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(71) Applicant: **DEVICOR MEDICAL PRODUCTS, INC.** [US/US]; 300 E-Business Way, Fifth Floor, Cincinnati, Ohio 45241 (US).

(72) Inventor: **TANGHAL, Emmanuel**; 3617 Slazenger Ct., Mason, Ohio 45040 (US).

(74) Agents: **CHESSER, Wilburn L.** et al.; Arent Fox, LLP, 1717 K Street, N.W., Washington, District of Columbia 20006-5344 (US).

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(54) Title: MARKER DELIVERY DEVICE AND METHOD OF DEPLOYING A MARKER

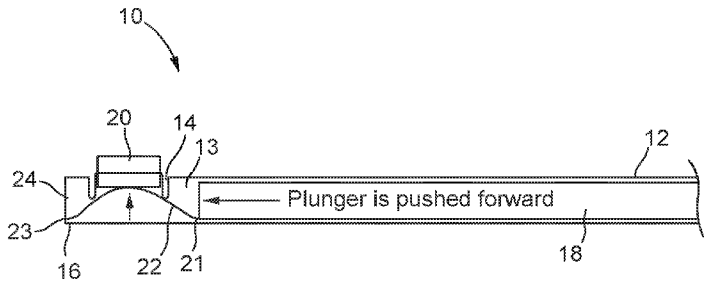

Fig. 5

(57) Abstract: A marker delivery device is described and claims. The marker delivery device is used to implant a detectable marker after a biopsy procedure is performed. The marker delivery device includes a cannula comprising a distal end and a marker exit positioned proximate the distal end; a rod extending within the cannula; and a flexible deployer operatively coupled with the rod and positioned proximate the marker exit.

MARKER DELIVERY DEVICE AND METHOD OF DEPLOYING A MARKER

RELATED APPLICATION

[0001] The present Application for Patent claims priority to U.S. Provisional Application No. 62/254,018 entitled "MARKER DELIVERY DEVICE AND METHOD OF DEPLOYING A MARKER" filed November 11, 2015, which is assigned to the assignee hereof, and incorporated herein by reference in its entirety.

Field of the Invention

[0002] The present invention relates generally to marker delivery devices and methods of deploying a marker.

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, MRI guidance, PEM guidance, BSGI guidance, or otherwise.

[0004] Example 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. Pat. No. 6,626,849, entitled "MRI Compatible Surgical Biopsy Device," issued Sept. 30, 2003; U.S. Pat. No. 7,442,171, entitled "Remote Thumbwheel for a Surgical Biopsy Device," issued Oct. 28, 2008; 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. Pat. No. 9,095,326, entitled "Biopsy System with Vacuum Control Module," issued August 4,

2015; U.S. Pat. No. 8,251,916, entitled "Revolving Tissue Sample Holder for Biopsy Device," issued Aug. 28, 2012; and U.S. Pat. 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.

[0005] 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®, CORMARK™, HYDROMARK®, and MAMMOSTAR™ 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. 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; U.S. Pat. No. 6,371,904, entitled "Subcutaneous Cavity Marking Device and Method," issued Apr. 16, 2002, U.S. Pub. No. 2014/0276037, entitled "Biopsy Site Marker Applier," published Sept. 18, 2004; U.S. Pub. No. 2013/0237912, entitled "Biopsy Marker Delivery Device," published Sept. 12, 2013; U.S. Pat. No. 8,371,443, entitled "Biopsy Marker Delivery Device," issued Sept. 10, 2013; U.S. Pat. No. 8,241,299, entitled "Biopsy Marker Delivery Configured to Retain Marker Prior to Intended Deployment," issued Aug. 14, 2012; U.S. Pat. No. 8,068,895, entitled "Biopsy Site Marker Deployment Instrument," issued Nov. 14, 2011; and U.S. Pat. No. 8,414,602, entitled "Biopsy Device and Methods,"

issued Apr. 9, 2013. The disclosure of each of the above-cited U.S. Patents and U.S. Patent Application Publications is incorporated by reference herein.

