris 7 from the interior surface 9 of lumen 8 of the indwelling catheter system 1.

Turning now to **FIG. 3**, one embodiment of a catheter patency system 10 consistent with the present disclosure is generally illustrated. The catheter patency system 10 includes an elongated body (shaft) 14 having a proximal section P, a distal section D, and an intermediate section I disposed between the proximal section P and the distal section D. The elongated body 14 is sized and shaped to be at least partially received within the lumen 8 of the indwelling catheter system 1. The elongated body 14 is formed from one or more materials having sufficient flexible, pushability (i.e., ability to transmit force to the distal portion or tip), and kink resistance to be advanced 20 within bends and contours of the lumen 8 of the indwelling catheter system 1.

According to one embodiment, one or more portions of the elongated body 14 (e.g., the proximal section P, distal section D, and intermediate section I) may have 30 different flexibilities, pushabilities, and/or kink resistances. For example, the proximal section P may be more rigid compared to the intermediate section I, and the intermediate section I may be more rigid compared to the distal section D. The distal section D may be the most flexible. One or more of the sections P, I, D may include, for example, a spiral reinforcement and/or different materials to allow the flexibility,

pushability, and kink resistance to be customized and/or selected along the length of the elongated body 14.

The distal section D may optionally include a distal end tip 21 configured to reduce and/or eliminate the potential of the tip 21 from becoming caught in and/or damaging the indwelling catheter system 1, particularly the lumen 8, as the catheter patency system 10 is advanced into and through the lumen 8 of the indwelling catheter system 1. For example, the tip 21 may include a resiliently deformable portion configured to deflect the tip 21 as the catheter patency system 10 is advanced through the lumen 8. According to one embodiment, the tip 21 may include a balloon and/or may have a rounded configuration.

The proximal section P of the elongated body 14 may include a handle 16. The handle 16 may facilitate the gripping of the elongated body 14 by a user (e.g., a surgeon, clinician) when advancing the elongated body 14 of the catheter patency system 10 into and/or out of the lumen 8 of the indwelling catheter system 1 and/or

rotating the catheter patency system 10 about the longitudinal axis L. The handle 16 may include, but is not limited to, a T-handle, an area with increased friction (gripability). The handle 16 may also provide a stop member which contacts against the indwelling catheter system 1 to prevent the tip 21 of the catheter patency system 10 from extending into the vasculature (e.g. lumen 4 of the blood vessel).

Alternatively (or in addition), the proximal section P may include a coupler portion 18, **FIG. 4**, configured to be coupled to a separate mechanical, electrical or electro-mechanical rotary driver 20, e.g., a drill. The coupler portion 18 may include a plurality of engagement faces to securely engage and mate with an engagement head 22 of the rotary device, e.g. drill chuck.

As discussed herein, the catheter patency system 10 also includes at least one cleaner 12. While the cleaner 12 is illustrated as being located on at least a portion of the distal section D, it should be appreciated that this is for illustrative purposes only and that one or more of the cleaners 12 may be located along any portion (including the entire length) of the elongated body 14.

According to one embodiment, the cleaner 12 may include one or more cleaning members, such as brushes 24. The brushes 24 may be arranged in any configuration. The configuration may include one or more rows of cleaning elements,

such as one or more rows of bristles 26, which may be arranged such that the bristles 26 extending longitudinally along a length of the distal section D. The one or more rows of bristles 26 may also be arranged in a circular (ring) configuration, a spiral configuration and/or a helical configuration. The bristles 26 may be configured to 5 extend generally radially outwardly from the elongated body 14 as protrusions, and may be arranged to provide bumps and/or ridges. The bristles 26 may be formed of the same or different materials. For example, the bristles 26 may include different materials to adjust the stiffness and/or friction.

The bristles 26 may extend radially outwardly from the elongated body 14 10 (i.e., the radial length R) such that the bristles 26 generally engage and/or contact against a portion of the interior surface 9 (**FIG. 2**) of the lumen 8 of the indwelling catheter system 1 while the catheter patency system 10 is moved within the lumen 8 of the indwelling catheter system 1 (e.g., the lumen 8). To remove debris 7, the elongated body 14 of the catheter patency system 10 may be advanced generally in 15 the direction of arrow A (**FIG. 2**) and/or rotated about its longitudinal axis L while within the lumen 8 of the indwelling catheter system 1 (e.g., using with the handle 16 (**FIG. 3**) and/or the rotary driver 20 (**FIG. 4**)).

According to one embodiment, the bristles 26 may be configured to be 20 arranged in an expanded position (e.g., as generally illustrated in **FIG. 4**) and a collapsed or retracted position (as generally illustrated in **FIG. 5**). In the expanded position (see, for example, **FIG. 6**), the bristles 26 are arranged extended generally radially outwardly such that the bristles 26 generally engage and/or contact against a portion of the interior surface 9 of the lumen 8 of the indwelling catheter system 1 to remove debris 7. In the collapsed position, the bristles 26 may be arranged generally 25 more towards the elongated body 14 such that the overall cross-section of the catheter patency system 10 (e.g., the diameter) may be reduced.

As may be appreciated, the catheter patency system 10 may be more easily advanced within the lumen 8 of the indwelling catheter system 1 while in the collapsed position compared to the expanded position. Additionally, the catheter 30 patency system 10, when in the collapsed position, is less likely to inadvertently dislodge debris 7 from the lumen 8 of the indwelling catheter system 1 while being advanced into the lumen 8 of the indwelling catheter system 1 (i.e., when the

elongated body 14 of the catheter patency system 10 is advanced in the direction generally opposite to arrow A in **FIG. 2**). As may be appreciated, it may be beneficial to reduce and/or eliminate debris 7 from becoming inadvertently dislodged from the lumen 8 of the indwelling catheter system 1 while advancing the elongated body 14 of the catheter patency system 10 into the lumen 8 of the indwelling catheter system 1 since the inadvertently removed debris 7 may enter into the host's vasculature where it could be deposited elsewhere in the circulatory system, or in the lumen 8 of the catheter system 1, such as in the catheter 2, particularly if there is a valve located in the distal end 3 of the catheter 2.

According to one embodiment, the bristles 26 may be configured to easily bend, collapse, fold, or otherwise move towards the elongated body 14 into the collapsed position as the catheter patency system 10 is advanced into the lumen 8 of the indwelling catheter system 1, and extend radially outwardly into the expanded position when the catheter patency system 10 is advanced out of the lumen 8 of the indwelling catheter system 1 (e.g., withdrawn from the indwelling catheter patency system 10 generally in the direction of arrow A in **FIG. 2**). For example, the bristles 26 may have a limited range of motion.

According to another embodiment, the catheter patency system 10 may include a position selector 28 (**FIG. 5**). The position selector 28 may be configured to allow the user to articulate the cleaner 12 between the collapsed and expanded positions (or any position therebetween). For example, the position selector 28 may include a switch, tab or slider coupled to the bristles 26 that urges the bristles 26 generally radially outwardly and inwardly. The user may push the position selector 28 to select between the expanded and collapsed positions, such as by moving the position selector 28 distally to expand the bristles 28 and moving the position selector proximally to contract the bristles 26. In at least one embodiment, the bristles 26 may at least partially retract into a portion of the elongated body 14.

Turning now to **FIGS. 7** and **8**, another embodiment of the cleaner 12 is generally illustrated. The cleaner 12 may include one or more augers 30. The augers 30 may include one or more flanges 32 extending generally radially outwardly from the elongated body 14 having a generally spiral configuration, helical configuration, and/or an arcuate configuration. The flanges 32 may extend completely or partially

around the periphery and/or circumference of the elongated body 14 and may be made from a resiliently deformable material. The radial length R of the flanges 32 may be selected such that the augers 30 generally engage and/or contact against a portion of the interior surface 9 (**FIG. 8**) of the indwelling catheter system 1 while the catheter 5 patency system 10 is moved within the lumen 8 of the indwelling catheter system 1. The auger 30 may extend along any portion of the elongated body 14, for example, the distal section D as generally illustrated in **FIG. 7** and/or along substantially the entire length of the elongated body 14 as generally illustrated in **FIG. 8**.

To remove debris 7, the catheter patency system 10 may be rotated as 10 described herein. The rotation of the auger 30 causes debris 7 to be dislodged from the interior surface 9 of the indwelling catheter system 1. Additionally, rotation of the auger 30 causes dislodged debris 7 to be urged proximally (e.g., generally away from the distal section D and generally towards the proximal section P), thereby reducing and/or eliminating the potential for dislodged debris 7 to exit the indwelling catheter 15 system 1 and enter into the host's circulatory system or be lodged elsewhere in the indwelling catheter system 1.

With reference to **FIGS. 9-11**, yet another embodiment of the cleaner 12 is generally illustrated. The cleaner 12 may include one or more protrusions 34 (e.g. 20 bumps, flanges ribs) extending generally radially outwardly from the elongated body 14. For example, the protrusions 34 may have a generally spherical and/or hemispherical configuration as generally illustrated in **FIG. 9**, a generally ring and/or ridged configuration as generally illustrated in **FIG. 10**, and/or a knurled portion as generally illustrated in **FIG. 11**. The protrusions 34 may have a radial length R selected such that the protrusions 34 generally engage and/or contact against a portion 25 of the interior surface 9 (**FIG. 8**) of the lumen 8 of the indwelling catheter system 1 while the catheter patency system 10 is moved within the lumen 8 of the indwelling catheter system. The protrusions 34 may be separated by flexible segments 36. To remove debris 7, the elongated body/shaft 14 of the catheter patency system 10 may be advanced generally in the direction of arrow A and/or rotated about its longitudinal 30 axis L while within the lumen 8 of the indwelling catheter system 1 (e.g., using with the handle 16 (**FIG. 3**) and/or the rotary driver 20 (**FIG. 4**)).

According to yet another embodiment as shown in **FIG. 12**, the cleaner 12 may include a one or more strands 37 configured to form an abrasive surface configured to dislodge debris 7 from the lumen 8 of the indwelling catheter system 1. For example, a single strand 37 may be twisted. Alternatively, a plurality of strands 5 may be twisted, woven or braided. Similar to other embodiments, the elongated body 14 of the catheter patency system 10 may be advanced generally in the direction of arrow A and/or rotated about its longitudinal axis L while within the lumen 8 of the indwelling catheter system 1 (e.g., using with the handle 16 (**FIG. 3**) and/or the rotary driver 20 (**FIG. 4**) to remove debris 7.

10 It should be appreciated that the catheter patency system 10 is not limited to each individual type of cleaner 12 described herein. Additionally, the catheter patency system 10 may include a plurality of cleaners 12. For example, as shown in **FIG. 13**, the catheter patency system 10 may include one or more protrusions 34, one or more brushes 24, and/or one or more augers 30. For example, the elongated body 15 14 may include a plurality of protrusion 34 and bristles 26 configured to dislodge debris 7 (not shown for clarity). An auger 30 may be located distally from the protrusions 34 and bristles 26, and may be configured to urge dislodged debris 7 proximally (thereby reducing and/or eliminating dislodged debris 7 from entering into the host's circulatory system or being lodged elsewhere in indwelling catheter system 20 1). However, this is just an example, and other configurations are within the scope of the present disclosure.

Turning now to **FIGS. 14-16**, another embodiment of the catheter patency system 10 is generally illustrated. The catheter patency system 10 includes an elongated body 14 defining at least one lumen 38 and an inflatable balloon 40. 25 According to one embodiment, the lumen 38 may include an inflation lumen configured to at least partially inflate the balloon 40. For example, the balloon 40 may be coupled to the tip 21 of the elongated body 14 and in fluid communication with the inflation lumen 38 as generally illustrated in **FIG. 14**. The opposite end of the inflation lumen 38 may be configured to be coupled to an inflation fluid source 30 (e.g., a source of saline, water, heparin, contrast fluid, which is not shown for clarity) to inflate the balloon 40.

In practice, elongated body 14 of the catheter patency system 10 may be advanced into the lumen 8 of the indwelling catheter system 1 while the balloon 40 is deflated (or at least partially deflated). To remove debris 7, the balloon 40 may be inflated via the inflation lumen 38 such that the balloon 40 contacts the interior 5 surface 9 of the lumen 8 of the indwelling catheter system 1 as generally illustrated in **FIGS. 15, 16A, and 16B**.

According to at least one embodiment, the balloon 40 may generally form a seal with the interior surface 9 of the lumen 8 to thereby preventing dislodged debris 7 from exiting the indwelling catheter system 1 and entering into the host's circulatory 10 system. The catheter patency system 10 may be advanced generally in the direction of arrow A and/or rotated about its longitudinal axis L while within the lumen 8 of the indwelling catheter system 1 (e.g., using with the handle 16 (**FIG. 3**) and/or the rotary driver 20 (**FIG. 4**)) such that the cleaner 12 dislodges debris 7 as discussed herein. The dislodged debris 7 may be removed from the indwelling catheter system 1, for 15 example, using a vacuum source as discussed herein. Alternatively, while inflated, the balloon 40 may be retracted proximally within lumen 8, during which time the balloon 40 may scrape the interior surface 9 of the lumen 8 to remove more debris 7, as well as pull debris 7 out of the lumen 8.

Turning now to **FIG. 17**, another embodiment of the catheter patency system 20 10 is generally illustrated. Similar to **FIGS. 14-16**, the catheter patency system 10, **FIG. 17**, includes an elongated body 14 defining at least one lumen 38, and includes a balloon 40. An elongated, cannulated balloon shaft 42 is fluidly coupled to the balloon 40 and a fluid source (not shown for clarity). The cannulated balloon shaft 42 (and optionally the balloon 40) is configured to be at least partially received within 25 the lumen 38 (e.g., balloon lumen 38).

