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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 June 2010 (10.06.2010)

PCT

(10) International Publication Number
WO 2010/064062 A1

(51) International Patent Classification:
*A61F 9/007* (2006.01)

(21) International Application Number:
PCT/IB2008/000843

(22) International Filing Date:
8 April 2008 (08.04.2008)

(25) Filing Language: Italian

(26) Publication Language: English

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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, 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, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

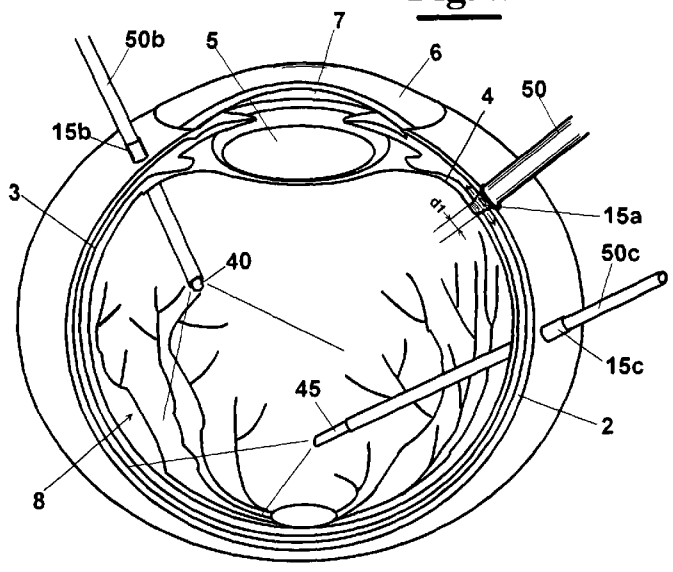
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, 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))*

(54) **Title**: GUIDING DEVICE FOR OPHTHALMIC MININVASIVE SURGERY

**Fig. 1**




(57) **Abstract**: A guiding device for noninvasive ophthalmic surgery, in particular, for vitrectomy, comprising a needle (10) having a first diameter (dl) and having a cutting profile (11) adapted to provide an incision (9) substantially circular through the sclera of an eye; and an expandable element (15) associated with the needle (10) and adapted to move from a collapsed configuration, at which the expandable element (15) is inserted by the needle (10) in the incision (9), to an expanded configuration, in which the expandable element (15) causes the walls of the incision (9) to enlarge resiliently up to a second diameter (d2) larger than the first diameter (dl). In a first embodiment the expandable element (15) engages in a removable way with the external surface of the needle (10) at a not sharpened profile (12) of it and, furthermore, a cannula (50), or ophthalmic trocar, is provided having a diameter corresponding to the second diameter that is put in in the expandable element (15), the trocar (50) enlarging the expandable element (15) from the first diameter to the second diameter, the needle (10) when withdrawing releasing the expandable element (15) enlarged by the trocar (50) at the incision (9). In a second embodiment the needle (10) has an axial recess (13) in which the expandable element (15) is housed, and means are provided (20) for causing the needle (10) to slide freely from the expandable element (15), whereby it is possible to remove the needle (10) from the substantially circular incision (9) by pushing the expandable element (15) out from the recess, in order to leave it, once extracted the needle (10), at the circular incision (9).

WO 2010/064062 A1

TITLE

GUIDING DEVICE for ophthalmic mininvasive surgery

TITLE

GUIDING DEVICE FOR ophthalmic mininvasive surgery

DESCRIPTION

Field of the invention

The present invention generally relates to the field of ophthalmic mininvasive microsurgery and, in particular, it relates to a disposable guiding device for vitreous-retinal surgery for treatment of ophthalmic diseases that relate to the retina and/or the vitreous humour.

Description of the technical problem

As well known, vitrectomy consists of removing the vitreous humour by means of micro-ophthalmic surgery techniques. This surgical procedure allows, in particular, to find an effective solution to many conditions otherwise unsolvable.

In particular, vitrectomy is a microsurgical procedure in the treatment of vitreous-retinal diseases, i.e. for treatment of ophthalmic diseases that relate to the retina and the vitreous humour that up to a few years needle were considered incurable. For example, vitrectomy is used for removing the opacity of the vitreous humour deriving from blood effusions and tractions that the vitreous humour same can apply to the retina.

Vitrectomy consists substantially of the removal of the vitreous body and can be necessary in the diseases that are characterised either by an alterated ratio between the retina and the vitreous body or by a loss of transparency of the latter.

Vitrectomy provides the use of cannulas, or "trocars", which allow the introduction of the necessary instruments in the site of operation.

