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(54) **Title**: DEVICE FOR SEALING PERFORATIONS IN BLOOD VESSELS

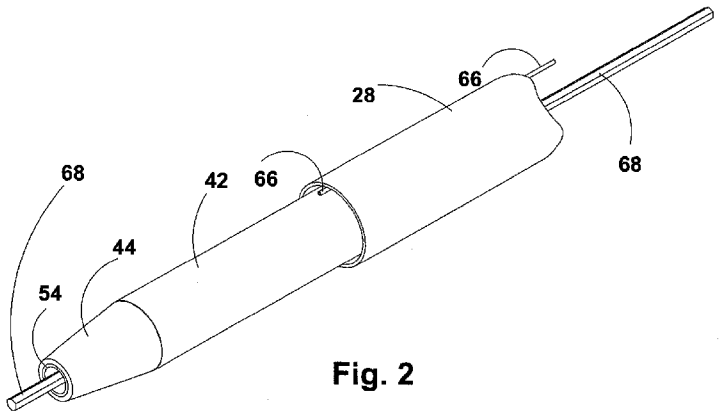

Fig. 2

(57) **Abstract**: A device useful in dealing with perforations in blood vessels and heart, including a probe having a distal end, an actuation console to which the proximal end of the probe is connected. The probe includes three coaxial cylindrical tubes each having an even diameter, all being concentric at least in one section of the probe. One of those tubes, having the smallest diameter, is attached firmly to a sleeve at its distal end. Another one of these tubes, referred to as the enveloping tube is the one tube with largest diameter yet reaching distally not as far as the distal end of the intermediate tube. Between those two tubes, a third coaxial one, is an intermediate tube having a diameter size measuring between that of the smallest diameter tube and that of the enveloping tube. A free tubular space exists between the intermediate tube and the enveloping tube, another property of the intermediate tube is that it is always static longitudinally respective of the console. A collapsible balloon, toroidal when inflated, further characterized as being slidable along a distal portion of the intermediate tube, firmly attached to the end of the enveloping tube. A feed tube, not coaxial with the probe, occupies some of the free tubular space, running alongside the intermediate tube externally from the console and reaching the distal end of the enveloping tube to optionally feed the balloon. The sleeve is capable of shape shifting from conical state, basically to such a state that its diameter grows bigger at the expense of its length, upon compression when the inner tube is pulled

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WO 2013/132493 A1

back towards the console. Two kinetic energy storing elements one for applying a pull on the inner tube towards the console, and another one for pushing the enveloping tube towards the distal tip of the probe, and with it the balloon attached to it, and a device for feeding the balloon with gas or liquid through the feed tube in order to inflate it.

DEVICE FOR SEALING PERFORATIONS IN BLOOD VESSELS

CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

This application claims priority from provisional patent application number 61608127 filed March 8, 2012 entitled "device for sealing perforations in blood vessels".

FIELD OF THE INVENTION

The present invention is a medical tool with an aim of plugging or closing apertures in blood vessels, heart or other organs. The tool is to be used in traumatic medical practices as well as in planned operations, typically during laparoscopic medical procedures.

BACKGROUND OF THE INVENTION

Devices manufactured for providing rapid solution or otherwise deal with haemorrhagic situations resulting from traumatic perforations or the occurrence of raptures in a blood vessel are well known. Examples with variants are disclosed in International patent application WO 2010/128469 A. As an example of commercially existing devices for treating vascular trauma or products in the process of preparing for commercializing, is "Temporary limb salvage shunt" by Vascutek LTD, Newmains Avenue, Inchinnan Industrial Estate , Renfrewshire, Scotland, PA4 9RR UK., as appears in FDA 510 (k) summary, number K070323. Other devices used in medicine are collectively known as "occluders", usually deployed in the body to seal off unwanted perforations in the heart. Among these Amplatzer® septal occluder is well known (see US Food and Drug Administration, medical devices, devices and medical procedures, device approval and clearances, PMA number P000039) it is used as an implant in the heart, including two mesged discs introduced by a delivery system. When the implant is set in place, the scenraio continues as

the tissues grow over the implant, forming a part of the heart, sealing the defective opening.

BRIEF DESCRIPTION OF THE DRAWINGS

[001] The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the appended drawings in which:

Figs. 1A-D are isometric descriptions of the distal end of the probe of the tool of the invention ;

Fig. 2 is an isometric description of the tip of the probe of the tool of the invention;

Figs 3A - B are isometric descriptions of the association of the balloon with the probe ;

Figs 3C - D are isometric descriptions of the deployment aspects relating to the balloon and discoid ;

Fig. 4 is an isometric description of the pumping mechanism for inflating the balloon;

Figs 5A - C are isometric descriptions of the internal components of the console and probe in steps of the deployment of the probe;

Figs 6A - B are isometric descriptions of the internal components of the console showing two spring types deployed in one functional device.

DESCRIPTION OF EMBODIMENTS OF THE INVENTION

A typical tool in accordance with the invention includes an actuation console and a probe. The tool is utilizable in medical practices such as sealing traumatic perforations or planned incision in blood vessels, heart and other

tissues. Additionally the tool is usable in emergency medicine, either in general laparoscopic or endoscopic surgery or in the field in general.

