

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

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
27 January 2011 (27.01.2011)

(10) International Publication Number
WO 2011/011743 A2

PCT

(51) International Patent Classification:

A61M 25/12 (2006.01) A61M 31/00 (2006.01)
A61M 25/01 (2006.01)

(21) International Application Number:

PCT/US2010/043 136

(22) International Filing Date:

23 July 2010 (23.07.2010)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/228,081 23 July 2009 (23.07.2009) US

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(81) Designated States (unless otherwise indicated, for every

kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, 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, TH, TJ, TM, TN, TR,
TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every

kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG,
ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU,
LV, MC, MK, MT, NL, NO, PL, PT, RO, 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 2011/011743 A2

(54) Title: DEFLATION AND REMOVAL OF IMPLANTABLE MEDICAL DEVICES

(57) Abstract: A deflation catheter device, comprising: a catheter tube having a proximal end and a distal end; a stylet disposed within the catheter tube; a stylet handle attached to the stylet; and a y-connector disposed near a proximal end of the catheter tube, configured to provide fluid communication from the distal end of the catheter tube and a suction port, and configured to provide access for the stylet from the proximal end of the catheter tube to the distal end of the catheter tube.

DEFLATION AND REMOVAL OF IMPLANTABLE MEDICAL DEVICES

RELATED APPLICATION

[0001] This application claims the full Paris Convention benefit of and priority to U.S. Provisional Patent Application Serial No. 61/228,081, filed July 23, 2009, the contents of which are incorporated by reference herein in their entirety, as if fully set forth herein.

[0002] This application incorporates by reference U.S. Pat. Pub. No. 2007/0100368, published May 3, 2007; U.S. Pat. Pub. No. 2007/0100369, published May 3, 2007; U.S. Pat. Pub. No. 2007/0149994, published June 28, 2007; WIPO Pub. No. WO 2007/053556, published October 5, 2007; WIPO Pub. No. WO 2007/053707, published October 5, 2007; WIPO Pub. No. WO 2007/053706, published October 5, 2007; and WIPO Pub. No. WO 2007/075810, published May 7, 2007; WIPO Pub. No. WO/2008/121831, published October 9, 2008; WIPO Pub. No. WO/2009/002989, published December 31, 2008; U.S. Patent App. Ser. No. 12/723,545, filed March 12, 2010; each as if fully set forth herein in its entirety.

BACKGROUND

[0003] This disclosure relates to devices and methods for deflation and removal of implantable medical devices. In particular, this disclosure relates to single or multiple balloon-type gastric space fillers and devices and methods for explant of the same.

SUMMARY

[0004] According to embodiments, disclosed is a deflation catheter device, comprising: a catheter tube having a lumen, a proximal end, and a distal end; a stylet disposed within the lumen of the catheter tube and configured to extend beyond the distal end of the catheter tube to puncture a wall of an implanted balloon device; a handle disposed at a proximal end of the catheter tube and attached to the stylet, wherein the handle is configured to controllably advance, retract, and rotate the stylet relative to the catheter tube; and a suction port disposed at a proximal end of

the catheter tube and being in fluid communication with the lumen of the catheter tube.

[0005] The deflation catheter device may further comprise a seal between the catheter tube and the handle, wherein the stylet crosses the seal from the handle to the lumen of the catheter tube without introducing leaks or pressure losses. The deflation catheter device may further comprise an interface between the handle and a base of the catheter tube configured to guide advancement, retraction, and rotation of the stylet relative to the catheter tube. The interface may be complementary threading. The deflation catheter device may further comprise an aspiration hole providing fluid communication between the interior of a balloon and the catheter tube. The catheter tube and the stylet may define a gap there between at the distal end of the catheter tube, wherein the gap provides fluid communication between the lumen of the catheter tube and an interior of the implanted balloon device while extended within the implanted balloon device. The catheter tube may contain at least one side hole, wherein the at least one side hole provides fluid communication between the lumen of the catheter tube and an interior of the implanted balloon device while extended within the implanted balloon device.

[0006] According to embodiments, disclosed is a deflation catheter device, comprising: a catheter tube having a lumen, a proximal end, and a distal end; a hollow needle device disposed within the lumen of the catheter tube and configured to extend beyond the distal end of the catheter tube to puncture a wall of an implanted balloon device; a handle disposed at a proximal end of the catheter tube and attached to the stylet, wherein the handle is configured to controllably advance, retract, and rotate the needle device relative to the catheter tube; and a suction port disposed at a proximal end of the catheter tube and being in fluid communication with the lumen of the catheter tube.