In practice, the cannulated balloon shaft 42 (and optionally the balloon 40) may be at least partially received within the lumen 38 of the catheter patency system 10 may be advanced into the lumen 8 of the indwelling catheter system 1. The balloon 40 may optionally be deflated (or at least partially deflated). To remove 30 debris 7, the balloon 40 may be inflated via a lumen 43 of the cannulated balloon shaft 42 such that the balloon 40 is advanced outwardly from the elongated body 14, for example, beyond the tip 21. The inflated balloon 40 may contact the interior

surface 9 of the lumen 8 of the indwelling catheter system 1 such that the balloon 40 generally forms a seal with the interior surface 9, thereby preventing dislodged debris 7 from exiting the indwelling catheter system 1 and entering into the host's circulatory system. The elongated body 14 and the cleaner 12 of the catheter patency system 10 may be advanced generally in the direction of arrow A and/or rotated about its longitudinal axis L while within the indwelling catheter system 1 (e.g., using with the handle 16 (**FIG. 3**) and/or the rotary driver 20 (**FIG. 4**)) such that the cleaner 12 dislodges debris 7 as discussed herein. The inflated balloon 40 may remain stationary while the elongated body 14 and cleaner 12 are withdrawn. The dislodged debris 7 may be removed from the indwelling catheter system 1, for example, using a vacuum source as discussed herein.

Referring now to **FIG. 18**, a further embodiment of the catheter patency system 10 is generally illustrated. The catheter patency system 10 may include an elongated body 14 defining at least one lumen 38 (e.g., fluid lumen) fluidly coupled to a fluid source (not shown for clarity) as well as a balloon 40 and one or more cleaners 12. The cleaners 12 may comprise fluid jets, nozzles, and/or flushing ports 44. In practice, the fluid lumen 38 may be coupled to a pressurized fluid source to supply fluid to at least partially inflate the balloon 40 such that the balloon 40 contacts the interior surface 9 of the lumen 8 of the indwelling catheter system 1 to generally form a seal with the interior surface 9, thereby preventing dislodged debris 7 from exiting the indwelling catheter system 1 and entering into the host's circulatory system. The pressurized fluid is also ejected from the ports 44 with sufficient force to at least partially dislodge debris 7 from the interior surface 9 of the lumen 8 of the indwelling catheter system 1. The dislodged debris 7 may be removed from the indwelling catheter system 1, for example, using a vacuum source as discussed herein.

Turning to **FIG. 19**, the catheter patency system 10 may include an elongated body 14 featuring a plurality of lumens, and optionally a balloon 40. For example, the elongated body 14 may include a flushing lumen 46 in fluid communication with a pressurized fluid source (not shown for clarity) and one or more fluid jets, nozzles, and/or flushing ports 44 (and optionally the balloon 40), optionally a separate balloon lumen 48 in fluid communication with a pressurized fluid source (not shown for clarity) and the balloon 40, and optionally a vacuum lumen 50 in fluid communication

with a vacuum source (not shown for clarity) and one or more vacuum ports, apertures or openings 52. The cleaner 12 may include any cleaner described herein (e.g., but not limited to, bristles, augur, protrusions, and fluid jets).

Similar to **FIG. 19**, the catheter patency systems 10, **FIG. 20-21**, may include 5 a balloon 40 having an elongated, cannulated balloon shaft 42 fluidly coupled to the balloon 40 and a fluid source (not shown for clarity). The cannulated balloon shaft 42 (and optionally the balloon 40) is configured to be moveably disposed within at least partially received within a balloon lumen 38 similar to catheter patency system 10 of **FIG. 17**. In the embodiment of **FIG. 20**, the cannulated balloon shaft 42 (and 10 optionally the balloon 40) is configured to be movably disposed within a balloon lumen 38. In the embodiment of **FIG. 21**, the balloon lumen 38 may optionally be coupled to a fluid source (not shown for clarity), for example to provide a flushing fluid to aid in moving the dislodged debris 7 towards the vacuum ports 52 and into the vacuum lumen 50.

15 Consistent with other embodiments described herein, the cleaner(s) 12 (**FIGS. 19-21**) are configured to dislodge debris 7 and the balloon 40 may generally prevent dislodged debris 7 from exiting the indwelling catheter system 1 and entering into the host's circulatory system. Dislodged debris 7 may be removed from the indwelling catheter system 1 via the vacuum ports 52 and vacuum lumen 50. Optionally, the 20 dislodged debris 7 may be removed with the aid of fluid from the flushing lumen 46 and/or balloon lumen(s) 38, 48.

Turning now to **FIG. 22**, the catheter patency system 10 may include a balloon 40 as described herein, and one or more cleaners 12 in the form of one or 25 more fluid jets, nozzles, and/or flushing ports 44. The ports 44 may be configured to eject fluid to dislodge debris 7 (e.g., but not limited to, pressurized fluid and/or fluid to at least partially dissolve and/or break-up debris) as described herein. The indwelling catheter system 1 may be coupled to a vacuum source (not shown for clarity) to remove the dislodged debris 7.

With reference to **FIG. 23**, one embodiment of the catheter patency system 10 30 is shown coupled with one or more fluid sources 52, inflation sources 54, and/or vacuum sources 56. One or more of the fluid sources 53, inflation sources 54, and/or vacuum sources 56 may be coupled to the elongated body 14 using a coupler 58. The

coupler 58 may be configured to allow the elongated body 14 to rotate along its longitudinal axis L, while the fluid sources 53, inflation sources 54, and/or vacuum sources 56 remain substantially stationary. According to one embodiment, the coupler 58 may include a hemostatic valve/port (e.g., a rotating hemostatic valve); 5 however, the catheter patency system 10 may be used with other types of couplers known to those skilled in the art.

According to yet another embodiment, the catheter patency system 10, **FIG. 24**, may include an elongated body 14 inserted within a reflective lumen 60. The elongated body 14, which may comprise a light tube, such as a fiber optic light tube, 10 may be optically coupled to a light source 62 (e.g., but not limited to, an ultraviolet light source) and may include one or more apertures 64 configured to emit light from the light source 62. The light emitted from the light source 62 and the apertures 64 may be configured to sterilize or loosen the adherence of debris 7 within the lumen 8 from within the indwelling catheter system 1. In other embodiments, the reflective 15 lumen 60 may be eliminated and the elongated body 8 may apply light at any location along the length thereof to the debris 7 within the lumen 8 from within the indwelling catheter system 1. The catheter patency system 10 may optionally include any of cleaners 12, flushing lumens/ports, vacuum sources/ports/lumens as described herein, and may also optionally include a balloon 40.

20 Any of the catheter patency systems 10 described herein may be inserted into an external communication channel (e.g., but not limited to, a needle extending through the host's skin from an access port) and advanced within the indwelling catheter system 1. Alternatively (or in addition), any of the catheter patency systems 10 described herein may be inserted through the host's skin and into the indwelling 25 catheter system 1 (e.g., an access port) using a needle.

Alternatively (or in addition), any of the catheter patency systems 10 described herein may be indwelling within the indwelling catheter system 1 until it is used (and optionally reused, removed, and/or replaced). For example, one embodiment of an indwelling catheter system 1 is generally illustrated in **FIG. 25**. In particular, the 30 indwelling catheter system 1 may include an access port 66 and a patency port 69. The access port 66 may be configured to provide fluid access to the lumen 8 for delivering and/or withdrawing fluid to/from the lumen 4 of a blood vessel (not shown

for clarity). For example, the access port 66 may optionally include a needle 68 configured to be selectively extended and retracted through the user's skin 70. Alternatively (or in addition), the first access port 66 may include a septum 72 through which a separate, external needle (not shown) may pass into a cavity in fluid communication with the lumen 8.

A catheter patency system 10 consistent with the present disclosure may be disposed at least partially within the lumen 8 of the indwelling catheter system 1 and the patency port 69. The patency port 69 may be configured to allow a user (e.g., a surgeon, clinician, host) to gain access to the catheter patency system 10 such that the user can operate the catheter patency system 10 to dislodge debris 7 as described herein. For example, the patency port 69 may be coupled to a portion of the access port 66 and/or the lumen 8 (e.g., by way of a coupler or seal 75) such that the catheter patency system 10 may be disposed therein and the patency port 69 is generally sealed from the access port 66. The patency port 69 may also include a needle 76 configured to selectively extend and retract through the user's skin 70 such that the user can gain access to (e.g., grasp) the catheter patency system 10 and operate the catheter patency system 10 as described herein.

It should be appreciated that any of the features described herein may be combined. For example, any of the cleaners, lumens, balloons or elongated shafts in any of the embodiments described herein may be combined with any of the cleaners, lumens, balloons, elongated shafts in any other embodiments.

While preferred embodiments of the present invention(s) have been described, it should be understood that various changes, adaptations and modifications can be made therein without departing from the spirit of the invention(s) and the scope of the appended claims. The scope of the invention(s) should, therefore, be determined not with reference to the above description, but instead should be determined with reference to the appended claims along with their full scope of equivalents. Furthermore, it should be understood that the appended claims do not necessarily comprise the broadest scope of the invention(s) which the applicant is entitled to claim, or the only manner(s) in which the invention(s) may be claimed, or that all recited features are necessary.

What is claimed is:

1. A patency system to maintain patency of an indwelling medical device, said patency system comprising:

5 an elongated shaft configured to be at least partially received within a portion of said indwelling medical device; and

at least one cleaner configured to at least partially dislodge debris formed within said indwelling medical device.

10 2. The patency system of claim 1 wherein:

said at least one cleaner includes a brush.

3. The patency system of claim 2 wherein:

said brush includes a plurality of bristles configured to extend generally 15 radially outwardly to contact an interior surface of said indwelling medical device.

4. The patency system of claim 3 wherein:

said plurality of bristles are configured to be arranged in an expanded position such that said plurality of bristles contact said interior surface, and a retracted position 20 wherein said plurality of bristles are arranged generally towards said elongated shaft such that an overall cross-section of the patency system is reduced compared to the expanded position.

5. The patency system of claim 4 further comprising:

25 a position selector to urge said plurality of bristles between said expanded and retracted positions.

6. The patency system of claim 1 wherein:

said at least one cleaner includes an auger.

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7. The patency system of claim 1 wherein:

said at least one cleaner includes an at least one protrusion.

8. The patency system of claim 7 wherein:
said at least one protrusion includes at least a hemispherical configuration.
- 5 9. The patency system of claim 7 wherein:
said at least one protrusion includes a plurality of protrusions separated by
flexible segments.
10. The patency system of claim 1 wherein:
10 said at least one cleaner includes at least strand.
11. The patency system of claim 1 further comprising:
at least one balloon.
- 15 12. The patency system of claim 11 wherein:
said at least one balloon, when expanded, is configured to generally prevent
dislodged debris from exiting said medical device.
13. The patency system of claim 11 wherein:
20 said at least one balloon is positioned at an end of said elongated shaft.
14. The patency system of claim 13 wherein:
said elongated shaft defines at least one lumen configured to supply an
inflation fluid to said balloon.
- 25 15. The patency system of claim 11 wherein:
said elongated shaft defines at least one lumen and wherein said balloon
includes an inflation lumen configured to be at least partially disposed within said
lumen of said elongated shaft, said inflation lumen configured to supply an inflation
30 fluid to said balloon.
16. The patency system of claim 15 wherein:

at least a portion of said balloon is configured to be moveably disposed within said lumen.

17. The patency system of claim 1 wherein:

5 said elongated shaft defines at least one flushing lumen having at least one flushing port configured to supply a flushing fluid within said medical device.

18. The patency system of claim 1 wherein:

10 said elongated shaft defines at least one vacuum lumen and at least one vacuum port configured to receive dislodged debris from within said medical device.

19. The patency system of claim 1 wherein:

said cleaner includes at least one fluid aperture configured to provide a fluid to dislodge debris from said medical device.

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20. The patency system of claim 1 further comprising:

at least one coupler configured to supply a source of fluid to at least one lumen of said elongated shaft.

