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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
7 April 2016 (07.04.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/051333 A1

(51) International Patent Classification:
A61F 2/04 (2006.01)

(21) International Application Number:
PCT/IB2015/057427

(22) International Filing Date:
28 September 2015 (28.09.2015)

(25) Filing Language: Italian

(26) Publication Language: English

(30) Priority Data:
MI2014A001707 30 September 2014 (30.09.2014) IT

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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, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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

Published:

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

(54) **Title**: ORTHOTOPIC ARTIFICIAL BLADDER ENDOPROSTHESIS

(57) **Abstract**: An orthotopic artificial bladder endoprosthesis comprises a casing (2) made of a PGA fiber fabric; said casing (2) having two first connectors (3) for the connection with the ureters of a patient and a second connector (4) for the connection with the urethra of a patient; a support element (5) being inserted in said casing (2); said support element (5) being switchable between an extended configuration, in which it supports and maintains in position the casing (2), and a retracted configuration.

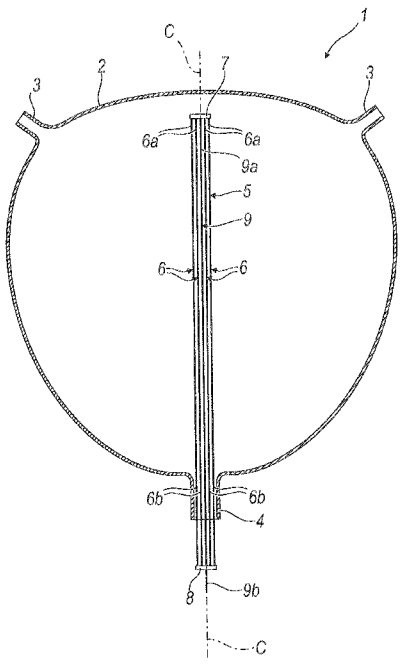

Fig. 1

WO 2016/051333 A1

ORTHOTOPIC ARTIFICIAL BLADDER ENDOPROSTHESIS

The present invention refers to an orthotopic artificial bladder endoprosthesis.

The application of the present invention lies in the replacement of the bladder of a patient, if the latter is suffering from incurable diseases serious as to compromise the correct function thereof.

Known bladder endoprostheses comprise a casing made of biocompatible and biodegradable material. The casing defines, at its interior, an enclosure for containing urine.

By way of example, the casing is made of PGA fiber fabric.

In order to give the casing the necessary structural rigidity, the known endoprosthesis comprises structural elements applied externally on the casing itself.

By way of example, the structural elements comprise a plurality of arms connected to each other to define an asterisk configuration and shaped so as to have dome-like form.

The structural elements are made of rigid biocompatible and biodegradable material. By way of example, the structural elements are made of PGA/PLA copolymer.

The casing is sufficiently rigid so as to stably keep its

shape and flexible such that it can be manually compressed to ensure that it empties.

The casing has a connection element located at a lower portion of the casing to connect with the patient's urethra. Similarly, two connection bodies are located at the top to enable connection with the ureters.

The connection element and bodies are also obtained with the biodegradable material.

Following the implant of the endoprosthesis in the patient, there is the formation of a musculo-fibrous tissue layer or fibrous capsule (not impermeable) around the casing, while the latter decomposes. In such a manner, a neobladder is generated around the endoprosthesis.

During the resorption, there is the formation of a transition epithelium layer, which is also called urothelium, which is advantageously impermeable. This is essential for ensuring the correct functioning of the prosthesis and of the neobladder that is being formed.

The obtainment of this type of endoprosthesis is complex and costly.

Indeed, the casing made of biocompatible and biodegradable material must be carefully coupled to the structural elements, which must in turn be precisely made and carefully shaped.

This renders the obtainment complex, long and costly.

In this context, the technical task underlying the present invention is to propose an orthotopic artificial bladder endoprosthesis which overcomes the abovementioned drawbacks of the prior art.

In particular, the object of the present invention is to provide an orthotopic artificial bladder endoprosthesis that is simpler and quicker to make.

The specified technical task and the specified object are substantially achieved by an orthotopic artificial bladder endoprosthesis comprising the technical characteristics set forth in one or more of the enclosed claims.

