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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 June 2010 (10.06.2010)

PCT

(10) International Publication Number
WO 2010/065389 A2

(51) **International Patent Classification**:
A61B 17/34 (2006.01) ***A61M 5/00*** (2006.01)
A61B 17/32 (2006.01)

(21) **International Application Number**:
PCT/US2009/065633

(22) **International Filing Date**:
24 November 2009 (24.11.2009)

(25) **Filing Language**: English

(26) **Publication Language**: English

(30) **Priority Data**:
61/117,755 25 November 2008 (25.11.2008) US

(71) **Applicant** *(for all designated States except US)*: **EPITEK, INC.** [US/US]; 4801 West 81st Street, Suite 105, Bloomington, Minnesota 55437 (US).

(72) **Inventors; and**
(75) **Inventors/Applicants** *(for US only)*: **BARDSLEY, Earl** [US/US]; 39 Copley Street, Newton, Massachusetts 02458 (US). **MA, Jianlu** [CN/US]; 18431 Upper Westmont Avenue North, Maple Grove, Minnesota 55311 (US). **HUYNH, Anthony** [US/US]; 1328 Dunbar Way, Mahtomedi, Minnesota 55115 (US).

(74) **Agent**: **SCHUMANN, Michael D.**; Hamre, Schumann, Mueller & Larson, P.C., P.O. Box 2902, Minneapolis, Minnesota 55402 (US).

(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, 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, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (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, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

WO 2010/065389 A2

(54) **Title**: METHODS AND DEVICES FOR PERICARDIAL ACCESS

(57) **Abstract**: A device for accessing an anatomic target area surrounded by a wall includes an elongated body having a passage longitudinally extending therethrough. An arm extends from the distal end of the elongated body, and does not obstruct the passage of the elongated body. A tooth member is disposed on an outer surface of the arm. The tooth member includes a penetrating end configured to engage the wall surrounding the target anatomic area. When used for accessing the pericardial space, the elongated body particularly the side of the arm, can be positioned against the parietal pericardium. The penetrating end engages the parietal pericardium. Once engaged, a working space is created by lifting the parietal pericardium. Other devices then can be introduced through the passage of the elongated body and into the pericardial space to perform a variety of procedures inside a patient.

METHODS AND DEVICES FOR PERICARDIAL ACCESS

PRIORITY INFORMATION

This application is being filed as a PCT International Stage Patent Application in the name of EPITEK, INC. and claims the benefit of priority of US Provisional Patent Application number 61/117755, filed November 25, 2008 and entitled "METHODS AND DEVICES FOR PERICARDIAL ACCESS" which is hereby incorporated by referenced in its entirety.

FIELD

The present disclosure relates generally to medical devices and methods. More particularly, the present disclosure relates to methods and devices for accessing the pericardial space in a minimally invasive manner.

BACKGROUND

The human heart is enveloped within a tissue structure referred to as the pericardium. The pericardium includes two major portions. The portion of the pericardium which lies immediately over the surface of the heart is referred to as the visceral pericardium. The second portion is formed as a sac around the visceral pericardium and is referred to as the parietal pericardium. Normally, the visceral and parietal pericardia lie in close contact with each other and are separated only by a thin layer of pericardial fluid. The space (really more of a potential space) between the visceral and parietal pericardia is referred to as the pericardial space.

Access to the pericardial space can be necessary or beneficial under a variety of circumstances. Open surgical access can be obtained via open sternotomy where the patient's sternum is divided and the parietal pericardium exposed. Such an approach, however, is highly traumatic, requiring general anesthesia and useful only under compelling circumstances. Access to the pericardial space can also be achieved using a thoracoscopic approach. Under general anesthesia, the left lung is deflated after which multiple holes are made for the thoracoscope and various instruments. The pericardium is then entered using standard videoscopic techniques. The thoracoscopic approach typically requires the placement of a chest tube and admission to the hospital for the initial 1-2 post-operative days. In other approaches, the pericardial space can be approached from a skin incision made below the xiphoid through which the parietal pericardium is identified.

It would be desirable to provide additional and improved methods and devices for the minimally invasive access to a patient's pericardial space. The methods and devices should

be suitable for a wide variety of minimally invasive approaches to the pericardium, including at least intercostal/transthoracic and subxiphoid approaches, and the like. The methods and devices should further provide for secure and stable capture of the parietal pericardium and permit the opening of a large space or volume between the parietal and visceral pericardia. Such access methods and apparatus should be useful for a wide variety of procedures to be performed in the pericardial space, including fluid withdrawal, drug delivery, diagnostic and therapeutic electrophysiology procedures, pacemaker lead implantation, defibrillator lead placement, transmyocardial revascularization, transmyocardial revascularization with drug delivery, placement of the left ventricular assist devices, placement of the arterial bypass graphs, in situ bypass, i.e., coronary artery-venous fistulae, placement of drug delivery depots, closure of the left arterial appendage, and the like.

U.S. Patent No. 6,423,051 discusses that an anchor structure of an access tube engages and captures the outer surface of the parietal pericardium and draws the parietal pericardium away from the visceral pericardium to create an enlarged pericardial space. After such enlargement, a needle or other access device can be introduced through the access tube into the pericardial space to provide access for a wide variety of purposes, including aspiration, infusion and guidewire placement.

SUMMARY

The present disclosure relates to accessing a target anatomic space surrounded by a wall. Generally, devices and methods for accessing an anatomic target area surrounded by such a wall are described. Devices described herein include an elongated body having a passage longitudinally extending therethrough. An arm extends from the distal end of the elongated body, and does not obstruct the passage of the elongated body. A tooth member is disposed on an outer surface of the arm. The tooth member includes a penetrating end configured to engage the wall surrounding the target anatomic space.

The devices and methods herein can be used to access and enlarge a variety of anatomic spaces, including for example the pericardial space. In the example of accessing and enlarging the pericardial space, the elongated body particularly the side of the arm, can be positioned against the parietal pericardium. The penetrating end of the tooth member engages and can penetrate through the parietal pericardium. Once engaged, a working space is created by lifting the parietal pericardium.

Generally, the devices and methods described herein can be useful for introducing other devices through the passage of the elongated body and into the pericardial space to perform a variety of procedures inside a patient.

In some embodiments, a device includes two arms disposed at and extending from the distal end of the elongated body. The two arms are spaced apart so as not to obstruct the passage of the elongated body, and each arm has a tooth member such that the tooth members are arranged on a common side of the device. In one embodiment, the two arms are coaxially arranged and generally parallel to each other and the elongated body.

In one embodiment, the penetrating end of the tooth members and the outer surface of the arm have a space therebetween.

In some examples, each arm includes a plurality of tooth members. The tooth members can be arranged on a common side of their respective arm. The tooth members each have a penetrating end. In some examples, the penetrating ends face generally in the same direction away from the distal end of the elongated body.

Sometimes, each arm includes tooth members disposed on opposing sides, such that the tooth members on one of the opposing sides of one arm are arranged on a common side as the tooth members on one of the opposing sides of the other arm. Likewise, the tooth members on the other opposing side of the one arm are arranged on a common side as the tooth members on the other opposing side of the other arm.