In a preliminary step, an incision is made of a measured size using a microscalpel, put in the cannula and introduced in the eye up to the site of interest. After the incision, the microscalpel is withdrawn leaving the cannula inserted in the eye. The cannula, during the operation, is used as channel of introduction for the surgical instruments.

A parameter that identifies the size of a variety of types of trocars is the so-called "gauge" (g), or caliber, which indicates a measure of the diameter.

Two standard calibers of trocars for ophthalmic microsurgery are common: the 25 g, having inner diameter equal to 450 μm and outer diameter equal to 500 μm, and the 23 g, having inner diameter equal to 650 μm and outer diameter equal to 720 μm.

In order to arrange in the operation field the trocar, as well as the necessary instruments for operation of ophthalmic surgery, such as optical fibres for internal lighting, micro-tweezers, micro-scissors, cannulas for infusion of physiological solutions, etc. It is therefore necessary to provide preliminarily an incision of a size corresponding up to about 18-20 gauges through the sclera and the conjunctive of the ocular globe. This often causes long time of post-surgical rehabilitation for the high invasivity of the operation.

Furthermore, the traditional 25 or 23 gauge ophthalmic trocars do not allow reaching the most peripheral zones of the retina and therefore they can be used only in determined ophthalmic surgical operations. Instead, it would be desirable having a larger trocar, even if to the detriment of invasivity.

Summary of the invention

It is therefore a feature of the present invention to provide a guiding device for ophthalmic mininvasive

surgery for reducing the size of the incision and then for speeding up the time for the post-surgical rehabilitation.

It is another feature of the present invention to provide a guiding device for ophthalmic mininvasive surgery that achieves also the most peripheral zones of the retina, which by means of traditional ophthalmic trocars it can be reached in a quite difficult way.

These and other features are accomplished with one exemplary guiding device according to the invention for mininvasive ophthalmic surgery, in particular for vitrectomy, comprising:

- a needle having a first diameter (d1) and having a cutting profile adapted to make a substantially circular incision through the conjunctive and the sclera of an eye; whose main feature is to provide an expandable element associated with said needle adapted to move from a collapsed configuration, at which said expandable element is inserted by the needle in said circular incision, to an expanded configuration, in which said expandable element causes the walls of the substantially circular incision to enlarge up to a second diameter (d2) larger than the first diameter (d1).

In a first exemplary embodiment, the expandable element engages in a removable way with the external surface of the needle at the a not sharpened edge thereof and , furthermore, a thin tube, or ophthalmic trocar, is provided having a diameter corresponding to the second diameter (d2) that is put in the expandable element causing it to enlarge from the first to the second diameter, said needle being eventually withdrawn releasing the expandable element expanded within the incision.

Therefore, the expandable element works as beveled portion for the cannula, which represents the actual duct

for introducing the surgical instruments at the site of operation.

Advantageously, the expandable element is put on the needle.

In an exemplary embodiment, the above described needle has an axial recess in which the expandable element is housed, and, furthermore, means are provided for leaving the needle to slide free independently from the expandable element. In particular, the means to let the needle slide free independently from the expandable element let the needle to be removed from the substantially circular incision by pushing the expandable element out from the recess in order to leave it, once extracted the needle, at the circular incision.

In particular, the means to let the needle slide free independently from the expandable element comprise a pushing element adapted to keep the expandable element at the substantially circular incision during the withdrawal of the needle.

In particular, the expandable element is made of a shape memory material.

Advantageously, the expandable element is a stent with reticular shape.

In particular, the expandable element has side wings adapted to be put out of the substantially circular incision to avoid that it can accidentally penetrate in the eye.

Advantageously, the first diameter (d1) is set between 24 g and 26 g, preferably it is equal to 25 g, whereas the second diameter is set between 21 g and 19 g, preferably it is equal to 20 g. After the extraction of the trocar having the size of the second diameter, the elasticity of the tissues turns back to the first diameter, with minimum invasivity of the operation. This

allows using surgical instruments and cannulas of relatively large sizes, having, then a reduced flexibility, without the need of providing incisions of large size on the conjunctive, thus reducing the time for the post-surgical rehabilitation.

Brief description of the drawings.

