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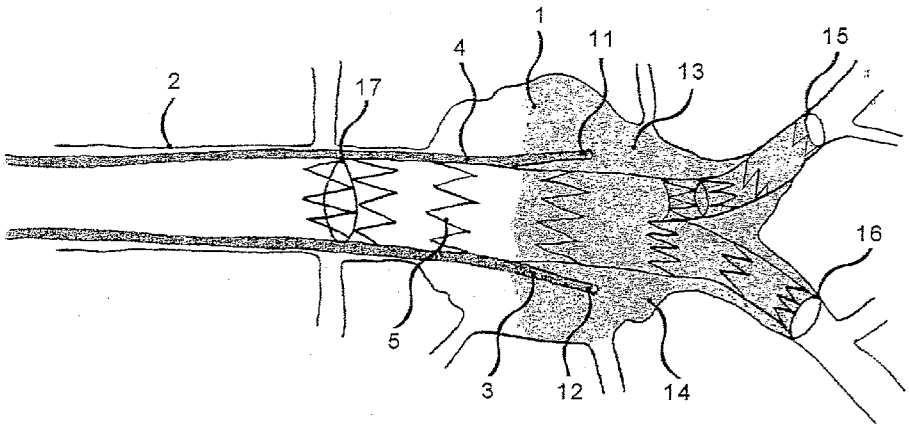
(54) **Title:** AN APPARATUS FOR THE INTRAPROCEDURAL EMBOLIZATION OF THE ANEURISMAL SAC



(57) **Abstract:** A device for the consolidation of an aortic endoprosthesis (5), characterised by the intraprocedural introduction, into the aneurismal sac (1) of the artery (2) to be treated, of a polymeric resin, according to the following steps: a) introduction of at least one catheter (3, 4), pre-mounted on the outer side of the endoprosthesis, into the damaged artery (2) until a position (15, 16) is reached where the distal end of the endoprosthesis (5) is to be positioned; b) gradual filling of the whole aneurismal area (1, 8, 9, 10, 13, 14) with the polymeric resin that gradually comes out of said catheter (3, 4); c) withdrawal or retraction of said catheter(s) (3, 4) during the gradual filling of the aneurismal sacs (1, 8, 9, 10, 13, 14); d) extraction of said catheter(s) (3, 4) from the access site.

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An apparatus for the intraprocedural embolization of the aneurismal sac

Technical Field

The present invention relates to an apparatus for the intraprocedural embolization of the aneurismal sac.

Background Art

Presently, endoprostheses differ from classical "bare" stents employed up to a year ago only in that they are covered by a cylindrical structure realized essentially in synthetic, biocompatible fabric, that are impermeable to liquids, particularly the blood. These arterial endoprostheses are internally implanted in the damaged arterial segment, by introducing them through well determined paths, using appropriate release systems. The endoprosthesis, after having been introduced inside the artery and after having been positioned in the damaged area under fluoroscopic guiding, is opened with usual, known techniques, so that it adequately contacts the internal wall of the damaged artery. The presence of the impermeable fabric, within that portion of the blood vessel, creates a neo-lumen within which the circulating blood can flow. Said neo-lumen, by internally lining the artery, insures that the blood pressure cannot act on the blood vessel portion which receives the endoprosthesis. This is a largely employed technique and is vastly applied to all pathologies in which the functionality of the artery wall is totally or partially damaged or impaired, or in other words, to all pathologies in which said artery wall is at the risk of rupture. The endoprosthesis, being interposed between the blood flow and the damaged artery wall, mechanically prevents the rupture of the artery wall, by protecting the entire damaged artery wall portion from high pressure and from the typical pulses of the aortic tract. The pathologies to which such techniques making use of artery endoprostheses are

applied are the thoracic aneurysms, the aneurysms of the abdominal aorta with or without the involvement of the iliac arteries, the aneurysms of the femoral-popliteal region, the aortic dissection, the lesions due to open or closed aortic traumas and lesions of peripheral arteries.

The aim of the endoprosthesis implantation is the exclusion from the blood flow, of the artery segment affected by the pathology. In case of an aneurysm, which until now constitutes the most frequent application field, the aim of the therapy is the complete exclusion of the aneurismal sac from the blood flow, with complete thrombosis of the same. The obvious advantage of this kind of therapy is the lower invasiveness with respect to classical surgical operations. This reduced invasiveness noticeably reduces mortality, morbidity, and the hospitalization time for those patients that are subjected to endoprosthesis treatment with respect to those treated by a traditional surgical operation.

The disadvantage in the use of this therapy is the higher number of failures which are mainly due to the continuing blood perfusion into the aneurismal sac also after the introduction of the endoprosthesis ("endoleak"), because of the dislocation and kinking of the endoprosthesis.

The first of the cited complications, the persisting perfusion (endoleak) into the aneurismal sac, is classified into four, distinct typologies. The perfusion of the first kind consists in the blood flow occurring in the areas in which the prosthesis lays on the artery wall itself. The prosthesis, in fact, is positioned in such a way as to cover, besides the aneurismal segment, also a healthy area of the vessel which is located both upstream and downstream of the lesion. These areas, which are defined as proximal and distal neck, are the areas in which the endoprosthesis, due to its radial force, adheres to the vessel itself. If in these areas there is a blood leak or infiltration between the vessel wall and the endoprosthesis, one speaks of perfusion of the first kind.