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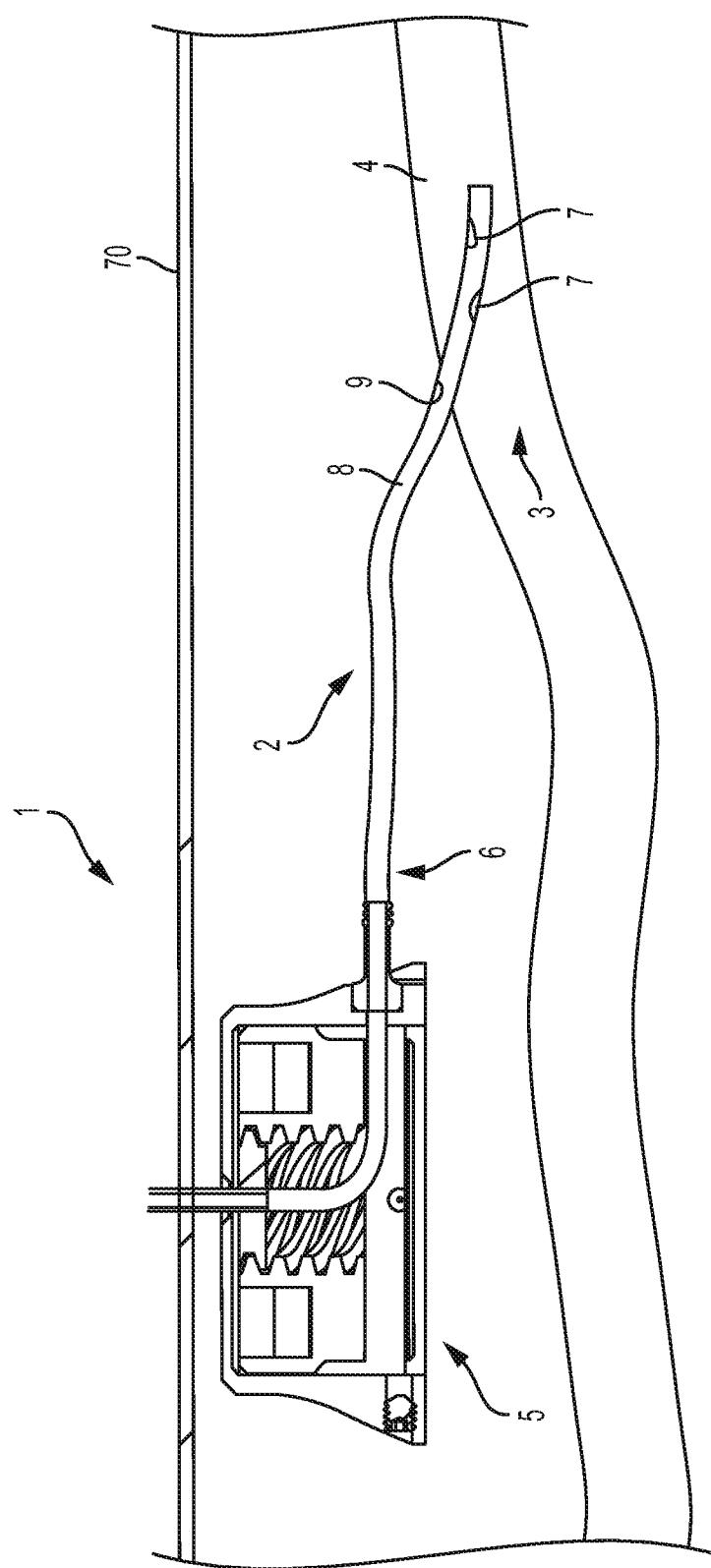
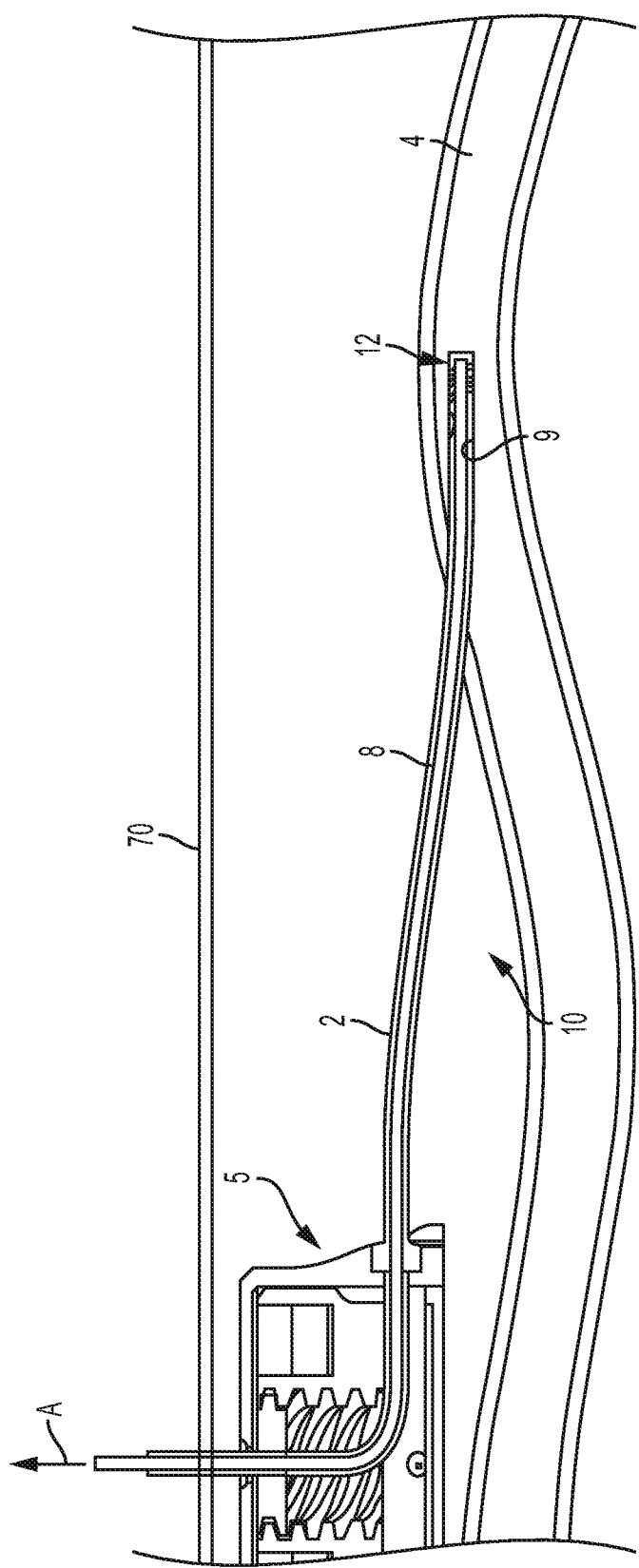
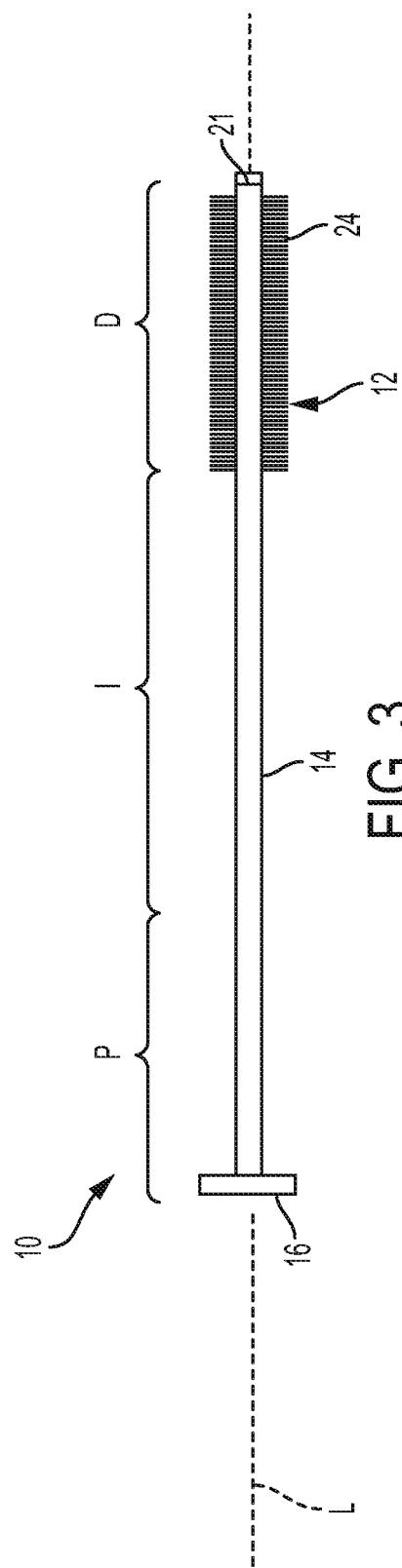


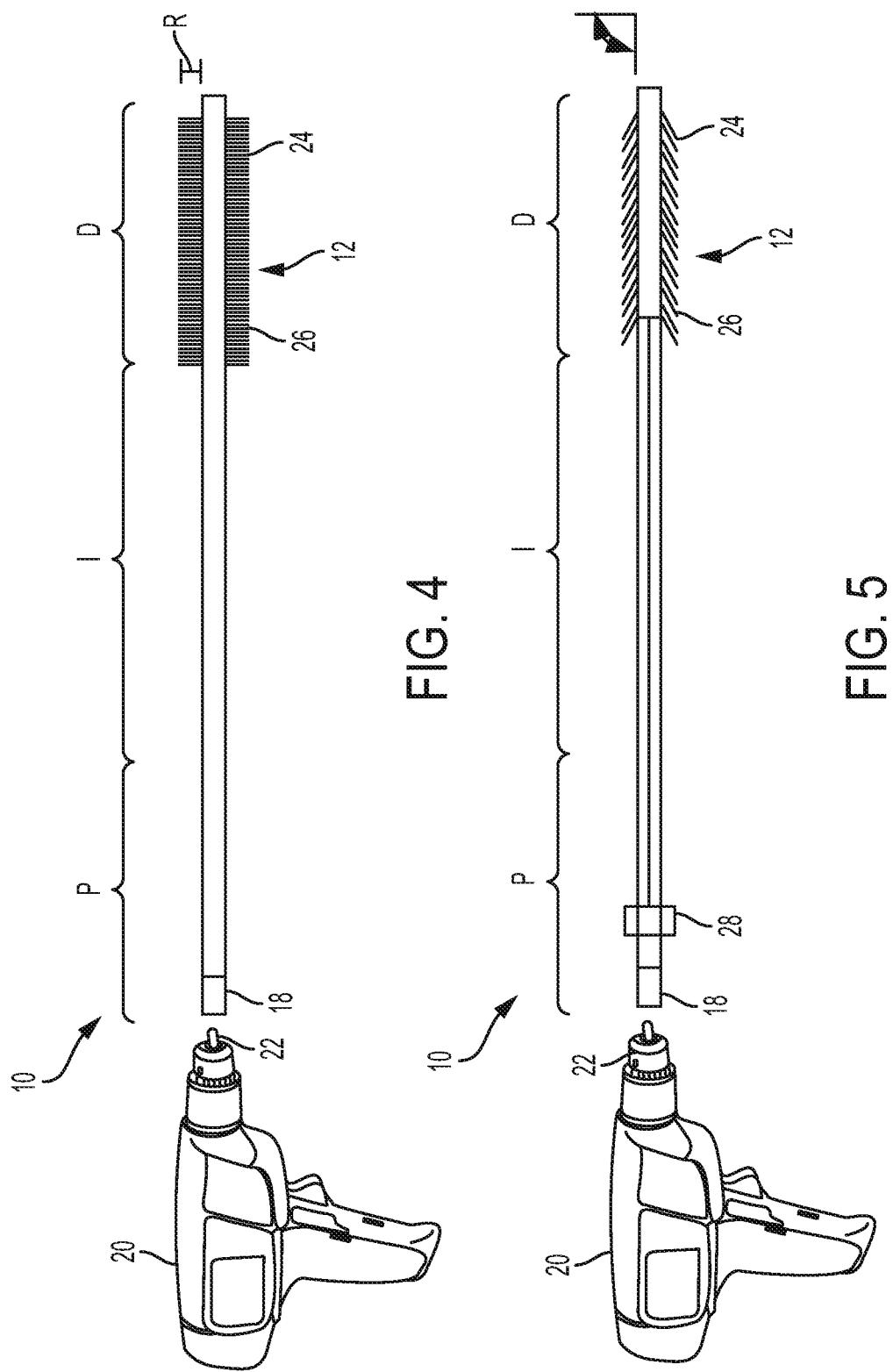
FIG. 1



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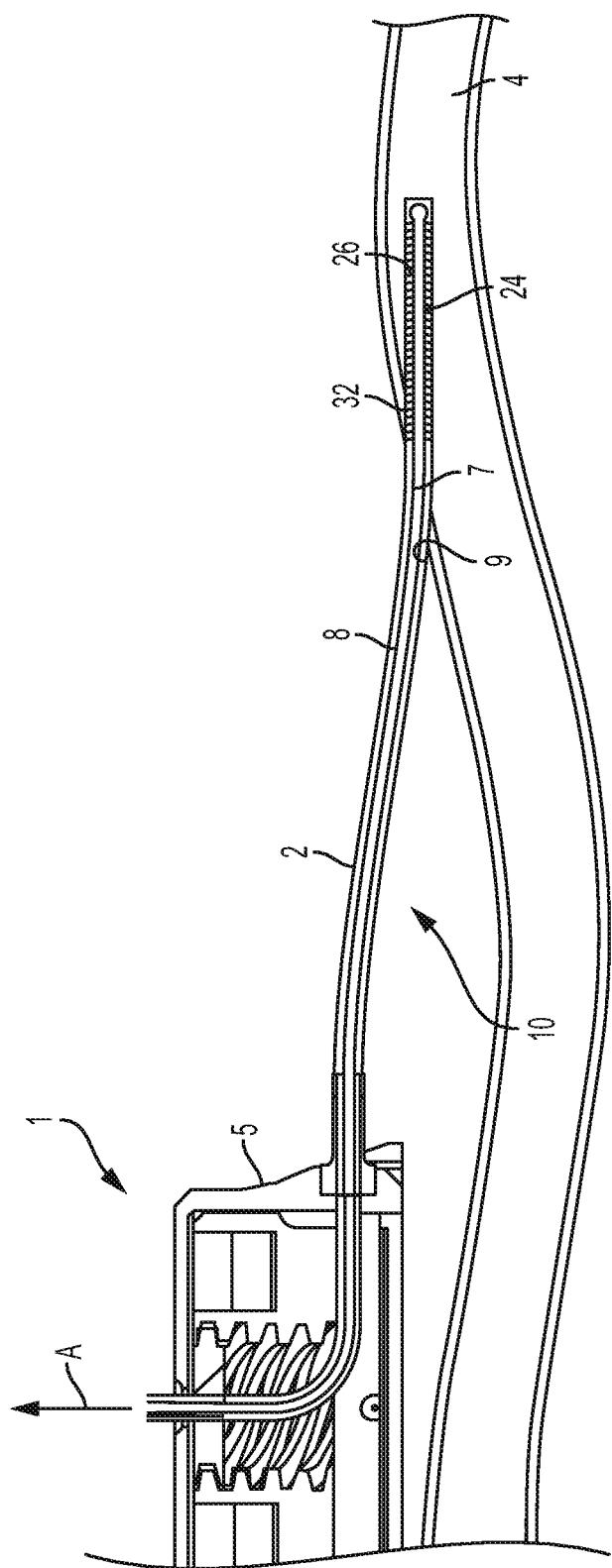