The invention will be now shown with the following description of an exemplary embodiment thereof, exemplifying but not limitative, with reference to the attached drawings wherein:

- Figures 1 and 2 show a partial diagrammatical cross sectional view of an ocular globe subject to an operation of vitrectomy for which the guiding device for mininvasive ophthalmic surgery, according to the invention, is used;
- Figures from 3A to the 3F show diagrammatically a succession of steps through which it is possible to put the necessary instruments for an operation of ophthalmic surgery, such as optical fibres, cannulas of infusion of physiologic solutions, micro-tweezers, micro-scissors, etc., in the operation field, by the device according to the invention;
- Figures from 4A to the 4E show diagrammatically a succession of steps through which it is possible to put the necessary instruments for an operation of ophthalmic surgery in the operation field, by an exemplary embodiment of the device shown in figures from 3A to 3F.

Description of preferred exemplary embodiments

With reference to figures 1 and 2, a device, according to the invention, for mininvasive ophthalmic surgery, in particular for vitrectomy, comprises, in a preferred exemplary embodiment, at least one expandable element 15 of tubular shape, capable of moving from a

collapsed configuration, in which it has a first diameter (d1), for example equal to 25g, (figure 1) to an extended configuration, in which it has an second diameter (d2), for example equal to 20g (figure 2).

In particular, expandable element 15, in the collapsed configuration, is put in an incision 9 of a determined diameter (d1), through the sclera 4 of the eye, for carrying out an operation of ophthalmic surgery. Once put in place, expandable element 15 assumes the extended configuration, allowing the introduction of the instruments necessary to the surgeon at the operation field. For example, an optical fibre 40 for internal lighting, or a cannula for infusion of a physiological solution 45, or a cannula 50 through which instruments such as micro-tweezers, or micro-scissors, are put in the operation field, can be necessary. Each instrument can be inserted in the operation field through a corresponding expandable element 15a-15c.

Expandable element 15 can be made, for example, of resilient material, for being associated with a needle 10 of diameter (d1) having a cutting profile 11, to make a substantially circular incision 9 through the sclera 4 of the eye, to carry out an operation of ophthalmic surgery.

As diagrammatically shown in figures from 3A to 3F, expandable element 15 engages in a removable way with the external surface of needle 10, for example putting it on, at a not sharpened edge 12, for putting it in the substantially circular incision 9 (figures 3A and 3B).

Then, a cannula 50, or ophthalmic trocar, having a diameter equal to diameter d2, is put in expandable element 15 (figures 3B and 3C) causing it to enlarge from diameter d1, to diameter d2 (figure 3D).

Needle 10 is, moreover, withdrawn, in order to remove it from the incision 9 (figure 3E), releasing in

the meantime expandable element 15 in the expanded configuration at incision 9 (figure 3F).

According to what above described, expandable element 15 works as beveled portion for cannula 50, which represents the actual duct for introducing the surgical instruments.

In an exemplary embodiment shown in figures from 4A to 4D, needle 10 has an axial recess 12 in which the expandable element of tubular shape is housed 15'.

In this case, means can be advantageously provided for leaving needle 10 to slide independently from expandable element 15.

In particular, the means for leaving needle 10 to slide independently from expandable element 15' can comprise a piston 20 operated by a stem 21 movable in recess 13. More in detail, as diagrammatically shown in figure 4B, during the removal of needle 10, expandable element 15' is kept, by a piston 20, at the substantially circular incision 9.

Expandable element 15' can be made of a shape memory material, for example of the type used for stents, commonly used in the surgical field. In this case, during the positioning step, expandable element 15' is forcedly kept in place by the inner walls of the recess 13 in a contained shape. Once removed needle 10 from incision 9, expandable element 15' is disengaged from recess 13 and can, then, turn back from contained shape (figure 4C), to one original shape in which it has a larger diameter, in particular, corresponding to d2 (figure 4D).

To avoid that during the positioning step in the incision, or during the operation of ophthalmic surgery, expandable element 15' can accidentally penetrate in the eye, side wings 16 are provided. Once disengaged from the recess 13, the side wings 16 are moved away from the

central body of expandable element 15' and are arranged around incision 9.

The device above described allows using surgical instruments and cannulas of relatively large sizes, having, then, a reduced flexibility, without the need of providing incisions of large size on the conjunctive, thus reducing the duration of the post-surgical rehabilitation.

The foregoing description of a specific embodiment will so fully reveal the invention according to the conceptual point of view, so that others, by applying current knowledge, will be able to modify and/or adapt for various applications such an embodiment without further research and without parting from the invention, and it is therefore to be understood that such adaptations and modifications will have to be considered as equivalent to the specific embodiment. The means and the materials to realise the different functions described herein could have a different nature without, for this reason, departing from the field of the invention. It is to be understood that the phraseology or terminology employed herein is for the purpose of description and not of limitation.

