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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 December 2009 (03.12.2009)

PCT

(10) International Publication Number
WO 2009/144728 A1

(51) International Patent Classification:
A61B 17/11 (2006.01)

(21) International Application Number:
PCT/IL2009/000535

(22) International Filing Date:
31 May 2009 (31.05.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/071,962 28 May 2008 (28.05.2008) US

(71) Applicant *(for all designated States except US)*: **SEAM-VAD LTD.** [IL/IL]; Building 1.1, High-Tech Village, Givat Ram Campus, The Hebrew University, Jerusalem 91391 P.O. Box 39158 Israel (IL).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **PAZ, Ronen** [IL/IL]; P.O.Box 2250, 31021 Haifa (IL). **HEICHAL, Yoav** [IL/IL]; 4 Hanarkis Street, 56905 Ganey Yehuda (IL).

(74) Agent: **REINHOLD COHN AND PARTNERS**; P.O.Box 13239, 61131 Tel Aviv (IL).

(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, 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, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) **Title**: ANASTOMOSIS DEVICE

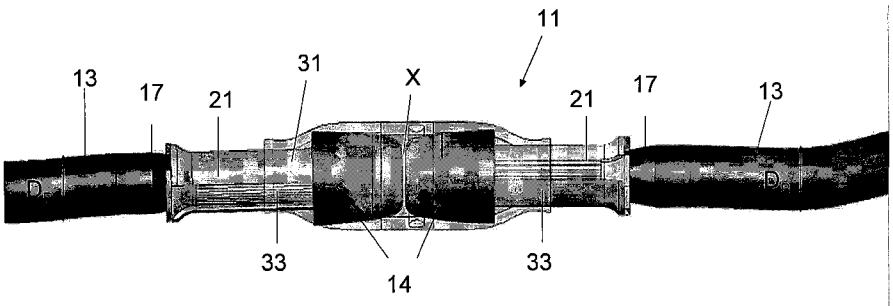

Fig. 1A

(57) **Abstract**: An anastomosis device (11) for use in coupling two ends of tubular stumps (13). The device comprises two hollow tubular members (21), adapted to be placed over said tubular stumps. The hollow tubular members are further capable of radially expanding from a first inner diameter to a second, larger inner diameter. Each hollow tubular member, while having the first inner diameter, being further adapted to allow everting of the stump proximal end over the tubular member proximal end. The device further comprises an elastic sleeve (31), adapted to be put on said tubular member proximal ends with the everted ends of said stumps, the sleeve further being adaptable to maintain said everted ends in a predetermined distance.

WO 2009/144728 A1

ANASTOMOSIS DEVICE

FIELD OF THE INVENTION

This invention relates to a device and a method for end-to-end anastomosis of tubular structures.

BACKGROUND OF THE INVENTION

An anastomosis is an operative union of two hollow or tubular structures. Anastomotic structures can be part of a variety of systems, such as the vascular system, the digestive system, or the genitourinary system. An anastomosis is termed end-to-end when the terminal portions of tubular structures are anastomosed.

A wide variety of anastomosis devices and methods have been developed for anastomosing ends of living vessels. End-to-end anastomosis may be accomplished either by suturing, stapling or mechanical coupling. Suturing is generally difficult to perform, especially when very small vessels are involved, and requires great skill and experience on the part of the surgeon. Stapling and mechanical coupling of blood vessels has been suggested to avoid the disadvantages of suturing, and to provide a faster, more reliable and relatively simple method of anastomosis.

US 4,214,586 discloses a three-piece anastomotic coupling device for end-to-end anastomosis of tubular members consisting of two open bore cylindrical adaptors and an open bore cylindrical connector. Each end of a tubular member is passed through the axial bore of an adaptor and everted over the end thereof. The adaptors are then inserted into opposite ends of the connector until the everted ends of the vessel abut under light compression. Integral locking means are provided to secure the adaptors and tubular members of the connector piece.

US 4,470,415 discloses a means and method for sutureless surgical anastomosis. A heat shrinkable sleeve is placed around two tubular members to be anastomosed and then shrunk to engage and maintain the two tubular members in an anastomotic relationship. The ends of the tubular members are everted over rigid or semi-rigid ferrules placed on the ends of the tubular members.

SUMMARY OF THE INVENTION

In accordance with one aspect of the present invention there is provided a device for anastomosis of a first and a second tubular stumps, each having a stump proximal end, each of said tubular stumps further having a shrunk outer diameter in their shrunk state and an expanded outer diameter in their expanded state. The device comprises a first and a second hollow tubular member, adapted to be placed over said first and second stumps, respectively. Each hollow tubular member has a tubular member proximal end, a tubular member middle section, a first inner diameter, which is at least equal to said shrunk outer diameter, and a second inner diameter, which is at least equal to said expanded outer diameter. The hollow tubular members are further capable of radially expanding from said first inner diameter to said second inner diameter. Each hollow tubular member, while having the first inner diameter, being further adapted to allow everting of the stump proximal end over the tubular member proximal end. The device further comprises an elastic sleeve having two sleeve ends, adapted to be put on said tubular member proximal ends with the everted ends of said stumps, the sleeve further being adaptable to maintain said everted ends in a predetermined distance.

The hollow tubular members are adapted to be expanded due to an expansion of said stumps from said shrunk state to said expanded state, and may be expanded to at least twice its original diameter. The hollow tubular members may comprise at least two segments, each segment partially overlapping with its neighboring segments, to create a diameter at least equal to said first inner diameter, and may further comprise restraining means for preventing it from having a diameter less than said first inner diameter, once the hollow tubular member is placed over said stump. Alternatively, the hollow tubular members may be prepared as a single body made of, for example, plastic polymer or metal allow.

The hollow tubular members may be expanded by a ratchet mechanism, a saw tooth mechanism, by means of spring or any other mechanism capable of expanding them to a desired diameter.

