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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 May 2016 (12.05.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/073912 A1

(51) International Patent Classification:
A61B 90/00 (2016.01) *A61B 17/00* (2006.01)
A61B 10/00 (2006.01)

(21) International Application Number:
PCT/US2015/059563

(22) International Filing Date:
6 November 2015 (06.11.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
14/534,952 6 November 2014 (06.11.2014) US
62/134,715 18 March 2015 (18.03.2015) 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))*

[Continued on next page]

(54) Title: SPRING-EJECTED BIOPSY MARKER

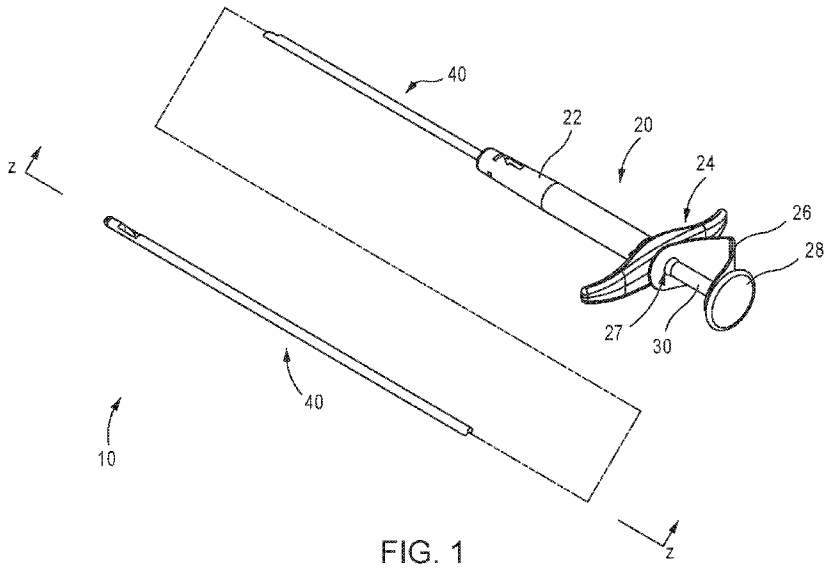

FIG. 1

(57) Abstract: A device for inserting a marker into tissue at a biopsy site including an elongate shaft that moves conjointly with a plunger, and a spring secured to the distal end of the shaft. The device may comprise a cannula configured to receive a distal end of the shaft, and with a crimp, dimples, or other features formed near the shaft's distal end. The cannula may comprise a lateral aperture where a marker may be ejected from the lumen thereof. A ramp portion may be formed in communication with the lateral aperture, and the ramp portion may comprise a preselected slope that controls the angle at which the marker is ejected.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

SPRING-EJECTED BIOPSY MARKER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Patent Application No. 14/534,952, entitled "SPRING-EJECTED BIOPSY MARKER," filed on November 6, 2014, and U.S. Provisional Patent Application No. 62/134,715, entitled "Biopsy Marker Delivery Device," filed on March 18, 2015, both of which are expressly incorporated by reference herein in their entirety.

TECHNICAL FIELD

[0002] This invention relates, generally, to devices that insert biopsy markers at biopsy sites. More particularly, it relates to a device that employs a spring to eject a marker into tissue from a lateral aperture of the device.

BACKGROUND

[0003] Biopsy samples have been obtained in a variety of ways in various medical procedures using a variety of devices. Biopsy devices may be used under stereotactic guidance, ultrasound guidance, Magnetic Resonance Imaging (MRI) guidance, Positron Emission Mammography (PEM) guidance, Breast Specific Gamma Imaging (BSGI) guidance, or otherwise. For instance, some biopsy devices may be fully operable by a user using a single hand, and with a single insertion, to capture one or more biopsy samples from a patient. In addition, some biopsy devices may be tethered to a vacuum module and/or control module, such as for communication of fluids (e.g., pressurized air, saline, atmospheric air, vacuum), for communication of power, and/or for communication of commands and the like. Other biopsy devices may be fully or at least partially operable without being tethered or otherwise connected with another device.

[0004] Merely example biopsy devices and biopsy system components are disclosed in U.S. Pat. No. 5,526,822, entitled "Method and Apparatus for Automated Biopsy and Collection of Soft Tissue," issued June 18, 1996; U.S. Pat. No. 5,928,164, entitled "Apparatus for Automated Biopsy and Collection of Soft Tissue," issued July 27, 1999; U.S. Pat. No. 6,017,316, entitled "Vacuum Control System and Method for Automated Biopsy Device," issued January 25, 2000; U.S. Pat. No. 6,086,544, entitled "Control Apparatus for an Automated Surgical Biopsy Device," issued July 11, 2000; U.S. Pat. No. 6,626,849, entitled "MRI Compatible Surgical Biopsy Device," issued September 11, 2003; U.S. Pat. No.

7,442,171, entitled "Remote Thumbwheel for a Surgical Biopsy Device," issued October 8, 2008; U.S. Pat. No. 7,648,466, entitled "Manually Rotatable Piercer," issued January 19, 2010; U.S. Pat. No. 7,854,706, entitled "Clutch and Valving System for Tetherless Biopsy Device," issued December 1, 2010; U.S. Pat. No. 7,938,786, entitled "Vacuum Timing Algorithm for Biopsy Device," issued May 10, 2011; U.S. Pat. No. 8,118,755, entitled "Biopsy Sample Storage," issued February 21, 2012; U.S. Pat. No. 8,206,316, entitled "Tetherless Biopsy Device with Reusable Portion," issued June 26, 2012; U.S. Pat. No. 8,241,226, entitled "Biopsy Device with Rotatable Tissue Sample Holder," issued August 14, 2011; and U.S. Pat. No. 8,702,623, entitled "Biopsy Device with Discrete Tissue Chambers," issued April 22, 2014. The disclosure of each of the above-cited U.S. Patents is incorporated by reference herein.

[0005] Additional example biopsy devices and biopsy system components are disclosed in U.S. Pat. Pub. No. 2008/0146962, entitled "Biopsy System with Vacuum Control Module," published June 19, 2008; U.S. Pat. Pub. No. 2008/0214955, entitled "Presentation of Biopsy Sample by Biopsy Device," published September 4, 2008; U.S. Pub. No. 2013/0041256, entitled "Access Chamber and Markers for Biopsy Device," published February 14, 2013; U.S. Pub. No. 2013/0053724, entitled "Biopsy Device Tissue Sample Holder with Bulk Chamber and Pathology Chamber," published February 28, 2013; U.S. Pub. No. 2013/0150751, entitled "Biopsy Device with Slide-In Probe," published June 13, 2013; U.S. Pub. No. 2013/0324882, entitled "Control for Biopsy Device," published December 5, 2013; and U.S. Pub. No. 2014/0039343, entitled "Biopsy System," published February 6, 2014. The disclosure of each of the above-cited U.S. Patent Application Publications is incorporated by reference herein.

[0006] In some settings, it may be desirable to mark the location of a biopsy site for future reference. For instance, one or more markers may be deposited at a biopsy site before, during, or after a tissue sample is taken from the biopsy site. Example marker deployment tools include the MAMMOMARK™, MICROMARK®, and CORMARK™ brand devices from Devicor Medical Products, Inc. of Cincinnati, Ohio. Further example devices and methods for marking a biopsy site are disclosed in U.S. Pub. No. 2009/0209854, entitled "Biopsy Method," published August 20, 2009; U.S. Pub. No. 2009/0270725, entitled "Devices Useful in Imaging," published October 29, 2009; U.S. Pub. No. 2010/0049084, entitled "Biopsy Marker Delivery Device," published February 25, 2010; U.S. Pub. No. 2011/0071423, entitled "Flexible Biopsy Marker Delivery Device," published March 24, 2011; U.S. Pub. No. 2011/0071424, entitled "Biopsy Marker Delivery Device," published March 24, 2011; U.S. Pub. No. 2011/0071391, entitled "Biopsy Marker Delivery Device with Positioning Component," published March 24, 2011; U.S. Pat. No. 6,228,055, entitled "Devices for

Marking and Defining Particular Locations in Body Tissue," issued May 8, 2001; U.S. Pat. No. 6,371,904, entitled "Subcutaneous Cavity Marking Device and Method," issued April 16, 2002; U.S. Pat. No. 6,993,375, entitled "Tissue Site Markers for In Vivo Imaging," issued January 31, 2006; U.S. Pat. No. 6,996,433, entitled "Imageable Biopsy Site Marker," issued February 7, 2006; U.S. Pat. No. 7,044,957, entitled "Devices for Defining and Marking Tissue," issued May 16, 2006; U.S. Pat. No. 7,047,063, entitled "Tissue Site Markers for In Vivo Imaging," issued May 16, 2006; U.S. Pat. No. 7,229,417, entitled "Methods for Marking a Biopsy Site," issued June 12, 2007; and U.S. Pat. No. 7,465,279, entitled "Marker Device and Method of Deploying a Cavity Marker Using a Surgical Biopsy Device," issued December 16, 2008. The disclosure of each of the above-cited U.S. Patents and U.S. Patent Application Publications is incorporated by reference herein.

SUMMARY OF THE INVENTION

[0007] Aspects of the present invention relate to devices and systems, as well as methods of making and using the same, that comprise a push rod, such as a plunger and/or a shaft, a tube or other cannula, a ramp portion, a lateral aperture, and a spring extending over at least a portion of the shaft. According to some aspects of the present invention, the device may be configured to eject a marker with the same amount of force each time it is used. In some aspects, the present device may operate independently of any force applied by a user and ensures a uniform, repeatable placement of the marker.

[0008] Additional advantages and novel features of these aspects will be set forth in part in the description that follows, and in part will become more apparent to those skilled in the art upon examination of the following or upon learning by practice of the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] FIG. 1 depicts a perspective view of an example marker delivery device, in accordance with aspects of the present invention.

[0010] FIG. 2 depicts a cross-sectional view of the distal end of the marker delivery device of FIG. 1, with the cross-section taken along line 2-2 of FIG. 1.

[0011] FIG. 3A depicts a side elevational view of the distal end of a shaft of the marker delivery device of FIG. 1.

[0012] FIG. 3B depicts a partial cross-sectional view of the distal end of the marker delivery device of FIG. 1, with the shaft and spring in an initial proximal position.

[0013] FIG. 3C depicts a partial cross-sectional view of the distal end of the marker delivery device of FIG. 1, with the shaft and spring partially advanced distally.

[0014] FIG. 3D depicts a partial cross-sectional view of the distal end of the marker delivery device of FIG. 1, with the shaft and spring fully advanced distally.

[0015] FIG. 4 depicts a cross-sectional view of a cannula of the marker delivery device of FIG. 1, with the cross-section taken along line 4-4 of FIG. 2.

[0016] FIG. 5 depicts a perspective view of an example marker for use with the marker delivery device of FIG. 1.

[0017] FIG. 6. depicts a perspective view of another example marker for use with the marker delivery device of FIG. 1.

[0018] FIG. 7 depicts a perspective view of yet another example marker for use with the marker delivery device of FIG. 1.

[0019] FIG. 8 depicts a perspective view of an example alternative cannula for use with the marker delivery device of FIG. 1.

[0020] FIG. 9 depicts a cross-sectional view of the cannula of FIG. 8, with the cross-section taken along line 9-9 of FIG. 8.

[0021] FIG. 10 depicts a perspective view of an example alternative marker delivery device, in accordance with aspects of the present invention.

[0022] FIG. 11A depicts a side elevational view of the marker delivery device of FIG. 9, with a plunger in an unactuated position.

[0023] FIG. 11B depicts another side elevational view of the marker delivery device of FIG. 9, with the plunger in a partially actuated position.

[0024] FIG. 11C depicts yet another side elevational view of the marker delivery device of FIG. 9, with the plunger in a fully actuated position.

[0025] FIG. 12 depicts a perspective view of another example alternative marker delivery device, in accordance with aspects of the present invention.

[0026] FIG. 13 depicts a cross-sectional view of the marker delivery device of FIG. 12, with the cross-section taken along line 13-13 of FIG. 12.

[0027] FIG. 14 depicts an end view of a cannula of the marker delivery device of FIG. 12.

[0028] FIG. 15 depicts a perspective view of another example alternative cannula for use with the marker delivery device of FIG. 1.

[0029] FIG. 16 depicts a cross-sectional view of the cannula of FIG. 15, with the cross-section taken along line 16-16 of FIG. 15.

[0030] FIG. 17A depicts a side elevation view of one various features of an example device with a broken-away part to indicate that the length of the structure may be any preselected length, in accordance with aspects of the present invention.

[0031] FIG. 17B depicts a longitudinal sectional view taken along line 1B-1B in FIG. 17A.

[0032] FIG. 17C depicts an enlarged view of the distal end of the structure depicted in FIG. 17B.

[0033] FIG. 17D depicts an alternative aspect where dimples replace the annular crimp of FIG. 1A.

[0034] FIG. 18A diagrammatically depicts an aspect of the present device in side elevation.

[0035] FIG. 18B depicts a longitudinal, side elevation sectional view of the structure depicted in FIG. 18A.

[0036] FIG. 18C depicts a longitudinal, top plan sectional view of the structure depicted in FIG. 18A.

[0037] FIG. 19 depicts a side elevation view of various features of an example device, in accordance with aspects of the present invention.

DETAILED DESCRIPTION

[0038] The following description of certain examples of various aspect of the present invention should not be used to limit the scope hereof. Other examples, features, aspects, variations, and advantages of the technology will become apparent to those skilled in the art from the following description, which is by way of illustration, one of the best modes contemplated for carrying out the technology. As will be realized, aspects of the invention are capable of other different and obvious implementations, all without departing from the

scope hereof. Accordingly, the drawings and descriptions should be regarded as illustrative in nature and not restrictive.

[0039] FIGs. 1-4 show a marker delivery device (10) that may be used with a biopsy device or targeting set to deliver a marker to a biopsy site. Marker delivery device (10) comprises a body (20) and a cannula (40). As shown in FIG. 1, body (20) comprises an elongate housing (22), a grip (24), a resilient member (26), and a plunger (28). Housing (22) couples body (20) to cannula (40). Additionally, housing (22) may enclose other operational components of marker deliver device (10), such as seals, springs, bushings, or other operational components that may be apparent to those of ordinary skill in the art in view of the teachings herein.

[0040] Grip (24) is positioned at the proximal end of housing (22) and is configured to be grasped by fingers of a user, for example. As will be described in greater detail below, grip (24) is generally configured to permit marker delivery device (10) to be operated with a single hand of a user. Grip (24) of the present example is of integral construction with housing (22). Although in other examples, grip (24) may be alternatively separate from housing (22).

[0041] Resilient member (26) is disposed between grip (24) and plunger (28). In particular, resilient member (26) of the present example comprises a leaf spring having two openings (27) in either end of resilient member (26). Openings (27) are configured to slidably receive a shaft (30). As will be described in greater detail below, shaft (30) is slidable relative to body (10) to selectively eject a marker (60) from marker delivery device (10). Although resilient member (26) is shown as a leaf spring, it should be understood that in other examples any other suitable resilient device may be used such as a coil spring.

[0042] Plunger (28) is positioned at the proximal end of shaft (30). Generally, plunger (28) is configured to be pushed by a user to actuate shaft (30) distally relative to body (20) and cannula (40). Additionally, as shown, plunger (28) abuts resilient member (26), such that resilient member (26) may return shaft (30) to the proximal position shown in FIG. 1 after a user has actuated marker delivery device via plunger (28). As will be described in greater detail below, plunger (28) and grip (24) are together configured such that a user may grasp grip (24) with two fingers (e.g., index finger and middle finger) and push plunger (28) with another finger (e.g., thumb), for example. It should be understood that, although not shown, plunger (28) may be equipped with a plunger lock or other locking feature to permit a user to ratchet or lock plunger (28) at a given position (e.g., to lock plunger (28) at a proximal position and/or to lock plunger (28) at a distal position, etc.).

Suitable locking features may include a resilient latching arm, a bayonet latching feature, a threaded feature, etc.

[0043] Cannula (40) is comprised of an elongate tubular shaft extending distally from housing (22). Generally, cannula (40) extends distally for a length suitable for insertion into a biopsy device or targeting set such that cannula (40) may extend to a biopsy site to deliver marker (60). In the present example, the distal end of cannula (40) includes a lateral aperture (42) and a distal tip (44). As shown in FIG. 1, lateral aperture (42) is positioned proximally of the distal end of cannula (40). As will be understood, the particular position of lateral aperture (42) relative to the distal end of cannula (40) is configured such that lateral aperture (42) may align with a corresponding lateral aperture of a needle of a biopsy device.

[0044] As best seen in FIG. 2, distal tip (44) is inserted into the distal end of cannula (40) and extends longitudinally into at least a portion of lateral aperture (42). The proximal end of distal tip (44) includes a ramp portion (46). As will be described in greater detail below, ramp portion (46) is configured to direct marker (60) from a cannula lumen (48) that extends longitudinally through cannula (40) and is in communication with lateral aperture (42).

[0045] Cannula lumen (48) extends from the proximal end of cannula (40) to the distal end of cannula (40). Although not shown in FIG. 2, it should be understood that in some examples cannula lumen (48) may extend into housing (22), such that shaft (30) of body (20) may be in communication with lumen. In particular, as can be seen in FIG. 2, shaft (30) extends thorough body (20) and into cannula (40) before terminating near the distal end of cannula (40). As will be described in greater detail below, shaft (30) is slidably disposed within cannula lumen (48) to engage marker (60) thereby driving marker (60) up ramp portion (46) and out of lateral aperture (42). In some aspects, the slope of the ramp portion (46) may control the angle at which marker (60) is ejected from the lumen of cannula (48).

[0046] Although shaft (30) of the present example is shown as being disposed coaxially within cannula lumen (48), in other examples shaft (30) may terminate within body (20) and a separate member, shaft, or rod may extend into cannula lumen (48).

[0047] According to some aspects of the present invention, as shown in FIG. 17A, the device may comprise a plunger (172) having an enlarged proximal end (171), which may serve as a handle for a user, for example. As shown in FIG. 17B, proximal end (173a) of elongate shaft (16) may be received within bore (172a) formed with plunger (172) and may be secured thereto so that the shaft (173) moves conjointly with plunger (172).

[0048] In this aspect, an elongate cannula (174) may slidingly receive the distal end of shaft (173). As shown in FIG. 17C, according to some aspects, an annular crimp (174a) may be formed in cannula (174) near its distal end. According to some aspects, the cannula (174) may comprise a lateral aperture (174b) where a marker (176) is ejected from the lumen of cannula (174).

[0049] As can be seen in FIG. 3A, the distal end of shaft (30) of the present example includes a spring (90) extending over at least a portion of the distal end of shaft (30). In particular, spring (90) of this example comprises a multi-pitch coil spring that is coaxial with at least a portion of shaft (30), which is configured to generate a force of between 1.9 and 2.4 lbs of force per 1/10 inch of compression, for examlpe. In the present example, spring (90) is comprised of biocompatible stainless steel, although any other suitable biocompatible material may be used. Spring (90) comprises a first pitch region (92), a second pitch region (94), and a third pitch region (96). First pitch region (92) and third pitch region (96) comprise a pitch that is substantially the same. It should be understood that the term "pitch" used herein refers generally to the spacing between each coil of spring (90). For instance, the pitch of first pitch region and third pitch region (96) may be relatively small relative to the pitch of second pitch region (94). The term "pitch" may also be understood to relate to the particular number of coils per a unit of axial distance (e.g., coils per inch).

[0050] The spacing between each coil of spring (90) in first pitch region (92) and third pitch region (96) of the present example may be relatively small or approximately zero, such that each coil of first pitch region (92) and third pitch region (96) is touching or nearly touching. As will be described in greater detail below, such a pitch may result in very little compression of first pitch region (92) and third pitch region (96) when spring (90) is being compressed. However, the spacing between each coil of spring (90) in second pitch region (94) may be relatively large in comparison to the spacing between each coil of spring (90) in first pitch region (92) and third pitch region (96). Accordingly, second pitch region (94) may compress much more relative to first pitch region (92) and third pitch region (96) when spring (90) is compressed. Although pitch regions (92, 94, 96) are shown as having particular pitches, it should be understood that each pitch region may have any other suitable pitch as will be apparent to those of ordinary skill in the art in view of the teachings herein.

[0051] First pitch region (92) and third pitch region (96) of the present example each comprise 24 to 25 coils, although first pitch region (92) and third pitch region (96) may contain any suitable number of coils. Although first pitch region (92) and third pitch region (96) are configured to undergo little compression relative to second pitch region (94) when spring (90) is compressed, it should be understood that first pitch region (92) and third pitch

region (96) may still be configured to flex laterally, such that shaft (30) may still exhibit some lateral movement within cannula (40) while maintaining contact with marker (60) via spring (90). It should also be understood from the foregoing that, due to the difference between the pitch of second pitch region (94) and the pitch of first and second pitch regions (92, 96), for example, second pitch region (94) may compress first (and to a greater extend) than first and second pitch regions (92, 96) when spring (90) encounters a longitudinally compressive load, such as during actuation of plunger (28).

[0052] According to some aspects of the present invention, as shown in FIG. 17B and 17C, spring (20) may be secured to the distal end of shaft (174). According to some aspects, the spring may comprise only two pitch regions (175b and 175c). I n some aspects, the coils may be tightly packed relative to one another at the distal end of the spring in pitch region (175c). According to some aspects, the proximal pitch region (175b) may comprise loosely packed coils. It should be appreciated that the spring with two pitch regions may function similarly to the spring with three pitch regions, as will be described in more detail below.

[0053] Turning back to FIG. 3A, as will be described in greater detail below, spring (90) may be generally fixedly secured to shaft (30), such that spring (90) first contacts marker (60) and then compresses as shaft (30) is advanced such that shaft (30) may eventually contact marker (60). In the present example, spring (90) is shown as being fixedly secured to shaft (30) at a point proximal to the distal end of shaft (30), such that only a portion of first pitch region (92) extends distally from the distal end of shaft (30). Of course, in other examples any suitable portion of spring (90) may extend from the distal end of shaft (30). Spring (90) of the present example may be fixedly secured to shaft (30) by laser welding, for example. In other examples, shaft (30) may simply include an annular protrusion or a plurality of protrusions that may prevent spring (90) from sliding proximally along shaft (30). In yet other examples, shaft (30) may include an annular protrusion or plurality of protrusions that may be configured to secure spring (90) via a press or interference fit. In yet other examples, other suitable features or methods of securing spring (90) to shaft (30) may be used, such as by screws, pins, or adhesives, as will be apparent to those of ordinary skill in the art in view of the teachings herein.

[0054] As shown in FIG. 17B, the device may comprise an annular detent (175a) weld formed integrally with shaft (173) and secures the proximal end of the spring to said shaft (173) so that said spring does not slide with respect to said shaft.

[0055] As shown in FIG. 3A, marker (60) of the present example comprises a biodegradable or otherwise resorbable body (62). Resorbable body (62) may be of a

generally cylindrically shape and may be comprised of collagen, hydrogel, and/or any other suitable material(s). Resorbable body (62) may include a metallic (e.g., titanium), generally radiopaque marker element (64) (shown in phantom) disposed within or otherwise carried by resorbable body (62). The marker element (64) of the present example is shaped as a coil spring, although it should be understood that marker element (64) may have any other shape suitable for enhancing radiographic visability. It should also be understood that metal is just one merely illustrative example of a kind of material that may be used to form marker element (64). Various other suitable materials that may be used will be apparent to those of ordinary skill in the art in view of the teachings herein.

[0056] In some instances it may be desirable to equip marker delivery device (10) with certain marker (60) retaining features to selectively secure marker (60) within cannula (40). For instance, cannula (40) of the present example includes two retaining dimples (50) disposed within cannula lumen (48) proximally of lateral aperture (42). As can best be seen in FIG. 4, dimples (50) may be disposed near the bottom of cannula (40) away from lateral aperture (42). Dimples (50) may be hemispherical in shape and protrude inwardly within cannula lumen (48), for example. Accordingly, dimples (50) may be configured to engage at least a portion of marker (60) to retain marker (60) within cannula lumen (48). However, because resorbable body (62) is comprised of collagen, hydrogel, and/or other deformable material(s), marker (60) may exhibit relatively elastic properties, such that marker (60) may be selectively forced past dimples (50) by shaft (30). Alternatively, marker (60) may be undersized relative to the inner diameter of cannula (40), such that marker (60) may be pushed upwardly and over dimples (50) when shaft (30) pushes marker (60). Although cannula (40) is shown as comprising two dimples (50), it should be understood that in other examples cannula (40) may comprise any other suitable number of dimples (50).

[0057] As shown in FIG. 17D, two circumferentially spaced apart dimples (174d) may be formed in cannula (174). Defining the top of cannula (174) as shown in FIG. 17D as being the zero degree (0°) position, a first dimple may be positioned approximately at the one hundred thirty five degree (135°) position and the second dimple may be positioned approximately at the two hundred twenty five degree (225°) position. According to some aspects, an annular crimp (174a) may be formed by a large number of closely spaced dimples. However, the preferred number of equidistantly, circumferentially spaced apart dimples may be as few as two, as depicted, to as many as eight or more. According to some aspects, if eight dimples are selected, for example, there may be one dimple at the zero degree (0°) position and one dimple every forty five degrees (45°) thereafter about the circumference of cannula (174).

[0058] Additionally or alternatively, dimples (50) may comprise other shapes besides a hemispherical shape. For instance, dimples (50) may be pyramidal, cubic, rhombic, or any other suitable shape as will be apparent to those of ordinary skill in the art in view of the teachings herein. As another merely illustrative example, an annular protrusion or crimp may extend inwardly in lumen (48), as a substitute for dimples (50). In yet another merely illustrative example, a relatively flexible flap or tab of integral construction with cannula (40) may extend inwardly in lumen (48), as yet another substitute for dimples (50).

[0059] According to some aspects, as shown in FIG. 18A-C, cannula (174) may comprise a flap (177), which is hidden from view in the side elevation view of FIG. 18A, and is visible in the longitudinal, side elevation sectional view of FIG. 18B and the longitudinal, top plan sectional view of FIG. 18C. According to some aspects, flap (177) and cannula (174) may be formed integrally with one another, and said flap may provide a detent, for example, that resists proximal-to-distal displacement of marker (176) by the shaft, e.g., flap (177) may perform a similar function as an annular crimp or dimples described herein. According to some aspects, this flap (177) may be employed when marker (176) is formed of a material that is not flexible and resilient, for example.

[0060] As shown in FIG. 19, according to some aspects, a protuberance or bulge (26) may be formed in the lumen of cannula (174), said bulge performing a similar function as flap (177). For example, both bulge (178) and flap (177) may be configured to flatten as a rigid marker (176) is pushed over these features.

[0061] FIGs. 3B-3D show an example use of marker delivery device (10). As can be seen in FIG. 3B, marker (60) is initially disposed inside cannula lumen (42) proximal to dimples (50). A user may then insert cannula (40) into a biopsy device or targeting set to deliver marker (60) at a biopsy site, with the biopsy device or targeting set already being positioned in tissue at the biopsy site. Cannula (40) may be positioned such that lateral aperture (42) is angularly and longitudinally aligned with a complementary lateral aperture of the needle or cannula of the biopsy device or targeting set. Once cannula (40) has been inserted into a biopsy device or targeting set and has been properly positioned therein, a user may initiate deployment by grasping grip (24) and pressing plunger (28) with a single hand or, alternatively, multiple hands, for example.

[0062] As plunger (28) is pressed distally, shaft (30) may be advanced distally relative to cannula (40) and body (20), as shown by the progression between FIGs. 3B and 3C. As the distal end of shaft (30) approaches marker (60), spring (90) may initially contact marker (60). As shown in FIGs. 3B and 3C, such contact may compress spring (90) as shaft (30) is advanced further, thereby storing potential energy within spring (90).

[0063] Additional advancement of shaft (30) may eventually lead to direct contact between marker (60) and the distal end of shaft (30). As can be seen in FIG. 3C, the distal end of shaft (30) may be generally aligned with the distal end of spring (90) at this stage. Once such direct contact is initiated, shaft (30) will begin to push marker (60) distally within cannula (40), thereby advancing marker (60) distally past and/or over dimples (50) and out of lateral aperture (42). Once marker (60) is distal of dimples (50), spring (90) may begin to expand via the potential energy generated during compression of spring (90). Such expansion of spring (90) may finally advance marker (60) laterally up ramp portion (46) of distal tip (44), out through lateral aperture (42) and into the biopsy site, as can be seen in FIG. 3D. It should be understood that first pitch region (92) may flex over dimples (50), extending past dimples (50). Thus, for example, the configuration of spring (90) may allow spring (90) to laterally deflect within lumen (48) in order for spring (90) to advance beyond dimples (50) without requiring any lateral deflection of shaft (30) within lumen. The coils forming first pitch region (92) may simply slide relative to each other in order to pass over dimples (50). In variations where dimples are arranged along a greater angular extent within lumen (48) (e.g., as in cannula (640) described below)), spring (90) may still deform to pass distally beyond dimples (50). For instance, the coils forming first pitch region (92) may slide relative to each other and tilt obliquely relative to the longitudinal axis of lumen (48) in order to reduce the effective outer diameter of spring (90), thereby allowing spring (90) to pass through the space defined between the dimples.

[0064] FIG. 5 shows an example alternative marker (160) that may be used in addition to or in lieu of marker (60) as described above. Marker (160) of the present example is substantially similar to marker (60). For instance, like with marker (60), marker (160) may comprise biodegradable or otherwise resorbable body (162). Resorbable body (162) may be of a generally cylindrical shape and may be comprised of collagen, hydrogel, and/or any other suitable material(s). Like resorbable body (62) described above, resorbable body (162) may include a metallic, generally radiopaque marker element (164) disposed within or otherwise carried by resorbable body (162). However, unlike marker element (64), marker element (164) of the present example may comprise a disc shaped central member (166) (shown in phantom) with three elongate protrusions (168) protruding radially outwardly from central member (166) and out of resorbable body (162). It should also be understood that metal is just one merely illustrative example of a kind of material that may be used to form marker element (164). Various other suitable materials that may be used will be apparent to those of ordinary skill in the art in view of the teachings herein.

[0065] In some examples, elongate protrusions (168) may protrude radially outwardly from central member (166) to provide friction against the interior of cannula (40).

Thus, for example, elongate protrusions (168) may be configured to contact the interior of cannula (40). Such a configuration may be used in conjunction with, or in lieu of, dimples (50), for example, to maintain marker (160) within cannula (40) to thereby prevent marker (160) from inadvertently falling out of cannula (40). Additionally, elongate protrusions (168) may engage tissue at the biopsy site to secure marker (160) at the biopsy site, thereby preventing marker (160) migration.

[0066] FIG. 6 shows another example alternative marker (260) that may be used in addition to or in lieu of marker (60) as described above. Marker (260) of the present example may be substantially similar to marker (60). For instance, like with marker (60), marker (260) may comprise biodegradable or otherwise resorbable body (262). However, unlike resorbable body (62), resorbable body (262) may comprise a hybrid of at least two materials. For instance, resorbable body (262) of the present example may comprise a generally cylindrically shaped collagen middle portion (261), two hydrogel intermediate portions (263), and two collagen end portions (265). Like resorbable body (62) described above, resorbable body (262) may include a metallic, generally radiopaque marker element (264) (shown in phantom) disposed within or otherwise carried by resorbable body (262). However, unlike marker element (64), marker element (264) of the present example may generally be rectangular with a central twist (266) so as to be configured to enhance the radiographic visibility of marker element (264). It should also be understood that metal is just one merely illustrative example of a kind of material that may be used to form marker element (264). Various other suitable materials that may be used will be apparent to those of ordinary skill in the art in view of the teachings herein.

[0067] FIG. 7 shows yet another example alternative marker (360) that may be used in addition to or in lieu of marker (60) as described above. Marker (360) of the present example may be substantially similar to marker (60). For instance, like with marker (60), marker (360) may comprise biodegradable or otherwise resorbable body (362). However, unlike resorbable body (62), resorbable body (362) may comprise a hybrid of at least two materials. For instance, resorbable body (362) of the present example may comprise a generally cylindrically shaped collagen outer shell (361) with a hydrogel inner core (363). Like resorbable body (62) described above, resorbable body (362) may include a metallic, generally radiopaque marker element (364) (shown in phantom) disposed within or otherwise carried by resorbable body (362). However, unlike marker element (64), marker element (364) of the present example may be generally rectangular with a central twist (366) so as to be configured to enhance the radiographic visibility of marker element (364). It should also be understood that metal is just one merely illustrative example of a kind of material that may be used to form marker element (364). Various other suitable materials

that may be used will be apparent to those of ordinary skill in the art in view of the teachings herein.