The probe :

In **Figs 1A - D** some details of the probe of the tool of the invention are shown. The distal end **24** of the probe **26** is the end that contacts the body of the treated individual. Enveloping tube **28** is a longitudinal cylindrical tube that harbours in its lumen several other longitudinal components of the system as will be described below, the distal portion of it is shown. Intermediate tube **42** is coaxial with enveloping tube **28** and somewhat smaller in diameter, at the distal end of which sleeve **44** is located, tapering towards the end. In **Fig. 1B** at the distal end of the probe, sleeve **44** is shown removed from its operational location, exposing inner cylindrical tube **54**. Inner tube **54** is coaxial with enveloping tube **28**. At **Fig. 1C**, in one embodiment, at the extreme end of inner tube **54** retracting ring **48** is connected. In embodiments in which retracting ring **48** is absent, the tapering tip of sleeve **44** is glued or otherwise firmly attached to the end of inner tube **54**. In **Fig. 1D** sleeve **44** is shown compressed, as a result of the compression effected by inner tube **54** in the direction of arrow **64**, forming a discoid bulge and reaching as far as the distal end of intermediate cylindrical tube **42**. At **Fig. 2**, a closer view of the tip of the probe of the invention is shown, at the distal end (the side proximal to the patient), sleeve 44 is substantially flush with the end of inner tube **54**. Guide wire **68** is an optional component that runs through the entire length of the probe, in the lumen of inner tube **54** and is extendable out said lumen distally. A role of the guide wire is to help insert the distal end of the probe inside a rupture in a vessel and ruptures/perforations in other organs of the body. Balloon feed tube (BFT) **66** runs from the console in the lumen of enveloping tube **28** is not coaxial with the probe, its function will be explained below. In Fig. **3A** the distal end of the probe is shown, with sleeve **44**, the face of inner tube **54**, intermediate tube **42**, BFT **66** and enveloping tube **28**. In **Fig. 3B**, balloon **70** is shown, somewhat inflated. The orifice, not shown here, of BFT **66** opens into the lumen of balloon **70**. It is noted at this point that the balloon in firmly attached to the distal end of enveloping tube **28**, or even best

described as being an integral part of the distal part of tube **28**. The balloon is slidable, either touching or non touching on intermediate tube **42**. In **Figs 3C – D**, balloon **70** is shown assuming two somewhat different shapes, in **Fig. 3C** the balloon appears as having a toroidal shape and in **Fig. 3D** the balloon is still toroidal but is more spherically shaped. In this figure, the two shape shifting modules in the tool of the invention are deployed, namely conical sleeve **44** is compressible to form a discoid, and concomitantly or subsequently balloon **70** is inflated causing tight seal of vessel's rupture/perforation from both inner and outer sides. In **Fig. 4B** BFT **66** which is the tube that reaches the lumen of balloon **70** to facilitate the inflation of the balloon from the user side. To summarize major properties of the tubes that make up the probe, all three are coaxial and even diameter all along, featuring free tubular space in between adjacent tubes, and a cylindrical lumen in the axial zone.

Syringe **74** is shown with is spout connected to tubing **76** which is a functional continuation of tubing **66**. By pressing syringe **74**, air, gas or a suitable liquid is passed from the syringe to balloon **70** inflating it if the force required to do so is obtained by the pressure applied by the syringe. The syringe can be activated manually or by applying mechanical, electric or hydraulic actuators. The syringe is a simple device readily available, but any suitable pump is applicable for use as a balloon inflating device in this tool .

Deployment of the probe and structural aspects

As described above, the sleeve is retracted and forced into a discoid by the movement of the inner tube towards the proximal direction, towards the user. This step is however typically reversible and the inner tube can be pushed forwards again, with a subsequent quenching of the discoid re-forming a sleeve. Typically, a full deployment of the probe of the invention is a procedure involving a sequence of three step. In step one, the sleeve is contracted forming a sealed discoid stopper for permitting sealing of a perforation in a vessel or other organ from the inner side. In step two, the deflated balloon is slid on or about the surface of the intermediate tube towards the discoid, and in step three, the balloon is inflated providing close

and tight sealing of the perforation in the blood vessel or other organ, by securing the perforation from the inner as well as the outer sides. More pictorial explanations of the deployment procedure are presented in **Figs 5A - C**. In **Fig**. **5A** collar **112** of the inner tube **54** holds a contracted spring **114**. Balloon **70** is deflated and sleeve **44** is quenched. At this state the probe can be inserted into a perforation or a vessel. Once the tip has been inserted in, let's say, a perforation, spring **114** is released by for example pressing a trigger (not shown). Collar **112** is urged by spring **114** to move in the direction of arrow **118**. As a result inner tube **54** moves towards the console and sleeve **44** comresses against the distal end of the intermediate tube lengthwise (in the direction of the probe) and spreads sideways, forming a vertically disposed discoid. At this state discoid **44** can practically be set against a perforation in a blood vessel for example. At this stage, spring **120** is contracted. In **Fig**. **5C**, collar **124** is released, spring **124** expands horizontally in the direction of arrow **128**, pushing collar **124** and the attached enveloping tube **28** with it in the direction of arrow **128**, pushing balloon **70** in the same direction, sliding over or touching intermediate tubing **42**. Therefore intermediate tube remains static with respect to console **134** throughout the deployment. At this stage, step three of the deployment is realized, by activating pump **74** to inflate balloon **70** (in this drawing shown quenched. As a general comment for these drawing (**5A-C**), the probe could be also much longer in reality with respect to the console for example for the use in laparoscopic and thoracoscopic and endoscopic procedures. For the sake of convenience it was drawn as if the probe is much shorter. In the ongoing description of **Figs 5A-C** the properties of the springs lends themselves readily to store kinetic energy when they are compressed, for example in **Fig**. **5C** both springs are shown compressed, ready to deliver their kinetic energy when released. In other embodiments, if other type of spring is used, for example tension spring in which the kinetic energy is stored when the spring is stretched rather than contracted, the arrangement of the spring/s is different as can be seen in **Figs**. **6A-B**. In **Fig**. **6A**, spring **114** is there no more, leaving an empty space **174** and instead, spring **172** is to be seen deployed to the left of collar **112** (compare with **Fig**. **5A**). In **Fig**. **6A** spring is stretched,

having stored potential energy that is delivered as kinetic energy when the spring is released. A released form of coil **172** is seen in **Fig. 6B** (to be compared with **Fig. 5B**). The same principle can be applied to the other spring in the system or to both springs. Moreover, instead of springs, elastic structures can be used as kinetic energy storing element other than springs, such as rubber structures, or plastic resin structures. Another possibility is to use pneumatic ("gas") struts which employ compression of gas as kinetic energy source. Indeed any kinetic energy storing element can be used to drive the tubes as described above providing they can move the mechanical structures in the geometrical constraints as dictated by the structural specifications.