FIG. 6

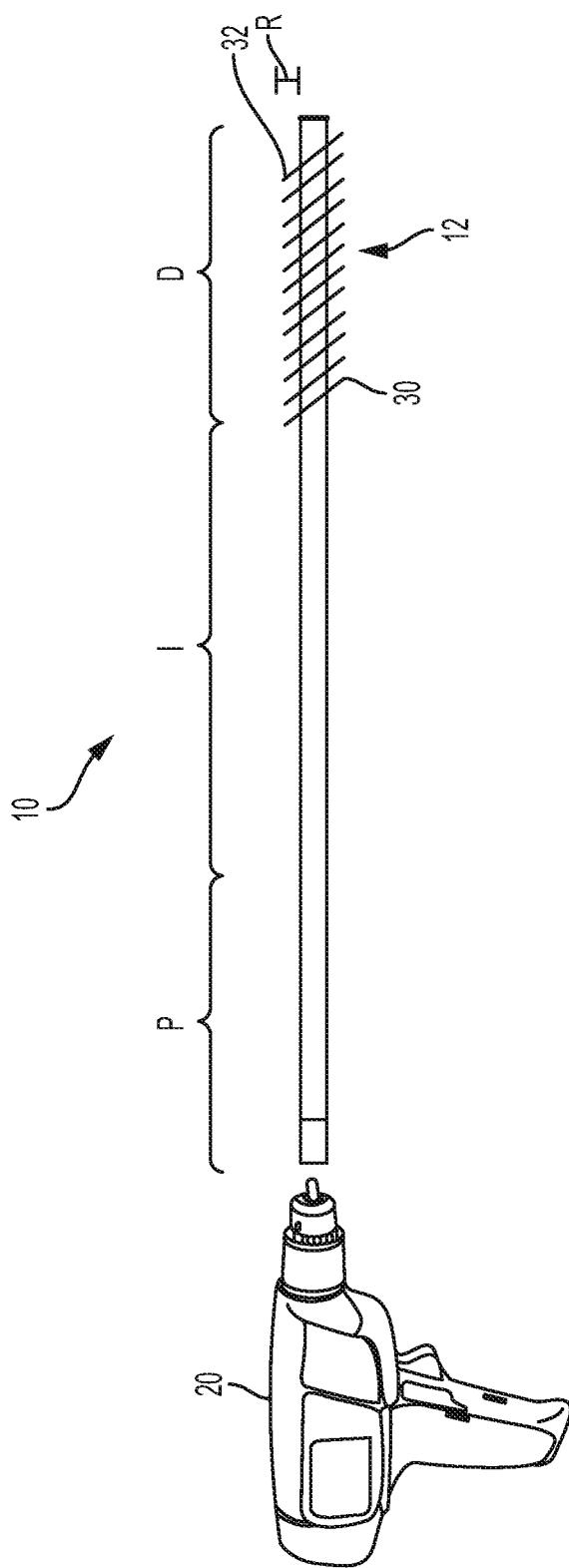


FIG. 7

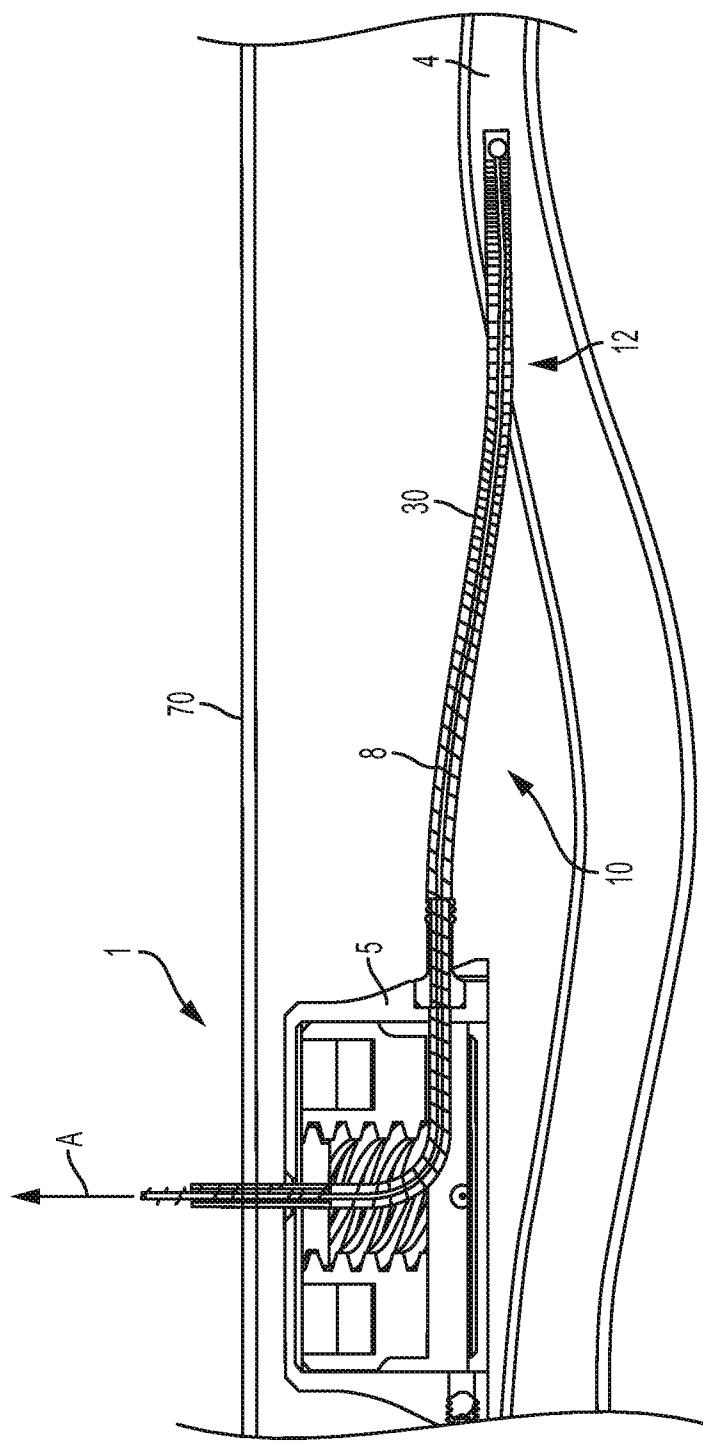


FIG. 8

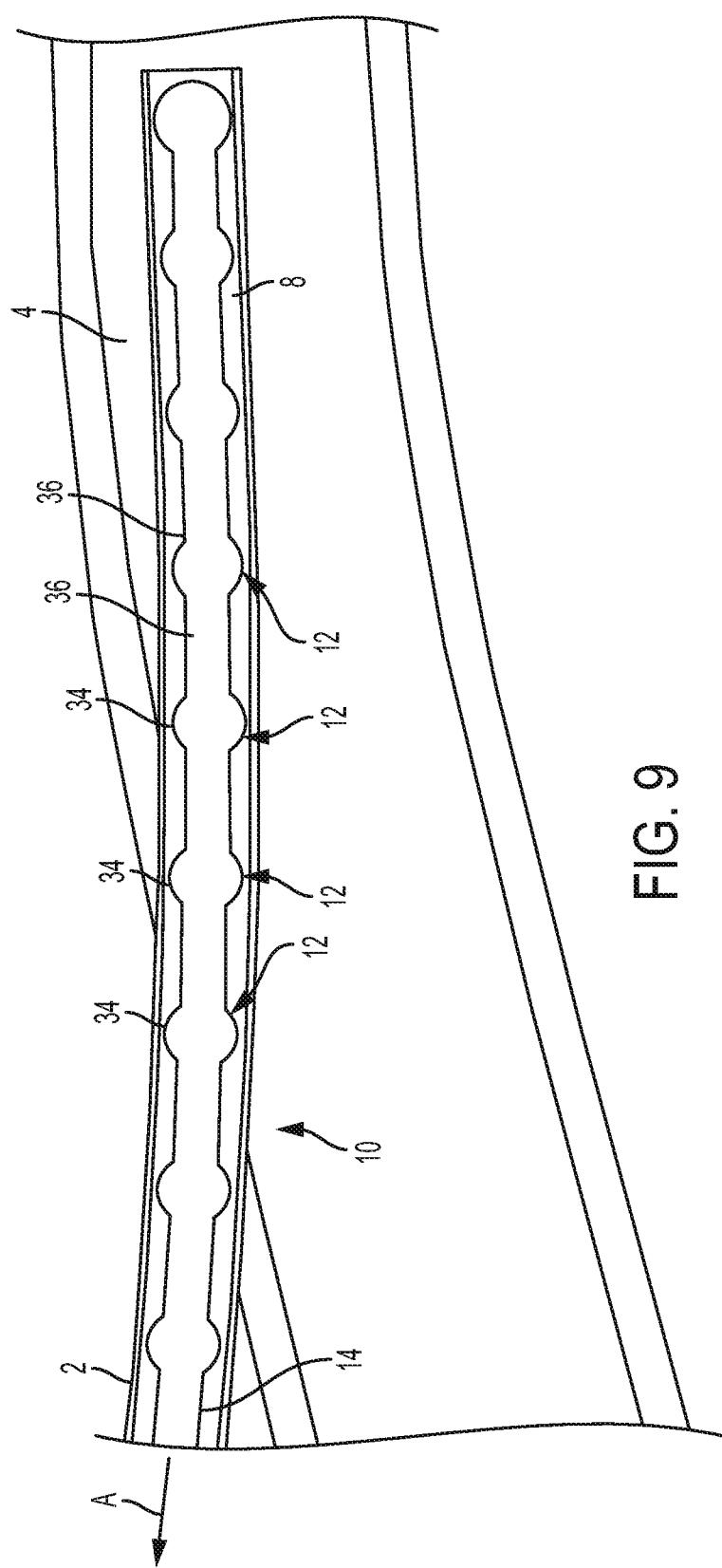


FIG. 9

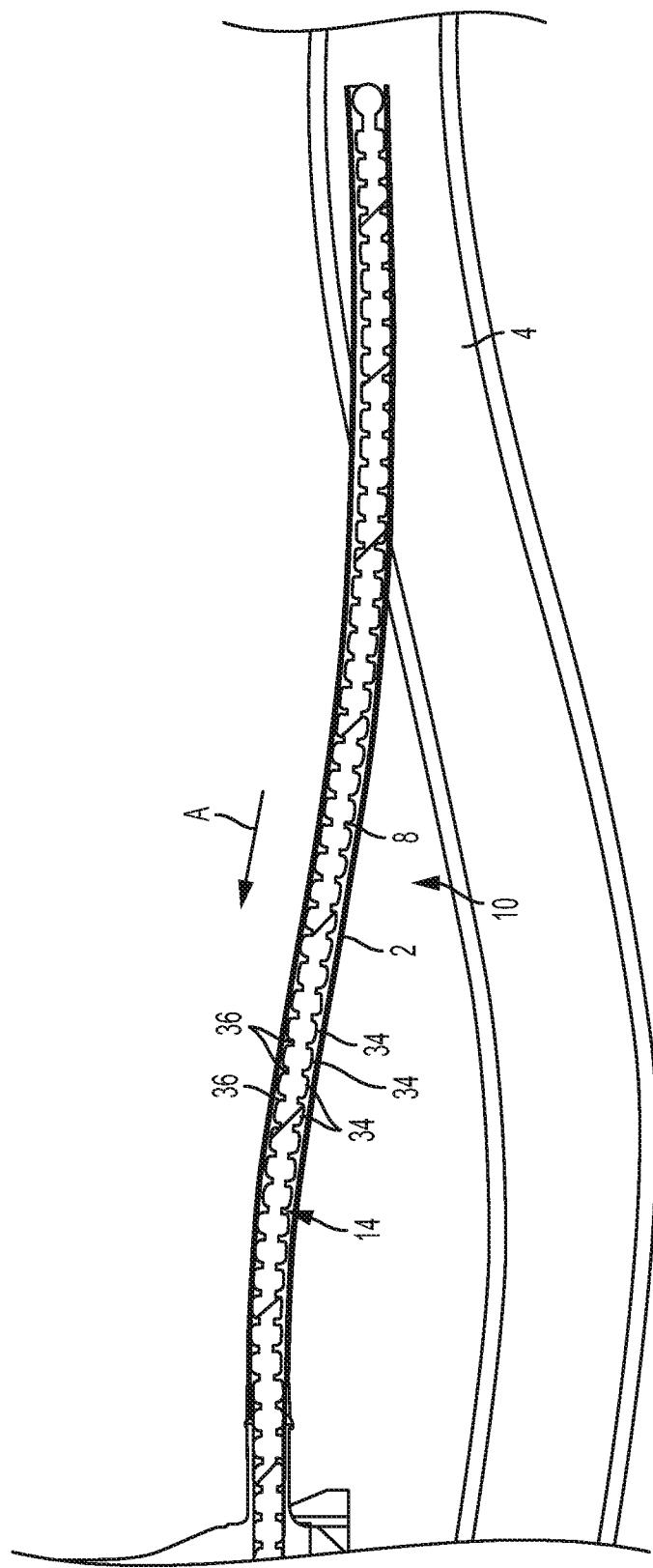


FIG. 10