[0006] However, when operating some of the above-described marker deployment devices, there is a risk that the marker will not fully deploy. When the marker is not fully deployed the marker may become snagged in the biopsy device and shift from its intended position. In some devices, there is also the risk of the tip of the deployment rod over-extending through the aperture of the biopsy device. Over-extension may lead to a risk of the over-extended portion being shorn off by the biopsy device's aperture and left inside the patient. Thus, there is a need in the art for a marker deployment system that minimizes or prevents these problems.

SUMMARY OF THE INVENTION

[0007] Aspects of the present invention provide, among other variations, a marker delivery device including a cannula comprising a distal end and a marker exit positioned proximate the distal end, a rod extending within the cannula, and a flexible deployer operatively coupled with the rod and positioned proximate the marker exit.

[0008] Another aspect of the present invention provides a method of deploying a marker including translating a rod within a cannula, the cannula comprising a distal end and a marker exit positioned proximate the distal end, flexing a flexible deployer operatively coupled with the rod and positioned proximate the marker exit, wherein the translating of the rod flexes the flexible deployer, and expelling the marker out of the marker exit, wherein the flexing of the flexible deployer expels the marker

[0009] Additional advantages and novel features of various aspects of the present invention 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 thereof.

BRIEF DESCRIPTION OF THE FIGURES

[00010] In the drawings:

[0011] FIG. 1 is a perspective view of an example marker delivery device in a pre-actuated state in accordance with aspects of the present invention;

[0012] FIG. 2 is a top view of the example marker delivery device of FIG. 1 in the pre-actuated state;

[0013] FIG. 3 is a side view of the example marker delivery device of FIG. 1 in the pre-actuated state;

[0014] FIG. 4 is a front view of the example marker delivery device of FIG. 2 in the pre-actuated state;

[0015] FIG. 5 is a side view of the example marker delivery device of FIG. 1 in a partially-actuated state;

[0016] FIG. 6 is a front view of the example marker delivery device of FIG. 1 in the partially-actuated state;

[0017] FIG. 7 is a perspective view of the example marker delivery device of FIG. 1 in a post-actuated state;

[0018] FIG. 8 is a side view of the example marker delivery device of FIG. 1 in the post-actuated state;

[0019] FIG. 9 is a front view of the example marker delivery device of FIG.1 in the post-actuated state; and

[0020] FIG. 10 is a side view of the example marker delivery device of FIG. 1 showing an example operative end.

DETAILED DESCRIPTION

[0021] The following description of certain examples of the invention should not be used to limit the scope of the present invention. Other examples, features, aspects, embodiments, advantages, and one of the best modes contemplated for carrying out of the invention will become apparent to those skilled in the art from the following description, which is by way of illustration only, and in no way designed to limit the scope of the present invention. As will be realized, the present invention is capable of other different and obvious aspects, all without departing from the scope of the present invention. Accordingly, the drawings and descriptions should be regarded as illustrative in nature and not restrictive.

[0022] An aspect of the present invention provides, among other features, a marker delivery device comprising a cannula including a distal end and a marker exit positioned proximate the distal end, a rod extending within the cannula, and a flexible deployer operatively coupled with the rod and positioned proximate the marker exit.

[0023] Another aspect of the present invention provides, among other features, a method of deploying a marker, comprising translating a rod within a cannula, the cannula comprising a distal end and a marker exit positioned proximate the distal end, flexing a flexible deployer operatively coupled with the rod and positioned proximate the marker exit, wherein the translating of the rod flexes the flexible deployer, and expelling the marker out of the marker exit, wherein the flexing of the flexible deployer expels the marker.

[0024] **Parts List**

Part Names	Number
device	10
cannula	12
lumen	13
exit	14
distal end	16
rod	18
marker	20
first end (2)	21
flexible deployer	22
second end	23
end cap	24
flexible flaps	26
operative end	30
hub	32
proximal end	34
grip	36
actuator	38
plunger	40

[0025] FIGS.1-8 provide examples illustrating the deployment end (e.g., the end where the marker is deployed) of a marker delivery device 10 which includes an elongate outer cannula 12 defining a lumen 13 therein. The cannula 12 may include a marker exit 14, such as side opening formed adjacent to, but spaced proximally from, the distal end 16 of the cannula 12. A rod 18 may extend within lumen 13 of the cannula 12 for acting upon a marker 20 during operation.