Materials and additional properties of the tool of the invention

The sleeve, or discoid of the invention are preferably made from braided medical fiber, as known in the art. Typically, the braided fibers forming a mesh of some sort, are impregnated with an impervious material such as a resin or rubber, as known in the art. Otherwise, the braided fibers can be completely covered by a plastic resin extruded cap that fits the area of the discoid. Additionally for some uses, the sleeve together with impregnated material are made of biodegradable materials (such as polyglycolic acid fiber) in order to facilitate leaving the sleeve inside the body for specific uses and allow for its disappearance by gradual absorption in the body. In such cases as the sleeve is to be left inside the patient, it may become necessary to engage the sleeve more strongly into the tissues of the patient, such as by suturing or gluing. The sleeve should not necessarily form a discoid upon contracting, other forms can be designed to suit different type of openings in the vessels. In a similar line of versatility, instead of a balloon at the distal end of enveloping tube **28**, a shape shifting element rather in the form of sleeve 44 may be employed. Mechanically it may function without the need for a pump but rather be in a semi-stable state that when activated it would promptly change shape from a cylindrical/conical state to a spread out state, very similar to an umbrella.

Some mechanical aspects of the probe

Optimal flexibility of the probe is a parameter that depends on the intended use of the probe. For example for endoscopic and laparoscopic uses greater flexibility at the distal part of the probe is advantageous than as required for other trauma treatments. In one aspect of the invention, the distal part of the probe is more flexible than the proximal part. This distribution of mechanical properties along the length of the probe allows the probe to be pushed forcefully forwards, yet at the distal part, some flexibility is bestowed, for example for fine tuning the placement of the tip by another tool, without manoeuvring of the entire probe.

Deployment scenarios

In one scenario, the probe is pushed through a perforation in a blood vessel. When the tip is definitely inserted inside the vessel, step one is invoked in which the discoid is formed from the sleeve by applying compression on the sleeve. A protective structure on the inner side of the rapture in the vessel is created. Then, the balloon is brought up to a proximity of the vessel by invoking step two. Then, at step three, the balloon is inflated closing in on the perforation. The discoid is flattened, the punctured vessel is sutured, and the discoid released from the tip completely and the balloon and the rest of the probe pulled back. In another scenario, while the discoid - balloon couple is stopping the perforation, two temporary endoscopic vessel clips, or tightening bands are applied to the damaged vessel each on a respective side of the damaged vessel, stopping the blood transport in the vessel. The clips are such as offered under the code PL522R, by Aesculap Inc, of 3773 Corporate Parkway Center Valley, PA 18034, USA. Instead of clips constricting bands may be used. When this is accomplished, the discoid is quenched by pushing the inner tube forwards (in the direction away from the console), and the tip can be removed from the now dry vessel. After which the perforation can be sutured, and subsequently compressing on both sides released. In another scenario, when the probe of the invention is fully deployed the vessel is sutured with the discoid inside, after which the discoid is detached from the probe without reverting to a flattened quenched position.

The lumen of the inner tube of the probe can be used to pump in air or liquid to clear away obstructing material from the locus of operation. Therefore it can be used to introduce fluid into the blood vessels during surgery. Reversely, the same lumen can be used to suck in liquids from the locus of operation, usually for clearing obstructing fluids, usually blood. The suction action can be achieved by connecting the inner tube at its proximal end to a vacuum pump or to an existing suction machine using an adaptor. Nevertheless, fluids can be delivered to the locus of intervention rather than sucked to achieve clearing of debris or obstructing matter, saline is an obvious candidate fluid in such cases.

CLAIMS

1. A device useful in dealing with perforations in blood vessels and heart, comprising:

- a probe having a distal end;
- an actuation console to which said proximal end of said probe is connected;
- said probe comprising three coaxial cylindrical tubes each having an even diameter, all being concentric at least in one section of said probe,
- wherein one of said tubes, having the smallest diameter, is attached firmly to a sleeve at its distal end, and wherein another one of these tubes, referred to as the enveloping tube is the one tube with largest diameter yet reaching distally not as far as the distal end of said intermediate tube, and in between said two tubes, a third coaxial one, is an intermediate tube having a diameter size measuring between said smallest diameter tube and said enveloping tube, such that a free tubular space exists between said intermediate tube and said enveloping tube, another property of the intermediate tube is that it is always static longitudinally respective of said console;
- a collapsible balloon, toroidal when inflated, further characterized as being slidable along a distal portion of said intermediate tube, firmly attached to the end of said enveloping tube;
- a feed tube, not coaxial with said probe, occupies some of said free tubular space, running alongside the intermediate tube externally from said console and reaching the distal end of said enveloping tube to optionally feed said balloon;
- said sleeve capable of shape shifting from conical state, basically to such a state that its diameter grows bigger at the

expense of its length, upon compression when said inner tube is pulled back towards the console;

- two kinetic energy storing elements one for applying a pull on said inner tube towards said console, and another one for pushing said enveloping tube towards the distal tip of said probe, and with it the balloon attached to it, and
- a device for feeding said balloon with gas or liquid through said feed tube in order to inflate said balloon.

2. The device according to claim **1**, wherein said sleeve can be shape shifted from conical in the quenched state to high diameter discoid shape when inner tube moves towards the console.

