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(54) Title: BIOPSY SITE MARKER APPLIER

(57) Abstract: A marker delivery device comprises a marker deployer cannula, a push rod, a biopsy site marker, and a ramped tip. The marker deployer cannula may have a marker exit in communication with an interior lumen of the cannula. The marker exit may comprise a distal end with a ramped surface. The biopsy site marker may be configured with a plurality of edges. The plurality of edges may be configured to engage at least a portion of the interior lumen of the cannula. The ramped tip may comprise a first ramped surface and a second ramped surface, the second ramped surface may align with the ramped surface of the distal end of the marker exit. The push rod may be used to push the biopsy site marker up the ramped tip and through the marker exit.

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BIOPSY SITE MARKER APPLIER

BACKGROUND

[0001] 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, MRI guidance, PEM guidance, BSGI guidance, or otherwise.

[0002] Merely exemplary biopsy devices are disclosed in U.S. Pat. No. 5,526,822, entitled "Method and Apparatus for Automated Biopsy and Collection of Soft Tissue," issued Jun. 18, 1996; U.S. Pat. No. 6,086,544, entitled "Control Apparatus for an Automated Surgical Biopsy Device," issued Jul. 11, 2000; U.S. Pub. No. 2003/0109803, entitled "MRI Compatible Surgical Biopsy Device," published Jun. 12, 2003, patented as U.S. Pat. No. 6,626,849; U.S. Pub. No. 2007/0118048, entitled "Remote Thumbwheel for a Surgical Biopsy Device," published May 24, 2007, patented as U.S. Pat. No. 7,442,171; 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 Feb. 21, 2012; U.S. Pub. No. 2008/0146962, entitled "Biopsy System with Vacuum Control Module," published Jun. 19, 2008; U.S. Patent No. 8,251,916, entitled "Revolving Tissue Sample Holder for Biopsy Device," issued Aug. 28, 2012; and U.S. Patent No. 8,532,747, entitled "Biopsy Marker Delivery Device," issued Sep. 10, 2013. The disclosure of each of the above-cited U.S. Patents and U.S. Patent Application Publications is incorporated by reference herein.

[0003] 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. Exemplary marker deployment tools include the MAMMOMARK™, MICROMARK®, and CORMARK™ brand devices from Devicor Medical Products, Inc. of Cincinnati, Ohio. Further exemplary devices and methods for marking a biopsy site are disclosed in U.S. Pub. No.

2005/0228311, entitled "Marker Device and Method of Deploying a Cavity Marker Using a Surgical Biopsy Device," published Oct. 13, 2005, patented as U.S. Pat. No. 7,465,279; U.S. Pat. No. 6,996,433, entitled "Imageable Biopsy Site Marker," issued Feb. 7, 2006; U.S. Pat. No. 6,993,375, entitled "Tissue Site Markers for In Vivo Imaging," issued Jan. 31, 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 Jun. 12, 2007; U.S. Pat. No. 7,044,957, entitled "Devices for Defining and Marking Tissue," issued May 16, 2006; U.S. Pat. No. 6,228,055, entitled "Devices for Marking and Defining Particular Locations in Body Tissue," issued May 8, 2001; and U.S. Pat. No. 6,371,904, entitled "Subcutaneous Cavity Marking Device and Method," issued Apr. 16, 2002. The disclosure of each of the above-cited U.S. Patents and U.S. Patent Application Publications is incorporated by reference herein.

[0004] While several systems and methods have been made and used for obtaining a biopsy sample, it is believed that no one prior to the inventor has made or used the invention described in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] While the specification concludes with claims which particularly point out and distinctly claim this technology, it is believed this technology will be better understood from the following description of certain examples taken in conjunction with the accompanying drawings, in which like reference numerals identify the same elements and in which:

[0006] FIG. 1 depicts a perspective view of a marker delivery device;

[0007] FIG. 2 depicts a cross-sectional view of a distal portion of the marker delivery device of FIG. 1;

[0008] FIG. 3 depicts a cross-sectional view of a marker being deployed from the distal portion of the marker delivery device of FIG. 1 and through a lateral tissue receiving port in a biopsy needle to mark a biopsy site;

[0009] FIG. 4 depicts a perspective view of another exemplary marker delivery device;

[0010] FIG. 5 depicts a perspective view of an endpiece of the marker delivery device of FIG. 4;

[0011] FIG. 6 depicts a cross-sectional view of a distal portion of the marker delivery device of FIG. 4;

[0012] FIG. 7 depicts a perspective view of an exemplary marker for use with the marker delivery device of FIG. 4;

[0013] FIG. 8 depicts a front view of the marker of FIG. 7;

[0014] FIG. 9 depicts a cross-sectional view of the marker of FIG. 7 within a shaft of the marker delivery device of FIG. 4;

[0015] FIG. 10 depicts a perspective view of another exemplary marker for use with the marker delivery device of FIG. 4;

[0016] FIG. 11 depicts a front view of the marker of FIG. 10;

[0017] FIG. 12 depicts a cross-sectional view of the marker of FIG. 10 within a shaft of the marker delivery device of FIG. 4;

[0018] FIG. 13 depicts a perspective view of another exemplary marker for use with the marker delivery device of FIG. 4;

[0019] FIG. 14 depicts a front view of the marker of FIG. 13; and

[0020] FIG. 15 depicts a cross-sectional view of the marker of FIG. 13 within a shaft of the marker delivery device of FIG. 4.

[0021] The drawings are not intended to be limiting in any way, and it is contemplated that various embodiments of the technology may be carried out in a variety of other ways, including those not necessarily depicted in the drawings. The accompanying drawings incorporated in and forming a part of the specification illustrate several aspects of the

present technology, and together with the description serve to explain the principles of the technology; it being understood, however, that this technology is not limited to the precise arrangements shown.

DETAILED DESCRIPTION

[0022] The following description of certain examples of the technology should not be used to limit its scope. Other examples, features, aspects, embodiments, 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, the technology described herein is capable of other different and obvious aspects, all without departing from the technology. Accordingly, the drawings and descriptions should be regarded as illustrative in nature and not restrictive.

[0023] I. Exemplary Marker Delivery Device

[0024] FIG. 1 illustrates a marker delivery device (10) which includes an elongate outer cannula (12) having a marker exit, such as side opening (14) formed adjacent to, but spaced proximally from, the distal end of the cannula (12).

[0025] A grip (16) can be provided at the proximal end of cannula (12). A push rod (18) can be provided, with push rod (18) extending coaxially in cannula (12) such that push rod (18) is configured to translate within cannula (12) to displace one or more markers through side opening (14) (see FIG. 2). Rod (18) may have sufficient rigidity in compression to push a marker from an internal lumen (15) of cannula (12) out through opening (14), yet be relatively flexible in bending. A plunger (20) is coupled at the proximal end of rod (18) for forcing rod (18) distally in cannula (12) to deploy a marker out of cannula (12).

[0026] A user may grasp grip (16) with two fingers, and may push on plunger (20) using the thumb on the same hand, so that marker delivery device (10) is operated by a user's single hand. A spring (not shown) or other feature may be provided about rod (18) to bias rod (18) proximally relative to grip (16) and cannula (12).

[0027] FIG. 2 depicts a cross-sectional view of a distal portion of the marker delivery device (10). FIG. 2 shows a biopsy marker (300) disposed in internal lumen (15) of cannula (12). In the present example, marker (300) comprise a biodegradable or otherwise resorbable body (306), such as a generally cylindrically shaped body of collagen, and a metallic, generally radiopaque marker element (310) (shown in phantom) disposed within or otherwise carried by body (306).

[0028] Cannula (12) may be formed of any suitable metallic or non-metallic material. In some versions, cannula (12) is formed of a thin walled hollow tube formed of a suitable medical grade plastic or polymer. One suitable material is a thermoplastic elastomer, such as Polyether block amide (PEBA), such as is known under the tradename PEBAX. Cannula (12) may be formed of PEBAX, and may be substantially transparent to visible light and X-ray.

[0029] Side opening (14) may be formed by cutting away a portion of the wall of cannula (12). Side opening (14) communicates with an internal lumen (15) of cannula (12). Side opening (14) may extend axially (in a direction parallel to the axis of lumen (15)) from a proximal opening end (14A) to a distal opening end (14B), as illustrated in FIG. 2.

[0030] In the present example, distal tip (22) extends from the distal end of cannula (12) and is rounded as shown in FIG. 2. Referring to FIG. 2, the distal end of cannula (12) is closed by a unitary endpiece (21), with a portion of endpiece (21) extending into internal lumen (15) of cannula (12). Endpiece (21) may be a molded or cast component. Endpiece (21) comprises a tip (22), a ramp (210) having a ramp surface (212), and a marker engaging element (240). Ramp surface (212) aids in directing marker (300) from internal lumen (15) through side opening (14). Marker engaging element (240) helps to retain marker (300) in internal lumen (15) until the user intends to deploy marker (300).