[0026] Operative end 30, not shown in FIGs 1-9, is where the user operates the device. An example operative end 30 is shown in FIG. 10 and is described separately below. The operative end 30 may include a hub coupled with a proximal end of the cannula 12 and include a grip. An actuator may be provided that translates the rod 18 within the lumen 13 of the cannula 12 when the actuator is actuated. For example, the actuator may include a plunger coupled with the rod 18. The rod 18 may have sufficient rigidity in compression to push the marker 20 from an internal lumen of the cannula 12 out through the exit 14. The rod 18 may also be relatively flexible. The plunger may be coupled at the

proximal end of the rod 18 for forcing the rod 18 distally in the lumen 13 of the cannula 12 to deploy the marker 20 out of the cannula 12. In operation, the user may grasp the grip with two fingers of one hand, and may push on plunger using the thumb on the same hand, so that marker delivery device 10 is operated by a user's single hand. A spring or other feature may be provided about rod 18 to bias rod 18 proximally relative to the grip and the cannula 12.

[0027] The cannula 12 may be formed of any suitable metallic or non-metallic material. In some versions, the 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), available commercially for sale under the tradename PEBAX, see http://www.pebax.com/en/pebax-range/product-viewer/Pebaxsup-sup-00001/. The cannula 12 may be formed of PEBAX, and may be substantially transparent to visible light and X-ray. The rod 18 may be formed of the same or different material.

[0028] The operative end of the device 10 may include any suitable structure for allowing the operator to grip the device and actuate the rod 18. That is, the deployment features described herein are applicable to any type of marker deployment device in which a rod is used to expel the marker. For example, the actuator, the grip, and/or the plunger may be as disclosed in any of the above-noted references, e.g., U.S. Pat. Nos. 6,371,904; 6,993,375; 6,996,433; 7,044,957; 7,047,063; 7,229,417; 7,465,279; 8,068,895; 8,241,299; 8,371,443 and 8,414,602, and U.S. Published Patent Application Number 2013/0237912, now abandoned and U.S. Published Patent Application Number 2014/0276037; which patents and patent applications are all incorporated by reference.

[0029] FIGS. 1-4 show the deployment end of the example marker deployment device 10 in a pre-actuated state. FIGS. 5 and 6 show the deployment end of the marker deployment device 10 in a partially actuated state. FIGS. 7-9 show the deployment

end of the marker deployment device 10 in a fully actuated state. In the front views of FIGS. 4, 6, and 9, the end of the device is transparent so that the inside elements can be viewed.

[0030] As best seen in FIGS. 1, 3, 5, 7, and 8, the marker deployment device 10 may further include a flexible deployer 22. The flexible deployer 22 may be integral with or separately attached to the rod 18 at a first end 21 of the rod 18. The flexible deployer 22 may be made from the same or different material as the rod 18. As seen in FIGS. 1 and 3, in the pre-actuated state, the flexible deployer may be relatively flat, e.g., extending substantially parallel to an inner surface of the cannula 12 or parallel to the longitudinal axis of the cannula. That is, in the pre-actuated state, the flexible deployer 22 is in a non-flexed state. As best seen in FIGS. 1-3, in the pre-actuated state, the flexible deployer 22 may extend from the rod 18 such that a second end 23 of the flexible deployer 22 terminates at, or substantially at, an end cap 24 of the cannula 12. Furthermore, as seen in FIGS. 1, 3, and 4, in the pre-actuated state, the marker 20 is completely contained within cannula 12 and rests on top of flexible deployer 22. The flexible deployer 22 may have sufficient resiliency such that the flexible deployer 22 is biased to the position shown in FIGS. 1-4 prior to force being applied by the operator.

[0031] The exit 14 of the cannula 12 may be defined and partially or fully enclosed by pair of flexible flaps 26. As best seen in FIGS. 1 and 2, the flexible flaps 26 may cover the marker 20 in the pre-actuated state. The flexible flaps 26 may have sufficient resiliency such that the flexible flaps 26 are biased to the position shown in FIGS. 1 and 2 prior to force being applied by the operator. That is, the flexible flaps 26 may act as a door that blocks the marker 20 from exiting the cannula 12, absent the intentional application of force on the rod 18. In this manner, the marker 20 may rest just underneath the exit 14, without the risk of the marker 20 unintentionally being released from the cannula 12.

