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(54) Title: BALLOON CATHETER DEVICE

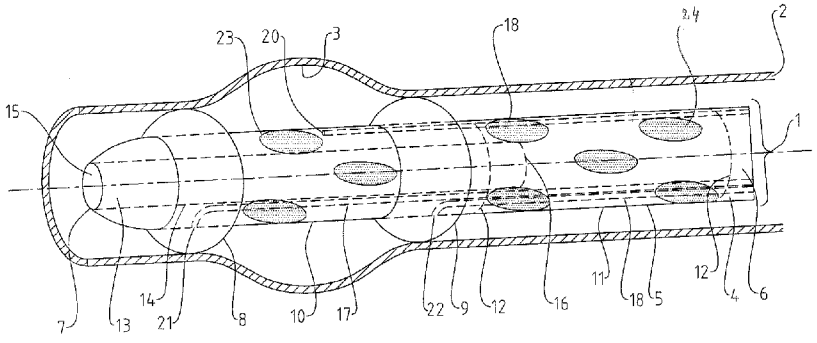

FIG.1

(57) Abstract: The present invention relates to a balloon catheter device (1) intended to be placed within a conduit (2) of a biological flux, for administering a therapeutic composition to luminal walls (3) of said conduit (2), comprising: - an outer catheter (4) and a distal balloon (8) and a proximal balloon (9) around the outer catheter (4), wherein a first segment (10) of the wall of the outer catheter between the distal balloon (8) and the proximal balloon (9) is permeable to the therapeutic composition, a second segment (11) of the wall of the outer catheter between the proximal balloon (9) and the proximal end is permeable to the biological flux; - a hollow cylinder (13) having a wall (14) substantially impermeable to the biological flux, with a first opened end (15) and a second opened end (16), wherein the first opened end (15) is hermetically fitted through the opening (7) of the distal end of the outer catheter, and the second opened end (16) opens in the portion of the lumen of the outer catheter underneath said second segment (11); - at least two inner catheters for respectively inflating the distal and proximal balloons (17,18) and at least one inner catheter for delivering the therapeutic composition (19).

Balloon catheter device

Field of the invention

The present invention relates to a balloon catheter device suitable for administering cells at sites of an individual body where they are needed. The invention also relates to methods of use of such a device.

Background of the invention

Cell therapy intends to correct defects, for example skin or vascular defects, in tissues of an individual by administering cells suitable to cure said defect to the individual.

Various methods for administering cells at a defect site exist. For instance, in the case of skin wounds or burns in an individual, autologous dermal fibroblasts can be cultivated on a biocompatible lattice which is then grafted onto the individual *e.g.* as described by Coulomb *et al.* (1998) *Plast. Reconstr. Surg.* 101:1891-1903. The main drawback associated to this technique lies in the long culture time necessary for the dermal fibroblast to colonize the lattice prior to implantation.

In the case of the treatment of vascular defects, the cells can be injected at the site of defect for instance using an angioplasty balloon catheter provided with micro needles (*e.g.* Infiltrator®). However, the drawback of this technique is that blood circulation is interrupted in the vessel during administration of the cells. Besides, this technique is not adapted for protocol in large vessels and may be harmful by itself, either for the tissues surrounding the site of defect, in particular because of jet lesions, or for the cells to be administered.

Accordingly, it is an object of the invention to provide devices and methods capable of overcoming these drawbacks.

Summary of the invention

The present invention thus relates to to a balloon catheter device intended to be placed within a conduit of a biological flux, for administering a therapeutic composition to luminal walls of said conduit, wherein when the inflated balloon catheter device is in place in the conduit, the biological flux can freely flow through said device, the therapeutic composition fills a chamber delimited by the wall of the conduit and the device, and contact between the biological flux and the therapeutic composition is prevented.