A method for accessing the inside of the pericardial sac of a subject's heart includes first inserting an access device, such as described above, proximate the pericardial sac of a subject's heart. The pericardial sac is then engaged with the tooth member of the access device and along a longitudinal side of the arm. The tooth member is used to engage the pericardial sac by sliding the longitudinal side of the arm along the pericardial sac. The pericardial space is expanded by lifting the pericardial sac away from the heart. A needle is delivered through the passage of the elongated body, and the pericardial sac is punctured with the needle to gain access of the pericardial space.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A is a perspective view of an embodiment of a device for accessing an anatomical space.

Fig. 1B is a side view of the device of Fig. 1A.

Fig. 1C is a sectional view of the device of Fig. 1A.

Fig. 2 is a view of the device of Fig. 1A in use and schematically showing the device accessing a pericardial space.

Fig. 3A is a perspective view of the device of Fig. 1A shown with one embodiment of an introducer sheath.

Fig. 3B is another perspective view of the device of Fig. 1A shown with the introducer sheath of Fig. 3A.

Fig. 4 is a schematic view of one embodiment of a kit incorporating the device of Fig. 1A, the introducer sheath of Fig. 3A, another access device, and instructions for use.

Fig. 5 is a perspective view of another embodiment of a device for accessing an anatomical space.

Fig. 6B is a side view of another embodiment of a device for accessing an anatomical space.

Fig. 6A is a side view of the device of Fig. 6A showing a close-up view of the arm.

DETAILED DESCRIPTION

The present disclosure relates to devices, systems, kits and methods for accessing an anatomic space surrounded by a wall and for creating a working space to perform a variety of procedures inside the working space. The wall may include a membrane, a capsule or the adventia, muscularis and endothelial layers of a hollow organ or vessel. The devices, systems, kits and methods are particularly useful for minimally invasive access procedures, but could also be used for accessing internal anatomic spaces where initial access to the wall of the outer surfaces is achieved via open surgical or other techniques. In one example, the disclosed devices and methods can be particularly useful for accessing a patient's pericardial space for performing a wide variety of procedures.

The phrase "anatomic space" is meant to include any natural, potential, or created space or cavity within a patient's body where it may be desirable to gain access for surgical, diagnostic, therapeutic, or any other purpose. In some embodiments, the anatomic space is within an organ or structure located beneath the patient's skin, such as the pericardial space which lies between the visceral and parietal pericardia, both of which lie beneath the chest wall and rib cage. Other internal organs which may be accessed include but are not limited to the intestines, fallopian tubes, gall bladder, kidneys, and the like.

Figs. 1A-C show an embodiment of a device 10 for accessing an anatomic space surrounded by a wall. Generally, the device 10 includes an elongated body 12 and a passage 14 that extends longitudinally through the elongated body 12 from a proximate end 22 to a

distal end 24. The device 10 further includes at least one arm 20 with at least one tooth member 18 thereon. The arm 20 is disposed at the distal end 24 of the elongated body 12. The arm 20 extends from the distal end 24 and does not obstruct the passage 14 of the elongated body 12. The at least one tooth member 18 is disposed on an outer surface of the arm 20. The tooth member 18 has a penetrating end configured to engage the wall surrounding a desired anatomic space. As shown in this embodiment, the penetrating end faces away from the distal end 24 of the elongated body 12.

As shown in the embodiment of Figs. 1A-C, the device 10 includes two arms 20. That is, in some examples the device 10 includes two arms 20 disposed at and extending from the distal end 24 of the elongated body 12. As shown, the two arms 20 are spaced apart so as not to obstruct the passage 14 of the elongated body 12. Each arm 20 has a tooth member 18, such that the tooth members 18 are arranged on a common side of the device 10. In one preferred embodiment, the two arms 20 as shown are coaxially arranged and are generally parallel to each other and with the elongated body 12. It will be appreciated that the device 10 is not limited to two arms, as one arm may be employed.

More specifically, each arm 20 can include a plurality of tooth members 18 disposed on an outer surface of each arm 20. As shown in Figs. 1A-C, the tooth members 18 are arranged on a common side of the respective arm 20, and each has a penetrating end. As shown in this embodiment, the penetrating ends face generally in the same direction away from the distal end 24 of the elongated body 12. It will be appreciated that the penetrating ends in some examples may face toward the distal end of the elongated body 12, and in other examples may face in both directions, that is both toward and away from the distal end of the elongated body 12. It also will be appreciated that the number of tooth members is not meant to be limiting so long as there is a sufficient number of tooth members to engage a respective wall that surrounds the anatomic space where access is desired. That is, one or more tooth members can be sufficient.

As shown, each arm 20 includes tooth members 18 disposed on opposing sides, where the tooth members 18 on one of the opposing sides of one arm 20 are arranged on a common side as the tooth members 18 on one of the opposing sides of the other arm 20. Likewise, the tooth members 18 on the other opposing side of the one arm 20 are arranged on a common side as the tooth members on the other opposing side of the other arm 20.

With further reference to the elongated body 12, the elongated body 12 can be relatively flexible. Generally, the elongated body 12 is configured as an access tube with the central passage 14. The elongated body 12 may have a wide variety of specific structures and

configurations, but generally comprises a tubular or cylindrical body having the proximal end 22 and the distal end 24. The elongated body 12 can have a wide variety lengths and diameters and be constructed in various configurations and of various materials. In some embodiments, the elongated body 12 has a length in the range from 10 cm to 30 cm, more usually from 18 cm to 24 cm, and a relatively narrow maximum width, in some cases, having a diameter in the range from 3 mm to 20 mm, and sometimes from 4 mm to 10 mm. The elongated body 12 can be made of a variety of materials, for example, Pebax®, polypropylene, polyethylene, Nylon, stainless steel, Nitinol, titanium, Co-Cr based alloys, or the like.

The elongated body 12 in some embodiments may also be curved (not shown) longitudinally from the proximate end 22 to the distal end 24. Such a curvature can be helpful for navigation and positioning of the device 10 during use, for example, accessing the pericardial space.

With reference to the passage 14, the passage 14 is generally configured as a central passage through the elongated body 12, so that another access device for performing treatment in an anatomic space can easily pass through the elongated body 12. Examples of other access devices can include those described in U.S. Patent No. 6,423,051 and U.S. Application Serial No. 12/118,915 filed May 12, 2008, both of which are herewith incorporated by reference in their entirety. Such examples of other access devices can include a needle or other tools that are intended to be used within the anatomical space (e.g. pericardial space). In some embodiments, the passage 14 generally has the same length as that of the elongated body 12, and in some cases has a diameter in the range from 1 mm to 6 mm, and sometimes in the range from 1.5 mm to 4 mm.

With further reference to the arms, Figs. 1A-C show the arms having a distal end that can be configured and constructed with a rounded portion. The rounded portion can help prevent or at least minimize tissue damage and unnecessary trauma that might be encountered with more rigid, sharp ends. It will be appreciated that the distal end may be other shapes than rounded, as long as the distal end can help prevent or at least minimize tissue damage and unnecessary trauma when the device is used.