[0068] FIGs. 8 and 9 show an example alternative cannula (440) that may be incorporated into biopsy marker device (10) described above. Cannula (440) of the present example may be substantially similar to cannula (40) described above, except as otherwise noted herein. For instance, cannula (440) comprises an elongate tubular shaft (441), which includes a lateral aperture (442) proximal of a distal tip (444) and a cannula lumen (448) extending through cannula (440). However, unlike cannula (40), cannula (440) may include a metal sheath (452) disposed over at least a portion of the distal tip of cannula (440). It should also be understood that metal is just one merely illustrative example of a kind of material that may be used to form sheath (452). Various other suitable materials that may be used will be apparent to those of ordinary skill in the art in view of the teachings herein. Metal sheath (452) may be configured to provide structural reinforcement to the distal end of cannula (440). For instance, metal sheath (452) may prevent the distal end of cannula (440) from buckling or otherwise deforming during use of cannula (440). In addition or in the alternative, when cannula (440) is formed of a material having less hardness than metal sheath (452), metal sheath (452) may prevent the relatively softer material of cannula (440) from being scraped or shaven by an edge defining a lateral aperture of a biopsy needle in which cannula (440) is inserted.

[0069] Lateral aperture (442) of the present example may be integrated into both cannula (440) and metal sheath (452). As shown in FIG. 8, lateral aperture (442) is cut out of cannula (440) and metal sheath (452) at an angle such that cannula (440) and metal sheath (452) together form aligned beveled edges (445, 454, 456). For example, metal sheath (452) may include a distal beveled edge (454) and a proximal beveled edge (456). Distal beveled edge (454) of metal sheath (452) may be aligned with a ramp portion (446) of distal tip (444), with both distal beveled edge (454) and ramp portion (446) being oriented at substantially similar angles. Similarly, proximal beveled edge (456) of metal sheath (452) may be aligned with a beveled proximal edge (445) of cannula, with both proximal edges (445, 456) being oriented at substantially similar angles.

[0070] Beveled edges (445, 454, 456) and ramp portion (446) may be beveled at an angle suitable to reduce trauma to tissue while still maintaining lateral aperture (442) at a large enough dimension for markers (60, 160, 260, 360) to pass thereby. In the present example, the bevel angle of distal beveled edge (454) and ramp portion (446) is steeper relative to the bevel angle of proximal beveled edges (456, 445). Although a particular relationship between distal beveled edge (454) and ramp portion (446), and proximal

beveled edges (445, 456) is shown, it should be understood that no limitation to the example shown is intended, and in other examples the respective bevel angles may be varied as will be understood by those of ordinary skill in the art in view of the teachings herein.

[0071] As shown in FIG. 9, distal tip (444) of the present example is integral with shaft (441). Distal tip (444) and shaft (441) may be configured to receive metal sheath (452), such that metal sheath (452) provides support to distal tip (444). In some variations, metal sheath (452) may be attached to distal tip (444) and shaft (441) by overmolding, for example, such that distal tip (444) and shaft (441) are injection molded into metal sheath (452). In other examples, metal sheath (452) may simply be attached to distal tip (444) and shaft (441) by adhesive bonding, mechanical fastening, or any other suitable fastening.

[0072] Metal sheath (452) of the present example comprises a metallic biocompatible material, such as stainless steel, titanium, and/or any other suitable metal(s). However, no limitation to only these examples is intended. For instance, in other examples, metal sheath (452) may comprise a plastic that is relatively dense relative to shaft (441) and distal tip (444). In yet other examples, metal sheath (452) may comprise a ceramic material. In still other examples, metal sheath (452) may be comprised of any other suitable material as will be apparent to those of ordinary skill in the art.

[0073] FIGs. 10-11C show an example alternative marker delivery device (510) that is similar to marker delivery device (10) described above. For instance, marker delivery device (510) may comprise a body (520) and a cannula (540). Body (520) may comprise an elongate housing (522), a grip (524), and a plunger (528). Housing (522) may e substantially similar to housing (22) described above. However, unlike housing (22), housing (522) of the present example may include additional components that are configured to provide multiple actuation positions for plunger (528), as will be described in greater detail below.

[0074] Similar to plunger (28) described above, plunger (528) of the present example may be positioned at the proximal end of a shaft (530) that extends longitudinally through body (520) and cannula (540). Also similarly to plunger (28) described above, plunger (528) of the present example may be used in conjunction with grip (524) for one handed actuation of marker delivery device (510), for example. However, unlike plunger (28), plunger (528) of the present example may be configured to have multiple actuation positions, as will be described in greater detail below.

[0075] Cannula (540) may be substantially similar to cannula (40) described above and may be comprised of an elongate tubular shaft extending distally from housing (522). Generally, cannula (540) may extend distally for a length suitable for insertion into a biopsy

device or targeting set, such that cannula (540) may extend to a biopsy site to deliver any one of the markers (60, 160, 260, 360) described herein through a lateral aperture (542) near the distal end of cannula (540).

[0076] FIGs. 11A-11C show an example operational mode of marker delivery device (510). As can be seen in FIG. 11A, plunger (528) of body (520) begins in an initial, proximal position. When plunger (528) is disposed in the initial position, marker delivery device (510) may be inserted into a biopsy device or targeting set to position lateral aperture (542) of cannula (540) at a biopsy site, for example, with lateral aperture (542) being longitudinally and angularly alignable with a similar lateral aperture of the biopsy device or targeting set.

[0077] Once marker delivery device (510) is positioned within a biopsy device or targeting set, a user may desire to place marker (60, 160, 260, 360) at the biopsy site. To so place marker (60, 160, 260, 360), a user may advance plunger (528) to a partially actuated position as shown in FIG. 11B. In the present example, housing (522) includes various components that are configured to advance shaft (530) to eject marker (60, 160, 260, 360) from lateral aperture (542) when plunger (528) is advanced to the partially actuated position.

[0078] In some instances, it may be desirable to rotate cannula (540) within a biopsy device or targeting set after deployment of marker (60, 160, 260, 360). For instance, after deployment of marker (60, 160, 260, 360), marker (60, 160, 260, 360) may remain relatively close to lateral aperture (542) of cannula (540), such that it may be possible for at least a portion of marker (60, 160, 260, 360) to re-enter lateral aperture (542). In such a case, removal of marker delivery device (510) may cause damage to marker (60, 160, 260, 360), for example, because marker (60, 160, 260, 360) may become caught between lateral aperture (542) and a corresponding lateral aperture of a biopsy device or targeting set. Accordingly, marker delivery device (510) may be generally configured to selectively rotate cannula (540), for example, to facilitate removal of cannula (540) without a marker (60, 160, 260, 360) becoming lodged between lateral aperture (542) and a corresponding lateral aperture in a biopsy device or targeting set.

[0079] As shown in FIG. 11C, plunger (528) is advanced to a fully actuated position to initiate rotation of cannula (540) relative to body (520). It should be understood that to achieve such functionally, the inside of housing (522) may include springs, levers, gears, cams or other mechanical apparatuses that may be assembled to cause rotation of cannula (540). Various components and features that may be used to provide such rotation of cannula (540) relative to body (520) in response to full advancement of plunger (528) relative to body (520) will be apparent to those of ordinary skill in the art in view of the teachings herein. It should be understood that in the present example, the aforementioned

components of housing (522) may be configured to rotate cannula (540) 180° relative to body (520), for example. In other examples, housing (522) may be configured to rotate cannula (540) any suitable angle relative to body. By way of example only, housing (522) may be configured to rotate cannula (540) 90°, 270°, or any other suitable radial distance.

[0080] Once plunger (528) has been advanced to the fully actuated position to rotate cannula (540), for example, marker delivery device (510) may be removed from the biopsy device or targeting set. Alternatively, in some examples, marker delivery device (510) may be equipped to deploy multiple markers (60, 160, 260, 360). In such examples, housing (522) may be optionally configured to return cannula (540) to its original position for deployment of another marker (60, 160, 260, 360) upon retraction of plunger (528). The sequence described above may be again reinitiated. It should be understood that, although the sequence described above is described as comprising two discrete advancements of plunger (528) by a user, in other examples plunger (528) may be optionally advanced in a single stroke. In such an example, among other things, marker (60, 160, 260, 360) may be deployed and then cannula (540) may be immediately rotated thereafter.

[0081] FIGs. 12-14 show another example alternative marker delivery device (610) that is similar to marker delivery device (10) described above. For instance, marker delivery device (610) may comprises a body (620) and a cannula (640). Body (620) may comprises an elongate housing (622), a grip (624), and a plunger (628). Housing (622), grip (624), and plunger (628) may be substantially similar to housing (22), grip (24), and plunger (28) described above, such that the individual details of such components will not be repeated at this point of the description.

[0082] Cannula (640) may be substantially similar to cannula (40) described above, in that cannula (640) may be comprised of an elongate tubular shaft extending distally from housing (522). Generally, as shown in FIGs.12-14, cannula (640) extends distally for a length suitable for insertion into a biopsy device or targeting set, such that cannula (640) may extend to a biopsy site to deliver any one of the markers (60, 160, 260, 360) described herein. However, unlike cannula (40), cannula (640) of the present example may lack a lateral aperture. Instead, cannula (640) may comprise, for example, an open distal tip (644) that is in communication with a cannula lumen (628) extending through cannula (640). Thus, cannula (640) may be configured to deploy a marker (60) longitudinally out through open distal tip (644).

[0083] As can best be seen in FIGs. 13 and 14, cannula (640) may further comprise a plurality of dimples (650) similar to dimples (50) of cannula (40). For example, dimples (650) may generally be configured to selectively retain marker (60) within cannula (240).

Dimples (650) may comprise a hemispherical shape that is substantially similar to dimples (50) described above. However, unlike cannula (40) as shown above, cannula (640) of the present example may comprise three dimples (650). As can be seen in FIG. 14, dimples (650) may be oriented at equal distances around the inner diameter of cannula (640). It should be understood that, like with dimples (50) described above, dimples (650) of the present example may comprise any other suitable shape and/or configuration as will be apparent to those of ordinary skill in the art in view of the teachings herein.

[0084] FIGs. 15 and 16 show an example alternative cannula (740) that may be incorporated into biopsy marker device (10) described above. Cannula (740) of the present example may be substantially similar to cannula (40) described above, except as otherwise noted herein. For instance, cannula (740) of this example may comprise an elongate tubular shaft (741), which may include a lateral aperture (742) proximal to a distal tip (744). Shaft (741) may further define a cannula lumen (748), which extends through cannula (740) and is in communication with lateral aperture (742). Unlike cannula (40), lateral aperture (742) of cannula (740) may have a tear drop shape that widens as lateral aperture (742) extends proximally. Thus, for example, the distal portion of lateral aperture (742) may be narrower than the proximal portion of lateral aperture (742). It should be understood that, in some examples, at least a portion of lateral aperture (742) (e.g., the distal portion of lateral aperture (742)) may also be sized slightly smaller relative to lateral aperture (42) described above. Such sizing may permit lateral aperture (742) to accommodate a smaller marker, for example.

[0085] As can be seen in FIG. 16, cannula (740) may also vary from cannula (40) in that distal tip (744) may comprise a compound ramp portion (746). For example, distal tip (744) may comprise three discrete ramp portions (743, 745, 747) and two relatively flat portions (749, 751). Ramp portions (743, 745, 747) are shown in FIG. 16 as being ramped at similar angles, although the particular angle of each ramp portion (743, 745, 747) may be varied in other examples. Generally, ramp portions (743, 745, 747) may be configured to progressively deflect a marker (not shown) through lateral aperture (742). Such a progressive deflection may be desirable, for example, to prevent the marker from exiting cannula (740) prematurely and to prevent the marker from re-entering lateral aperture (742) after the marker has been delivered to a biopsy site.

[0086] Flat portions (749, 751) may be generally parallel along their planar flat area to the longitudinal axis of cannula (740), for example. Flat portions (749, 751) may be configured to provide spacing between ramp portions (743, 745, 747) and to alter the trajectory as the marker moves from ramp portion (743, 745, 474) to ramp portion (743, 745,

747). For instance, in an example use, the marker may first travel up a first ramp portion (743) as the marker is advanced distally. First ramp portion (743) may provide some degree of resistance to such distal motion of the marker. By way of example only, first ramp portion (743) may be configured and operable in accordance with at least some of the description in U.S. Patent No. 8,532,747, entitled "Biopsy Marker Delivery Device," issued September 10, 2013, the disclosure of which is incorporated by reference herein.

[0087] Once the marker has passed first ramp portion (743), the marker may travel along a first flat portion (749), then travel up a second ramp portion (745) at an angle generally parallel to the angle of second ramp portion (745). Second ramp portion (745) may provide a cam surface, thereby ejecting the marker through lateral aperture (742). A second flat portion (751) may prevent the marker from re-entering lateral aperture (742). When cannula (740) is removed from a biopsy device or targeting set, a third ramp portion (747) may deflect any portion of the marker that may remain in lateral aperture (742) fully out of lateral aperture (742). In addition to or in lieu of the foregoing, and by way of example only, compound ramp portion (746) may be constructed and operable in accordance with at least some of the description of U.S. Pub. No. 2014/0276037, entitled "Biopsy Site Marker Applier," published September 18, 2014, the disclosure of which is incorporated by reference herein.

[0088] The present invention has been disclosed with respect to a biopsy marker deployer device. However, various features and components disclosed in the figures may be employed in devices useful with radioisotope applications, as in PEM, BSGI, and other imaging methods that may employ a radioisotope or other radiation source, for example, in connection with imaging a biopsy procedure.

[0089] Aspects of the devices disclosed herein are generally designed to be disposed of after a single use, but could be designed to be used multiple times. After forming the marker, and inserting the marker into the deployer, for example the biopsy device may be sterilized. The device may then be placed in a package, such as plastic or TYVEK bag.

[0090] The packaged biopsy device may then be placed in a field of radiation, such as gamma radiation, x-rays, or high-energy electrons to sterilize the device and packaging. A device may also be sterilized using any other technique known in the art, including but not limited to beta or gamma radiation, ethylene oxide, or steam.

[0091] While the aspects described herein have been described in conjunction with the example aspects outlined above, various alternatives, modifications, variations, improvements, and/or substantial equivalents, whether known or that are or may be

presently unforeseen, may become apparent to those having at least ordinary skill in the art. Accordingly, the example aspects, as set forth above, are intended to be illustrative, not limiting. Various changes may be made without departing from the spirit and scope of the disclosure. Therefore, the disclosure is intended to embrace all known or later-developed alternatives, modifications, variations, improvements, and/or substantial equivalents.

[0092] Thus, the claims are not intended to be limited to the aspects shown herein, but are to be accorded the full scope consistent with the language of the claims, wherein reference to an element in the singular is not intended to mean "one and only one" unless specifically so stated, but rather "one or more." All structural and functional equivalents to the elements of the various aspects described throughout this disclosure that are known or later come to be known to those of ordinary skill in the art are expressly incorporated herein by reference and are intended to be encompassed by the claims. Moreover, nothing disclosed herein is intended to be dedicated to the public regardless of whether such disclosure is explicitly recited in the claims. No claim element is to be construed as a means plus function unless the element is expressly recited using the phrase "means for."

[0093] It is understood that the specific order or hierarchy of the processes / flowcharts disclosed is an illustration of example approaches. Based upon design preferences, it is understood that the specific order or hierarchy in the processes / flowcharts may be rearranged. Further, some features/steps may be combined or omitted. The accompanying method claims present elements of the various features/steps in a sample order, and are not meant to be limited to the specific order or hierarchy presented.

[0094] Further, the word "example" is used herein to mean "serving as an example, instance, or illustration." Any aspect described herein as "example" is not necessarily to be construed as preferred or advantageous over other aspects. Unless specifically stated otherwise, the term "some" refers to one or more. Combinations such as "at least one of A, B, or C," "at least one of A, B, and C," and "A, B, C, or any combination thereof" include any combination of A, B, and/or C, and may include multiples of A, multiples of B, or multiples of C. Specifically, combinations such as "at least one of A, B, or C," "at least one of A, B, and C," and "A, B, C, or any combination thereof" may be A only, B only, C only, A and B, A and C, B and C, or A and B and C, where any such combinations may contain one or more member or members of A, B, or C. Nothing disclosed herein is intended to be dedicated to the public regardless of whether such disclosure is explicitly recited in the claims.

WHAT IS CLAIMED:

1. A marker delivery device comprising:

a tube, having a first end and a lateral aperture;

at least one biopsy marker disposed proximally of the lateral aperture;

a push rod having a first end disposed at least partially within the tube, wherein the push rod is movable in a direction toward its first end to engage the at least one biopsy marker; and

a resilient member extending from the first end of the push rod, wherein the resilient member is configured to engage the at least one biopsy marker when the push rod is moved in a direction toward its first end to drive the at least one biopsy marker through the lateral aperture of the tube.

2. The marker delivery device of claim 1, wherein the tube comprises a protrusion extending radially inwardly.

3. The marker delivery device of claim 2, wherein the inwardly extending protrusion is positioned proximal to the lateral aperture.

4. The marker delivery device of claim 2, wherein the inwardly extending protrusion comprises an annular protrusion.

5. The marker delivery device of claim 2, wherein the inwardly extending protrusion comprises at least two dimples.

6. The marker delivery device of claim 2, wherein the inwardly extending protrusion comprises a flap.

7. The marker delivery device of claim 1, further comprising:

a tip inserted into the first end of the tube.

8. The marker delivery device of claim 7, wherein the tip comprises:

a ramp portion.

9. The marker delivery device of claim 8, wherein the ramp portion comprises:

a preselected slope that dictates an angle at which the biopsy marker is ejected from the tube.

10. The marker delivery device of claim 1, wherein the resilient member comprises a spring.

11. The marker delivery device of claim 10, wherein the spring comprises:

at least a first pitch region; and

a second pitch region;

wherein the coils of the first pitch region are more tightly packed relative to the second pitch region.

12. The marker delivery device of claim 1, wherein the biopsy marker comprises:

a resorbable body.

13. The marker delivery device of claim 1, wherein the biopsy marker comprises:

a deformable material.

14. A marker delivery device comprising:

a tube having a first end, wherein the first end includes an opening and a plurality of stop members, wherein the plurality of stop members are disposed proximally of the opening;

at least one biopsy marker disposed proximally of the plurality of stop members of the tube; and

a push rod having a first end disposed at least partially within the tube, wherein the push rod is movable in a direction toward its first end to drive the at least one biopsy marker past the plurality of stop members and through the opening of the tube.

15. The marker delivery device of claim 14, further comprising:

a tip inserted into the first end of the tube.

16. The marker delivery device of claim 15, wherein the tip comprises a ramp portion.

17. The marker delivery device of claim 14, wherein the opening comprises a lateral aperture.

18. The marker delivery device of claim 14, further comprising a resilient member extending from the distal end of the push rod.

19. A marker delivery device comprising:

a cannula, having a first end and a first opening, wherein the cannula comprises a first material;

at least one biopsy marker disposed proximally of the first opening;

a sleeve, wherein the sleeve is disposed over the lateral aperture and at least a portion of the first end of the cannula, wherein the sleeve comprises a second opening, wherein the second opening of the sleeve is configured to align with the first opening of the cannula to form a lateral aperture, wherein the sleeve further comprises a second material, wherein the second material of the sleeve has a flexibility or resiliency less than a flexibility or resiliency of the first material of the cannula; and

a member having a first end disposed at least partially within the cannula, wherein the member is movable in a direction toward its first end to deploy the at least one biopsy marker through the lateral aperture formed by the first opening and the second opening.

20. A marker delivery device comprising:

a tube, having a first end and a lateral aperture;

at least one biopsy marker disposed proximally of the lateral aperture;

a push rod having a first end disposed at least partially within the tube, wherein the push rod is movable in a direction toward its first end to deploy the at least one biopsy marker; and

an actuator having a plunger, wherein the actuator is in communication with the tube and the push rod, wherein the plunger of the actuator is movable through a first position and a second position, wherein the actuator is configured to move the push rod in a direction toward its first end when the plunger is moved to the first position, wherein the actuator is configured to rotate the tube when the plunger is moved to the second position.