[0007] The needle device may further comprise: a sharpened needle tip at a distal end of the needle device; a channel extending axially within the needle device; and an obturator within the channel. A smooth transition from the needle tip to a portion of the obturator may be provided when the obturator is in an extended state. The deflation catheter device may further comprise a spring in the channel tending to

place the obturator in the extended state. The sharpened needle tip may be exposed and the smooth transition removed when the obturator is in a retracted state. The obturator may be configured to be retracted by retracting a portion thereof at a proximal end of the catheter tube. The obturator may be configured to be retracted by applying low pressure within the channel relative to a pressure exterior to the channel. The obturator may be configured to be retracted by pressing it against the implanted balloon device.

[0008] According to embodiments, disclosed is a method of deflating a balloon, comprising: providing a deflation catheter device comprising a catheter tube and a stylet within the catheter tube; delivering the deflation catheter to an implanted balloon device with the stylet being retracted relative to the distal end of the catheter tube; positioning the catheter tube against a surface of the implanted balloon device; actuating a handle to advance the stylet relative to the catheter tube and the implanted balloon device, whereby the stylet contacts and punctures a wall of the implanted balloon device; advancing at least a portion of the catheter tube through the wall of the implanted balloon device; and aspirating fluid from within the implanted balloon device through the lumen from a distal end thereof to a suction port at a proximal end of the lumen without removing the stylet from the catheter tube.

[0009] Actuating the handle may simultaneously rotate the stylet. The method may further comprise: retracting the stylet within the lumen to be concealed by the distal end of the lumen. The method may further comprise: removing the deflation catheter from the balloon. The method may further comprise: reusing the deflation catheter to deflate additional balloons without reloading the stylet into the catheter tube. The method may further comprise: retrieving the implanted balloon device from an implant location.

DRAWINGS

[0010] The above-mentioned features and objects of the present disclosure will become more apparent with reference to the following description taken in conjunction with the accompanying drawings wherein like reference numerals denote like elements and in which:

- [001 1] Figure 1A shows a perspective view of a catheter device;
- [0012] Figure 1B shows a front view of a catheter device;
- [001 3] Figure 1C shows a side view of a catheter device;
- [0014] Figure 1D shows a cross sectional view of a catheter device;
- [0015] Figure 2 shows a cross sectional view of a catheter tube with stylet;
- [0016] Figure 3 shows a cross sectional view of a catheter tube with stylet;
- [0017] Figure 4A shows a cross sectional view of a needle device with obturator in an extended state;
- [0018] Figure 4B shows a cross sectional view of a needle device with obturator in a retracted state; and
- [0019] Figure 5 shows a cross sectional view of a needle device with obturator in an extended state.

DETAILED DESCRIPTION

[0020] Various catheter devices having a piercing needle may be used during deflation of intragastric balloon systems to puncture a balloon and aspirate its contents. A catheter device that utilizes a coring mechanism to breach the balloon wall may also be used to aspirate fluid from the balloon. For some of these catheter devices, the needle is connected to a stylet that resides within the catheter tube and has a handle that extends out of a port in the catheter designated for connecting to suction equipment. To puncture the balloon, the handle is pushed forward to advance the needle-tipped stylet into the balloon. It is noted that without any optional control mechanism, the user may accidentally push the handle and expose the needle prematurely. After puncturing the balloon and inserting the catheter through the puncture, the stylet must be removed from the catheter through the port such that suction equipment may be connected to the catheter. In the case that the balloon system has multiple balloons, the stylet is reloaded into the catheter tube or a new catheter device is used in order to puncture additional balloons.

[0021] According to embodiments, a novel catheter system is disclosed herein for addressing implantable, inflatable medical devices efficiently, safely, and

controllably. The present inventors have developed new catheter devices that allow for puncture and aspiration of fluid from multiple balloons without requiring removal of tools or reconnecting suction tubing and that further provides a controlled advancement and retraction of the needle tip.

[0022] According to embodiments, disclosed is deflation catheter device 1 having a proximal end near a user and a distal end near a location of operation. According to embodiments, and as shown in Figures 1A, 1B, 1C, and 1D, deflation catheter device 1 comprises a y-connector at or near the proximal end. The y-connector connects a distal segment of catheter tube 10 with two segments: handle 30 and suction port 50. Suction port 50 may connect suction equipment (e.g., a pump or syringe) to catheter tube 10, such that suction port 50 is in fluid communication with the lumen of catheter tube 10. In this manner, access via fluid communication with the distal end of catheter tube 10 is provided at the proximal end thereof.