3. A device according to claim **1**, wherein a guide wire is located inside the cylindrical lumen of the inner tube, and is extendable out of said lumen distally.

4. A device according to claim **1** wherein said sleeve is made from braided medical fiber.

5. A device as in claim 4, wherein said braided medical fiber is impregnated with impervious material.

6. A device as in claim 4, wherein said braided medical is made of biologically degradable material.

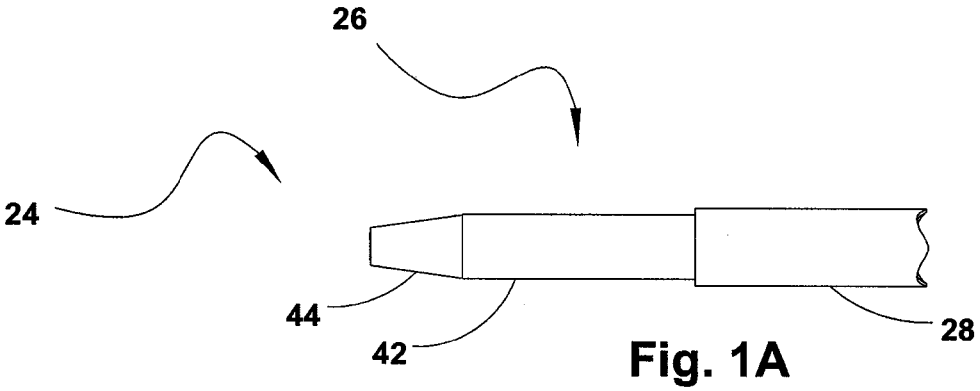

Fig. 1A

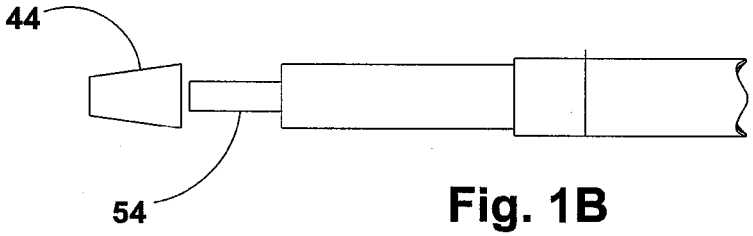

Fig. 1B