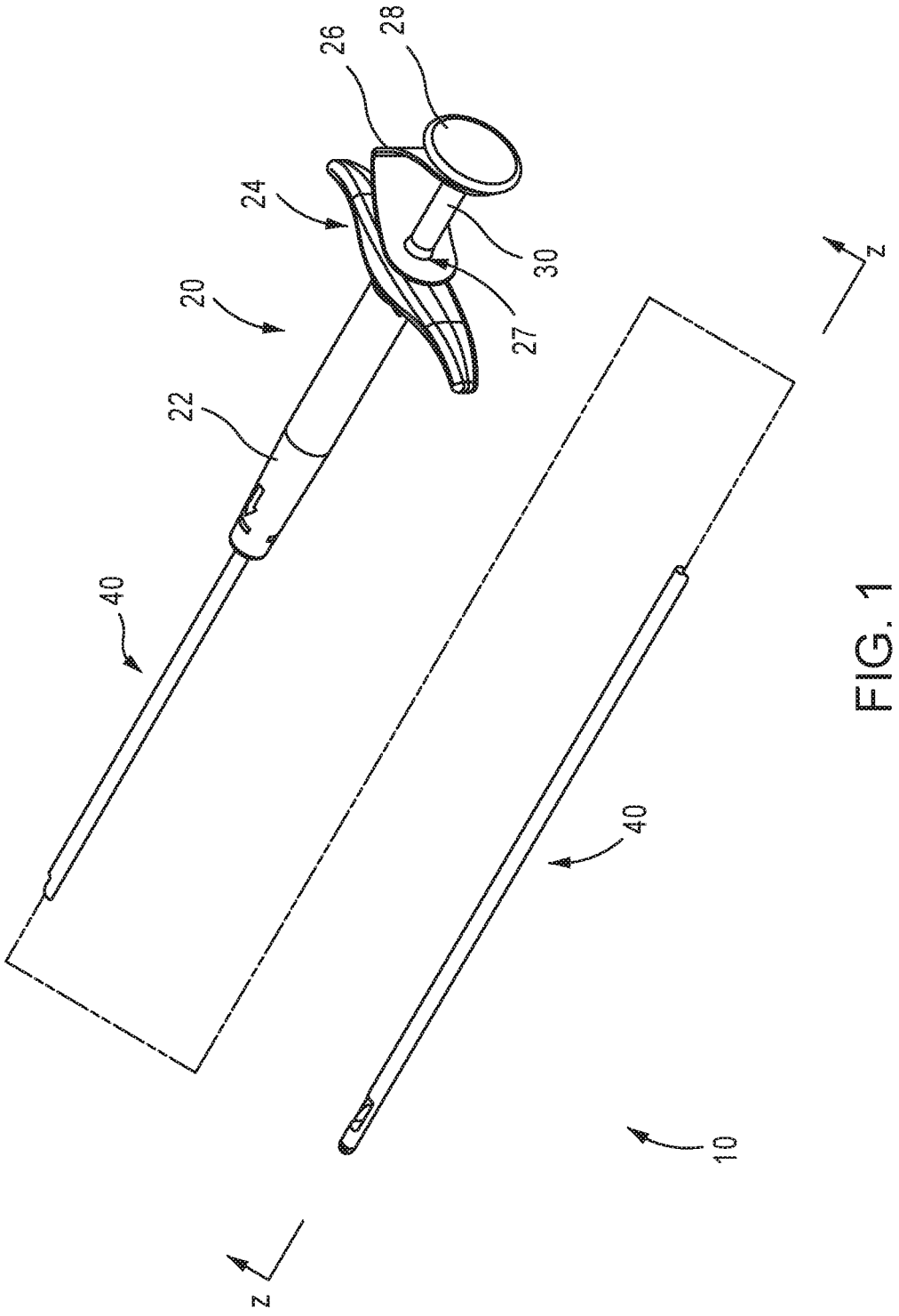


FIG. 1

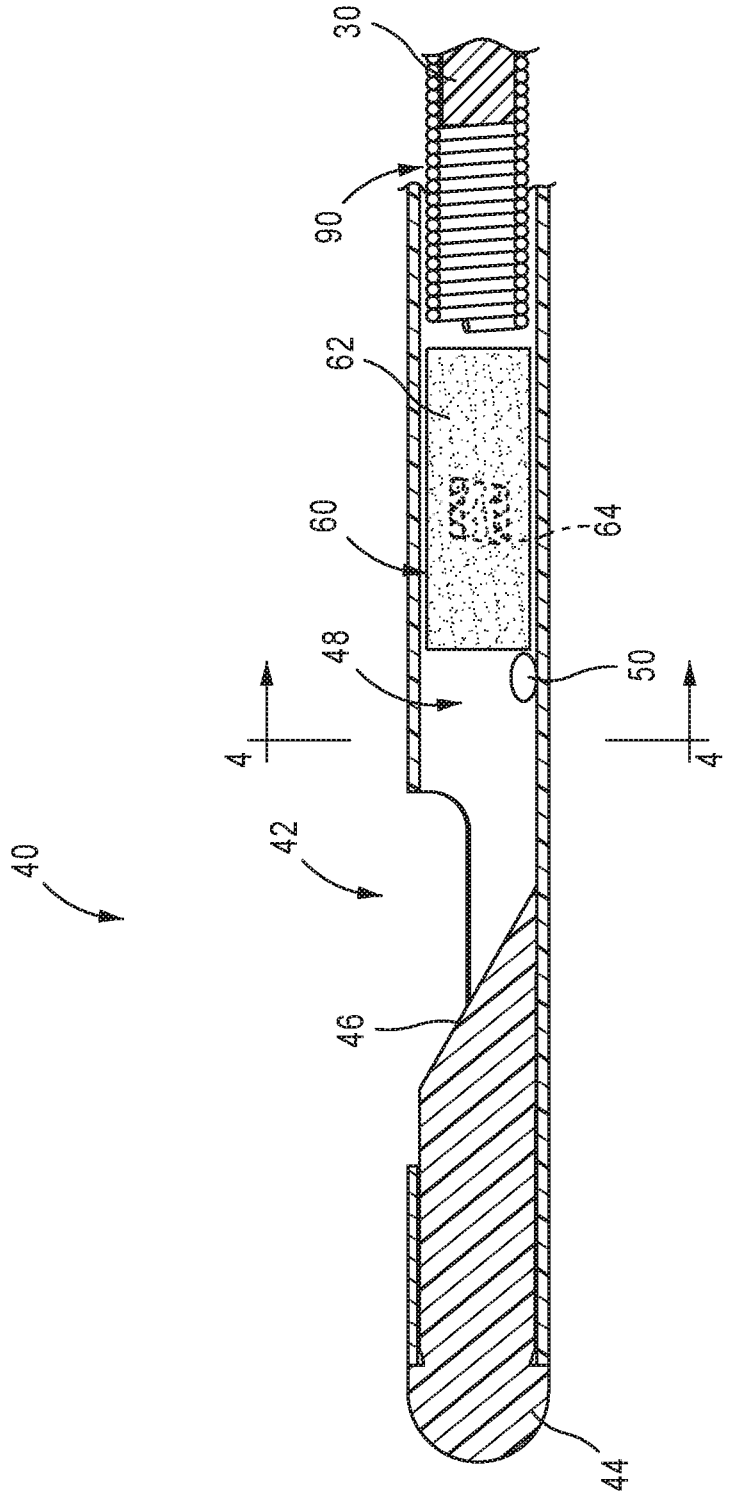


FIG. 2

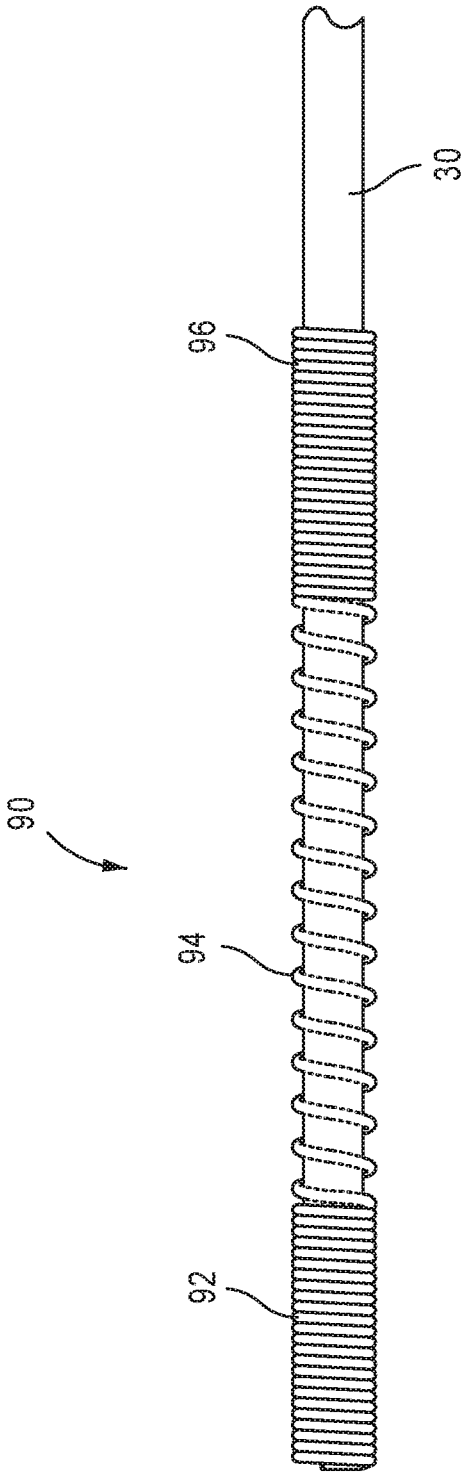


FIG. 3A

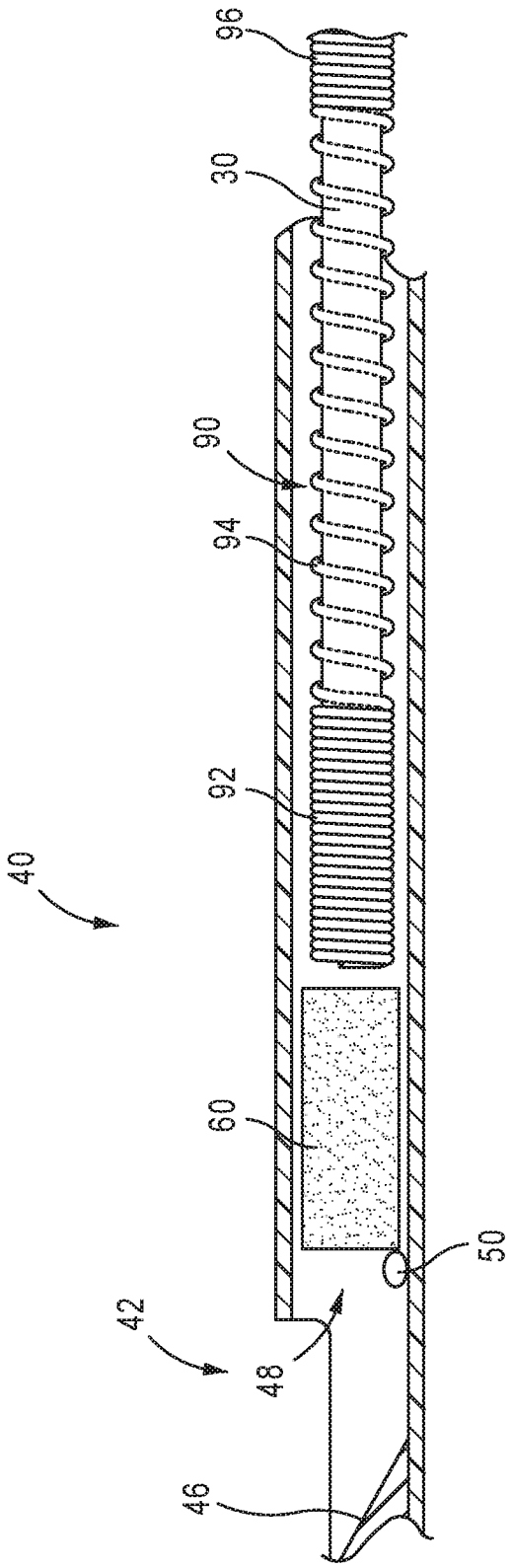


FIG. 3B

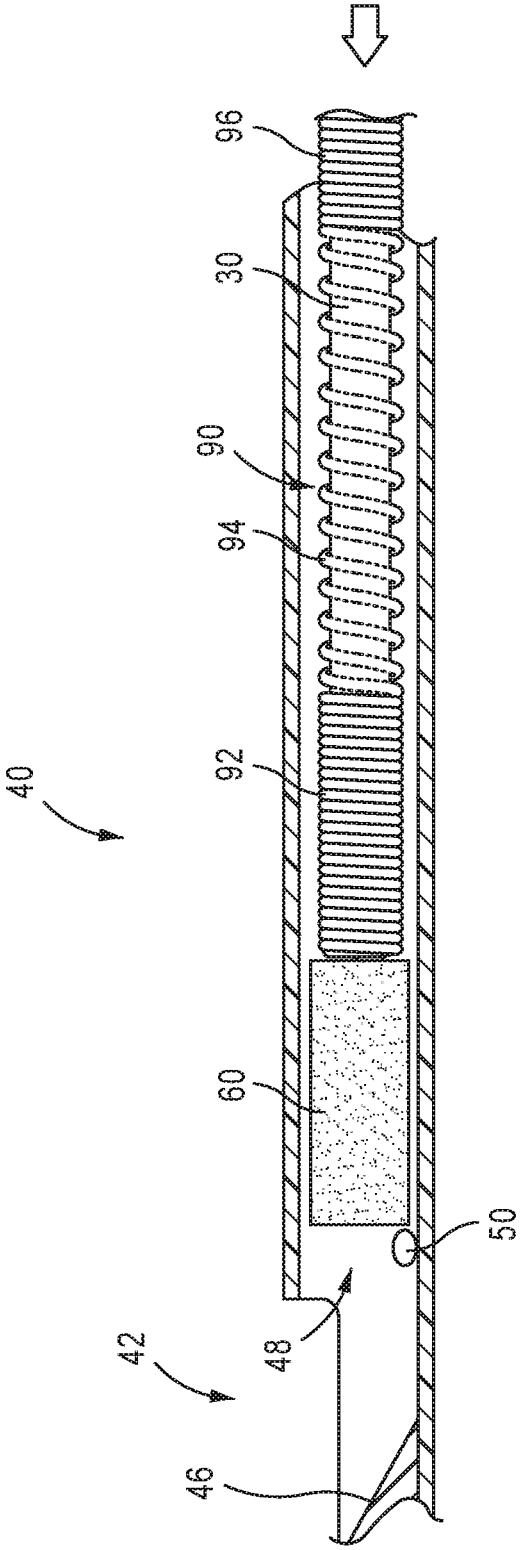


FIG. 3C

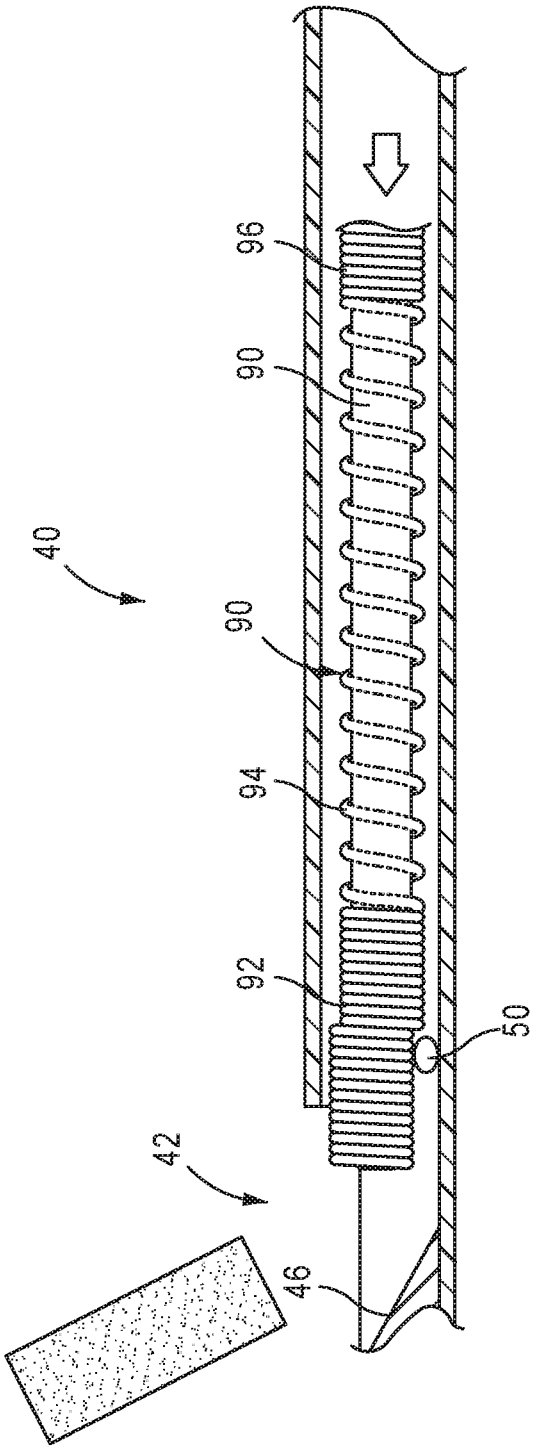


FIG. 3D

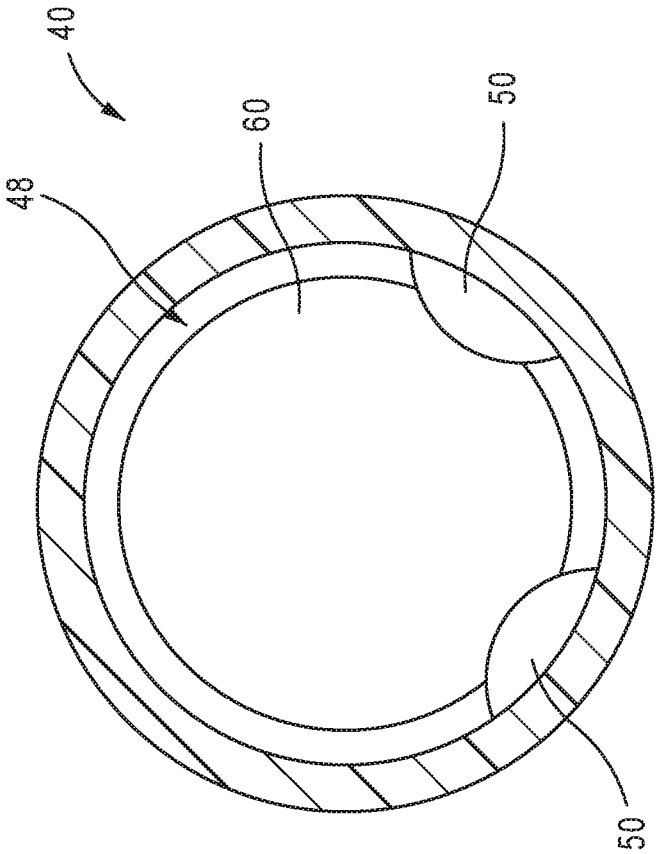


FIG. 4

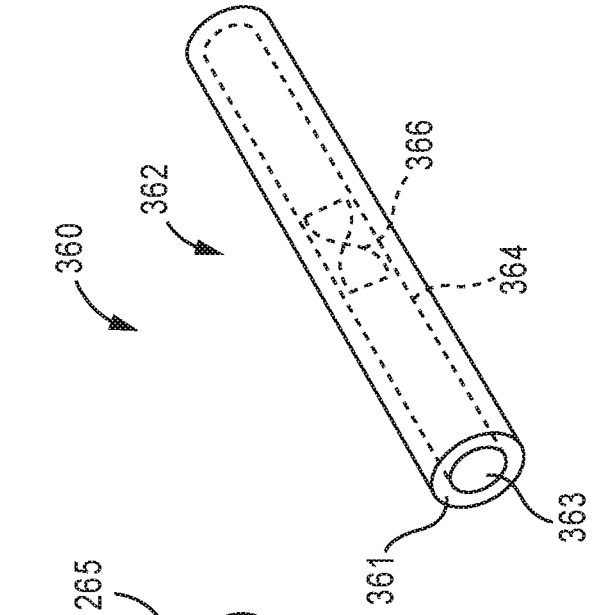


FIG. 7

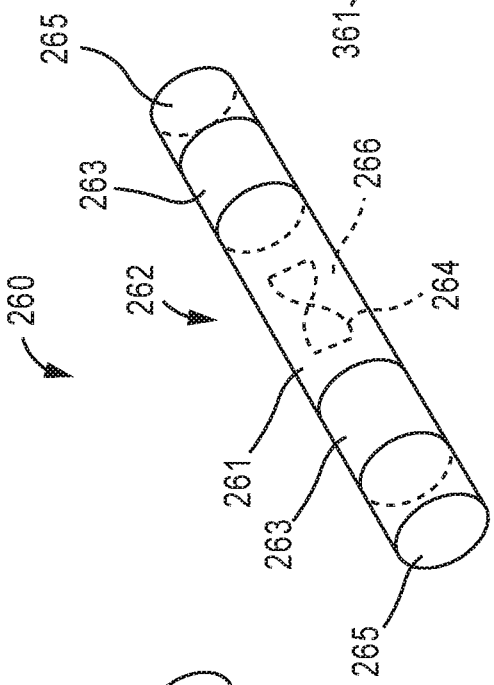


FIG. 6

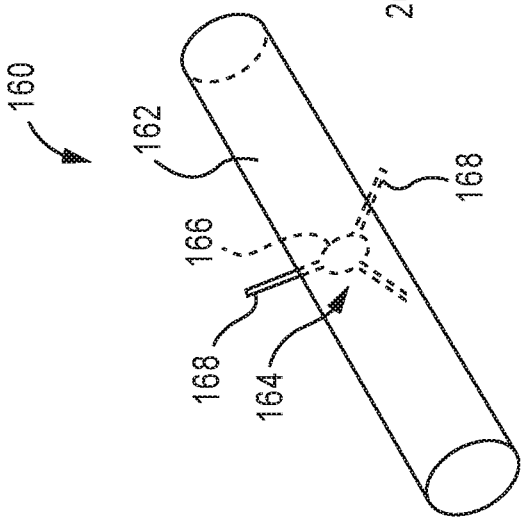


FIG. 5

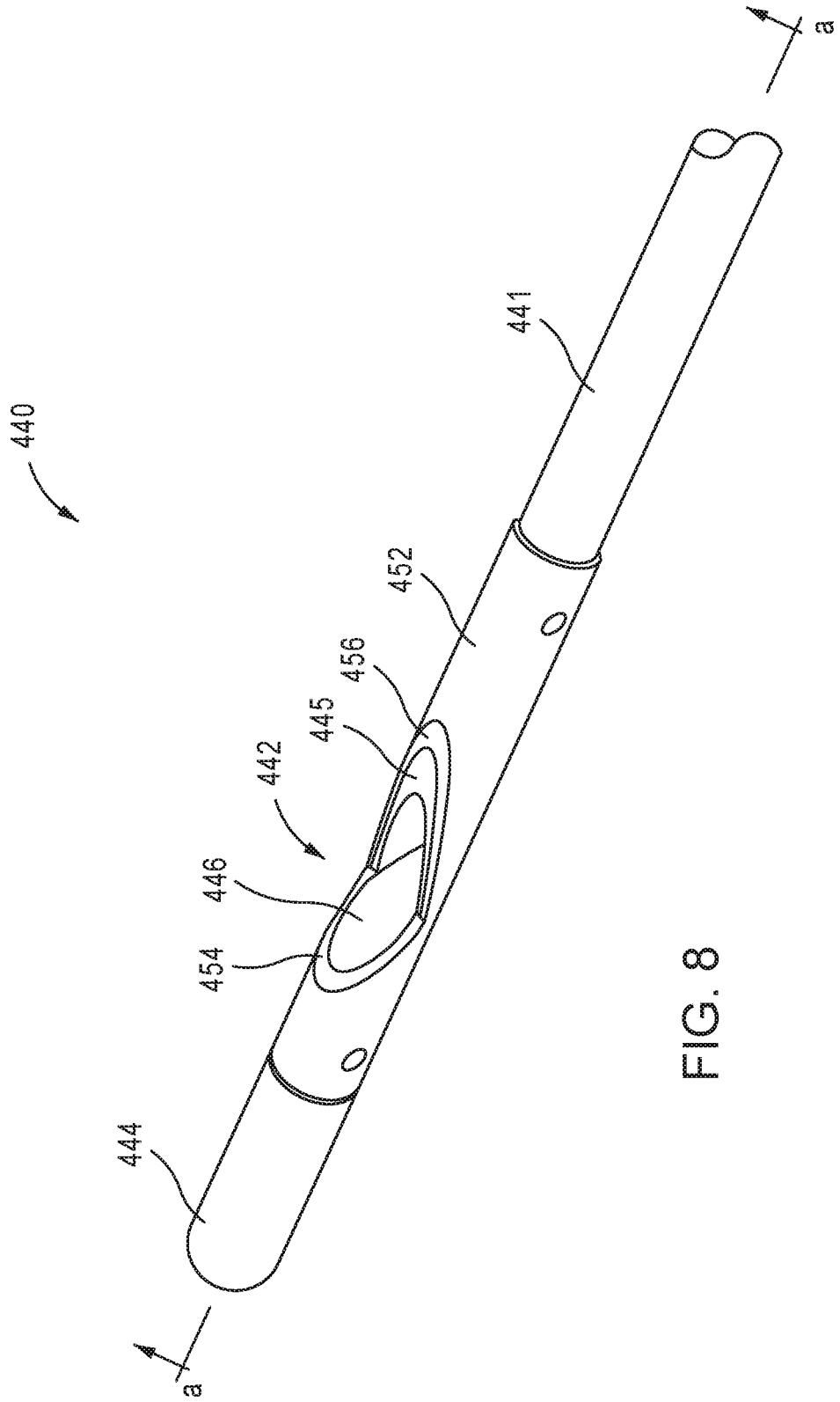


FIG. 8

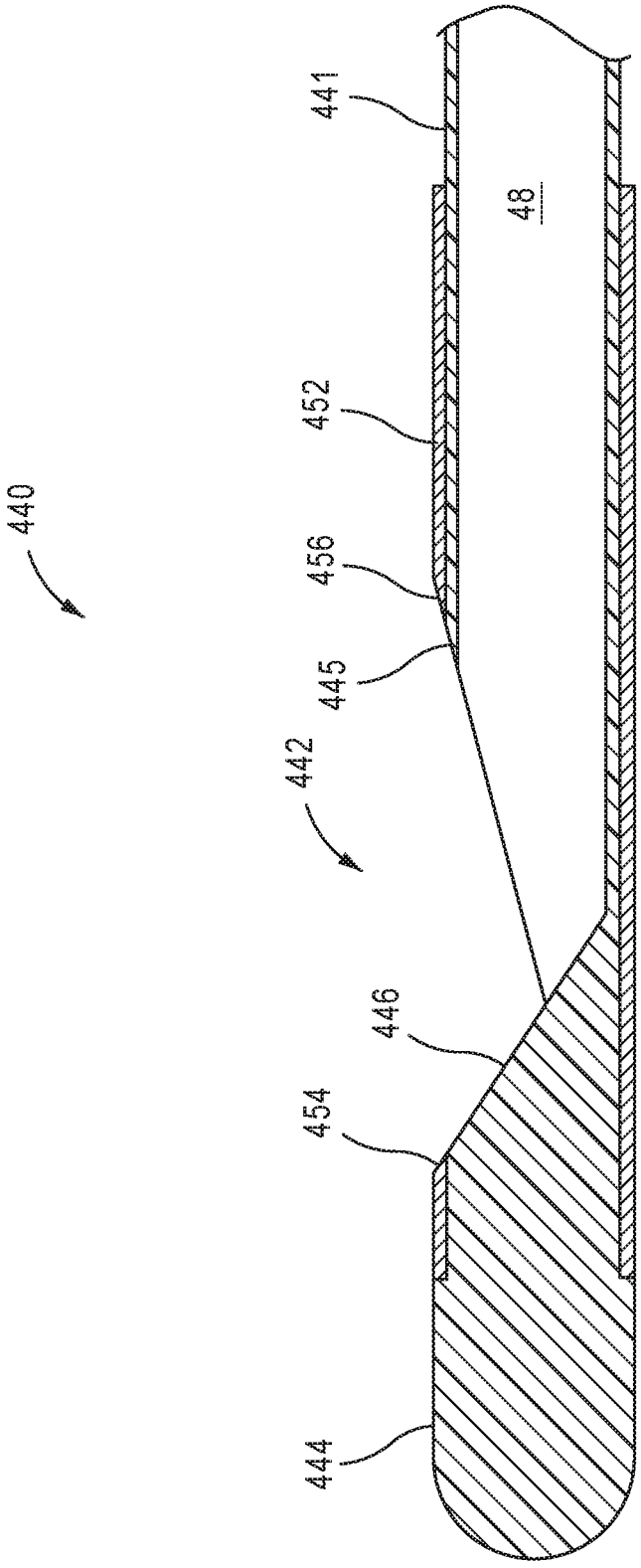


FIG. 9

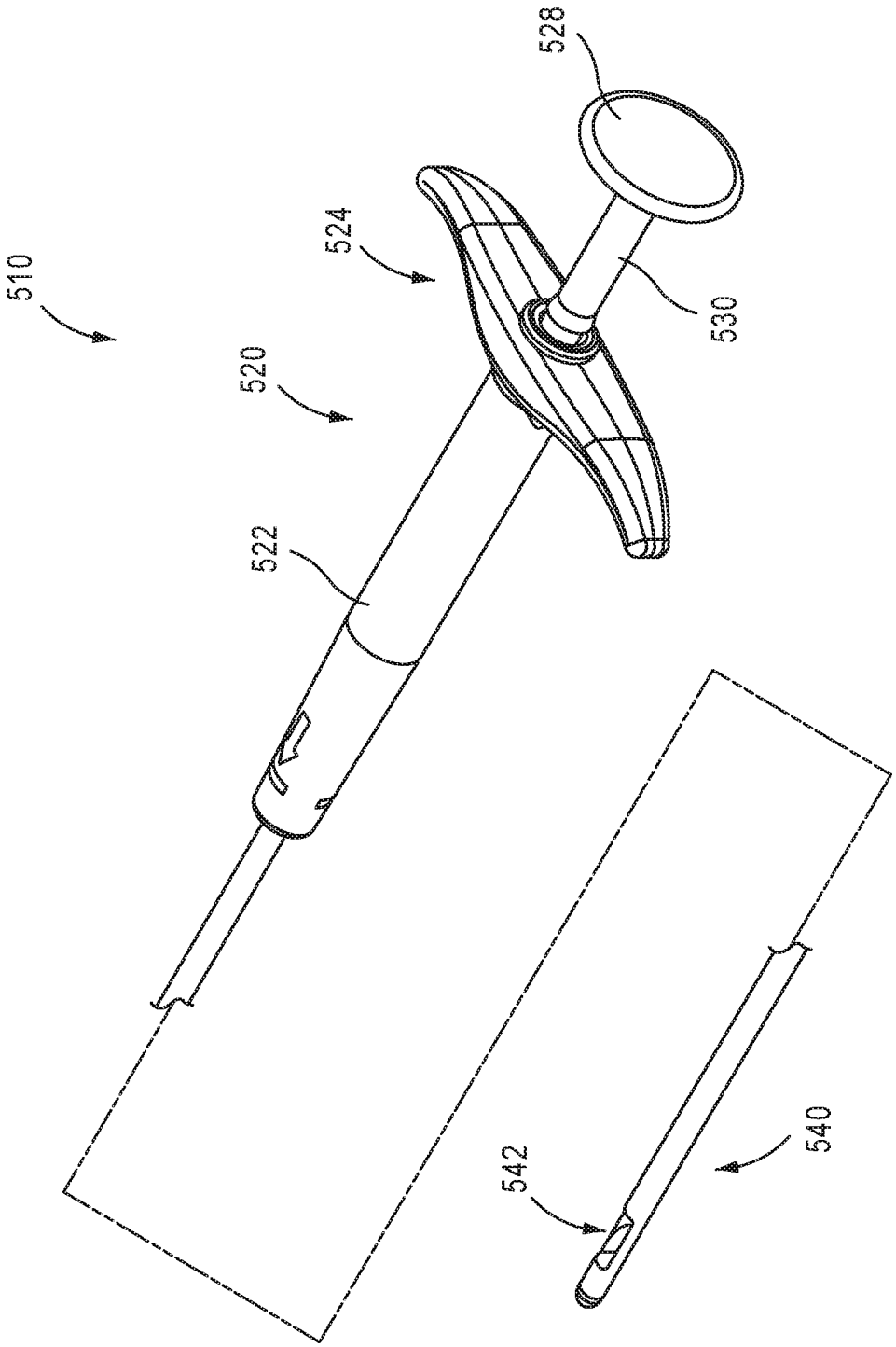


FIG. 10

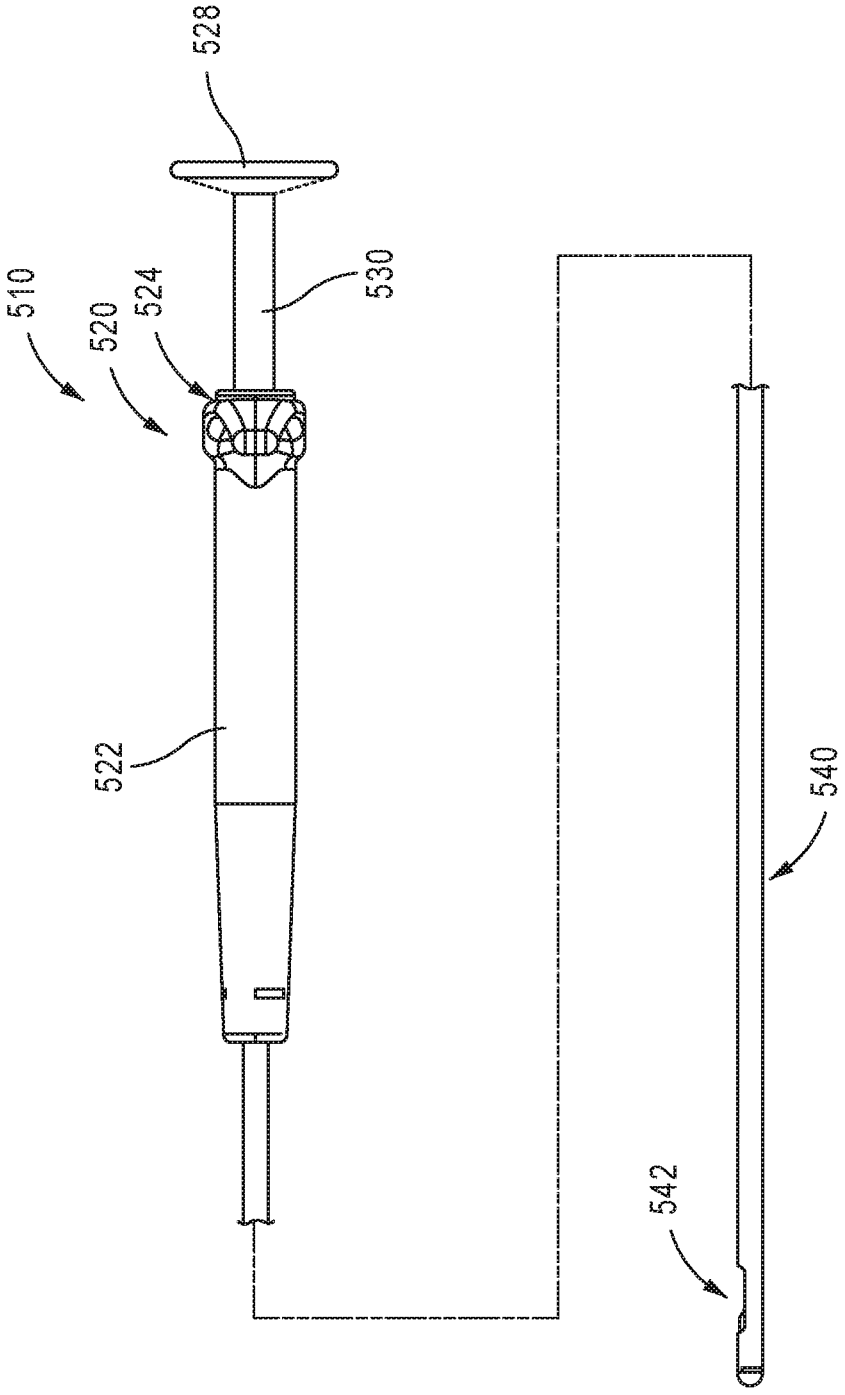


FIG. 11A

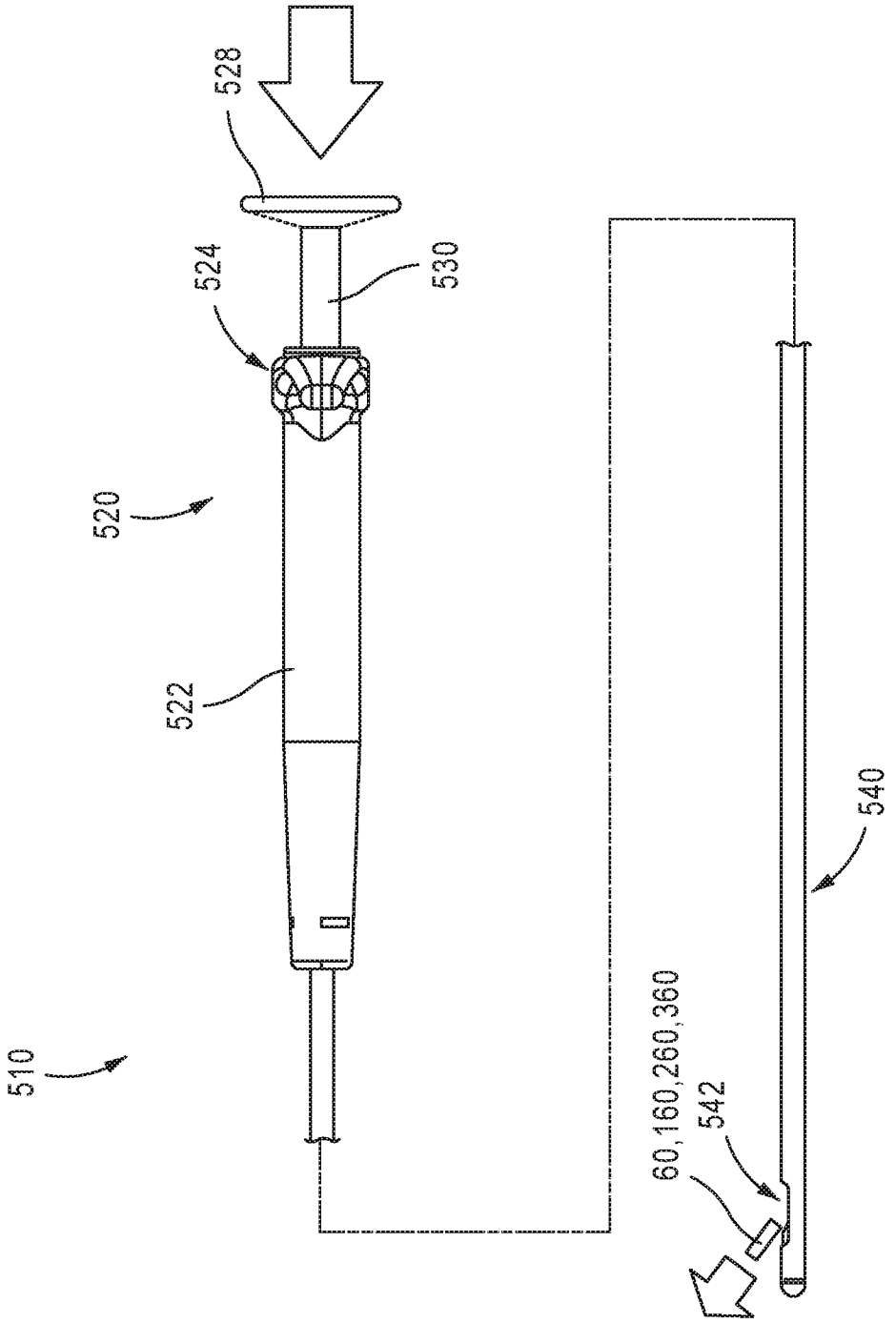


FIG. 11B

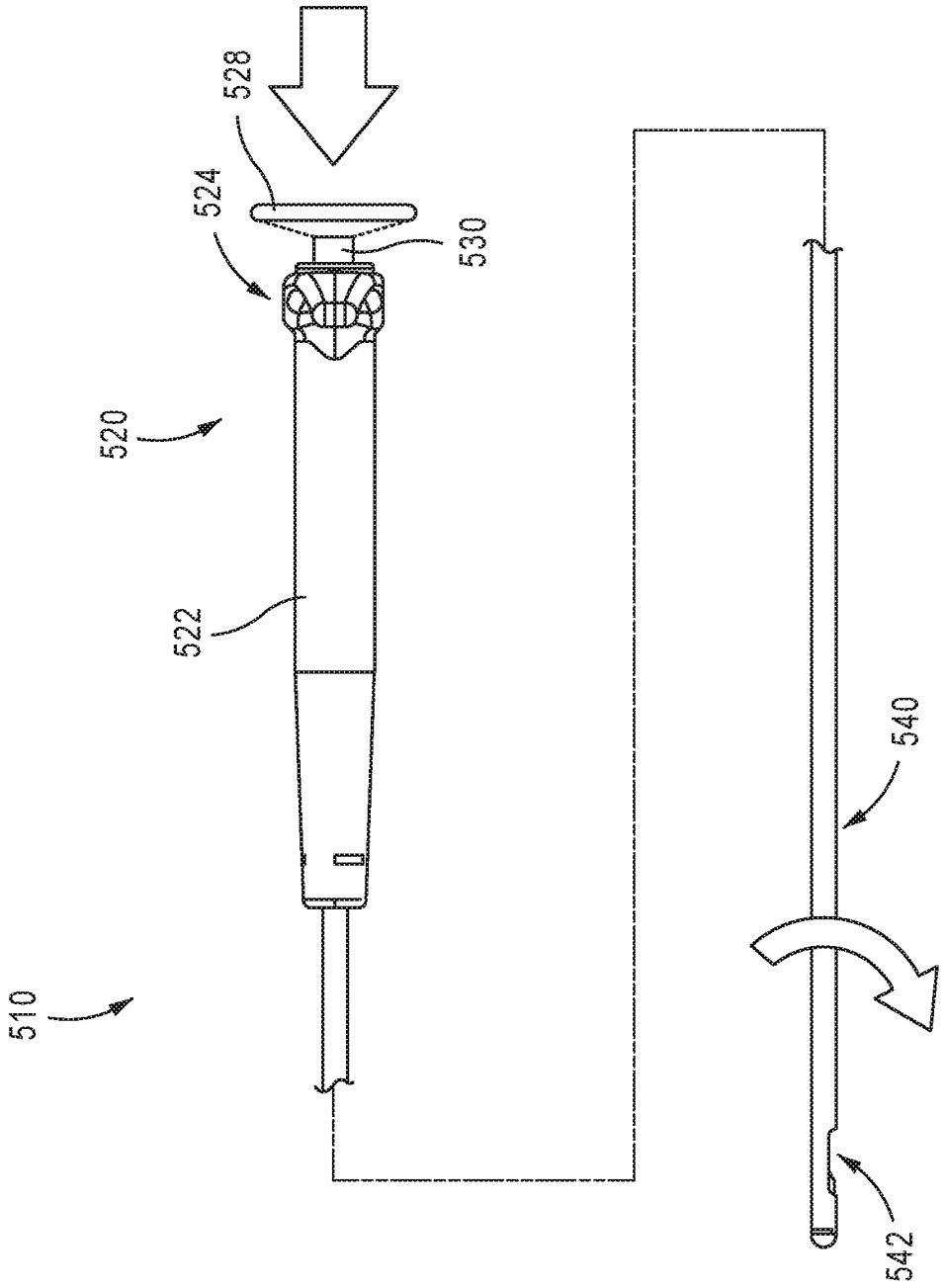


FIG. 11C

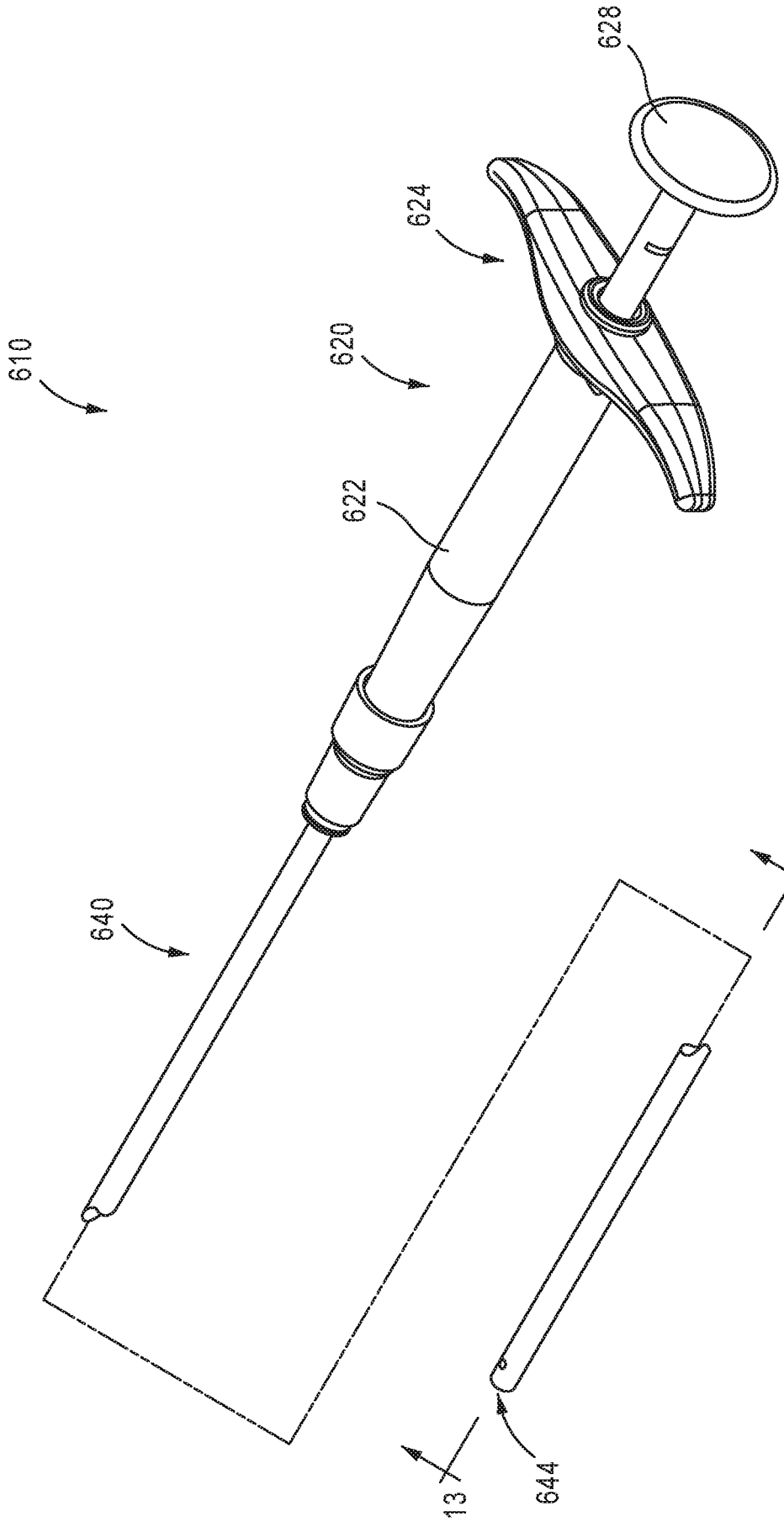


FIG. 12

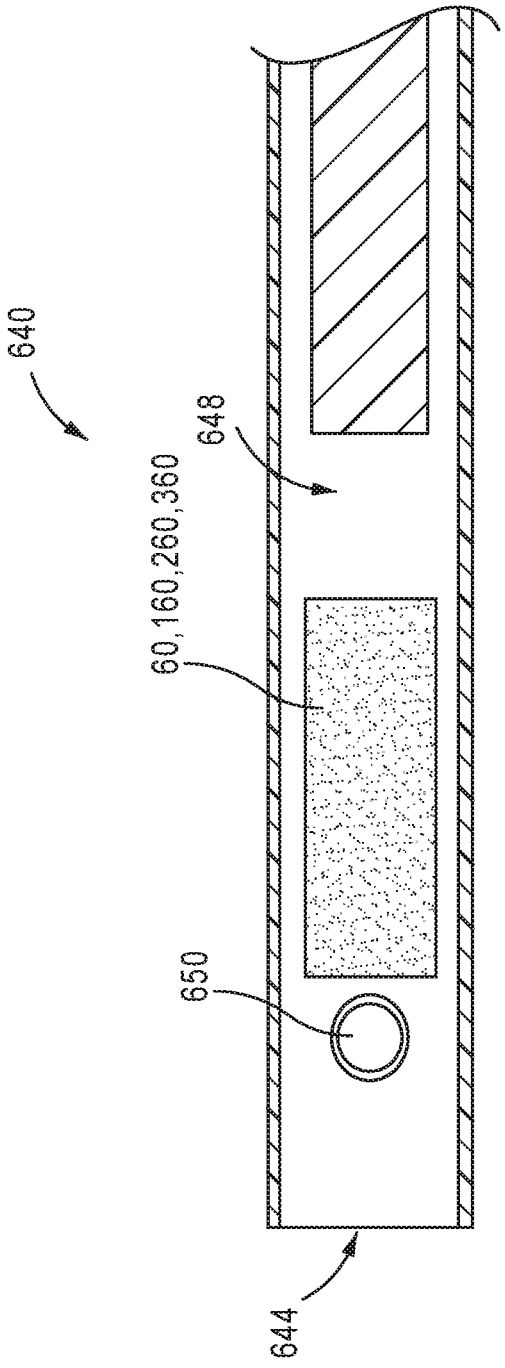


FIG. 13

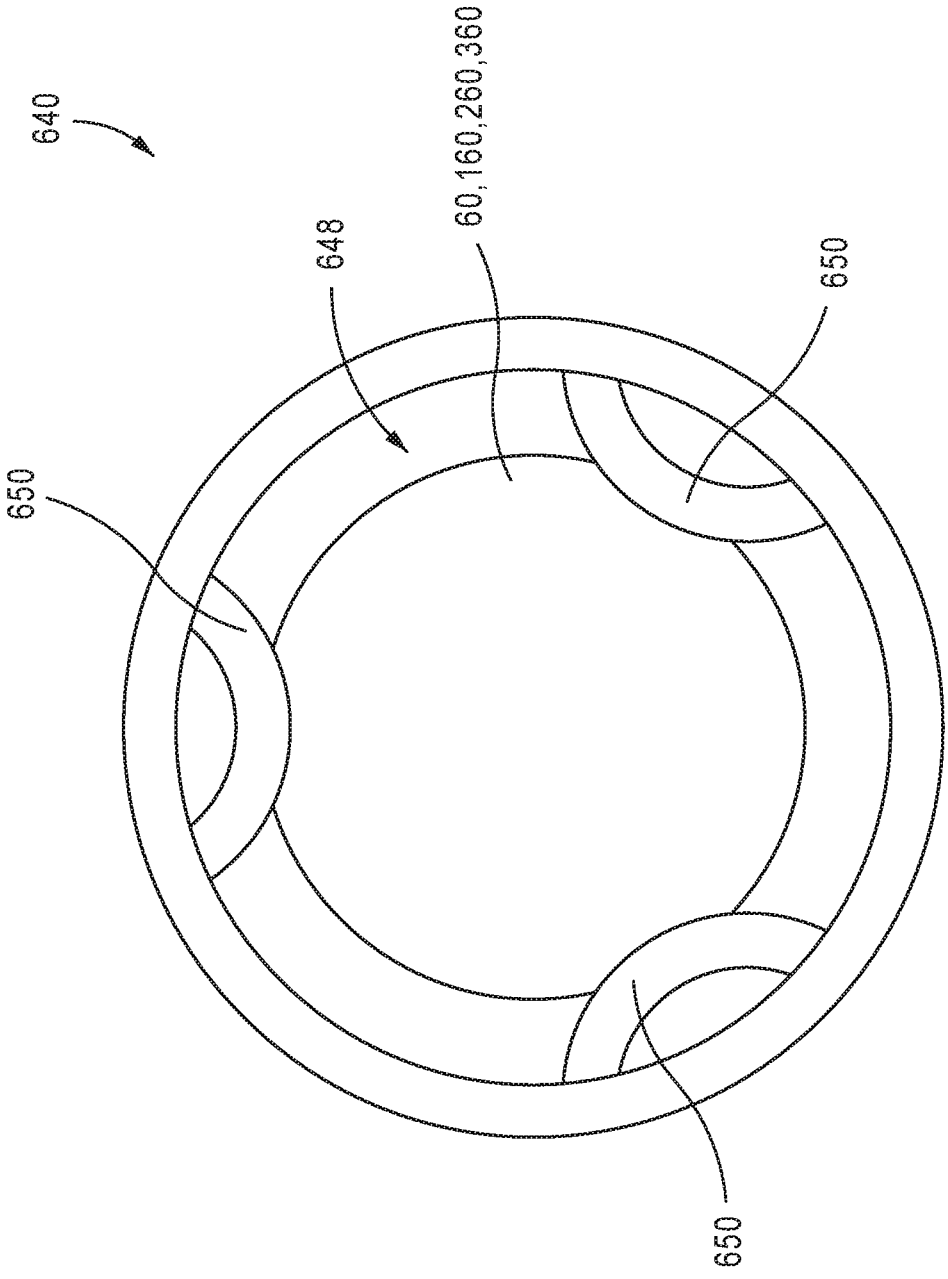


FIG. 14

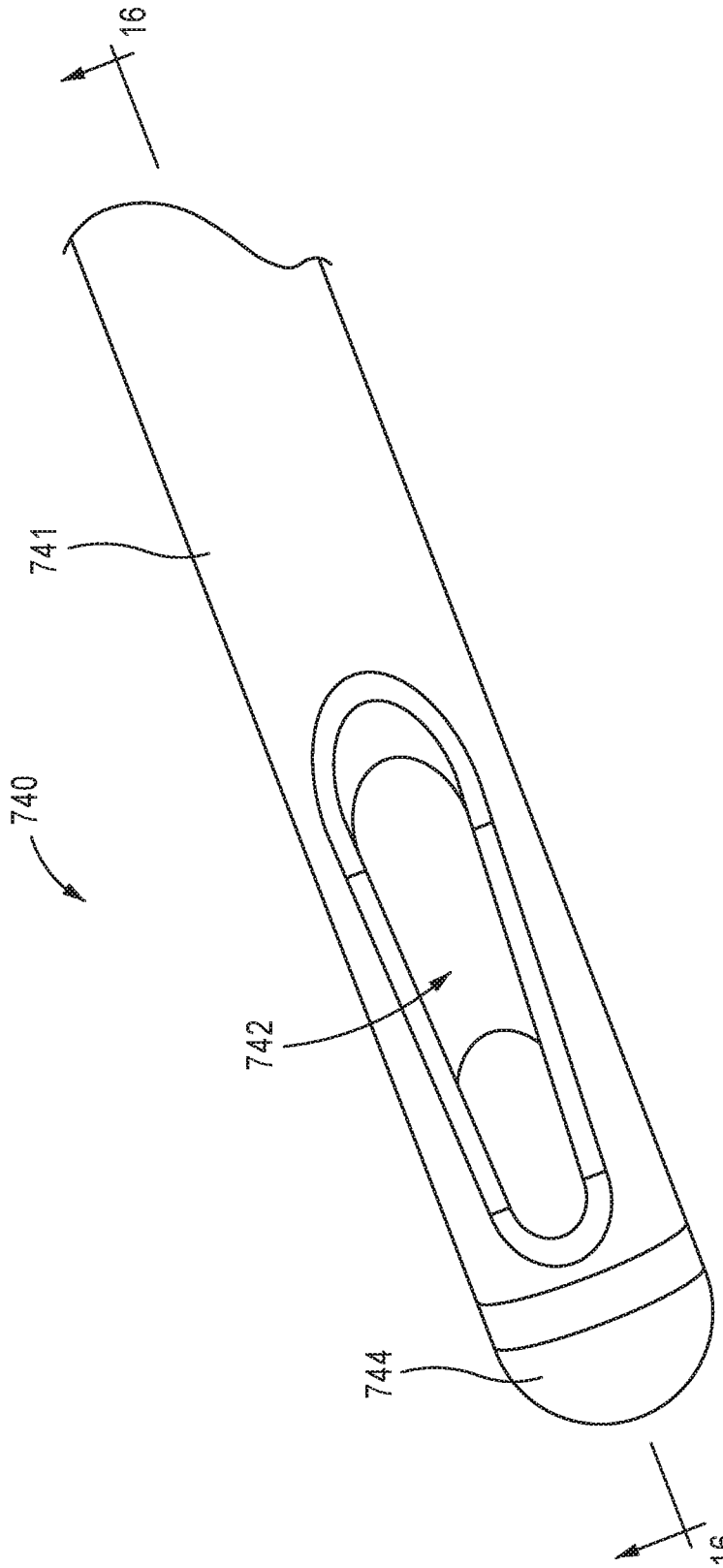


FIG. 15

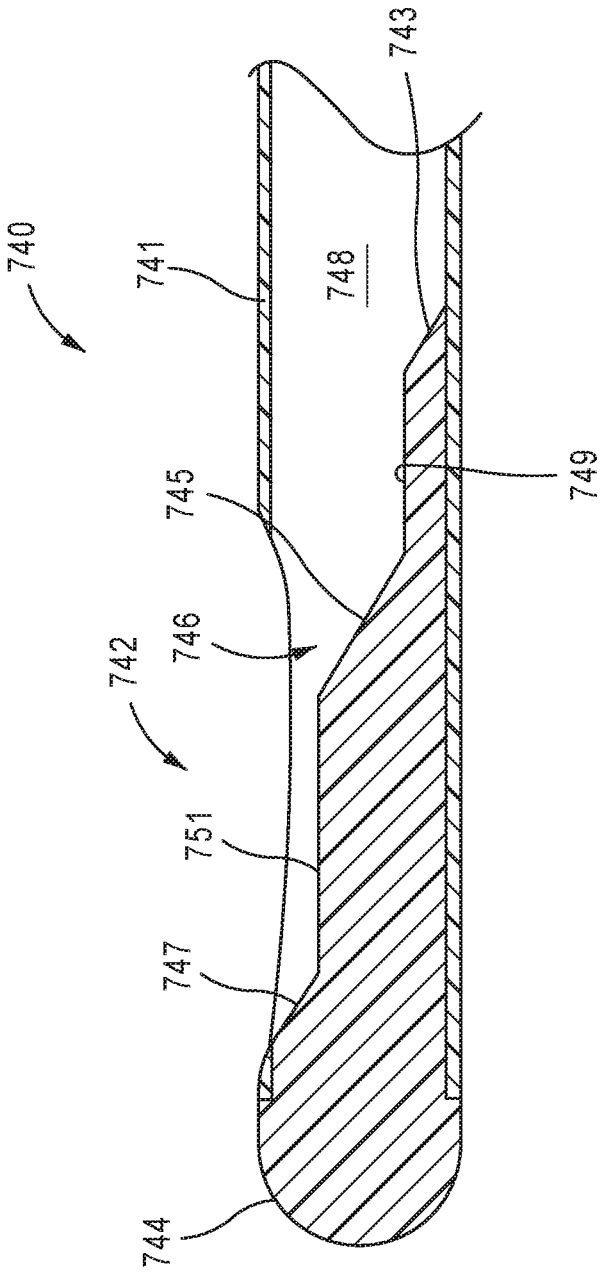


FIG. 16

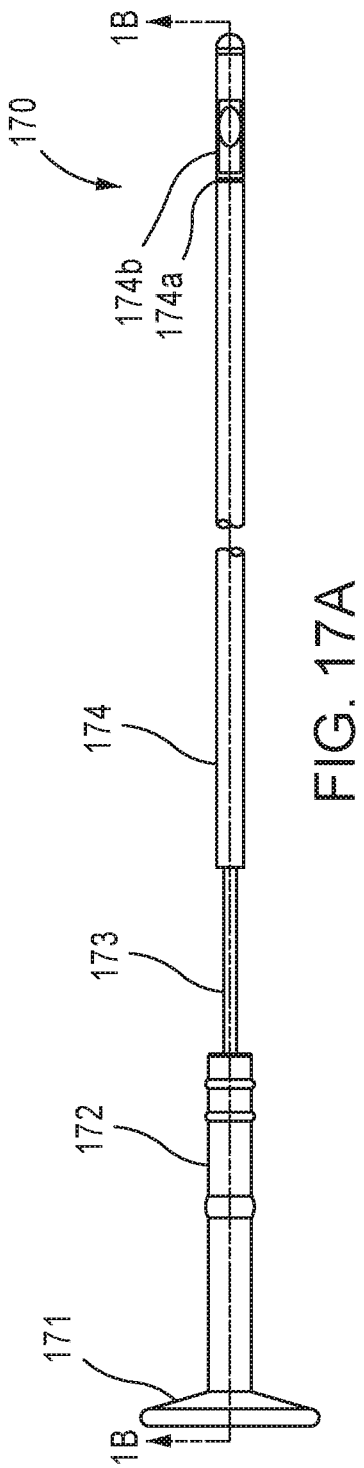


FIG. 17A

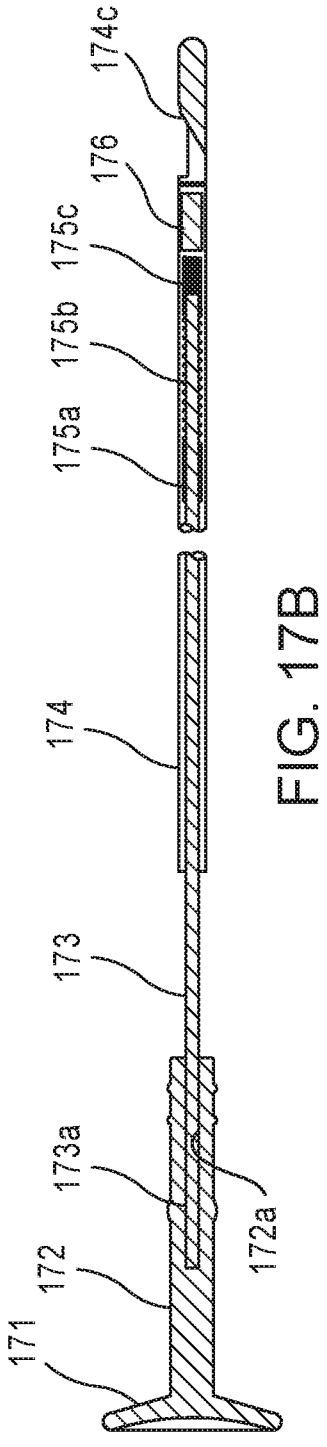


FIG. 17B

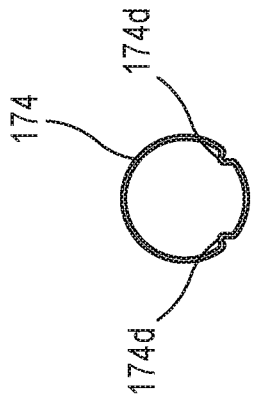


FIG. 17D

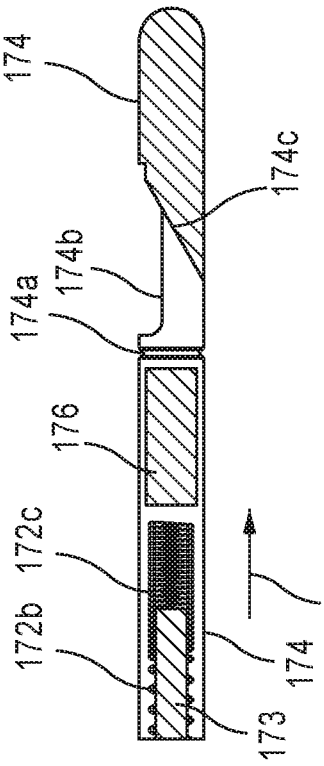


FIG. 17C

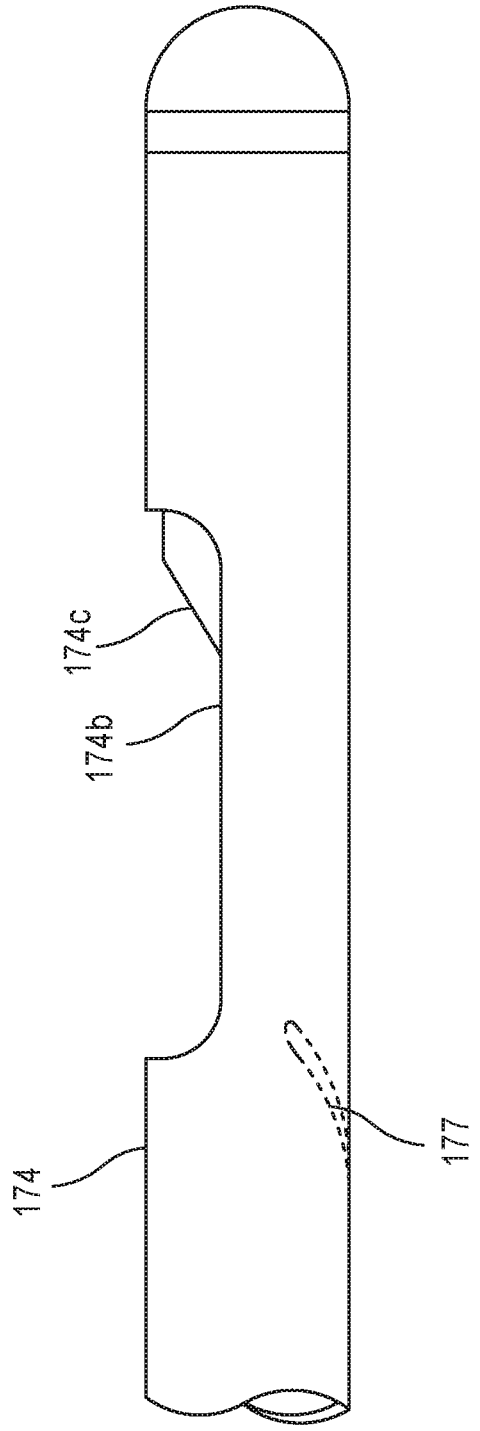


FIG. 18A

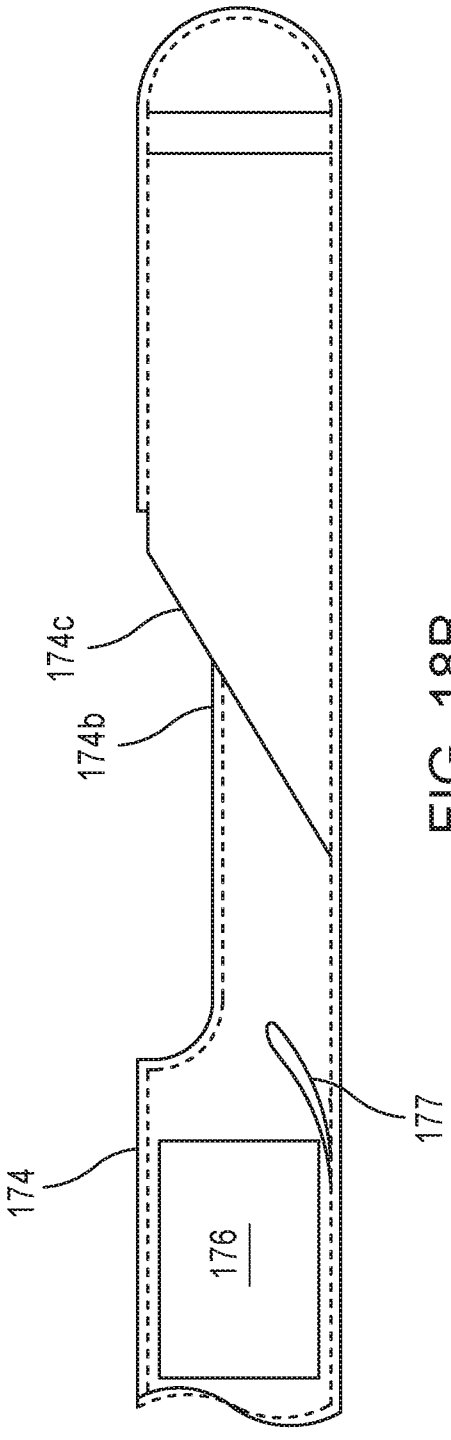


FIG. 18B

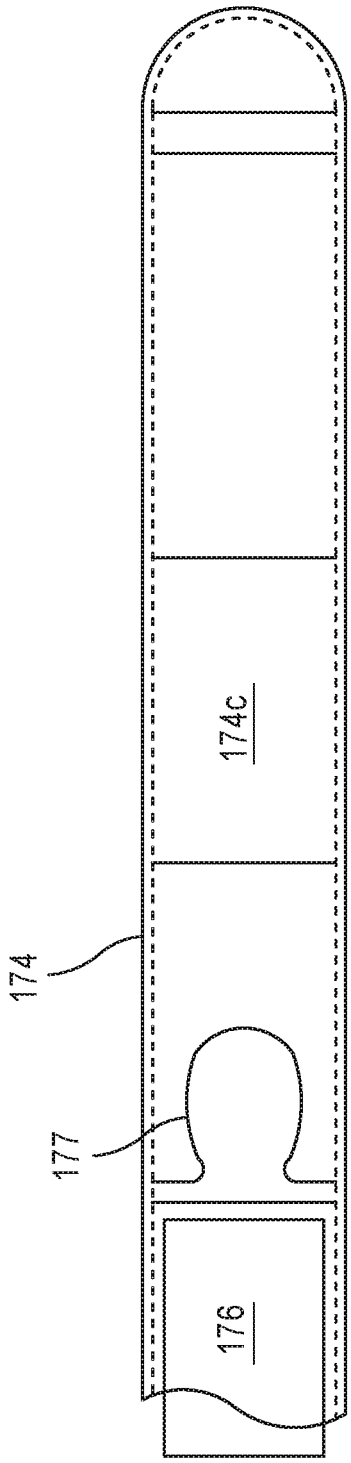


FIG. 18C

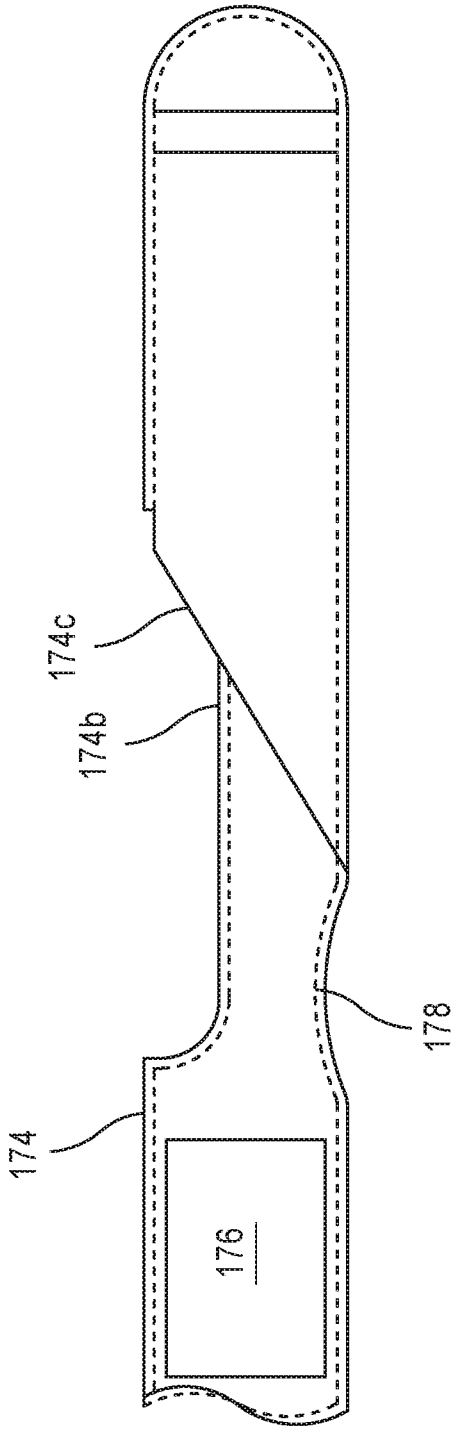


FIG. 19

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/059563

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B90/00 A61B10/00
ADD. A61B17/00

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)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2007/069105 A2 (SUROS SURGICAL SYSTEMS INC [US]; HARDIN TERRY [US]; NICOSON ZACHARY [U) 21 June 2007 (2007-06-21) paragraphs [0050] - [0061]; figures 1,7-11	1-10,12, 13
X	US 2011/071423 A1 (SPEEG TREVOR W V [US] ET AL) 24 March 2011 (2011-03-24) cited in the application	1-9,12, 13
Y	paragraphs [0022] - [0028], [0038] - [0043], [0049] - [0051]; figures 1-9	15-18
A	US 2008/119881 A1 (VETTER JAMES W [US]) 22 May 2008 (2008-05-22) paragraphs [0081], [0082]; figures 24,25	10

-/--

[X] Further documents are listed in the continuation of Box C.

[X] 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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"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	Date of mailing of the international search report
18 March 2016	30/03/2016

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Maier, Christian

2