[0031] Marker engaging element (240) is disposed within internal lumen (15), and at least a portion of marker engaging element (240) is disposed distally of proximal end (14A) of side opening (14). Marker engaging element (240) extends along a portion of the floor of cannula (12) under opening (14) such that marker engaging element (240) is positioned to reinforce the portion of cannula (12) in which opening (14) is formed. For

instance, by positioning marker engaging element (240) underneath opening (14), as shown in FIG. 2, element (240) helps to stiffen cannula (12) in the region where wall of cannula (12) is cut to form opening (14). As shown in FIG. 2, marker engaging element (240) extends from the proximal most portion of ramp surface (212), and does not extend proximally of side opening (14), though in other embodiments, a portion of element (240) may extend proximally of opening (14).

[0032] As shown in FIG. 2, marker engaging element (240) is in the form of a step having a generally uniform thickness (T) along element's (240) axial length, except that element (240) has a tapered proximal end (242). Tapered proximal end (242) forms an included angle with the longitudinal axis of lumen (15) (included angle with a horizontal line in FIG. 2) of about 45 degrees, while ramp surface (212) forms an included angle with the longitudinal axis of about 30 degrees. Of course, any number of other suitable angles may be used. Thickness (T) may be greater than wall thickness (t) of cannula (12). In some versions, thickness (T) is at least about twice thickness (t). For instance, thickness (T) may be between about 0.018 inch to about 0.040 inch, and wall thickness (t) may be between about 0.005 inch to about 0.008 inch. The internal diameter of lumen (15) may be about 0.120 inches. Of course, any number of other suitable thicknesses and diameters may be used.

[0033] As shown in FIG. 2, an upwardly facing surface (244) (surface facing opening (14)) of marker engaging element (240) extends distally to contact ramp surface (212), so that there is not a space or gap between surface (244) and ramp surface (212). Such an arrangement is advantageous to reduce the possibility that marker (300), upon moving past marker engaging element (240), may become lodged between marker engagement element (240) and ramp (212). In some versions, marker engaging element (240), ramp (210), and/or tip (22) are formed of, or include, a material that is relatively more radiopaque than the wall of cannula (12). For instance, where element (240), ramp (210), and tip (22) are formed as an integral endpiece (21), endpiece (21) may include a radiopaque additive, such as barium sulfate. For instance, endpiece (21) may be a component molded of PEBAX, with about 20 percent by weight barium sulfate added to the molten PEBAX mold composition. The relatively more radiopaque marker engaging

element (240), ramp (210), and tip (22) may be useful in distinguishing the position of those components using radiographic imaging. Also, where ramp (210) and/or step of engaging element (240) are positioned in association with opening (14), the addition of a radiopaque material can help identify the position of opening (14), and the position of marker (300) relative to opening (14) before, during, or after deployment of marker (300).

[0034] Only one marker (300) is shown disposed in lumen (15) in the figures. However, it should be understood that multiple markers (300) may be disposed in marker delivery device (10), such as in an end to end configuration. Markers (300) may have the same size and shape, or alternatively have different sizes and/or shapes.

[0035] Cannula (12) may be generally transparent to visible light and x-ray, and endpiece (21) may be generally opaque to visible light and x-ray. It may be desirable to color endpiece (21) with a dye or other suitable colorant in the liquid mold composition. For instance, it may be desirable to have different size markers (300) (e.g. length and/or diameter) for different biopsy procedures. For instance, it may be desirable to provide a larger marker (300) if a relatively large biopsy sample is taken, and a smaller marker (300) if a relatively small biopsy sample is taken. Endpiece (21) may be colored using one of multiple colors to indicate the size of marker (300) disposed in cannula (12). For instance, if three marker (300) sizes are provided, endpiece (21) may be colored one of three colors to identify which of marker (300) sizes are disposed in cannula (12) of a marker device (10). Endpiece (21) may also be colored to indicate a particular size (diameter or length) biopsy needle with which marker delivery device (10) is to be used. Additionally, multiple marker delivery devices (10) could be packaged in kit form, with the kit including marker delivery devices (10) having different size markers (300) and correspondingly colored endpieces (21).

[0036] Referring to FIG. 3, marker delivery device (10) is used to deploy a marker (300) to mark a biopsy location within a patient. In FIG. 3, a cannular biopsy needle (1000) is shown having a closed distal end with piercing tip (1002) and a lateral tissue receiving aperture (1014). Marker deployer (10) is introduced to a biopsy site through biopsy

needle (1000), which may be the same needle (1000) used to collect a tissue sample from the biopsy site. Biopsy needle (1000) may be of the type used with single insertion, multiple sample vacuum assisted biopsy devices. Several such biopsy devices are disclosed in the various patents and patent applications that have been referred to and incorporated by reference herein, though other biopsy devices may be used.

[0037] FIG. 3 shows the distal end of marker deployer (10) disposed within needle (1000). Needle (1000) may be positioned in tissue, and a biopsy sample may be obtained through opening (1014), thereby providing a biopsy cavity adjacent opening (1014). Then, after the tissue sample has been obtained and transferred proximally through needle (1000), and without removing needle (1000) from the patient's tissue, deployer (10) is inserted into a proximal opening in needle (1000). In FIG. 3, needle (1000) and deployer (10) are positioned such that opening (14) of cannula (12) and opening (1014) of needle (1000) are substantially aligned axially and circumferentially. Then, with deployer (10) and needle (1000) so positioned at the biopsy site, push rod (18) is advanced to deploy marker (300) up ramp surface (212), through opening (14), and then through opening (1014), into the biopsy cavity.

[0038] In some instances, distal opening end (14B) may not align with ramped surface (212) due to inadvertent errors during manufacturing and/or assembly of marker delivery device (10). Accordingly, a marker (300) may become caught on distal opening end (14B) when marker (300) is deployed from device (10). It may therefore be desirable to include a second ramped feature on endpiece (21) to allow smooth deployment of marker (300) from device (10) even if ramped surface (212) and distal opening end (14B) are misaligned, as will be seen below.

[0039] FIG. 4 shows another exemplary marker delivery device (110) that is similar to marker delivery device (10), except that marker delivery device (110) comprises a compound ramped endpiece (121). Like marker deliver device (10), marker delivery device (110) comprises a cannula (112), a side opening (114), a grip (116), a plunger (120), and an endpiece (121). As shown in FIG. 5, endpiece (121) is similar to endpiece (21) in that endpiece (121) comprises a ramp (311), and a rounded distal tip (122).

Marker engaging element (340) and tip (122) are similar to and tip (22). Ramp (311) is similar to ramp (210), except that ramp (311) comprises a first ramped surface (312) and a second ramped surface (314) distal to first ramped surface (312). Second ramped surface (314) inclines at a smaller angle than first ramped surface (312) relative to the longitudinal axis of endpiece (121).

[0040] FIG. 6 shows endpiece (121) coupled with cannula (112), such that a portion of endpiece (121) is inserted within a distal portion of cannula (112). Marker engaging element (340) is adjacent to side opening (114) of cannula (112). A tapered proximal end (342) of marker engaging element (340) forms an included angle with the longitudinal axis of lumen (115) of about 45 degrees. First ramped surface (312) forms an included angle with the longitudinal axis of lumen (115) of about 30 degrees. Second ramped surface (314) forms an included angle with the longitudinal axis of lumen (115) of about 21 degrees. Of course, any number of other suitable angles may be used. A distal opening end (114B) of opening (114) is formed at substantially the same angle as second ramped surface (314) such that second ramped surface (314) and distal opening end (114B) of cannula (112) form a substantially flush surface when endpiece (121) is inserted within cannula (112). For instance, endpiece (121) may be insert molded within cannula (112) and formed with tapered proximal end (342), marker engagement element (340), and first ramped surface (312). Side opening (114) may then be cut to form a proximal opening end (114A), distal opening end (114B), and second ramped surface (314) of endpiece (121). This creates a substantially flush surface between cannula (112) and endpiece (121). In some other versions, endpiece (121) may be manufactured and then assembled with cannula (112). Second ramped surface (314) and distal opening end (114B) may then be cut together after assembly of endpiece (121) and cannula (112). In some other versions, second ramped surface (314) and distal opening end (114B) may be cut and then assembled together. Even if second ramped surface (314) and distal opening end (114B) are inadvertently misaligned during assembly, a marker (300) may smoothly deploy from device (110) because second ramped surface (314) and distal opening end (114B) have a shallower angle than first ramped surface (312).