In particular, the present invention relates to a balloon catheter device intended to be placed within a conduit of a biological flux, for administering a therapeutic composition to luminal walls of said conduit, comprising:

- an outer catheter comprising a wall, a lumen, a distal end provided with an opening and a proximal end;

- a distal balloon and a proximal balloon around the outer catheter, the distal balloon being located between the distal end of the outer catheter and the proximal balloon, wherein the diameter of said distal and proximal balloons, when they are inflated, is essentially that of the inner diameter of said biological conduit;

wherein a first segment of the wall of the outer catheter between the distal balloon and the proximal balloon is permeable to the therapeutic composition, a second segment of the wall of the outer catheter between the proximal balloon and the proximal end is permeable to the biological flux, the portions of the lumen of the outer catheter underneath said first and second segments being delimited by at least one impermeable seal, and the lumen of the outer catheter accommodates:

- a hollow cylinder having a wall substantially impermeable to the biological flux, with a first opened end and a second opened end, wherein the first opened end is hermetically fitted through the opening of the distal end of the outer catheter, and the second opened end opens in the portion of the lumen of the outer catheter underneath said second segment;

- at least two inner catheters for respectively inflating the distal and proximal balloons and at least one inner catheter for delivering the therapeutic composition, wherein the inner catheters are provided with a distal end and a proximal end, the proximal end extending to the proximal end of the outer catheter, the distal end of the at least one inner catheter for delivering the therapeutic composition opening in the portion of the lumen of the outer catheter underneath said first segment, and the distal ends of the at least two catheters for respectively inflating the distal and proximal balloons respectively opening in the distal and proximal balloons.

The present invention also relates to a percutaneous transluminal method for treating a site of defect of the luminal walls of a conduit for a biological flux in an individual, comprising:

- placing a non-inflated balloon catheter device according to the invention within the conduit such that the site of defect is located between the distal and proximal balloons;

- inflating the distal and proximal balloons, preferably by inflating the distal balloon first and then the proximal balloon;

- delivering a therapeutic composition intended to treat the site of defect with the inner catheter for delivering the therapeutic composition so that the therapeutic composition is in contact with the site of defect;

- maintaining the therapeutic composition in contact with the site of defect for a time sufficient for the therapeutic composition to exert its therapeutic effect;
- removing the therapeutic composition;
- deflating the first and second balloons;
- removing the balloon catheter device from the conduit.

The balloon catheter device and method of the invention are particularly advantageous in that the biological flux, for instance blood, circulating through the conduit, for instance an artery, can flow uninterrupted through the hollow cylinder, while the therapeutic composition is maintained in contact with a site of defect of the luminal walls of said biological conduit. Besides, interactions between the therapeutic composition and the biological flux are prevented.

Brief description of the drawings

Figure 1 is an external diagrammatic view of a first embodiment of the balloon catheter device according to the invention in place in a conduit for a biological flux.

Figure 2 is a longitudinal cut of a diagrammatic view of the first embodiment represented in Figure 1.

Detailed description of the invention

Definitions

As intended herein a “conduit for a biological flux” relates to any conduit which can be found in a human or an animal body which function is to conduct fluids or gases within the body. Conduits for a biological flux notably encompass the vascular (*e.g.* an artery or a vein), digestive (*e.g.* a small bowel segment), respiratory (*e.g.* a tracheobronchic segment, the larynx, or a bronchus), or uro-genital conduits (*e.g.* an urethra, an ureter, or a fallopian tube).

As intended herein a “site of defect of the luminal walls of a conduit” relates to a lesion or a disease of the internal wall of said conduit. In particular, as intended herein a “site of defect of the luminal walls of a biological conduit” relates to a defect of vascular walls, preferably of arterial walls, which notably occurs upon abnormal cicatrisation of lesions of these walls. The lesions can be of various origins, such as hypoxia, lipid overload, hemodynamic factors, atheroma, atheromatous plaque rupture, or hypertension.

Abnormal cicatrisation notably results from a disequilibrium between degradation and synthesis of the extracellular matrix, which disequilibrium induces pathological vascular remodelling. Manifestations of abnormal cicatrisation particularly encompass vascular enlargement (*e.g.* aneurism, in particular of the aorta), aortic dissection, loss of elastin and vascular constriction (*e.g.* stenosis, occurring in the course of atherogenesis, or restenosis, in particular post-angioplasty restenosis).

As intended herein a "therapeutic composition" relates to any composition comprising an agent which has the ability to promote, accelerate, or improve the correction of a site of defect of the luminal walls of a biological conduit. The agent can be a compound in solution, such as a compound selected from the group constituted of growth factors and cytokines. The agent can also be a cell suspension intended for cell therapy.

As intended herein "cell therapy", for example using stem cells or gingival fibroblasts, relates to the correction of defects, for example vascular defects, in biological conduits of an individual by administering cells suitable to cure said defect to said individual.