The perfusion of the second kind involves instead the aneurismal sac through the

blood coming from the artery branches extending from the aneurism itself.

The perfusion of the third kind occurs because of the passage of blood through the contact areas between two prosthesis segments. This may occur when the lesion is very long or in cases where the pathology involves the abdominal aorta below the kidney and the iliac arteries. In this case the main segment is positioned, which in turn distally bifurcates into two branches; the first of these branches, the longer one, continues in the homolateral iliac artery at the access seat, the second of these branches, the shorter one, is extended by the insertion of a rectilinear segment – with controlateral access to the first -, inserted in a coaxial manner with respect to the same branch.

The perfusion of the fourth kind is instead caused by porosity and discontinuities of the same lining cloth.

The dislocation of the endoprosthesis consists instead in the migration of the prosthesis under the pushing action of the pressure existing in the artery, due to the pulsation force. Due to these thrusts, a bad adhesion of the anchoring area of the prosthesis to the vessel wall could cause a distal sliding of the prosthesis.

The bending, internationally known as "kinking", represents on the other hand an excessive curvature of the prosthesis segment along its main axis. This may cause the dislocation of the prosthesis at the level of its proximal and distal neck, or may cause such dislocation in the intercommunication areas between two prosthesis segments, or finally, it could give rise to turbulent motions of the blood flow that could be a cause of thrombosis.

In the long run, the kinking could negatively affect the mechanical resistance characteristics of the prosthesis itself. All the above complications are extremely dangerous because of the reduced protection from the risk of rupture (breakage) of the aneurismal lesion.

For this reason, various systems have been used which are apt to avert and cure these complications; all endeavours for preventing and curing the perfusion, the dislocation

and kinking, have success percentages that vary amply.

However, these systems increase the invasiveness of the procedure in an undefined manner and for this reason these techniques put the patient at risk of various complications; according to the use of very expensive materials and longer hospitalization times, they increase the total cost of the therapy and at the same time they reduce the probability of success. The failure of the endoprosthesis therapy may lead to a surgical conversion in a short time or in the long run. The perfusion, the dislocation, and the kinking, all represent (till now) unsolved problems of the endovascular therapy of arterial aneurisms.

Disclosure of Invention

The procedural technique introduced by the present invention has the object of preventing such intraprocedural complications. The innovation consists in the injection of a specific liquid resin, which is subjected to polymerisation and solidification, in the segment of the vessel excluded from the blood flow after the endoprosthesis has been brought to its definitive position. The injection of said resin is effected by means of at least one angiographic catheter, brought to its position before release of the endoprosthesis.

Said catheters, whose features are like those of commercial-kind catheters, will preferably be selected each time according to the operation modalities. The catheter(s) is (are) introduced in the blood flow, through an additional access, or through the same arterial access used to push forward the release system of the endoprosthesis, and then, it (they) is (are) pushed forwards inside the arterial circulation system until it (they) reaches (reach) the area of the vessel to be treated. After the positioning of the catheter(s), the usual positioning and opening of the endoprosthesis is effected. After the opening operation, the stretch or segment of the artery that remains excluded, will be excluded in the future from the blood flow in a natural way. Thus, the catheter(s), reaching the interior of the excluded segment or

stretch, is/are exactly interposed between the external wall of the endoprosthesis and the inner, damaged wall of the native artery. The distal end of the catheter(s) is positioned in a position corresponding to one of the terminations of the excluded stretch or segment, and specifically at the position of the distal end, that is the end opposite the access site. Summing up, if the catheter(s) enters (enter) from a cranial access with respect to the endoprosthesis, their end will be positioned at the level of the caudal end, whereas, if the catheters enter from a caudal access with respect to the area where the endoprosthesis is positioned, then their end will be positioned at the cranial end of the excluded segment.

As a result, the catheter(s) completely pass(es) through the excluded segment , by extending from one end to the other in the direction of the longitudinal axis, and their distal end is located at the distal end of the excluded segment.

The proximal end passes instead through the area of the neck. The end(s) of the catheter(s) and the whole area within the excluded segment or stretch, are not in contact with the blood flow. After at least one catheter has been positioned, the endoprosthesis is introduced, positioned and opened inside the damaged artery stretch. At this point, the resin, appropriately premixed with a selected, radioopaque contrast medium, is injected through the abovementioned catheter(s). During this injection, which is entirely performed under fluoroscopic control, the catheter(s) is(are) slowly but gradually retracted (withdrawn), until the whole excluded segment is completely filled.

When the distal end of the catheter(s) reaches a position near the proximal neck, the injection is stopped. Then, the catheter(s) is(are) extracted by simply unthreading it(them), since by that time they have been already withdrawn beyond the excluded segment or stretch, wherein, during this last extraction step, a negative pressure is generated by simply applying a vacuum to the inside of the catheter(s). At the end of the procedure described above the excluded segment or stretch is not only excluded form the blood stream, but it will also be stably filled with a biocompatible material

having an optimum imperviousness and elasticity, or alternatively, it will be filled with one or more detachable balloons of a commercial kind.