[0041] Marker delivery device (110) may be used to deploy a marker (300) to mark a

biopsy location within a patient. For instance, marker delivery device (110) may introduced to a biopsy site through a biopsy needle (1000), which may be the same needle (1000) used to collect a tissue sample from the biopsy site. Needle (1000) may be positioned in tissue, and a biopsy sample may be obtained through opening (1014), thereby providing a biopsy cavity adjacent opening (1014). Then, after the tissue sample has been obtained and transferred proximally through needle (1000), and without removing needle (1000) from the patient's tissue, marker delivery device (110) is inserted into a proximal opening in needle (1000). Needle (1000) and marker delivery device (110) are positioned such that opening (114) of cannula (112) and opening (1014) of needle (1000) are substantially aligned axially and circumferentially. A marker (300) is positioned within lumen (115) of cannula (112) proximal to marker engaging element (340) such that marker engaging element (340) holds marker (300) within cannula (112). Then, with deployer (110) and needle (1000) so positioned at the biopsy site, a push rod (118) is advanced to deploy marker (300). As push rod (118) advances marker (300), marker (300) cammingly slides along ramped proximal end (342) of marker engaging element (340), along an upwardly facing surface (344) and up first and second ramped surface (312, 314). Marker (300) is then deployed through opening (114), and then through opening (1014) of needle (1000), into the biopsy cavity.

[0042] II. Exemplary Marker

[0043] FIGS. 7-8 show an exemplary marker (400) that may be deployed from a marker delivery device (10, 110) to mark a biopsy site. Marker (400) is similar to marker (300) described above, except that marker (400) has a modified shape compared to the cylindrical shape of marker (300). As best seen in FIG. 8, marker (400) comprises a rounded top surface (402) positioned between corners (410, 412) extending outwardly from marker (400). A side surface (408) extends downwardly from corner (410) and an opposing side surface (404) extends downwardly from corner (412). A rounded bottom surface (406) joins side surfaces (404, 408). Marker (400) is biodegradable or otherwise resorbable. Accordingly, marker (400) may be made of collagen or any other suitable material, including but not limited to the various marker body materials taught in the various references cited herein. Marker (400) comprises a generally radiopaque (e.g.,

metallic) marker element (not shown) disposed within or otherwise carried by marker (400).

[0044] Marker (400) may be inserted within cannula (12, 112) of a marker delivery device (10, 110) for deployment to a biopsy site, as shown in FIG. 9. When marker (400) is inserted within cannula (12, 112), corners (410, 412) and bottom surface (406) engage the inner diameter of cannula (12, 112). Accordingly, corners (410, 412) may flex inwardly or otherwise deform when corners (410, 412) engage cannula (12, 112). This may cause side surfaces (404, 408) to deflect outwardly. In some versions, side surfaces (404, 408) deflect outwardly to contact the inner diameter of cannula (12, 112), while in other versions, side surfaces fail to contact the inner diameter of cannula (12, 112). The contact of corners (410, 412) and bottom surface (406) of marker (400) with cannula (12, 112) provides sufficient frictional resistance between marker (400) and cannula (12, 112) to prevent marker (400) from inadvertently falling out of side opening (14, 114) before push rod (18, 118) is actuated to deploy marker (400), while still allowing marker (400) to be deployed from cannula (12, 112) without requiring excessive force. Because marker (400) engages cannula (12, 112) with corners (410, 412), the force needed to push marker (400) out of cannula (12, 112) may be less than the force needed to push marker (300) out of cannula (12, 112).

[0045] FIGS. 10-11 show another exemplary marker (500) that may be deployed from a marker delivery device (10, 110) to mark a biopsy site. Marker (500) is similar to marker (300) described above, except that marker (500) has a modified shape compared to the cylindrical shape of marker (300). As best seen in FIG. 11, marker (500) comprises a rectangular shape having a top surface (502), a bottom surface (506), and side surfaces (504, 508). Accordingly, surfaces (502, 504, 506, 508) form corners (501, 503, 505, 507) between surfaces (502, 504, 506, 508). Although marker (500) has a rectangular shape in the present example, marker (500) may also comprise other suitable shapes, such as a square, triangle, pentagon, or other polygons. Marker (500) is biodegradable or otherwise resorbable. Accordingly, marker (500) may be made of collagen or any other suitable material, including but not limited to the various marker body materials taught in the various references cited herein. Marker (500) comprises a generally radiopaque

(e.g., metallic) marker element (not shown) disposed within or otherwise carried by marker (500).

[0046] Marker (500) may be inserted within cannula (12, 112) of a marker delivery device (10, 110) for deployment to a biopsy site, as shown in FIG. 12. When marker (500) is inserted within cannula (12, 112), corners (501, 503, 505, 507) engage the inner diameter of cannula (12, 112). Accordingly, corners (501, 503, 505, 507) may flex inwardly or otherwise deform when corners (501, 503, 505, 507) engage cannula (12, 112). This may cause surfaces (502, 504, 506, 508) to deflect outwardly. In some versions, surfaces (502, 504, 506, 508) deflect outwardly to contact the inner diameter of cannula (12, 112), while in other versions, surfaces (502, 504, 506, 508) fail to contact the inner diameter of cannula (12, 112). The contact of corners (501, 503, 505, 507) of marker (500) with cannula (12, 112) provides sufficient frictional resistance between marker (500) and cannula (12, 112) to prevent marker (500) from inadvertently falling out of side opening (14, 114) before push rod (18, 118) is actuated to deploy marker (500), while still allowing marker (500) to be deployed from cannula (12, 112) without requiring excessive force. Because marker (500) engages cannula (12, 112) with corners (501, 503, 505, 507), the force needed to push marker (500) out of cannula (12, 112) may be less than the force needed to push marker (300) out of cannula (12, 112).

[0047] FIGS. 13-14 show another exemplary marker (600) that may be deployed from a marker delivery device (10, 110) to mark a biopsy site. Marker (600) is similar to marker (300) described above, except that marker (600) comprises a plurality of ribs (601, 603, 605) extending outwardly from marker (600). Ribs (601, 603, 605) extend longitudinally along exterior surface (602) of marker (600) and are equally spaced around exterior surface (602) of marker (600). Although three ribs (601, 603, 605) are shown, any other suitable number of ribs (601, 603, 605) may be used. Ribs (601, 603, 605) may also be unevenly positioned around exterior surface (602) of marker (600). As best seen in FIG. 14, each rib (601, 603, 605) comprises a protrusion (604, 606, 608) extending outwardly from each rib (601, 603, 605). The diameter of marker (600) may be about 0.066 inches. Ribs (601, 603, 605) may extend beyond the diameter of marker (600) by about 0.0025 inches. Of course any other suitable diameters and lengths may be used. It should be

noted that protrusions (604, 606, 608) are merely optional. Marker (600) is biodegradable or otherwise resorbable. Accordingly, marker (600) may be made of collagen or any other suitable material, including but not limited to the various marker body materials taught in the various references cited herein. Marker (600) comprises a generally radiopaque (e.g., metallic) marker element (not shown) disposed within or otherwise carried by marker (600).

[0048] Marker (600) may be inserted within cannula (12, 112) of a marker delivery device (10, 110) for deployment to a biopsy site, as shown in FIG. 15. When marker (600) is inserted within cannula (12, 112), ribs (601, 603, 605) engage the inner diameter of cannula (12, 112). Accordingly, ribs (601, 603, 605) may flex inwardly or otherwise deform when ribs (601, 603, 605) engage cannula (12, 112). Ribs (601, 603, 605) may deflect such that protrusions (604, 606, 608) engage the inner diameter of cannula (12, 112). Accordingly, protrusions (604, 606, 608) may help to maintain marker (600) within cannula (12, 112). Exterior surface (602) of marker (600) may also deflect outwardly when marker (600) is inserted within cannula (12, 112). In some versions, surface (602) deflects outwardly to contact the inner diameter of cannula (12, 112), while in other versions, surface (602) fails to contact the inner diameter of cannula (12, 112). The contact of ribs (601, 603, 605) and/or protrusions (604, 606, 608) of marker (600) with cannula (12, 112) provides sufficient frictional resistance between marker (600) and cannula (12, 112) to prevent marker (600) from inadvertently falling out of side opening (14, 114) before push rod (18, 118) is actuated to deploy marker (600), while still allowing marker (600) to be deployed from cannula (12, 112) without requiring excessive force. Because marker (600) engages cannula (12, 112) with ribs (601, 603, 605), the force needed to push marker (600) out of cannula (12, 112) may be less than the force needed to push marker (300) out of cannula (12, 112).

[0049] III. Conclusion

[0050] It should be appreciated that any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated material does not conflict with existing

definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

[0051] Embodiments of the present invention have application in conventional endoscopic and open surgical instrumentation as well as application in robotic-assisted surgery.

[0052] By way of example only, embodiments described herein may be processed before surgery. First, a new or used instrument may be obtained and if necessary cleaned. The instrument may then be sterilized. In one sterilization technique, the instrument is placed in a closed and sealed container, such as a plastic or TYVEK bag. The container and instrument may then be placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation may kill bacteria on the instrument and in the container. The sterilized instrument may then be stored in the sterile container. The sealed container may keep the instrument sterile until it is opened in a medical facility. 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.