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2013/006101 A1 (MCHUGO VINCENT [IE] ET AL) 3 January 2013 (2013-01-03) paragraphs [0019] - [0024], [0030]; figure 2	14 15-18
X	US 2010/063345 A1 (YUASA MASARU [JP]) 11 March 2010 (2010-03-11) paragraphs [0040] - [0047], [0105]; figures 1-3,7,14-16,30	14-16,18
X	US 2014/243844 A1 (CLANCY MICHAEL [IE] ET AL) 28 August 2014 (2014-08-28) paragraphs [0034] - [0039]; figures 3,3A,4,4A	14,17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/059563

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

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

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

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

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

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

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

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

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

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

1-18

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

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-13

A marker delivery device comprising a tube, having a first end and a lateral aperture, at least one biopsy marker disposed proximally of the lateral aperture, a push rod having a first end disposed at least partially within the tube, wherein the push rod is movable in a direction toward its first end to engage the at least one biopsy marker, and a resilient member extending from the first end of the push rod, wherein the resilient member is configured to engage the at least one biopsy marker when the push rod is moved in a direction toward its first end to drive the at least one biopsy marker through the lateral aperture of the tube, so that resilient member stays in contact with the marker during deployment for better control of marker ejection.

---

2. claims: 14-18

A marker delivery device comprising a tube having a first end, wherein the first end includes an opening and a plurality of stop members, wherein the plurality of stop members are disposed proximally of the opening, at least one biopsy marker disposed proximally of the plurality of stop members of the tube, and a push rod having a first end disposed at least partially within the tube, wherein the push rod is movable in a direction toward its first end to drive the at least one biopsy marker past the plurality of stop members and through the opening of the tube, so that the markers are retained within the tube by the stop members to avoid inadvertent movement of the markers within the tube.