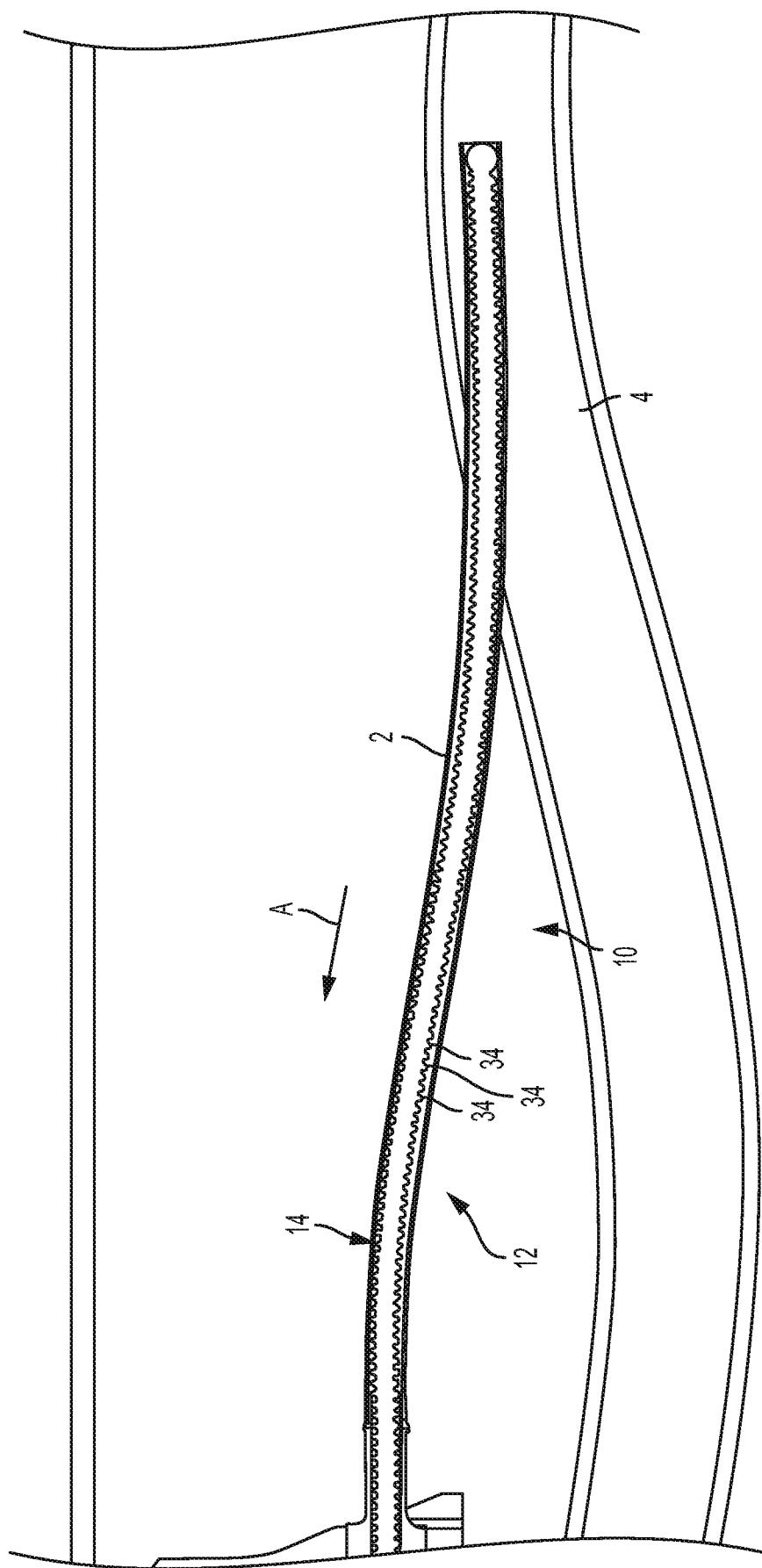


FIG. 11

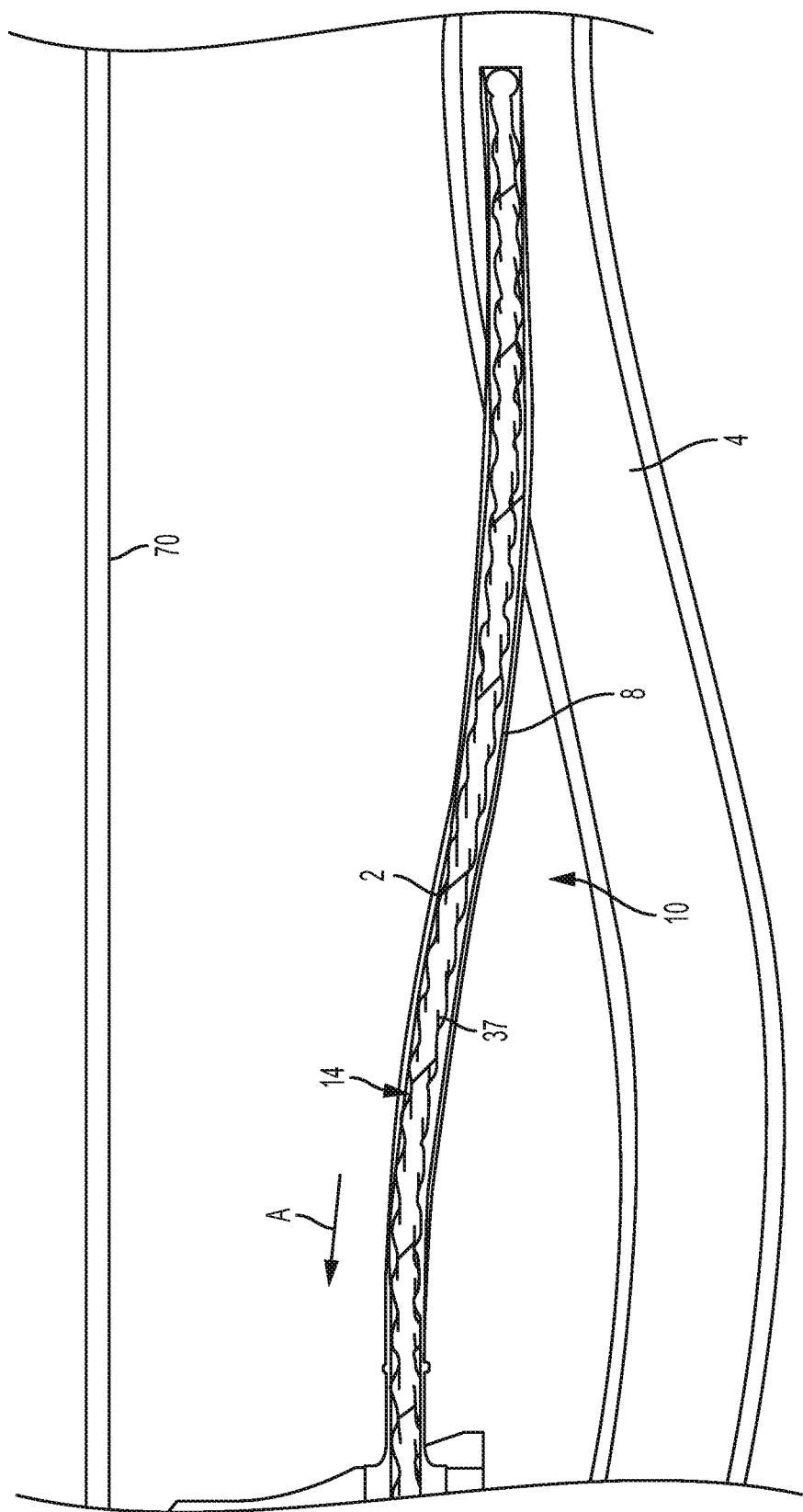


FIG. 12

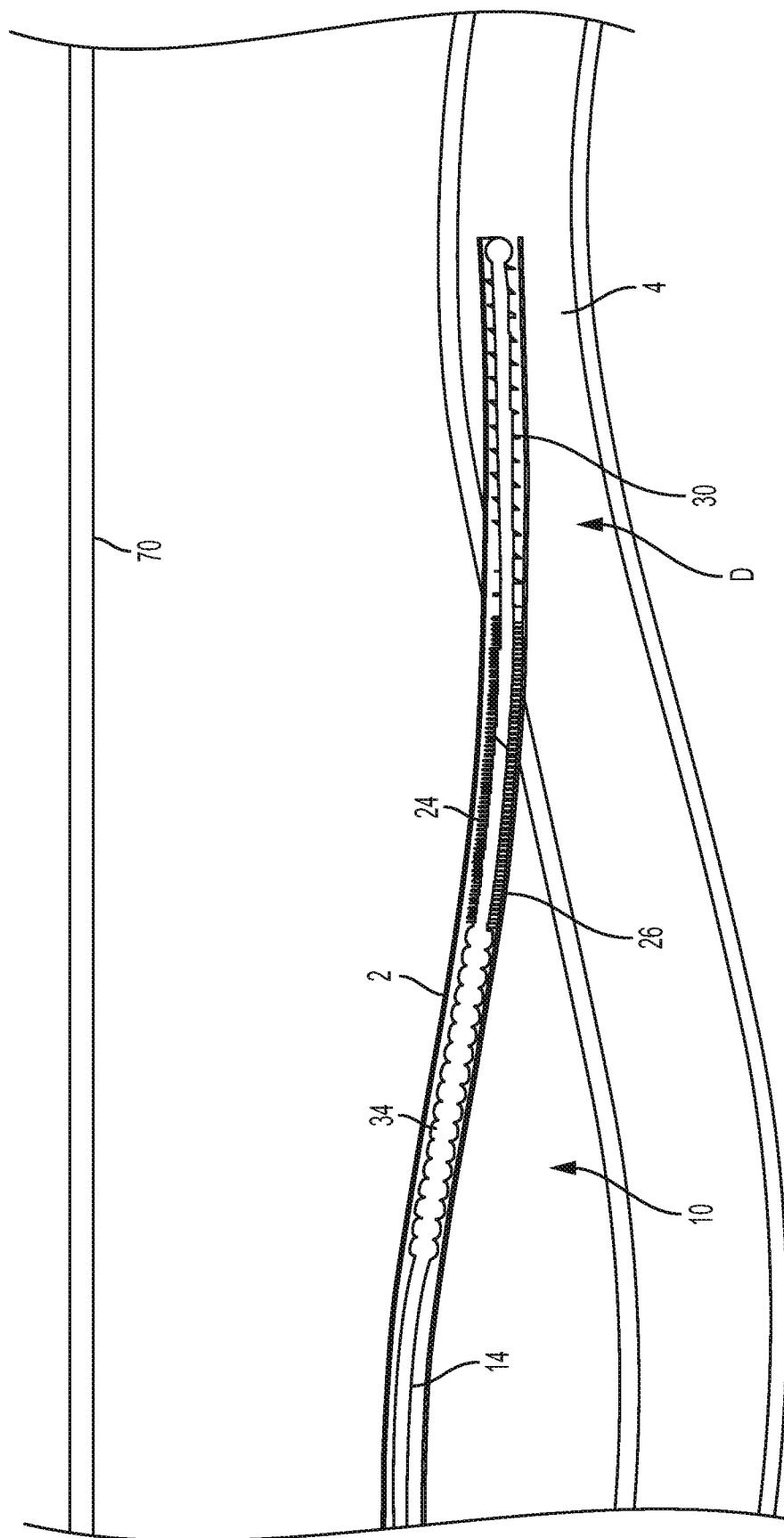


FIG. 13

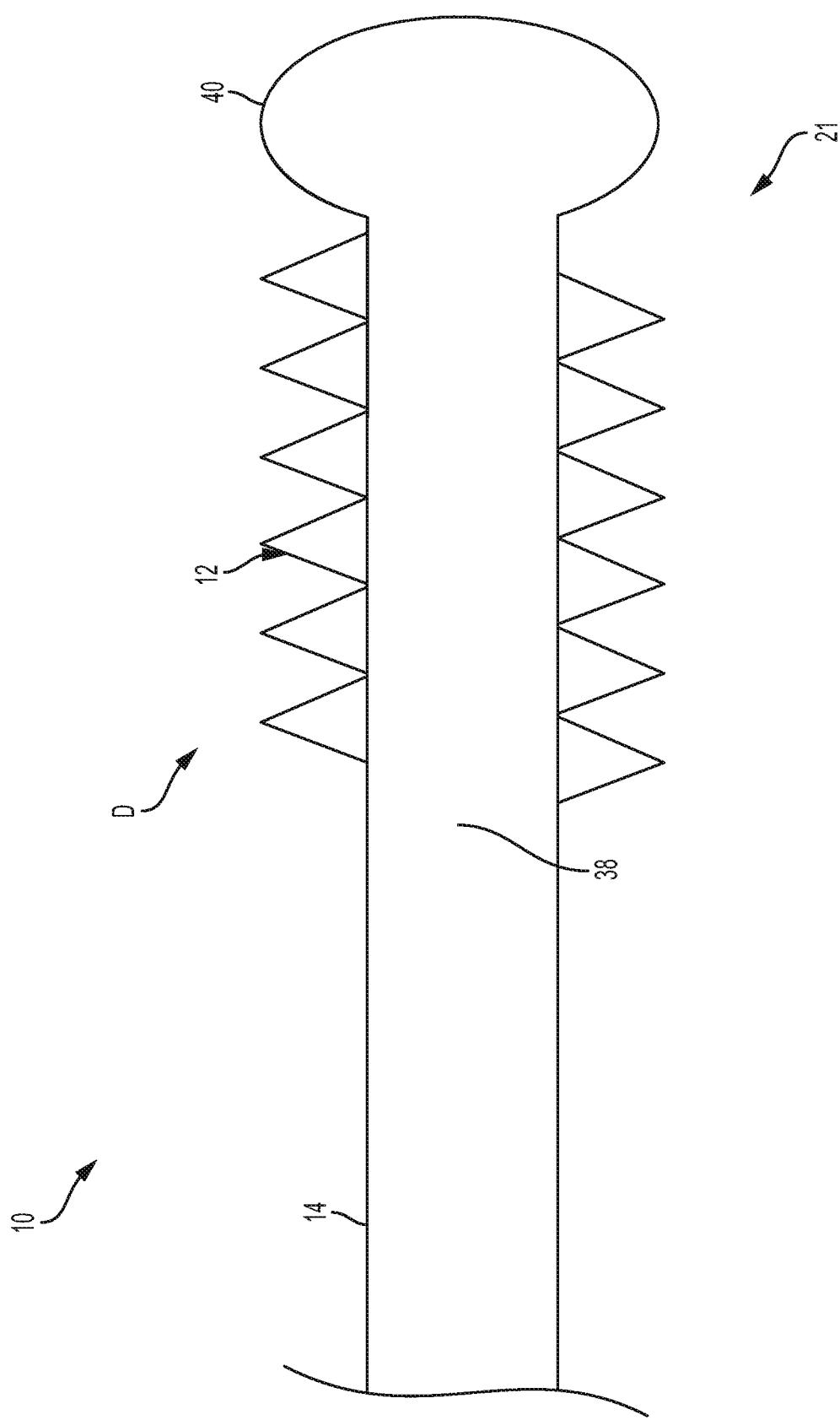


FIG. 14