As with the elongated body 12, the arms 20 may also be longitudinally curved from the distal end 24 of the elongated body to the distal end of the arms 20 (e.g. to distal end with the rounded portion; see e.g. device 200 of Figs. 6A-6B).

With reference to the penetrating ends of the tooth members 18, spaces 16 are between the outer surface of the arm 20 and each tooth member 18, so as to assist with

engaging the wall of surrounding an anatomic space where access is desired (e.g. pericardial space inside the pericardial sac). The penetrating ends are configured with a relatively sharp point or edge that can allow the tooth member 18 to engage, or otherwise grab the desired or target tissue wall. It will be appreciated that each tooth member 18 is constructed and arranged to at least suitably engage an outer surface of a wall of an anatomic space. In some cases, the penetrating ends of the tooth members can penetrate through the wall that surrounds the target anatomic space.

With reference to the device 10 in operation, methods for accessing the inside of an anatomical space surrounded by a wall can be achieved. In one embodiment, accessing the pericardial space inside the pericardial sac is desired to perform various procedures on the heart. Fig. 2 shows one example of such a method. The device 10 as described herein is inserted proximate the pericardial sac PS of a subject's heart. The pericardial sac PS is then engaged with the tooth member(s) 18 of the device 10. Engagement with the pericardial sac is accomplished by sliding (see arrow A in Fig. 2) the arm 20 of the device 10 along the pericardial sac PS, such that the tooth member(s) 18 can penetrate the pericardial sac PS. Under such an approach, pericardial sac PS is engaged by the arm 20 along the side of the device 10, such as tangentially to the pericardial sac PS. The space within the pericardial sac PS can then be expanded. In one example, the space can be expanded by lifting or drawing at least the arms 20 of the device 10 away from the pericardium (see arrow B of Fig. 2).

With further reference to engagement of the pericardial sac PS, once the penetrating ends of the tooth member(s) engage the pericardial sac PS, the arms 20 can be rotated to further secure the engagement, such as before lifting or drawing the arms 20 away from the pericardium (see arrow C of Fig. 2). Thus, once the pericardial sac is engaged, the device 10 is able to draw the parietal pericardium away from the visceral pericardium to create an enlarged pericardial space.

As described above, once the pericardial sac has been engaged and the pericardial space is expanded; another access tool can be delivered through the passage 14 of the elongated body 12. One example of another access tool is using a needle to puncture the pericardial sac PS to gain access into the pericardial space. When the penetrating ends of the tooth members 18 have engaged and captured the tissue, the access device can pass through the region of tissue that is being held and stabilized by the tooth members. The access device enters into the interior volume of the anatomic space, and can be used to perform a treatment in the working space created by the device 10.

In operation, the other access device(s) can be passed through the passage 14 of the elongated body 12 so that it may extend out at the distal end 24 of the elongated body 12. Generally, the other access device(s) is configured and arranged to be introduced through the passage 14 of the elongated body 12 and through a target region of the wall of the anatomic space.

With further reference to the other access device(s) that can be introduced through the passage 14, such suitable access devices can include but are not limited to a needle, stylet, or other elongate structure having a sharpened distal tip for passage through the tissue of the wall of the anatomic space.

In some embodiments, the access device is in the form of a hollow needle or stylet having a sharpened distal end. That is, in some examples the access device that may be used can also have a passage to permit introduction of a guidewire, infusion or aspiration of fluids, placement of leads or other implantable devices, or the like. Placement of a guidewire within the anatomic space may further provide for introduction of a wide variety of other diagnostic and therapeutic catheters and devices. The access device can be longer than the elongated body 12 so that it may be passed therethrough. In some cases, the access device has a length in the range from 12 cm to 35 cm, more usually from 20 cm to 26 cm. The maximum width or diameter of the access device may vary, so long as the access device can be introduced through the elongated body 12. In some examples, the diameter of the access device may be in the range from 1mm to 6.0 mm, preferably from 1.5 mm to 4 mm.

It will be appreciated that such needles, stylets, or other elongate structure having a sharpened distal tip for passage through the tissue of the wall of the anatomic space are well known and are available commercially, for example as off the shelf products. Further, such access devices are shown and described in U.S. Patent No. 6,423,051, and U.S. Application No. 12/118,915 filed May 12, 2008, both of which are herewith incorporated by reference in their entirety. It also will be appreciated that the access devices shown and discussed are merely exemplary, and that various access devices can be accommodated through the passage 14 of the elongated body 12, and for use to perform various procedures inside a body of a patient.

A system for accessing an anatomic space can include the device 10 and another access device such as described herein. It will be appreciated that the construction of such a system could be varied in a number of ways for a variety of purposes. For example, the tubular structures of the elongated body and/or the access device could be non-linear, telescoping, perforated, or many other configurations. Additional features, such as additional

passages, imaging capabilities, pneumostatic valves, and the like, could also be added within the scope of the present disclosure.

Sometimes, a sheath can be employed for introducing the device 10. For example, Figs. 3A-B show a sheath 11 that can be sized and configured to house the device 10. The size of the sheath 11 relative to the device 10 is not meant to be limiting, so long as the sheath 11 can cover the device 10 and allow the device to slide within the sheath 11. As shown, the sheath 11 can include a plurality of flexible portions 13 formed on a distal end 15. In one embodiment, the flexible portions 13 are flexible petals. In one embodiment, the distal end 15 of the sheath 11 is tapered so that the distal end can be easily navigated and placed proximate the targeted anatomic space (see e.g. Fig. 3A). The flexible portions 13 are designed to flex or bend outward to provide an opening through which the device 10 can be exposed from the distal end 15 of sheath 11 at the appropriate time (see e.g. Fig. 3B). When the distal end 15 of sheath 11 is placed proximate to the anatomic space, the sheath can be withdrawn. When the sheath 11 is withdrawn, the distal end of the arms 20 of the device 10 will contact the flexible portions 13. As the sheath 11 is further withdrawn or pulled back, the arms 20 can bend or move the flexible portions 13 outward, so that the arms and tooth members are exposed through the opening formed when the flexible portions 13 are moved out of the way. When the device 10 is in position, the sheath 11 can be removed.

In the example of accessing the pericardial space, the device 10 can be introduced by the sheath 11 as described in Figs. 3A-B over the surface of the parietal pericardium PP, for instance via a subxiphoid approach. After reaching the parietal pericardial surface, the sheath 11 can be withdrawn and removed, so that the device 10 is exposed and can then be used to engage the pericardial sac and expand the pericardial space.

Such sheaths are also described for example in U.S. Patent No. 6,423,051 and U.S. application serial no. 12/118,915 filed on May 12, 2008, both of which are herewith incorporated by reference in their entirety. It will be appreciated that the above examples may be modified as desired, suitable, and/or necessary.

