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(54) Title: VALVE ASSEMBLY AND INTRODUCER

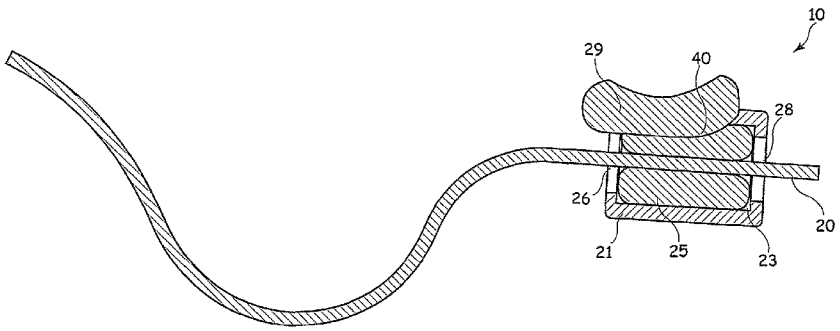

Figure 6

(57) Abstract: A haemostatic or check-flow valve (10) for an implant deployment device (12) includes a conformable valve element such as a gel-filled sack (25) inside a valve housing (21). An actuator (29) is provided in the valve housing (21), and is operable to reduce the effective volume of a valve chamber (23) provided within the valve housing (21). Reduction in the effective volume of the valve chamber (23) causes the conformable sack (25) to change shape, thereby to close a bore (27) that extends longitudinally through the sack (25).

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VALVE ASSEMBLY AND INTRODUCER

Description

Technical Field

[0001] The present invention relates to a valve assembly for sealing the proximal end of an introducer such as an implant deployment device. In particular it relates to a haemostatic valve. This invention also relates to an introducer or catheter assembly including a valve as taught herein.

Background Art

[0002] It is well known to perform a variety of surgical procedures by the introduction of an interventional device into the body, for example, into an arterial or venous blood vessel, or into a laparoscopic or other cavity artificially maintained in the body. Typical of the former type of procedure are coronary angiography (e.g., where an X-ray contrast fluid is inserted into the coronary artery) and percutaneous transluminal coronary angioplasty (PTCA). These and other procedures involve the introduction of an interventional device, such as a catheter (open or closed end), a guide wire, a balloon, a stent, an atherectomy device, or the like into the vessel or cavity in question. The single generic term "catheter" should be understood herein to include all of such interventional devices, unless the context limits the meaning of the term.

[0003] Procedures for introducing a catheter into a blood vessel include the cut-down method and the Seldinger technique. The Seldinger technique is well known, and first involves opening a blood vessel with a needle, inserting a guide wire into the vessel through the lumen of the needle, withdrawing the needle and inserting a dilator over the guide wire. The dilator is located inside an associated sheath which is also inserted into the vessel, and the dilator is sealed to the sheath by a haemostasis or haemostatic valve through which the dilator passes. The dilator is removed, and the catheter inserted through the sheath and haemostatic valve into the vessel.

[0004] During the performance of the Seldinger technique and other procedures, care must be taken to avoid the undesirable introduction of air into the vessel (air embolism) and the undesirable leakage of blood, other fluids or a cavity-pressurising gas from the patient (as much for the protection of health care practitioners as of the patient). As procedures for introducing catheters and other interventional devices have become more widely accepted, the procedures have also become more diverse, and the variety of sizes and types of devices employed has grown dramatically. The risks of inward or outward leakage thus become greater.

[0005] Known valves are well described in the prior art, for example, in WO 2004/045386, US 2005/0171479, WO 2005/058409, WO 2006/005855, and WO 2007/030746.

[0006] Known valves are generally very complex. In light of the variety in the sizes and types of catheters and other devices to be handled, it is not always possible with prior art devices to provide a haemostatic seal or other check valve that seals an introducer sheath or other device with a high degree of effectiveness.

Disclosure of The Invention

[0007] The present invention seeks to provide an improved valve for an implant deployment device.

[0008] According to a first aspect of the present invention, there is provided a valve assembly for an introducer including: a valve chamber providing a variable valve volume; a self-contained sealing element located within the valve chamber, the sealing element being conformable; and a volume reduction device operable to reduce the valve volume of the valve chamber, whereby reduction in the valve volume of the valve chamber deforms the sealing element to adjust the valve to a sealing configuration.

[0009] The valve assembly is able to provide an effective seal irrespective of whether a catheter or other interventional device passes though the valve. It is also able to provide an effective seal around devices having a wide range of diameters and/or of uneven shape.

[00010] The variable valve volume may be defined by a valve housing.

[00011] Preferably the sealing element includes a conformable sack. The conformable sack changes shape and the volume of the valve chamber reduces in order to provide a seal. The sealing element may have a substantially fixed volume.

[00012] The sealing element is preferably substantially cylindrical in a relaxed configuration and preferably includes a bore extending therethrough. The sealing element is thus able to deform into the bore space when the volume of the valve chamber reduces.

[00013] In a preferred embodiment, the sealing element is formed from silicone; the sealing element may include a sack filled with silicone gel or any flowable and substantially non-compressible material.

[00014] The valve assembly may include an actuator for reducing the effective volume of the valve chamber. The actuator may include a projection that extends into the valve chamber when actuated, and may include a button, that may be slidable. Provision of a slidable button allows a surgeon or clinician easily to manipulate the valve assembly to provide the desired level of valve closure.

[00015] The actuator may include an eccentrically mounted wheel. The valve chamber may be formed by a valve housing and the valve housing may be compressible to reduce the valve volume of the valve chamber. The valve housing may include a plurality of portions that move towards one another to reduce the length of the valve chamber.

