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(54) **Titre : Orthotopic artificial bladder endoprosthesis.**

(57) **Abrégé :**

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; an inflatable element (5) inserted in said casing (2); said inflatable element (5) being switchable between an inflated configuration, in which it supports and maintains in position the casing (2), and a deflated configuration.

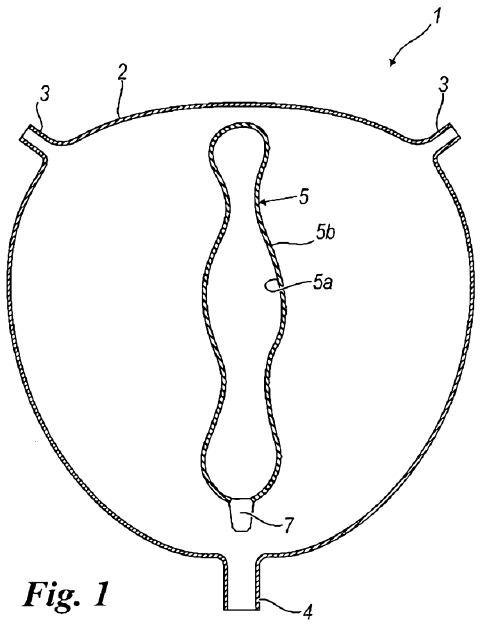


Fig. 1

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 a 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 balloon casing made with an impermeable layered silicone membrane covered with a layer made of biocompatible and biodegradable material. According what is known, the biocompatible and biodegradable covering material is a fabric made of PGA fiber.

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 bodies are also covered 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 covering of the casing, while the biodegradable material 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 covering made of biocompatible and biodegradable material must be obtained in order to fit on the silicon casing.

In fact, extreme precision is necessary for the correct relative sizing of casing and covering. It is known that the covering also covers the connectors.

This renders the obtainment complex, long and costly.

Other known solution as, for example, in WO2014/057444 discloses an orthotopic artificial bladder endoprosthesis comprising a cuff substantially rigid and shaped as a balloon and comprising an inner surface and an outer surface defining a space suitable for the containment of the urine; according to said solution the rigidity of the cuff and their stable and extended position is obtained

by using layers of material made of multilayered silicone suitable for obtaining a cuff sufficiently rigid so as to maintain a balloon shape and, at same time, sufficiently flexible so as to allow deformation caused by external pressure aimed to drain the bladder itself.

Another solution is disclosed in WO98/50100 as a device suitable for feeding an under pressure fluid inside a balloon inserted in a body chamber and aimed to allow and cause a tissue expansion of said cavity affected by a pathology.

Other know documents, as WO2007/075545, disclose a catheter or a device to drain liquid from body cavity or from a cavity obtained by surgery, with said device comprising a shaft, an expandable balloon connected to an end of the shaft, a permeable layer arranged outside the expandable balloon and with the shaft comprising a duct discharging the drainage liquid and also comprising a duct for feeding under pressure fluid in the balloon so as to inflate said balloon.

Another document, US4219026, discloses a bladder hemostatic catheter having an elongated shaft provided with a duct or lumen extending along the shaft and also comprising an inflatable balloon made of elastic material covering the distal end of the shaft and with said balloon that when inflated takes a substantially

spherical shape suitable to fill the bladder and to exert the pressure requested for terminating the hemorrhages.

An artificial bladder prosthesis in disclosed also in FR2759575 as comprising a containment element made of a double layered material comprising an inner layer and an outer layer made of different materials and with said different material suitable for allowing the implant of the containment element in the patient body avoiding transplant rejection and avoiding drawbacks related to the fact that the urine in the containment element can damage the containment element itself and, furthermore, said double layered material id realized with the aim to keep the rigid shape of the containment element itself.

Another artificial bladder is disclosed in WO2007/095193, as defined by a structure comprising two hemispherical portions joined one to the other and provided with outer flanges suitable for allowing a manipulation of said portions prior or during the surgery and also for allowing the connection of said two portions.