As described, once the working space is created by the device 10, another access device may be introduced through the passage 14 of the elongated body 12, and into the working space created. The additional access device can then perform a wide variety of tasks and protocols. Such tasks and protocols can include but are not limited to infusion or aspiration of fluids, drug and/or contrast media delivery, diagnostic and therapeutic electrophysiology procedures, pacemaker lead implantation, defibrillator lead placement, transmysocardial revascularization, transmysocardial revascularization with drug delivery,

placement of left ventricular assist devices, placement of arterial bypass graphs, in situ bypass, i.e., coronary artery-venous fistulae, placement of drug delivery depots, closure of the left atrial appendage, or the like.

In a further embodiment, the device 10 as described may be packaged into a kit for accessing a pericardial space between a visceral pericardium and a parietal pericardium. Referring to Fig. 4, a kit 70 in accordance with the inventive principles herein comprises at least one device 10 and instructions for use (IFU) setting forth a method according to the present disclosure for accessing an anatomic space. Optionally, the kit 70 may further include at least one access device 30 (e.g. needle), at least one sheath 11, as well as packaging 50, for example in the form of a box, pouch, tray, tube, or the like. The kit 70 could further include a guidewire and other components or instruments as known in the art and that may be useful for positioning the device 10 and access device in performing the access methods. Instructions for use (IFU) can be printed on a separate sheet of paper in the form of a package insert, but could also be printed partly or wholly on the packaging itself. It will be appreciated that any of the device 10, access device 30, etc, may be disposed after use.

As described, the device and methods herein can be particularly useful for accessing the pericardial space or other bodily cavities. The device 10 generally can be used to create a 'tent' from the pericardial sac so that a needle or other access device(s) with a tip can be used to puncture the pericardial sac and obtain access inside the pericardial sac. Other devices, tools, and assemblies, such as a guidewire, sheath or guide catheters can be inserted in the pericardial sac through the access site, created by the device and methods described herein. The devices and methods described herein can provide ease of operation without direct visualization and provide a less traumatic alternative when contacting internal bodily structures. By employing the devices and methods described a more simplified procedure and operation to access an anatomic space can be achieved.

With reference to Fig. 5, another embodiment of a device 100 for accessing an anatomic space surrounded by a wall is described. As with device 10, the device 100 generally includes an elongated body 102 and a passage 104 that extends longitudinally through the elongated body 102 from a proximate end 122 to a distal end 124. The device 100 further includes at least one arm 112 with at least one tooth member 118 thereon. As with device 10, the device 100 includes spaces 116 between the tooth members 118 and the outer surface of the arms, and the distal end 120 of the arms 112 can include a rounded portion to help prevent or at least minimize tissue damage and unnecessary trauma. Each

tooth member 118 has a penetrating end configured to engage the wall surrounding a desired anatomic space.

Device 100 has substantially the same structure as device 10, except that the penetrating ends of the tooth members face in both directions (e.g. facing both toward and away from the distal end 124 of the elongated body 102). In operation, the arms 112 can be moved forwardly (in the direction away from the elongated body 102) and/or backwardly (in the direction toward the elongated body 102). See arrow D pointing in two directions. The penetrating ends facing both directions can provide additional flexibility when engaging the wall surrounding the target anatomic space.

As described above, the arms of the device can be longitudinally curved from the distal end of the elongated body to the distal end of the arms (e.g. to distal end with the rounded portion). With reference to Figs 6A and 6B, another embodiment of a device 200 for accessing an anatomic space surrounded by a wall is described. As with the devices above, the device 200 generally includes an elongated body 202 and a passage 204 that extends longitudinally through the elongated body 202 from a proximate end 222 to a distal end 224. The device 200 further includes at least one arm 212 with at least one tooth member 218 thereon. As with devices described above, the device 200 includes spaces 216 between the tooth members 218 and the outer surface of the arms 212, and the distal end 220 of the arms 212 can include a rounded portion to help prevent or at least minimize tissue damage and unnecessary trauma. Each tooth member 218 has a penetrating end configured to engage the wall surrounding a desired anatomic space.

Device 200 has substantially the same structure as device 100, except that the arms 212 are longitudinally curved from the distal end of the elongated body to the distal end of the arms (e.g. to distal end with the rounded portion). The arms can be pre-curved to provide ease of navigation, such as over the pericardium of the heart.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

CLAIMS

What is claimed is:

1. A device for accessing a target anatomic area surrounded by a wall comprising:

an elongated body having a proximate end, a distal end, and a passage longitudinally extending through the elongated body from the proximate end to the distal end;

at least one arm disposed at the distal end of the elongated body, the arm extending from the distal end and does not obstruct the passage of the elongated body; and

at least one tooth member disposed on an outer surface of the arm, the tooth member having a penetrating end configured to engage the wall surrounding the target anatomic area.

2. The device of claim 1, wherein the elongated body is flexible.

3. The device of claim 1, wherein the elongated body is curved.

4. The device of claim 1, wherein the at least one arm includes two arms disposed at and extending from the distal end of the elongated body, the two arms are spaced apart so as not to obstruct the passage of the elongated body, each arm having a tooth member such that the tooth members are arranged on a common side of the device.

5. The device of claim 4, wherein the two arms are coaxially arranged and generally parallel with the elongated body.

6. The device of claim 4, wherein each arm includes a plurality of tooth members disposed on each arm, such that the tooth members are arranged on a common side of the respective arm, the tooth members each having a penetrating end.

7. The device of claim 4, wherein each arm includes tooth members disposed on opposing sides, the tooth members on one of the opposing sides of one arm are arranged on a common side as the tooth members on one of the opposing sides of the other arm, and the tooth members on the other opposing side of the one arm are arranged on a common side as the tooth members on the other opposing side of the other arm.

8. The device of claim 1, wherein the at least one arm having a distal end, the distal end having a portion configured to prevent or at least minimize tissue damage.

9. The device of claim 1, wherein the arm is curved from the distal end of the elongated body to a distal end.

10. The device of claim 1, wherein the penetrating end of the at least one tooth member and the outer surface of the at least one arm have a space therebetween.

11. A method for accessing the inside of the pericardial sac of a subject's heart comprising:

inserting an access device proximate the pericardial sac of a subject's heart, the access device including an elongated body having a passage longitudinally extending through the elongated body from a proximate end to a distal end, at least one arm disposed at and extending from the distal end of the elongated body, such that the arm does not obstruct the passage of the elongated body; and at least one tooth member disposed on an outer surface of the arm, the tooth member having a penetrating end configured to engage the pericardial sac;

engaging the pericardial sac with the tooth member of the access device and along a longitudinal side of the arm, by sliding the arm along the pericardial sac;

expanding a space within the pericardial sac;

delivering a needle through the passage of the elongated body; and

puncturing the pericardial sac with the needle to gain access of the space.