The hollow tubular members may further be X-ray, ultrasound or Doppler transparent and may be used with imaging techniques such as for example Computerized Tomography (CT), Magnetic Resonance Imaging (MRI) or Isotopic Scanning.

The elastic sleeve may further have at least one holding means for maintaining said everted ends in said distance, and is further adapted to cover the everted ends of the stumps and at least a part of the middle sections of the hollow tubular members.

The predetermined distance between the everted ends of the stumps is chosen so as to provide maximal healing. The distance may be in a range of 0 to about 5 mm, more particularly, in a range of about 0.5 mm to about 3 mm, more particularly about 2 mm. The term "about" in the context of the present invention means +/- 10% of the defined value. In one embodiment the distance is equal to zero (i.e. whereby the everted ends of the stumps are in contact with each other). Specifically, when the hollow tubular members are blood vessels, the distance between the everted ends allows the formation of a blood clot, which serves as a natural substrate for regeneration of the blood vessel wall. Without wishing to be bound by theory, allowing a space for generation of a blood clot mimics the natural course of events which occur following rupture of a blood vessel. Blood platelets play a key role in maintaining the integrity of the vascular system through their ability to arrest bleeding (haemostasis) and promote repair of injured blood vessels (Jackson et al., Trends Cardiovasc Med. 2000 Jul;10(5):192-7). The rupture of a blood vessel initiates a clotting procedure which initially prevents blood loss and subsequently provides both an infrastructure as well as suitable stimulants for gradual formation of blood vessel wall tissue, including the intima, media and serosa (adventitia).

The device may further comprise an applicator capable of at least placing the hollow tubular members over the stumps.

The device may further be drug eluting.

According to another aspect of the present invention, there is provided a hollow tubular member adapted to be placed over a stump having a stump proximal end, a shrunk outer diameter in its shrunk state, and an expanded outer diameter in its expanded state. The hollow tubular member comprises a tubular member proximal end, a tubular member middle section, a first inner diameter, which is at least equal to said shrunk outer diameter, and a second inner diameter, which is at least equal to said expanded outer diameter. The hollow tubular member is further capable of radially expanding from said first inner diameter to said second inner diameter, each hollow tubular member, while having the first inner diameter, being further adapted to allow everting of the stump proximal end over the tubular member proximal end.

According to another aspect of the present invention, there is provided a method of performing an anastomosis of a first and a second tubular stumps, each having a stump proximal end, and further having a shrunk outer diameter in its shrunk state and an expanded outer diameter in its expanded state, the method comprising:

- providing a device comprising a first and a second hollow tubular members, each having a tubular member proximal end, a tubular member middle section, a first inner diameter, which is at least equal to said shrunk outer diameter, and a second inner diameter, which is at least equal to said expanded outer diameter, said hollow tubular members further being capable of radially expanding from said first inner diameter to said second inner diameter; and an elastic sleeve having two sleeve ends;
- determining first inner diameter of the hollow tubular members;
- placing the first hollow tubular member over the first stump, while it is in its shrunk state;
- placing the second hollow tubular member over the second stump, while it is in its shrunk state;
- everting the proximal ends of the first and second stumps over the proximal ends of the first and second hollow tubular members, respectively;
- putting the sleeve ends on the corresponding proximal ends of the hollow tubular members with the everted proximal ends of the stumps; and
- maintaining the everted proximal ends of the stumps in a predetermined distance from each other.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, embodiments will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Figs. 1A and 1B schematically illustrate a device according to the present invention, with its tubular members in a partially shrunken and final expanded state, respectively

Fig. 2A is a schematic perspective view a hollow tubular member constituting a part of the device shown in Fig. 1;

Fig. 2B is a schematic front view a hollow tubular member constituting a part of the device shown in Fig. 1;

Fig. 3 is a schematic illustration of the hollow tubular member shown in Fig. 2 in different states;

Fig. 4 is a schematic illustration of the hollow tubular member shown in Figs. 2,3A and 3B, put over a blood vessel;

Figs. 5A and 5B schematically show an everting process according to the present invention;

Figs. 6A and 6B are illustrations a sleeve constituting a part of the device shown in Fig. 1.

DETAILED DESCRIPTION OF EMBODIMENTS

Fig.1A illustrates a device generally designated 11 for anastomosis of two blood vessels 13 having proximal ends 15 (shown in Figs. 4 and 5A). The device 11 comprises two hollow tubular members 21, described below, and an elastic sleeve 31 having two ends 33. The blood vessels have an outer diameter D_B, which may vary according to a state of the blood vessel 13. In its shrunk state the blood vessel 13 has a shrunk diameter, so that D_B=D_{SH} and in its expanded state the blood vessel 13 has an expanded diameter, so that D_B= D_{EX}, i.e. D_{SH} ? D_B ? D_{EX}.

Figs. 2A, 2B and 3 show the tubular member 21 in more detail. The tubular member 21 has a proximal end 23 of a frustum cone shape, a middle section 25 and a concave distal end 27, the shape of which lowers the risk of hurting the blood vessel. The tubular member has an inner diameter D_M (Fig. 2B) determined so as to fit the blood vessel. The tubular member 21 comprises three overlapping segments 29 and restraining means 20, such as for example a ratchet mechanism or saw tooth mechanism.

As shown in Fig. 3, the tubular member 21 is radially expandable. Consequently, D_M may vary between any desired initial diameter D_{IN} and any desired final diameter D_F, i.e. D_{IN} ? D_M ? D_F. Due to the restraining means 20 the tubular member 21 is prevented from shrinking to any diameter smaller than its current diameter. Therefore, the tubular member 21 can only expand outwardly (i.e. increase its diameter).

During operation, the tubular member 21 is assembled out of its segments 29 over the blood vessel 13, as shown in Fig. 4, while the blood vessel 13 is in its shrunk state and has the diameter D_{SH}. Alternatively, the tubular member 21 may be assembled out of its segments 29 prior to the procedure, so that during operation the blood vessel 13 is inserted through the tubular member 21.