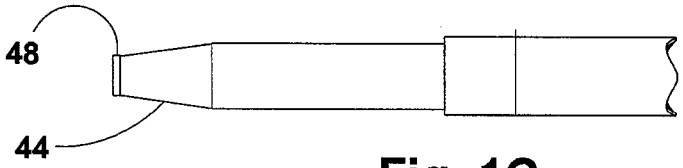

Fig. 1C

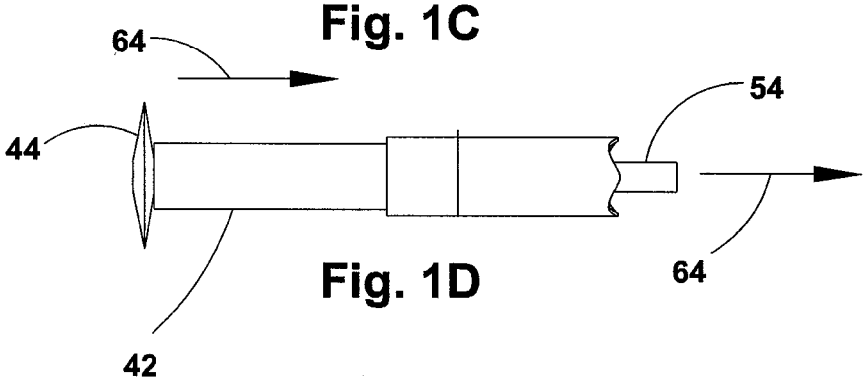

Fig. 1D

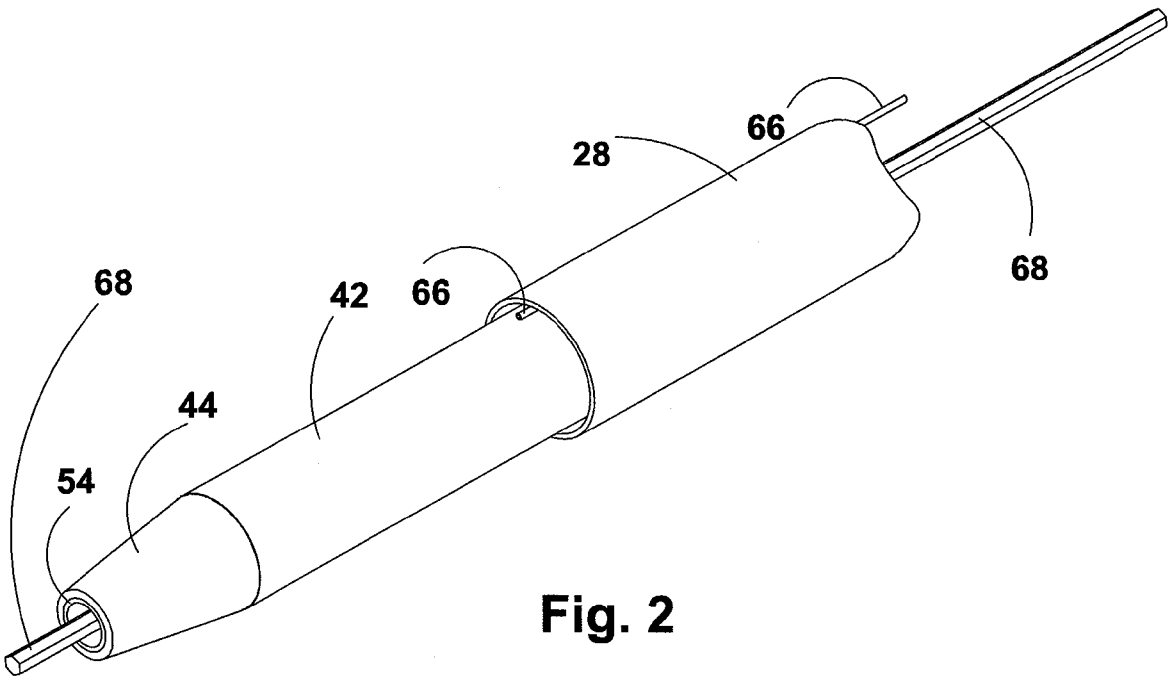

Fig. 2

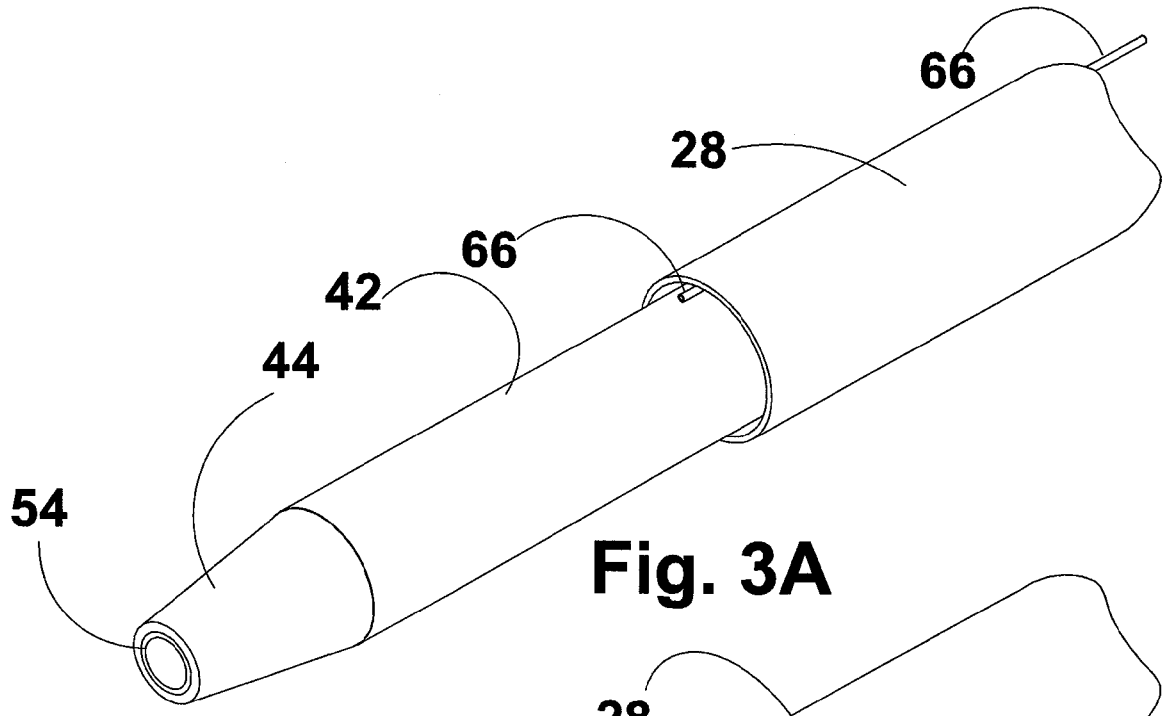

Fig. 3A

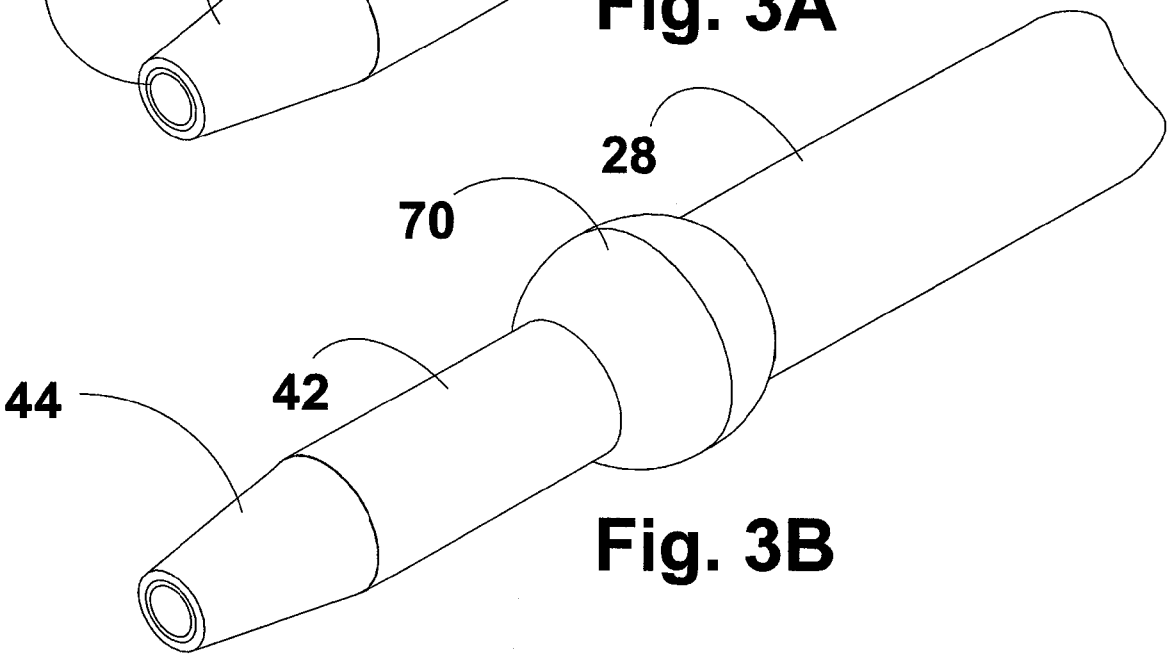

Fig. 3B

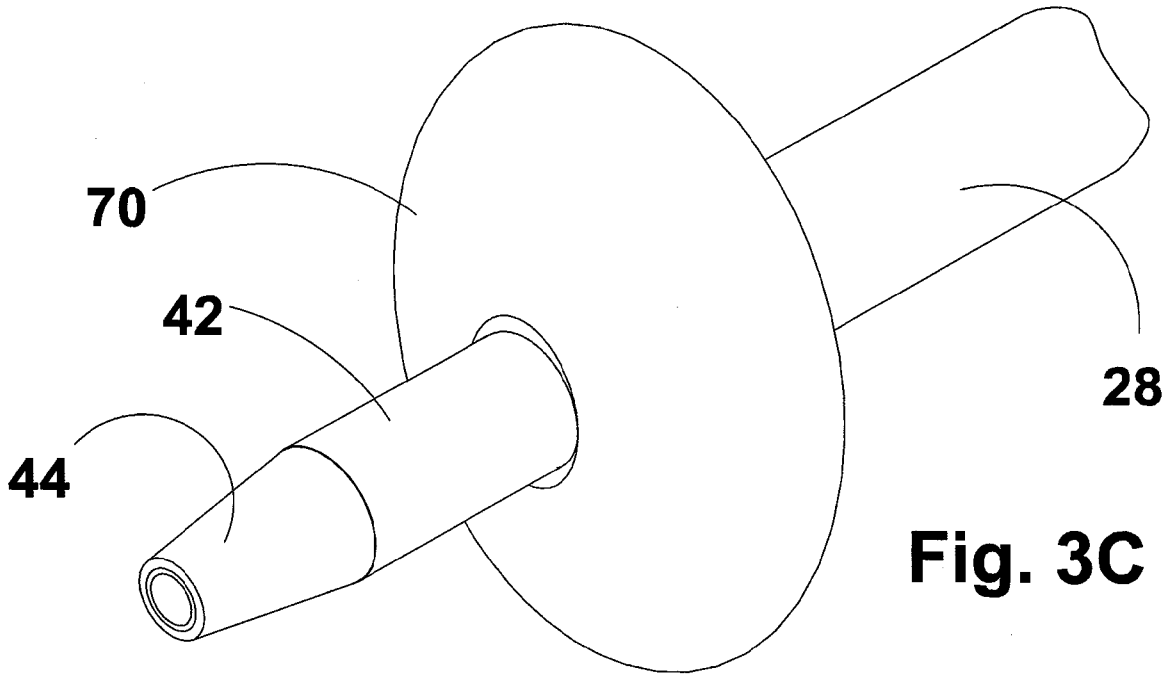

Fig. 3C

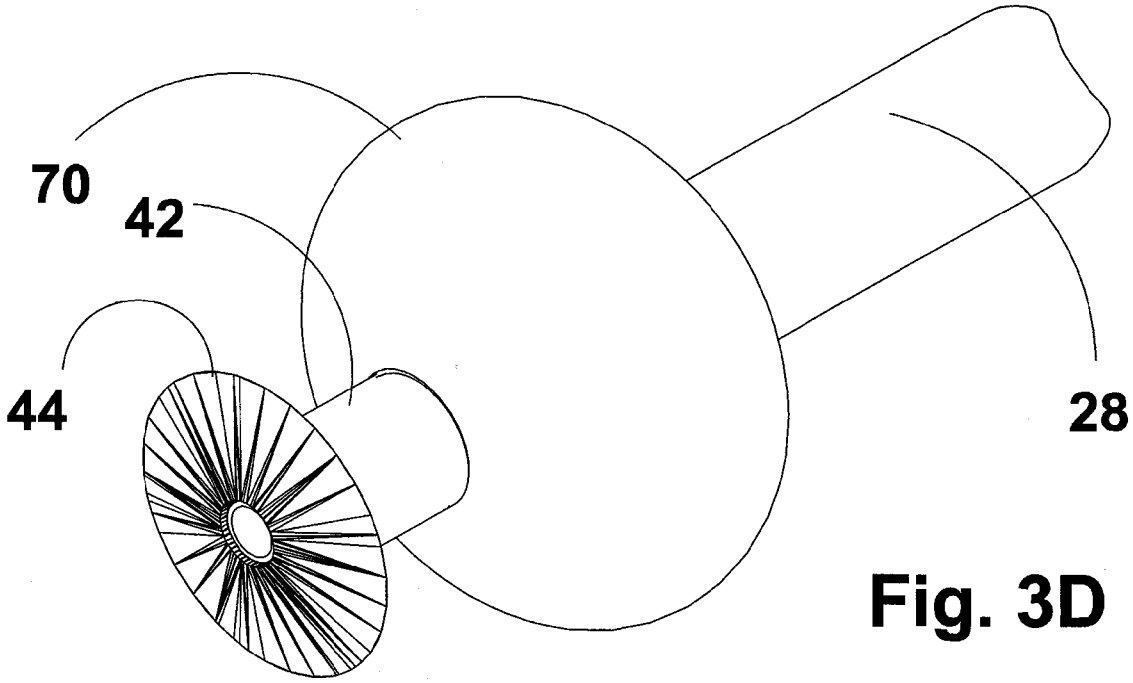

Fig. 3D

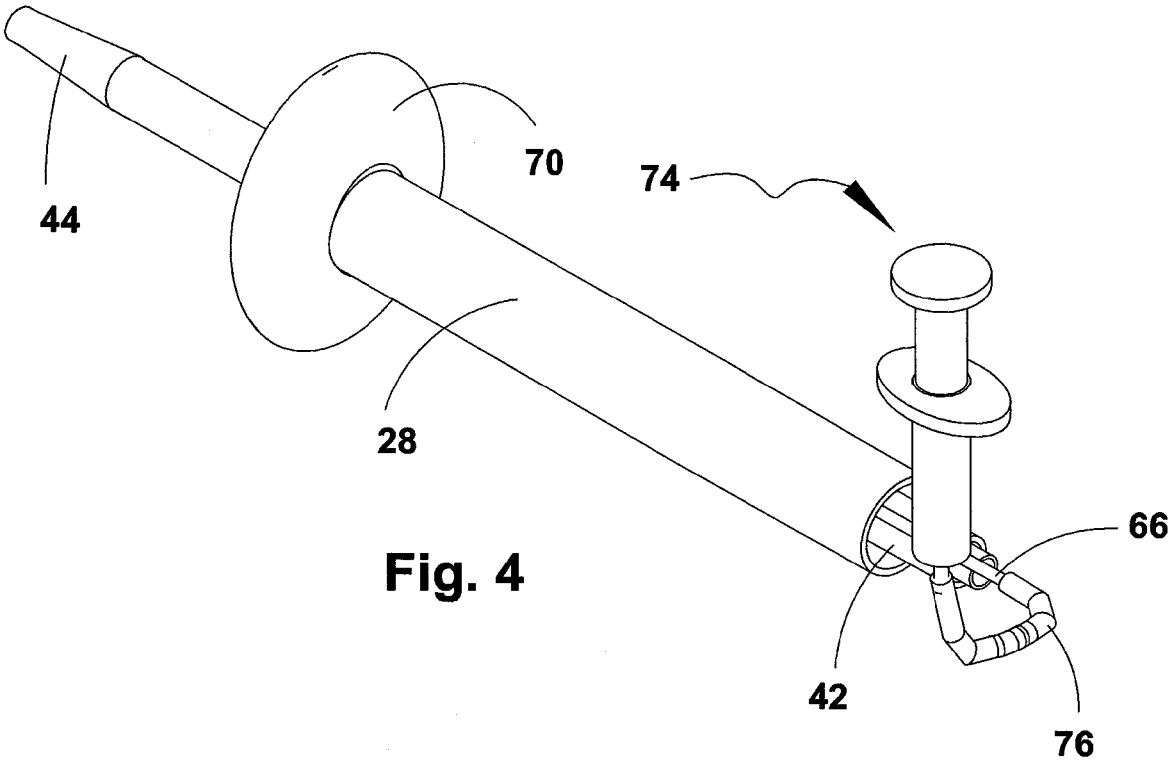

Fig. 4

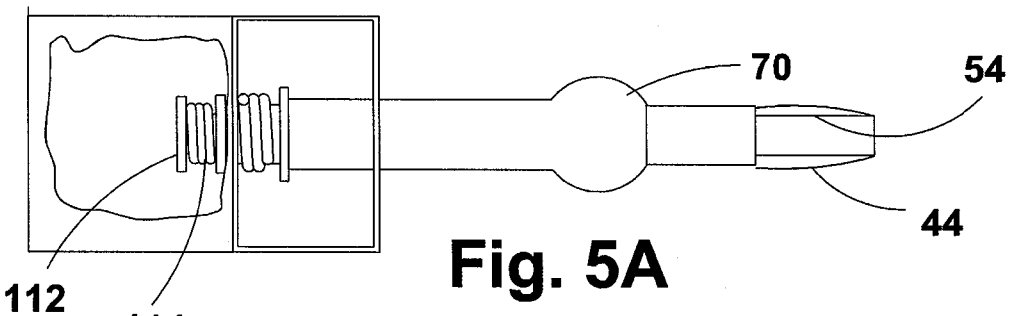

Fig. 5A

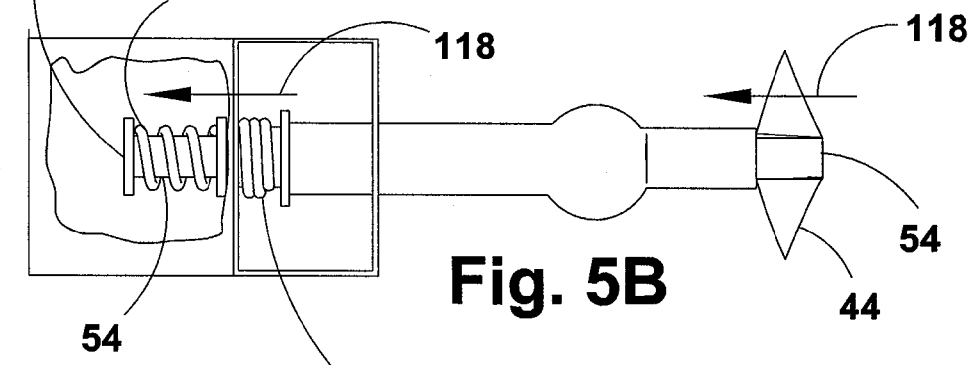

Fig. 5B

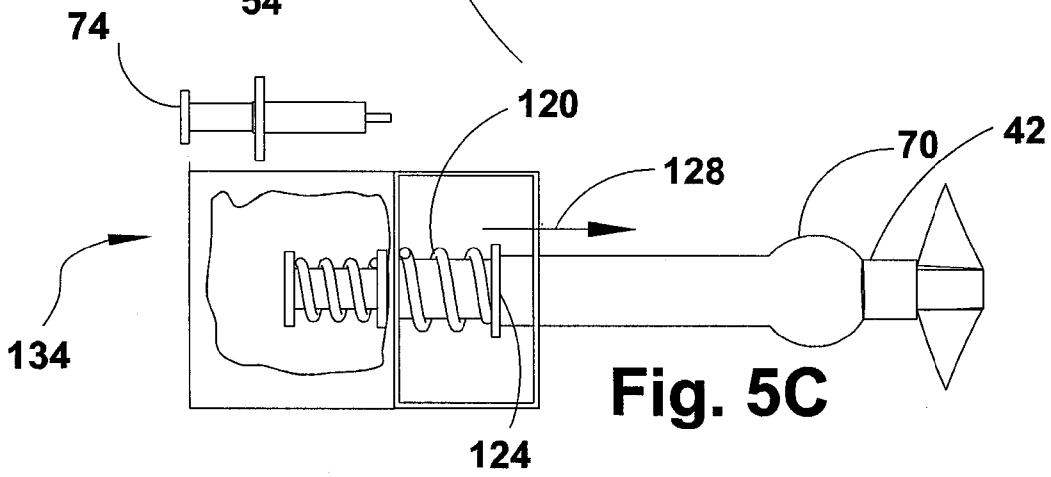

Fig. 5C

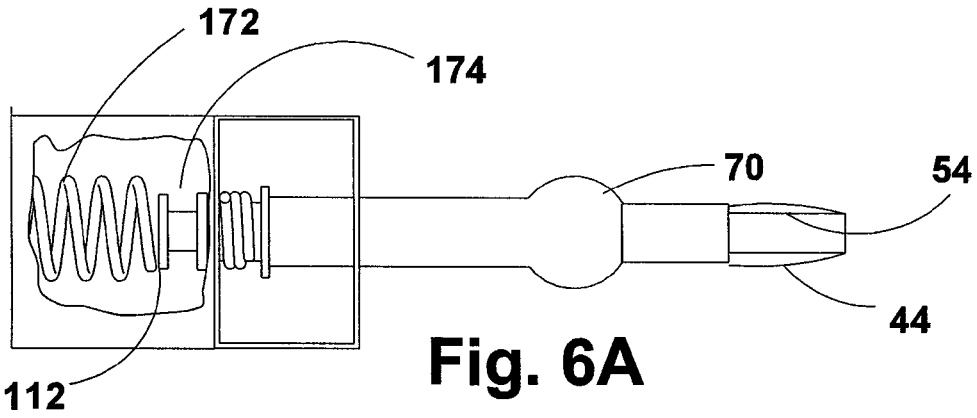