---

3. claim: 19

A marker delivery device comprising a cannula, having a first end and a first opening, wherein the cannula comprises a first material, at least one biopsy marker disposed proximally of the first opening, a sleeve, wherein the sleeve is disposed over the lateral aperture and at least a portion of the first end of the cannula, wherein the sleeve comprises a second opening, wherein the second opening of the sleeve is configured to align with the first opening of the cannula to form a lateral aperture, a member having a first end disposed at least partially within the cannula, wherein the member is movable in a direction toward its first end to deploy the at least one biopsy marker through the lateral aperture formed by the first opening and the second opening, wherein the sleeve further comprises a second material, wherein the second material of the sleeve has a flexibility or resiliency less than a flexibility or

resiliency of the first material of the cannula, so that the sleeve provides structural reinforcement to the cannula to prevent deformation of the cannula during use.

---

4. claim: 20

A marker delivery device comprising a tube, having a first end and a lateral aperture, at least one biopsy marker disposed proximally of the lateral aperture, a push rod having a first end disposed at least partially within the tube, wherein the push rod is movable in a direction toward its first end to deploy the at least one biopsy marker, and an actuator having a plunger, wherein the actuator is in communication with the tube and the push rod, wherein the plunger of the actuator is movable through a first position and a second position, wherein the actuator is configured to move the push rod in a direction toward its first end when the plunger is moved to the first position, wherein the actuator is configured to rotate the tube when the plunger is moved to the second position, so that re-entry of the deployed marker into the device is prevented to avoid damage to the marker during removal of the device from the deployment site.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2015/059563

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2007069105 A2	21-06-2007	US 2007142725 A1	21-06-2007
		US 2010286627 A1	11-11-2010
		WO 2007069105 A2	21-06-2007
US 2011071423 A1	24-03-2011	NONE	
US 2008119881 A1	22-05-2008	EP 2129306 A2	09-12-2009
		US 2008119881 A1	22-05-2008
		US 2012109174 A1	03-05-2012
		WO 2008063570 A2	29-05-2008
US 2013006101 A1	03-01-2013	AU 2012275765 A1	23-01-2014
		CA 2840174 A1	03-01-2013
		CN 103648416 A	19-03-2014
		EP 2725990 A1	07-05-2014
		JP 2014526914 A	09-10-2014
		US 2013006101 A1	03-01-2013
		WO 2013003119 A1	03-01-2013
US 2010063345 A1	11-03-2010	JP 5015087 B2	29-08-2012
		JP 2010035770 A	18-02-2010
		US 2010063345 A1	11-03-2010
US 2014243844 A1	28-08-2014	EP 2967642 A1	20-01-2016
		US 2014243844 A1	28-08-2014
		WO 2014133777 A1	04-09-2014

(19)中华人民共和国国家知识产权局

(12)发明专利申请

(10)申请公布号 CN 107106254 A
(43)申请公布日 2017.08.29

(21)申请号 201580071997.2

(22)申请日 2015.11.06

(30)优先权数据
14/534,952 2014.11.06 US
62/134,715 2015.03.18 US

(85)PCT国际申请进入国家阶段日
2017.07.04

(86)PCT国际申请的申请数据
PCT/US2015/059563 2015.11.06

(87)PCT国际申请的公布数据
WO2016/073912 EN 2016.05.12

(71)申请人 DEVICOR医疗产业收购公司
地址 美国俄亥俄州

(72)发明人 弗雷德里克·阿哈里
蒂莫西·齐默 比克·权·阮

(74)专利代理机构 北京清亦华知识产权代理事务所(普通合伙) 11201
代理人 宋融冰

(51)Int.Cl.
A61B 90/00(2016.01)

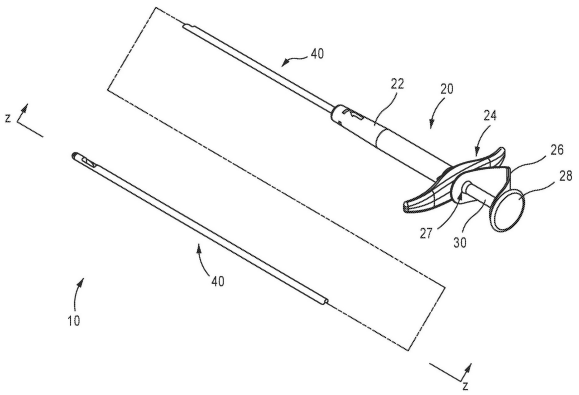
权利要求书2页 说明书13页 附图26页

(54)发明名称

弹簧弹出的活检标记物

(57)摘要

一种用于将标记物插入活检部位处的组织的装置，包括与柱塞共同地移动的细长轴，以及紧固至所述轴的远端的弹簧。该装置可以包括构造成接收所述轴的远端的套管，并且所述套管带有靠近所述轴的远端形成的褶皱、凹陷或者其它特征。套管可以包括侧向孔，在该侧向孔处标记物能够从套管的腔中弹出。可以形成与所述侧向孔连通的斜坡部分，并且所述斜坡部分可以包括控制标记物弹出的角度的预选坡度。



CN 107106254 A

1.一种标记物输送装置,包括:

管,所述管具有第一端和侧向孔;

至少一个活检标记物,所述至少一个活检标记物接近所述侧向孔设置;

推杆,所述推杆具有至少部分地设置在所述管内的第一端,其中所述推杆沿朝向其第一端的方向可移动以接合所述至少一个活检标记物;以及

弹性构件,所述弹性构件从所述推杆的所述第一端延伸,其中所述弹性构件构造成当所述推杆沿朝向所述推杆的第一端的方向移动时接合所述至少一个活检标记物以驱动所述至少一个活检标记物穿过所述管的所述侧向孔。

2.根据权利要求1所述的标记物输送装置,其中所述管包括径向地向内延伸的凸起。

3.根据权利要求2所述的标记物输送装置,其中所述向内延伸的凸起接近于所述侧向孔而定位。

4.根据权利要求2所述的标记物输送装置,其中所述向内延伸的凸起包括环形凸起。

5.根据权利要求2所述的标记物输送装置,其中所述向内延伸的凸起包括至少两个凹陷。

6.根据权利要求2所述的标记物输送装置,其中所述向内延伸的凸起包括舌片。

7.根据权利要求1所述的标记物输送装置,还包括:

尖端,所述尖端插入所述管的所述第一端。

8.根据权利要求7所述的标记物输送装置,其中所述尖端包括斜坡部分。

9.根据权利要求8所述的标记物输送装置,其中所述斜坡部分包括规定活检标记物从所述管弹出的角度的预选坡度。

10.根据权利要求1所述的标记物输送装置,其中所述弹性构件包括弹簧。

11.根据权利要求10所述的标记物输送装置,其中所述弹簧包括至少一个第一螺距区域以及第二螺距区域;其中所述第一螺距区域的线圈相对于所述第二螺距区域更加紧密地堆积。

12.根据权利要求1所述的标记物输送装置,其中所述活检标记物包括可吸收的本体。

13.根据权利要求1所述的标记物输送装置,其中所述活检标记物包括可变形的材料。

14.一种标记物输送装置,包括:

管,所述管具有第一端,其中所述第一端包括开口和多个止挡构件,其中所述多个止挡构件接近所述开口设置;

至少一个活检标记物,所述至少一个活检标记物接近所述管的所述多个止挡构件设置;以及

推杆,所述推杆具有至少部分地设置在所述管内的第一端,其中所述推杆沿朝向所述推杆的第一端的方向可移动以驱动所述至少一个活检标记物经过所述多个止挡构件并且穿过所述管的所述开口。

15.根据权利要求14所述的标记物输送装置,还包括:

尖端,所述尖端插入所述管的所述第一端。

16.根据权利要求15所述的标记物输送装置,其中所述尖端包括斜坡部分。

17.根据权利要求14所述的标记物输送装置,其中所述开口包括侧向孔。

18.根据权利要求14所述的标记物输送装置,还包括:

弹性构件，所述弹性构件从所述推杆的远端延伸。

19.一种标记物输送装置，包括：

套管，所述套管具有第一端和第一开口，其中所述套管包括第一材料；

至少一个活检标记物，所述活检标记物接近所述第一开口设置；

套，其中所述套设在侧向孔和所述套管的第一端的至少一部分上，其中所述套包括第二开口，其中所述套的所述第二开口构造成与所述套管的所述第一开口对准以形成侧向孔，其中所述套还包括第二材料，其中所述套的所述第二材料具有比所述套管的第一材料的柔性或者弹性小的柔性或者弹性；以及

构件，所述构件具有至少部分地设置在所述套管内的第一端，其中所述构件沿朝向所述构件的第一端的方向可移动以通过由所述第一开口和所述第二开口形成的所述侧向孔来部署所述至少一个活检标记物。

20.一种标记物输送装置，包括：

管，所述管具有第一端和侧向孔；

至少一个活检标记物，所述至少一个活检标记物接近所述侧向孔设置；

推杆，所述推杆具有至少部分地设置在所述管内的第一端，其中所述推杆沿朝向所述推杆的第一端的方向可移动以部署所述至少一个活检标记物；以及

致动器，所述致动器具有柱塞，其中所述致动器与所述管和所述推杆连通，其中所述致动器的所述柱塞能够移动通过第一位置和第二位置，其中所述致动器构造成当所述柱塞移动至所述第一位置时，沿朝向所述推杆的第一端的方向移动所述推杆，其中所述致动器构造成当所述柱塞移动至所述第二位置时，旋转所述管。

弹簧弹出的活检标记物

[0001] 相关申请的交叉引用

[0002] 本申请要求2014年11月6日提交的标题为“SPRING-EJECTED BIOPSY MARKER(弹簧弹出的活检标记物)”、申请号为14/534,952的美国专利申请以及2015年3月18日提交的标题为“Biopsy Marker Delivery Device(活检标记物输送装置)”、申请号为62/134,715的美国临时申请的权益,两个文献的全部内容通过引用明确地并入本文。

技术领域

[0003] 本公开一般地涉及在活检部位处插入活检标记物的装置。特别地,本公开涉及一种装置,其采用弹簧将标记物从该装置的侧向孔弹出至组织中。

背景技术

[0004] 已经使用多种装置在不同医疗程序中以多种方式获得了活检样本。可以在立体定位引导、超声引导、磁共振成像(MRI)引导、正电子发射乳腺摄影(PEM)引导、胸腺特异性伽玛成像(BSGI)引导或其他引导下使用活检装置。例如,一些活检装置能够由使用者完全利用单手操作,并且通过单次插入以从患者处捕获一个或多个活检样本。此外,一些活检装置可以被拴系至真空模块和/或控制模块上,如用于连通流体(例如,压缩空气、盐水、大气、真空)的连通、传送能量、和/或传达指令等。其他活检装置可以是完全或至少部分可操作的,而不被拴系或以另外的方式与另一个装置连接。

[0005] 仅作为示例的活检装置和活检系统部件公开于美国专利第5,526,822号,题为“Method and Apparatus for Automated Biopsy and Collection of Soft Tissue”,1996年6月18日授权公告;美国专利第5,928,164号,题为“Apparatus for Automated Biopsy and Collection of Soft Tissue”,1999年7月27日授权公告;美国专利第6,017,316号,题为“Vacuum Control System and Method for Automated Biopsy Device”,2000年1月25日授权公告;美国专利第6,086,544号,题为“Control Apparatus for an Automated Surgical Biopsy Device”,2000年7月11日授权公告;美国专利第6,626,849号,题为“MRI Compatible Surgical Biopsy Device”,2003年9月11日授权公告;美国专利第7,442,171号,题为“Remote Thumbwheel for a Surgical Biopsy Device”,2008年10月8日授权公告;美国专利第7,648,466号,题为“Manually Rotatable Piercer”,2010年1月19日授权公告;美国专利第7,854,706号,题为“Clutch and Valving System for Tetherless Biopsy Device”,2010年12月1日授权公告;美国专利第7,938,786号,题为“Vacuum Timing Algorithm for Biopsy Device”,2011年5月10日授权公告;美国专利第8,118,755号,题为“Biopsy Sample Storage”,2012年2月21日授权公告;美国专利第8,206,316号,题为“Tetherless Biopsy Device with Reusable Portion”,2012年6月26日授权公告;美国专利第8,241,226号,题为“Biopsy Device with Rotatable Tissue Sample Holder”,2011年8月14日授权公告;和美国专利第8,702,623号,题为“Biopsy Device with Discrete Tissue Chambers”,2014年4月22日授权公告。上述每个美国专利

的公开内容以引用的方式并入本文。

[0006] 其它示例性活检装置和活检系统部件公开于美国专利公开第2008/0146962号,题为“Biopsy System with Vacuum Control Module”,2008年6月19日公布;美国专利公开第2008/0214955号,题为“Presentation of Biopsy Sample by Biopsy Device”,2008年9月4日公布;美国专利公开第2013/0041256号,题为“Access Chamber and Markers for Biopsy Device”,2013年2月14日公布;美国专利公开第2013/0053724号,题为“Biopsy Device Tissue Sample Holder with Bulk Chamber and Pathology Chamber”,2013年2月28日公布;美国专利公开第2013/0150751号,题为“Biopsy Device With Slide-In Probe”,2013年6月13日公布;美国专利公开第2013/0324882号,题为“Control for Biopsy Device”,2013年12月5日公布;和美国专利公开第2014/0039343号,题为“Biopsy System”,2014年2月6日公布。上述每个美国专利申请公开的公开内容以引用的方式并入本文。

[0007] 在一些情况中,可能希望标记活检部位的位置以供未来参考。例如,可在从活检部位获取组织样本之前、期间或之后将一个或多个标记物放置在活检部位处。示例性标记物部署工具包括来自Devicor Medical Products,Inc.of Cincinnati,Ohio的MAMMOMARK™、MICROMARK®和CORMARK™品牌装置。用于标记活检部位的其它示例性装置和方法公开于美国公开第2009/0209854号,题为“Biopsy Method”,2009年8月20日公布;美国公开第2009/0270725号,题为“Devices Useful in Imaging”,2009年10月29日公布;美国公开第2010/0049084号,题为“Biopsy Marker Delivery Device”,2010年2月25日公布;美国公开第2011/0071423号,题为“Flexible Biopsy Marker Delivery Device”,2011年3月24日公布;美国公开第2011/0071424号,题为“Biopsy Marker Delivery Device”,2011年3月24日公开;美国公开第2011/0071391号,题为“Biopsy Marker Delivery Device with Positioning Component”,2011年3月24日公布;美国专利第6,228,055号,题为“Devices for Marking and Defining Particular Locations in Body Tissue”,2001年5月8日授权公告;美国专利第6,371,904号,题为“Subcutaneous Cavity Marking Device and Method”,2002年4月16日授权公告;美国专利第6,993,375号,题为“Tissue Site Markers for In Vivo Imaging”,2006年1月31日授权公告;美国专利第6,996,433号,题为“Imageable Biopsy Site Marker”,2006年2月7日授权公告;美国专利第7,044,957号,题为“Devices for Defining and Marking Tissue”,2006年5月16日授权公告;美国专利第7,047,063号,题为“Tissue Site Markers for In Vivo Imaging”,2006年5月16日授权公告;美国专利第7,229,417号,题为“Methods for Marking a Biopsy Site”,2007年6月12日授权公告;和美国专利第7,465,279号,题为“Marker Device and Method of Deploying a Cavity marker Using a Surgical Biopsy Device”,2008年12月16日授权公告。上述美国专利和美国专利申请公开中每者的公开内容以引用的方式并入本文。

发明内容

[0008] 本公开的方面涉及装置和系统,以及制造和使用所述装置和系统的方法。所述装置和系统包括推杆(例如柱塞和/或轴)、管或者其它套管、斜坡部分、侧向孔,以及在所述轴的至少一部分上延伸的弹簧。根据本公开的一些方面,装置可以构造成在每次使用它时,以相同量的力弹出标记物。在一些方面中,本装置可以不依赖于由使用者施加的任何力来操

作，并且确保一致地、可重复地放置所述标记物。

[0009] 这些方面的附加优点和新颖特征将在下面的描述中部分地提出，并且部分对于本领域技术人员而言将通过下面的审查变得更加明显或者通过本公开的实践了解到。

附图说明

[0010] 图1描绘根据本公开的方面的示例性标记物输送装置的立体图。

[0011] 图2描绘标记物输送装置的远端的截面图，其中该截面沿图1中的线2-2截取。

[0012] 图3A描绘图1中的标记物输送装置的轴的远端的侧视图。

[0013] 图3B描绘图1中的标记物输送装置的远端的局部截面图，其中轴和弹簧在初始的近侧位置。

[0014] 图3C描绘图1中的标记物输送装置的远端的局部截面图，其中轴和弹簧部分地向远侧前进。

[0015] 图3D描绘图1中的标记物输送装置的远端的局部截面图，其中轴和弹簧完全地向远侧前进。

[0016] 图4描绘图1中的标记物输送装置的套管的截面图，其中该截面沿图2中的线4-4截取。

[0017] 图5描绘用于图1中的标记物输送装置的示例性标记物的立体图。

[0018] 图6描绘用于图1中的标记物输送装置的另一个示例性标记物的立体图。

[0019] 图7描绘用于图1中的标记物输送装置的再一个示例性标记物的立体图。

[0020] 图8描绘用于图1中的标记物输送装置的示例性替代套管的立体图。

[0021] 图9描绘图8中的套管的截面图，其中该截面沿图8中的线9-9截取。

[0022] 图10描绘根据本公开的方面的示例性替代标记物输送装置的立体图。

[0023] 图11A描绘根据图9中的标记物输送装置的侧视图，其中柱塞在未驱动位置。

[0024] 图11B描绘根据图9中的标记物输送装置的另一个侧视图，其中柱塞在部分驱动位置。

[0025] 图11C描绘根据图9中的标记物输送装置的再一个侧视图，其中柱塞在完全驱动位置。

[0026] 图12描绘根据本公开的方面的另一个示例性替代标记物输送装置的立体图。

[0027] 图13描绘图12中的标记物输送装置的截面图，其中该截面沿图12中的线13-13截取。

[0028] 图14描绘图12中的标记物输送装置的套管的端视图。

[0029] 图15描绘用于图1中的标记物输送装置的另一个示例性替代套管的立体图。

[0030] 图16描绘图15中的套管的截面图，其中该截面沿图15中的线16-16截取。

[0031] 图17A描绘根据本公开的方面的具有脱离零件的示例性装置的各种特征的侧视图，以表明结构的长度可以是任何预选的长度。

[0032] 图17B描绘沿图17A中的沿1B-1B截取的纵向截面图。

[0033] 图17C描绘在图17B中所绘结构的远端的放大图。

[0034] 图17D描绘替代方面，其中凹陷代替图1A中的环形褶皱。

[0035] 图18A以侧视图概略地描绘本装置的一个方面。

[0036] 图18B描绘在图18A所绘结构的纵向的侧视截面图。

[0037] 图18C描绘在图18A所绘结构的纵向的俯视截面图。

[0038] 图19描绘根据本公开的方面的示例性装置的各个特征的侧视图。

具体实施方式

[0039] 本公开的各个方面的某些示例的以下描述不应该用于限制其范围。通过以下描述，本技术的其它示例、特征、方面、变型和优点对本领域技术人员来说将变得明显，这些描述以图示的方式进行，是预期用于实施本技术的最佳模式之一。将认识到，本公开的方面能够具有其它不同且明显的实现方式，所有这些实现方式均不脱离其范围。因此，附图和描述在本质上应该视为说明性和非限制性的。

[0040] 图1-图4示出标记物输送装置(10)，该标记物输送装置(10)可以用于活检装置或者靶向组，以便将标记物输送到活检部位。标记物输送装置(10)包括本体(20)以及套管(40)。如图1所示，本体(20)包括细长壳体(22)、手柄(24)、弹性构件(26)以及柱塞(28)。壳体(22)将本体(20)联接到套管(40)。此外，壳体(22)可以封闭标记物输送装置(10)的其它操作部件，例如密封件、弹簧、衬套，或者鉴于本文的教导，对于本领域普通技术人员来说是明显的其它操作部件。

[0041] 手柄(24)被定位在壳体(22)的近端处，并且例如被构造成由使用者的手指抓握。如在下面将更详细描述的，手柄(24)一般构造成允许标记物输送装置(10)由使用者单手操作。本示例的手柄(24)与壳体(22)一体地构造。然而在其它示例中，替代地，手柄(24)可以与壳体(22)分开。

[0042] 弹性构件(26)设置在手柄(24)和柱塞(28)之间。特别地，本示例的弹性构件(26)包括具有两个开口(27)的板簧，所述两个开口(27)在弹性构件(26)的任一端上。开口(27)构造成可滑动地接收轴(30)。如在下面将更详细描述的，轴(30)相对于本体(10)是可滑动的，以便选择性地从标记物输送装置(10)弹出标记物(60)。尽管弹性构件(26)示出为板簧，可以理解的是，在其它示例中，可以使用任何其它合适的弹性装置，例如螺旋弹簧。

[0043] 柱塞(28)被定位在轴(30)的近端处。柱塞(28)通常被构造成由使用者推动以便相对于本体(20)和套管(40)向远侧致动轴(30)。此外，如示出的，柱塞(28)抵靠弹性构件(26)，使得在使用者已经通过柱塞(28)驱动标记物输送装置后，弹性构件(26)可以使轴(30)返回到在图1中示出的近侧位置。如在下面将更详细描述的，柱塞(28)和手柄(24)共同构造，例如使得使用者可以使用两个手指(例如，食指和中指)抓握手柄(24)，并且使用另一个手指(例如，拇指)推动柱塞(28)。可以理解的是，尽管未示出，柱塞(28)可以装配有柱塞锁或者其它锁定特征，以便允许使用者将柱塞(28)棘轮啮合或者锁定在给定位置处(例如，将柱塞(28)锁定在近侧位置和/或将柱塞(28)锁定在远侧位置等等)。合适的锁定特征可以包括弹性闩锁臂，卡口闩锁特征，螺纹特征等等。

[0044] 套管(40)包括从壳体(22)向远侧延伸的细长的管状轴。套管(40)通常向远侧延伸一段适于插入活检装置或者靶向组的长度，使得套管(40)可以延伸到活检部位以输送标记物(60)。在本示例中，套管(40)的远端包括侧向孔(42)和远侧尖端(44)。如在图1中示出的，侧向孔(42)被定位成接近于套管(40)的远端。如会被理解的，侧向孔(42)相对于套管(40)的远端的特定位置被构造成使得侧向孔(42)可以与活检装置的针的相应的侧向孔对准。

[0045] 如在图2中最能看出，远侧尖端(44)被插入套管(40)的远端，并且纵向地延伸进入侧向孔(42)的至少一部分。远侧尖端(44)的近端包括斜坡部分(46)。如在下面将更详细描述的，斜坡部分(46)构造成引导来自套管腔(48)的标记物(60)，该套管腔(48)纵向地延伸穿过套管(40)且与侧向孔(42)连通。

[0046] 套管腔(48)从套管(40)的近端延伸至套管(40)的远端。尽管未在图2中示出，应当理解的是，在一些示例中，套管腔(48)可以延伸进入壳体(22)，使得本体(20)的轴(30)可以与腔连通。特别地，如可以在图2中看出的，轴(30)延伸贯穿本体(20)且在终止于套管(40)的远端附近之前，进入套管(40)中。如在下面将更详细描述的，轴(30)可滑动地设置在套管腔(48)内以便接合标记物(60)，从而驱动标记物(60)到斜坡部分(46)上并且从侧向孔(42)出去。在一些方面中，斜坡部分(46)的坡度可以控制标记物(60)从套管腔(48)弹出的角度。

[0047] 尽管本示例的轴(30)示出为同轴地设置在套管腔(48)内，在其它示例中，轴(30)可以终止在本体(20)内，并且单独的构件、轴或者杆可以延伸进入套管腔(48)。

[0048] 根据本公开的一些方面，如在图17A中所示的，装置可以包括具有放大的近端(171)的柱塞(172)，例如，所述近端(171)可以用作用于使用者的把手。如在图17B中所示的，细长轴(16)的近端(173a)可以被接收在形成在柱塞(172)上的孔(172a)内，并且可以紧固至其上，从而轴(173)可以与柱塞(172)共同移动。

[0049] 在这个方面中，细长套管(174)可滑动地接收轴(173)的远端。如在图17C中所示的，根据一些方面，在套管(174)内在其远端附近可以形成环形褶皱(174a)。根据一些方面，套管(174)可以包括侧向孔(174b)，在所述侧向孔(174b)处将标记物(176)从套管(174)的腔内弹出。

[0050] 如在图3A中可以看到的，本示例的轴(30)的远端包括弹簧(90)，该弹簧(90)在轴(30)的远端的至少一部分上延伸。特别地，该示例的弹簧(90)包括与轴(30)的至少一部分同轴的多螺距螺旋弹簧，例如，所述弹簧(90)被构造成每1/10英寸的压缩产生1.91至2.4磅力之间的力。在本示例中，弹簧(90)由生物相容的不锈钢组成，然而可以使用任何其它合适的生物相容的材料。弹簧(90)包括第一螺距区域(92)、第二螺距区域(94)和第三螺距区域(96)。第一螺距区域(92)和第三螺距区域(96)包括基本上相同的螺距。应当理解的是，本文使用的术语“螺距”一般指弹簧(90)的每个线圈之间的间距。例如，第一螺距区域和第三螺距区域(96)的螺距相对于第二螺距区域(94)的螺距可以较小。术语“螺距”也可以理解为涉及每单元轴向距离的线圈(例如，每英寸的线圈)的特定数量。

[0051] 在本示例的第一螺距区域(92)和第三螺距区域(96)中，弹簧(90)的每个线圈之间的间距可以相对较小或者接近于零，使得第一螺距区域(92)和第三螺距区域(96)的每个线圈彼此接触或者接近接触。如在下面将更详细描述的，在压缩弹簧(90)时，这样的螺距可以导致第一螺距区域(92)和第三螺距区域(96)的压缩非常小。然而，与在第一螺距区域(92)和第三螺距区域(96)中的每个线圈之间的间距相比，在第二螺距区域(94)中的弹簧(90)的每个线圈之间的间距可以相对较大。因此，当压缩弹簧(90)时，相对于第一螺距区域(92)和第三螺距区域(96)，第二螺距区域(94)可以被压缩得更多。尽管螺距区域(92、94、96)示出为具有特定的螺距，应当理解的是，鉴于本文的教导，对于本领域普通技术人员来说明显的是，每个螺距区域可以具有任何合适的螺距。

[0052] 本示例的第一螺距区域(92)和第三螺距区域(96)均包括24至25圈，然而第一螺距

区域(92)和第三螺距区域(96)可以包括任何合适的圈数。尽管第一螺距区域(92)和第三螺距区域(96)被构造成在压缩弹簧(90)时，相对于第二螺距区域(94)，经受很小的压缩，应当理解的是第一螺距区域(92)和第三螺距区域(96)仍可以构造成侧向挠曲，使得轴(30)在通过弹簧(90)与标记物(60)保持接触时，仍可以在套管(40)内进行一些侧向运动。从前述中还应当理解的是，由于第二螺距区域(94)的螺距与第一螺距区域(92)和第三螺距区域(96)的螺距之间的不同，例如当弹簧(90)遭受纵向压缩载荷时，比如在柱塞(28)的驱动期间，第二螺距区域(94)可以较第一螺距区域(92)和第二螺距区域(94)首先(并且更大程度地)压缩。

[0053] 根据本公开的一些方面，如图17B和图17C中所示的，弹簧(20)可以紧固至轴(174)的远端。根据一些方面，弹簧可以仅包括两个螺距区域(175b和175)。在一些方面中，线圈可以相对于彼此被紧密地堆积在螺距区域(175c)中的弹簧的远端处。根据一些方面，近侧的螺距区域(175b)可以包括稀松地堆积的线圈。应当理解的是，具有两个螺距区域的弹簧可以类似于具有三个螺距区域的弹簧起作用，如在下面将更详细描述的。

[0054] 返回图3A，如在下面将更详细描述的，一般地，弹簧(90)固定地紧固至轴(30)，使得弹簧(90)首先接触标记物(60)，然后当轴(30)前进时被压缩，最终使得轴(30)可以接触标记物(60)。在本示例中，弹簧(90)示出为在接近于轴(30)的远端的点处固定地紧固至轴(30)，使得只有一部分第一螺距区域(92)从轴(30)的远端向远侧延伸。当然，在其它示例中，弹簧(90)的任何合适的部分可以从轴(30)的远端延伸。例如，本示例的弹簧(90)可以通过激光焊接固定地紧固至轴(30)。在其它示例中，轴(30)可以简单地包括环形凸起或者多个凸起，凸起可以防止弹簧(90)沿轴(30)向近侧滑动。在另一些其它示例中，轴(30)可以包括环形凸起或者多个凸起，凸起可以构造成通过压配合或者过盈配合紧固弹簧(90)。在另一些其它示例中，鉴于本文的教导，对于本领域普通技术人员来说明显的是，可以使用将弹簧(90)紧固至轴(30)的其它合适的特征或者方法，例如，螺钉、销或者胶合剂。

[0055] 如在图17B中所示的，装置可以包括与轴(173)一体焊接形成的环形止动器(175a)，并且将弹簧的近端紧固至所述轴(173)，从而所述弹簧相对于所述轴不滑动。

[0056] 如在图3A中所示的，本示例的标记物(60)包括可生物降解的或者以其它方式可吸收的本体(62)。可吸收本体(62)可以具有大致圆柱形的形状，并且可以由胶原、水凝胶和/或其它任何合适的材料组成。可吸收本体(62)可以包括金属的(例如，钛)、通常不透射线的标记元素(64)(以虚影示出)，该标记元素(64)设置在可吸收本体(62)内，或者以其它方式由可吸收本体(62)承载。本示例的标记元素(64)成形为螺旋弹簧，然而应当理解的是，标记元素(64)可以具有适于加强放射照相可见性的任何其它形状。还应当理解的是，金属仅是一种可以用于形成标记元素(64)的材料的一个说明性示例。鉴于本文的教导，对于本领域普通技术人员来说明显的是，可以使用各种其它合适的材料。

[0057] 在一些示例中，可能需要为标记物输送装置(10)配备某些标记物(60)保持特征，以便选择性地将标记物(60)紧固在套管(40)内。例如，本示例的套管(40)包括两个保持凹陷(50)，凹陷(50)设置在套管腔(48)内接近于侧向孔(42)。如在图4中最能看出，凹陷(50)可以远离侧向孔(42)设置在套管(40)的底部附近。例如，凹陷(50)可以是半球形形状，并且在套管腔(48)内向内凸出。因此，凹陷(50)可以构造成接合标记物(60)的至少一部分，以便将标记物(60)保持在套管腔(48)内。然而，因为可吸收本体(62)由胶原、水凝胶和/或其它

可变形材料组成，标记物(60)可以具有相对弹性的属性，使得标记物(60)可以通过轴(30)被选择性地强制通过凹陷(50)。替代地，标记物(60)可以具有相对于套管(40)的内径小一些的尺寸，使得当轴(30)推动标记物(60)时，标记物(60)可以被向上推动越过凹陷(50)。尽管套管(40)被示出为包括两个凹陷(50)，应当理解的是，在其它示例中，套管(40)可以包括任何其它合适数量的凹陷(50)。

[0058] 如在图17D中示出的，沿周向间隔开的两个凹陷(174d)可以形成在套管(174)中。若将如图17D所示的套管(174)的顶部定义为0°位置，则第一凹陷可以定位在接近135°位置处且第二凹陷可以定位在接近225°位置处。根据一些方面，环形褶皱(174a)可以由大量的紧密间隔的凹陷形成。然而，沿周向等距地间隔开的凹陷的优选数量可以少至两个，如所描绘的，多至八个或者更多。根据一些方面，例如，如果选定八个凹陷，在0°位置处可以有一个凹陷，此后围绕套管(174)的周向每45°可以有一个凹陷。

[0059] 附加地或替代地，除半球形形状之外，凹陷(50)还可以包括其它形状。例如，鉴于本文的教导，对于本领域普通技术人员来说明显的是，凹陷(50)可以是角锥体、立方体、菱形，或者其它任何合适的形状。如另一个仅是说明性的示例，环形凸起或者褶皱可以伸入腔(48)内，作为凹陷(50)的替代物。在又一个仅是说明性的示例中，具有与套管(40)整体式构造的相对柔性的舌片或者接片可以伸入腔(48)内，作为凹陷(50)的又一个替代物。