[0023] According to embodiments, seal 100 may be provided near suction port 50 to prevent leakage or vacuum loss between the distal portion of catheter tube 10 and another segment connected to the y-connector (e.g., portion containing handle 30). As shown in Figure 1D, stylet 20 may cross seal 100 from the handle side to the distal segment of catheter tube 10 without allowing leakage or vacuum loss between the distal portion of catheter tube 10 and the handle portion. For example, seal 100 may be configured to allow stylet 20 to pass from the proximal end of catheter tube 10 into the fluid path without allowing leaks around stylet 20. Thus, suction port 50 is provided with exclusive fluid communication access to the lumen of catheter tube 10. This configuration allows for aspiration of fluid through catheter tube 10 without having to remove stylet 20 from the distal segment of catheter tube 10. Also, this enables the user to efficiently puncture and aspirate multiple balloons consecutively because, after deflating one balloon, stylet 20 may simply be retracted to be within catheter tube 10 and advanced again to puncture another balloon without having to entirely reload stylet 20 and risk damaging the catheter.

[0024] According to embodiments, interface 40 may be provided for control of stylet 20 relative to catheter tube 10. Interface 40 may allow controlled

advancement, retraction, and/or rotation of stylet 20 as well as selective securing of its position relative to catheter tube 10 when not in use.

[0025] For example, as shown in Figure 1, a threaded interface between base 60 of catheter tube 10 and stylet 20 may permit the advancement or retraction of stylet 20 when handle 30 is rotated. According to embodiments, interface 40 may be located proximally or distally along the length of catheter tube 10 (i.e., base 60 thereof). This feature provides for the controlled movement of stylet 20. The ratio of axial travel to the number of rotations may be controlled by the pitch of the threaded interface (for example, approximately 6 threads per inch), which may be optimized for efficient advancement of stylet 20 and consistent puncture of balloons by the rotating stylet 20. The threaded interface may be designed with stops in the threads that limit how far stylet 20 can advance relative to catheter tube 10. For example, stylet 20 may be prohibited from extending beyond approximately 2 cm past the distal tip of the catheter for safety. The threaded interface may be designed with stops in the threads that limit how far stylet 20 can retract relative to catheter tube 10. For example, the amount of retraction may be limited to just within catheter tube 10 for efficient deployment of stylet 20. Another feature of a threaded interface is that the risk of accidentally exposing the tip is eliminated because the user must intentionally actuate stylet 20 by rotating handle 30 in order to advance stylet 20. According to embodiments, handle 30 may be actuated by a motorized device that rotates stylet 20 designed with threads or linearly advances stylet 20 without threads. Other types of interfaces are contemplated, including spring-loaded, pressure activated, hydraulically-powered, interfacing gears, etc.

[0026] According to embodiments, after puncturing a balloon system, fluid may be aspirated from the balloon system through or into catheter tube 10 via an aspiration hole when at least a portion of stylet 20 is advanced beyond the distal opening of catheter tube 10.

[0027] According to embodiments, as shown in Figure 2, gaps 14 may be provided at or near the distal end of catheter tube 10 for aspiration between catheter tube 10 and stylet 20, as shown in Figure 2. For example, the distal opening that accommodates stylet 20 may also be used for aspiration, as shown in the left side of

Figure 2. Gaps 14 may be effective as the portion containing the same is advanced beyond the wall of the balloon and into the interior thereof.

[0028] According to embodiments, as shown in Figure 3, catheter tube 10 is designed with side holes 16 along the length thereof, such that fluid may be suctioned into catheter tube 10 even when stylet 20 is fully or partially occluding the distal tip opening. Side holes 16 may be effective as the portion containing the same is advances beyond the wall of the balloon and into the interior thereof.

[0029] According to embodiments, devices and components may be configured for use within a scope device, such as a gastroscope or endoscope. Various dimensions of such a system may be used and customized based on the needs of the application and the use. For example, for use through a 2.8 mm diameter gastroscope channel, catheter tube 10 may have an outer diameter of about .100" to about .107", an inner diameter of about .070" to about .086", and a length of about 50" to about 75". Markings may be printed on the distal section of the catheter to indicate the 1 cm and 2 cm mark of the catheter. By further example, stylet 20 may have a wire diameter of about .030" to about .040" and a coring tip diameter of about .040" to about .052". According to embodiments, stylet 20 may be constructed of a custom wire rope (e.g. the Helical Hollow Strand®, Fort Wayne Metals, Inc., Fort Wayne, Indiana), which has superior column strength and translates rotation better than standard wire rope. Such a stylet wire design ensures a consistent coring motion at the tip for successful puncture of the balloon system without tearing the balloon skin.