Fig. 1A

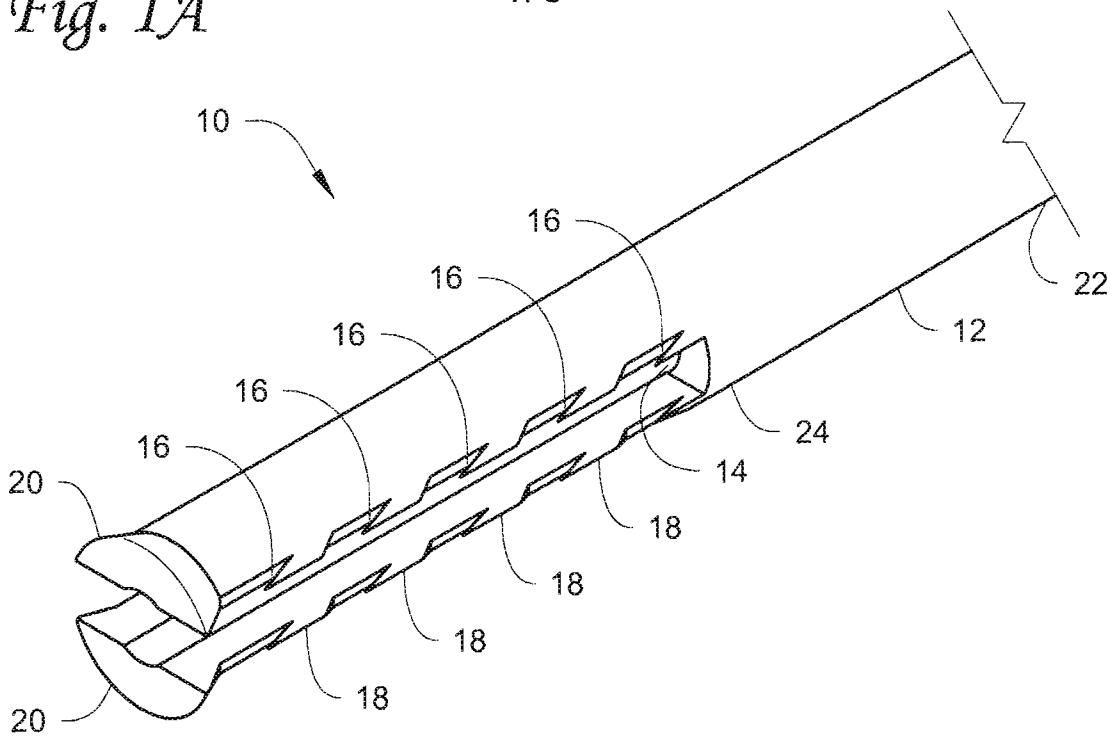


Fig. 1B

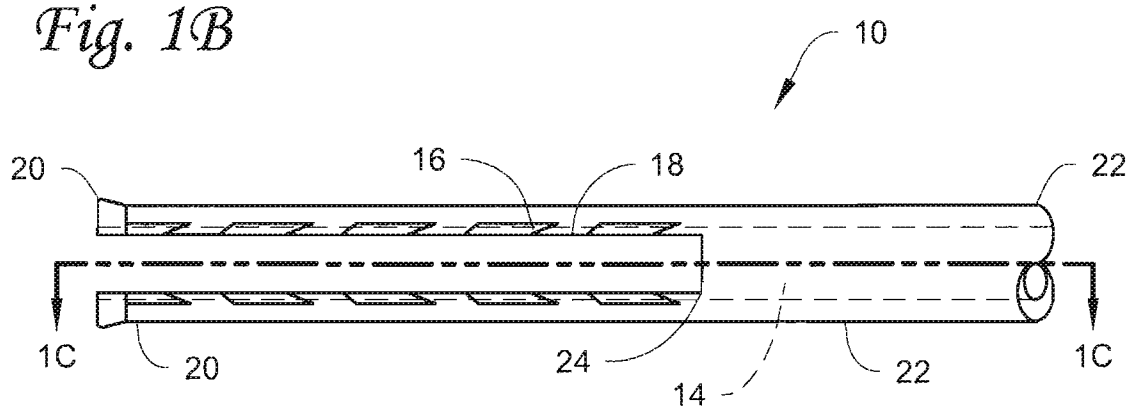


Fig. 1C

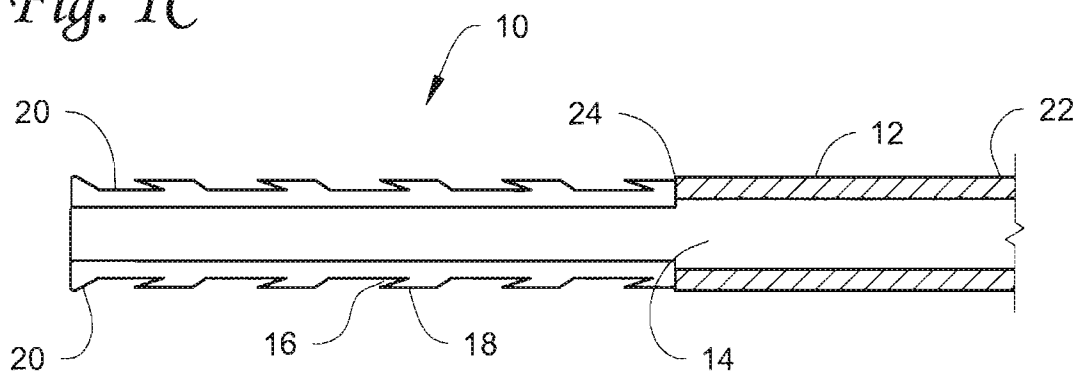
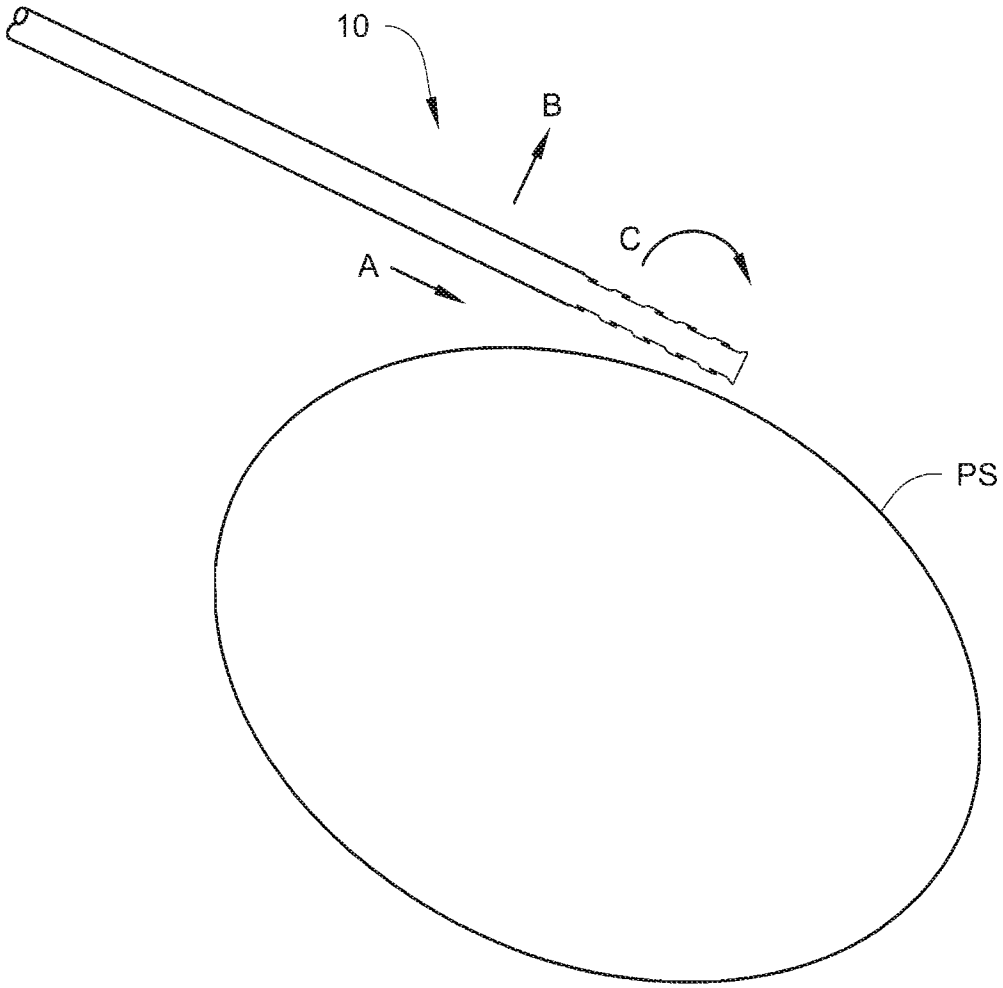