[0060] 根据一些方面，如在图18A到图18C中所示的，套管(174)可以包括舌片(177)，该舌片在图18A的侧视图中是隐藏于视野之外的，并且在图18B的纵向的侧视剖面图以及图18C的纵向的俯视剖面图中是可见的。根据一些方面，舌片(177)和套管(174)可以彼此一体地形成，并且所述舌片可以提供例如抵抗由轴驱动的标记物(176)从近侧到远侧的位移的止动器，即舌片(177)可以执行与本文描述的环形褶皱或者凹陷类似的功能。根据一些方面，例如，当标记物(176)由非柔性和非弹性材料形成时，可以采用此舌片(177)。

[0061] 如图19所示，根据一些方面，在套管腔(174)中可以形成隆起或者鼓起(26)，该鼓起执行与舌片(177)类似的功能。例如，鼓胀(178)和舌片(177)均可以构造成当刚性标记物(176)被推过这些特征时变平。

[0062] 图3B到图3D示出了标记物输送装置(10)的示例性使用。如从图3B中可以看出，标记物(60)起初设置在套管腔(42)内接近凹陷(50)。然后使用者可以将套管(40)插入活检装置或者靶向组，从而在活检装置或者靶向组已经被定位在活检部位处的组织中时，在活检部位处输送标记物(60)。套管(40)可以定位使得侧向孔(42)可以成角度地纵向地与活检装置或者靶向组的针或者套管的互补侧向孔对准。一旦套管(40)已经插入活检装置或者靶向组并且被恰当地定位在其中，例如，使用者可以通过用单手，或者替代地用多个手，抓住手柄(24)并按压柱塞(28)来开始部署。

[0063] 当柱塞(28)被向远侧按压时，轴(30)可以相对于套管(40)和本体(20)向远侧前进，如由图3B和图3C之间的变化示出的。当轴(30)的远端接近标记物(60)时，弹簧(90)可以首先接触标记物(60)。如图3B和图3C所示，当轴(30)进一步前进时，这种接触可以压缩弹簧(90)，从而在弹簧(90)内储存势能。

[0064] 轴(30)的附加前进可以最终导致标记物(60)和轴(30)的远端之间的直接接触。如在图3C中可以看到，在这个阶段，轴(30)的远端可以大致与弹簧(90)的远端对准，一旦开始这种直接接触，轴(30)将开始在套管(40)内向远侧推动标记物(60)，从而使标记物(60)向

远侧前进，经过和/或越过凹陷(50)并从侧向孔(42)出去。一旦标记物(60)远离凹陷(50)，弹簧(90)可以开始通过在弹簧(90)的压缩期间产生的势能而伸张。如从图3D可以看到的，弹簧(90)的这种伸张最终可以使标记物(60)侧向地前进到远侧尖端(44)的斜坡部分(46)上，通过侧向孔(42)出去并进入活检部位。可以理解的是，第一螺距区域(92)可以在凹陷(50)上方挠曲，延伸经过凹陷(50)。由此，例如，弹簧(90)的构造可以允许弹簧(90)在腔(48)内侧向地偏斜，使得不需要轴(30)在腔内的任何偏斜，弹簧(90)就可以前进超过凹陷(50)。形成第一螺距区域(92)的线圈可以相对于彼此简单地滑动以便越过凹陷(50)。在凹陷在腔(48)内沿更大的角度范围布置的变型中(例如在下面描述的套管(640)中)，弹簧(90)仍然可以变形以向远侧超越凹陷(50)。例如，形成第一螺距区域(92)的线圈可以相对于彼此滑动并相对于腔(48)的纵向轴线倾斜地翘起，以便减小弹簧(90)的有效外径，从而允许弹簧(90)通过凹陷(50)之间限定的空间。

[0065] 图5示出了示例性替代标记物(160)，该标记物(160)可以附加至或者代替上述标记物(60)而被使用。本示例的标记物(160)基本上类似于标记物(60)。例如，像标记物(60)一样，标记物(160)可以包括可生物降解的或者以其它方式可吸收的本体(162)。可吸收本体(162)具有大致圆柱形的形状，且可以由胶原、水凝胶，和/或其它任何合适的材料组成。如上述可吸收本体(62)，可吸收本体(162)可以包括金属的、通常不透射线的标记元素(164)，该标记元素(164)设置在可吸收本体(162)内，或者以其它方式由可吸收本体(162)承载。然而，不像标记元素(64)，本示例的标记元素(164)可以包括圆盘状的中心构件(166)(以虚影示出)，该中心构件(166)具有从中心构件(166)径向地向外凸出且从可吸收本体(162)出去的三个细长凸起(168)。还应当理解的是，金属仅是一种可用于形成标记元素(164)的材料的一个说明性的示例。鉴于本文的教导，对于本领域普通技术人员来说明显的是，可以使用各种其它合适的材料。

[0066] 在一些示例中，细长凸起(168)可以从中心构件(166)径向地向外凸出以便提供与套管(40)内部的摩擦。由此，例如，细长凸起(168)可以构造成接触套管(40)的内部。这种构造可以连同或者代替凹陷(50)而被使用，例如以将标记物(160)保持在套管(40)内，从而防止标记物(160)无意中从套管(40)掉出。此外，细长凸起(168)可以接合活检部位处的组织以将标记物(160)紧固在活检部位处，从而防止标记物(160)移动。

[0067] 图6示出另一个示例性替代标记物(260)，该标记物(260)可以附加至或者代替上述标记物(60)而被使用。本示例的标记物(260)可以基本上类似于标记物(60)。例如，像标记物(60)一样，标记物(160)可以包括可生物降解的或者以其它方式可吸收的本体(262)。然而，不像可吸收本体(62)，可吸收本体(262)可以包括至少两种材料的混合物。例如，本示例的可吸收本体(262)可以包括大致为圆柱形形状的胶原中间部分(261)、两个水凝胶中段部分(263)以及两个胶原末端部分(265)。如上述可吸收本体(62)，可吸收本体(262)可以包括金属的、通常不透射线的标记元素(264)(以虚影示出)，该标记元素(264)设置在可吸收本体(262)内，或者以其它方式由可吸收本体(262)承载。然而，不像标记元素(64)，本示例的标记元素(264)通常可以是具有中心扭曲(264)的矩形，以便构造成加强标记元素(264)的放射照相的可见性。还应当理解的是，金属仅是一种可以用于形成标记元素(264)的材料的一个说明性示例。鉴于本文的教导，对于本领域普通技术人员来说明显的是，可以使用各种其它合适的材料。

[0068] 图7示出了又一个示例性替代标记物(360)，该标记物(360)可以附加至或者代替上述标记物(60)而被使用。本示例的标记物(360)可以基本上类似于标记物(60)。例如像标记物(60)一样标记物(360)可以包括可生物降解的或者以其它方式可吸收的本体(362)。然而，不像可吸收本体(62)，可吸收本体(362)可以包括至少两种材料的混合。例如，本示例的可吸收本体(362)可以包括大致为圆柱形形状的具有水凝胶内核(363)的胶原外壳(361)。如上述可吸收本体(62)，可吸收本体(362)可以包括金属的、通常不透射线的标记元素(364)(以虚影示出)，该标记元素(364)设置在可吸收本体(362)内，或者以其它方式由可吸收本体(362)承载。然而，不像标记元素(64)，本示例的标记元素(364)通常可以是具有中心扭曲(364)的矩形，以便构造成加强标记元素(364)的放射照相的可见性。还应当理解的是，金属仅是一种可以用于形成标记元素(364)的材料的一个说明性示例。鉴于本文的教导，对于本领域普通技术人员来说明显的是，可以使用各种其它合适的材料。

[0069] 图8和图9示出了示例性替代套管(440)，该套管(440)可以合并到上述活检标记物装置(10)。本示例的套管(440)可以基本上类似于上述套管(40)，除了此处另外注明的之外。例如，套管(440)可以包括细长管状轴(441)，该管状轴(441)包括接近远侧尖端(444)侧向孔(442)，以及延伸穿过套管(440)的套管腔(448)。然而，不像套管(40)，套管(440)可以包括金属护套(452)，该护套(452)套设在套管(440)的远侧尖端的至少一部分上。还应当理解的是，金属仅是一种可以用于形成护套(452)的材料的一个说明性示例。鉴于本文的教导，对于本领域普通技术人员来说明显的是，可以使用各种其它合适的材料。金属护套(452)可以构造成为套管(440)的远端提供结构加强。例如，在使用套管(40)期间，金属护套(452)可以防止套管(440)的远端屈曲，或者以其它方式变形。附加地或者替代地，当套管(440)由具有较金属护套(452)低的硬度的材料形成时，金属护套(452)可以防止套管(440)的相对较软的材料被限定活检针的侧向孔的边缘刮掉或者剃掉，套管(440)插入该活检针中。

[0070] 本示例的侧向孔(442)可以集成到套管(440)和金属护套(452)两者上。如图8所示，以一定角度在套管(440)和金属护套(452)上切出侧向孔(442)，使得套管(440)和金属护套(452)共同形成对准的斜切边缘(445、454、456)。例如，金属护套(452)可以包括远侧斜切边缘(454)以及近侧斜切边缘(456)。金属护套(452)的远侧斜切边缘(454)可以与远侧尖端(444)的斜坡部分(446)对准，其中远侧斜切边缘(454)和斜坡部分(446)均以基本上相似的角度定向。类似地，金属护套(452)的近侧斜切边缘(456)可以与套管的近侧斜切边缘(445)对准，其中近侧边(445、456)以基本上相似的角度定向。

[0071] 斜切边缘(445、454、456)和斜坡部分(446)能够以一定角度倾斜，该角度适于减少对组织的创伤同时仍然保持侧向孔(442)具有用于标记物(60)通过其的足够大的尺寸。在本示例中，远侧斜切边缘(454)和斜坡部分(446)的倾斜角比近侧斜切边缘(456、445)的倾斜角更陡。尽管示出了远侧斜切边缘(454)和斜坡部分(446)与远侧斜切边缘(445、456)之间的特定关系，应当理解的是，不旨在对示出的示例进行任何限制，并且鉴于本文的教导，对于本领域普通技术人员来说可以理解的是，在其它示例中，各个倾斜角可以变化。

[0072] 如图9所示，本示例的远侧尖端(444)与轴(441)集成。远侧尖端(444)和轴(441)可以构造成接收金属护套(452)，使得金属护套(452)提供对远侧尖端(444)的支撑。在一些变型中，金属护套(452)可以通过例如二次成型被附接至远侧尖端(444)和轴(441)，使得远侧

尖端(444)和轴(441)注塑成型到金属护套(452)中。在其它示例中，金属护套(452)可以通过粘合剂粘接、机械紧固或者任何其它合适的紧固方式简单地附接至远侧尖端(444)和轴(441)。

[0073] 本示例的金属护套(452)包括金属的生物相容材料，例如不锈钢、钛，和/或任何其它合适的金属。不旨在对这些示例进行任何限制。例如，在其它示例中，金属护套(452)可以包括相对于轴(441)和远侧尖端(444)相对密实的塑料。在再一些示例中，金属护套(452)可以包括陶瓷材料。在又一些示例中，对于本领域普通技术人员来说明显的是，金属护套(452)可以由任何其它合适的材料组成。

[0074] 图10到图11C示出了示例性替代标记物输送装置(510)，该标记物输送装置(510)与上述标记物输送装置(10)相似。例如，标记物输送装置(510)可以包括本体(520)以及套管(540)。本体(520)可以包括细长壳体(522)、手柄(524)以及柱塞(528)。壳体(522)可以基本上类似于上述壳体(22)。然而，不像壳体(22)，如将在下面详述的，本示例的壳体(522)可以包括构造成提供用于柱塞(528)的多个驱动位置的附加部件。

[0075] 类似于上述柱塞(28)，本示例的柱塞(528)可以定位在轴(530)的近端处，轴(530)纵向地延伸穿过本体(520)和套管(540)。同样类似于上述柱塞(28)，例如，本示例的柱塞(528)可以连同手柄(524)一起使用，该手柄用于单手驱动标记物输送装置(510)。然而，不同于柱塞(28)，如将在下面详述的，本示例的柱塞(528)可以构造成具有多个驱动位置。

[0076] 套管(540)可以基本上类似于上述套管(40)，且可以包括从壳体(522)向远侧延伸的细长管状轴。一般地，套管(540)可以向远侧延伸一段适合插入活检装置或者靶向组的长度，使得套管(540)可以延伸到活检部位，以通过接近套管(540)的远端的侧向孔(542)输送本文描述的标记物(60、160、260、360)中的任一个。

[0077] 图11A到图11C示出了标记物输送装置(510)的示例性操作模式。如从图11A中可以看到，本体(520)的柱塞(528)起始于初始的近侧位置。当柱塞(528)设在初始位置时，可以将标记物输送装置(510)插入活检装置或者靶向组中，以将套管(540)的侧向孔(542)定位在活检部位处，例如，侧向孔(542)能够纵向地且成角度地与活检装置或者靶向组的类似侧向孔对准。

[0078] 一旦将标记物输送装置(510)定位在活检装置或者靶向组中，使用者可能期望将标记物(60、160、260、360)放置在活检部位处。为了如此放置标记物(60、160、260、360)，使用者可以使柱塞(528)前进到如图11B所示的部分驱动位置。在本示例中，壳体(522)包括各种部件，所述各种部件被构造成使轴(530)前进，以当柱塞(528)前进到部分驱动位置时，将标记物(60、160、260、360)从侧向孔(542)弹出。

[0079] 在一些示例中，在部署标记物(60、160、260、360)后，可能期望将套管(540)在活检装置或者靶向组内进行旋转。例如，在部署标记物(60、160、260、360)后，标记物(60、160、260、360)可以保持相对靠近于套管(540)的侧向孔(542)，使得标记物(60、160、260、360)的至少一部分可以再进入侧向孔(542)中。在这种情况下，移除标记物输送装置(510)可能会对标记物(60、160、260、360)造成损坏，因为标记物(60、160、260、360)可能会陷在侧向孔(542)和活检装置或者靶向组的相应的侧向孔之间。因此，标记物输送装置(510)一般可以构造成选择性地旋转套管(540)，例如，便于移除套管(540)，而不会使标记物(60、160、260、360)卡在侧向孔(542)和活检装置或者靶向组的相应的侧向孔之间。

[0080] 如图11C所示，柱塞(528)前进到完全驱动位置以开始相对于本体(520)旋转套管(540)。应当理解的是，为了实现此功能，壳体(522)内可以包括弹簧、杠杆、齿轮、凸轮或者可以装配以引起套管(540)旋转的其它机械设备。鉴于本文的教导，对于本领域普通技术人员来说明显的是，可以使用各种部件和特征以响应于柱塞(528)相对于本体(520)的完全前进而提供套管(540)相对于本体(520)的这种旋转。应当理解的是，在本示例中，壳体(522)的前述部分可以构造成将套管(540)相对于本体(520)旋转例如180°。在其它示例中，壳体(522)可以构造成将套管(540)相对于本体旋转任何合适的角度。仅通过举例的方式，壳体(522)可以构造成将套管(540)旋转90°、270°或者任何其他合适的径向距离。

[0081] 一旦柱塞(528)已经前进到完全驱动位置以旋转套管(540)，例如，可以将标记物输送装置(510)从活检装置或者靶向组移除。替代地，在一些示例中，标记物输送装置(510)可以配备成部署多个标记物(60、160、260、360)。在这种示例中，可选地，壳体(522)可以构造成在柱塞(528)缩回时，将套管(540)返回到其原始位置，用于部署另一个标记物(60、160、260、360)。上述顺序可以再次重新开始。应当理解的是，尽管上述顺序描述为包括由使用者驱动的柱塞(528)的两个不连续的前进，在其它示例中，可选地，柱塞(528)能够以单行程方式前进。在这个示例中，除了其他方面之外，可以部署标记物(60、160、260、360)，并且然后可以立即旋转套管(540)。

[0082] 图12-图14示出了另一个示例性替代标记物输送装置(610)，该标记物输送装置(610)与上述标记物输送装置(10)相似。例如，标记物输送装置(610)可以包括本体(620)以及套管(640)。本体(620)可以包括细长壳体(622)、手柄(624)以及柱塞(628)。壳体(622)、手柄(624)以及柱塞(628)可以基本上类似于上述壳体(22)、手柄(24)以及柱塞(28)，因此这些部件的各个细节将不会在此处描述中重复。

[0083] 套管(640)可以与上述套管(40)基本类似之处在于，套管(640)可以包括从壳体(522)向远侧延伸的细长管状轴。一般地，如图12到图14所示，套管(640)可以向远侧延伸一段适合插入活检装置或者靶向组的长度，使得套管(640)可以延伸到活检部位以输送本文描述的标记物(60、160、260、360)中的任一个。然而，与套管(40)不同，本示例的套管(640)可以没有侧向孔。反而，套管(640)可以包括例如敞开的远侧尖端(644)，该远侧尖端(644)与延伸穿过套管(640)的套管腔(648)连通。由此，套管(640)可以构造成通过敞开的远侧尖端(644)纵向地部署标记物(60)。

[0084] 如从图13和图14中最能看出，套管(640)还可以包括类似于套管(40)的凹陷(50)的多个凹陷(650)。例如，凹陷(650)一般构造成选择性地将标记物(60)保持在套管(240)内。凹陷(650)可以包括基本上类似于上述凹陷(50)的半球形形状。然而，与上面示出的套管(40)不同，本示例的套管(640)可以包括三个凹陷(650)。如从图14中可以看到，凹陷(650)可以绕套管(640)的内径以相等距离定向。应当理解的是，如同上述凹陷(50)，鉴于本文的教导，对于本领域普通技术人员来说可以理解的是，本示例的凹陷(650)可以包括任何其它合适的形状和/或构造。

[0085] 图15和图16示出了示例性替代套管(740)，该套管(740)可以合并到上述活检标记物装置(10)。本示例的套管(740)可以基本上类似于上述套管(40)，除了此处另外注明的之外。例如，本示例的套管(740)可以包括细长管状轴(741)，该管状轴(741)包括接近远侧尖端(744)的侧向孔(742)。轴(741)可以进一步限定套管腔(748)，该套管腔(748)延伸穿过套

管(740)且与侧向孔(742)连通。与套管(40)不同，套管(740)的侧向孔(742)可以具有随着侧向孔(742)向近侧延伸而变宽的泪滴形状。由此，例如，侧向孔(742)的远侧部分可以比侧向孔(742)的近侧部分窄。应当理解的是，在一些示例中，侧向孔(742)的至少一部分(例如侧向孔(742)的远侧部分)也可以相对于上述侧向孔(42)具有稍小的尺寸。这种尺寸可以允许侧向孔(742)容纳例如较小的标记物。

[0086] 如从图16中可以看到，套管(740)也可以不同于套管(40)，因为远侧尖端(744)可以包括复合的斜坡部分(746)。例如，远侧尖端(744)可以包括三个不连续的斜坡部分(743、745、747)以及两个相对平坦的部分(749、751)。斜坡部分(743、745、747)如图16所示以相似角度成斜面，然而在其它示例中每个斜坡部分(743、745、747)的特定角度可以变化。一般地，斜坡部分(743、745、747)可以构造成使标记物(未示出)渐进地偏斜穿过侧向孔(742)。这种渐进的偏斜是值得期望的，例如，可以防止标记物过早地退出套管(740)，并且在已经将标记物输送到活检部位后，可以防止标记物再进入侧向孔(742)。

[0087] 例如，平坦部分(749、751)一般可以沿它们的平面的平坦区域平行于套管(740)的纵向轴线。平坦部分(749、751)可以构造成提供斜坡部分(743、745、747)之间的间距并且当标记物从斜坡部分(743、745、747)移动到斜坡部分(743、745、747)时，改变轨迹。例如，在示例性使用中，当标记物向远侧前进时，标记物首先可以行进到第一斜坡部分(743)上。第一斜坡部分(743)可以对标记物向远侧的运动提供一定程度的阻力。仅作为示例，可以根据2013年9月10日授权公告的标题为“Biopsy Marker DeliveryDevice”的美国专利号8,532,747中的至少一些描述来构造和操作第一斜坡部分(743)，该美国专利的公开内容以引用的方式并入本文。

[0088] 一旦标记物已经经过第一斜坡部分(743)，标记物可以沿第一平坦部分(749)行进，然后以大致平行于第二斜坡部分(745)的角度的角度行进到第二斜坡部分(745)上。第二斜坡部分(745)可以提供凸轮表面，从而通过侧向孔(742)弹出标记物。第二平坦部分(751)可以防止标记物再进入侧向孔(742)。当将套管(740)从活检装置或者靶向组移除时，第三斜坡部分(747)可以使标记物的可能保持在侧向孔(742)中的任何部分完全偏斜离开侧向孔(742)。附加至或者代替前述，并且仅作为示例地，可以根据2014年9月18日公布的标题为“Biopsy Site Marker Applier”的美国公开第2014/0276037号中的至少一些描述来构造和操作复合斜坡部分(746)，该美国专利申请公开的公开内容以引用的方式并入本文。

[0089] 关于活检标记物部署器的本发明已经公开。然而，例如，在图中公开的各种特征和部件可以被利用在对放射性同位素应用有用的装置中，如在PEM、BSGI以及采用放射性同位素或者其它放射源的其它成像方法中，例如与成像活检过程相关。

[0090] 本文公开的装置一般设计成单次使用后将被处理掉，但是也可以设计成多次使用。在形成标记物并且将标记物插入部署器中后，例如可以对活检装置进行杀菌消毒。然后，可以将该装置放入包装中，例如，塑料或者特卫强(TYVEK)袋子。

[0091] 然后，包装的活检装置可以放入辐射场中，(例如γ辐射、X射线或者高能电子)以对装置和包装杀菌消毒。还可以使用在本领域已知的任何其它技术对装置杀菌消毒，包括但不限于β或者γ辐射、环氧乙烷或者蒸汽。

[0092] 虽然已经连同以上概述的示例性方面一起描述了本文描述的方面，无论已知的还是目前未预料或可能未预料到的，对于至少具有本领域普通技术的人员而言，各种替换、修

改、变型、改进和/或实质等同将变得显而易见。因此，如以上提出的，示例性方面旨在说明而不是限制。在没有背离本公开的精神和范围的情况下，可以进行各种改变。因此，本公开旨在包含所有已知或者后来开发的替代、修改、变型、改进和/或实质等同。

[0093] 由此，权利要求不旨在被本文示出的方面限制，但是要符合与权利要求的语言一致的全部范围，其中，提及单数形式的元件不旨在表示“一个且仅一个”，除非具体地如此陈述，而是“一个或多个”。本领域普通技术人员已知或者后来成为已知的、在整个公开描述的各种方面的元件的所有结构和功能的等同物通过引用的方式明确地并入本文，并且旨在被权利要求所包含。而且，本文公开的任何内容都不旨在奉献给公众，无论这种公开内容是否明确地记载在权利要求中。不要将权利要求元件解释为装置加功能，除非明确利用短语“用于…的装置”来叙述该权利要求元件。

[0094] 应当理解的是，公开的过程/流程图的具体顺序或者层次是示例性方法的说明。基于设计偏好，应当理解的是，可以重新堆积公开的过程/流程图中的具体顺序或者层次。进一步地，可以结合或者忽略一些特征/步骤。附带的方法权利要求以样品顺序呈现各种特征/步骤的元件，并且并不意味着限制所呈现的具体顺序或者层次。

[0095] 进一步地，本文使用的单词“示例”意味“用作示例、实例或者说明”。本文描述为“示例”的任何方面不一定解释为较其它方面是优选的或者有利的。除非另外特别地声明，术语“一些”是指一个或者多个。例如“A、B或者C中的至少一个”、“A、B和C中的至少一个”以及“A、B、C或者它们的任何组合”的组合包括了A、B和/或C的任意组合，并且可以包括多个A，多个B，或者多个C。具体地，各种组合，例如“A、B或者C中的至少一个”、“A、B和C中的至少一个”以及“A、B、C或者其任意组合”，可以是只有A、只有B、只有C、A和B、A和C、B和C，或者A和B和C，其中任意这种组合可以包含A、B或者C中的一个或者多个成员。本文公开的任何内容都不旨在奉献给公众，无论这种公开内容是否明确地记载在权利要求中。