[0032] When it is desirable to release the marker 20 from the cannula 12, the operator may begin to apply force on the rod 18 to translate the rod 18 toward the end cap 24 at the distal end of the cannula 12. As noted above, the movement of the rod 18 may be achieved by any known actuation mechanism, and in particular, any actuation mechanism disclosed in the U.S. Patents and U.S. Published Patent Applications incorporated by reference above. As the rod 18 begins to translate toward the end cap 24, the flexible deployer 22 begins to flex upwardly, e.g., perpendicularly relative to the longitudinal axis of cannula 12. The flexing of the flexible deployer 22 occurs because the rod 18 is integral with or attached to the flexible deployer 22 at the first end 21. Moving the rod 18 forces the second end 23 of the flexible deployer 22 to push against the end cap 24. As the rod 18 continues to be pushed toward the end cap 24, the flexible deployer 22 continues to flex toward the flexible flaps 26. Because the marker 20 rests on the flexible deployer 22, the flexing of the flexible deployer 22 also causes the marker 20 to move upwardly toward the flexible flaps 26 (e.g., substantially perpendicular to the longitudinal axis of the cannula) and press against the flexible flaps 26. As more force is applied on the rod 18, more force is in turn applied to the flexible deployer 22, and more force is in turn is applied against the flexible flaps 26 by the marker 20. The application of force continues until the flexible flaps 26 are forced opened and marker begins pushing through the exit 14, exit 14 becoming enlarged with the flexible flaps 26 being opened.

[0033] As shown in FIGS. 5 and 6, during a point of partial actuation, where the rod 18 has been pushed some of the way, but not completely, the marker 20 partly extends out of the exit 14 and the flexible flaps 26 contact the sides of the marker 20.

[0034] After the partial actuation state, with the application of further force on the rod 18, the fully actuated state shown in FIGS. 7-9 will be reached. As shown in FIGS. 7-9, the rod 18 has been translated fully within the cannula 12 and the flexible deployer 22 has

been fully flexed sufficient to completely eject the marker 20 out of the cannula 12. With the marker 20 having exited beyond the flexible flaps 26, the resiliency of the flaps biases the flaps back downward to their original position prior to the start of actuation. That is, because the marker 20 is no longer applying opening pressure on the flexible flaps 26 (via the flexible deployer 22), the flexible flaps 26 will close. Because the flexible flaps 26 are now closed, the marker 20 is prevented from inadvertently returning into the cannula 12.

[0035] The marker deployment device described herein may be used in conjunction with any suitable biopsy device known in the art used as part of a biopsy procedure. For example, the marker deployment device may used in conjunction with any of the biopsy devices described in U.S. Patent Numbers 5,526,822; 6,086,544; 6,626,849; 7,442,171; 7,938,786; 8,118,755; 8,251,916; 8,532,747and 9,095,326.

[0036] FIG. 10 shows the marker deployment device 10 with an example operative end 30. The operative end 30 may include a hub 32 coupled with a proximal end 34 of the cannula 12 and include a grip 36. An actuator 38 may be provided that translates the rod 18 within the lumen 13 of the cannula 12 when the actuator 38 is actuated. For example, the actuator 38 may include a plunger 40 coupled with the rod 18. In operation, the user may grasp the grip 36 with two fingers of one hand, and may push on plunger 40 using the thumb on the same hand, so that marker delivery device 10 is operated by a user's single hand.

[0037] The marker may be any suitable marker known in the art. See the markers described and claimed in U.S. Patent Numbers 5941890, 6162241, 6270464, 6356782, 6790185, 7668582 8,068,895, 8320993 and 8600481.

[0038] For example, as described in U.S. Pat. No. 8,068,895 the marker may comprise a marker body and a marking element. In some variations, the marker body may be visible under ultrasound imaging, while the marking element may be visible under MRI and X-ray, among other imaging modalities. For instance, the marker body may be formed of

polyethylene glycol hydrogel, bovine collagen, cellulose, beta glucan, Polylactic acid/Polyglycolide, Glycoprene® implantable grade polymers available from http://poly-med.com/services/implantable-grade-polymers-catalogue/glycoprene/, gelatinous materials such as hydrogel, and/or any other suitable material(s), including combinations thereof. Furthermore, the marker body may be biodegradable or bioabsorbable, or may have other properties. The marking element may comprise a stainless steel structure, a titanium structure, a ceramic structure, a pellet, or other suitable geometric shaped structure. Any other material(s) may be used for the marking element, including combinations thereof. In some variations, the marker body may be formed of a square collagen pad that is folded and/or rolled about a titanium the marking element to form a substantially cylindraceous marker. The marker may then be compressed radially inward in this example before being inserted into the cannula for deployment. The marker may have a variety of alternative configurations, may be formed using a variety of techniques, and may be used in a variety of other ways as described in some of the U.S. Patents and U.S. Patent Application Publications incorporated by reference above.