Fig. 6A

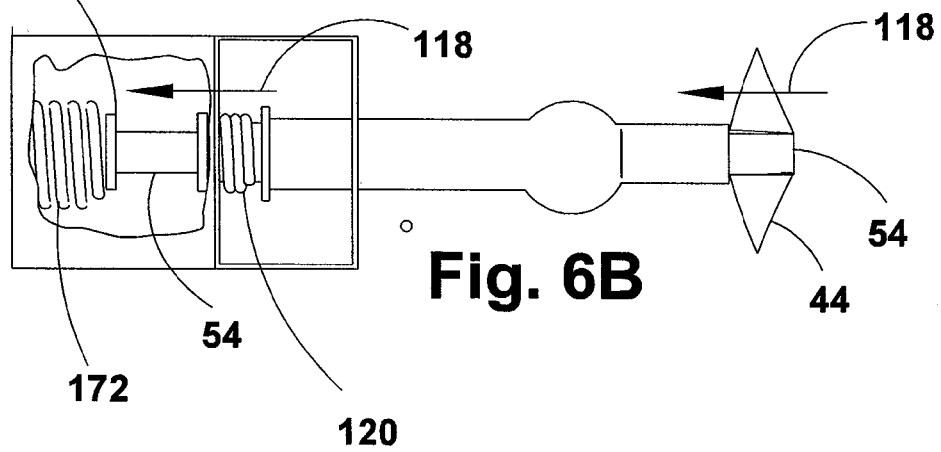

Fig. 6B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2013/050207

A. CLASSIFICATION OF SUBJECT MATTER
IPC (2013.01) A61B 17/00

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)
IPC (2013.01) A61B, A61F, 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 practicable, search terms used)
Databases consulted: THOMSON INNOVATION, Google Patents
Search terms used: perforat*, punctur*, raptur*, incision, access, vessel, intraluminal, vascular, organ, heart, seal*, closure, plug, ballon, inflated, toroidal, movable, slid*