This condition absolutely prevents the possibility of any perfusion phenomena, since it is intuitive that a space filled with a semisolid material cannot receive any kind of fluid. Moreover, even assuming that the space is not completely filled and that voids still exist inside the excluded segment, the blood flow inside said segment would be largely hindered and would become slow and stagnant, and this condition promotes a thrombosis and the resulting clot formation. Any voids would therefore be filled by coagulated blood or thrombi, within a few hours from the end of the above described procedure and in particular after the anticoagulant effect of the heparin has disappeared – heparin is usually administered in the procedure to facilitate the operation -.

An additional advantage of the technique introduced by the present invention consists in the improved adherence of the endoprosthesis. Actually, in contrast with the prior art, according to which the endoprosthesis is anchored and supported only in the proximal and distal areas of the damaged artery, while remaining suspended and totally free in its central part, in the new procedure the endoprosthesis now has a support and anchoring along its whole extent. A result of this is an increased protection against two of the most widespread complications for this kind of operations, that is, the dislocation of the endoprosthesis and the "kinking" of the same. Both the catheter(s) and the resin to be used as "filler", may be selected among commercial products available nowadays for clinical use, or may be realised ad hoc if they must posses specific features.

The advantages of the technique introduced by the present invention lie in its extreme simplicity, in the limited invasiveness, and in the velocity of execution. This technique is to be intended as an intraprocedural method that only slightly extends the duration of the operation, leaving practically unaltered the invasiveness of the operation considered as a whole. The "additional invasiveness" actually

consists simply in an additional puncture of the artery, for each additional catheter to be introduced.

Moreover, it may be stated that this innovative technique provides more certainty (reliability) in relation to mechanical stability and imperviousness. Among the advantageous characteristics of the resin we wish to point out its viscosity, which is sufficiently high to allow the prevention of its downflow in case it happens to penetrate inside blood vessels of a few millimetres in diameter, like the normal artery branches dealt with in this context. In this respect, an additional safety element is given by physiopathological considerations: after any kind of endoprosthesis has been grafted, the excluded segment is subject to pressures far less than those existing in the surrounding arterial system. For this reason, immediately after the positioning (grafting) of the endoprosthesis, in the artery branches the flow changes from centrifugal to centripetal, and this, in any case, noticeably reduces the embolic risk or renders it negligible.

Brief Description of Drawings

FIGURE 1 shows the damaged segment of the abdominal aorta, with special emphasis on the aneurismal sac; two catheters have been introduced inside the artery;

FIGURE 2 shows the abdominal stretch or tract of the aorta into which, besides the two catheters, the endoprosthesis closed by its release system has also been introduced;

FIGURE 3 shows the abdominal stretch or tract of the aorta 2, where the endoprosthesis has been placed in order to exclude the aneurismal sac;

FIGURE 4 shows the abdominal tract or stretch of the aorta where the endoprosthesis has been placed, together with the additional endoprosthesis which involves the iliac

artery; the two catheters are interposed between the endoprostheses and the artery wall;

FIGURE 5 shows the abdominal stretch of the aorta, wherein a polymeric resin comes out of the catheters and initially fills the locations 8, 9 and 10 located in the immediate proximity of the catheter ends 11 and 12;

FIGURE 6 shows the abdominal tract of the aorta, wherein, during their withdrawal, a polymeric resin comes out of the two catheter ends and this resin progressively fills the aneurismal sacs;

FIGURE 7 shows the aneurismal sacs that have been completely filled with the polymeric resin which came out of the catheters;

FIGURE 8 shows the endoprosthesis entirely enveloped by the polymeric resin that came out of the catheters, after it has completely filled the aneurismal sacs;

FIGURE 9 shows the release system which contains the compressed endoprosthesis, ready for its release, and the catheter for the embolization or filling.

FIGURE 9B shows a cross-section of the release system of the endoprosthesis obtained at the level of line 20 indicated in Fig. 9. This figure shows the catheter for the embolization operation, the closed meshes or stitches of the stent 22, the folded up cloth of the endoprosthesis 23, the central channel 24 used for the passage of the guide-wire.

Description of Preferred Embodiments

Example 1

In the following, an endovascular repair procedure for an aneurism of the abdominal aorta, located underneath the kidney, will be described; the procedure will employ an endoprosthesis 5 assisted by the technique introduced in accordance with the present invention.

The aneurismal lesion extends 2 cm distally from the beginning of the renal arteries, up to the aortic bifurcation 2, by involving the proximal part of the right common iliac artery.