The initial diameter D_{IN} of the tubular member 21 is then determined to be at least equal to the shrunk diameter D_{SH} of the blood vessel 13. As shown in Figs. 5A and 5B, the proximal end 15 of the blood vessel 13 is then everted over the proximal end 23 of the tubular member 21, the frustum cone shape of which facilitates the eversion, so that everted proximal end 14 of the blood vessel 13 tightly surrounds the proximal end 23 of the tubular member 21.

After the proximal ends 15 of the blood vessels 13 are everted over the tubular members 21, as shown in Figs. 1 and 6B, the elastic sleeve 31 (Fig. 6A) is put over the tubular members 21, first over one everted end 14 and then over the other. The elastic sleeve 31 is long enough to cover both everted ends 14 and at least parts of the middle sections 25 of the tubular members 21, in any diameter D_M that the middle section 25 may have. In this state, portions of the blood vessels 13 proximal to the tubular members 21 still have certain narrowing 17 relative to the diameter D_B.

The elastic sleeve 31 holds the blood the everted proximal ends 14 in the everted position. In addition, elastic sleeve 31 maintains the everted proximal ends 14 in any desired, predetermined distance X one from the other (Fig. 1). This may be achieved by stoppers, for example rings, situated within the elastic sleeve 31 and preventing the everted ends 14 from getting closer than the distance X. The stoppers may also be situated within the tubular members 21. The range of the distances X between the everted proximal ends 14 may be in a range of 0 to about 5 mm, more particularly, in a range of about 0.5 mm to about 3 mm, more particularly about 2 mm.

After the procedure described above is over, the blood vessels 13 return to their expanded state, due to the blood flow therethrough, as shown in Fig. 1B. According to the expansion of the blood vessels 13, the tubular members 21 also expand and their expanded diameter D_F corresponds to the expanded diameter D_{EX} of the blood vessels 13, i.e. D_F ? D_{EX}. The expansion of the tubular members 21 may occur as a result of the expansion of the blood vessels 13 or by other means, as will be further described. In this

state the blood vessels 13 has a uniform diameter D_B and no narrowing exits on portions thereof.

The dilatation of the blood vessel 13 may be performed by a balloon. In this case, the blood vessel 13 is expanded to at least twice its original diameter. Therefore, the tubular members 21, and consequently the elastic sleeve 31, are adapted to expand at least to the size allowing the insertion and the passage of the inflated balloon through the blood vessel 13. This expandable characteristic permits further increasing of tubular members 21 internal diameter, by means of forced balloon inflation within their lumen.

The device 11 may further be drug eluting, so that each of its components, namely, the tubular members 21 and/or the elastic sleeve 31 may be adapted to release drugs.

All the above described components of the device 11 may be made of inert materials such as silicon, latex, Teflon, Dacron, etc. The components may also be made of absorbent materials, such as polyglactin 910 (Vicryl).

The device 11, though described with reference to the vascular system, may be applicable to other systems of the human body, such as the digestive system or the genitourinary system.

Those skilled in the art to which this invention pertains will readily appreciate that numerous changes, variations, and modifications can be made without departing from the scope of the invention, *mutatis mutandis*.

CLAIMS:

1. A device for anastomosis of a first and a second tubular stumps, each having a stump proximal end, and further having a shrunk outer diameter in its shrunk state and an expanded outer diameter in its expanded state, the device comprises:

- a first and a second hollow tubular members, adapted to be placed over said first and second stumps, respectively, each having a tubular member proximal end, a tubular member middle section, a first inner diameter, which is at least equal to said shrunk outer diameter, and a second inner diameter, which is at least equal to said expanded outer diameter, the tubular members further being capable of radially expanding from said first inner diameter to said second inner diameter, each tubular member, while having the first inner diameter, being further adapted to allow everting of the stump proximal end over the tubular member proximal end; and
- an elastic sleeve having two sleeve ends, adapted to be put on said tubular member proximal ends with the everted ends of said stumps, the sleeve further being adaptable to maintain said everted ends in a predetermined distance.

2. A device according to Claim 1, wherein the tubular member comprises at least two segments, each segment partially overlapping with its neighboring segments, to create a diameter at least equal to said first inner diameter.

3. A device according to Claims 1 or 2, wherein the tubular member further comprising restraining means for preventing it from having a diameter less than said first inner diameter, once the tubular member is placed over said stump.

4. A device according to anyone of Claims 1 to 3, wherein the tubular member is adapted to be expanded due to an expansion of said stumps from said shrunk state to said expanded state.

5. A device according to anyone of Claims 1 to 4, wherein the sleeve further comprises at least one holding means for maintaining said everted ends in said distance.

6. A device according to Claim 1, wherein the sleeve is further adapted to cover the everted ends of the stumps and at least a part of the middle sections of the tubular members.

7. A device according to anyone of Claims 1 to 6, wherein said distance is between zero and about 5 mm.

8. A device according to Claim 7, wherein said distance is equal to zero.

9. A device according to Claim 7, wherein said distance is equal to about 2 mm.

10. A device according to anyone of Claims 1 to 9, wherein the device is drug eluting.

11. A hollow tubular member adapted to be placed over a stump having a stump proximal end, a shrunk outer diameter in its shrunk state and an expanded outer diameter in its expanded state, the tubular member comprises a tubular member proximal end, a tubular member middle section, a first inner diameter, which is at least equal to said shrunk outer diameter, and a second inner diameter, which is at least equal to said expanded outer diameter, the tubular members further being capable of radially expanding from said first inner diameter to said second inner diameter, each tubular member, while having the first inner diameter, being further adapted to allow everting of the stump proximal end over the tubular member proximal end.