As intended herein a "cell suspension" for a cell therapy relates to a liquid composition comprising cells in a medium suitable to sustain survival and optionally growth of these cells. The medium is also preferably suitable to facilitate cell adhesion and migration. Such media are well known to the man skilled in the art, and notably comprise growth factors and cytokines.

As intended herein, "gingival fibroblasts" relate to mesenchymal cells which are capable of migrating, adhering and proliferating within the soft connective tissues of the gum, thereby maintaining the integrity of the gingival tissue which is exposed to numerous aggressions, such as mechanical stresses, bacterial infections, or pH and temperature variations. Gingival fibroblasts are in particular described in Gogly *et al.*, (1997) *Clin. Oral Invest.* 1:147-152; Gogly *et al.* (1998) *Biochem. Pharmacol.* 56:1447-1454; and Ejeil *et al.* (2003) *J. Periodontol.* 74:188-195.

Depending on environmental conditions, gingival fibroblasts are capable to modulate their phenotype, and to respond by proliferating, migrating, synthesising matrix components or matrix-related enzymes.

Gingival fibroblasts synthesise collagens (*e.g.* types I, III, V, VI, VII, XII), elastic fibers (oxytalan, elaunin and elastin), proteoglycans and glycosaminoglycans (*e.g.* decorin, biglycan), glycoproteins (*e.g.* fibronectin, tenascin). Simultaneously, gingival fibroblasts synthesise enzymes that are able to degrade the macromolecular compounds (matrix metelloproteinases; MMPs), but also enzymes inhibiting active forms of MMPs

(Inhibitors of metalloproteinases; TIMPs). Gingival fibroblasts are thus important actors of extracellular matrix remodelling.

Procedures for taking, culturing and preserving gingival fibroblasts are well known to the man skilled in the art and are particularly described in Naveau *et al.* (2006) *J. Periodontol.* 77:238-47.

Preferred embodiments

A preferred embodiment of the balloon catheter device of the invention is represented in Figures 1 and 2, which show the conduit for a biological flux (2) in which the balloon catheter device (1) is intended to be placed for administering a therapeutic composition to the luminal walls (3) of said conduit (2). The balloon catheter device (1), comprises:

- an outer catheter (4) comprising a wall (5), a lumen (6), a distal end provided with an opening (7) and a proximal end;
- a distal balloon (8) and a proximal balloon (9) around the outer catheter (4), the distal balloon (8) being located between the distal end of the outer catheter (7) and the proximal balloon (9), wherein the diameter of said distal and proximal balloons (8,9), when they are inflated, is essentially that of the inner diameter of said biological conduit (2);

wherein a first segment (10) of the wall of the outer catheter between the distal balloon (8) and the proximal balloon (9) is permeable to the therapeutic composition, a second segment (11) of the wall of the outer catheter between the proximal balloon (9) and the proximal end is permeable to the biological flux, the portions of the lumen of the outer catheter underneath said first and second segments (10,11) being delimited by at least one impermeable seal (12), and the lumen of the outer catheter accommodates:

- a hollow cylinder (13) having a wall (14) substantially impermeable to the biological flux, with a first opened end (15) and a second opened end (16), wherein the first opened end (15) is hermetically fitted through the opening (7) of the distal end of the outer catheter, and the second opened end (16) opens in the portion of the lumen of the outer catheter underneath said second segment (11);
- at least two inner catheters for respectively inflating the distal and proximal balloons (17,18) and at least one inner catheter for delivering the therapeutic composition (19), wherein the inner catheters are provided with a distal end and a proximal end, the proximal end extending to the proximal end of the outer catheter, the distal end (20) of the at least one inner catheter for delivering the therapeutic composition (19) opening in the portion of the lumen of the outer catheter underneath said first segment (10), and the

distal ends of the at least two catheters for respectively inflating the distal and proximal balloons (21, 22) respectively opening in the distal and proximal balloons (8,9).

As will be clear to one of skill in the art, when the inflated balloon catheter device is in place in the conduit, the biological flux can freely flow through the hollow cylinder (13), entering the opening (15) and exiting by the opening (16) and then through the permeable wall of the second segment. In the meantime, the therapeutic composition delivered by the inner catheter (18) can fill a chamber delimited by the wall of the conduit, the distal and proximal balloons, and the wall of the hollow cylinder (*i.e.* the chamber constituted by the lumen of the conduit and the lumen of the balloon catheter device comprised between the distal and proximal balloons) so that the therapeutic composition is in contact with the wall of the conduit to be treated. Furthermore, contact between the biological flux and the therapeutic composition is prevented.