[0053] Embodiments of the devices disclosed herein can be reconditioned for reuse after at least one use. Reconditioning may include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, embodiments of the devices disclosed herein may be disassembled, and any number of the particular pieces or parts of the devices may be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, embodiments of the devices may be reassembled for subsequent use either at a reconditioning facility, or by a surgical team immediately prior to a surgical procedure. Those skilled in the art will appreciate that reconditioning of a device may

utilize a variety of techniques for disassembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

[0054] Having shown and described various embodiments of the present invention, further adaptations of the methods and systems described herein may be accomplished by appropriate modifications by one of ordinary skill in the art without departing from the scope of the present invention. Several of such potential modifications have been mentioned, and others will be apparent to those skilled in the art. For instance, the examples, embodiments, geometrics, materials, dimensions, ratios, steps, and the like discussed above are illustrative and are not required. Accordingly, the scope of the present invention should be considered in terms of the following claims and is understood not to be limited to the details of structure and operation shown and described in the specification and drawings.

I/we claim:

1. A marker delivery device comprising:

(a) a marker deployer cannula comprising:

(i) a distal end;

(ii) a proximal end;

(iii) a internal lumen; and

(iv) a marker exit comprising a distal end, wherein the distal end comprises a ramped surface;

wherein the marker exit is spaced proximal to the distal end, wherein the marker exit is in communication with the internal lumen;

(b) a push rod having a distal end, wherein the push rod is slidably disposed within the marker deployer cannula;

(c) a biopsy site marker; and

(d) a ramped tip, the ramped tip comprising:

(i) a distal tip; and

(ii) a ramp having a first ramped surface and a second ramped surface, wherein the ramp extends proximally from the distal tip, wherein the first ramped surface is positioned proximally from, and directly adjacent to, the second ramped surface, wherein the first ramped surface has a first incident angle, wherein the second ramped surface has a second incident angle, wherein the second ramped surface is configured to align with the ramped surface of the distal end of the marker exit;

wherein the ramped tip is insertable into the distal end of the marker

delployer cannula;

wherein the marker delivery device is operable to deploy the biopsy site marker at a biopsy site.

2. The marker delivery device of claim 1, wherein the ramped tip further comprises a marker engaging element.

3. The marker delivery device of claim 2, wherein the marker engaging element extends proximally from the ramp.

4. The marker delivery device of claim 2, wherein the marker engaging element comprises a tapered proximal end.

5. The marker delivery device of claim 1, wherein the first incident angle of the first ramped surface is larger than the second incident angle of the second ramped surface.

6. The marker delivery device of claim 1, wherein the ramped surface of the distal end of the marker exit comprises an incident angle.

7. The marker delivery device of claim 1, wherein the incident angle of the ramped surface of the distal end of the marker exit is substantially the same as the second incident angle of the second ramped surface of the ramped tip.

8. The marker delivery device of claim 1, wherein the marker exit further comprises a proximal end, wherein the proximal end has a ramped surface having an incident angle, wherein the incident angle of the ramped surface of the proximal end is substantially the same as the incident angle of the distal end of the marker exit.

9. The marker delivery device of claim 1, wherein the outwardly extending edges of the biopsy site marker comprise a plurality of ribs extending from a substantially cylindrical surface of the biopsy site marker.

10. The marker delivery device of claim 9, wherein each rib of the plurality of ribs comprises a protrusion, wherein each protrusion is configured to engage at least a portion of the

internal lumen of the marker deployer cannula.

11. The marker delivery device of claim 1, wherein the plurality of outwardly extending edges of the biopsy site marker are defined by four sides of the biopsy site marker.

12. The marker delivery device of claim 11, wherein the each side of the four sides joins to another side to form each outwardly extending edge of the plurality of edges of the biopsy site marker.

13. The marker delivery device of claim 1, wherein the biopsy site marker further comprises a rounded bottom surface, wherein the bottom surface is configured to engage at least a portion of the internal lumen of the marker deployer cannula.

14. The marker delivery device of claim 13, wherein the plurality of outwardly extending edges comprises two corners, wherein the two corners are defined by two side surfaces extending from the rounded bottom surface and a rounded top surface.

15. A system comprising:

(a) a biopsy device comprising a biopsy needle, wherein the biopsy needle has a distal end comprising a tissue piercing tip, and a tissue receiving aperture placed proximally to the distal end;

(b) a marker delivery device comprising:

(i) a marker deployer cannula comprising a distal end, an internal lumen, and a marker exit, wherein the marker exit is spaced proximal to the distal end, wherein the marker exit is in communication with the internal lumen, wherein the marker exit comprises a distal end having a ramped surface;

(ii) a push rod having a distal end, wherein the push rod is slidably disposed the marker deployer cannula, and

(iii) a ramped tip comprising a distal tip and a ramp;

(c) a biopsy site marker, wherein the biopsy site marker has a plurality of edges, wherein the each edge of the plurality of edges is configured to engage at least a portion of an inner diameter of the marker deployer cannula;

wherein marker delivery device is configured to be insertable into the biopsy device such that the marker exit of the marker delivery device is aligned with the tissue receiving aperture of the biopsy device, wherein the push rod is configured to urge the biopsy site marker up the ramp of the ramped rip and through the tissue receiving aperture of the biopsy device.

16. The system of claim 15, wherein the ramp of the ramped tip comprises a first ramped surface and a second ramped surface, wherein the first ramped surface of the ramp has a first included angle, wherein the second ramped surface of the ramp has a second incident angle, wherein the ramped surface of the distal end of the marker exit has an incident angle, wherein the first incident angle is greater than the second incident angle, wherein the second incident angle is substantially the same as the incident angle of the ramped surface.

17. The system of claim 15, wherein each edge of the plurality of edges of the biopsy site marker comprises a rib, wherein the rib comprises at least one protrusion, wherein the rib and the protrusion of each edge of the plurality of edges is configured are configured to engage at least a portion of the inner diameter of the marker deployer cannula.

18. The system of claim 15, wherein the biopsy site marker comprises a top rounded surface and a rounded bottom surface, wherein the rounded bottom surface defines two side surfaces, wherein the side surfaces and the rounded top surface together define a first edge and a second edge of the plurality of edges.

19. The system of claim 15, wherein the biopsy site marker comprises compressed collegen.

20. A marker delivery device comprising:

(a) a cannula comprising a distal tip, a side opening and a grip coupled to the

cannula, wherein the side opening is positioned proximally relative to the distal tip, wherein the side opening comprises a distal end having a ramp;

(b) at least one biopsy marker disposed proximally of the side opening within the cannula;

(c) a push rod, having a distal end and a plunger coupled to the push rod, wherein the push rod is slidably disposed within the cannula proximal to the at least one biopsy marks; and

(d) a ramped endpiece disposed within the distal end of the cannula, wherein the ramped endpiece comprises a distal tip and a compound ramp, wherein at least a portion of the distal tip extends distally from the distal end of the cannula, wherein the compound ramp extends proximally from the distal end of the ramped endpiece, wherein the ramp comprises a first ramped surface adjacent to a second ramped surface, wherein the second ramped surface is configured to align with the ramp of the distal end of the side opening;

wherein the grip and the plunger are configured to be manipuled by a single hand, wherein the push rod is movable in a distal direction to deploy the at least one biopsy marker from the tube through the side opening.