[0030] According to embodiments, stylet 20 may have one or more of a variety of designs and configurations. Stylet 20 may have a needle tip configuration taking the shape of a coring needle, a sharpened conical point, or a sharpened beveled point. Other geometries and shapes are contemplated as effective for achieving the results disclosed herein, as recognized by those having ordinary skill in the art.

[0031] According to embodiments, as shown in Figure 4, hollow needle device 80 and obturator 70 are disclosed. Hollow needle device 80 includes channel 84, with obturator 70 disposed therein. Needle device 80 may be sheathed within an

introducer tube for efficient delivery through an endoscope. For example, needle device 80 may be within the lumen of catheter tube 10.

[0032] According to embodiments, obturator 70 may be configured to provide a smooth transition at needle tip 82, such that it may be delivered to the balloon system without harming the patient or damaging the endoscope while obturator 70 is in an extended state (shown in Figures 4A and 5). In the extended state, at least a portion of obturator 70 is extended beyond the distal end of needle tip 82, such that a sharpened portion of needle tip 82 is not exposed, but rather made into part of a smooth transition.

[0033] According to embodiments, catheter tube 10 may provide the features of needle device 80, as disclosed herein. According to embodiments, catheter tube 10 may include needle tip 82 at a distal end thereof, wherein catheter tube 10 is configured to puncture a balloon wall. According to embodiments, catheter tube 10 may house stylet 20 or obturator 70 in a lumen thereof, with features as disclosed herein.

[0034] According to embodiments, catheter tube 10 may be a delivery system, such as an endoscope, gastroscope, etc., wherein devices housed therein may be advanced to provide features and functionality at an operation location.

[0035] According to embodiments, obturator 70 may be retracted to a retracted state, as shown in Fig. 4B. In the retracted state, needle tip 82 is more exposed and capable of puncturing a target, as the smooth transition to obturator 70 has been removed. Retraction of obturator 70 activates the cutting, coring, puncturing, or other functionality of the needle tip. Obturator 70 may be retracted by a variety of methods. For example, the balloon wall may push obturator 70 back against a spring 90 as shown in Fig. 5. Obturator 70 may be retracted manually via a portion accessible at a proximal end by a user. Obturator 70 may be retracted by relatively low pressure applied to channel 84 relative to pressure exterior to channel 84.

[0036] According to embodiments, a method to puncture and deflate a balloon system using devices, systems, and components described herein is disclosed. According to embodiments, suction tubing from a pump is connected to suction port

50 of the device's y-connector. At the user's discretion, suction may be started prior to or after inserting the catheter into the balloon system.

[0037] According to embodiments, the device is delivered through the instrument channel of an endoscope to the implanted balloon system. With the distal end of stylet 20 retracted relative to the distal end of catheter tube 10, the catheter is positioned perpendicular against the surface of the balloon system. The user then rotates handle 30 or otherwise actuates stylet 20 to rotate and/or advance stylet 20. The tip of stylet 20 contacts and punctures the balloon skin.

[0038] According to embodiments, the user advances the catheter to insert the device at least partially through the puncture. At this point, fluid may be aspirated from the inside of the balloon through gaps 14, side holes 16, or other fluid connections from within the balloon device. After the first balloon has been sufficiently deflated, handle 30 is rotated in the opposite direction or otherwise actuated to retract stylet 20 relative to catheter tube 10. Catheter tube 10 is then removed from the balloon.

[0039] According to embodiments, where needle device 80 is delivered via catheter tube 10, needle device 80 may be activated and operated as disclosed herein to puncture a balloon in combination with aspiration operations to evacuate fluid from within the balloon.

[0040] According to embodiments, the device may be repositioned against another balloon and the procedure may be repeated to puncture and suction fluid from additional balloons. The operations may be performed in the above or any variety of sequences that provides the desired results.

[0041] According to embodiments, a kit of parts is disclosed, including components disclosed herein, for use by a user. Included in the kit may be instructions for use.