After having isolated surgically both the common femoral arteries, two 5F - introduction sheaths are positioned in both brachial arteries. From each of these accesses an angiographic catheter - of diameter 5 F and of the kind Multipurpose - is pushed forwards, and after having reached the abdominal aorta, these are positioned with their tip in the common iliac artery, in the area of the distal neck. An aorto 5-bisiliac 7 endoprosthesis is now positioned in accordance with the conventional technique. Through the right-hand femoral artery, which is surgically isolated, a release system 6 of the endoprosthesis is pushed forwards, and this system, after its correct positioning, is released. From the left-hand iliac artery the second segment is introduced and pushed forwards, which will extend the apposite iliac branch. The endoprosthesis 5 is at this moment totally in its place. Thereafter a possible dilation obtained with the aid of a balloon will be effected in the areas of neck 15, 16 and 17. Then, a resin is injected from the ends 11 and 12 of the catheters, monitoring at the same time - with a fluoroscopic control - its downflow into the aneurismal sac 1. During the progressive filling of this sac, the catheters 3 and 4 are slowly withdrawn, thereby allowing the gradual filling of the most cranial areas 8, 9, 10 and thereafter of the areas 13 and 14. After the whole aneurismal area 1 has been filled with resin, the injection is stopped and the catheters 3 and 4 are withdrawn until they reach the zone located outside the excluded area of the vessel. During this latter retraction operation, a simultaneous suction is performed inside the catheters 3 and 4 in order to prevent the resin contained in the catheters 3 and 4 from

accidentally reaching the arterial stream, by generating a suction pressure (vacuum) in the ends 11 and 12 of the catheters 3 and 4. A possible additional dilation with a balloon is performed in the area of the proximal neck 17.

The entire procedure is terminated after an angiographic check.

Example 2

An endovascular repair work is described in case of an abdominal aneurism having anatomic-pathological features corresponding entirely to the above example but involving the use of an endoprosthesis 19 compressed inside a release system which contains an embolization (= filling) catheter 18 pre-mounted on the outer side of the endoprosthesis.

The release system is positioned, under fluoroscopic control, in the desired target, and the endoprosthesis 19 is then released together with the embolization catheter 18 which is present in the release system.

The embolization catheter 18, is thus interposed between the outer wall of the endoprosthesis and the inner wall of the arterial lumen. Thereafter, the controlateral positioning of the iliac extension is performed. The resin is injected through the embolization catheter 18, under fluoroscopic monitoring, and the catheter 18 is retracted while the aneurismal sac is gradually filled exactly in the manner already described in Example 1. When the complete filling operation of the aneurismal sac 1 is terminated, this injection operation ends and only the catheter 18 is withdrawn (removed) to the outside of the vessel area excluded by the endoprosthesis.

A possible additional dilation with the aid of a balloon is thereafter performed in the area of the collet (collar).

After the angiography, performed for checking purposes, the entire procedure is terminated.

Claims

1. A device for the consolidation or strengthening of an aortic endoprosthesis (5), characterised by the intraprocedural introduction, into the aneurismal sac (1) of the artery (2) to be treated, of a polymeric resin according to the following steps:

a) introduction of at least one catheter (3, 4) into the damaged artery (2), until a position (15, 16) is reached where the distal end of the endoprosthesis (5) is to be positioned;

b) introduction and positioning of the endoprosthesis (5) within the artery (2), so that the endoprosthesis is positioned inside said at least one catheter (3, 4);

c) gradual filling of the whole aneurismal area (1, 8, 9, 10, 13, 14) with the resin that gradually comes out of said catheter (3, 4);

d) withdrawal of said catheter during the gradual filling of the aneurismal sacs;

e) extraction of said catheter(s) (3, 4) from the introduction site.

2. A device according to claim 1, wherein a suction action is applied at the proximal end of the catheter (3, 4) in order to generate a negative pressure in proximity of the distal ends (11, 12) at the time said catheter (3, 4) has reached, during its withdrawal, the proximal neck(17) of the endoprosthesis (5).

3. A device according to claims 1 and 2, wherein the polymeric resin is any kind of natural or synthetic resin suited, due to its elasticity, fluidity, biocompatibility and polymerisation features, for the specific requirements of the invention.

4. A device according to the preceding claims, wherein said polymeric resin can be directly injected into the aneurismal sac (1) through at least one catheter (3, 4) or it may be introduced into one or more detachable balloons.

5. A device according to any of the preceding claims, wherein said catheter (3) is any catheter of a conventional kind.

6. A device according to the preceding claims, wherein the consolidation or strengthening can be performed on a simple endoprosthesis or on a modular endoprosthesis, independently of the extent and localization of the damaged arterial area.

7. A device according to the preceding claims, wherein at least one catheter (3, 4) is pre-mounted on the external side of the endoprosthesis, in order to be subsequently inserted into the artery to be treated simultaneously with the introduction of the endoprosthesis (5), and for its removal after the treatment.

8. A device according to the preceding claims, wherein a guide suited for the advancement of the catheter is externally pre-mounted on the endoprosthesis, in order to be subsequently inserted into the artery to be treated, simultaneously with the introduction of the endoprosthesis, said guide being withdrawn at the end of the treatment.

9. A device according to the preceding claims, wherein at least one catheter (3, 4), or any guide suited for its insertion, can be introduced in the course of the procedure, either before, or during, or after the introduction of the endoprosthesis.