Fig. 2



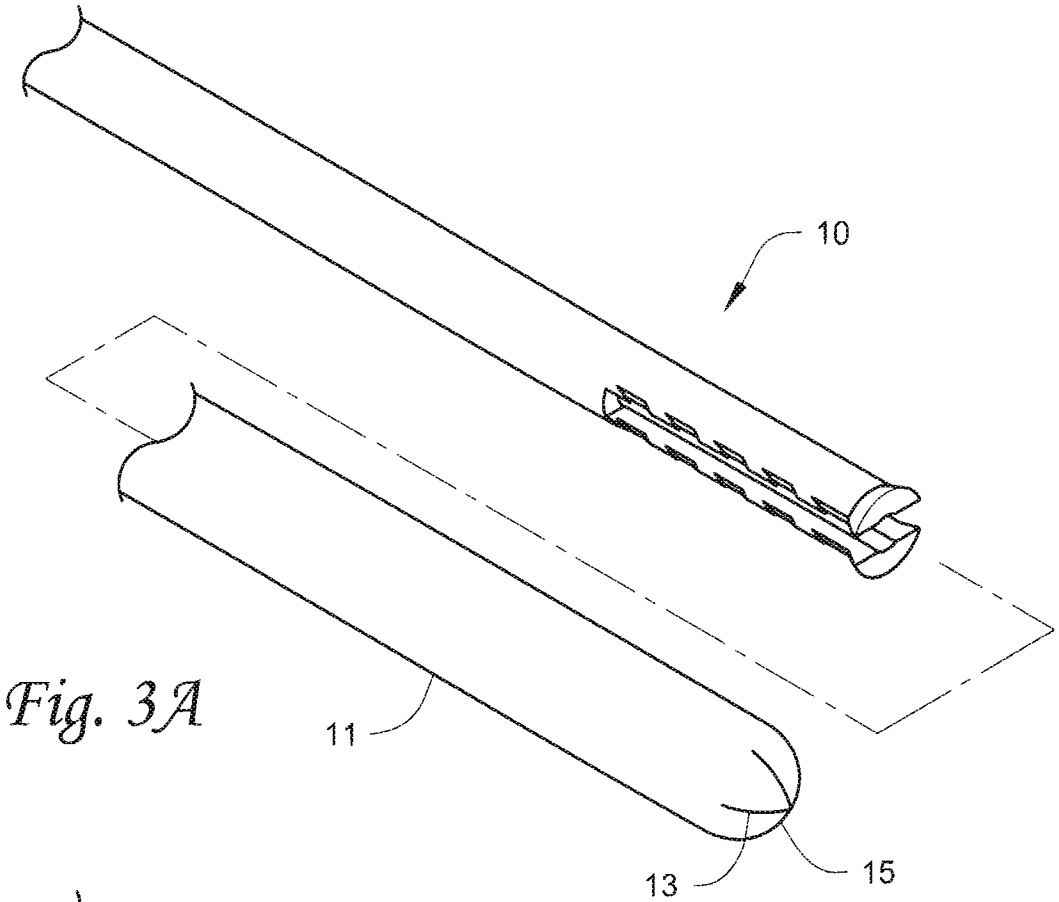


Fig. 3A

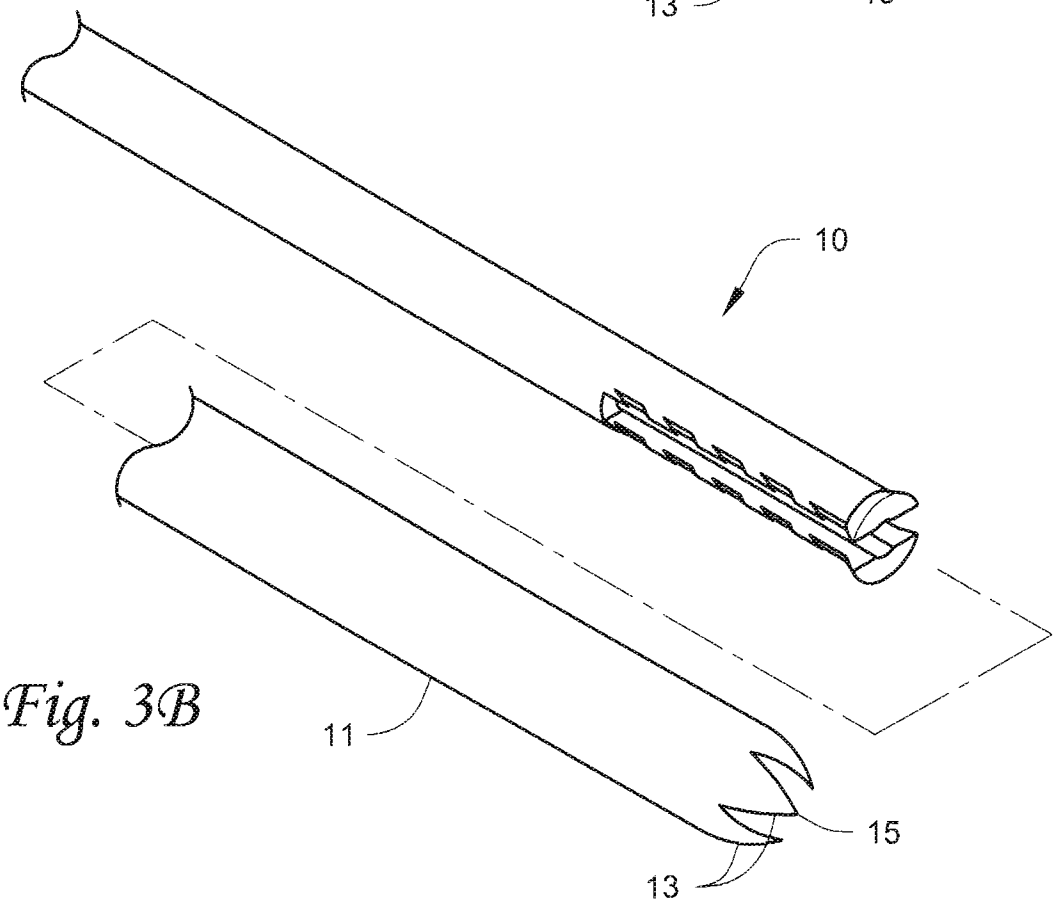