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	FR 2607706 A1 LEFEBVRE JEAN MARIE 10 Jun 1988 (1988/06/10) the whole document	1-6
Y	WO 2010128469 A1 DELIVERANCE LTD 11 Nov 2010 (2010/11/11) the whole document	1-6
Y	EP 2275041 A1 TYCO HEALTHCARE 19 Jan 2011 (2011/01/19) figures 5-6, paragraph [0044]	1

☐ Further documents are listed in the continuation of Box C. ☒ 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
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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
04 Jul 2013	08 Jul 2013
Name and mailing address of the ISA: Israel Patent Office Technology Park, Bldg.5, Malcha, Jerusalem, 9695101, Israel Facsimile No. 972-2-5651616	Authorized officer LEVI Moria Telephone No. 972-5651753

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专利名称(译)	用于密封血管穿孔的装置		
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摘要(译)

本发明涉及一种使用该装置处理组织（例如血管和器官）中的穿孔的装置和方法。该装置包括具有内部构件和可在内部构件上滑动的外部构件的主体，可操作地连接到内部构件的远侧构件，其中远侧构件具有缩回和展开构造。该装置还包括近侧构件，该近侧构件可操作地联接到外部构件并且具有缩回构造，其中近侧构件基本上平坦地抵靠主体和展开构造。该装置可用于创伤医疗实践，无论是在现场，还是在紧急和/或手术室中。特别地，该装置可以用于计划的一般和/或微创手术，例如在腹腔镜，胸腔镜和其他可能已经引起医源性主要血管损伤的微创手术期间。