CLAIMS

1. Guiding device for mininvasive ophthalmic surgery, in particular for vitrectomy, comprising:
- a needle having a first diameter (d1) and having a cutting profile adapted to make a substantially circular incision through the sclera of an eye;
**characterised in that** an expandable element is provided associated with said needle, said expandable element being adapted to move from a collapsed configuration, at which said expandable element is inserted by said needle in said circular incision, to an expanded configuration, in which said expandable element causes the walls of said substantially circular incision to enlarge resiliently up to a second diameter (d2) larger than said first diameter (d1).

2. Guiding device for mininvasive ophthalmic surgery, according to claim 1, wherein said expandable element engages in a removable way with the external surface of said needle at the a not sharpened edge thereof and, furthermore, a thin tube, or ophthalmic trocar, is provided having a diameter corresponding to said second diameter that is put in said expandable element, said trocar enlarging said expandable element from said first diameter to said second diameter, said needle being eventually withdrawn releasing said expandable element enlarged by said trocar at said incision.

3. Guiding device for mininvasive ophthalmic surgery, according to claim 1, wherein said expandable element is put on said needle.

4. Guiding device for mininvasive ophthalmic surgery, according to claim 1, wherein said needle has an axial

recess in which said expandable element is housed, and means are provided for allowing said needle to slide free independently from said expandable element, whereby it is possible to remove said needle from said substantially circular incision by pushing said expandable element out from said recess in order to leave it, once extracted the needle, at said circular incision.

5. Guiding device for mininvasive ophthalmic surgery, according to claim 1, wherein said means for allowing said needle to slide free independently from said expandable element comprises a pushing element adapted to keep said expandable element at said substantially circular incision when withdrawing said needle.

6. Guiding device for mininvasive ophthalmic surgery, according to claim 1, wherein said expandable element is made of a shape memory material.

7. Guiding device for mininvasive ophthalmic surgery, according to claim 1, wherein said expandable element is a stent with reticular shape.

8. Guiding device for mininvasive ophthalmic surgery, according to claim 1, wherein said expandable element has side wings adapted to be put out of said substantially circular incision to avoid that it can accidentally penetrate in the eye.

9. Guiding device for mininvasive ophthalmic surgery, according to claim 1, wherein said first diameter (d1) is set between 24 g and 26 g, preferably equal to 25 g, whereas the second diameter (d2) is set between 21 g and 19 g, preferably equal to 20 g.