The outer and inner catheters (4, 17, 18, 19) can be made of any material suited for manufacturing a catheter. Such materials are well known to one of skill in the art and notably encompass silicon. As will be clear to one of skill in the art, the catheters can be of one piece or assembled from several parts. The at least one seal (12) can be made of any material suited for providing an impermeable joint, such as silicon for instance. One of skill skilled in the art will know where to add other seals, for instance on both sides of the distal and/or proximal balloons.

In a preferred embodiment of the balloon catheter device of the invention, the hollow cylinder (13) extends beyond the opening (7) of the distal end of the outer catheter and the wall of the part of the hollow cylinder which extends beyond the opening (7) is permeable to the biological flux. The length of the part of the hollow cylinder extending beyond the opening (7) is preferably of from 10 mm to 25 mm.

Preferably, the permeable segments (10,11) comprise holes (23,24), as well as the part of the hollow cylinder (13) which extends beyond the opening (7). As intended herein, the holes preferably have a diameter of from about 1 mm to about 10 mm, more preferably of about 1 mm to about 3 mm. Such large diameters ensure that where the therapeutic composition is to be delivered through the holes, the diameter is such that jet lesions of the walls of the conduit are avoided. Besides, the holes should preferably be such that that they allow cells, which may be present in the biological flux or in the therapeutic composition, to go through the holes undamaged. Thus, the holes preferably present with beveled and/or smooth borders.

Besides, the inner catheter for delivering the therapeutic composition (18) comprises at least one valve for preventing a return of the therapeutic composition upon the delivery thereof. It is preferred that this valve can be opened by an operator of the

balloon catheter device of the invention so as to aspirate the therapeutic composition once it has been sufficiently contacted with the luminal wall to be treated and/or the balloon catheter device of the invention is to be removed. Besides, it also preferred that the inner catheter for delivering the therapeutic composition (19) is suitable for delivering a therapeutic composition comprising a cellular suspension.

In a preferred embodiment of the balloon catheter device according to invention, the distance between the distal and proximal balloons (8,9) is of from about 5 mm to about 200 mm. It is also preferred that the diameter of the opening of the hollow cylinder (13) is of from about 1 mm to about 5 mm. It is also preferred that the diameter of the inflated distal and proximal balloons (8,9) is of from about 5 mm to about 50 mm. In yet another preferred embodiment, the balloon catheter device according to the invention is such that it is suitable to be placed in a biological conduit (2) selected from the group consisting of a vascular conduit, a digestive conduit, a respiratory conduit and an uro-genital conduit. It is particularly preferred that the balloon catheter device according to the invention is intended for treating an aortic aneurism, in this case the distance between the distal and proximal balloons (8,9) is of about 10 mm to about 100 mm, the diameter of the opening of the hollow cylinder (13) is of from about 1 mm to about 5 mm, and the diameter of the inflated distal and proximal balloons (8,9) is of from about 5 mm to about 50 mm.

In another preferred embodiment of the balloon catheter device according to the invention, the hollow cylinder (13) is made out of silicone. Besides, it is also preferred that the wall of the hollow cylinder (13) is coated with an anticoagulant.

In another preferred embodiment, the balloon catheter device according to the invention further comprises a guiding inner catheter, in particular suitable to accommodate a guide wire. The guide wire is useful in that it helps preventing harming the luminal walls of the conduit during the placement of the balloon catheter device. Preferably, where a guide wire is used, the guide wire is first introduced in the conduit to be treated and then, once it has reached a site of defect of the luminal walls to be treated, the balloon catheter device is fit on the guide wire and driven to the site of defect. Similarly to the other inner catheters (17,18, 19), its is preferred that the guiding inner catheter is inside the outer catheter, outward from the hollow cylinder and that it extends essentially along the whole length of the outer catheter.

In another preferred embodiment, the balloon catheter device according to the invention, further comprises a marker for localizing the device (1) in the biological conduit (2), the marker can be placed between the distal and proximal balloons (8,9) and be suitable for endoartherial echography for instance.

In yet another preferred embodiment, the above-defined device is suitable for a single use only, *i.e.* it cannot be re-used a second time when it has already been used for cell therapy in an individual.