Fig. 3B

Fig. 4

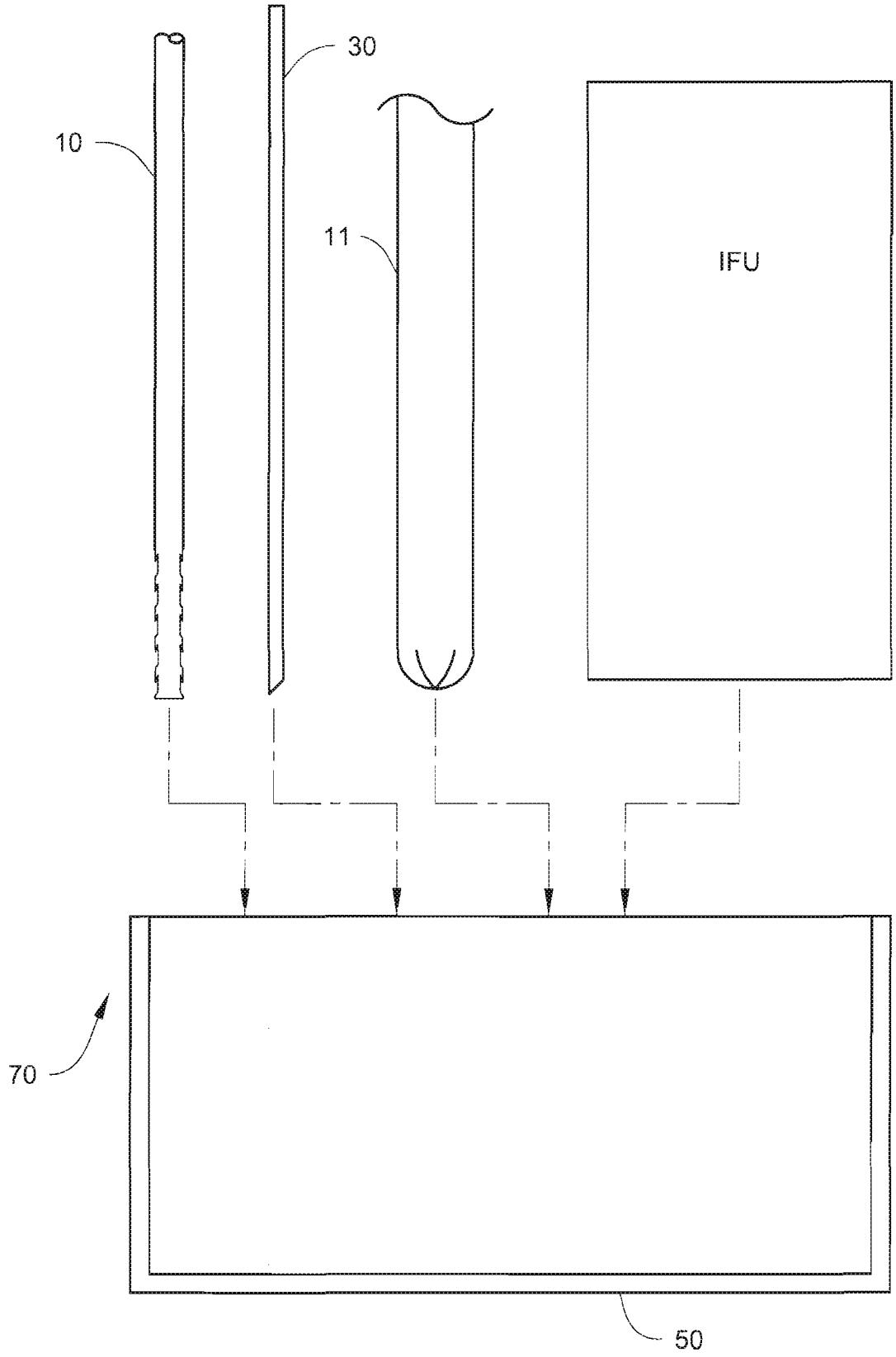
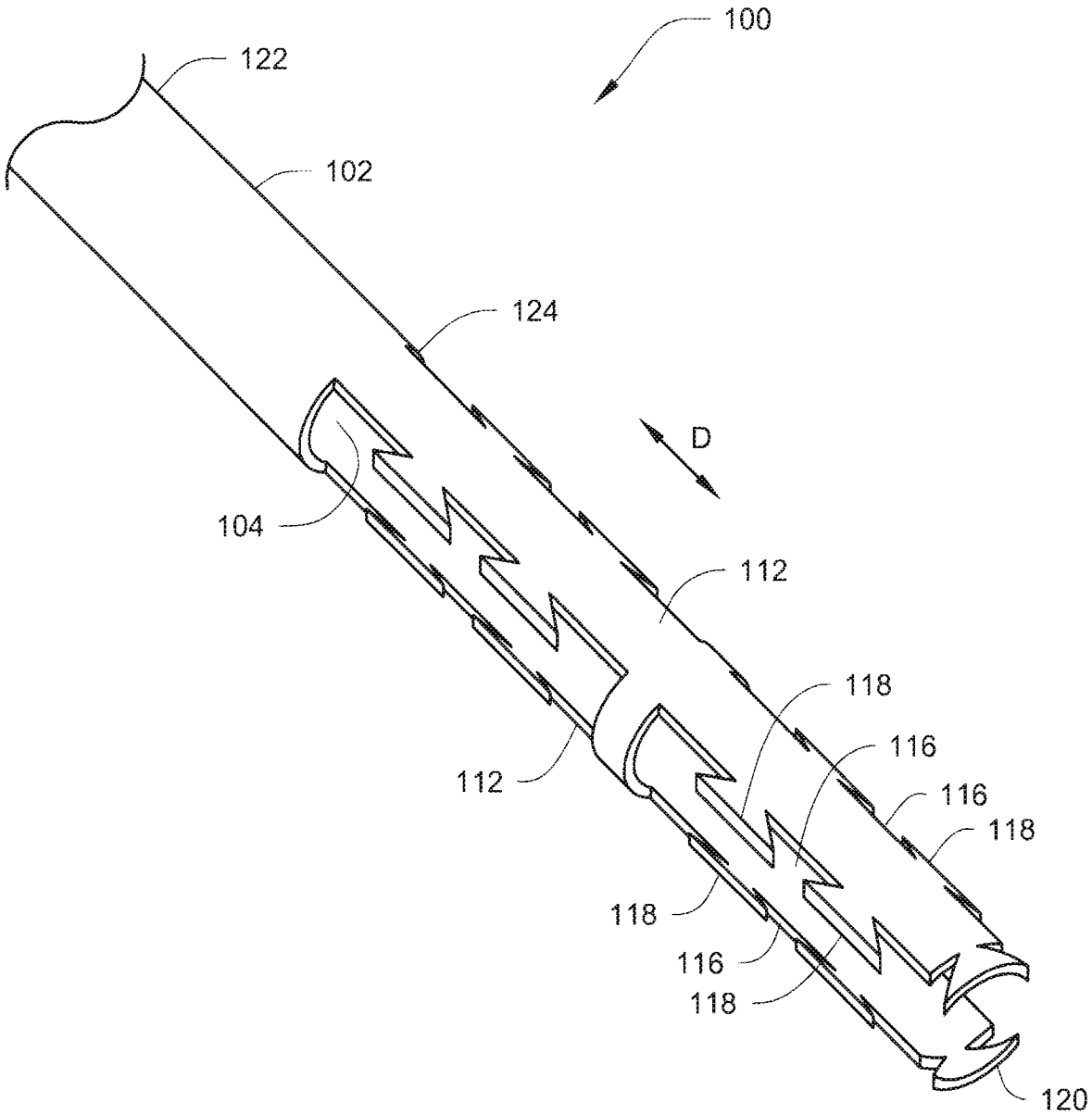