Fig. 1

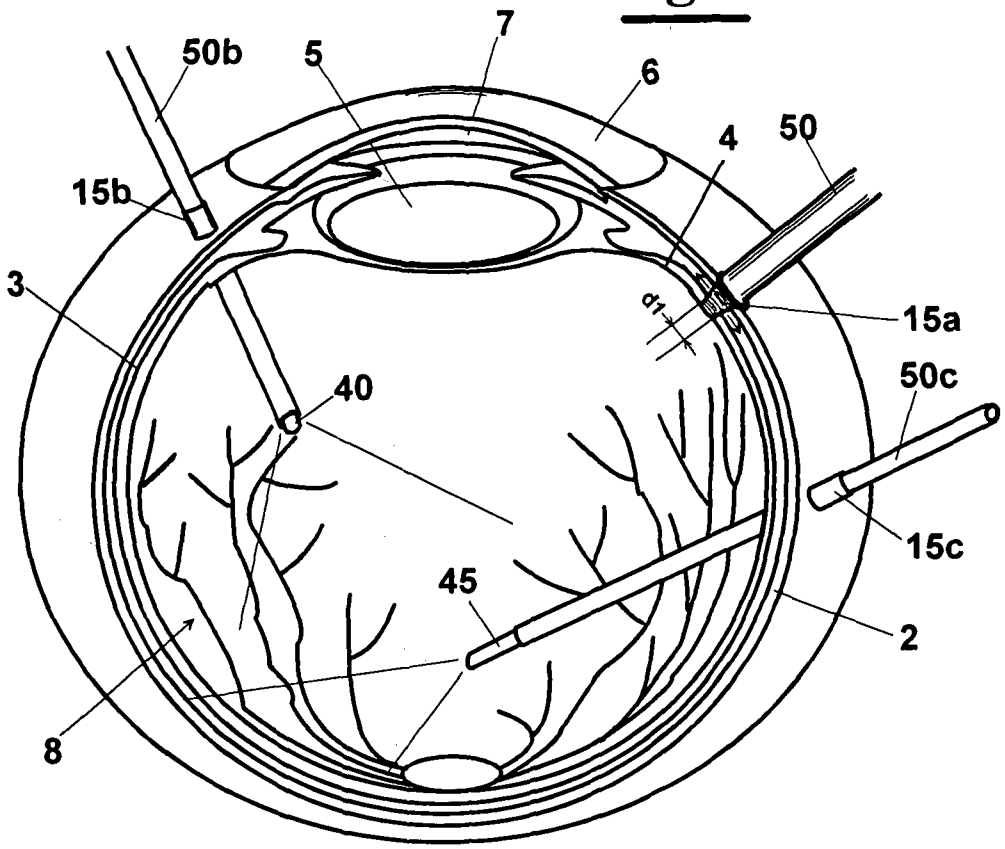

50b
5
7
6
4
50
15b
3
d1
15a
40
50c
15c
45
2
8

Fig. 2

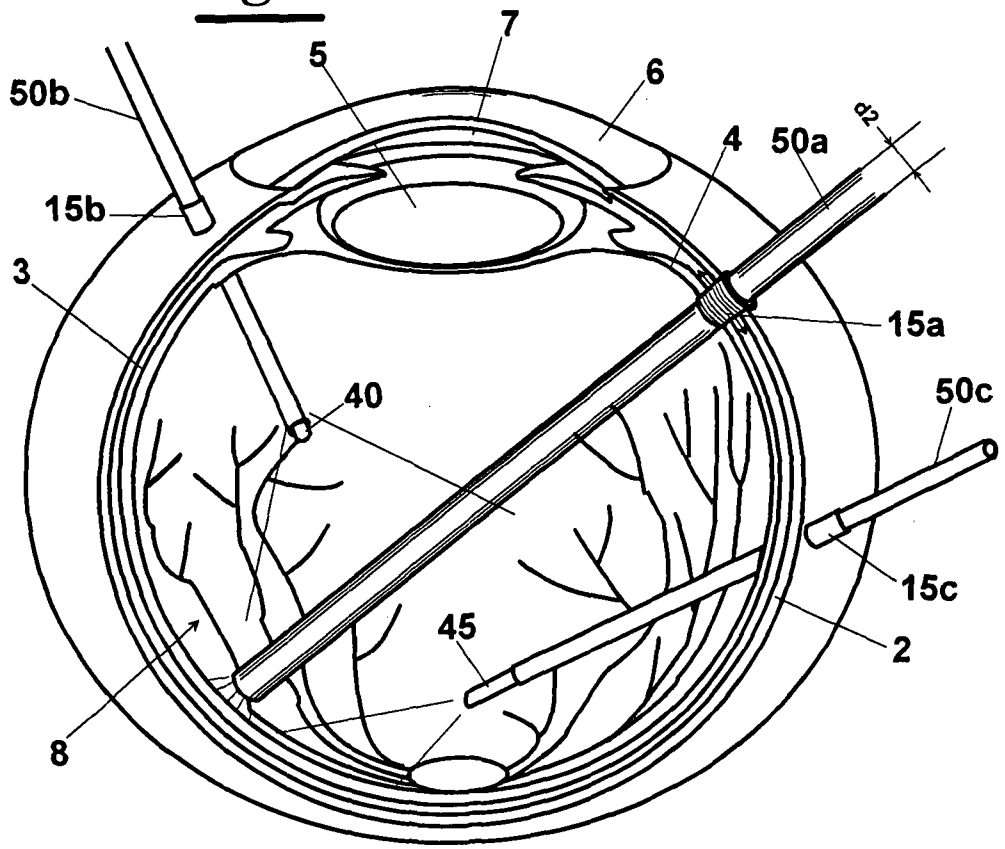

5
7
50b
6
4
50a
d2
15b
3
15a
40
50c
15c
45
2
8

Fig. 3A

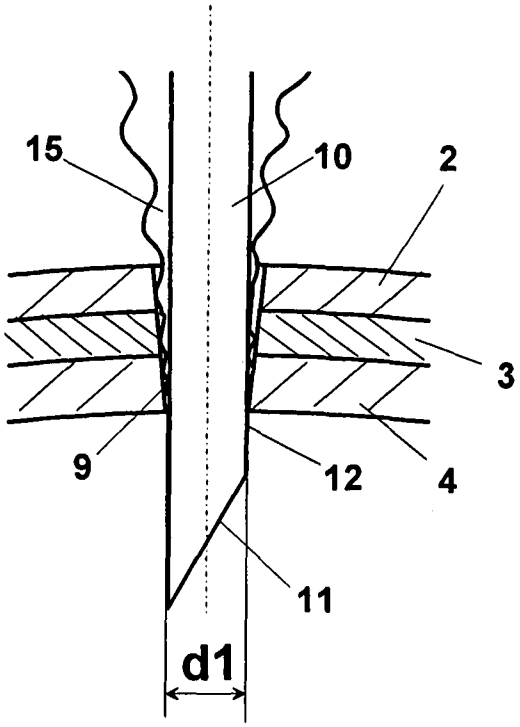



Fig. 3B

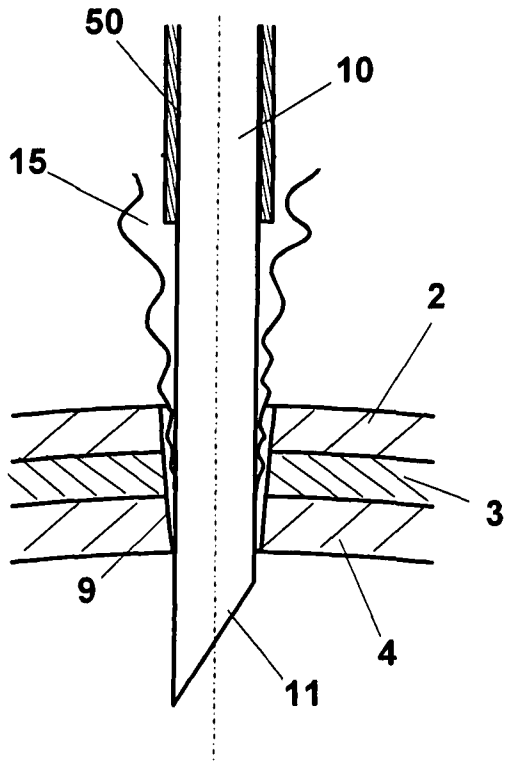



Fig. 3C

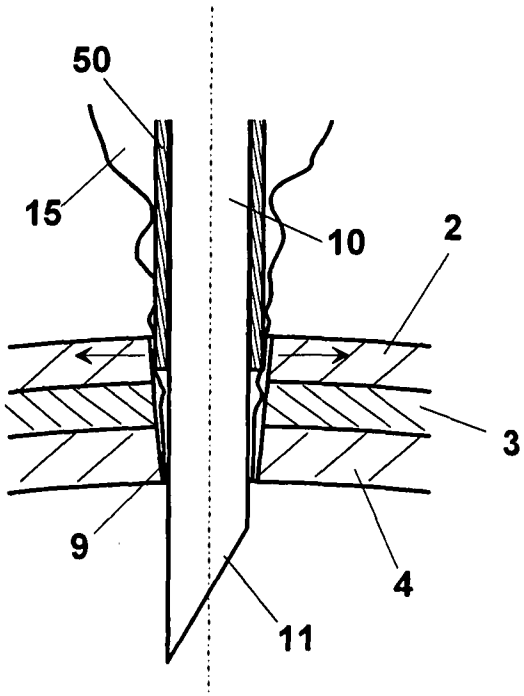



Fig. 3D