All the known solutions for bladder prosthesis are complex under a constructional point of view, the implant or surgery and so on and, as a consequence, they are 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, 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 of the 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 an inflatable element 5 placed within the casing 2.

The inflatable element 5 is switchable between an

inflated configuration (figure 2) and a deflated configuration (figure 1).

In the inflated configuration, the inflatable element 5 supports the casing 2 in an enlarged, taut and operative configuration.

The inflated configuration is maintained for the entire time necessary for the formation of the neobladder, which occurs at the same time as the progressive dissolution of the PGA casing 2.

Normally, as stated, the time necessary for the dissolution of the PGA fibers is approximately one month. Therefore, the inflatable element 5 in the inflated configuration has a structural function for the casing 2. Purely by way of example, the inflatable element 5 has, in the inflated configuration, a volume comprised between 300 cm^3 and 400 cm^3, preferably substantially equal to 350 cm^3.

The deflated configuration is instead selected during the step of storing the endoprosthesis 1 before its implant in the patient. Furthermore, the deflated configuration is restored when, following the dissolution of the casing 2, the neobladder is formed and the inflatable element 5 must be removed, by way of example, by means of cystostomy.

The inflatable element 5 is constituted by a silicone

membrane. Preferably, the inflatable element 5 is constituted by a multilayer silicone membrane.

Purely by way of example, the membrane comprises substantially 20 layers, each of approximately 30 µm thickness.

The membrane with which the inflatable element 5 is obtained has a thickness comprised between 500 µm and 700 µm, preferably the thickness of the membrane is substantially 600 µm.

The inflatable element 5 has an internal surface 5a directed towards an enclosure 6 for containing a fill fluid.

In addition, the inflatable element 5 has an external surface 5b internally directed towards the casing 2.

Advantageously, the external surface 5b of the inflatable element 5 is covered with a layer of turbostratic pyrolytic carbon.

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

The application of the carbon layer on the external surface 5b of the inflatable element 5 allows avoiding the risk that the fibrous capsule being formed could adhere to the casing 2 itself. In addition, the layer of turbostratic pyrolytic carbon prevents the formation of crusts due to urine.

The application of the carbon layer on the external surface 5b also allows protecting the inflatable element 5 from the corrosion caused by urine.

In the inflated configuration, the inflatable element 5 has a substantially spherical shape.

The inflatable element 5 also has a valve 7, which allows introducing and extracting a fill fluid in the enclosure 6 interior.

Purely by way of example, the fill fluid is a physiological solution.

It is observed that the inflatable element 5 is independent of the casing 2. In other words, the inflatable element 5 is completely detached from the casing 2. In still other words, no connection means of any type are provided arranged between the casing 2 and the inflatable element 5.

More particularly, the valve 7 is independent of the first connectors 3 and/or of the second connector 4. In other words, the valve 7 is not in any way connected with the first connectors 3 and/or the second connector 4.

It is also observed that the inflatable element 5 is inserted in the casing 2 during the manufacturing of the endoprosthesis 1.

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, as stated by means of resorbable sutures, the inflatable element 5 is brought into the inflated configuration. In order to do this, the surgeon identifies the valve 7, e.g. by means of suitable diagnostic instruments, and reaches it, through the second connector 4, with a duct for transferring physiological solution through the patient's urethra. The surgeon then accesses the enclosure 6 and fills it with the physiological solution until the enclosure 6 and filled in the correct manner.

Once the valve 7 is disengaged and the correct inflation of the inflatable element 5 is verified together with its positioning, the second connector 4 is fixed to the urethra by means of 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 brings the inflatable element 5 back into the deflated configuration. Its function has now terminated, since the neobladder has been successfully formed.

Once the inflatable element 5 is deflated, the surgeon cuts the neobladder so as to access its interior, tracing the now-deflated inflatable element 5 in order to extract it.

The subsequent reclosure of the neobladder and of the operation site concludes the implant operation of the endoprosthesis 1.

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

The drain tube goes beyond the sphincter of the patient and reaches the second connector 4, and is fixed thereto. The end of the drain tune comprises a Dacron® mesh in order to achieve the connection.

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.