Further characteristics and advantages of the present invention will be clearer from the exemplifying and therefore non-limiting description of a preferred but not exclusive embodiment an orthotopic artificial bladder endoprosthesis, as illustrated in the enclosed drawings, in which:

- figure 1 is a schematic view of an orthotopic artificial bladder endoprosthesis in accordance with the present invention in a first configuration; and
- figure 2 is a schematic view of the endoprosthesis of figure 1 in a second configuration.

With reference to the enclosed drawings, reference number

1 overall indicates an orthotopic artificial bladder endoprosthesis in accordance with the present invention.

The endoprosthesis 1 comprises a casing 2 made with a PGA fiber fabric.

The PGA (polyglycolide or polyglycolic acid) used in the fabric - with which the casing 2 is obtained - is preferably homopolymer. PGA is a highly biocompatible and resorbable polymer that is resistant to urine. In detail, the resorption time of PGA is approximately one month.

The fabric casing 2 can be obtained by weaving the PGA thread in various ways, giving rise to a knitted fabric, a woven fabric or a non-woven fabric.

Preferably, the fabric of the casing 2 is a knitted fabric, still more preferably a warp knitted fabric.

In such cases, the fabric of the casing 2 has a rougher surface capable of assuming a net configuration with sufficiently small meshes.

In detail, its weft is such that its interstitial space is less than 200 μm, preferably around 160 μm, corresponding to an average area of the holes equal to approximately 0.02 mm^2. This ensures impermeability to urine, preventing leaks.

Furthermore, once the endoprosthesis 1 is inserted, the covering is impregnated with blood and in particular with plasma, which allows the antibiotic drugs to be

effective.

Furthermore, the fabric of the casing 2 is preferably textured so as to give it even greater surface roughness and greater rigidity and impermeability. The greater roughness of the fabric limits the risk of adhesion of the fibrous capsule.

Purely by way of example, the fabric of the casing 2 has a thickness substantially comprised between 0.3 mm and 0.6 mm, more preferably comprised between 0.4 mm and 0.53 mm, still more preferably being substantially 0.45 mm.

In addition, the thread with which the fabric of the casing is obtained has a density comprised between 50 and 200 denier.

The casing 2 substantially has a spherical shape and has first connectors 3 intended to be connected, by means of resorbable suture, with the ureters of a patient.

The casing 2 also has a second connector 4 intended to be connected, by means of resorbable suture, to the urethra of a patient.

The casing 2 can be obtained by means of joining two hemispherical caps. Alternatively, the casing 2 can be obtained in a single piece.

Purely by way of example, the casing 2 has a volume comprised between 300 cm^3 and 400 cm^3, preferably substantially equal to 350 cm^3.

The endoprosthesis 1 also comprises a support element 5 inserted within the casing 2.

The support element 5 is deformable in a manner such to be switchable between an extended configuration and a retracted configuration.

In the extended configuration, the support element 5 is marked by a maximum volume. Consequently, the support element 5 enlarges the casing 3 from the interior, supporting it and maintaining it in position. In this configuration, the casing 2 maintains the desired and appropriate shape during the step of creation of the neobladder and of simultaneous dissolution of the casing 2 itself.

In the retracted configuration, the support element 5 has minimum volume and is unable to enlarge and support the casing 2. This configuration is usefully employed in the step of storage and installation of the endoprosthesis 1 and in the step of elimination of the support element 5 when the neobladder is formed.

The support element 5 comprises a plurality of arms 6 that are connected to each other.

In detail, each arm 5 has a first end 6a and a second end 6b. The first ends 6a are connected to each other, as are the second ends 6b.

The arms 6 are arranged parallel to each other and around

a central axis “C”, angularly equidistant in a manner such that the support element 5 has an axially-symmetric configuration.

The arms 6 all have the same length.

In accordance with the present invention, when the support element 5 is situated in the retracted configuration, the distance between the first 6a and the second ends 6b is maximum. When the support element 5 is situated in the extended configuration, the distance between the first 6a and the second ends 6b is minimum.