As regards the transluminal percutaneous method according to the invention, the implantation procedure of the device of the invention will be apparent to one of skill in the art and can for instance follow the general procedure adopted for stent implantation. It is preferred that the distal balloon is inflated first, to stop the flow of the flux, which preferably comes in direction of the distal end of the outer catheter, so that, when the proximal balloon is inflated, the lumen of the conduit between the balloons is essentially empty, *i.e.* essentially exempt of biological material carried by the biological flux.

In particular, the percutaneous transluminal method of the invention is for treating an aortic aneurism and comprises:

- introducing a deflated catheter balloon device intended for treating an aneurism of the aorta as defined above in a femoral artery;
- guiding the deflated catheter balloon device mounted on a guide wire to a site of aneurism in the aorta;
- placing the balloon catheter device such that the site of aneurism is located between the distal and proximal balloons;
- inflating the distal and proximal balloons;
- delivering a therapeutic composition intended to treat the site of defect with the inner catheter for delivering the therapeutic composition so that the therapeutic composition is in contact with the site of defect;
- maintaining the therapeutic composition in contact with the site of defect for a time sufficient for the therapeutic composition to exert its therapeutic effect;
- removing the therapeutic composition;
- deflating the distal and proximal balloons;
- removing the balloon catheter device from the aorta through the femoral artery.

Preferably, in the percutaneous transluminal method of the invention, the therapeutic composition comprises a cellular suspension, which more preferably comprises stem cells and/or gingival fibroblasts.

Advantageously, gingival fibroblasts have been shown to treat arterial-remodelling pathologies (WO 2006/013261) and more recently to promote and to accelerate skin wound healing. Advantageously also, gingival fibroblasts are easily sampled and cultured. Besides, gingival fibroblasts possess a high expansion rate. Accordingly, gingival fibroblasts provide for an almost limitless source of autologous fibroblasts.

It is also preferred that the cells of the cellular suspension are autologous, that is they are taken from the individual to whom they are intended to be administered. Preferably the individual is a mammal and more preferably a human. However, the cells can also be allogenic, that is taken from another individual of the same species or heterologous, that is taken from another individual of another species.

Preferably also, in the percutaneous transluminal method of the invention, the therapeutic composition is maintained in contact with the site of defect for a time of from about 10 to 30 min. Besides, it is preferred that the totality of the volume of the chamber delimited by the wall of the conduit, the distal and proximal balloons, and the wall of the hollow cylinder (*i.e.* the chamber constituted by the lumen of the conduit and the lumen of the balloon catheter device comprised between the distal and proximal balloons) be filled by the therapeutic composition. The number of cells to be delivered by the balloon catheter device should preferably be of from 10^5 to 10^9/ml. Besides, the volume (*e.g.* of from 100 µl to 20 ml) of the therapeutic composition delivered should preferably be such that the agent filled up in the cavity is under pressure, so that it tends to migrate in direction of the defect, is.

It shall be evident to a man skill in the art, that the many arrangements and embodiments, not precisely set forth, could be practiced under the teachings of the present invention, as set forth in the following claims.

CLAIMS

1.- A balloon catheter device (1) intended to be placed within a conduit (2) of a biological flux, for administering a therapeutic composition to luminal walls (3) of said conduit (2), comprising:

- an outer catheter (4) comprising a wall (5), a lumen (6), a distal end provided with an opening (7) and a proximal end;

- a distal balloon (8) and a proximal balloon (9) around the outer catheter (4), the distal balloon (8) being located between the distal end of the outer catheter (7) and the proximal balloon (9), wherein the diameter of said distal and proximal balloons (8,9), when they are inflated, is essentially that of the inner diameter of said biological conduit (2);

wherein a first segment (10) of the wall of the outer catheter between the distal balloon (8) and the proximal balloon (9) is permeable to the therapeutic composition, a second segment (11) of the wall of the outer catheter between the proximal balloon (9) and the proximal end is permeable to the biological flux, the portions of the lumen of the outer catheter underneath said first and second segments (10,11) being delimited by at least one impermeable seal (12), and the lumen of the outer catheter accommodates:

- a hollow cylinder (13) having a wall (14) substantially impermeable to the biological flux, with a first opened end (15) and a second opened end (16), wherein the first opened end (15) is hermetically fitted through the opening (7) of the distal end of the outer catheter, and the second opened end (16) opens in the portion of the lumen of the outer catheter underneath said second segment (11);

- at least two inner catheters for respectively inflating the distal and proximal balloons (17, 18) and at least one inner catheter for delivering the therapeutic composition (19), wherein the inner catheters are provided with a distal end and a proximal end, the proximal end extending to the proximal end of the outer catheter, the distal end (20) of the at least one inner catheter for delivering the therapeutic composition (19) opening in the portion of the lumen of the outer catheter underneath said first segment (10), and the distal ends of the at least two catheters for respectively inflating the distal and proximal balloons opening (21, 22) in the distal and proximal balloons (8,9).