[0039] While this invention has 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 of the invention, 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 invention. Therefore, the invention is intended to embrace all known or later-developed alternatives, modifications, variations, improvements, and/or substantial equivalents.

Claims:

1. A marker delivery device, comprising:

a cannula comprising a distal end and a marker exit positioned proximate the distal end;

a rod extending within the cannula; and

a flexible deployer operatively coupled with the rod and positioned proximate the marker exit.

2. A method of deploying a marker, comprising:

translating a rod within a cannula, the cannula comprising a distal end and a marker exit positioned proximate the distal end;

flexing a flexible deployer operatively coupled with the rod and positioned proximate the marker exit, wherein the translating of the rod flexes the flexible deployer; and

expelling the marker out of the marker exit, wherein the flexing of the flexible deployer expels the marker.

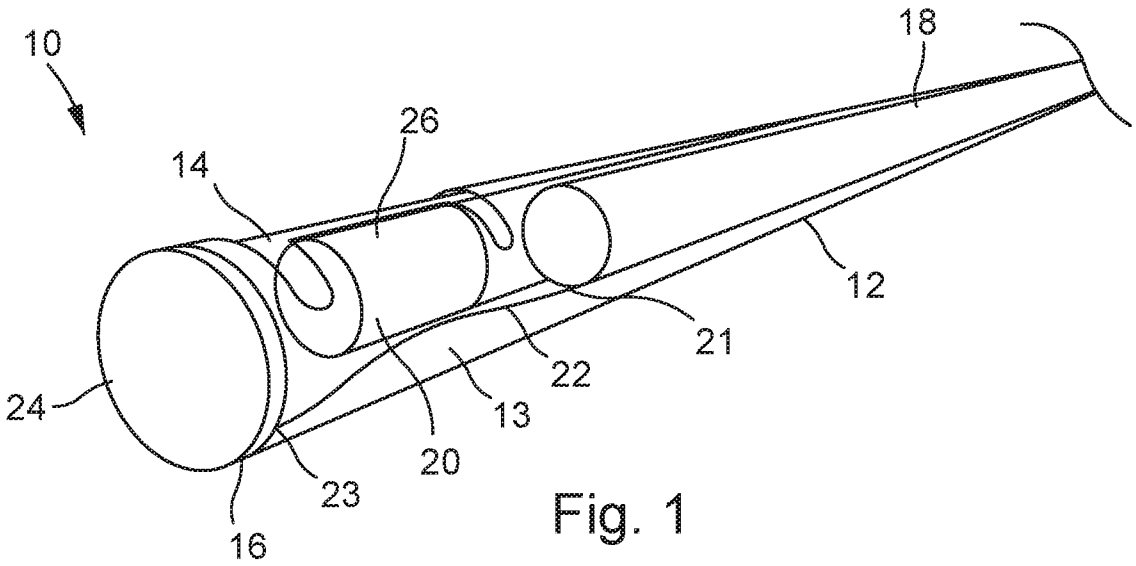

Fig. 1

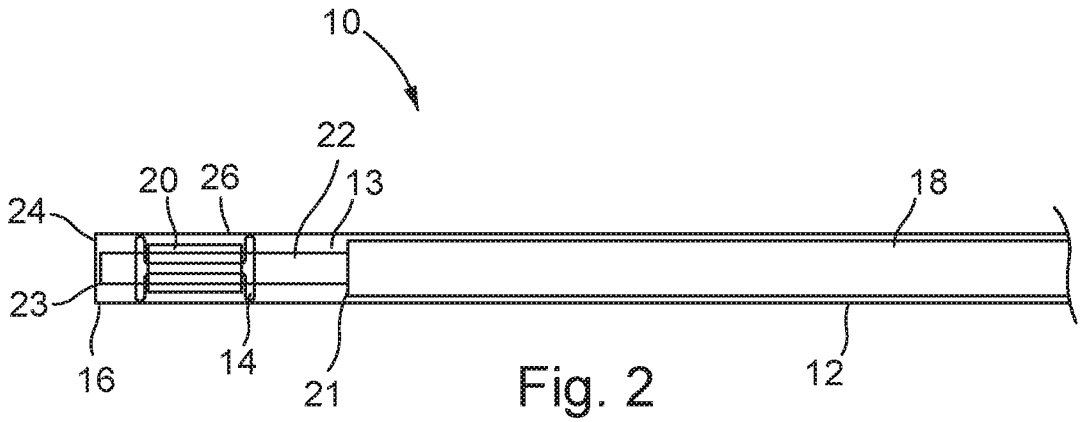

Fig. 2

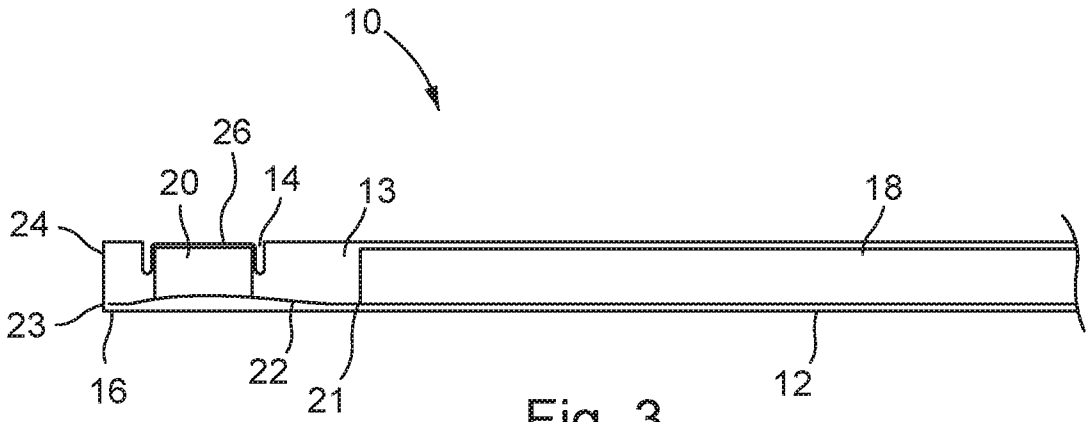

Fig. 3

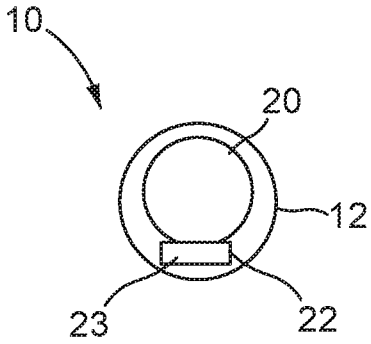