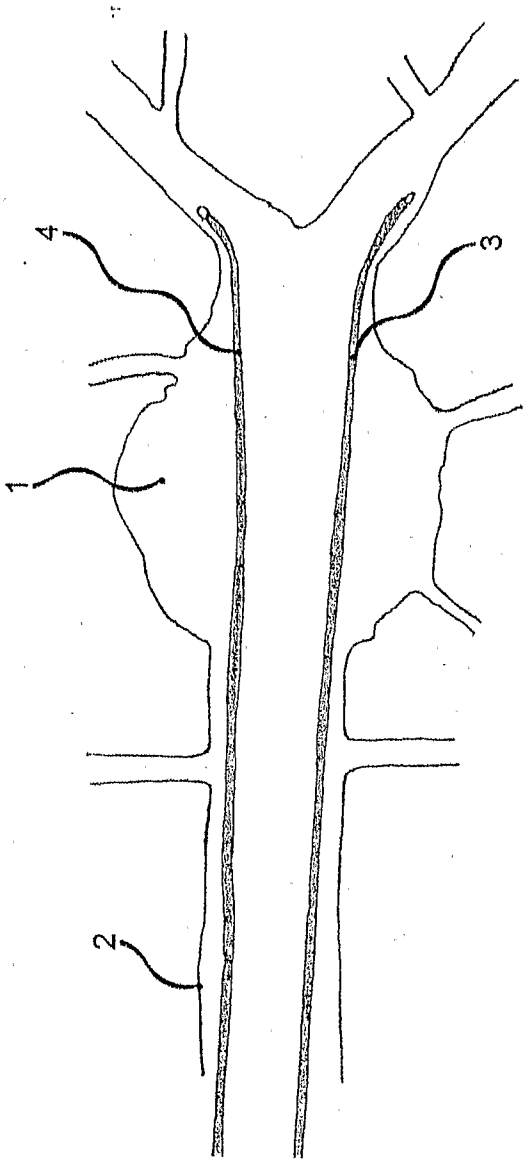


FIG. 1

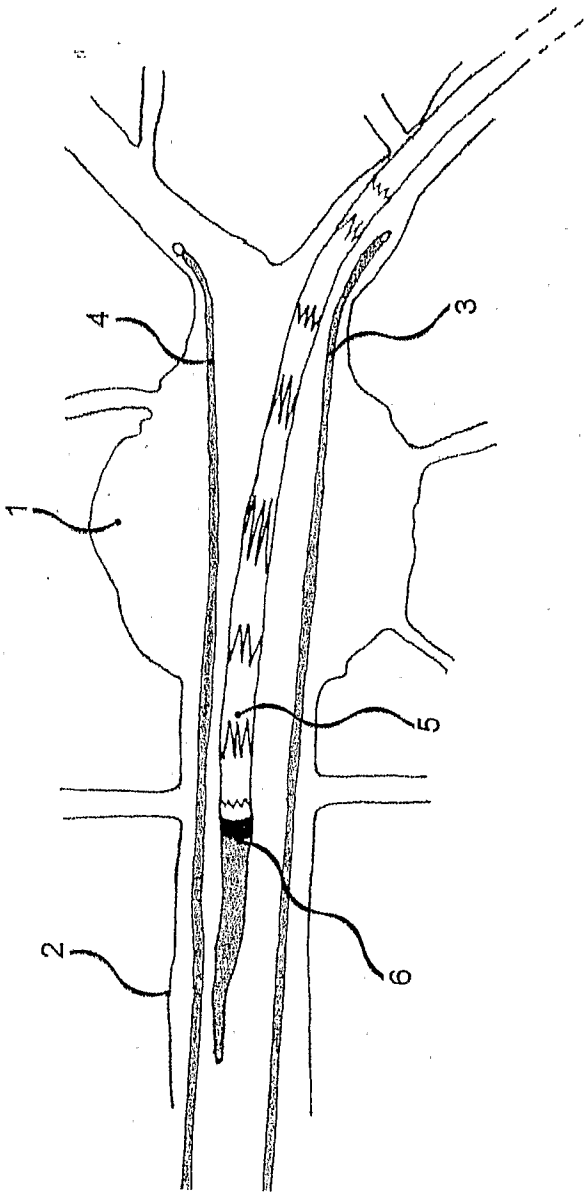


FIG. 2

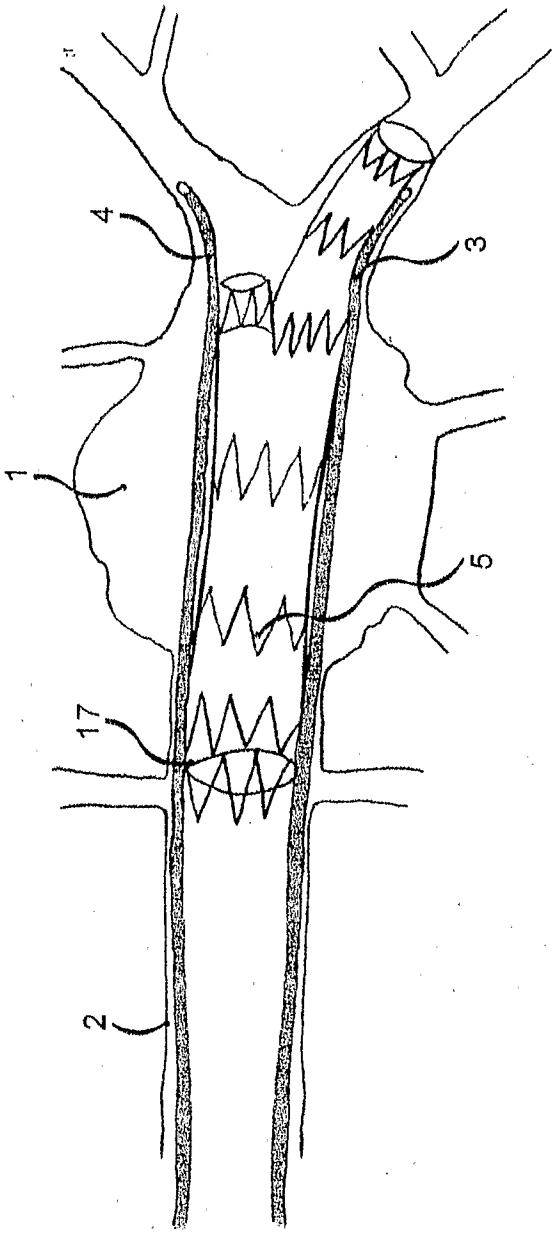


FIG. 3

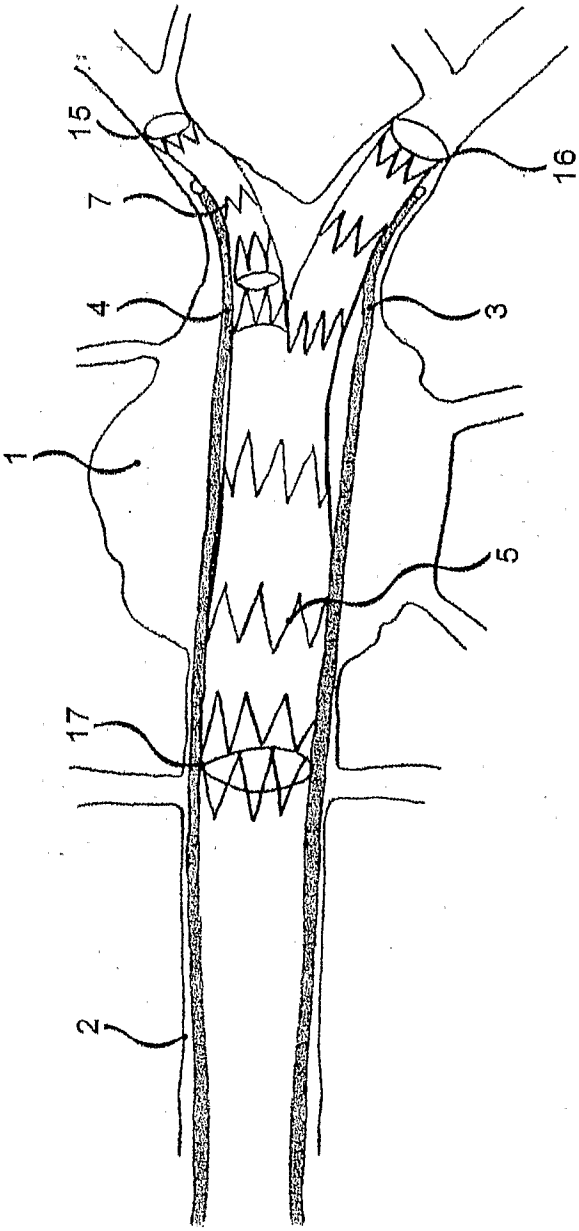


FIG. 4

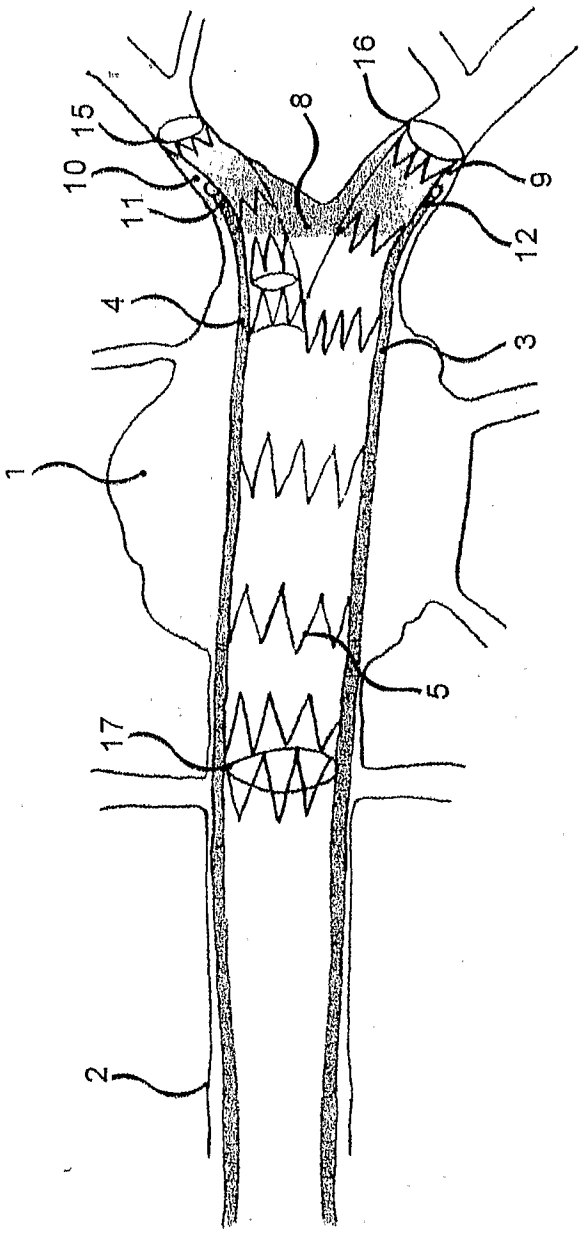


FIG. 5

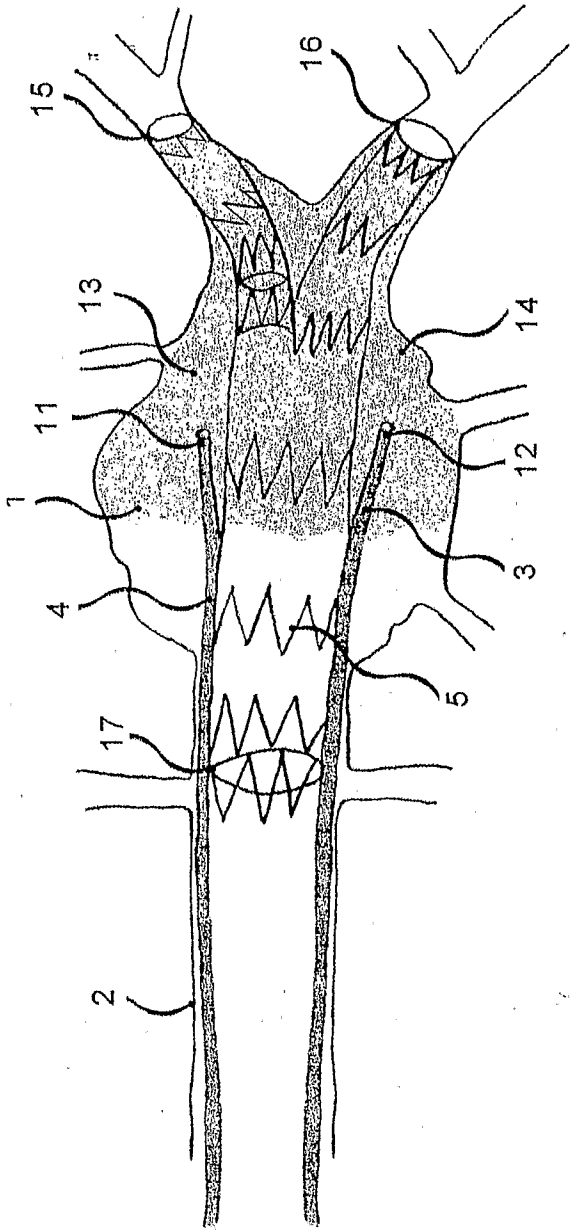


FIG. 6

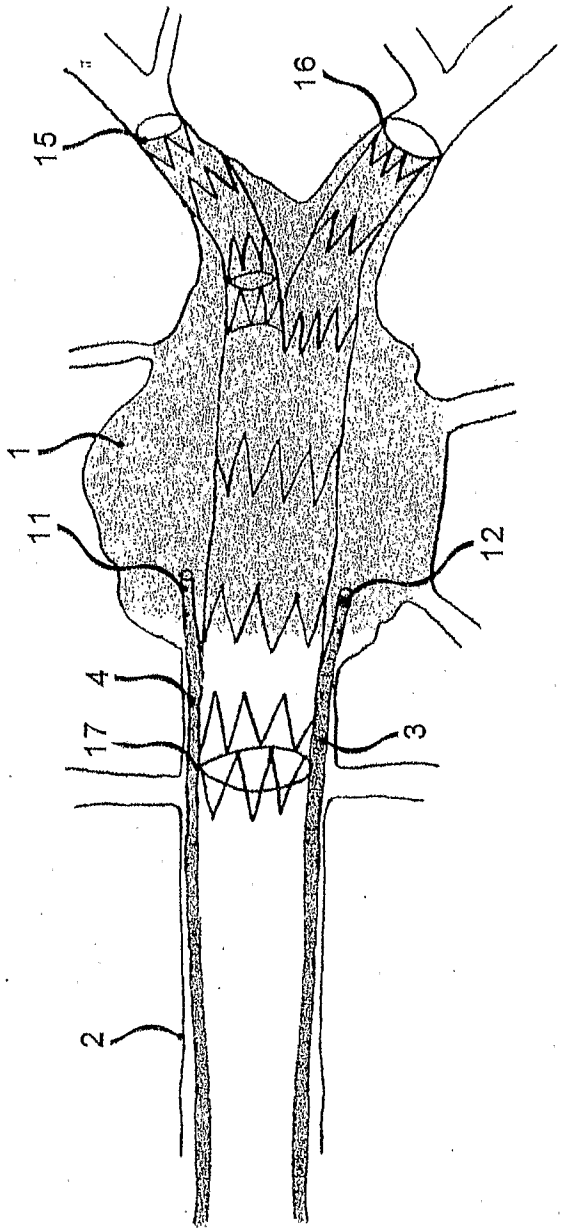