12. A tubular member according to Claim 11, further comprising at least two segments, each segment partially overlapping with its neighboring segments, to create a diameter at least equal to said first inner diameter.

13. A tubular member according to Claims 11 or 12, further comprising restraining means for preventing it from having a diameter less than said fist inner diameter, once the tubular member is placed over said stump.

14. A tubular member according to anyone of Claims 11 to 13 further adapted to be expanded due to an expansion of said stumps from said shrunk state to said expanded state.

15. A method of performing an anastomosis of a first and a second tubular stumps, each having a stump proximal end, and further having a shrunk outer diameter in its shrunk state and an expanded outer diameter in its expanded state, the method comprising:

- providing a device comprising a first and a second hollow tubular members, each having a tubular member proximal end, a tubular member middle section, a first inner diameter, which is at least equal to said shrunk outer diameter, and a second inner diameter, which is at least equal to said expanded outer diameter, said tubular members further being capable of radially expanding from said first inner diameter to said second inner diameter; and an elastic sleeve having two sleeve ends;
- determining first inner diameter of the tubular members;
- placing the first tubular member over the first stump, while it is in its shrunk state;

- placing the second tubular member over the second stump, while it is in its shrunk state;
- everting the proximal ends of the first and second stumps over the proximal ends of the first and second tubular members, respectively;
- putting the sleeve ends on the corresponding proximal ends of the tubular members with the everted proximal ends of the stumps; and
- maintaining the everted proximal ends of the stumps in a predetermined distance from each other.

16. A method according to Claim 15, wherein the tubular member comprises at least two segments, each segment partially overlapping with its neighboring segments, to create a diameter at least equal to said first inner diameter.

17. A method according to Claims 15 or 16, further comprising preventing the tubular members from having a diameter less than said first inner diameter, once the tubular member is placed over said stump.

18. A method according to anyone of Claims 15 to 17, further comprising expanding of the tubular member due to an expansion of said stumps from said shrunk state to said expanded state.

19. A method according to anyone of Claims 15 to 18, further comprising maintaining said everted proximal ends of the stumps in said distance by at least one holding means of the sleeve.

20. A method according to Claim 19, further covering by the sleeve the everted ends of the stumps and at least a part of the middle sections of the tubular members.