In more detail, when the support element 5 is situated in the retracted configuration, the arms 6 have a substantially rectilinear form. When the support element 5 is situated in the extended configuration, the arms 6 are deformed in order to have a substantially curved form with a mutual moving-apart progression.

In such a manner, the deformed and curved arms 6 support the casing 2, which maintains a desired form.

The support element 5 comprises a first connection body 7, to which the first ends 6a of the arms 6 are fixed.

The first connection body 7 can be shaped as a circle or ring. The first ends 6a of the arms 6 are fixed at the perimeter of the first connection body 7, at points preferably equidistant from each other.

Furthermore, the support element 5 also comprises a

second connection body 8 to which the second ends 6b of the arms 6 are connected and fixed.

The second connection body 8 can be shaped as a circle or ring. The second ends 6b of the arms 6 are fixed at the perimeter of the second connection body 8, at points preferably equidistant from each other.

In the passage between the retracted configuration and the extended configuration, the first 7 and the second 8 connection body are in a mutual approaching and/or moving-apart relationship.

In order to allow the deformation of the support element 5 from the retracted configuration to the extended configuration (and vice versa), the support element 5 comprises a rod 9 having a first 9a and a second end 9b.

The rod 9 is fixed to the first connection body 7 at its first end 9a. The second end 9b is free.

The rod 9 is arranged parallel to the arms 6.

The rod 9 is preferably centrally arranged with respect to the arms 6. In particular, the rod 9 is placed along the central axis “C”.

The rod 9 passes through an opening made in the second connection body 8, continuing beyond.

In other words, the length of the rod 9 is greater than the length of the arms 6.

During use, the rod 9 is necessary in order to move the

first ends 6a of the arms 6 close to the second ends 6b. Indeed, by maintaining the second connection body 8 in pulling the rod 9, the first connection body 7 is moved close to the second connection body 8. Similarly, by maintaining the rod 9 stopped and pushing the second connection body 8, the first 7 and the second 8 connection body approach each other.

The approaching of the first 7 and second 8 connection body causes an action of compression on the arms 6, which are bent, opening them wide. The extended configuration is thus obtained.

Advantageously, the support element 5 is made of nickel-titanium intermetallic compound, also known by the term 'nitinol'.

Nitinol is a shape memory alloy provided with a very high elasticity (a characteristic known with the term 'superelasticity'); it is not magnetic and it has optimal corrosion resistance and good ductility. In addition, it has good biocompatibility.

Preferably, both the arms 6 and the first 7 and the second 8 connection body are made of nitinol.

The arms 6 are covered with a layer of turbostratic pyrolytic carbon.

The layer of turbostratic pyrolytic carbon has a thickness comprised between 0.2 μm and 0.3 μm.

The application of the carbon layer on the arms 6 allows avoiding the risk that the fibrous capsule being formed could adhere to the support element 5. In addition, the layer of turbostratic pyrolytic carbon prevents the formation of crusts due to urine.

Also the first 7 and the second 8 connection body can be covered with a layer of turbostratic pyrolytic carbon.

Advantageously, the entire support element 5 is covered with a layer of turbostratic pyrolytic carbon.

The endoprosthesis 1 also comprises a constraining member (not illustrated in the enclosed figures) operatively placed between the second connection body 8 and the rod 9. The constraining member allows stably fixing the relative position between the second connection body 8 and the rod 9. In particular, the constraining member is active for maintaining the support element 5 in the extended configuration, i.e. when the first 7 and the second 8 connection body are at their minimum distance.

In addition, a urine drain tube (not illustrated) can be provided, which is inserted in the urethra of the patient. The drain tube is optional.

The end of the drain tube inserted in the urethra of the patient reaches a point just downstream of the sphincter with respect to the endoprosthesis 1.

The end of the drain tube comprises a Dacron® mesh in

order to achieve the connection with the urethra.

The drain tube is made of silicone and is (internally and/or externally) covered with a layer of turbostratic pyrolytic carbon in order to prevent crusts.

The drain tube has minimum length of 15 cm.

The drain tube has a substantially circular section. The internal diameter is approximately 6 mm while the external diameter is approximately 9 mm.