FIG. 7

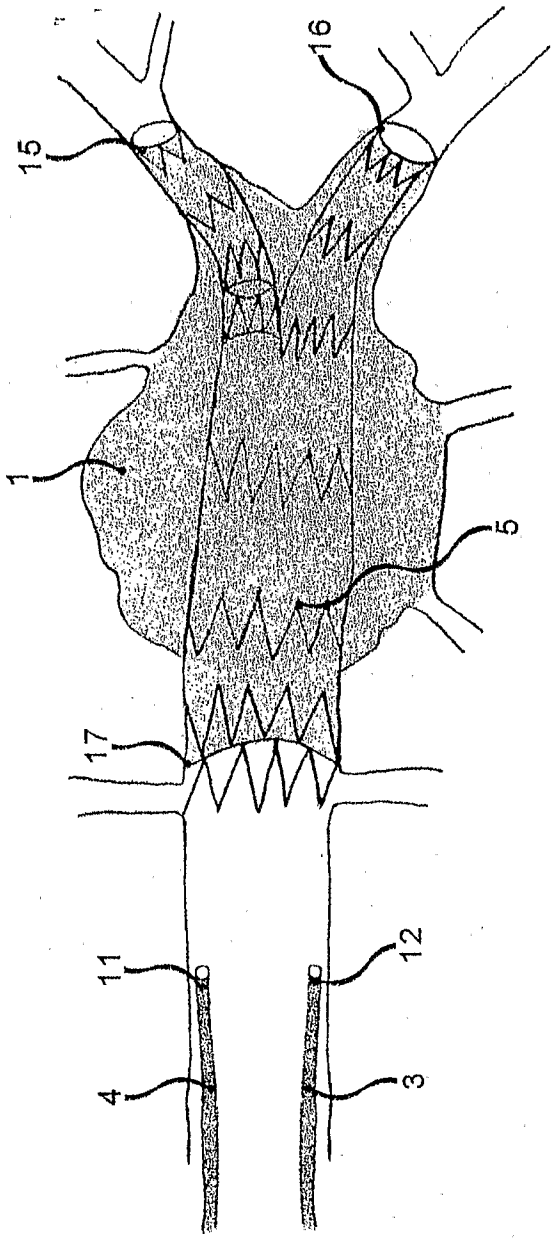


FIG. 8

FIG. 9

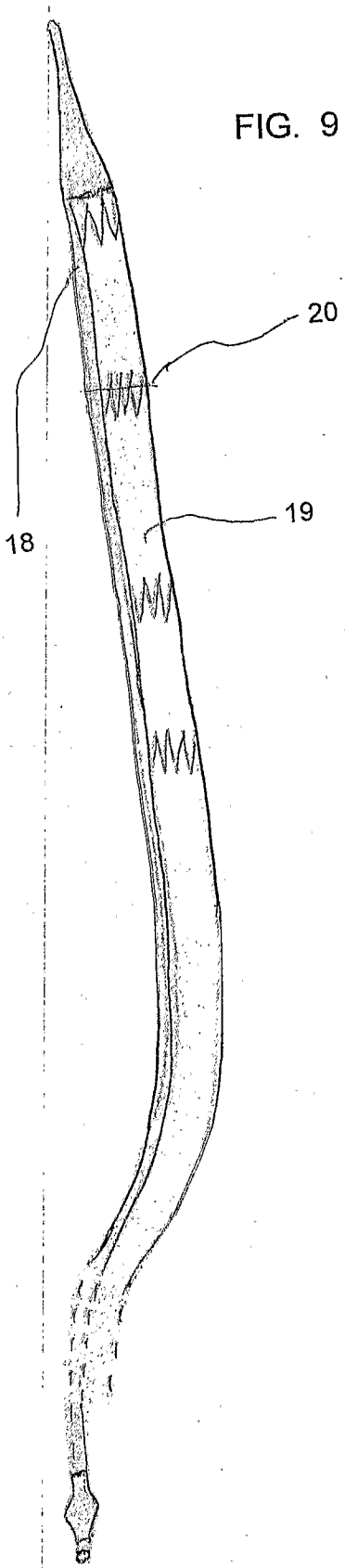
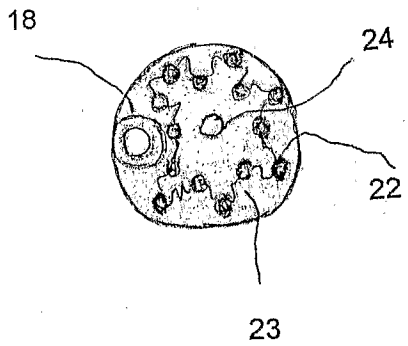


FIG. 9B



INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2006/000491

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/12 A61F2/06

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2004/103187 A (COOK BIOTECH INC [US]; OREGON HEALTH AND SCIENCE UNIV [US]; PAVCNIK DU) 2 December 2004 (2004-12-02) page 23, line 11 - line 15 figures 17-19	1-6,8,9
A		7
Y	US 6 306 154 B1 (HUDSON JOHN OVERTON [GB] ET AL) 23 October 2001 (2001-10-23) column 2, line 49 - line 54 column 7, line 31 - line 38	1-6,8,9
A	WO 96/01599 A (AMPLATZ CURTIS [US]) 25 January 1996 (1996-01-25) page 1, line 25 - page 2, line 2	1,4,5

☐ Further documents are listed in the continuation of Box C.

☒ 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
6 November 2006	13/11/2006

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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