[0042] While the method and agent have been described in terms of what are presently considered to be the most practical and preferred embodiments, it is to be understood that the disclosure need not be limited to the disclosed embodiments. It is intended to cover various modifications and similar arrangements included within the spirit and scope of the claims, the scope of which should be accorded the

broadest interpretation so as to encompass all such modifications and similar structures. The present disclosure includes any and all embodiments of the following claims.

[0043] It should also be understood that a variety of changes may be made without departing from the essence of the invention. Such changes are also implicitly included in the description. They still fall within the scope of this invention. It should be understood that this disclosure is intended to yield a patent covering numerous aspects of the invention both independently and as an overall system and in both method and apparatus modes.

[0044] Further, each of the various elements of the invention and claims may also be achieved in a variety of manners. This disclosure should be understood to encompass each such variation, be it a variation of an embodiment of any apparatus embodiment, a method or process embodiment, or even merely a variation of any element of these.

[0045] Particularly, it should be understood that as the disclosure relates to elements of the invention, the words for each element may be expressed by equivalent apparatus terms or method terms - even if only the function or result is the same.

[0046] Such equivalent, broader, or even more generic terms should be considered to be encompassed in the description of each element or action. Such terms can be substituted where desired to make explicit the implicitly broad coverage to which this invention is entitled.

[0047] It should be understood that all actions may be expressed as a means for taking that action or as an element which causes that action.

[0048] Similarly, each physical element disclosed should be understood to encompass a disclosure of the action which that physical element facilitates.

[0049] Any patents, publications, or other references mentioned in this application for patent are hereby incorporated by reference. In addition, as to each term used it should be understood that unless its utilization in this application is inconsistent with such interpretation, common dictionary definitions should be understood as

incorporated for each term and all definitions, alternative terms, and synonyms such as contained in at least one of a standard technical dictionary recognized by artisans and the Random House Webster's Unabridged Dictionary, latest edition are hereby incorporated by reference.

[0050] Finally, all referenced listed in the Information Disclosure Statement or other information statement filed with the application are hereby appended and hereby incorporated by reference; however, as to each of the above, to the extent that such information or statements incorporated by reference might be considered inconsistent with the patenting of this/these invention(s), such statements are expressly not to be considered as made by the applicant(s).

[0051] In this regard it should be understood that for practical reasons and so as to avoid adding potentially hundreds of claims, the applicant has presented claims with initial dependencies only.

[0052] Support should be understood to exist to the degree required under new matter laws - including but not limited to United States Patent Law 35 USC 132 or other such laws - to permit the addition of any of the various dependencies or other elements presented under one independent claim or concept as dependencies or elements under any other independent claim or concept.

[0053] To the extent that insubstantial substitutes are made, to the extent that the applicant did not in fact draft any claim so as to literally encompass any particular embodiment, and to the extent otherwise applicable, the applicant should not be understood to have in any way intended to or actually relinquished such coverage as the applicant simply may not have been able to anticipate all eventualities; one skilled in the art, should not be reasonably expected to have drafted a claim that would have literally encompassed such alternative embodiments.

[0054] Further, the use of the transitional phrase "comprising" is used to maintain the "open-end" claims herein, according to traditional claim interpretation. Thus, unless the context requires otherwise, it should be understood that the term "comprise" or variations such as "comprises" or "comprising", are intended to imply the inclusion of a stated element or step or group of elements or steps but not the exclusion of any other element or step or group of elements or steps.

[0055] Such terms should be interpreted in their most expansive forms so as to afford the applicant the broadest coverage legally permissible.

CLAIMS

1. A deflation catheter device, comprising:
 - a catheter tube having a lumen, a proximal end, and a distal end;
 - a stylet disposed within the lumen of the catheter tube and configured to extend beyond the distal end of the catheter tube to puncture a wall of an implanted balloon device;
 - a handle disposed at a proximal end of the catheter tube and attached to the stylet, wherein the handle is configured to controllably advance, retract, and rotate the stylet relative to the catheter tube; and
 - a suction port disposed at a proximal end of the catheter tube and being in fluid communication with the lumen of the catheter tube.
2. The deflation catheter device of claim 1, further comprising a seal between the catheter tube and the handle, wherein the stylet crosses the seal from the handle to the lumen of the catheter tube without introducing leaks or pressure losses.
3. The deflation catheter device of claim 1, further comprising an interface between the handle and a base of the catheter tube configured to guide advancement, retraction, and rotation of the stylet relative to the catheter tube.
4. The deflation catheter device of claim 3, wherein the interface is complementary threading.
5. The deflation catheter device of claim 1, further comprising an aspiration hole providing fluid communication between the interior of a balloon and the catheter tube.
6. The deflation catheter device of claim 1, wherein the catheter tube and the stylet define a gap there between at the distal end of the catheter tube, wherein the gap provides fluid communication between the lumen of the catheter tube and an interior of the implanted balloon device while extended within the implanted balloon device.