21. A method according to anyone of Claims 15 to 20, wherein said distance is between zero and about 5 mm.

22. A method according to Claim 21, wherein said distance is equal to 0.

23. A method according to Claim 21, wherein said distance is equal to about 2 mm.

24. A method according to anyone of Claims 15 to 23, wherein the device is drug eluting.

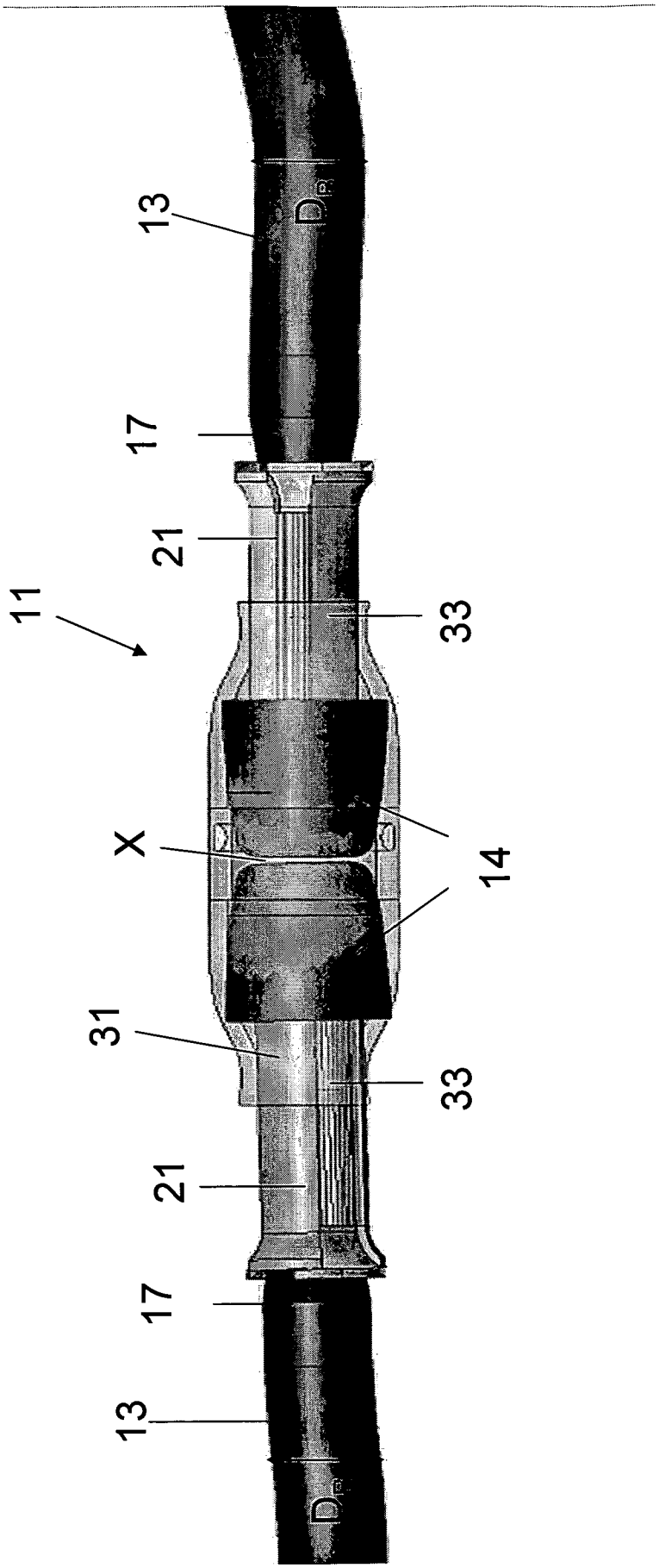

Fig. 1A

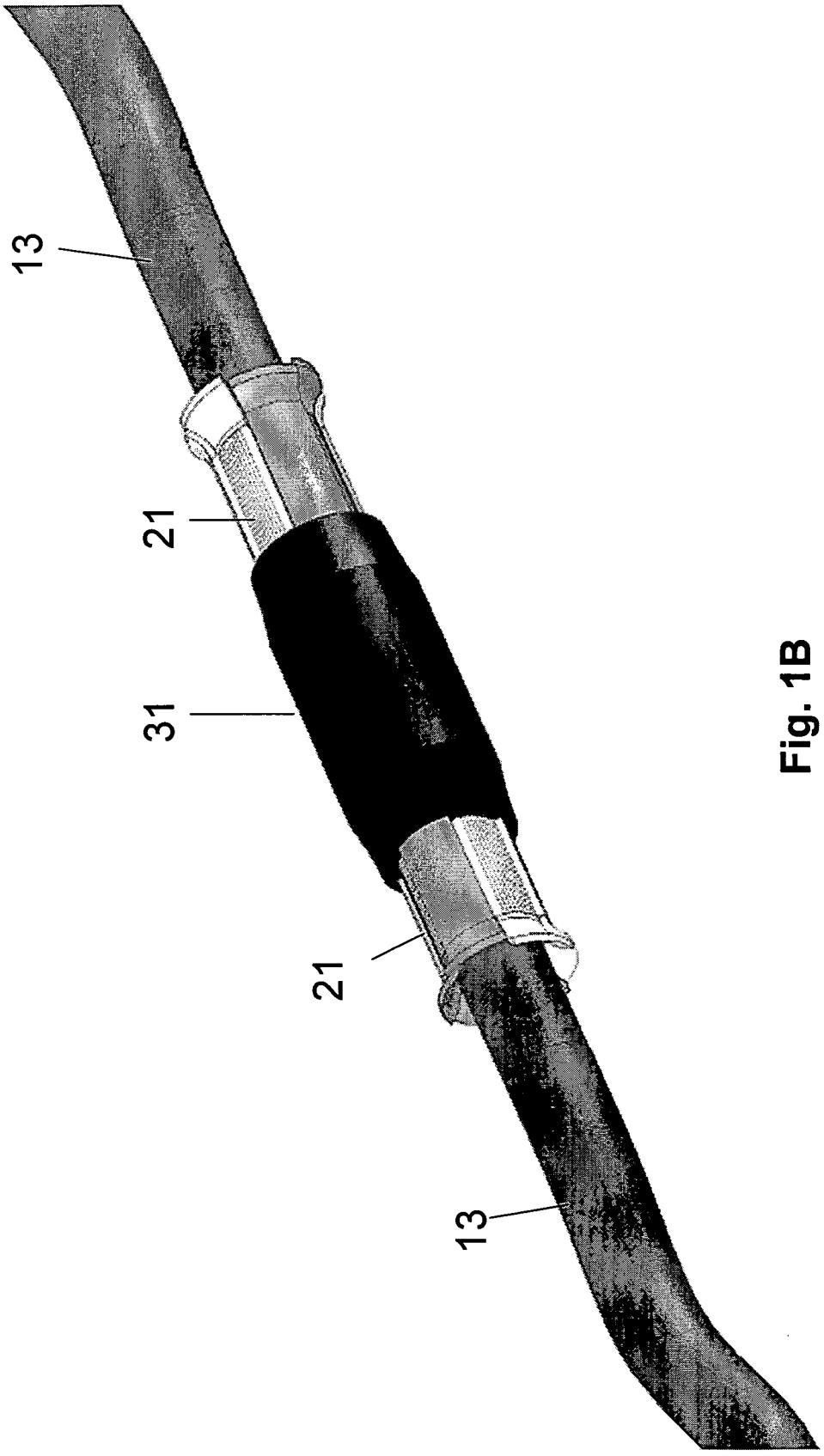

Fig. 1B

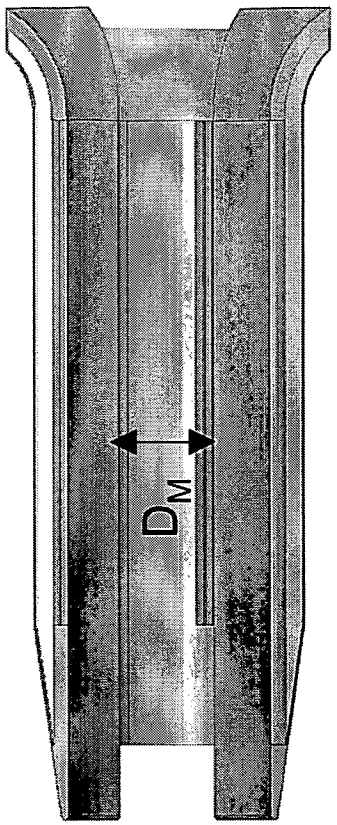

Fig. 2B

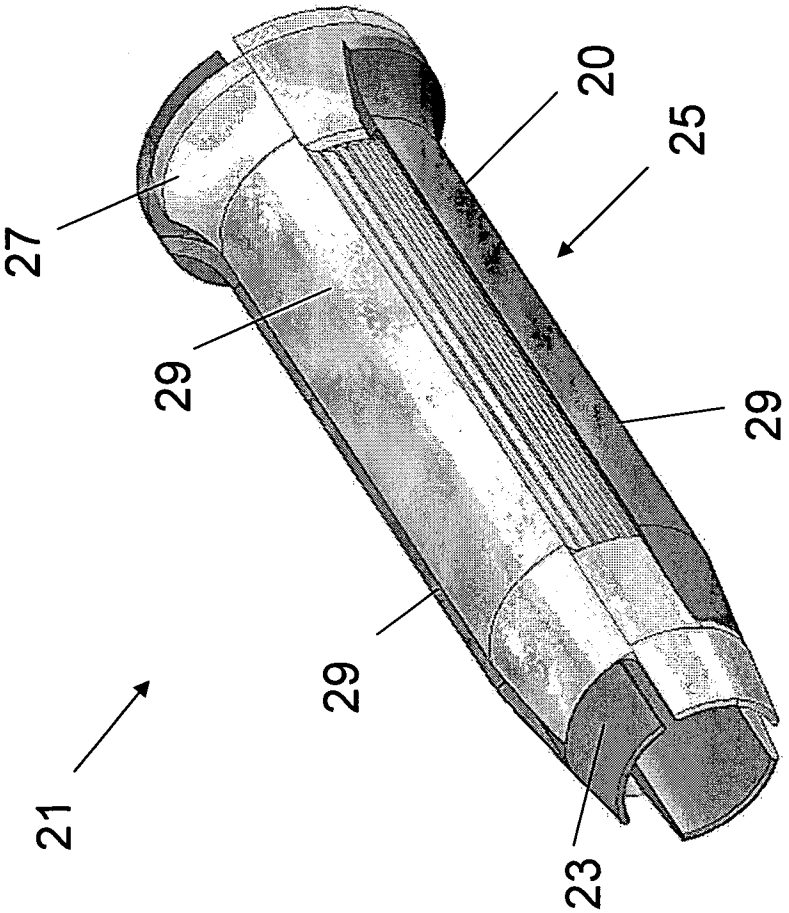