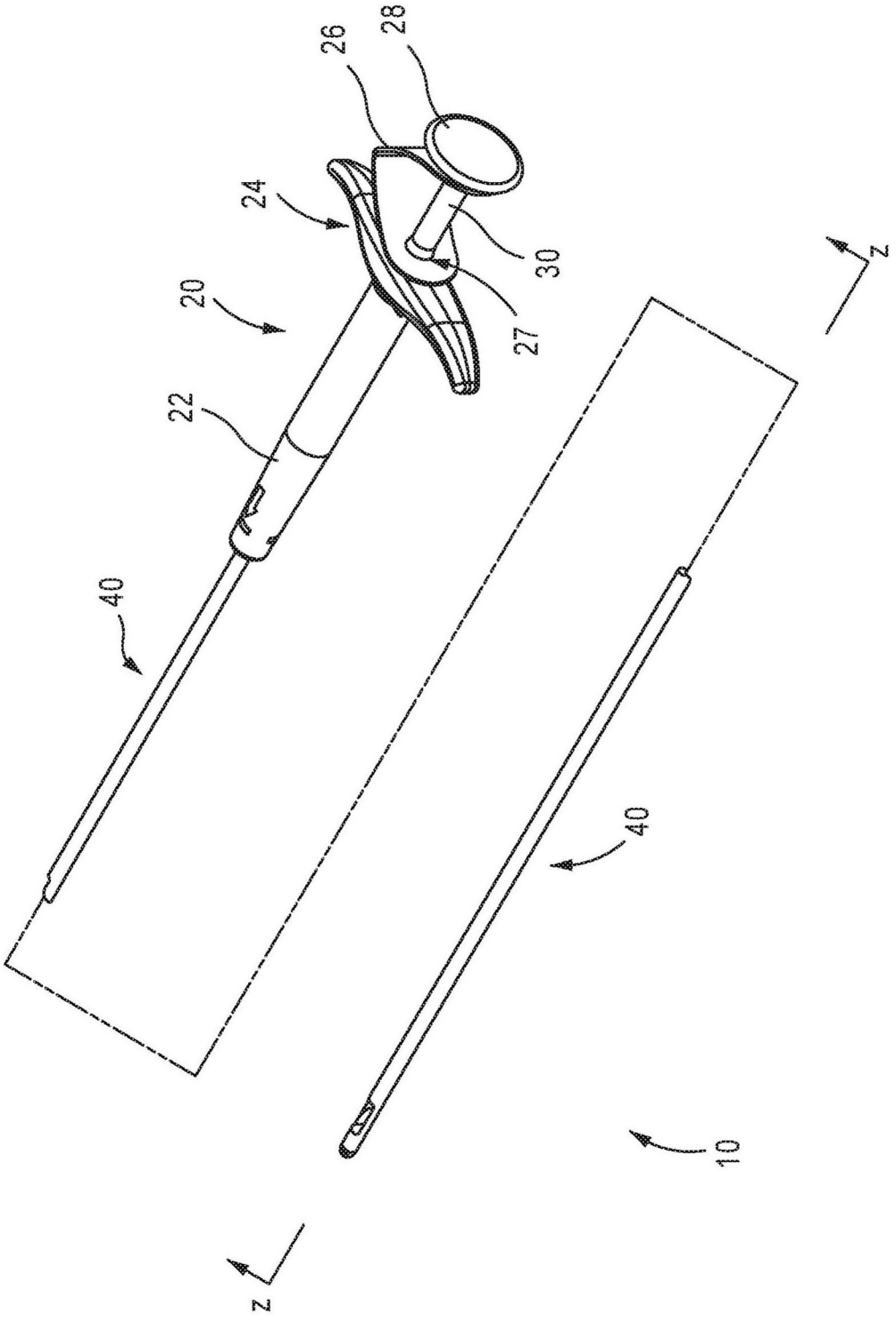


图1

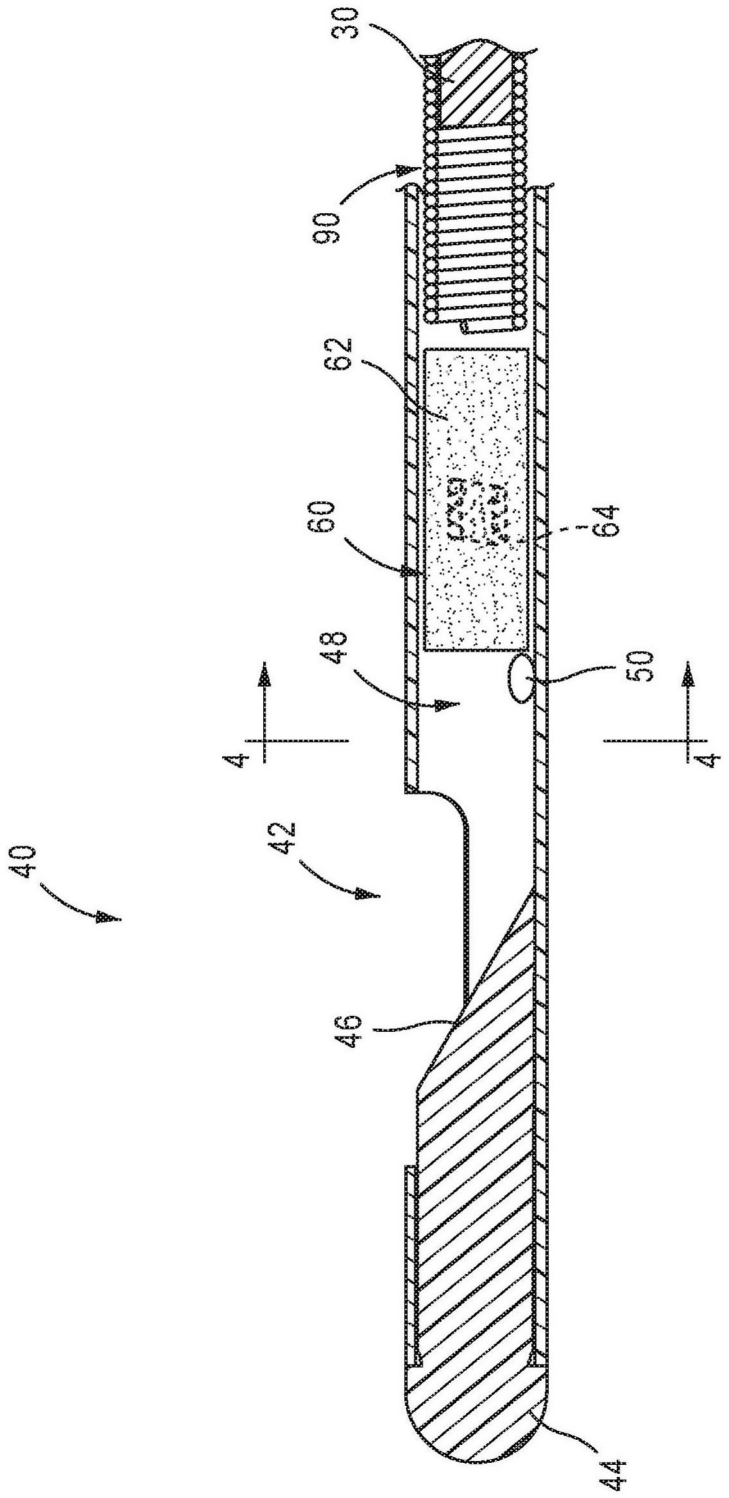


图2

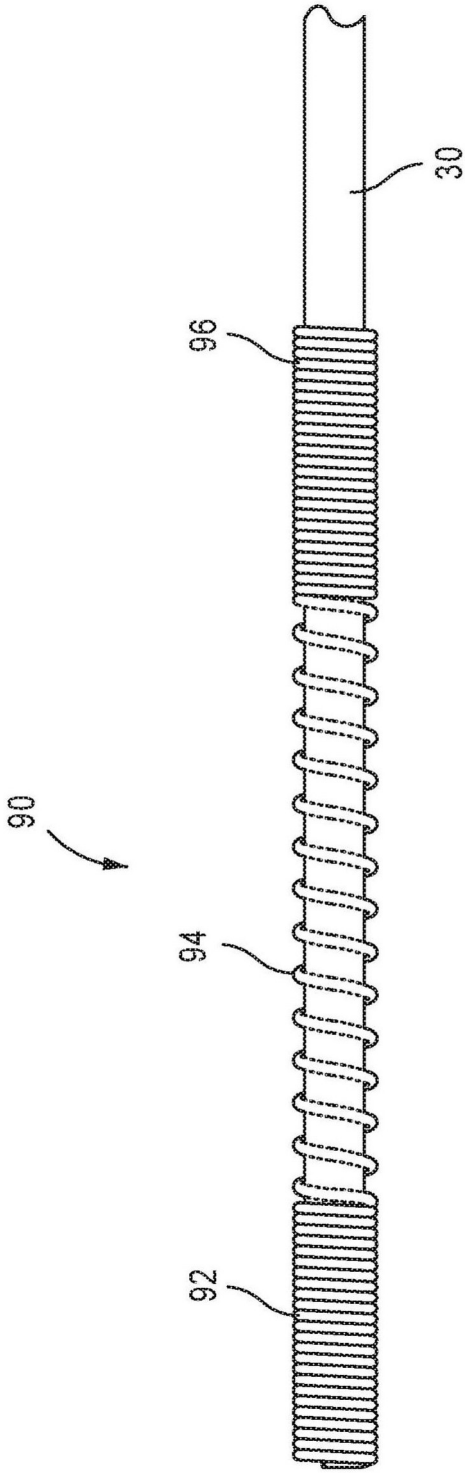


图3A

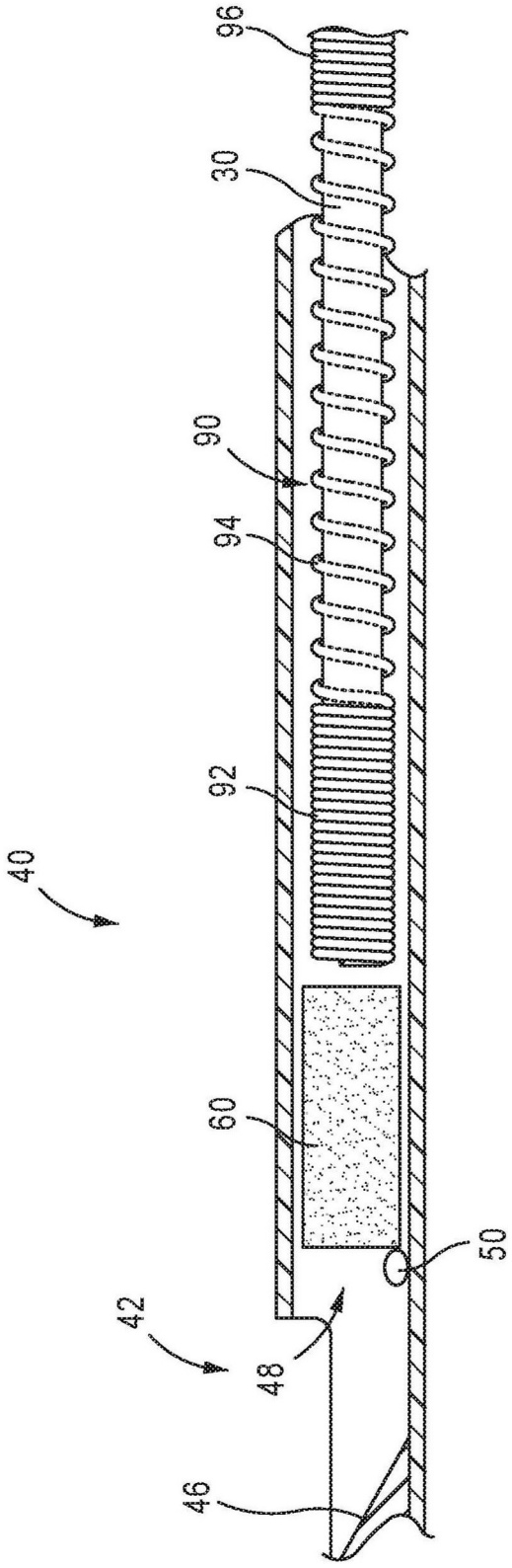


图3B

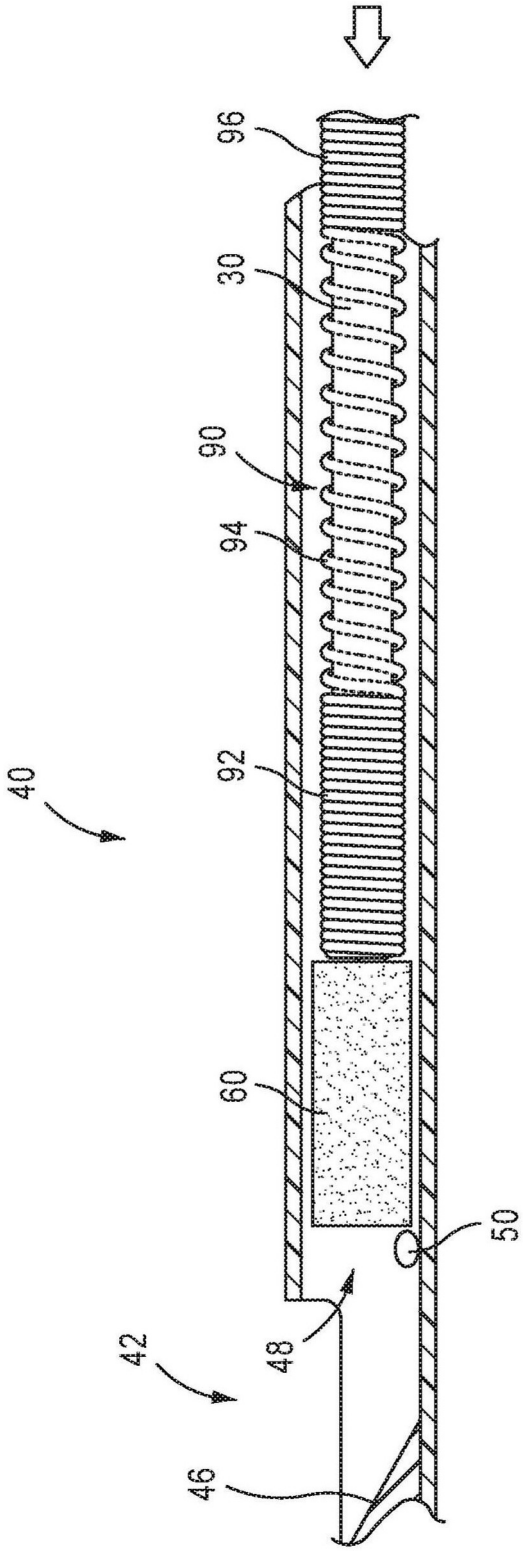


图3C

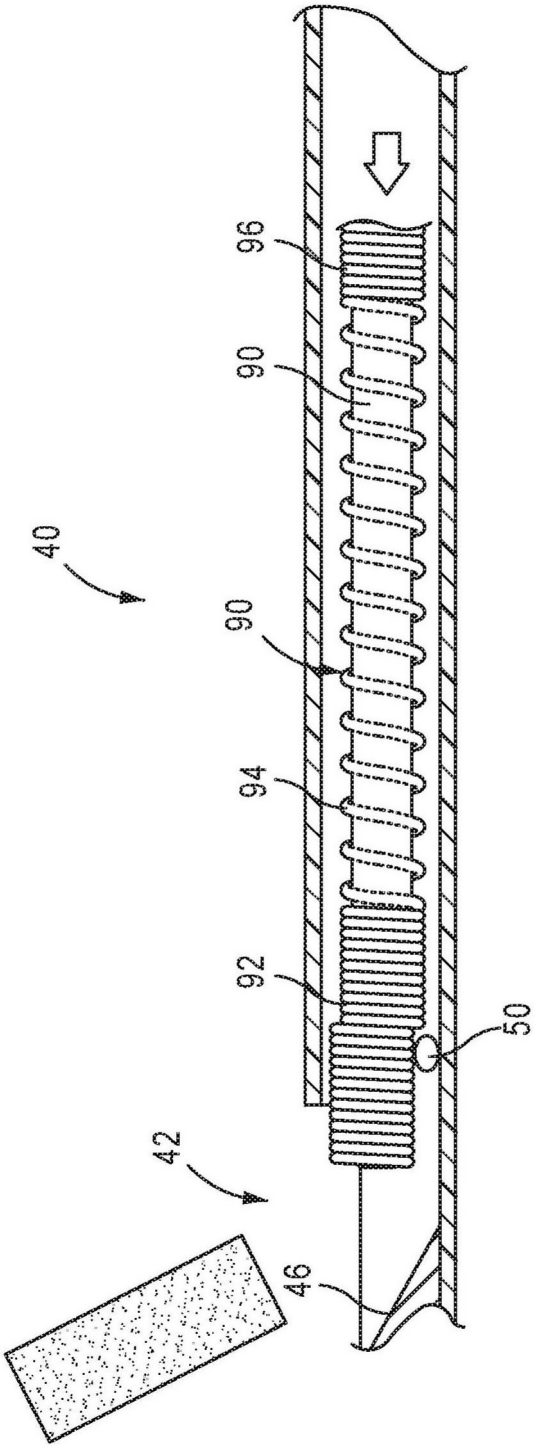


图3D

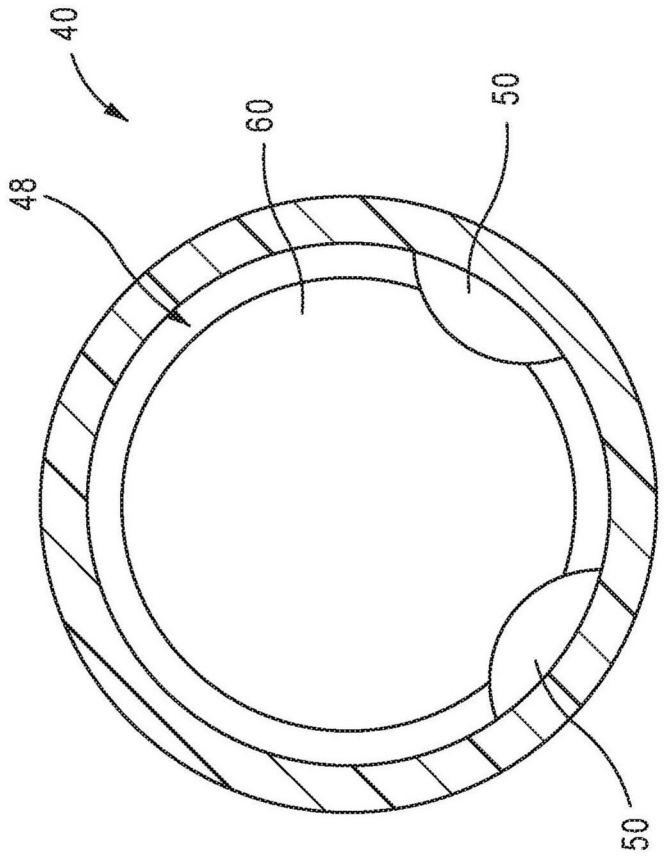


图4

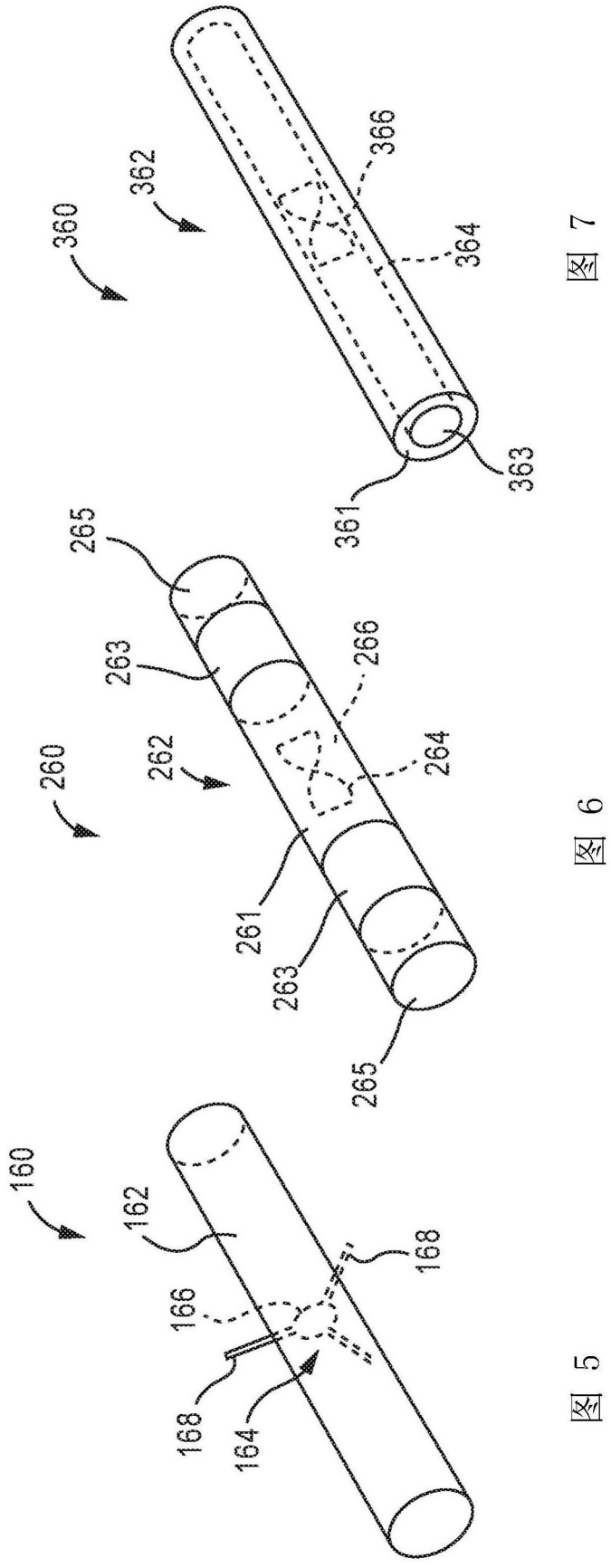

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图 5

图 6

图 7

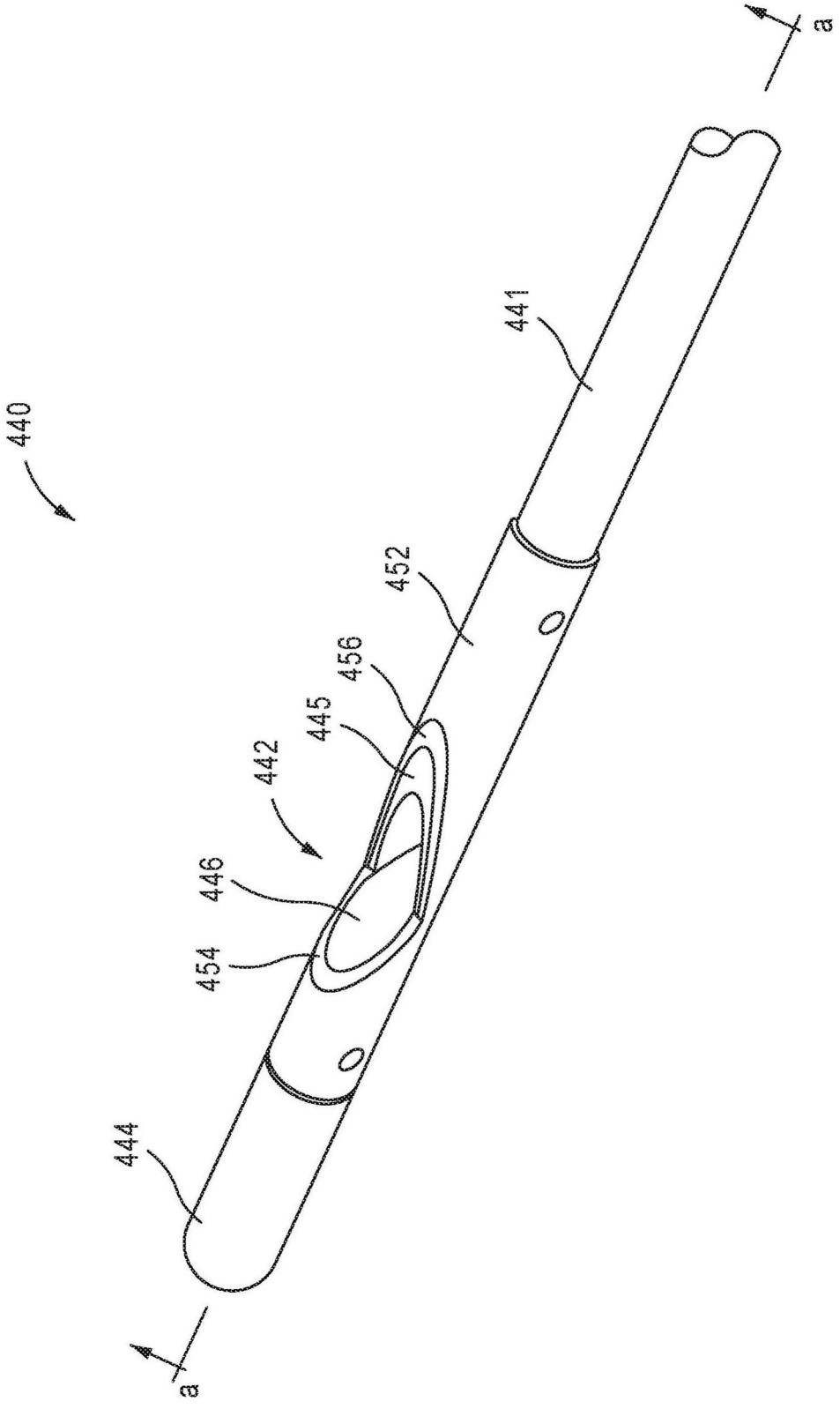

图8

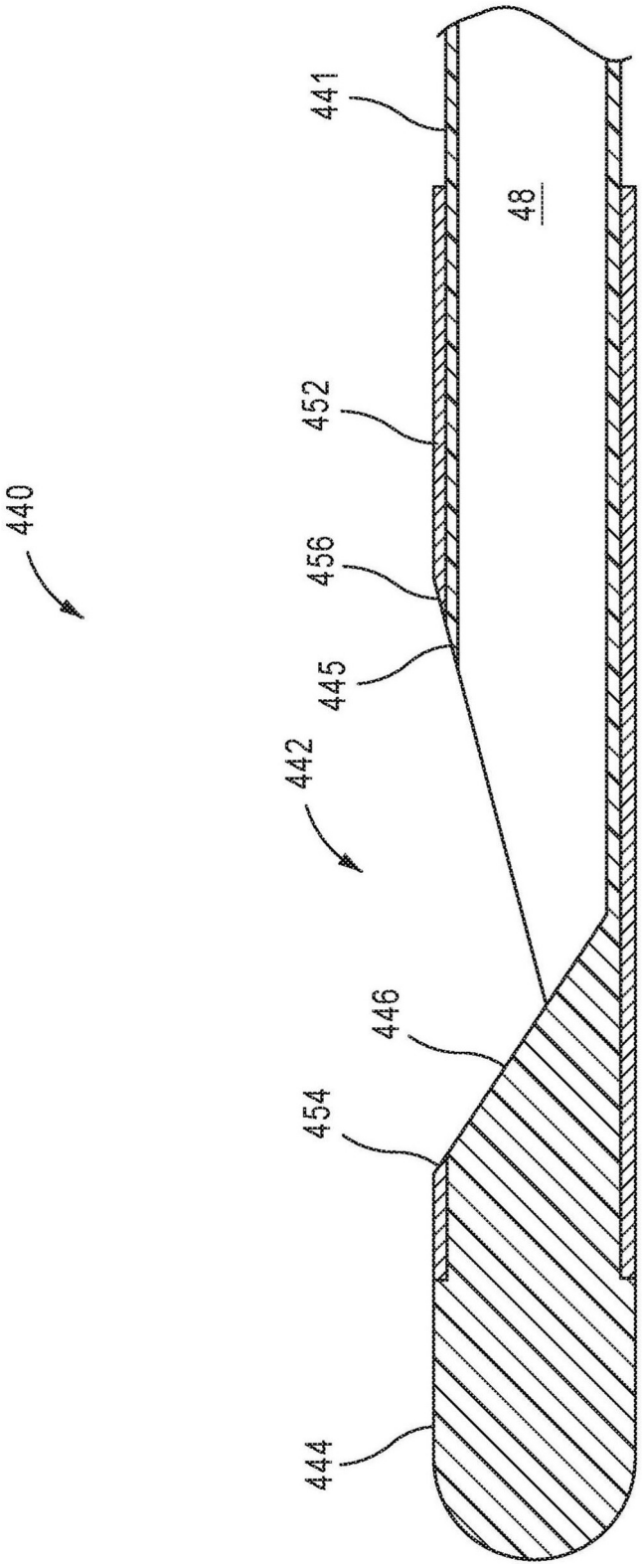

图9

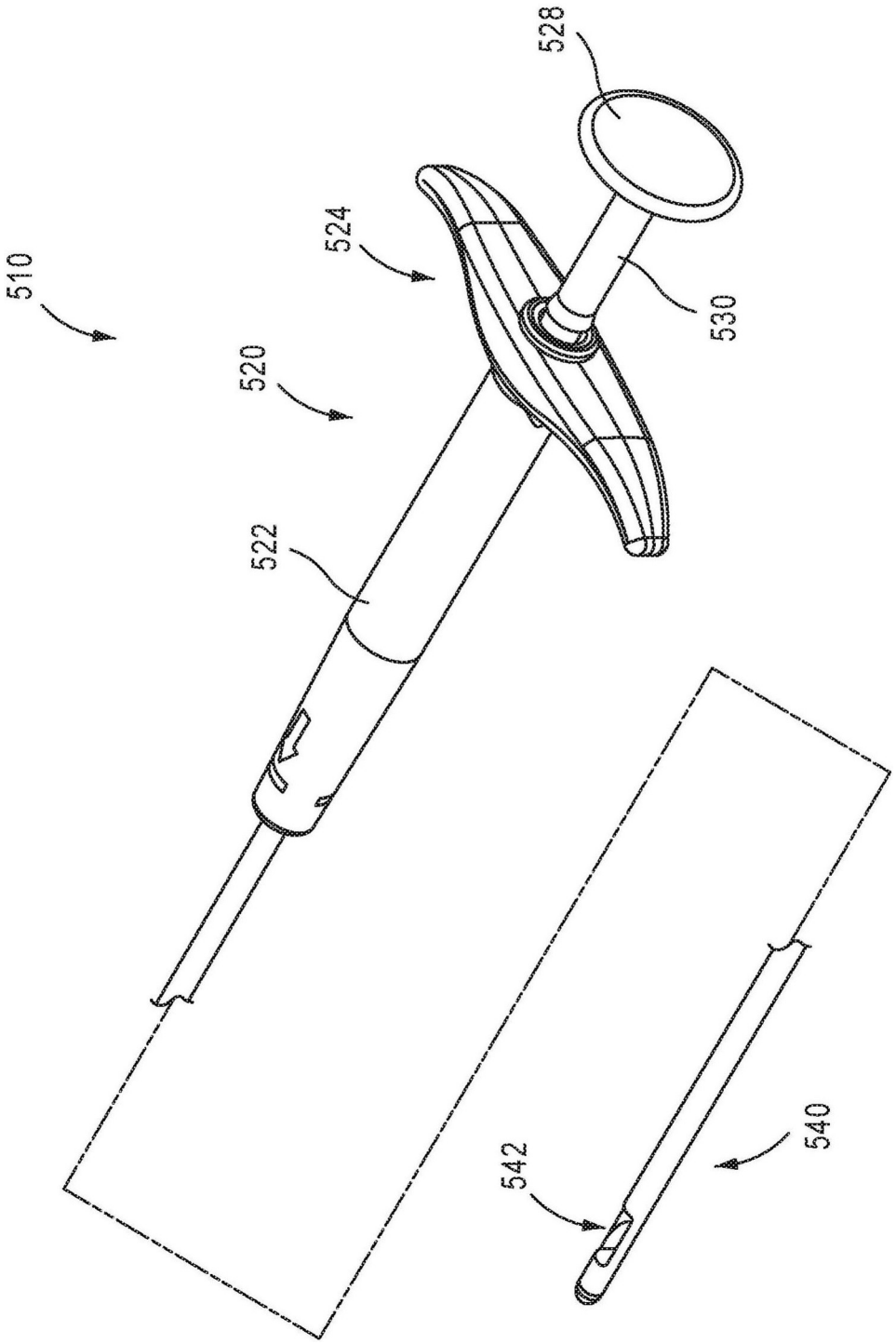

图10

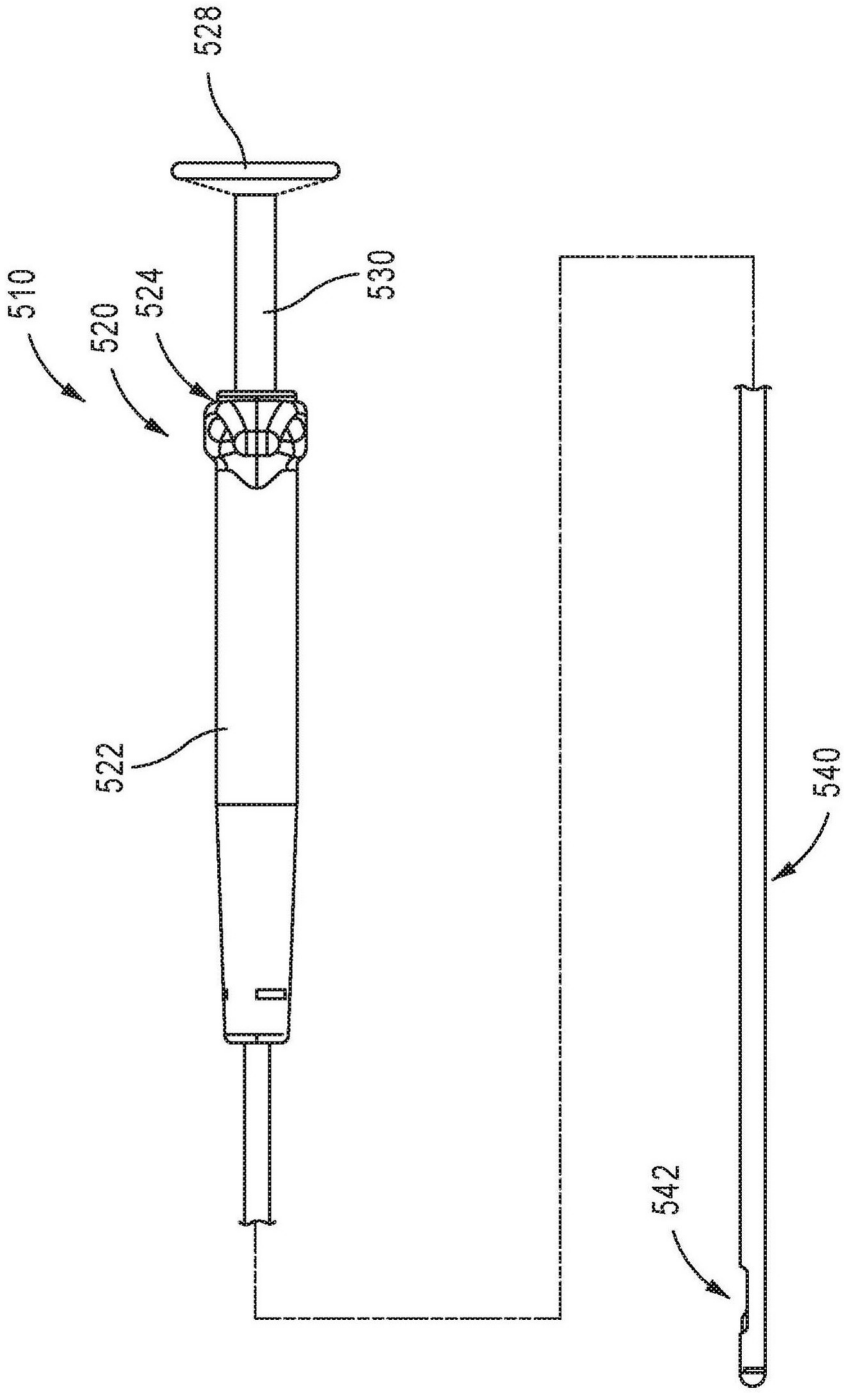

图11A

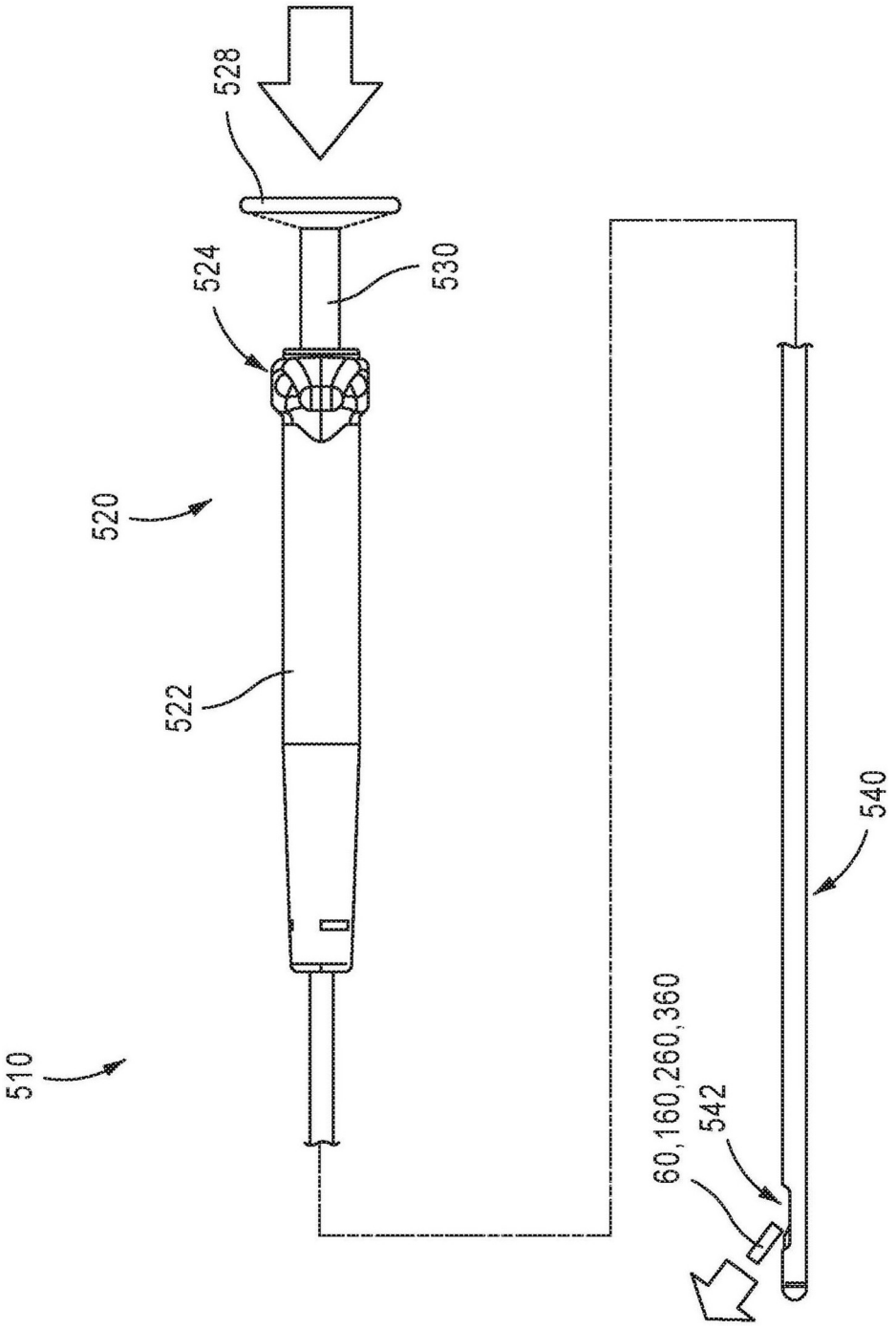