Fig. 5



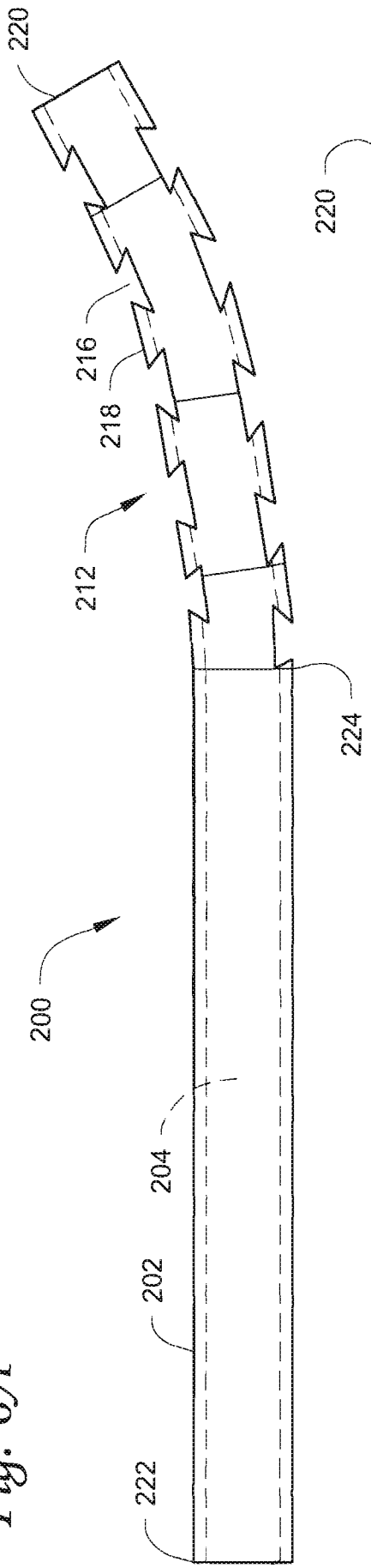


Fig. 6A

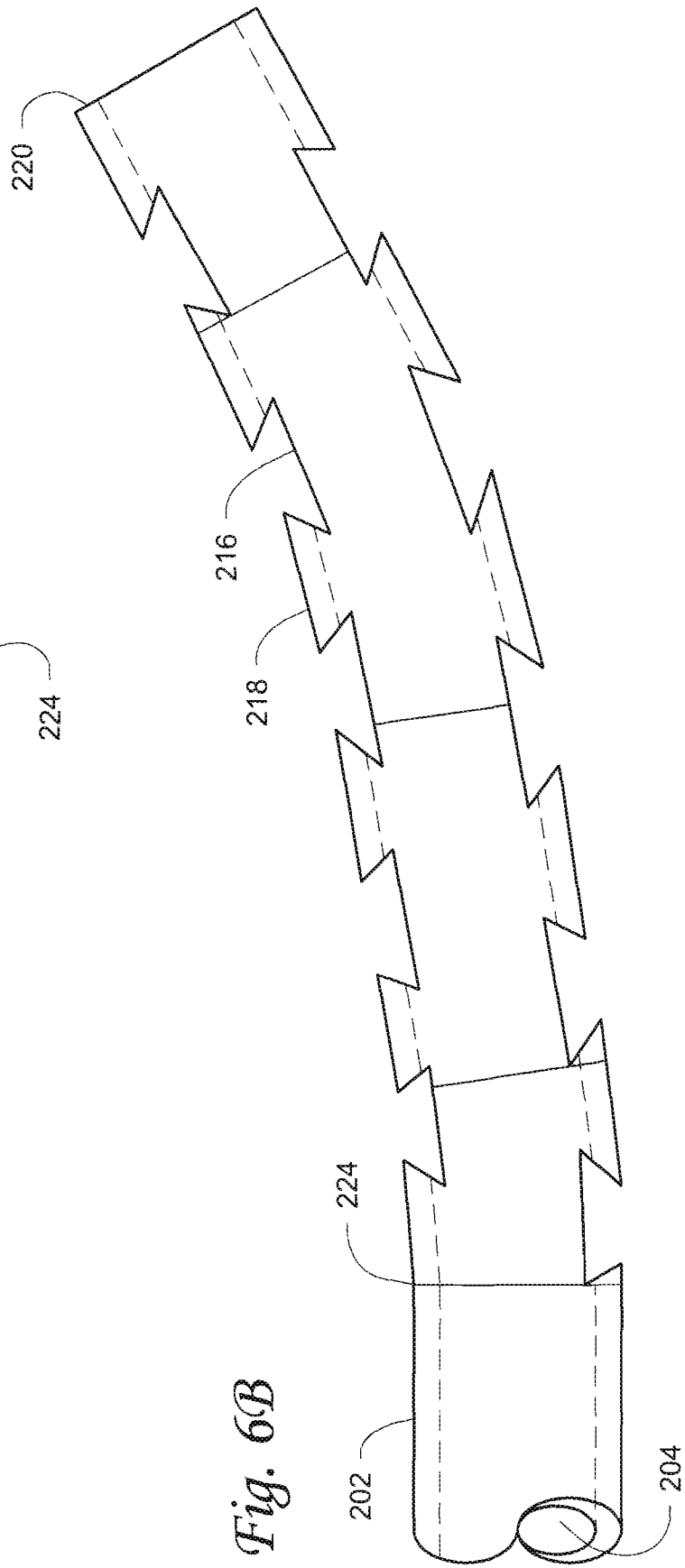


Fig. 6B