7. The deflation catheter device of claim 1, wherein the catheter tube contains at least one side hole, wherein the at least one side hole provides fluid communication between the lumen of the catheter tube and an interior of the implanted balloon device while extended within the implanted balloon device.

8. A deflation catheter device, comprising:
a catheter tube having a lumen, a proximal end, and a distal end;
a hollow needle device disposed within the lumen of the catheter tube and configured to extend beyond the distal end of the catheter tube to puncture a wall of an implanted balloon device;
a handle disposed at a proximal end of the catheter tube and attached to the stylet, wherein the handle is configured to controllably advance, retract, and rotate the needle device relative to the catheter tube; and
a suction port disposed at a proximal end of the catheter tube and being in fluid communication with the lumen of the catheter tube.

9. The deflation catheter device of claim 8, wherein the needle device further comprises:
a sharpened needle tip at a distal end of the needle device;
a channel extending axially within the needle device; and
an obturator within the channel.

10. The deflation catheter device of claim 9, wherein a smooth transition from the needle tip to a portion of the obturator is provided when the obturator is in an extended state.

11. The deflation catheter device of claim 10, further comprising a spring in the channel tending to place the obturator in the extended state.

12. The deflation catheter device of claim 9, wherein the sharpened needle tip is exposed and the smooth transition removed when the obturator is in a retracted state.

13. The deflation catheter device of claim 12, wherein the obturator is configured to be retracted by retracting a portion thereof at a proximal end of the catheter tube.

14. The deflation catheter device of claim 12, wherein the obturator is configured to be retracted by applying low pressure within the channel relative to a pressure exterior to the channel.

15. The deflation catheter device of claim 12, wherein the obturator is configured to be retracted by pressing it against the implanted balloon device.

16. A method of deflating a balloon, comprising:
providing a deflation catheter device comprising a catheter tube and a stylet within the catheter tube;
delivering the deflation catheter to an implanted balloon device with the stylet being retracted relative to the distal end of the catheter tube;
positioning the catheter tube against a surface of the implanted balloon device;
actuating a handle to advance the stylet relative to the catheter tube and the implanted balloon device, whereby the stylet contacts and punctures a wall of the implanted balloon device;
advancing at least a portion of the catheter tube through the wall of the implanted balloon device; and
aspirating fluid from within the implanted balloon device through the lumen from a distal end thereof to a suction port at a proximal end of the lumen without removing the stylet from the catheter tube.

17. The method of claim 16, wherein actuating the handle simultaneously rotates the stylet.

18. The method of claim 16, further comprising: retracting the stylet within the lumen to be concealed by the distal end of the lumen.

19. The method of claim 16, further comprising: removing the deflation catheter from the balloon.

20. The method of claim 16, further comprising: reusing the deflation catheter to deflate additional balloons without reloading the stylet into the catheter tube.

21. The method of claim 19, further comprising: retrieving the implanted balloon device from an implant location.

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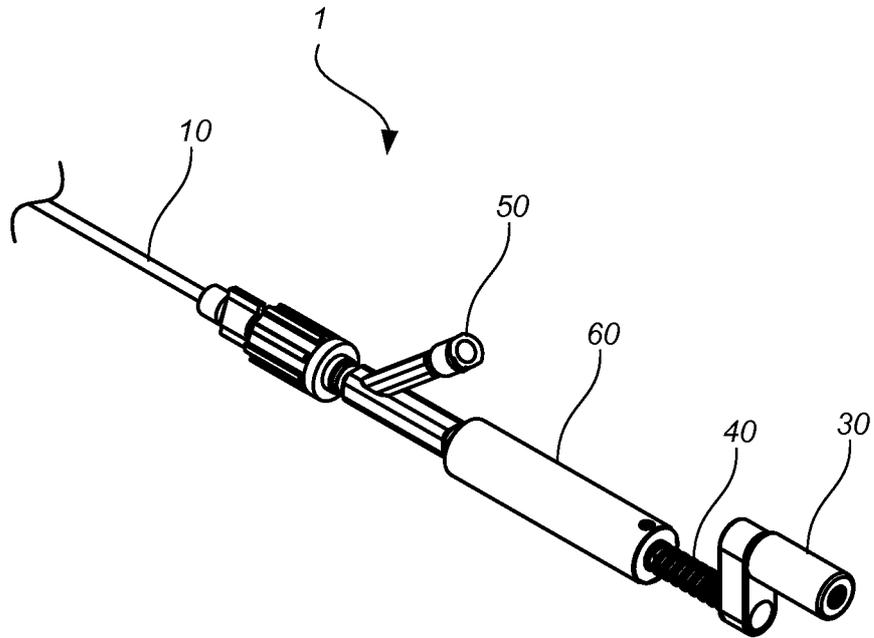