During use, the endoprosthesis 1 in accordance with the present invention is implanted once the natural bladder of the patient, e.g. compromised by a serious disease, is removed.

Once the connections with the ureters have been obtained, by means of resorbable sutures, the support element 5 is brought into the extended configuration. In order to do this, the surgeon moves the first connection body 7 and the second connection body 8 close to each other, by simultaneously operating on the rod 9 and on the second connection body 8.

The second connector 4 is fixed to the urethra by means of a resorbable suture and the operation site is reclosed.

At this point, it is necessary to wait the pre-established time period in order to allow the reconstruction of the neobladder.

After said period has passed, the surgeon reopens the operation site and moves the support element 5 back into the retracted configuration, e.g. by means of endoscope through the patient's urethra. Its function has now terminated, since the neobladder has been successfully formed.

In order to extract the support element 5, the surgeon operates by means of endoscope, removing such element through the urethra, preventing further surgical operations.

The invention thus described attains the preset object.

Indeed, the use of the support element, and its introduction in the PGA casing during manufacture of the endoprosthesis, allows a considerable simplification of the attainment of the endoprosthesis itself.

Indeed, the casing made of resorbable fabric and the deformable support element are obtained independent of each other and particular expedients and precision are not required.

A further and non-negligible advantage lies in the fact that the moving-apart of the support element can occur without any need of a further, invasive cystostomy, sparing the patient further discomfort and hospital stay.

CLAIMS

1. Orthotopic artificial bladder endoprosthesis comprising:

- a casing (2) made of PGA fiber fabric, said casing (2) having two first connectors (3) for the connection with the ureters of a patient and a second connector (4) for the connection with the urethra of a patient; characterized in that it also comprises

- a support element (5) inserted in said casing (2), said support element (5) being switchable between an extended configuration, in which it supports and maintains in position the casing (2), and a retracted configuration.

2. Endoprosthesis according to claim 1, characterized in that said support element (5) is deformable in order to pass from said retracted configuration to said extended configuration and vice versa.

3. Endoprosthesis according to claim 1 or 2, characterized in that said support element (5) comprises a plurality of arms (6), each having a first (6a) and a second (6b) end; said arms (6) being constrained to each other at the first (6a) and second ends (6b).

4. Endoprosthesis according to claim 3, characterized in that, in the restricted configuration, said arms (6) have substantially rectilinear form and, in the extended

configuration, said arms (6) are curved according to a mutual moving-apart expansion.

5. Endoprosthesis according to claim 3 or 4, characterized in that the arms (6) are arranged parallel to each other and around a central axis (C) and are angularly equidistant in a manner such that the support element (5) has an axially-symmetric configuration.

6. Endoprosthesis according to any one of the claims from 3 to 5, characterized in that, in the restricted configuration, the distance between the first (6a) and the second (6b) ends of the arms (6) is maximum and, in the extended configuration, the distance between the first (6a) and the second (6b) ends of the arms (6) is minimum.

7. Endoprosthesis according to any one of the preceding claims, characterized in that said support element (5) is made of nickel-titanium intermetallic compound.

8. Endoprosthesis according to any one of the claims from 3 to 7, characterized in that it comprises a first connection body (7) to which the first ends (6a) of the arms (6) are fixed, and a second connection body (8) to which the second ends (6b) of the arms (6) are fixed; the first (7) and the second (8) connection body being movable in a mutual approaching and/or moving-apart relationship in order to pass between the retracted

configuration and the extended configuration.

9. Endoprosthesis according to claim 8, characterized in that it comprises a rod (9) having a first end (9a) fixed to the first connection body (7) and a free second end (9b); said rod (9) passing through or in proximity to said second connection body (8).

10. Endoprosthesis according to claim 9, characterized in that it comprises a constraining member active between the rod (9) and the second connection body (8) in order to fix the rod (9) with respect to the second connection body (8) in the enlarged configuration of the support element (5).

11. Endoprosthesis according to any one of the claims from 3 to 10, characterized in that each arm (6) is covered with a layer of turbostratic pyrolytic carbon.