The invention thus described attains the preset object.

Indeed, the use of the inflatable 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 inflatable element are obtained independent of each other and particular expedients and precision are not required.

The invention is not limited to the embodiment/s illustrated in the drawings. Accordingly it should be understood that where features mentioned in the appended claims are followed by reference signs, such signs are included solely for the purpose of enhancing the intelligibility of the claims and are in no way limiting on the scope of the claims.

CLAIMS

1. Orthotopic artificial bladder endoprosthesis comprising:

- a casing (2) made of a PGA fiber fabric; said casing (2) having 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

- an inflatable element (5) inserted in said casing (2) and having a valve (7) for introducing and extracting a fill fluid, said inflatable element (5) being independent of the casing (2); said inflatable element (5) being switchable between an inflated configuration, in which it supports and maintains in position the casing (2), and a deflated configuration.

2. Endoprosthesis according to claim 1, characterized in that said inflatable element (5) has an external surface (5b) covered with turbostratic pyrolytic carbon.

3. Endoprosthesis according to claim 1 or 2, characterized in that said inflatable element (5) has a substantially spherical shape in said inflated configuration.

4. Endoprosthesis according to claim 1, characterized in that said valve (7) is independent of said first connectors (3) and/or said second connector (4).

5. Endoprosthesis according to any one of the preceding claims, characterized in that the inflatable element (5) is constituted by a multilayer silicone membrane.

ORTHOTOPIC ARTIFICIAL BLADDER ENDOPROSTHESIS

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; an inflatable element (5) inserted in said casing (2); said inflatable element (5) being switchable between an inflated configuration, in which it supports and maintains in position the casing (2), and a deflated configuration.

[Fig. 1]