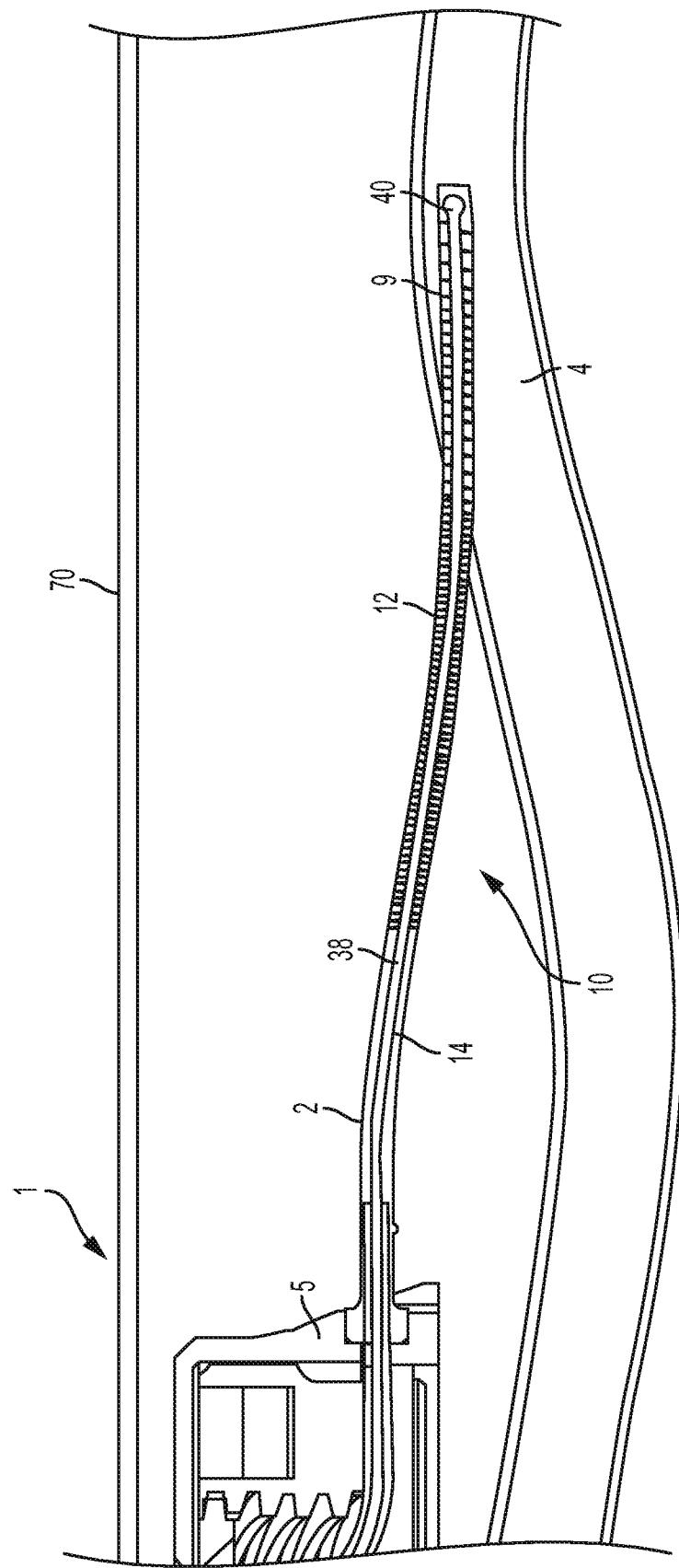


FIG. 15

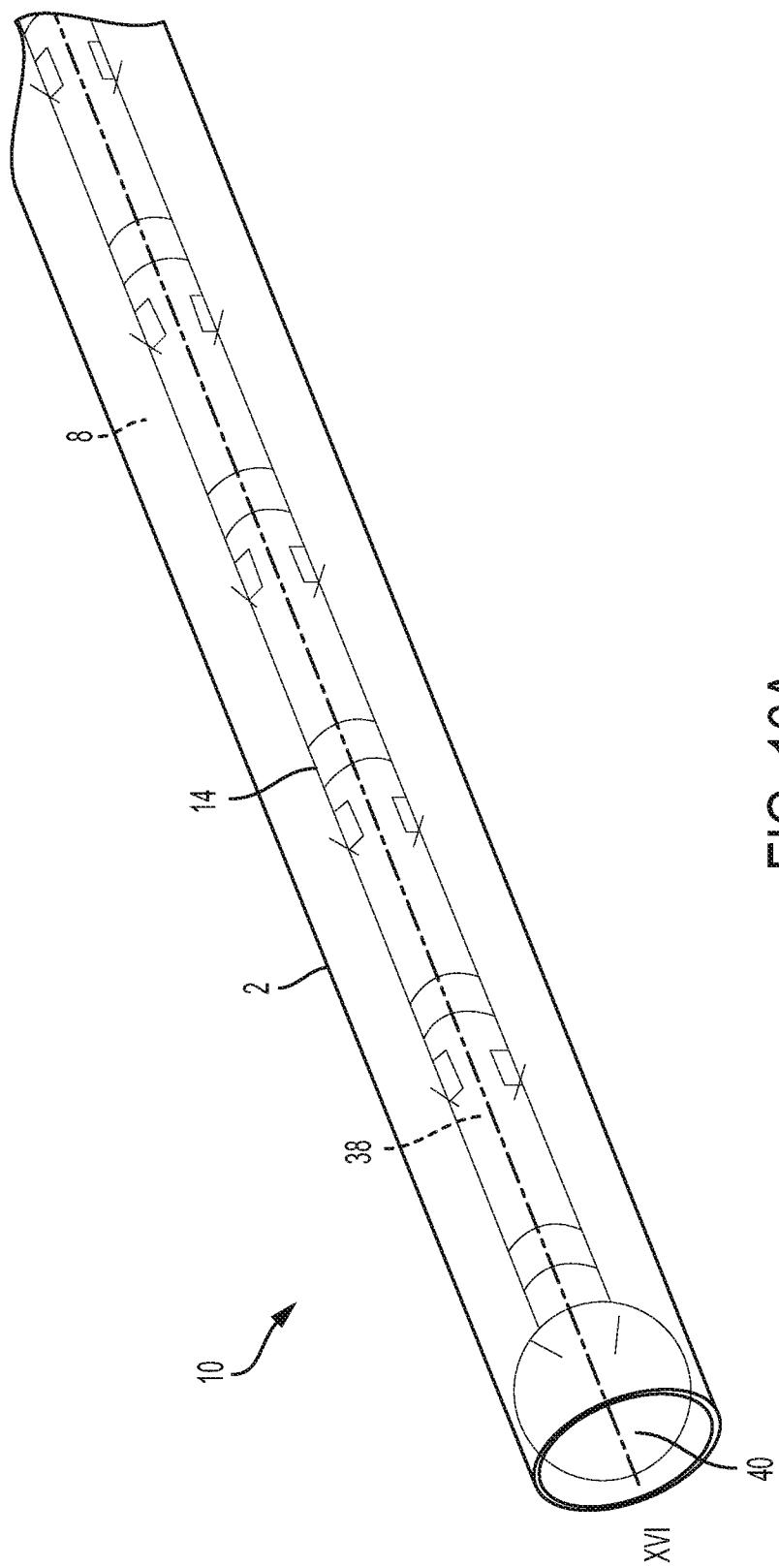


FIG. 16A

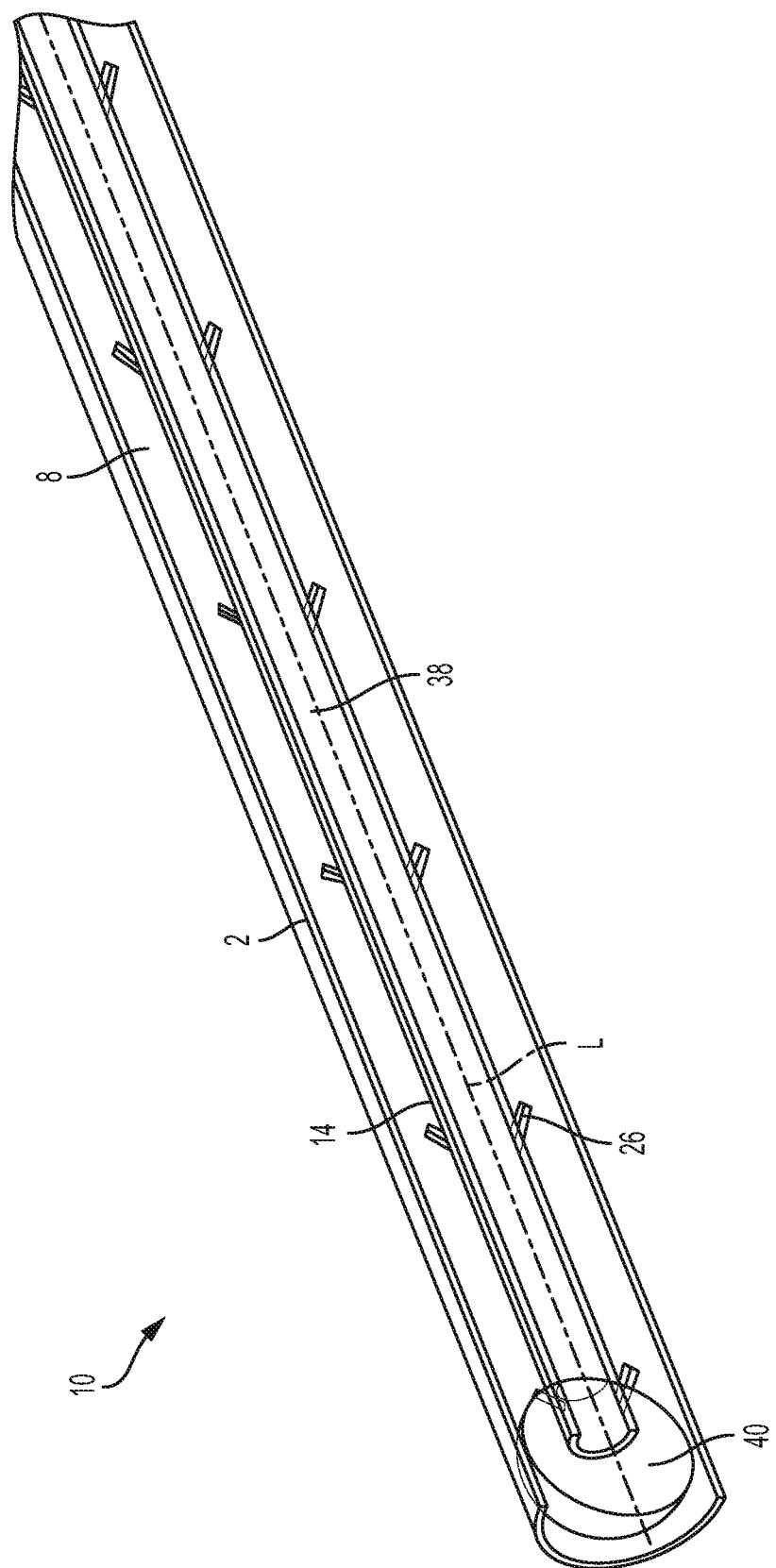


FIG. 16B

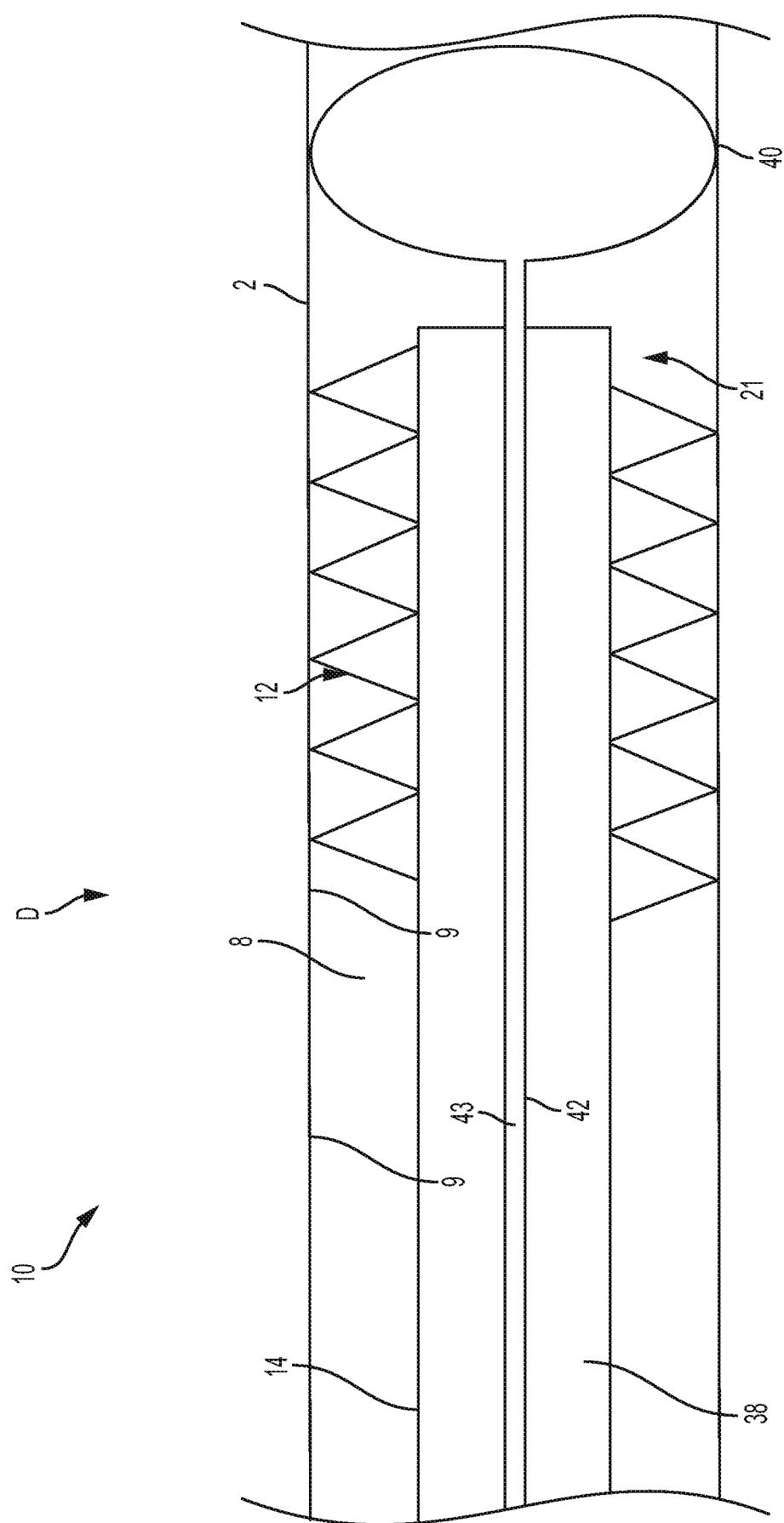
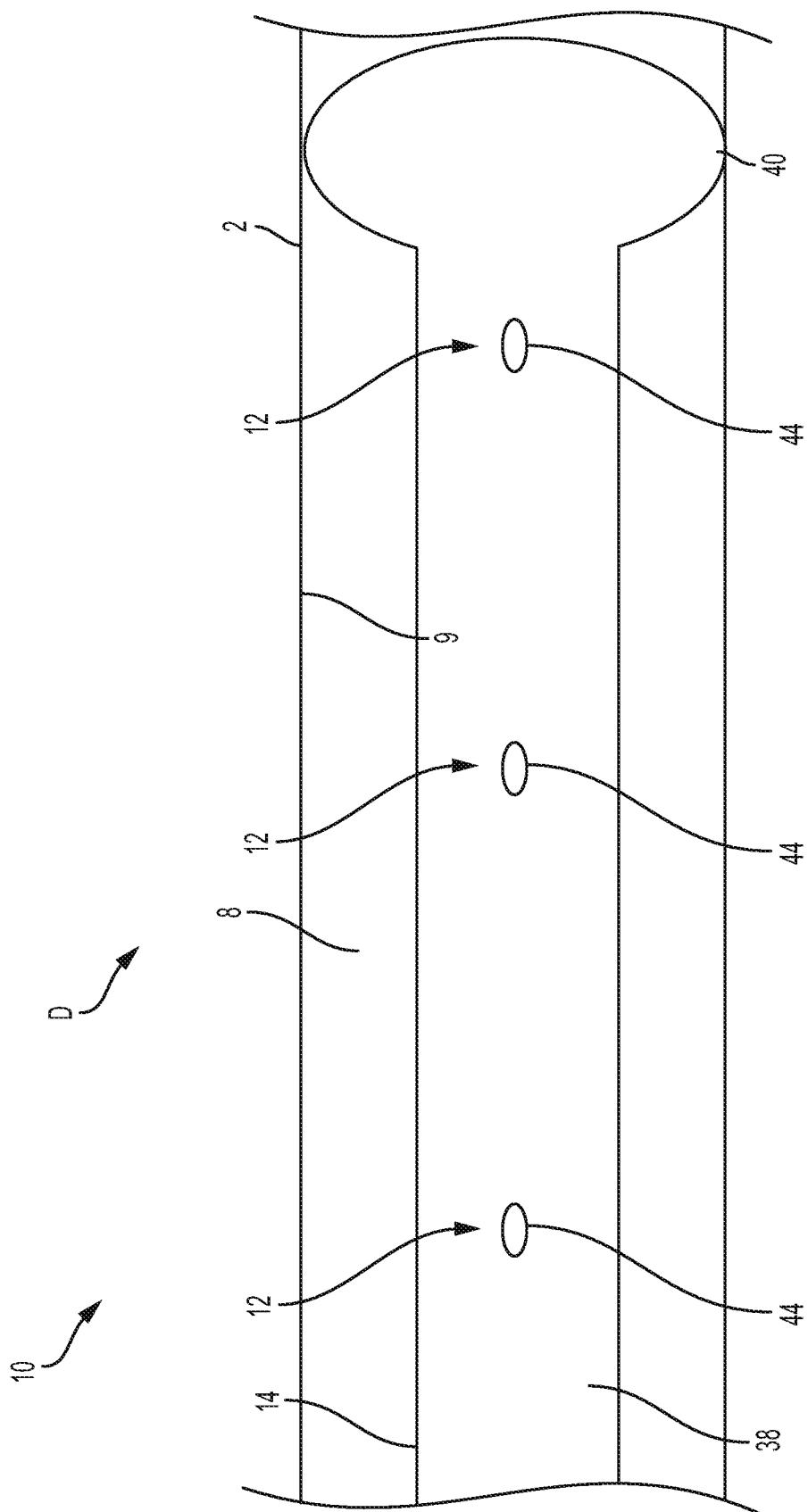