Fig. 4

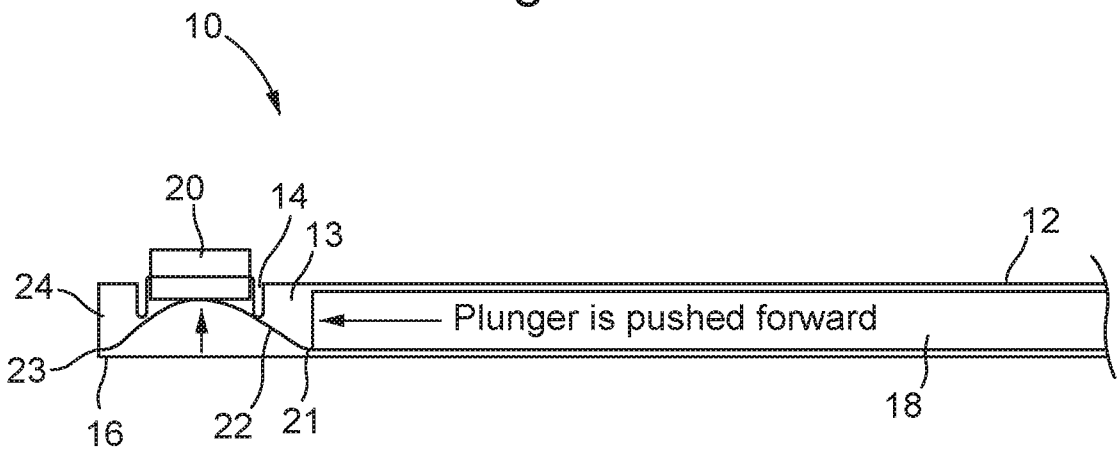

Fig. 5

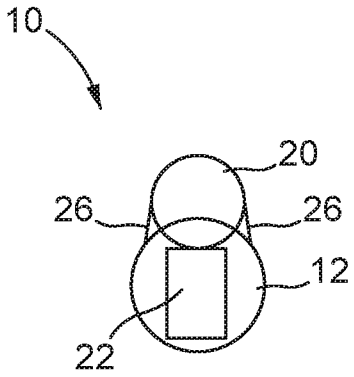

Fig. 6

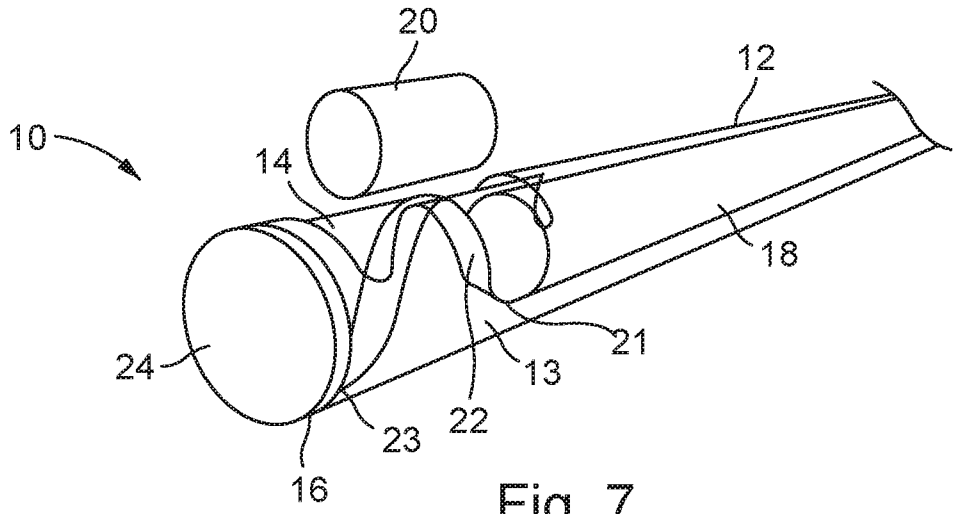

Fig. 7

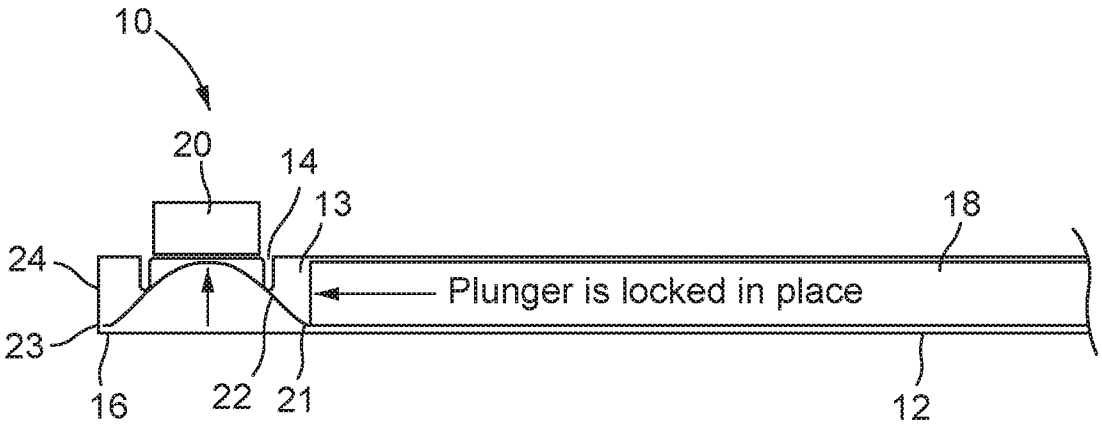

Fig. 8

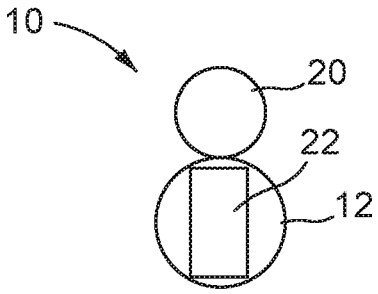

Fig. 9

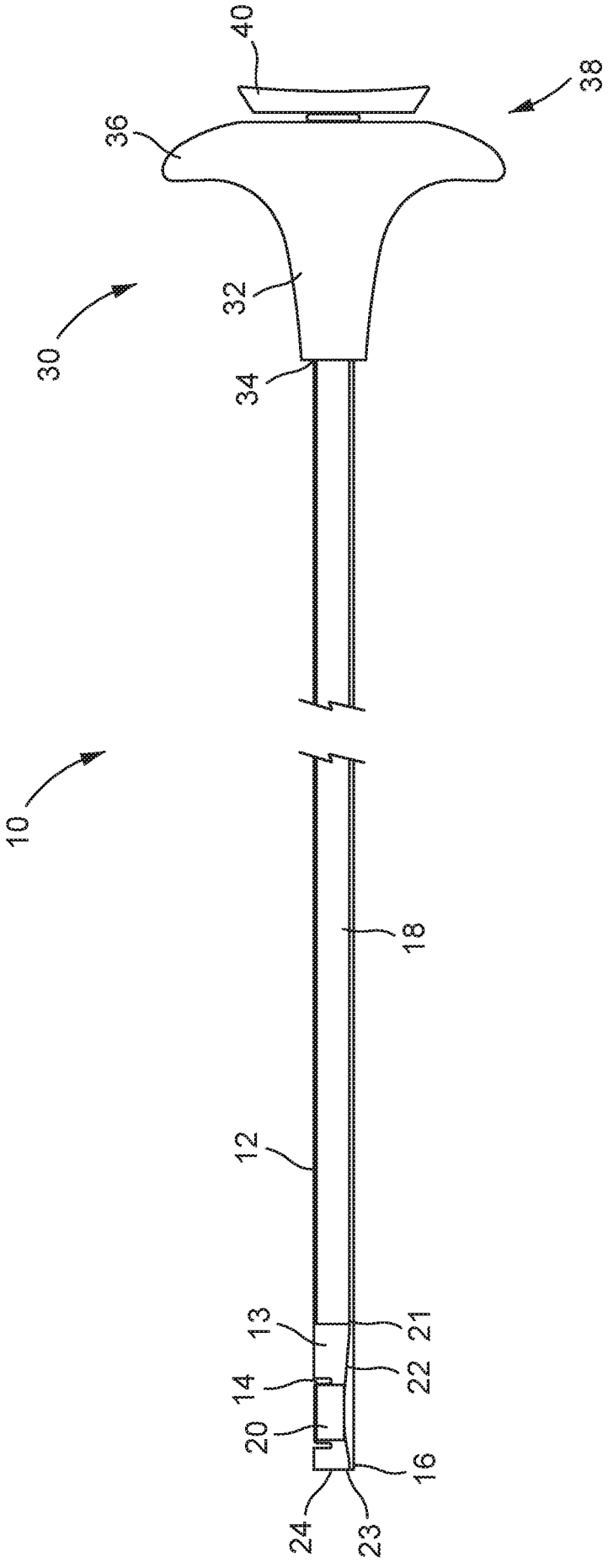

Fig. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/061170

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B90/00 A61B5/06
ADD.

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

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) figure 3A, 3B, paragraph [31-38]	1,2
X	US 2009/216150 A1 (REICHEL LEE [US] ET AL) 27 August 2009 (2009-08-27) figure 6, 8, paragraph [36, 39-41]	1,2
X	US 2006/224082 A1 (VETTER JAMES W [US] ET AL) 5 October 2006 (2006-10-05) figure 29, 30, paragraph [77]	1,2

-/--

[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

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Date of the actual completion of the international search	Date of mailing of the international search report
21 December 2016	19/01/2017

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	Kickler, Nils

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/061170

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