[00016] According to a second aspect of the present invention there is provided a valve assembly for an introducer including: a valve chamber; a self-contained sealing element in the form of a substantially cylindrical conformable sack, the sealing element including a bore extending therethrough; a projection able to extend into the valve chamber when activated by a slidable button, thereby to reduce the valve volume of the valve chamber and deform the sealing element and adjust the valve to the sealing configuration.

[00017] Preferred features of the first aspect of the present invention may be used with the second aspect of the present invention.

[00018] According to a third aspect of the present invention there is provided an introducer including a valve assembly as described above.

Brief Description of the Drawings

[00019] Preferred embodiments of the present invention are described below by way of example only, with reference to the accompanying drawings, in which:

[00020] Figure 1 shows a side view of an introducer including a valve;

[00021] Figure 2 illustrates the components of a valve of an embodiment of the invention;

[00022] Figure 3 illustrates the valve of Figure 2 in its assembled state;

[00023] Figures 4 to 9 are schematic illustrations of a valve of an embodiment of the invention in use; and

[00024] Figure 10 shows a sectional view of a valve.

Description of the Preferred Embodiments

[00025] It is to be understood that the Figures are schematic and do not show the various components to their actual scale. In many instances, the Figures show scaled up components to assist the reader.

[00026] In this description, when referring to a deployment assembly, the term distal is used to refer to an end of a component which, in use, is furthest from the surgeon during the medical procedure, including within a patient. The term proximal is used to refer to an end of a component closest to the surgeon and in practice in or adjacent an external manipulation part of the deployment or treatment apparatus.

[00027] By way of introduction and with reference first to Figure 1, an introducer provided with a haemostatic valve 10 is shown. The valve 10 may be a check flow valve in a fluid flow path of a medical device, or a haemostatic valve for an introducer for a catheter or other interventional device. More particularly, the valve 10 is shown as incorporated into a catheter introducer 12, and as such finds particular utility as a penetrable, haemostatic valve. The valve 10 is employed in the conventional fashion. For example, a guide wire 18 is first advanced through the valve 10, in a distal or downstream direction indicated by arrow 36, and into and through a conventional sheath 46 incorporated in the introducer 12. When the guide wire 18 is suitably positioned, an interventional device (exemplified by a catheter 20) is distally advanced over the guide wire 18 by fitting the distal end 24 of the catheter 20 over the proximal end of the guide wire 18. The catheter 20 conveniently includes a

proximal end 22 designed for connection to other medical treatment devices as appropriate. A side arm 16 may be provided for its usual functions, as may a suture hole 82 for securing the introducer 12 to a patient or to patient bedding.

[00028] An embodiment of valve 10 is now described with reference, in particular, to Figures 2 to 9.

[00029] The valve 10 includes a substantially cylindrical valve housing 21, which includes a proximal opening 26 and a distal opening 28. The distal opening 28 is, in this embodiment, attached to the proximal end of a sheath 46. The sheath 46 is conventional in nature. Between the proximal opening 26, the distal opening 28 and within the walls of the valve housing 21, a valve chamber 23 is formed.

[00030] The valve 10 also includes a sack or valve element 25, preferably formed from silicone or other conformable material. The sack 25 is also, in this embodiment, substantially cylindrical in shape with a bore 27 extending longitudinally therethrough. The sack 25 is sized to fit snugly within the valve chamber 23. The bore 27 is sized to correspond to the size of the sheath 46, although is not necessarily so. The sack 25 is filled with a gel, such as a silicone gel, or with any suitable flowable and substantially non-compressible material.

[00031] A slidable button 29 is provided within a longitudinally extending slot 32 in the valve housing 21. The slidable button 29 includes a projection 40 that extends into the valve chamber 23. The projection 40 acts to reduce the effective volume of the valve chamber 23, and to press against the sack 25 in so doing.

[00032] The substantially non-compressible nature of the sack 25 causes this to deform into the bore 27 thereof, thereby compressing this, as will be apparent from a review of Figures 4 to 9.

[00033] In use, an implant deployment device including a catheter introducer 12 is assembled by introducing a catheter 20 carrying an implant through the bore 27 of the valve 10 and into the sheath 46. To do this, the surgeon or clinician ensures that the slidable button 29 is in its proximal position (see Figures 4 and 5). In this position, the projection 40 sits only partially within the valve chamber 23. The sack 25 is thus in a relatively relaxed condition because the projection 40 only lightly presses against it.

[00034] When the sack 25 is in its relaxed condition (i.e. the valve 10 is open) the catheter 20 can be introduced through the valve 10 into the sheath 46 relatively easily (see Figures 4 and 5). Once this has been done, the slidable button 29 can be urged into a distal position (as shown in Figures 6 and 7). The projection 40 serves to reduce the effective volume of the valve chamber 23 and press firmly against the sack 25. This causes the sack 25 to alter its shape so as to compress inwardly to fill the reduced-volume valve chamber 23. This causes the bore 27 to be pushed into a sealing configuration around the catheter 20 (see Figures 6 and 7). Once the valve 10 is in its sealing configuration the entire implant deployment device can be introduced into a patient by threading over a previously deployed guide wire. The implant can then be released from the implant deployment device at the treatment site in a conventional manner.

[00035] There are many advantages to the above described embodiment. A very effective seal is formed around a medical instrument, such as a catheter 20, inserted through the valve 10. The gel provides conformability to the sack 25 so that the sack extends into its own bore 27 when the volume of the valve chamber 23 is reduced.