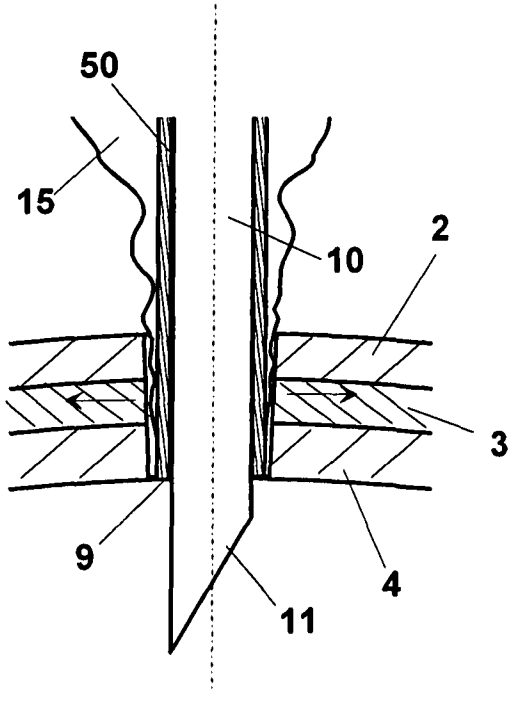


Fig. 3E

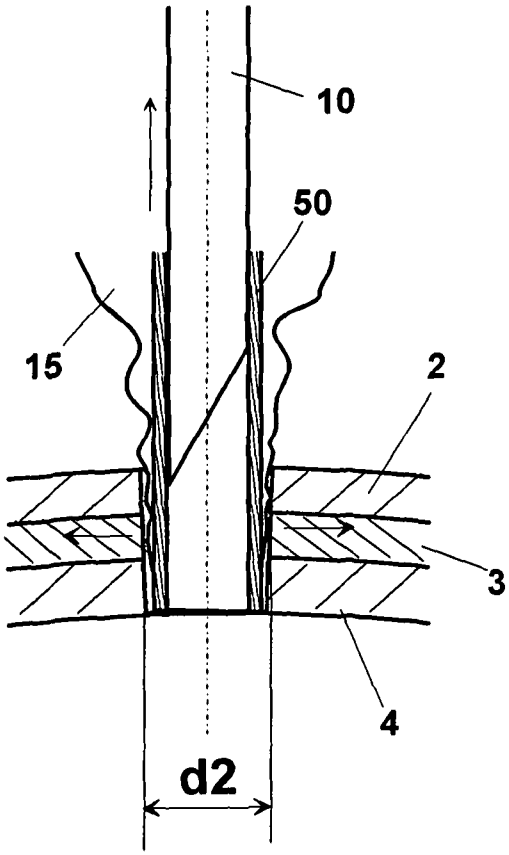



Fig. 3F

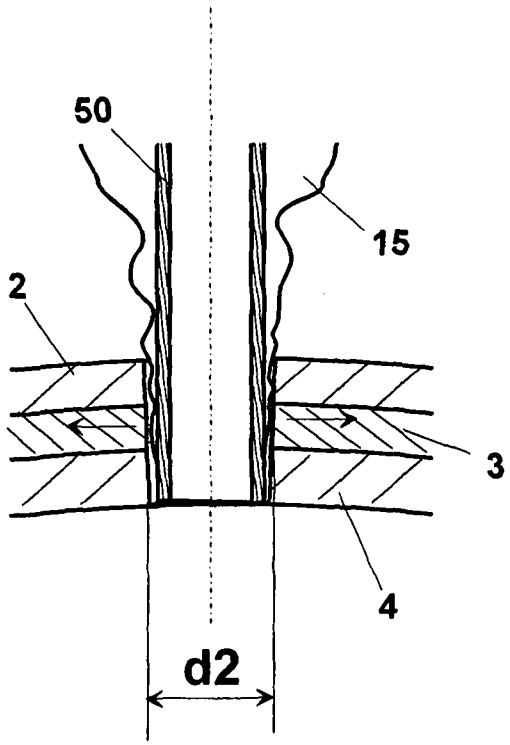


Fig. 4A

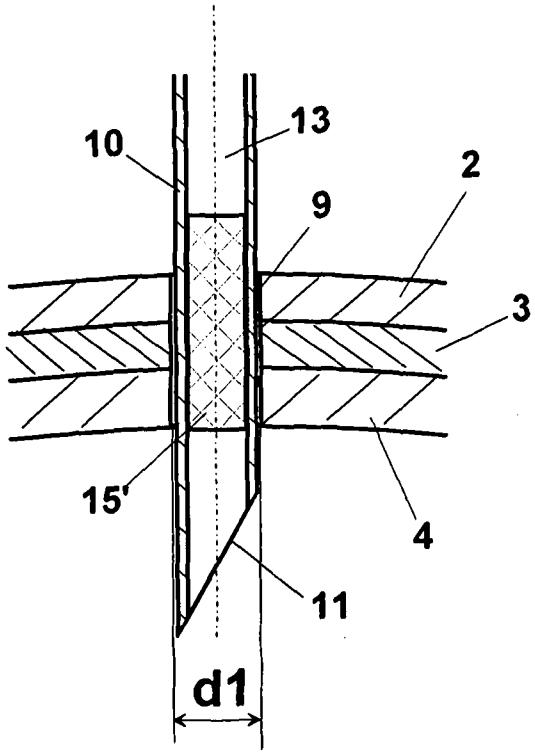



Fig. 4B

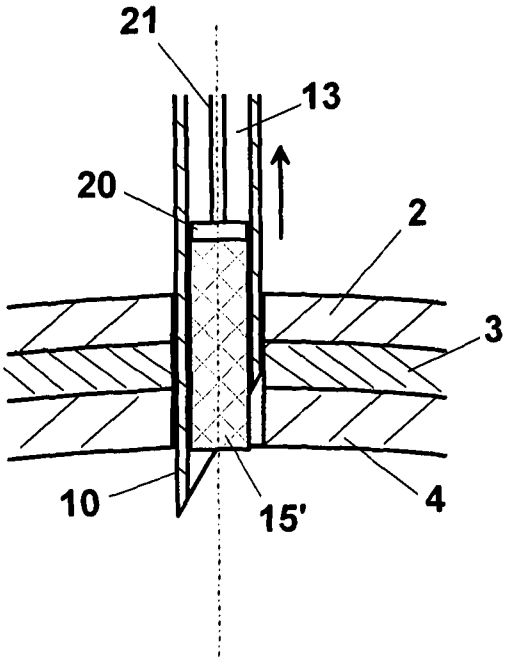



Fig. 4C

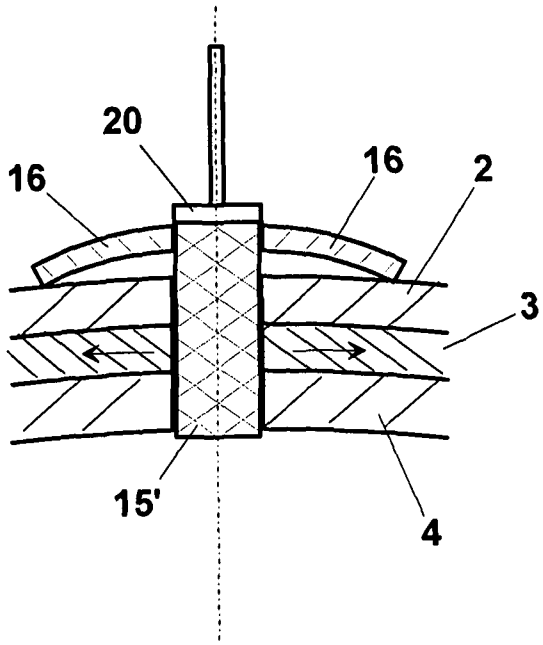
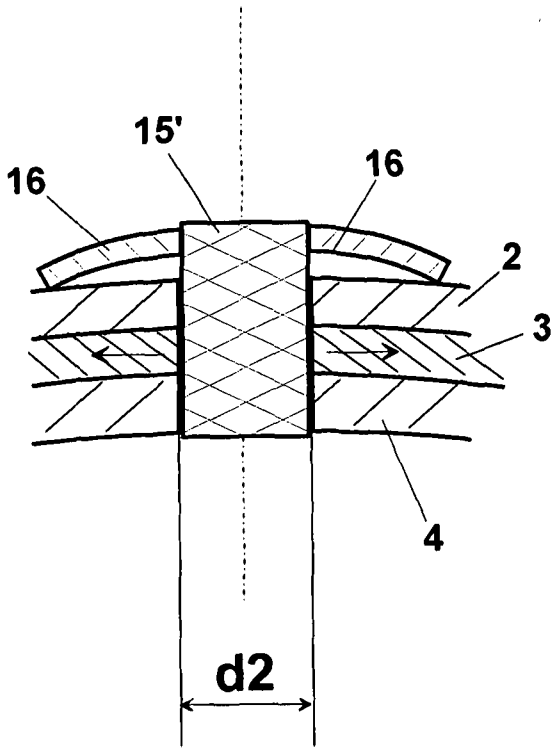