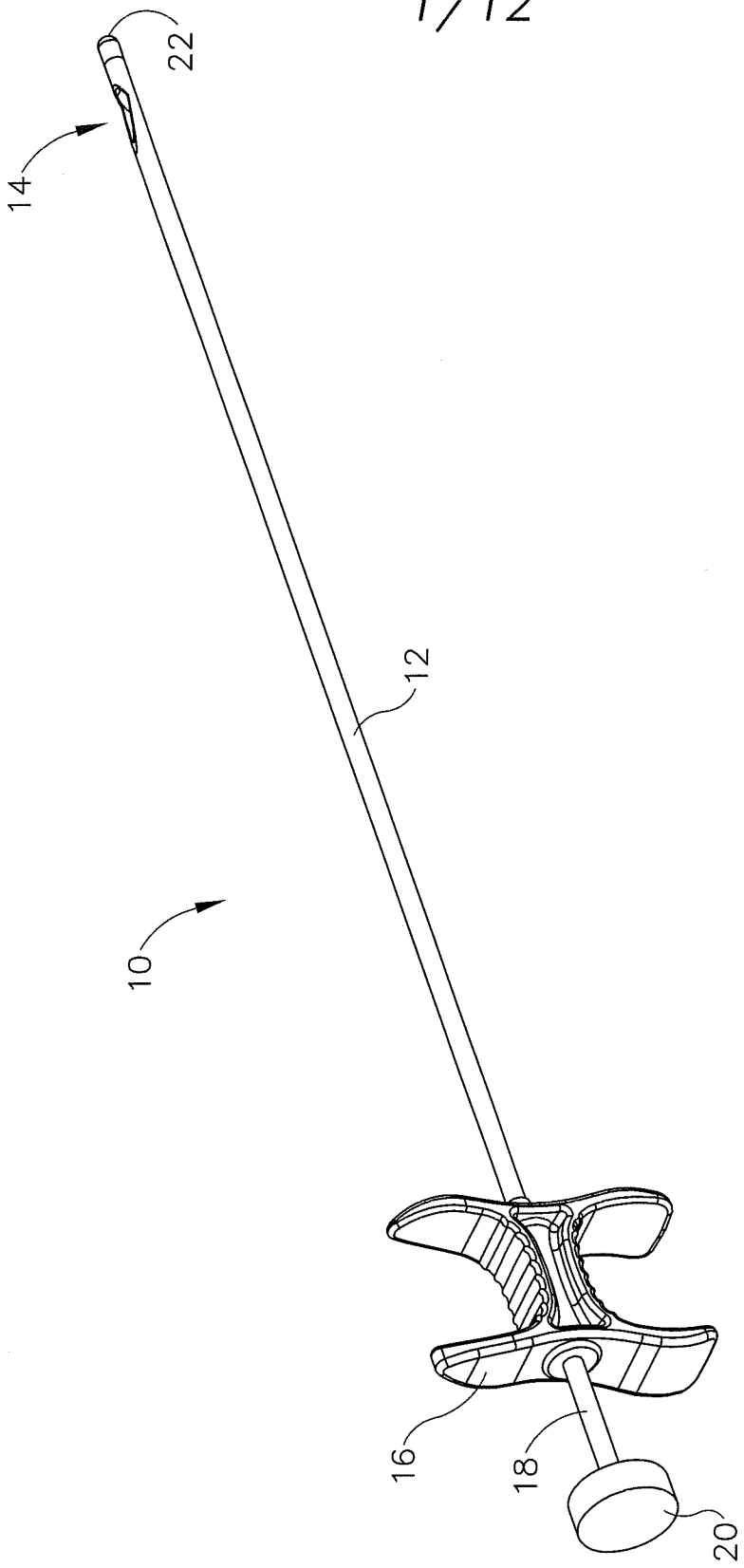

Fig. 1

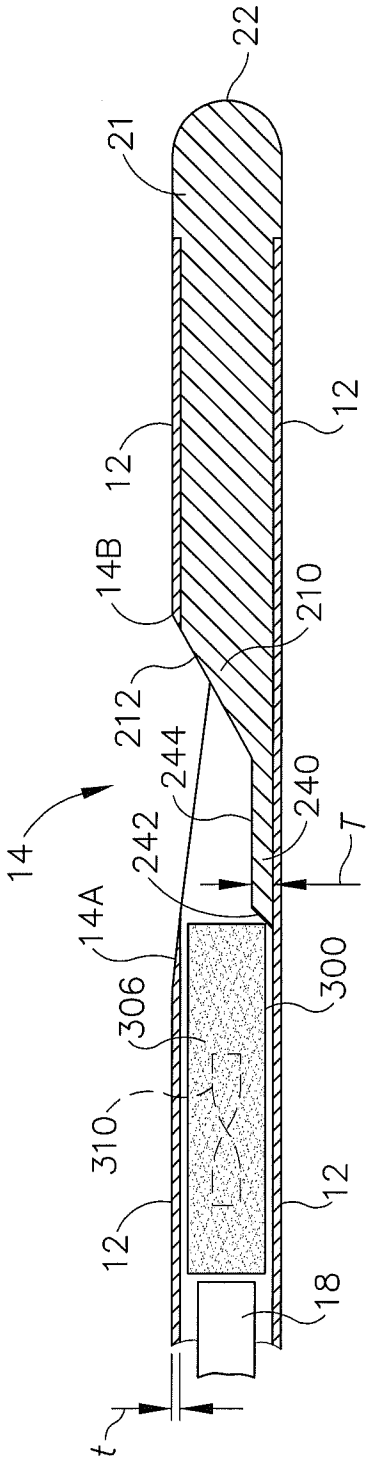

Fig.2

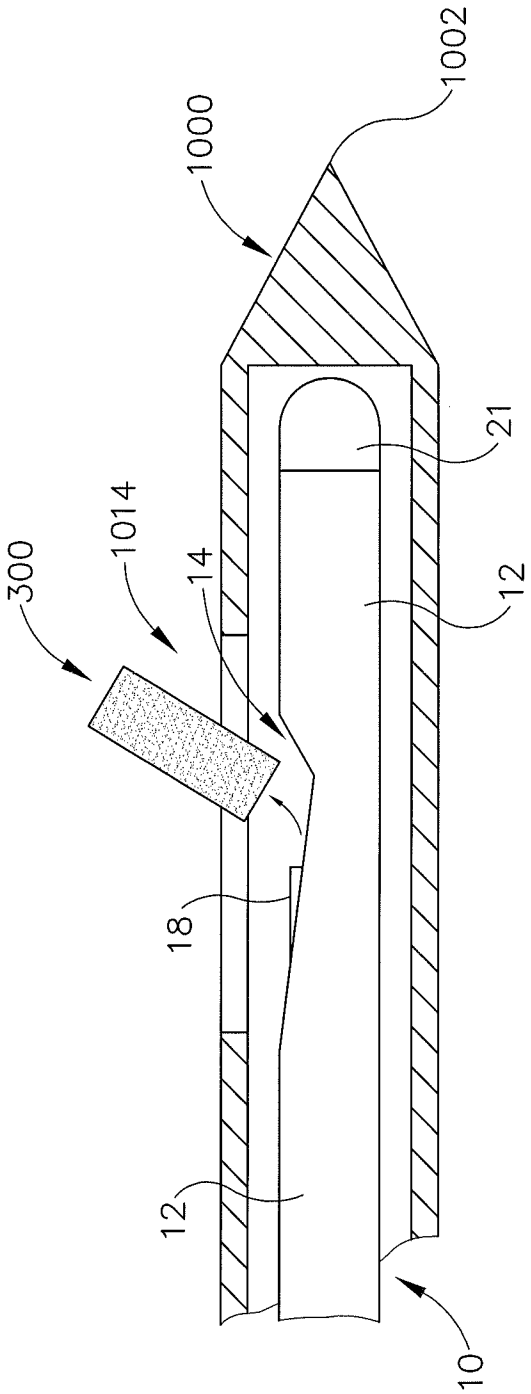

Fig.3

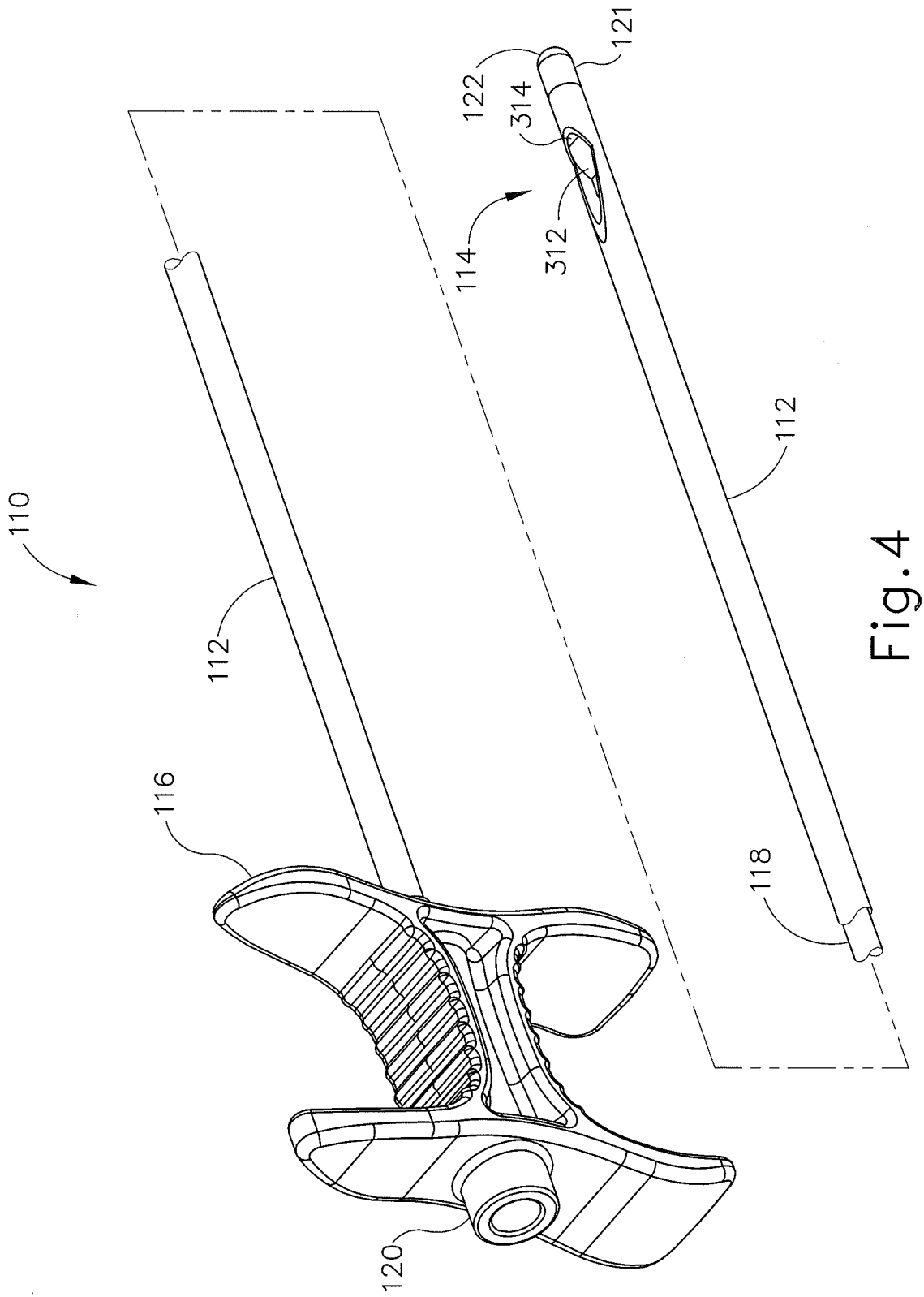

Fig.4