Fig. 1A

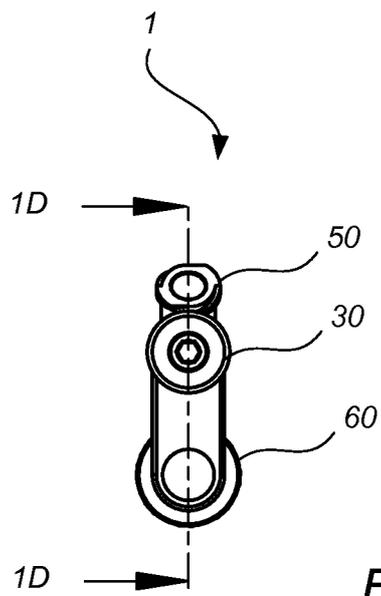


Fig. 1B

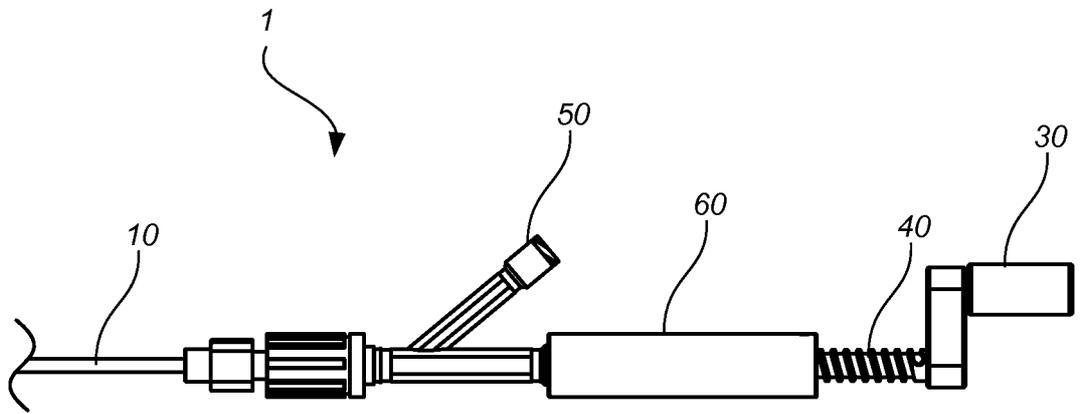


Fig. 1C

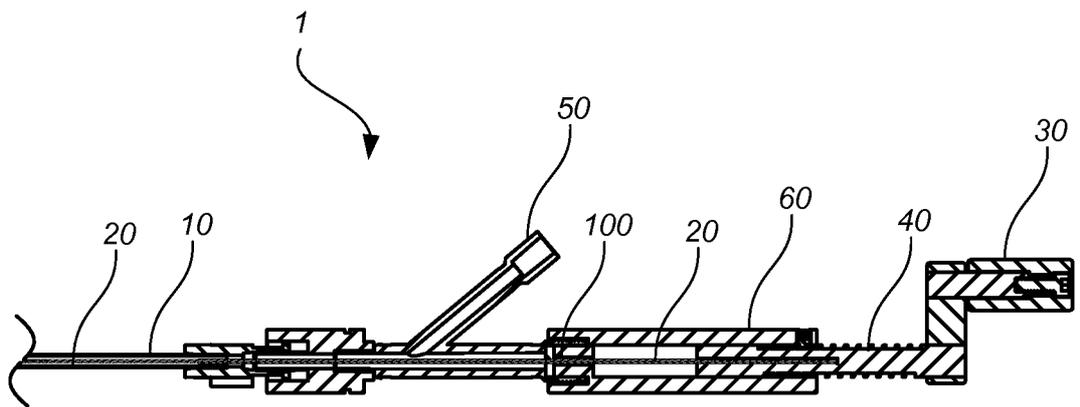


Fig. 1D

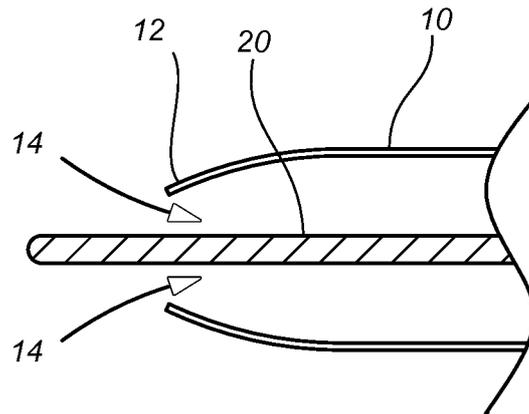


Fig. 2