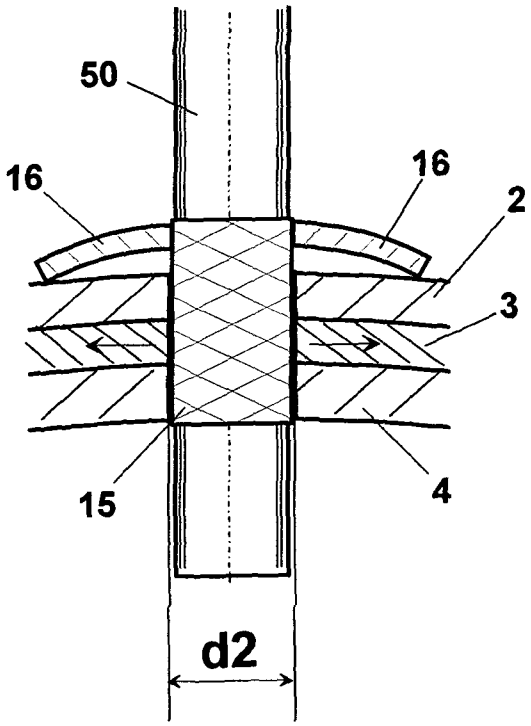



Fig. 4D



# Fig. 4E



# INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2008/000843

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F9/007

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 A61F

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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

[X] See patent family annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
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| 12 February 2009 | 20/02/2009 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Mayer-Martenson, E |

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International application No
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