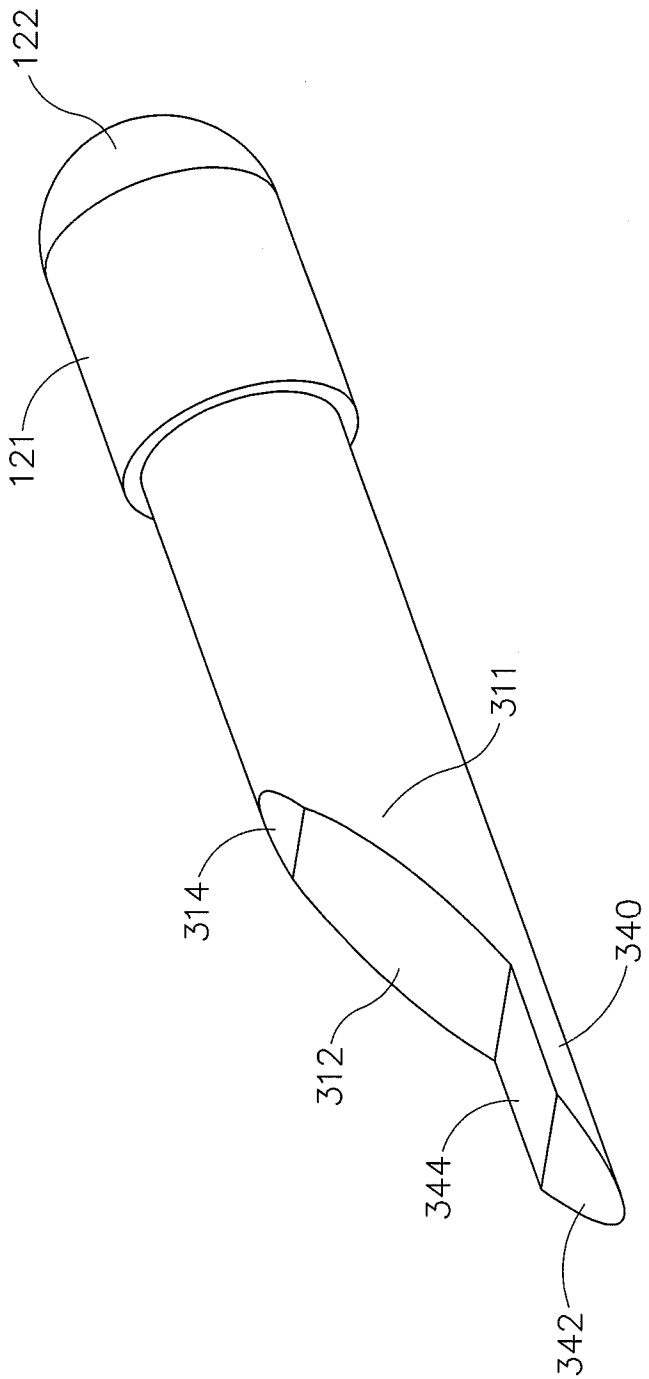

Fig.5

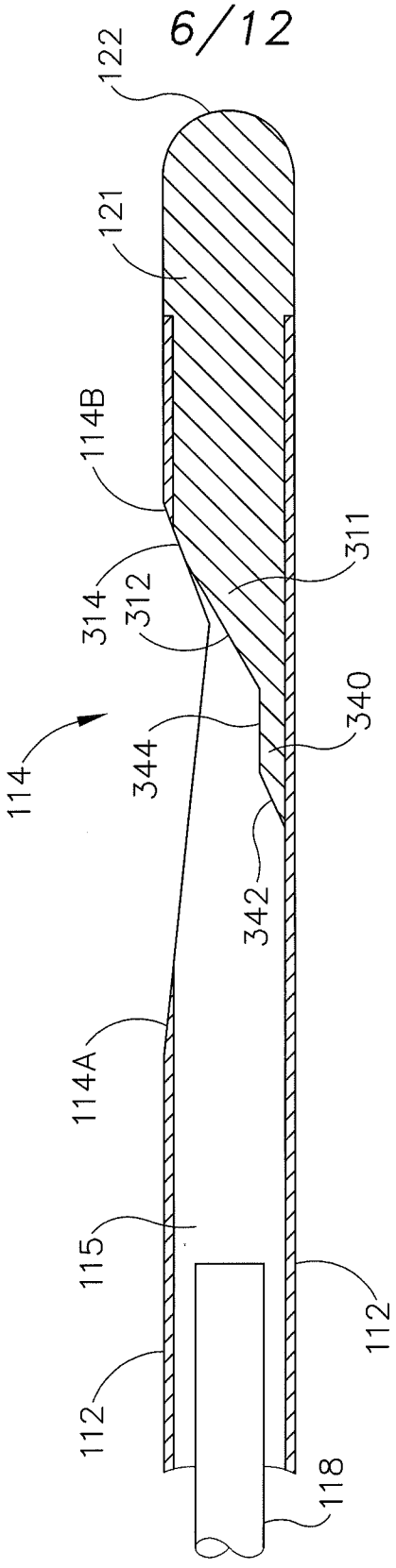

Fig.6

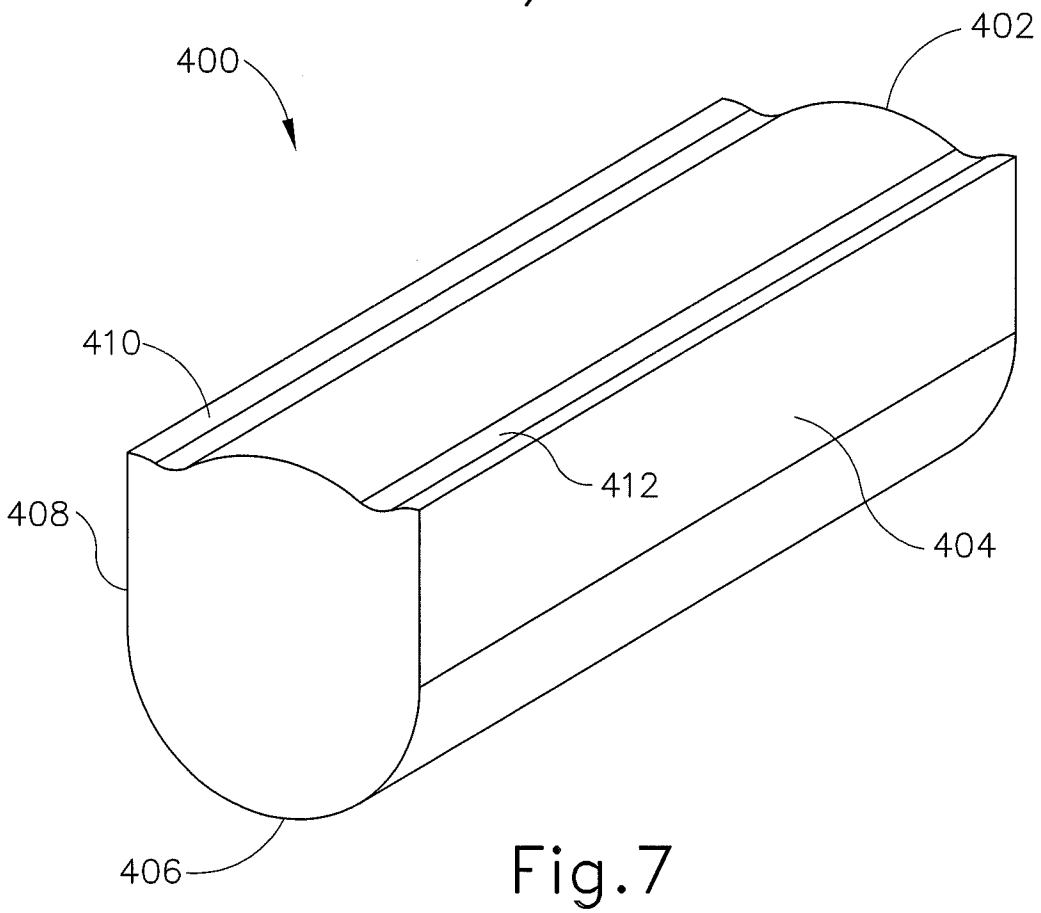

Fig.7

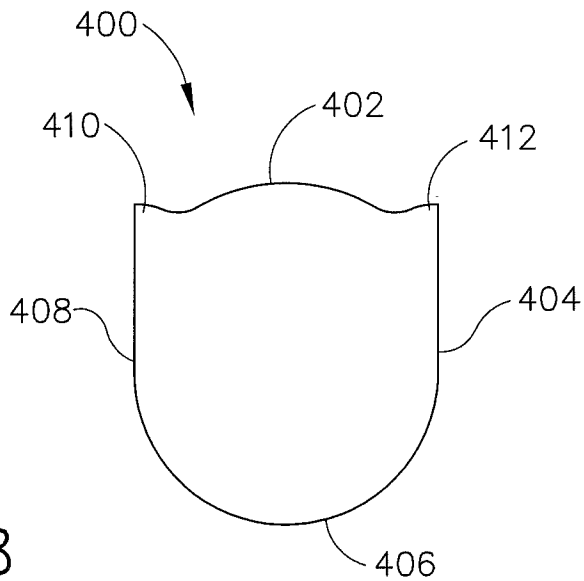

Fig.8

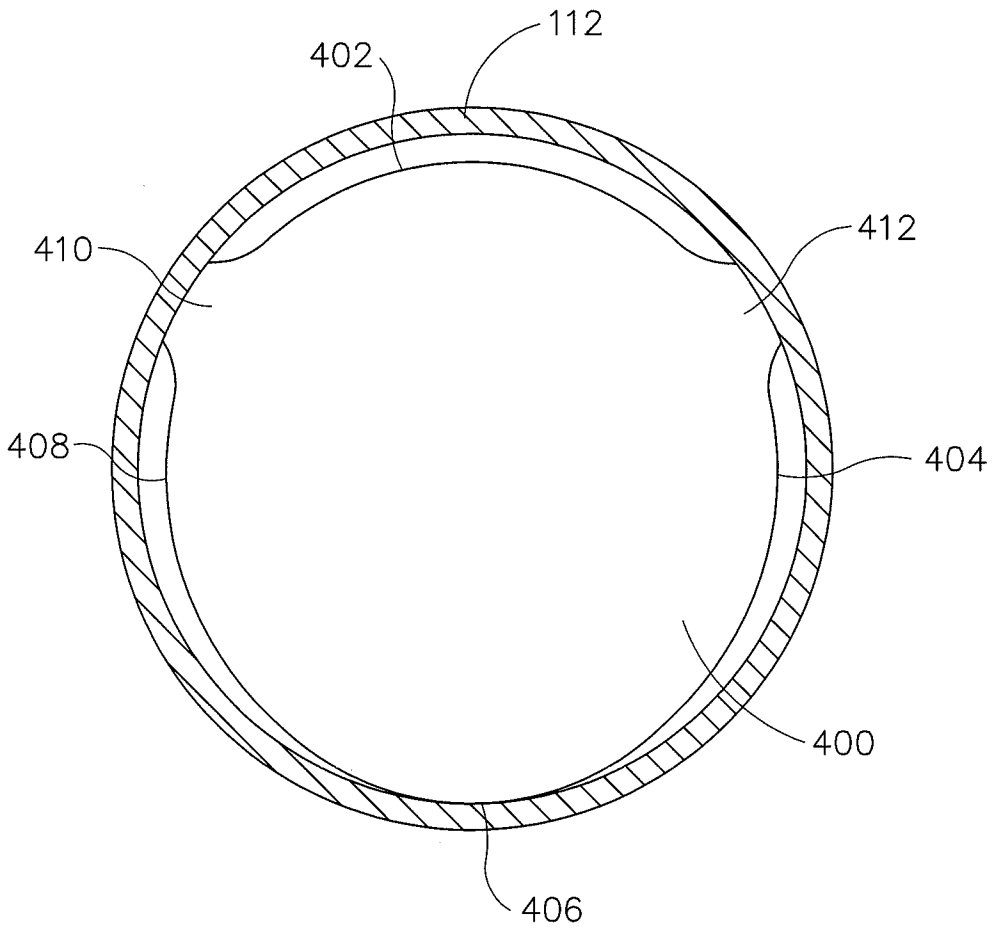