FIG. 17



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EIG.

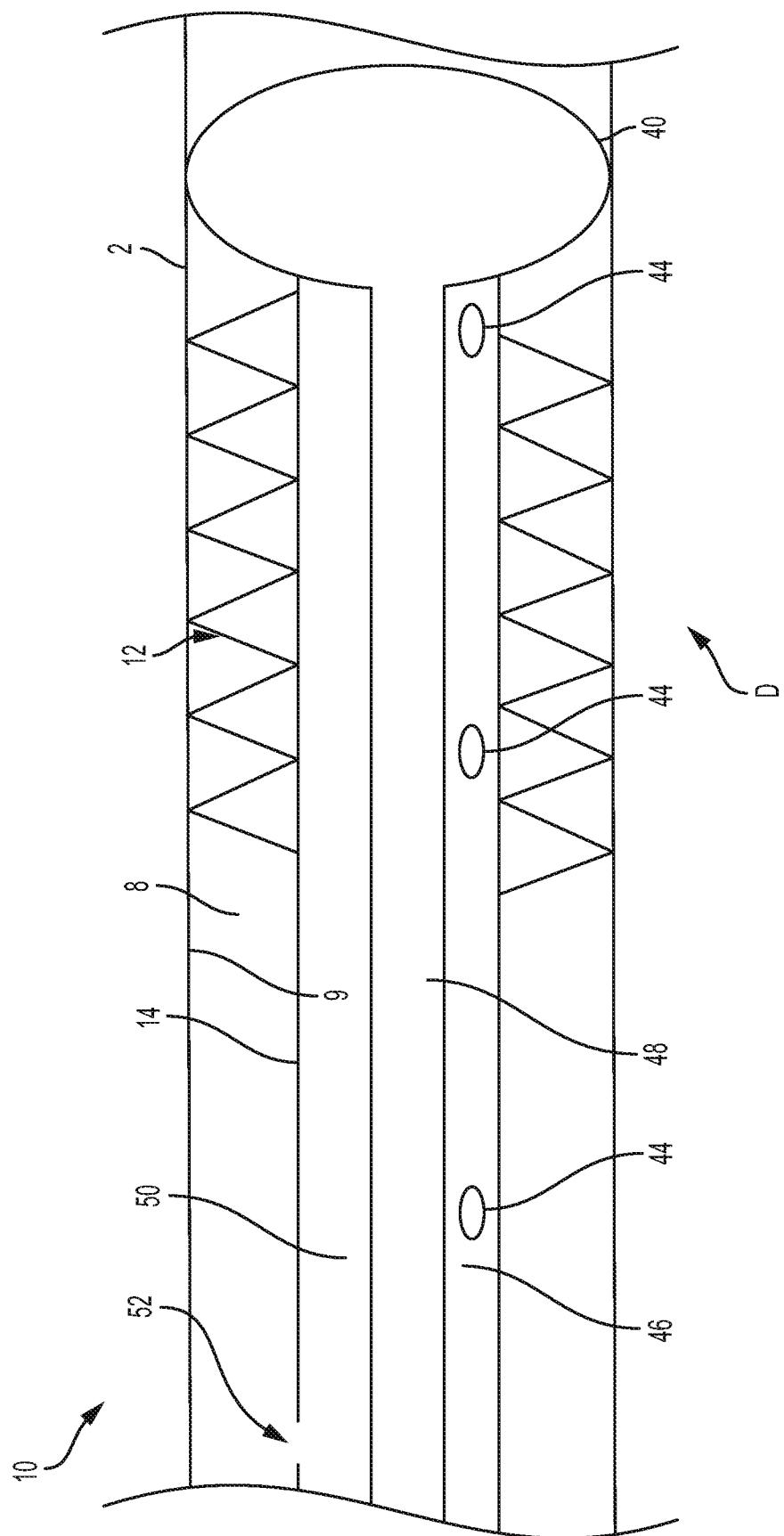


FIG. 19

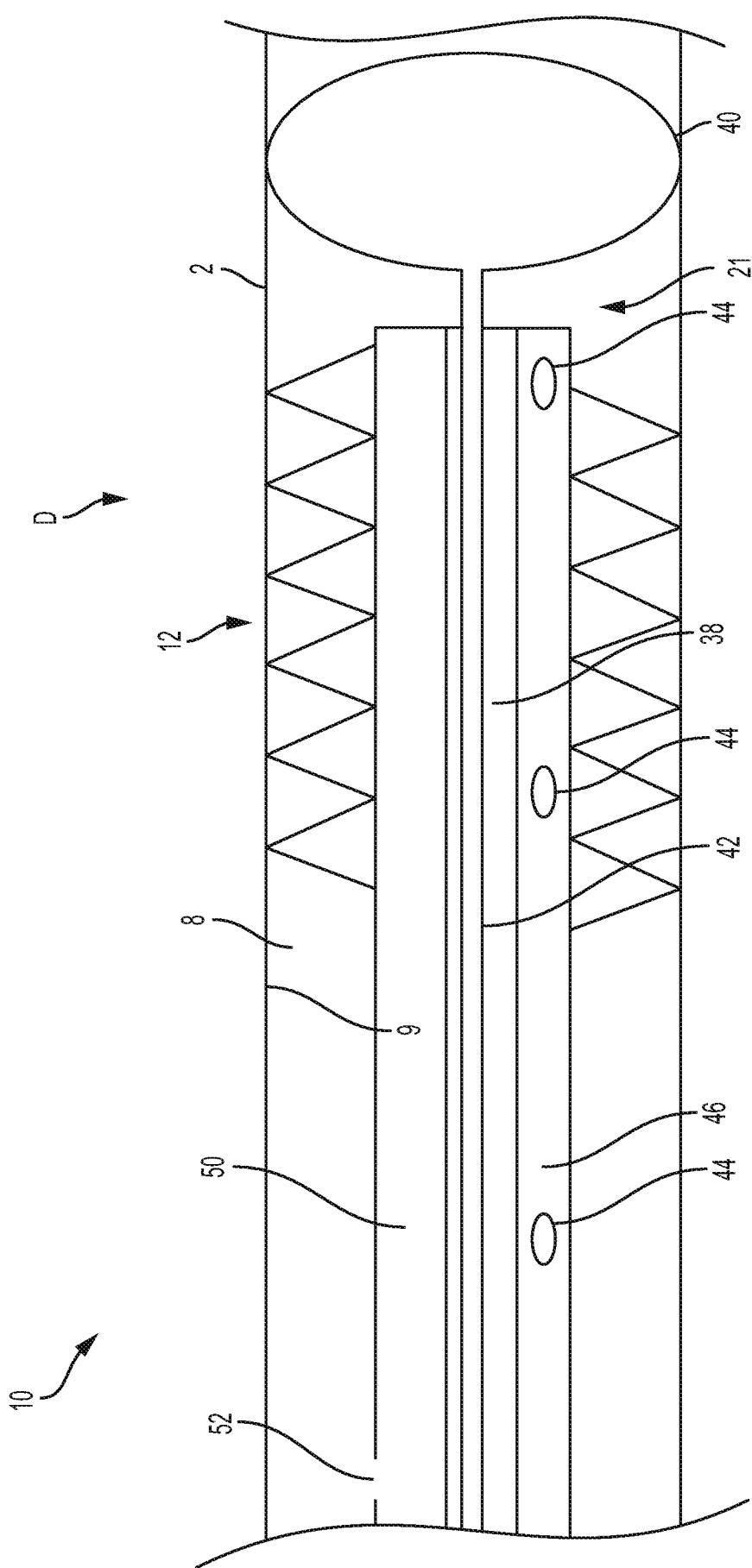


FIG. 20

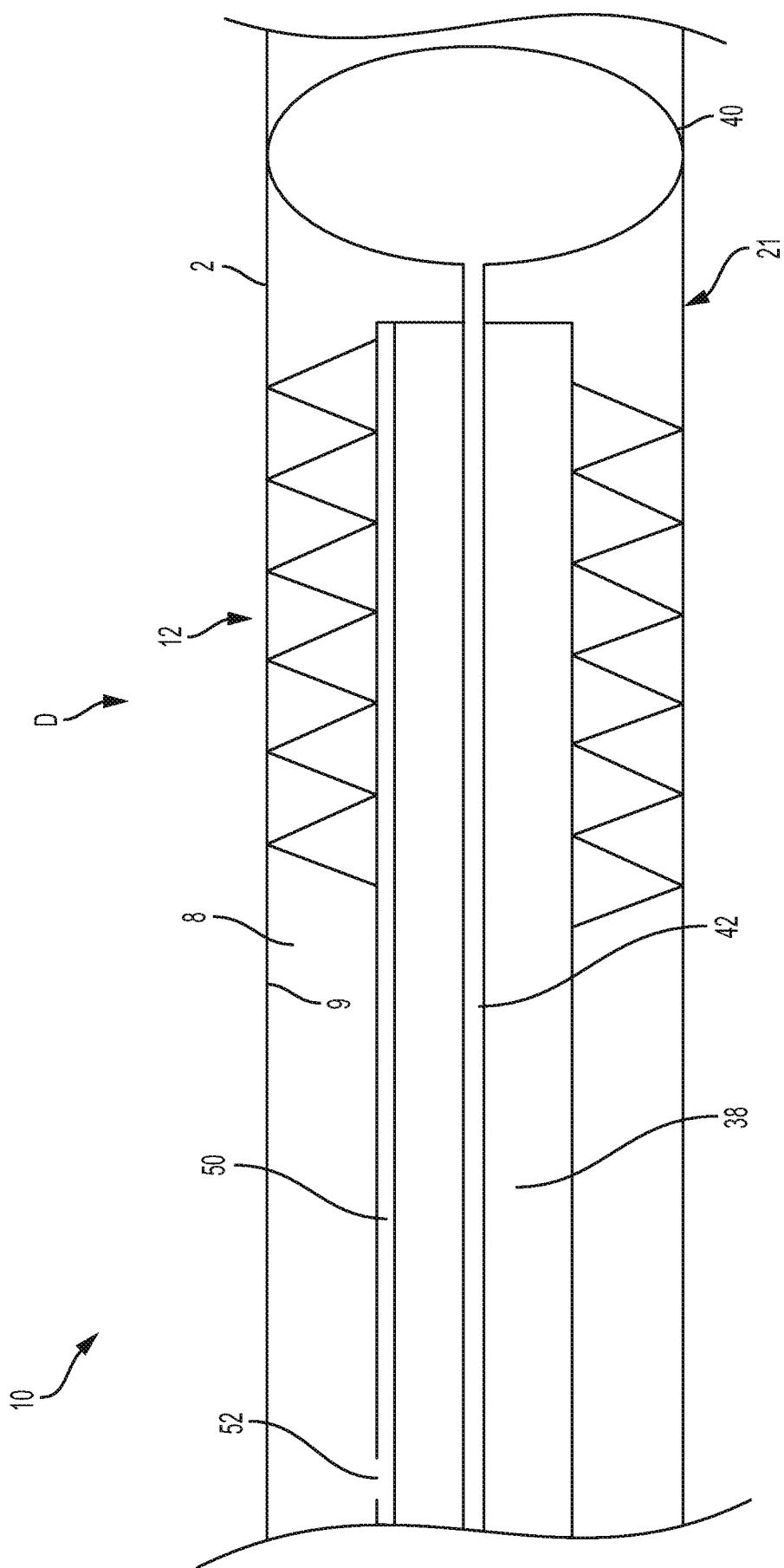


FIG. 21

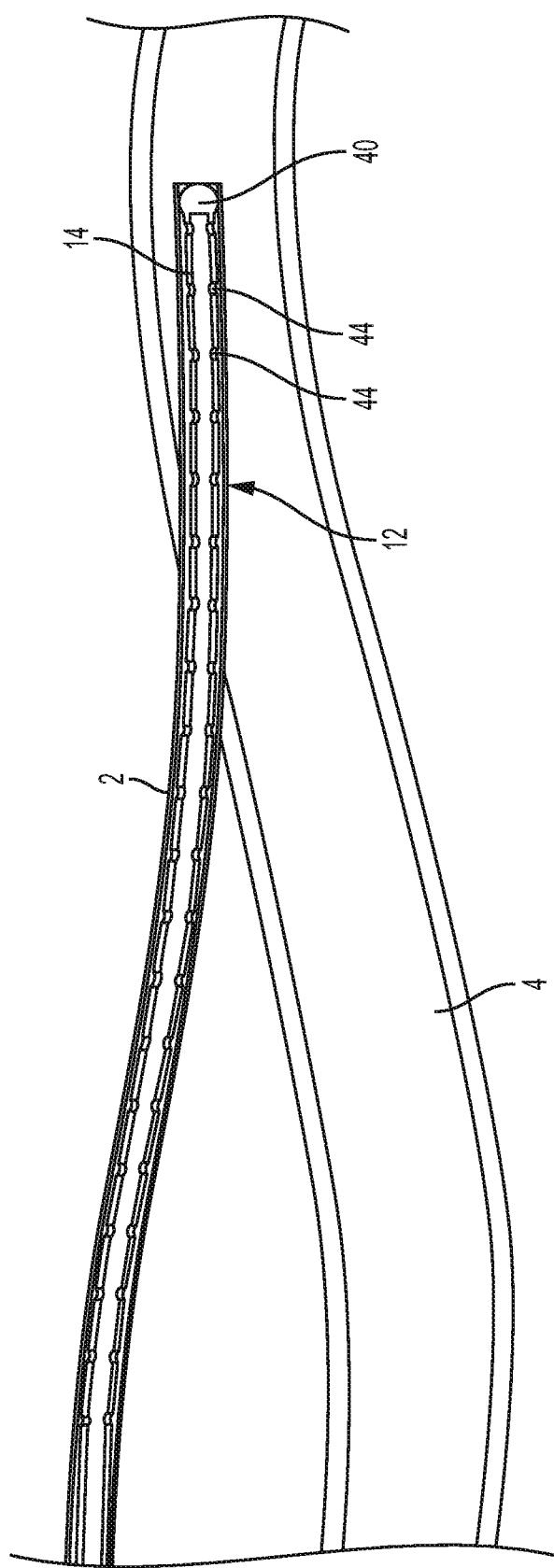


FIG. 22

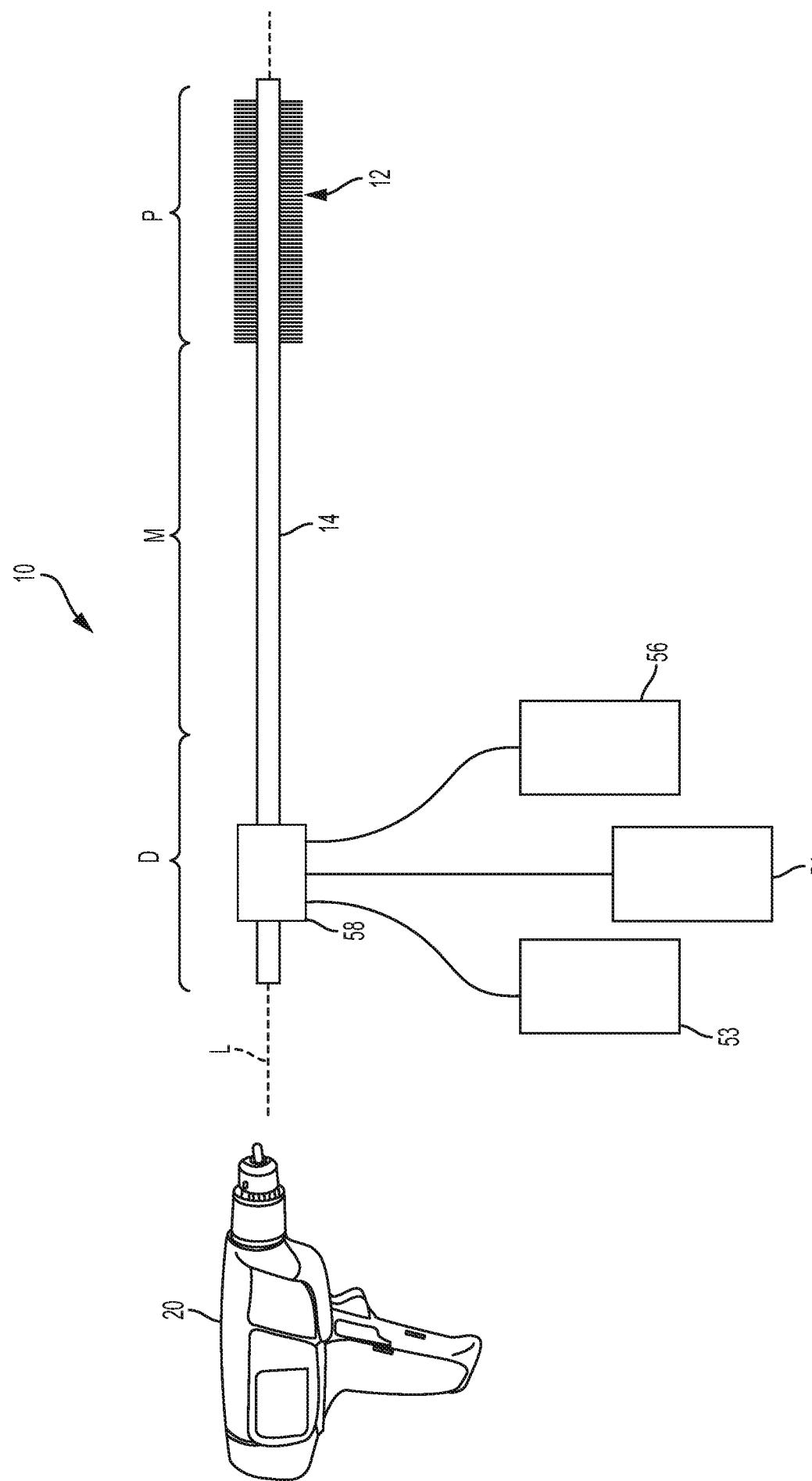
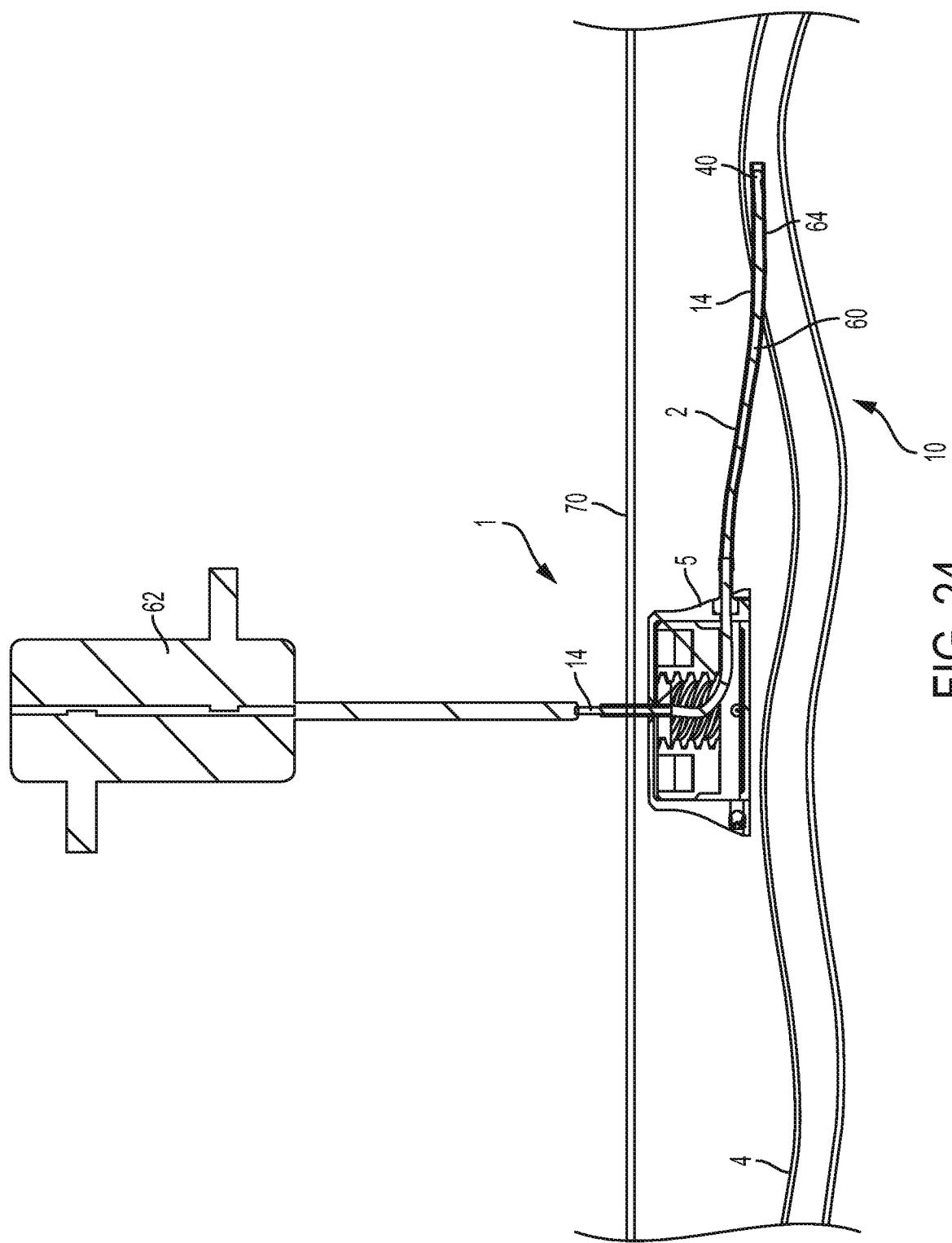


FIG. 23



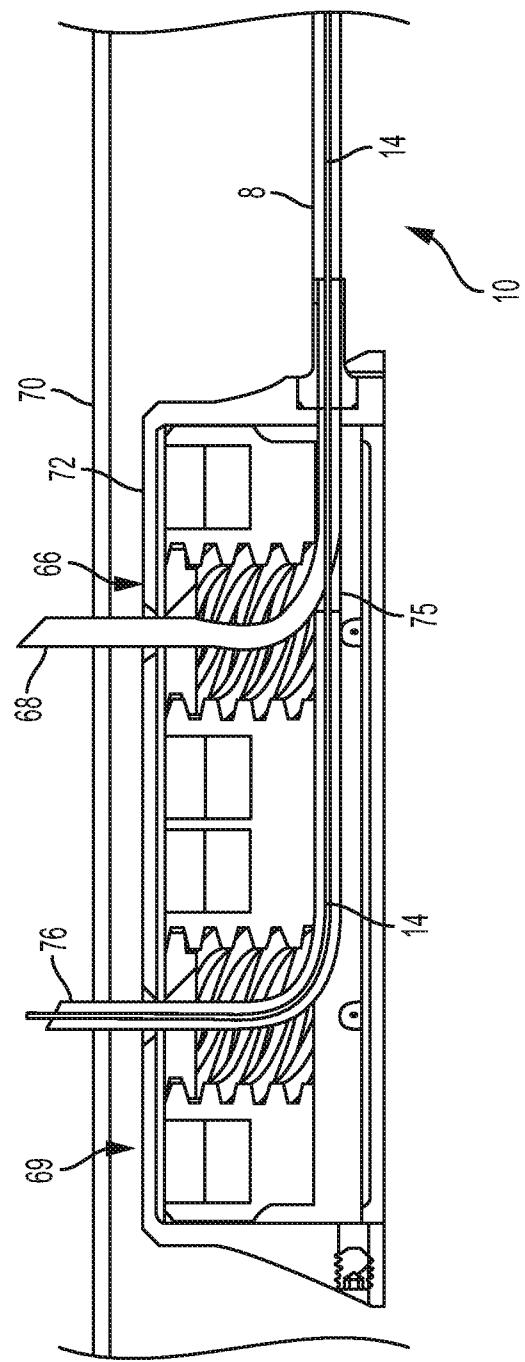


FIG. 25

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2015/066778

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 25/00 (2016.01)

CPC - A61M 2025/0019 (2016.01)

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)

IPC(8) - A61B 17/22; A61M 25/00; B08B 9/02, 9/027, 9/04 (2016.01) (2016.01)

CPC - A61B 1/122; A61M 2025/0019; B08B 9/0436 (2016.01) (2016.01)

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

USPC: 15/104.16, 104.18, 104.2, 159.1; 604/267 (keyword delimited)

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

Orbit, Google Patents, Google Scholar.

Search terms used: cleaner, brush, patency, debris, occlusion, blockage, catheter, stent, bristles, holes, balloons, vacuum ports, fluid port

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/0109837 A1 (MCBRIDE-SAKAL) 12 June 2003 (12.06.2003) entire document	1-3, 7-10, 17-20
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Y		4-6, 11-16
Y	US 6,030,397 A (MONETTI et al) 29 February 2000 (29.02.2000) entire document	4, 5
Y	US 4,228,802 A (TROTT) 21 October 1980 (21.10.1980) entire document	6
Y	US 5,702,413 A (LAFONTAINE) 30 December 1997 (30.12.1997) entire document	11-16

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:

“A” document defining the general state of the art which is not considered to be of particular relevance
 “E” earlier application or patent but published on or after the international filing date
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 “O” document referring to an oral disclosure, use, exhibition or other means
 “P” document published prior to the international filing date but later than the priority date claimed

“T” later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

“X” document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

“Y” document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

“&” document member of the same patent family

Date of the actual completion of the international search

12 February 2016

Date of mailing of the international search report

07 MAR 2016

Name and mailing address of the ISA/

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