[00036] Sealing efficiency of twistable seals (such as that illustrated in Figure 10) is determined by the depth of the seal in the longitudinal direction of the valve, in practice the depth of the seal which comes into contact with the outer walls of the insert. This can be seen for example in Figure 10, in which only a small portion of the twistable valve element 250 contacts the insert 20, thus providing a relatively narrow seal. A narrower seal provides less sealing effect and often also requires the provision of additional seals, such as the disc-shaped seals used in the device of US 2005/0171479. The seal of preferred embodiments of the present invention is not formed only at a single point but along a length of the longitudinal axis of the catheter 20. Therefore, a seal which is of a longitudinally greater extent provides a more secure seal than a "short" seal such as the twistable seal illustrated in Figure 10.

[00037] Figures 8 and 9 illustrate the valve 10 in a circumstance where the catheter 20 does not extend through the valve 10, and in which the slidable button 29 is in its distal position so that the valve 10 is in a sealing configuration. It can be seen that even without the catheter 20 taking up space within the valve chamber 23 an

effective seal extending longitudinally along the valve 10 is obtained. An effective seal is therefore also formed when no insert is present.

[00038] Thus, a seal can be provided both with and without an inserted catheter, medical device, or element. This occurs because the inner surfaces of the sack 25 forming the bore tend to compress inwardly in a rounded fashion to touch one another in a sealing condition. When a catheter or other element is located in the base, this causes the inner walls to be pressed around the catheter or other element and to deform in a more longitudinal manner.

[00039] It can be seen therefore that the sack 25 is able effectively to seal around inserts having differently-sized diameters and to conform around inserts having uneven, or non-circular transverse cross-sections.

[00040] The slidable button 29 forms a convenient means of actuating the valve 10 that can easily be controlled manually by the surgeon or clinician.

[00041] There are many modifications that could be made to the above-described embodiment. In particular, the skilled person would appreciate that there are many possible ways of reducing the effective volume of the valve chamber 23. For example, an eccentrically mounted wheel could be arranged within the wall of the valve housing 10 such that rotation of the wheel causes it to rotate into the valve chamber 23. A screw-threaded element could be provided between halves of the valve housing 10. This could enable the halves to be screwed into one another in order to compress the pouch 25 axially. In another modification, the valve housing 10 could be arranged such that it could otherwise reduce the effective volume of the valve chamber 23.

[00042] Other modifications will be apparent to the skilled person. The sack need not be filled with silicone gel. It could be filled with another substance (for example, a fluid or a particulate solid), such as any suitable liquid or with a gas such as air. The conformable material should be fluid-tight, but any suitable conformable material could be used.

[00043] The disclosures in US Provisional Patent Application Serial No. 61/191,004, filed September 4, 2008, from which the present application claims priority, and in the abstract accompanying this application are incorporated herein by reference.

Claims

1. A valve assembly (10) for an introducer (12) including:

a valve chamber (23) providing a variable valve volume;

a self-contained sealing element (25) located within the valve chamber, the sealing element being conformable; and

a volume reduction mechanism (29) operable to reduce the valve volume of the valve chamber;

whereby reduction in the valve volume of the valve chamber deforms the sealing element to adjust the valve to a sealing configuration.

2. A valve assembly (10) as claimed in claim 1, wherein the variable valve volume is defined by a valve housing (21).

3. A valve assembly (10) as claimed in claim 1 or 2, wherein the sealing element (25) includes a conformable sack.

4. A valve assembly (10) as claimed in claim 1, 2 or 3, wherein the sealing element (25) is substantially cylindrical in a relaxed configuration.

5. A valve assembly (10) as claimed in any preceding claim, wherein the sealing element (25) includes a bore (27) extending therethrough.

6. A valve assembly (10) as claimed in any preceding claim, wherein the sealing element (25) is formed from silicone.

7. A valve assembly (10) as claimed in any preceding claim, wherein the sealing element (25) includes a sack filled with a flowable and substantially non-compressible material.

8. A valve assembly (10) as claimed in any preceding claim, wherein the sealing element (25) includes a sack filled with silicone gel.

9. A valve assembly (10) as claimed in any preceding claim, including an actuator (29) for reducing the effective volume of the valve chamber (23).

10. A valve assembly (10) as claimed in claim 9, wherein the actuator (29) includes a projection (40) that extends into the valve chamber (23) when actuated.

11. A valve assembly (10) as claimed in claim 9 or 10, wherein the actuator (29) includes a button.

12. A valve assembly (10) as claimed in claim 9, 10 or 11, wherein the actuator (29) includes a slidable button.

13. A valve assembly (10) as claimed in claim 9, wherein the actuator (29) includes an eccentrically mounted wheel.

14. A valve assembly (10) as claimed in any of claims 1 to 8, wherein the valve chamber (23) is formed by a valve housing (21) and wherein the valve housing is compressible to reduce the effective volume of the valve chamber.

15. A valve assembly (10) as claimed in any of claims 1 to 8, wherein the valve chamber (23) is formed by a valve housing (21), wherein the valve housing includes a plurality of portions; and wherein the length of the valve chamber can be shortened by movement of the portions towards one another.