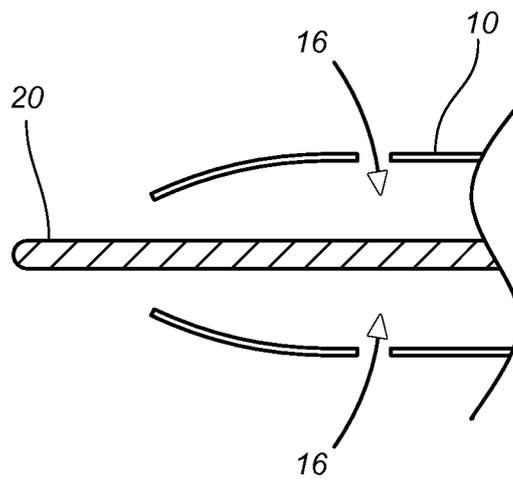


Fig. 3

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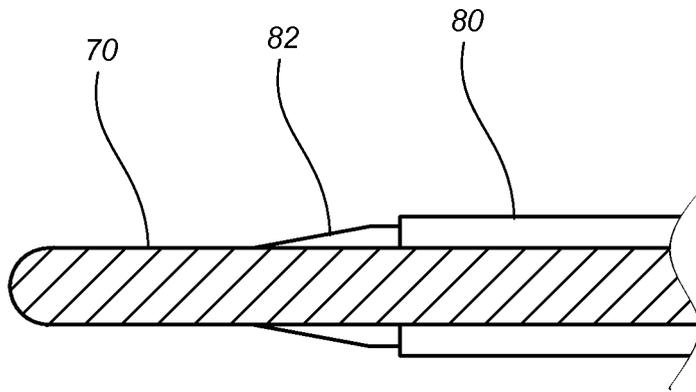


Fig. 4A

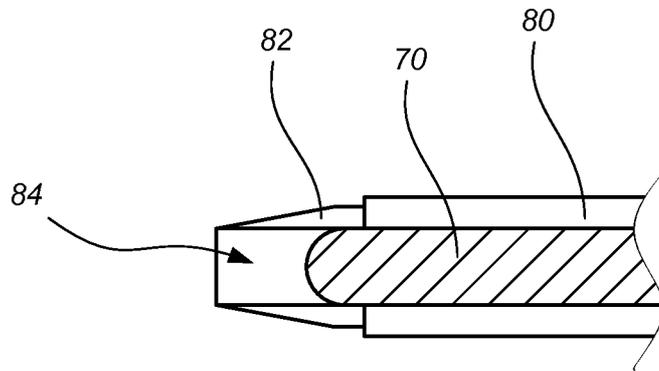


Fig. 4B

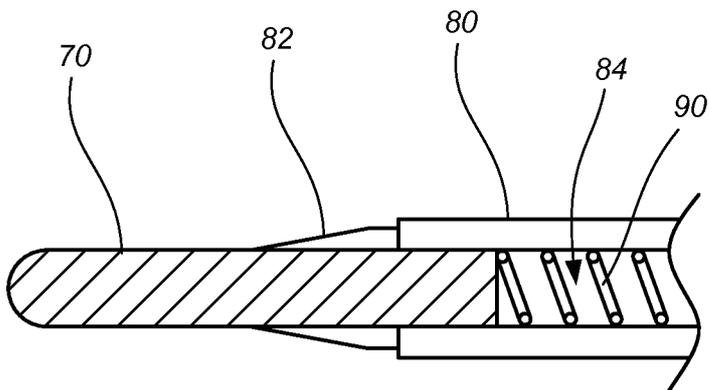


Fig. 5