2.- The balloon catheter device according to claim 1, wherein the hollow cylinder (13) extends beyond the opening (7) of the distal end of the outer catheter and the wall of the part of the hollow cylinder which extends beyond the opening (7) is permeable to the biological flux.

3.- The balloon catheter device according to claim 1 or 2, wherein the permeable segments (10,11) or the part of the hollow cylinder (13) which extends beyond the opening (7) comprise holes (23,24) having a diameter from about 1 mm to about 10 mm.

4.- The balloon catheter device according to any of claims 1 to 3, further comprising a guiding inner catheter intended for accommodating a guide wire.

5.- The balloon catheter device according to any of claims 1 to 4, further comprising a marker for localizing the device (1) in the conduit (2).

6.- The balloon catheter device according to any of claims 1 to 5, wherein the inner catheter for delivering the therapeutic composition (19) comprises at least one valve for preventing a return of the therapeutic composition upon the delivery thereof.

7.- The balloon catheter device according to any of claims 1 to 6, wherein the distance between the distal and proximal balloons (8,9) is of from about 5 mm to about 200 mm.

8.- The balloon catheter device according to any of claims 1 to 7, wherein the hollow cylinder (13) is made out of silicone.

9.- The balloon catheter device according to any of claims 1 to 8, wherein the wall of the hollow cylinder (13) is coated with an anticoagulant.

10.- The balloon catheter device according to any of claims 1 to 9, wherein the diameter of the opening of the hollow cylinder (13) is of from about 1 mm to about 5 mm.

11.- The balloon catheter device according to any of claims 1 to 10, wherein the diameter of the inflated distal and proximal balloons (8,9) is of from about 5 mm to about 50 mm.

12.- The balloon catheter device according to any of claims 1 to 11, wherein conduit (2) is selected from the group consisting of a vascular conduit, a digestive conduit, a respiratory conduit and an uro-genital conduit.

13.- The balloon catheter device according to any of claims 1 to 12, intended for treating an aortic aneurism, wherein the distance between the distal and proximal balloons (8,9) is of about 10 mm to about 100 mm, the diameter of the opening of the hollow cylinder (13) is of from about 1 mm to about 5 mm, and the diameter of the inflated distal and proximal balloons (8,9) is of from about 5 mm to about 50 mm.

14.- The balloon catheter of claim according to any of claims 1 to 13, wherein the inner catheter for delivering the therapeutic composition (19) is suitable for delivering a therapeutic composition comprising a cellular suspension.

15.- A percutaneous transluminal method for treating a site of defect of the luminal walls of a conduit for a biological flux in an individual, comprising:

- placing a non-inflated balloon catheter device according to any of claims 1 to 14 within the conduit such that the site of defect is located between the distal and proximal balloons;
- inflating the distal and proximal balloons;
- delivering a therapeutic composition intended to treat the site of defect with the inner catheter for delivering the therapeutic composition so that the therapeutic composition is in contact with the site of defect;
- maintaining the therapeutic composition in contact with the site of defect for a time sufficient for the therapeutic composition to exert its therapeutic effect;
- removing the therapeutic composition;
- deflating the first and second balloons;
- removing the balloon catheter device from the conduit.

16.- The percutaneous transluminal method according to claim 15, for treating an aortic aneurism comprising:

- introducing a deflated catheter balloon device as defined in claim 13 in a femoral artery;
- guiding the deflated catheter balloon device mounted on a guide wire to a site of aneurism in the aorta;
- placing the balloon catheter device such that the site of aneurism is located between the distal and proximal balloons;
- inflating the distal and proximal balloons;
- delivering a therapeutic composition intended to treat the site of defect with the inner catheter for delivering the therapeutic composition so that the therapeutic composition is in contact with the site of defect;

- maintaining the therapeutic composition in contact with the site of defect for a time sufficient for the therapeutic composition to exert its therapeutic effect;
- removing the therapeutic composition;
- deflating the distal and proximal balloons;
- removing the balloon catheter device from the aorta through the femoral artery.