16. An introducer (12) including a valve assembly (10) as claimed in any preceding claim.

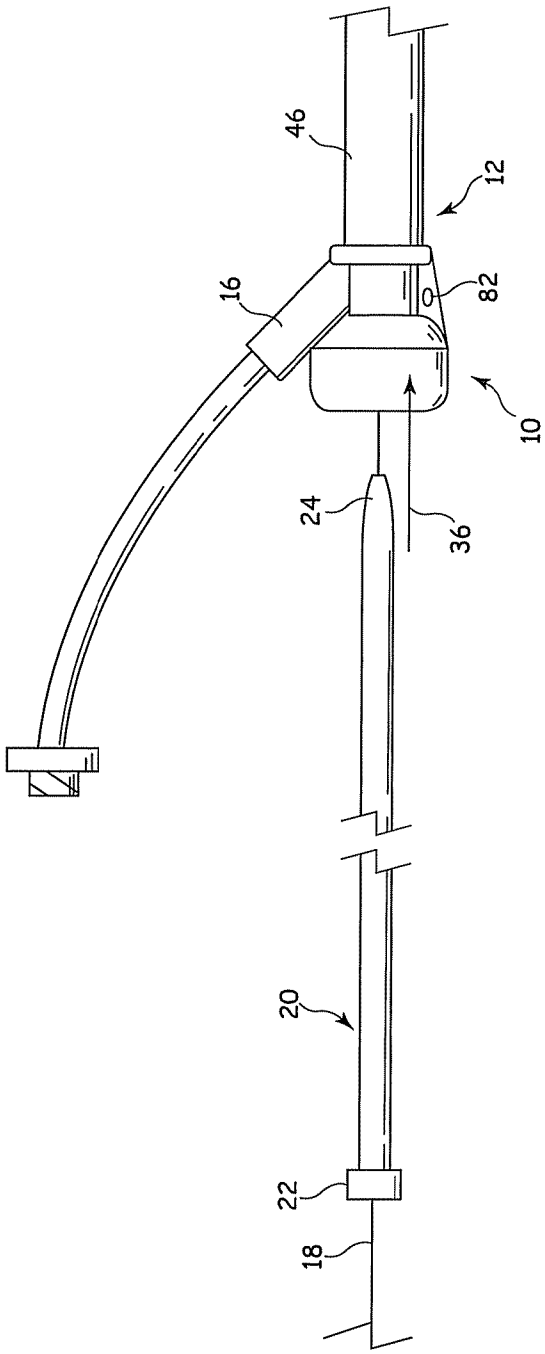

Figure 1

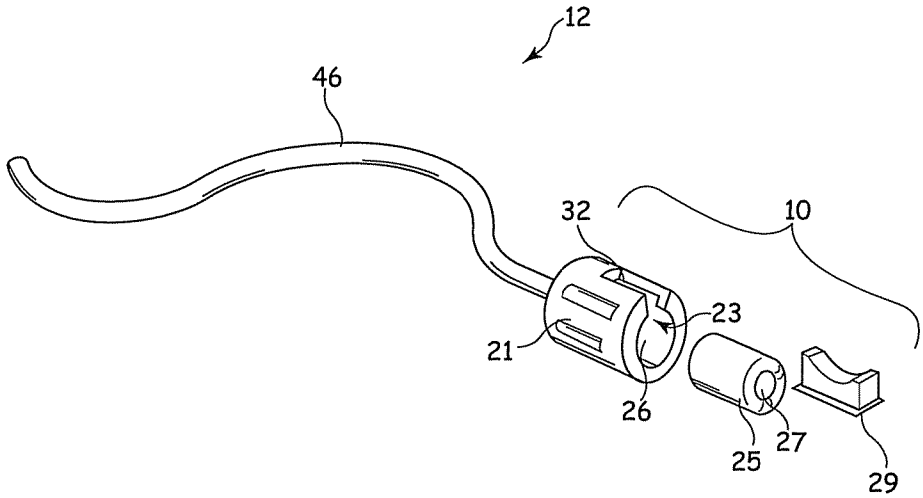

Figure 2

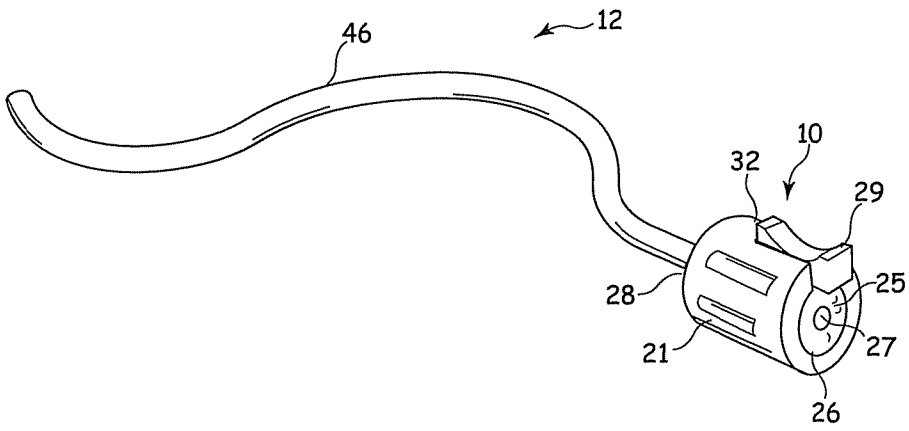

Figure 3

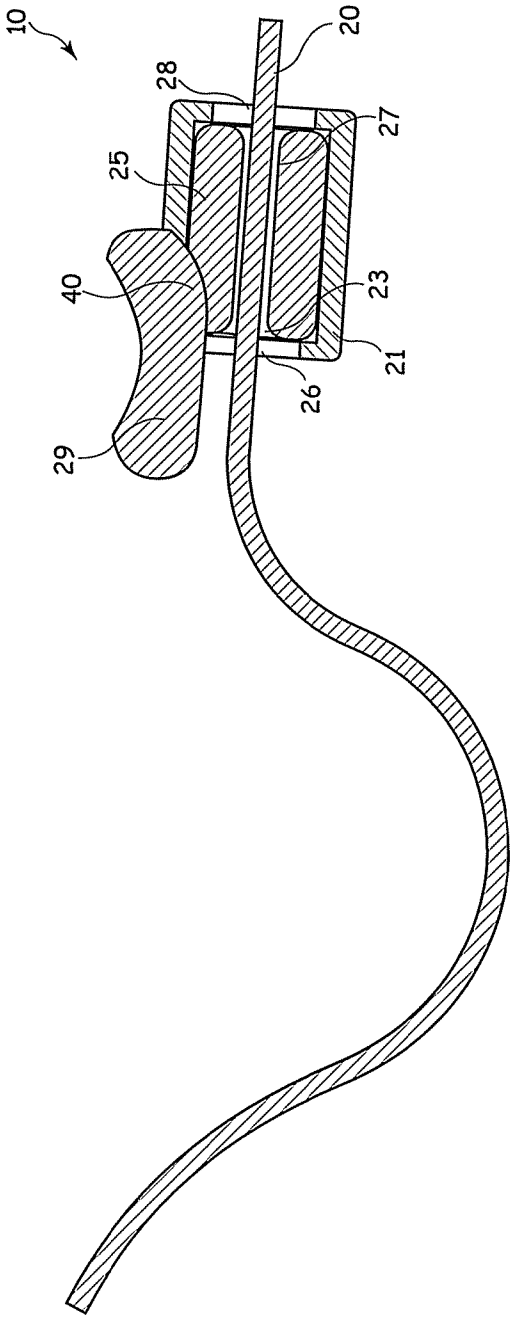

Figure 4

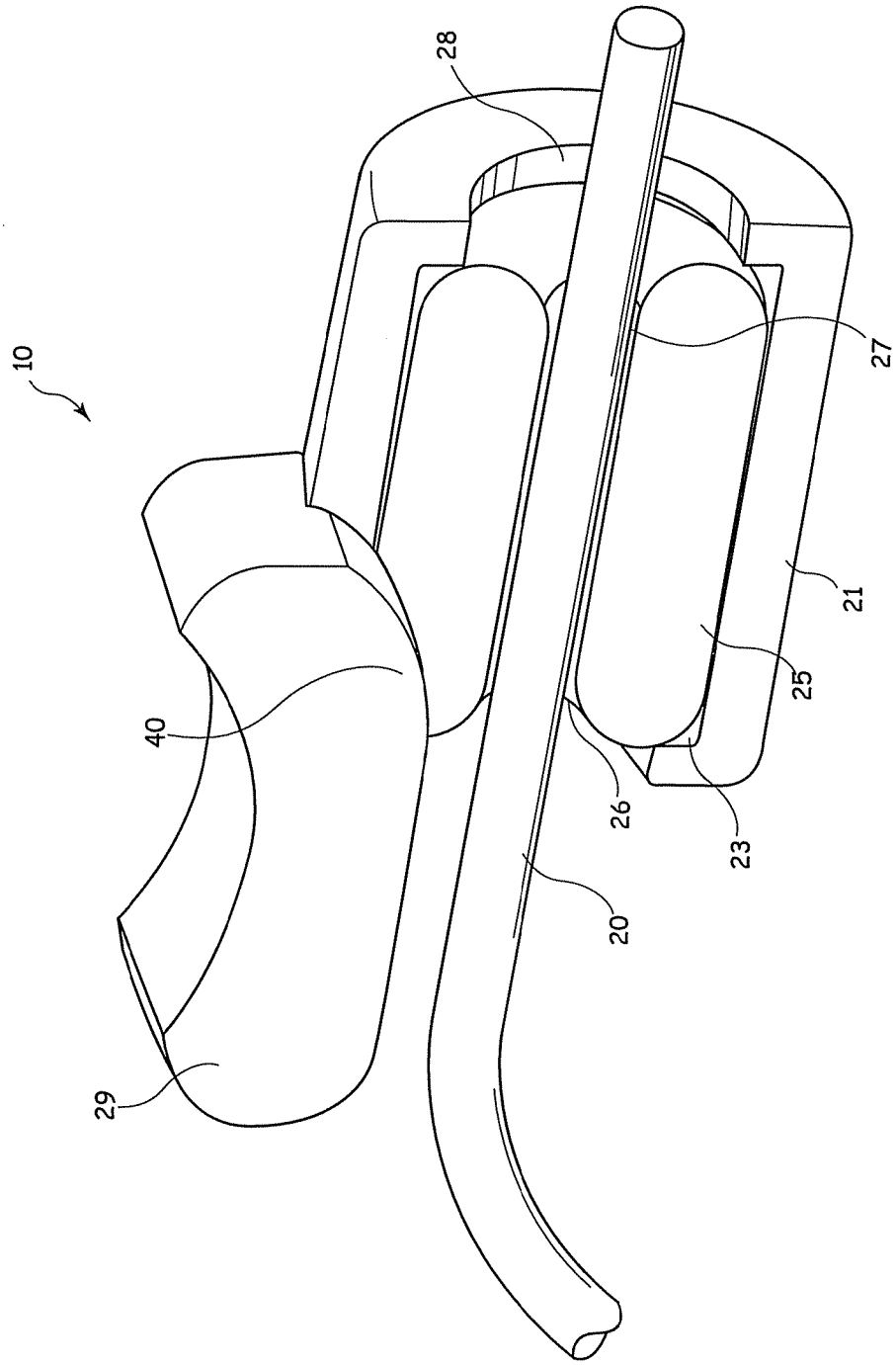

Figure 5

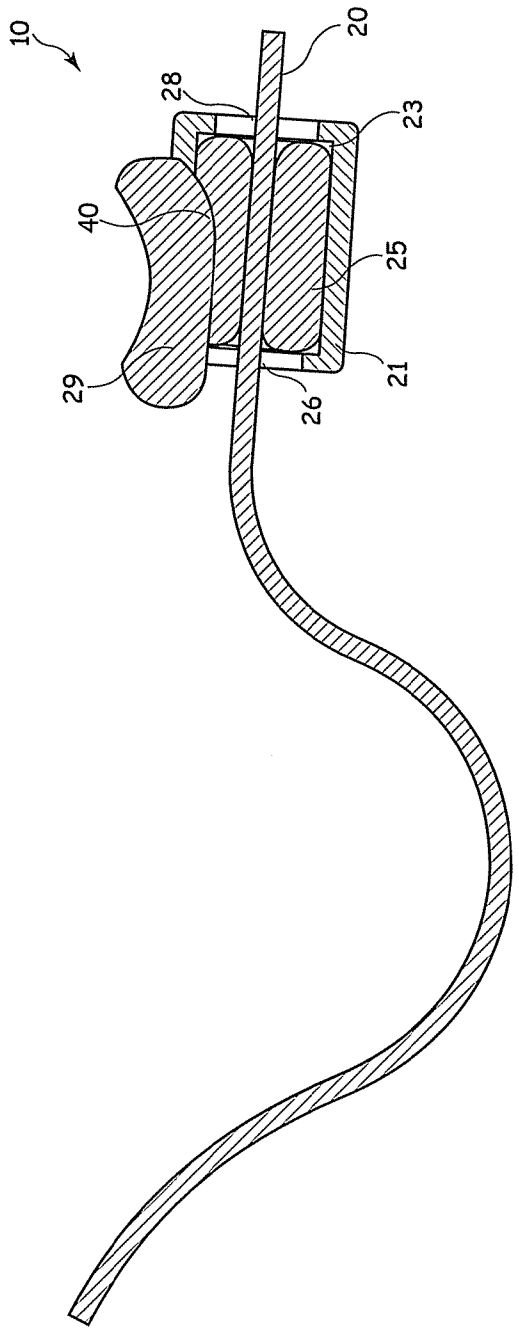