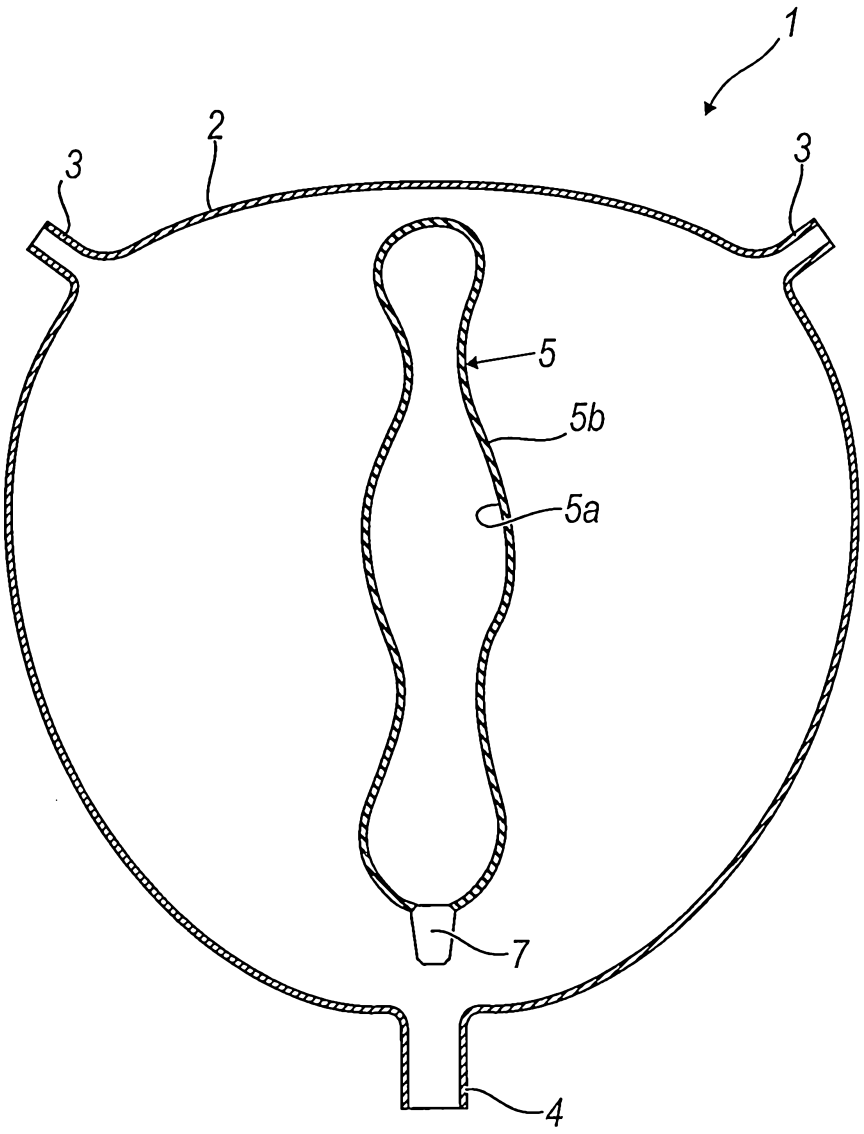


Fig. 1

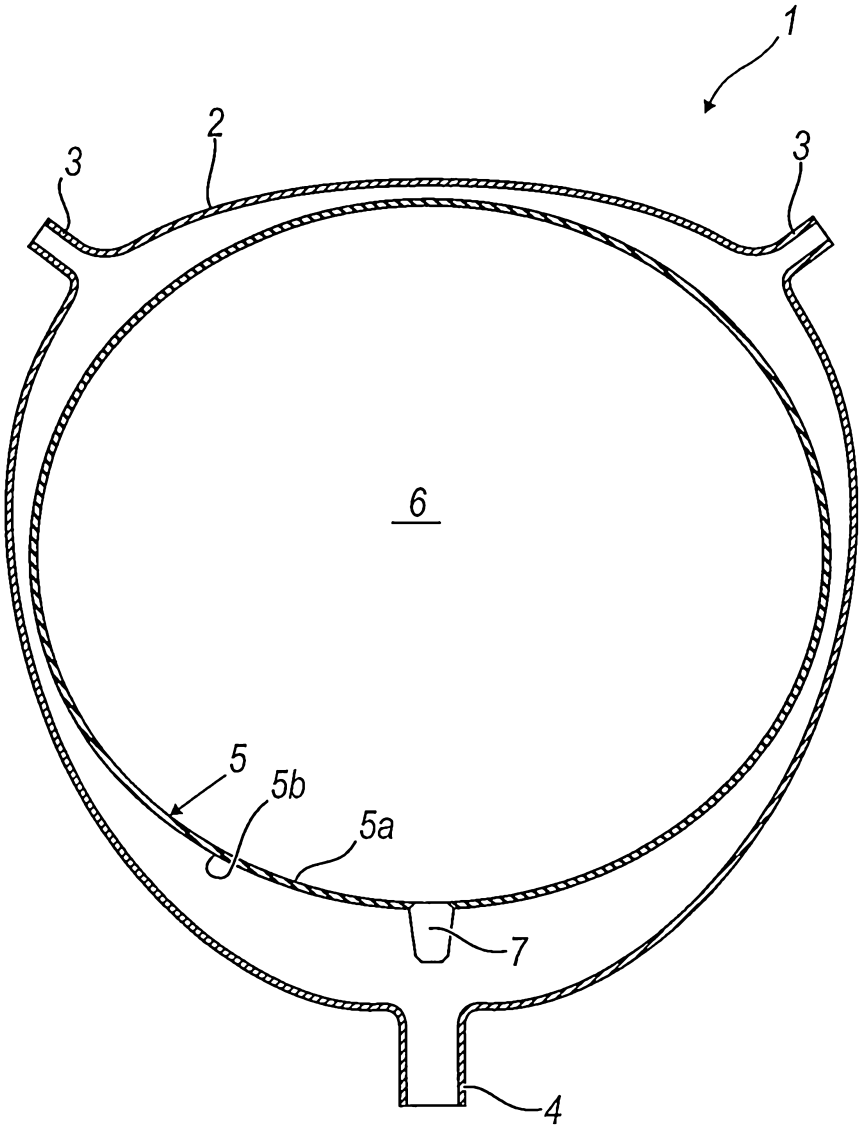


Fig. 2