图11B

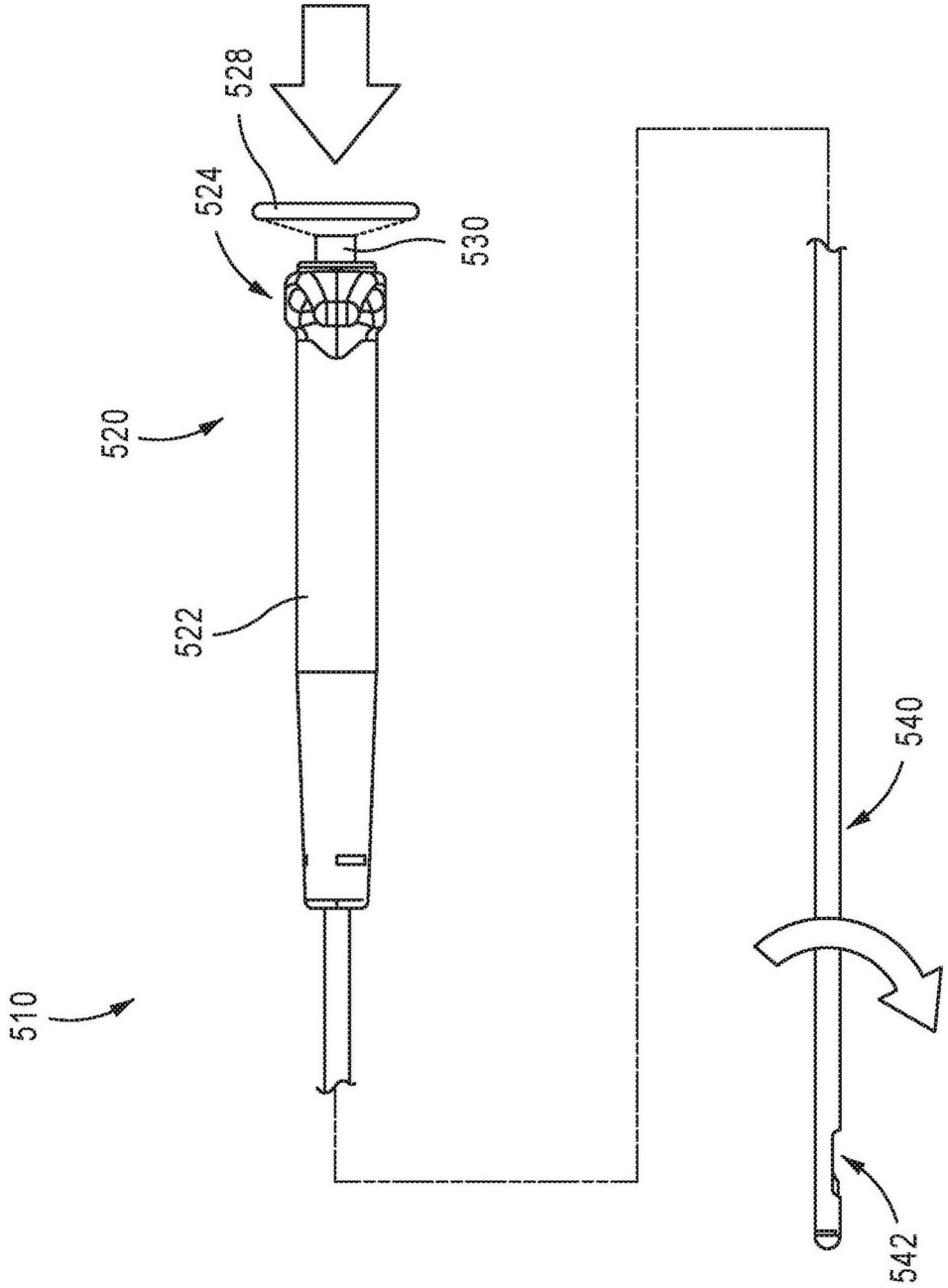

图11C

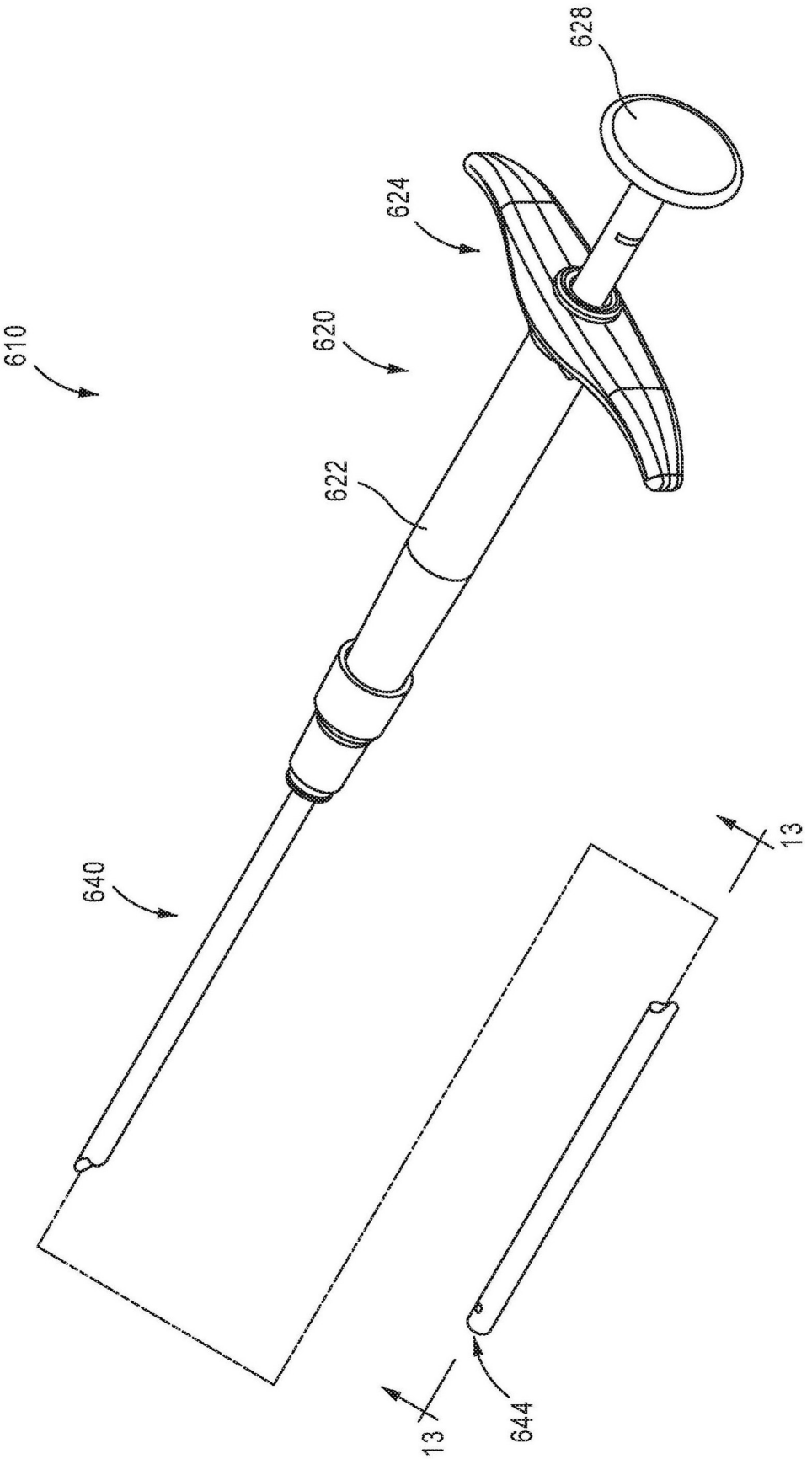

图12

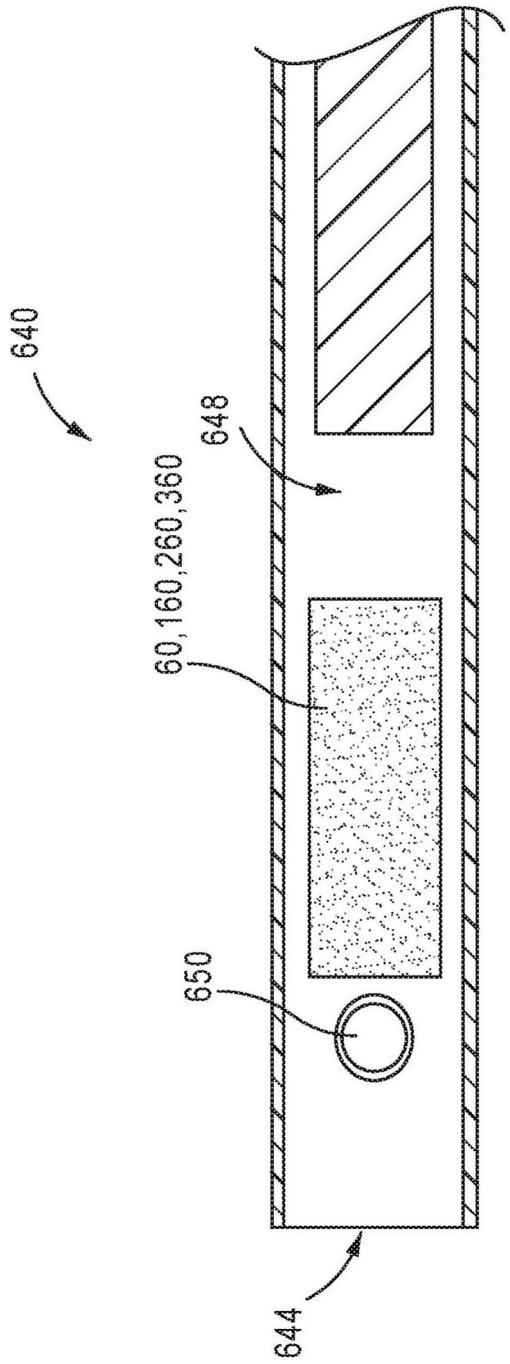

图13

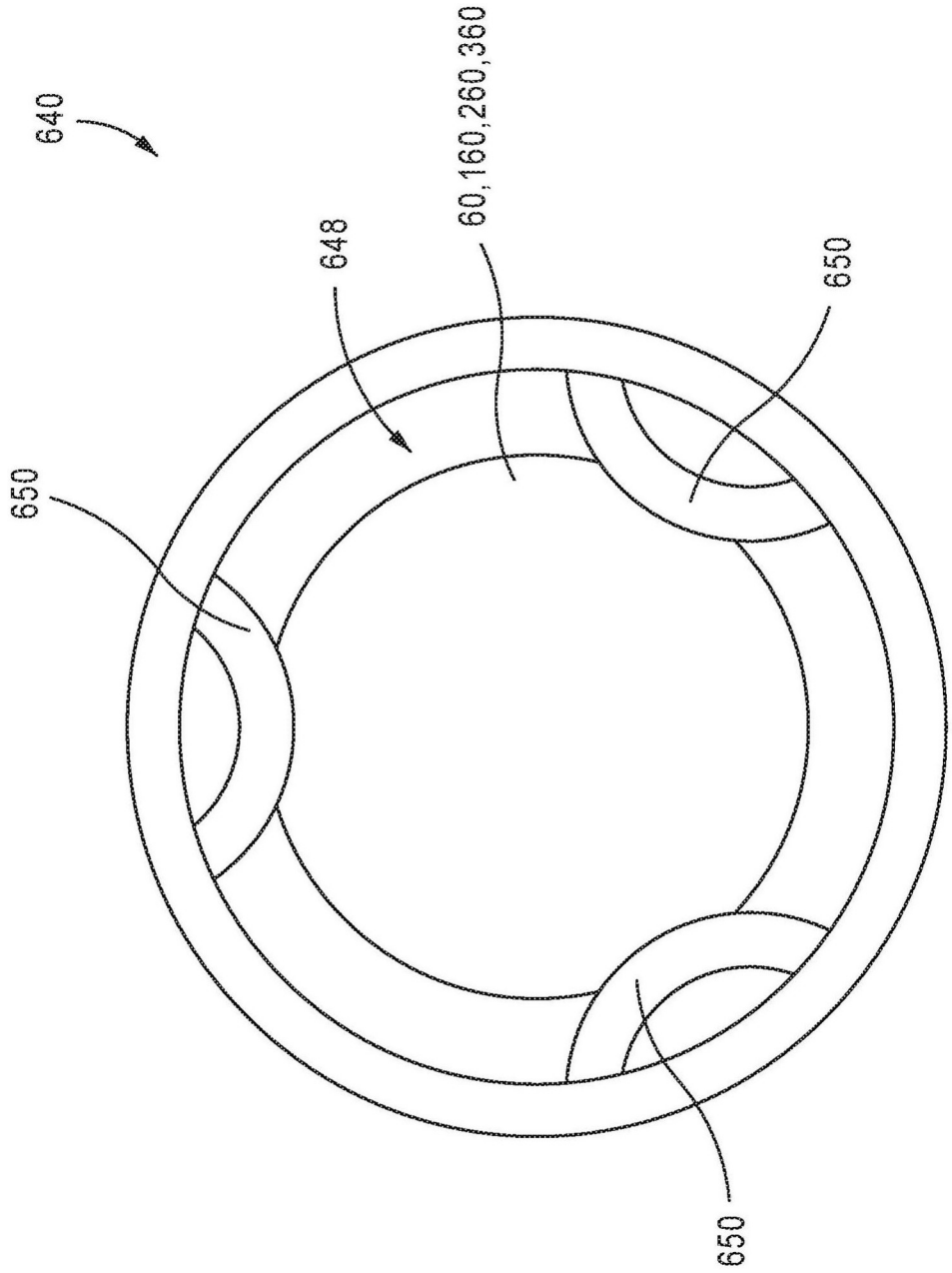

图14

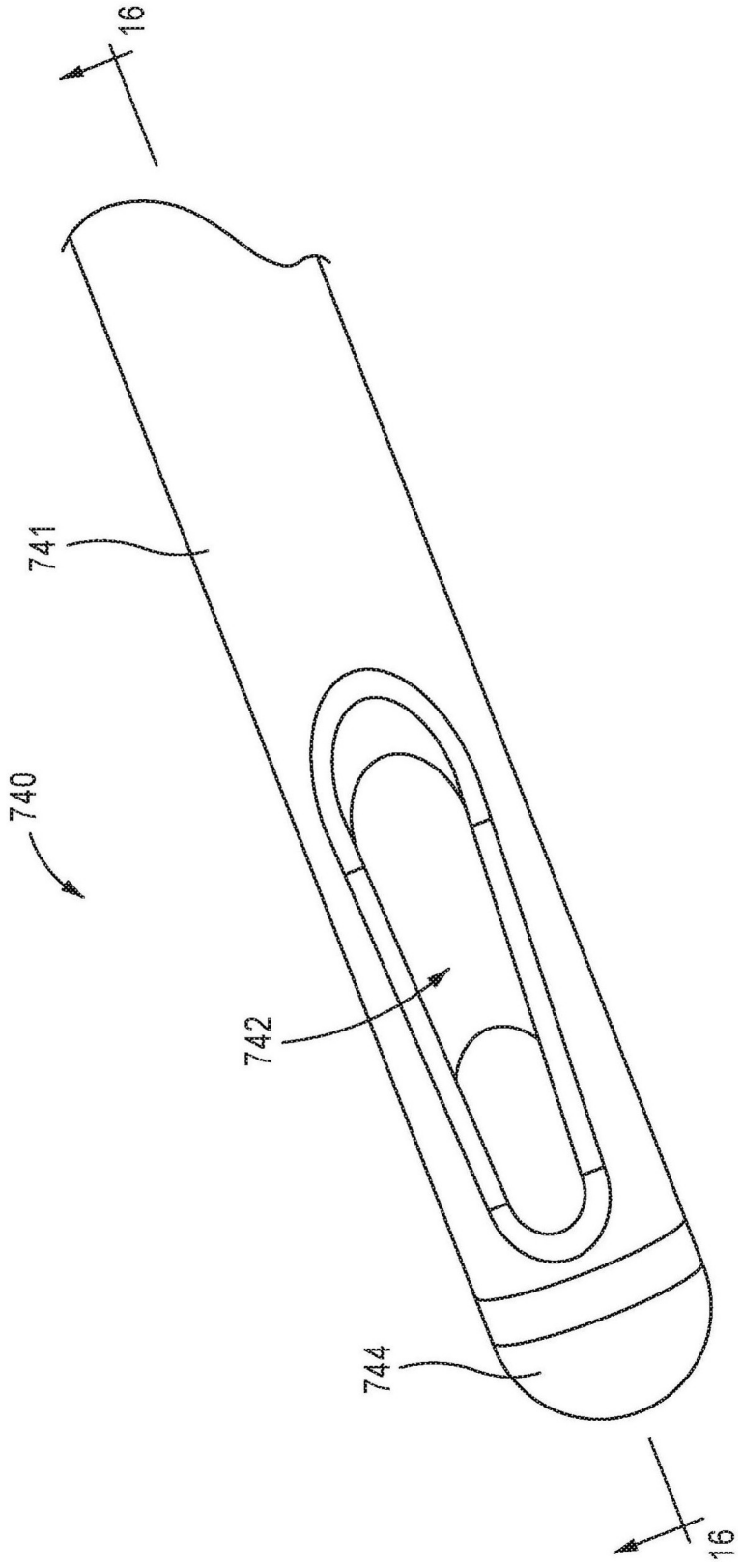

图15

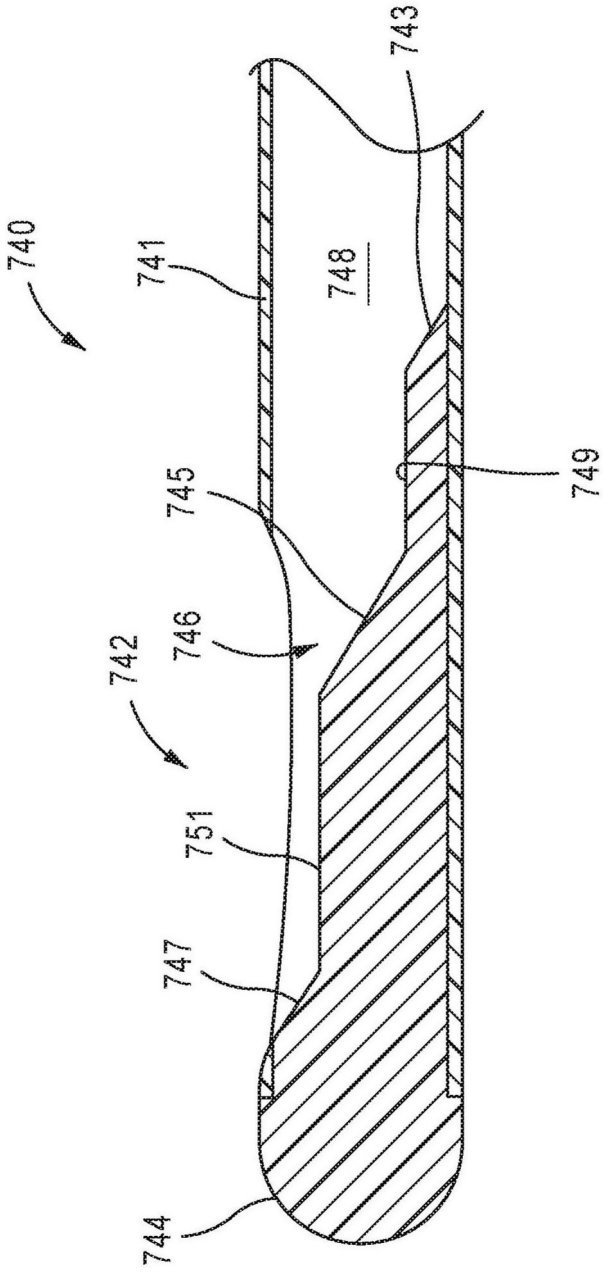

图16

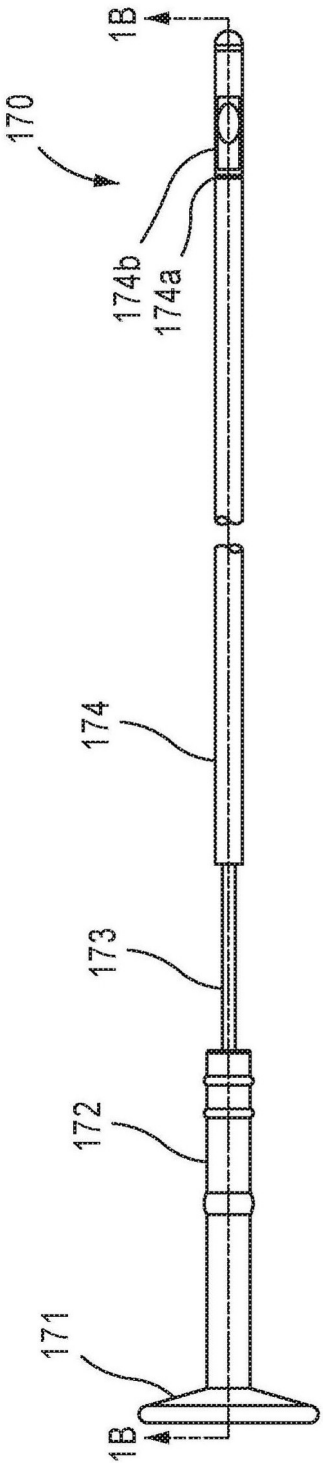

图17A

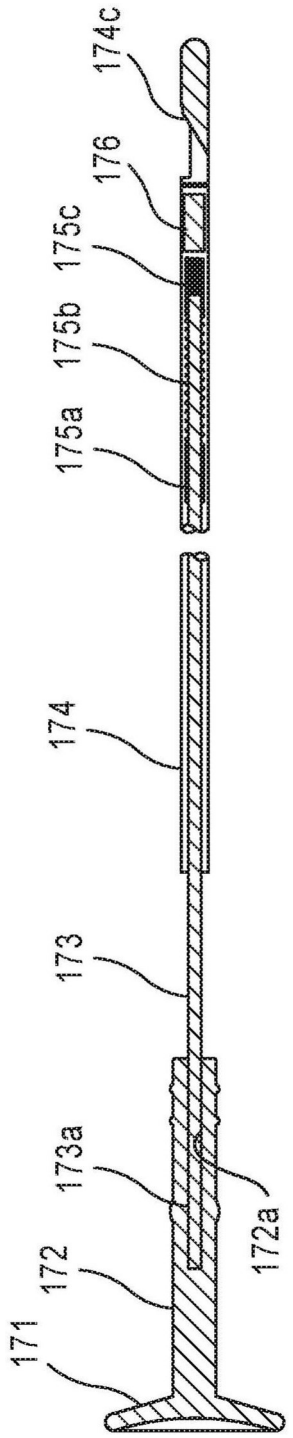

图17B

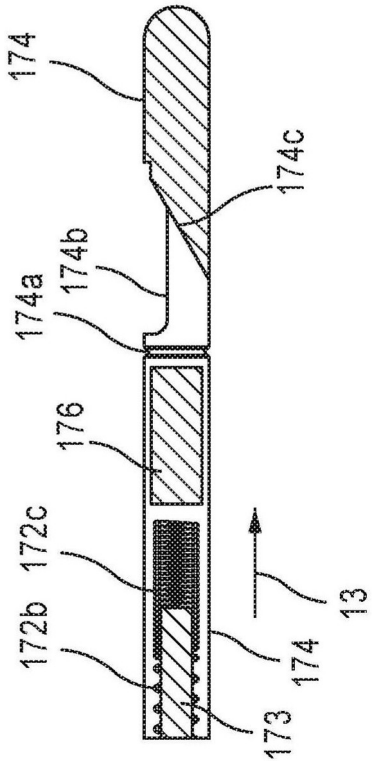

图17C

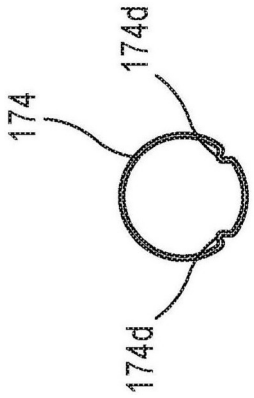

图17D

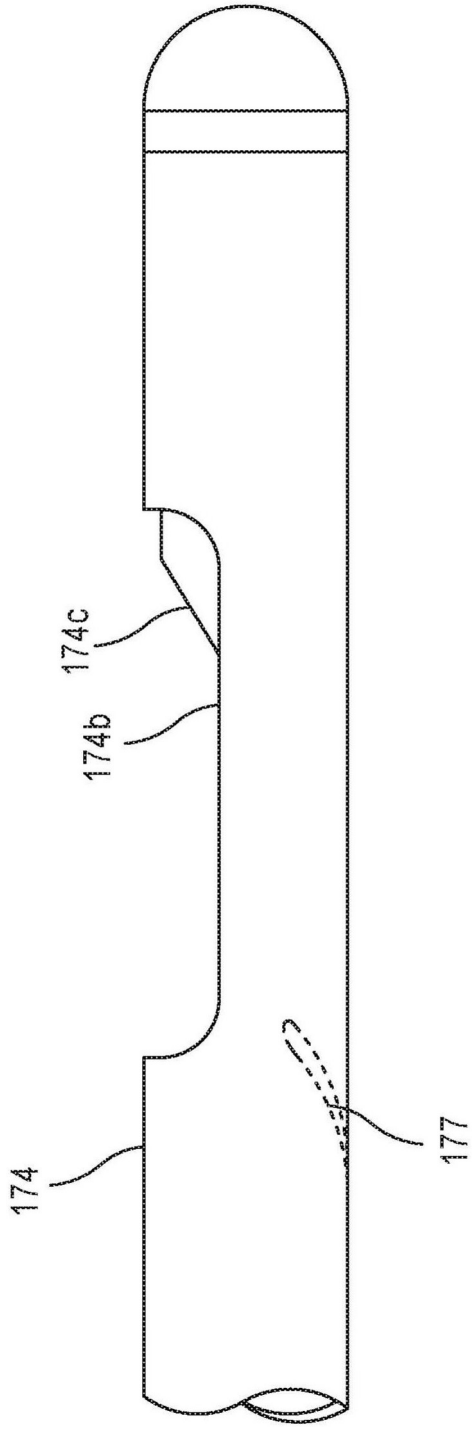

图18A

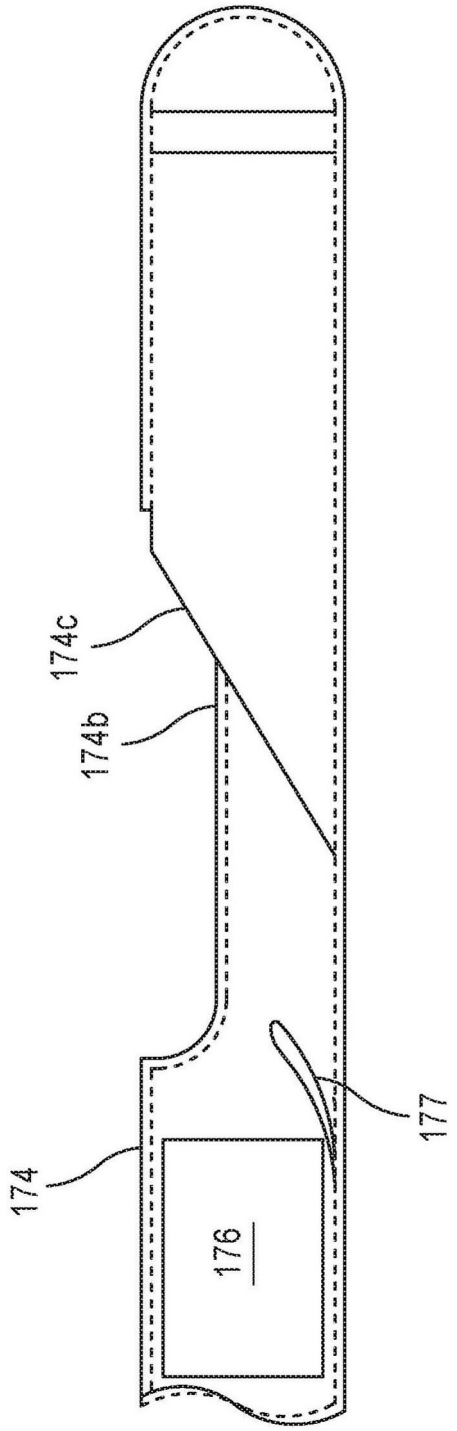

图18B

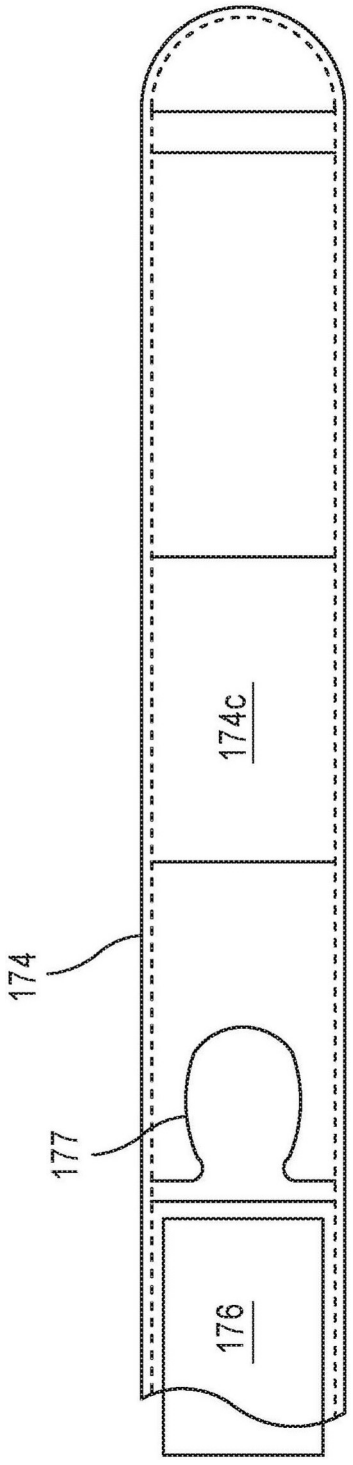

图18C

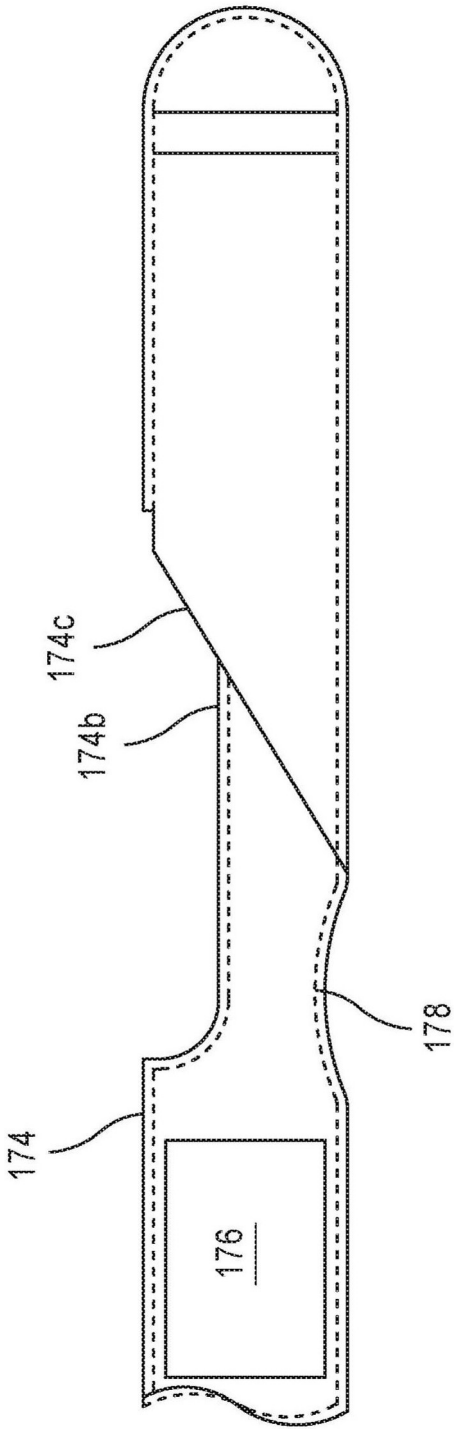

图19