Fig.9

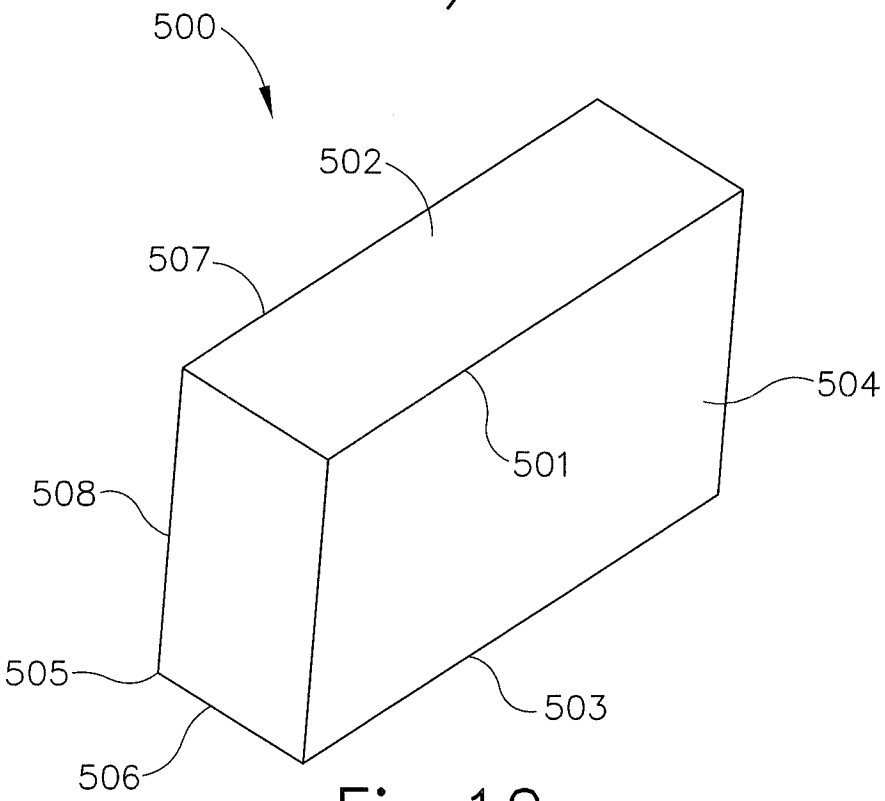
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Fig.10

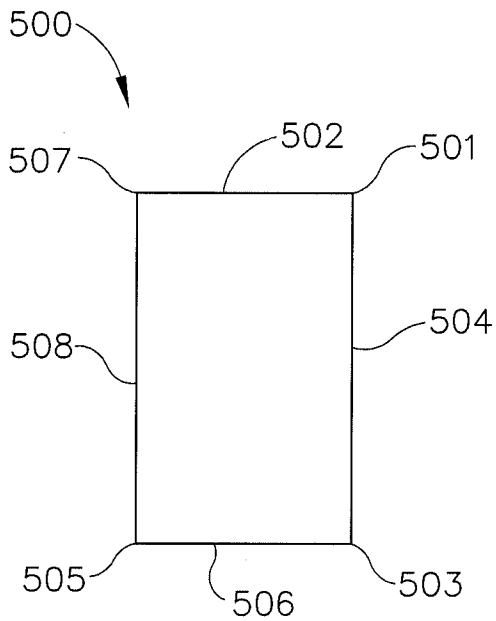
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Fig.11