Figure 6

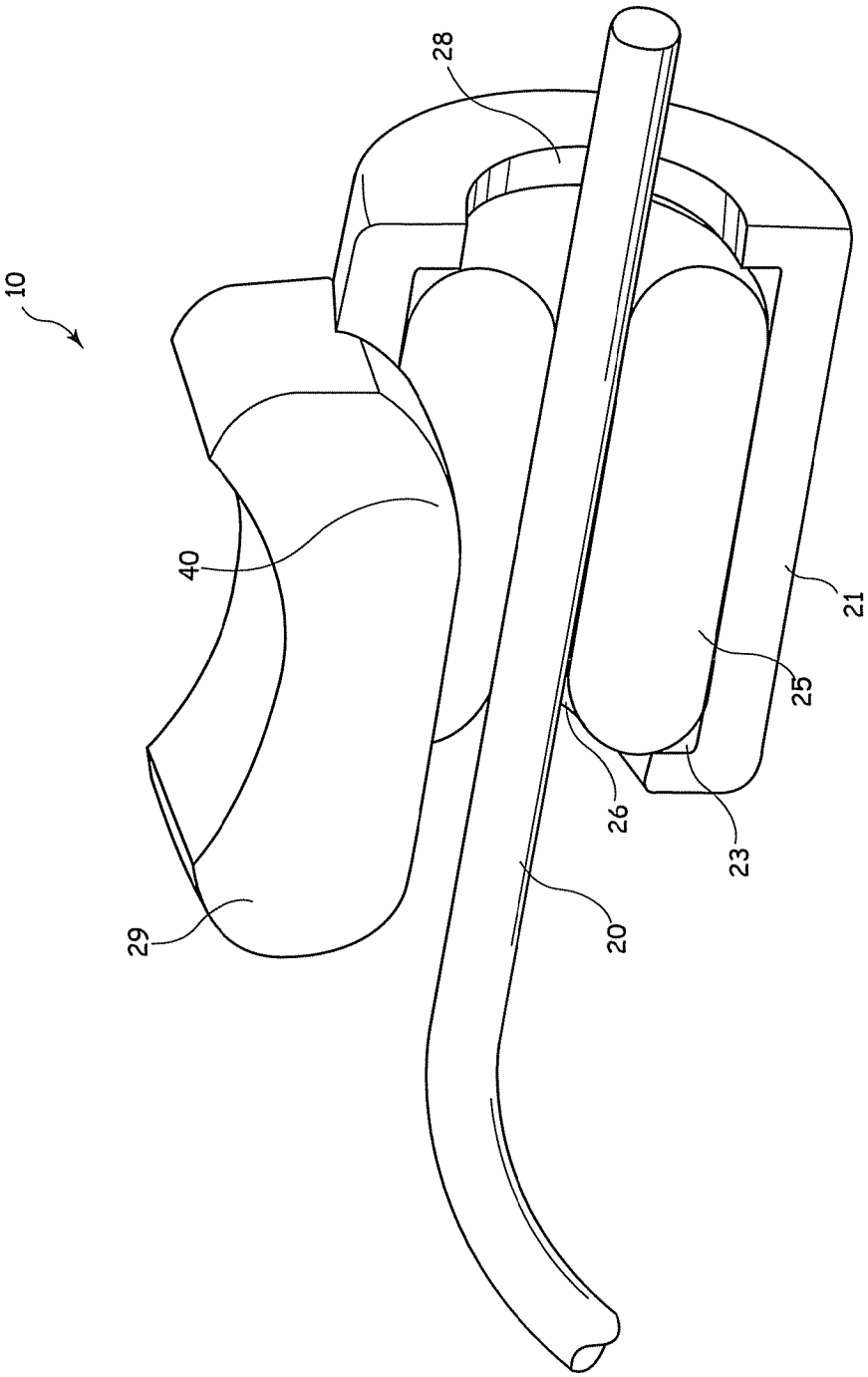

Figure 7

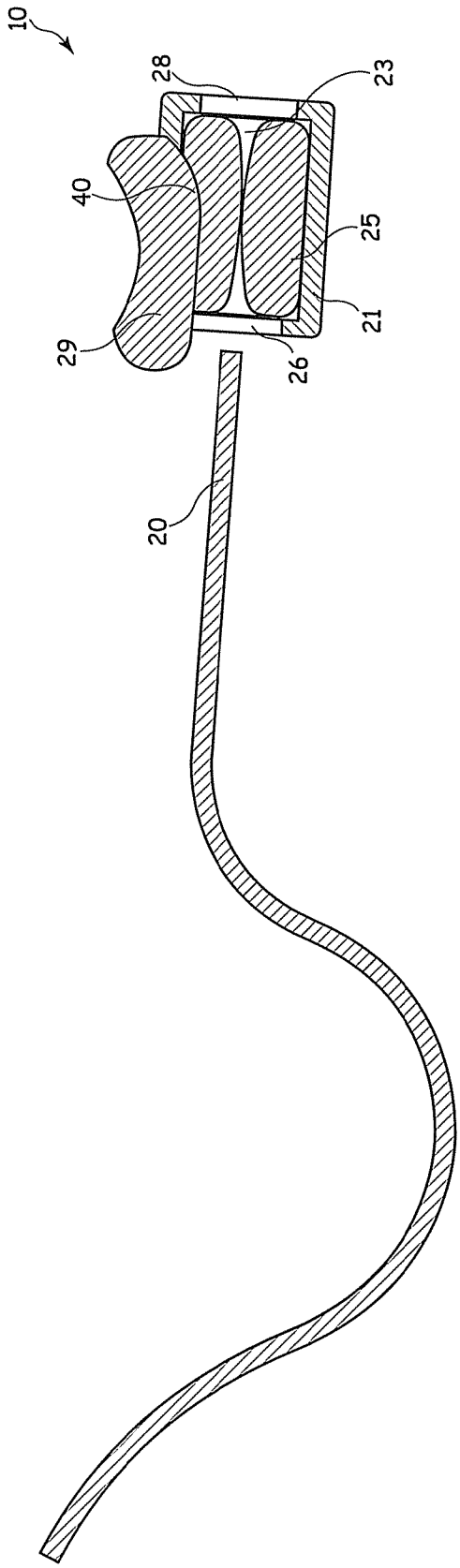

Figure 8

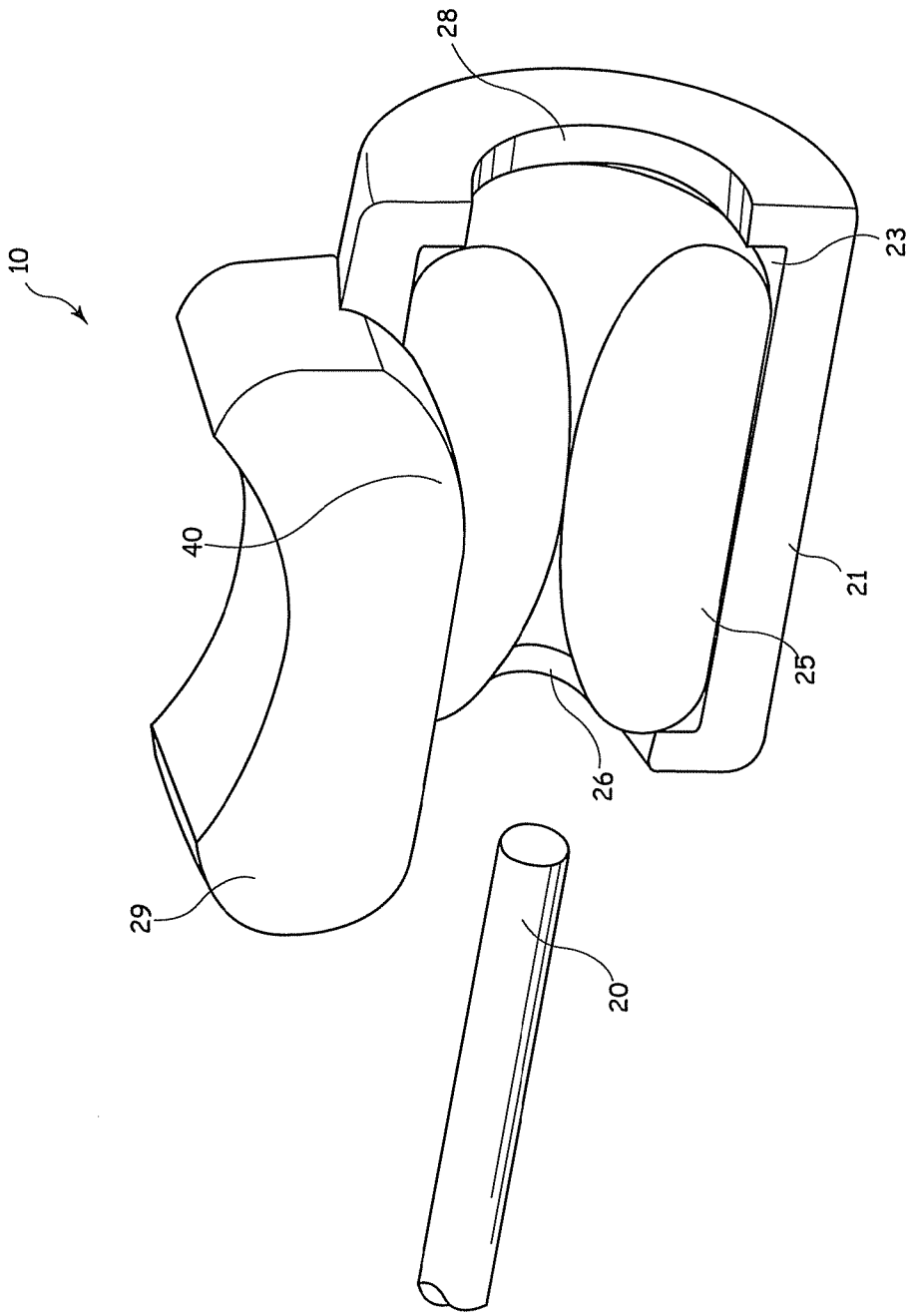

Figure 9

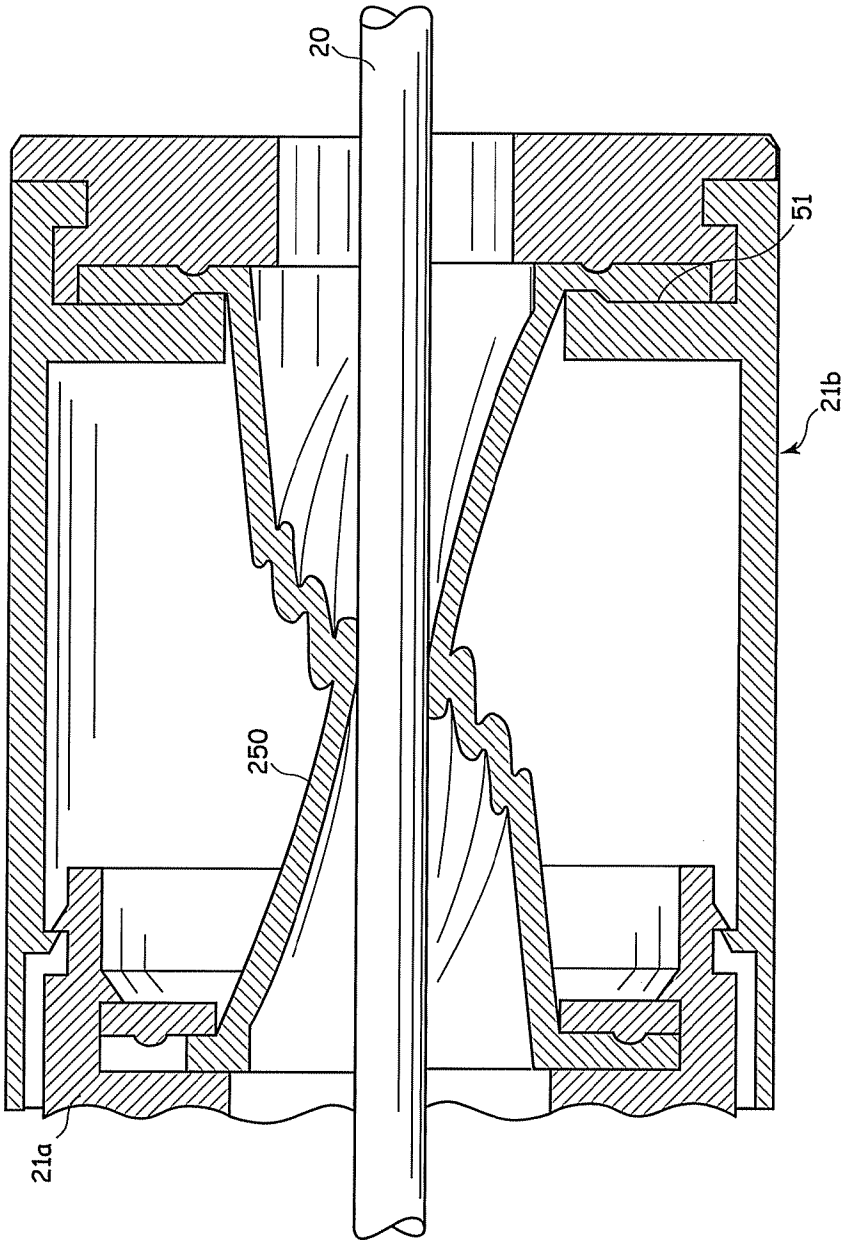

Figure 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/055700

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M39/06

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)
A61M

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 practical, 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	US 5 556 387 A (MOLLENAUER KENNETH H [US] ET AL) 17 September 1996 (1996-09-17) abstract claim 1 figures 6,7-9,10-12 column 11, lines 8,9 column 12, line 42 - line 59	1-16
X	US 5 071 411 A (HILLSTEAD RICHARD A [US]) 10 December 1991 (1991-12-10) abstract figures 1-10	1-16
X	US 3 977 400 A (MOOREHEAD HARVEY ROBERT) 31 August 1976 (1976-08-31) abstract figures 1-7	1-16

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

[X] See patent family annex.

* Special categories of cited documents :

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 February 2010	22/02/2010

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/055700

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/009171 A1 (UNIV GOETTINGEN GEORG AUGUST [DE]; HUSCHMAND NIA ABDOLHAMID [DE]) 29 January 2004 (2004-01-29) abstract figures 1-7	1-16
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Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/055700

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