Fig. 2A

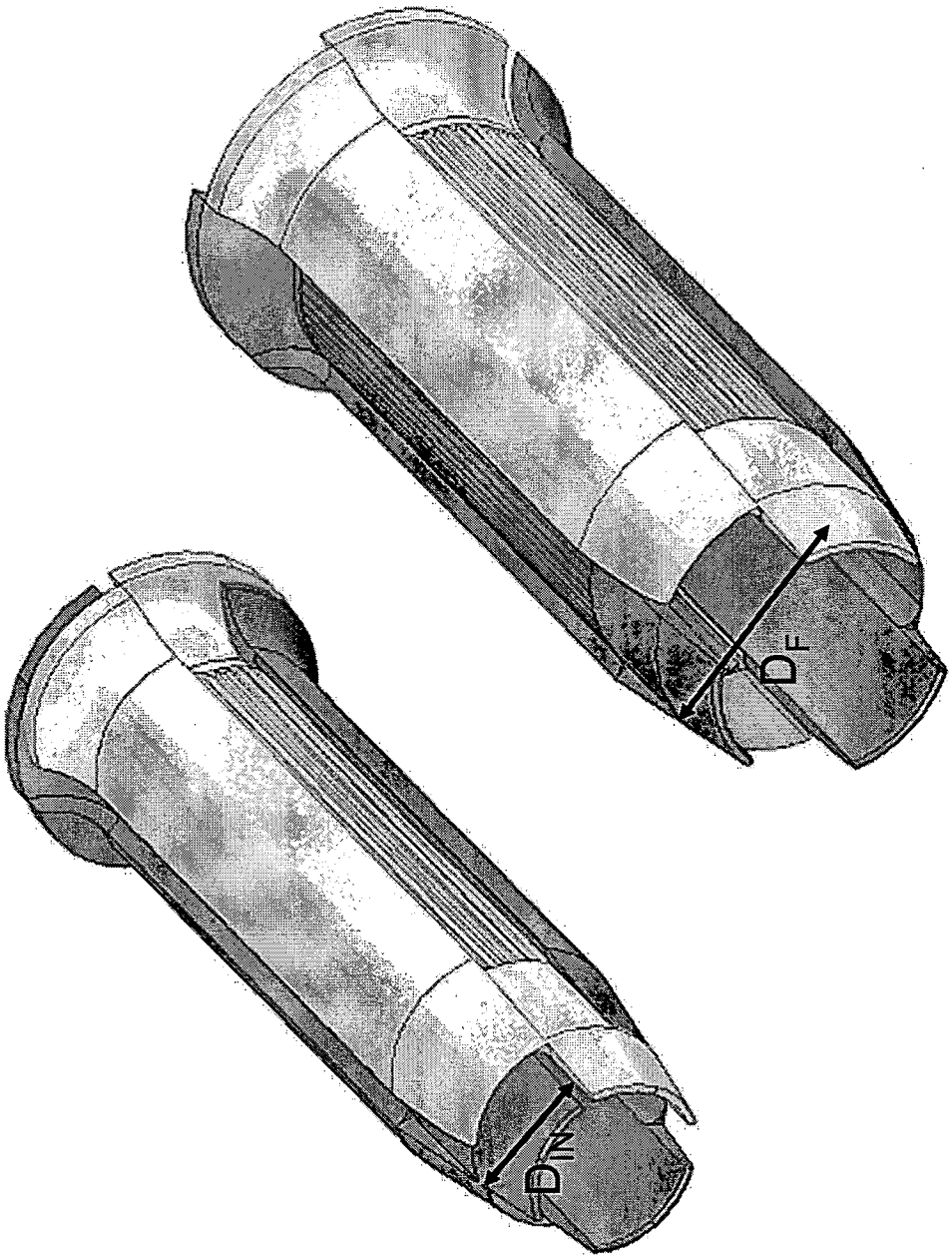

Fig. 3

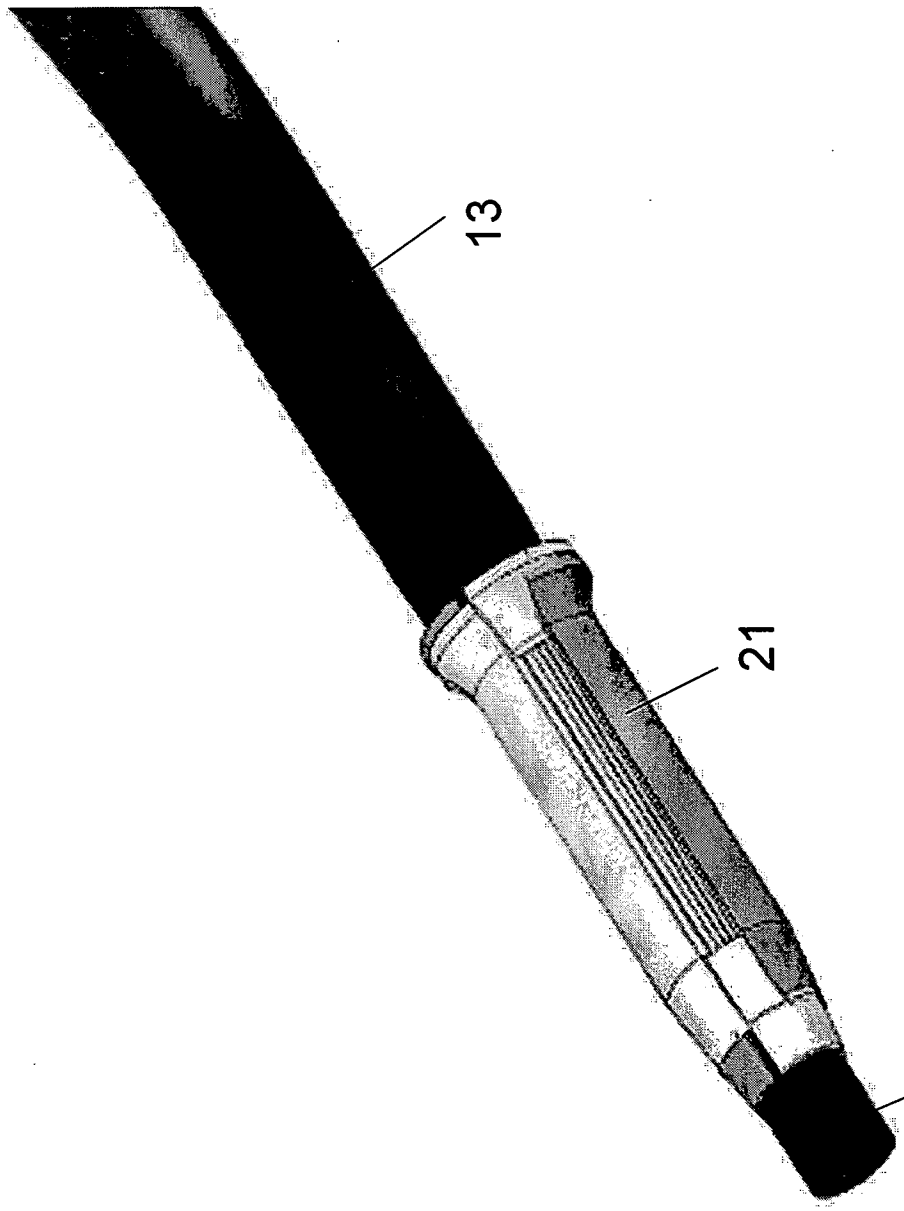

Fig. 4

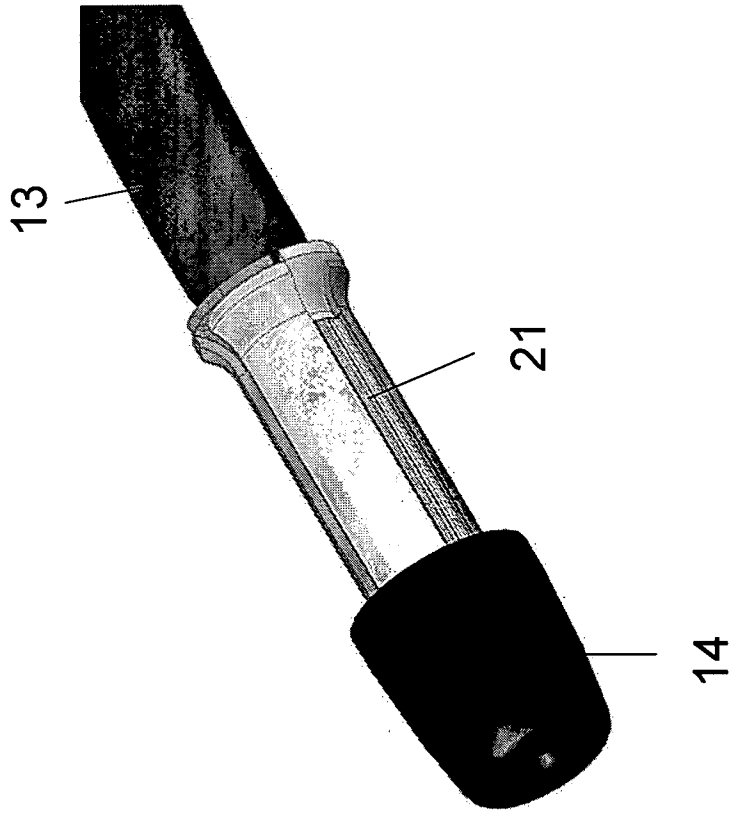

Fig. 5B

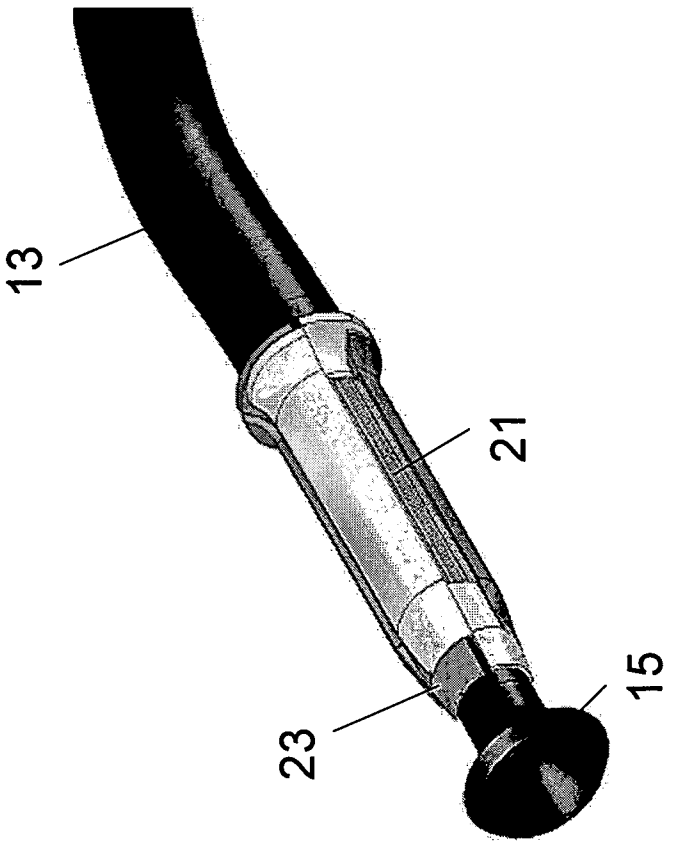

Fig. 5A

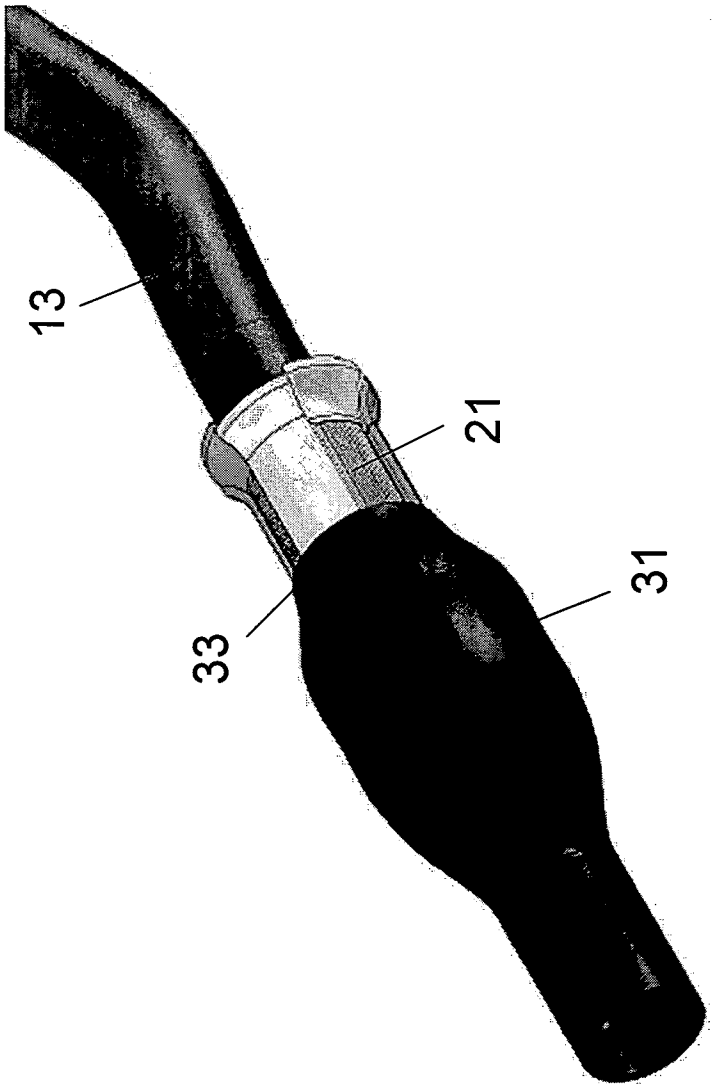

Fig. 6B

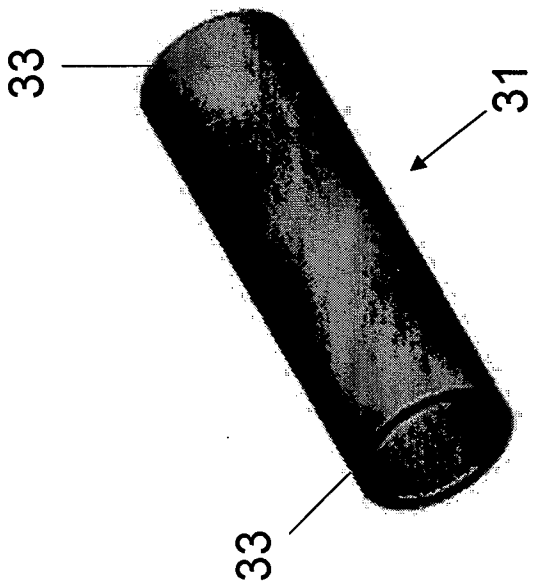

Fig. 6A

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2009/000535

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/11

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 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.
Y	US 4 470 415 A (WOZNIAK JOHN J [US]) 11 September 1984 (1984-09-11) cited in the application the whole document	1-10
X	WO 02/096299 A (HB MEDICALS CORP [KR]; LEE HOON BUM [KR]) 5 December 2002 (2002-12-05) page 7, line 16 - page 8, line 28	11-14
Y		1-10

☐ 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 document 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

"P" document published prior to the international filing date but later than the priority date claimed

"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

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 September 2009	07/10/2009

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	Strazdauskas, Gedas

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2009/000535

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 15-24
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IL2009/000535

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4470415 A	11-09-1984	NONE	
WO 02096299 A	05-12-2002	EP 1397077 A1	17-03-2004
		JP 2004528124 T	16-09-2004
		KR 20020091522 A	06-12-2002
		US 2004186489 A1	23-09-2004