17.- The percutaneous transluminal method according to claim 15 or 16, wherein the therapeutic composition comprises a cellular suspension.

18.- The percutaneous transluminal method according to any of claims 15 to 17, wherein the therapeutic composition comprises gingival fibroblasts.

19.- The percutaneous transluminal method according to any of claims 15 to 18, wherein the therapeutic composition is maintained in contact with the site of defect for a time of from about 10 to 30 min.

20.- A balloon catheter device intended to be placed within a conduit of a biological flux, for administering a therapeutic composition to luminal walls of said conduit, wherein when the inflated balloon catheter device is in place in the conduit, the biological flux can freely flow through said device, the therapeutic composition fills a chamber delimited by the wall of the conduit and the device, and contract between the biological flux and the therapeutic composition is prevented.

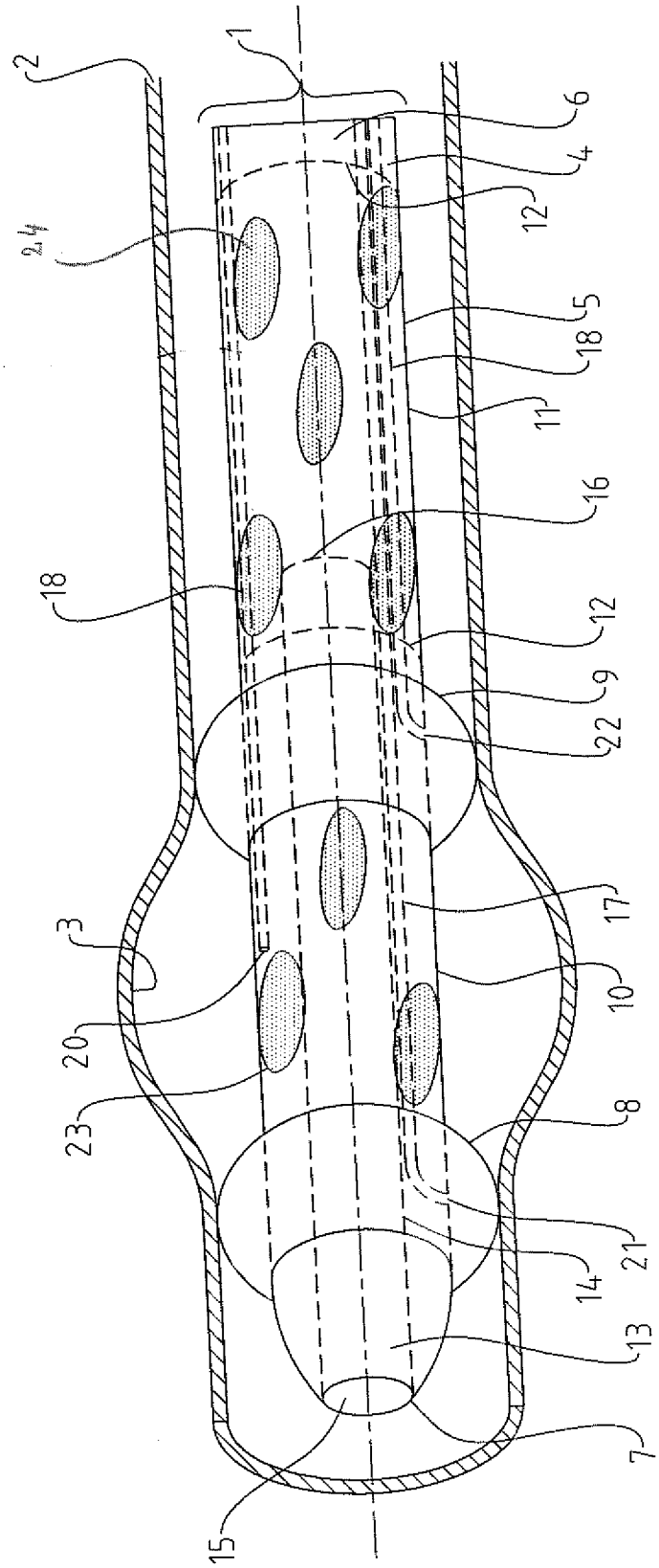

FIG. 1

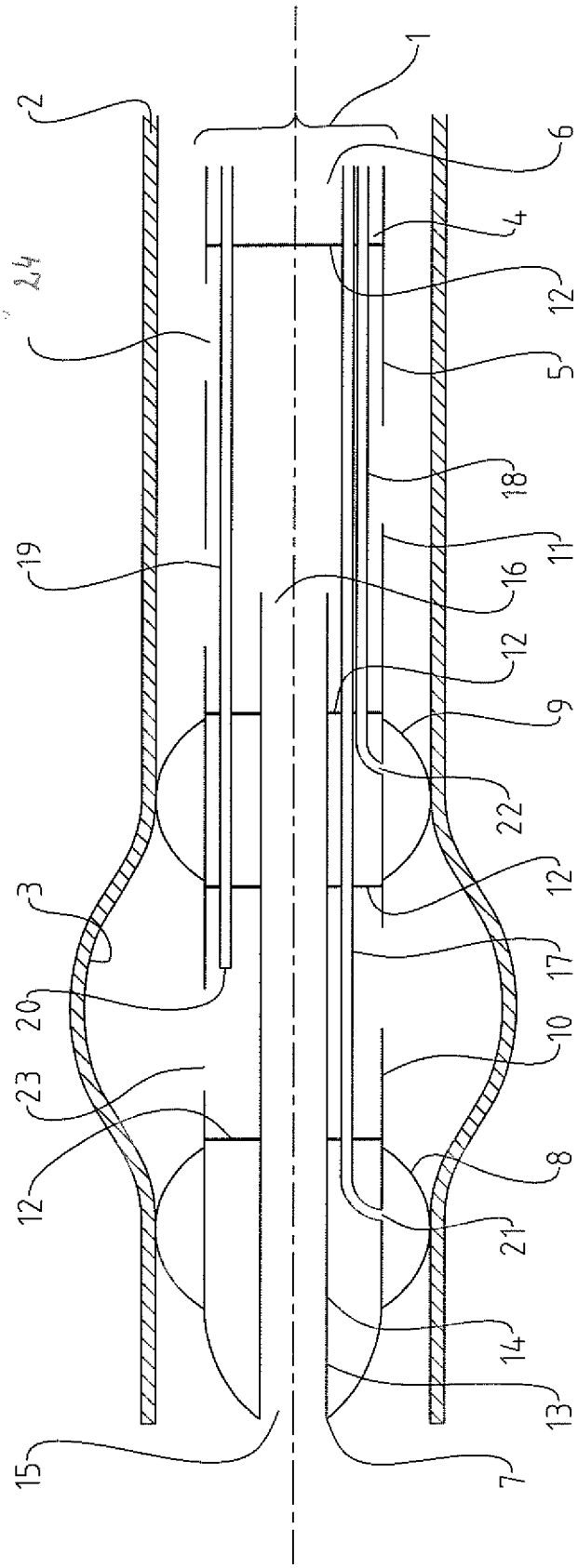

FIG.2

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2010/060801

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/00 A61M25/10
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)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 674 198 A (LEONE JAMES E [US]) 7 October 1997 (1997-10-07) column 1, line 5 - column 5, line 43; figures 1,2	1-12,14, 20
X	US 5 779 673 A (ROTH LAURENCE A [US] ET AL) 14 July 1998 (1998-07-14) column 18, line 44 - column 19, line 42; figures 12a, 12b	1-12,14, 20
X	EP 0 872 257 A2 (SCHNEIDER EUROP GMBH [CH]) 21 October 1998 (1998-10-21) the whole document	1-12,20
X	US 5 415 636 A (FORMAN MICHAEL R [US]) 16 May 1995 (1995-05-16) column 3, line 8 - column 4, line 20; figure 5	1-14,20

☐ 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
13 October 2010	03/11/2010

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	Rodrigues, Elodie

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2010/060801

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.: 15-19
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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 all searchable 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 report covers 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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 15-19

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery The percutaneous transluminal methods for a site of defect of the luminal walls of a conduit for a biological flux in an individual described in claims 15-19 comprise the step of placing a non-inflated balloon catheter device within the conduit. These methods are thus surgical methods.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2010/060801

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5674198 A	07-10-1997	NONE	
US 5779673 A	14-07-1998	NONE	
EP 0872257 A2	21-10-1998	AU 5944898 A	22-10-1998
		CA 2232277 A1	15-10-1998
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