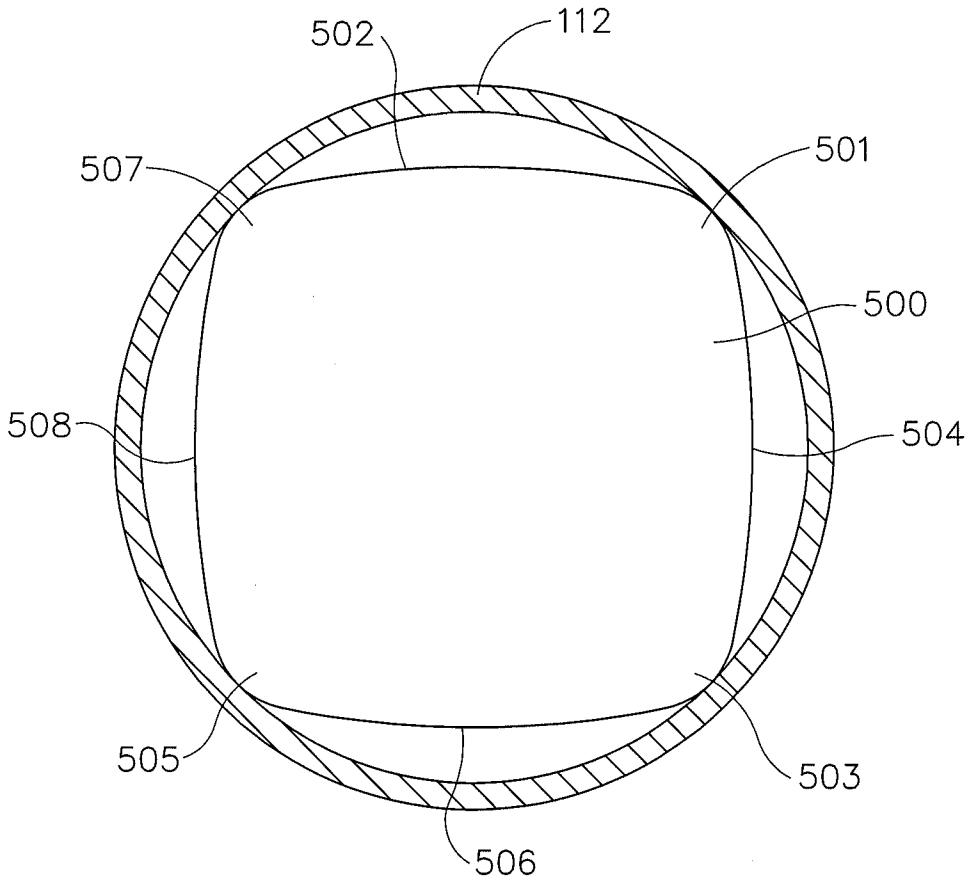

Fig.12

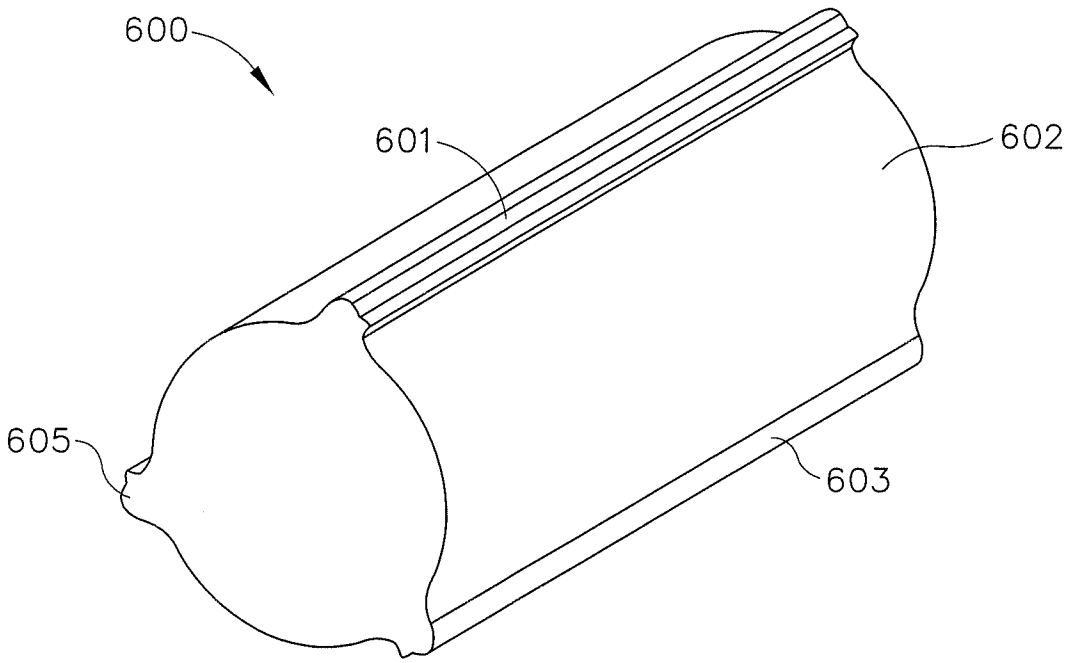

Fig.13

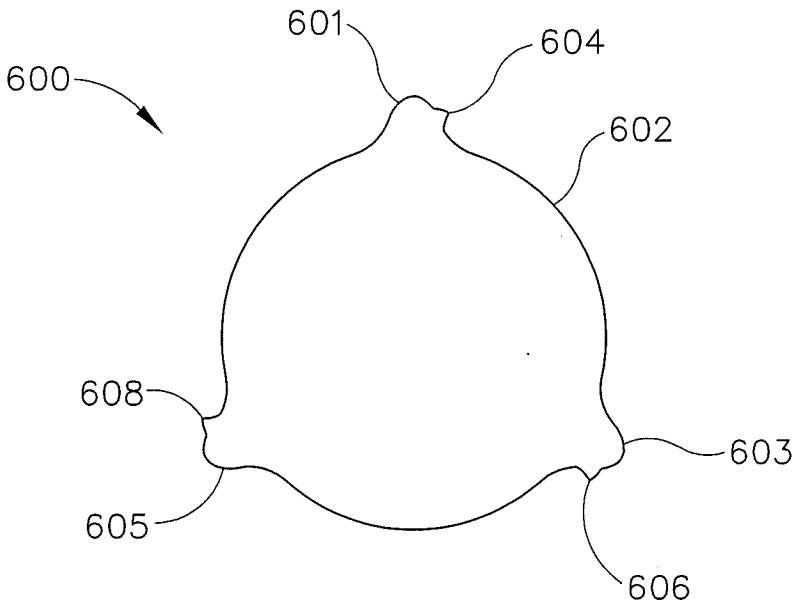

Fig.14

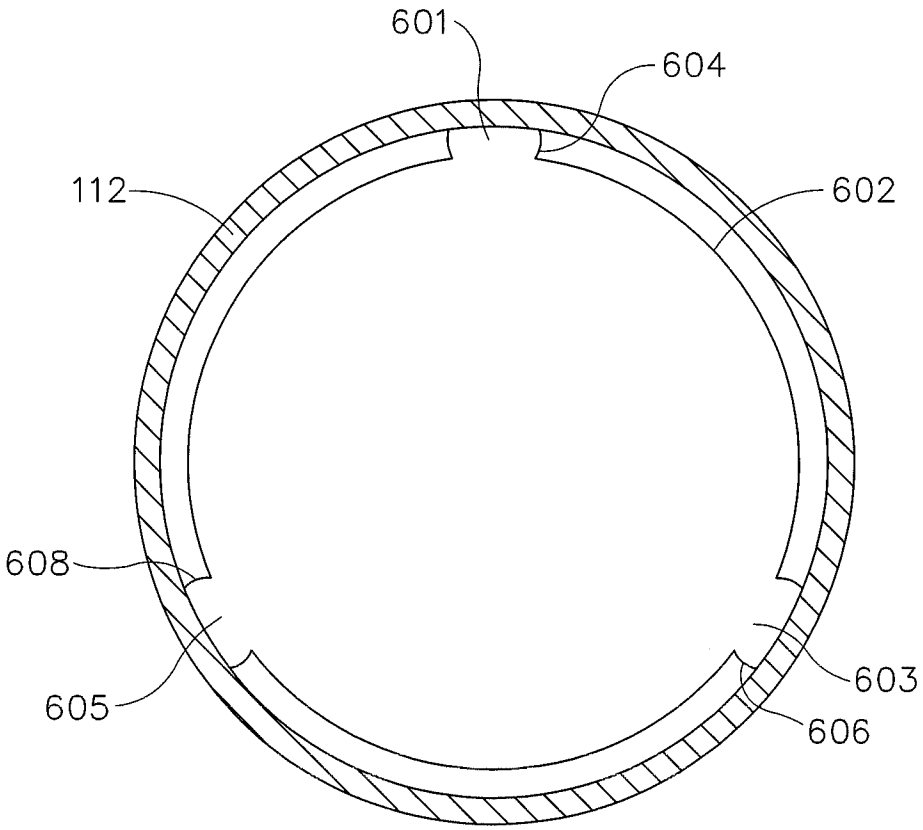

Fig.15