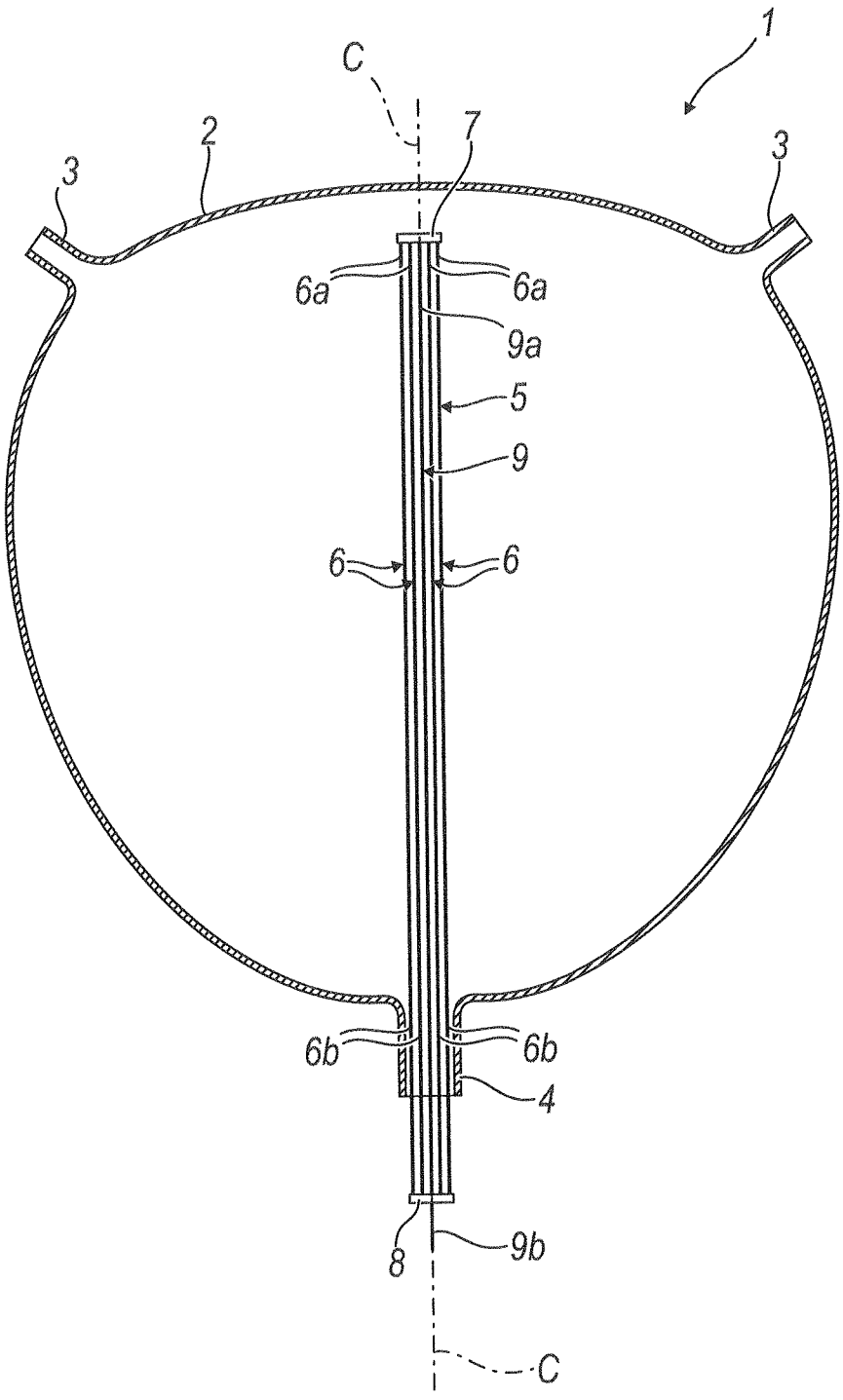

Fig. 1

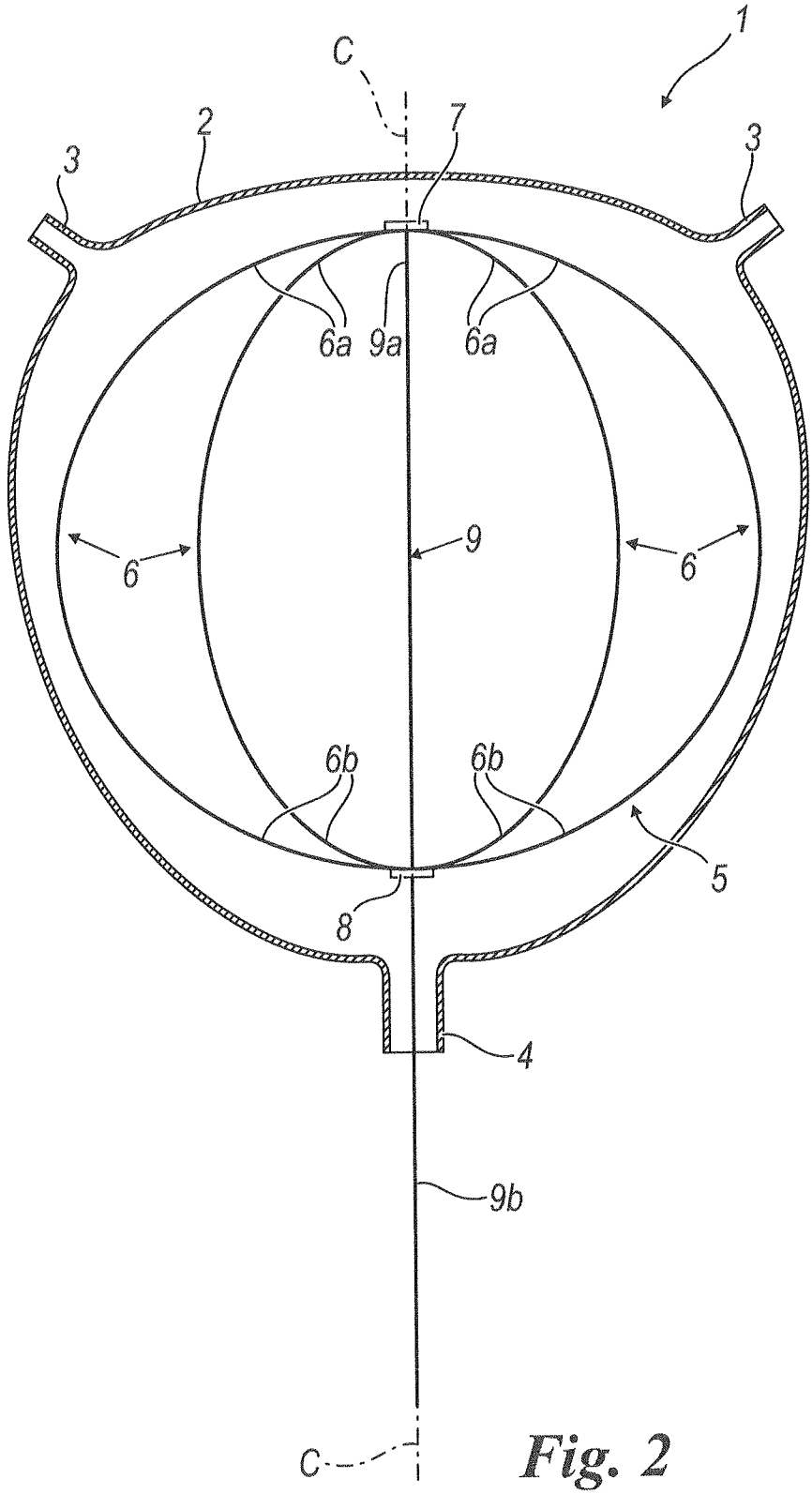

Fig. 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2015/057427

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/04
ADD.

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)
A61F 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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	page 3, line 17 - page 5, line 10 page 6, line 4 - page 9, line 17 figures 1, 2	11

X	FR 2 759 575 A1 (ASSIST PUBL HOPITAUX DE PARIS [FR]) 21 August 1998 (1998-08-21) page 8, line 9 - page 10, line 19; figures 1-3 page 12, line 26 - page 13, line 2	1,2

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

[X] See patent family annex.

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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
23 December 2015	14/01/2016

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

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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