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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61F 2/06

A1

(11) International Publication Number: **WO 00/45737**

(43) International Publication Date: 10 August 2000 (10.08.00)

(21) International Application Number: PCT/IT00/00032

(22) International Filing Date: 3 February 2000 (03.02.00)

(30) Priority Data:
MI99A000236 5 February 1999 (05.02.99) IT

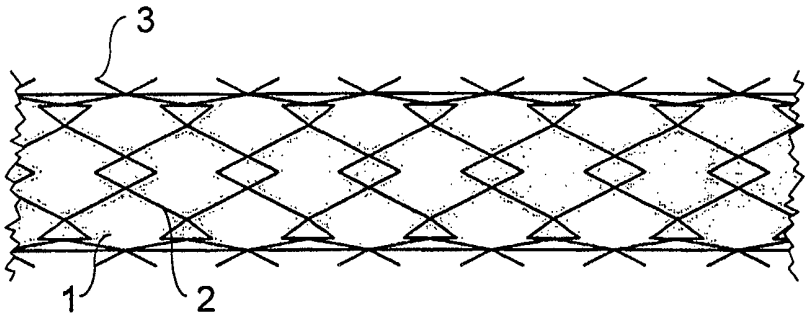
(71)(72) Applicants and Inventors: QUARETTI, Pietro [IT/IT]; Via Trevignano, 12, I-43025 Palanzano (IT). ROVERETO, Bruno [IT/IT]; Via Genova, 16, I-29100 Piacenza (IT). PASQUINUCCI, Marco [IT/IT]; Via Chiantigiana per il Ferrone, 43, Località Falciani, I-50029 Impruneta (IT).

(74) Agents: PIZZOLI, Antonio; Società Italiana Brevetti S.p.A., Via Carducci, 8, I-20123 Milano (IT) et al.

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.
In English translation (filed in Italian).

(54) Title: URETHRAL, BILIARY OR ESOPHAGAL TUBULAR ENDOPROSTHESIS



(57) Abstract

Tubular endoprosthesis, commonly known with the English name *stent*, comprising at least one tube (1) of biocompatible fabric integral with at least one tubular net (2) having substantially the same diameter, wherein some portions of the meshes of the tubular net (2) are bent so as to form a multiplicity of loops (3) protruding out of the tube (1) of biocompatible fabric. The present invention also relates to the use of said endoprosthesis.

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URETHRAL, BILIARY OR ESOPHAGAL TUBULAR ENDOPROSTHESIS

The present invention relates to a tubular endoprosthesis, commonly known with the English name *stent*, and particularly to an endoprosthesis which can be used for treating stenosis or an occlusion of urethral ducts or other non-sanguineous structures, for example those of the biliary ducts or of the esophagus. The present invention relates to the use of said endoprosthesis.

The ureter is known to be a muscle-membranous duct, provided with its own peristalsis and internally covered with a particular epithelium, called urothelium, which has the function of conveying to the bladder the urine excreted by the kidney. The stenosis or the total occlusion of the ureter leads to occlusive nephropathy which brings to a loss of the renal function if it is not treated in time. If the occlusion is bilateral, i.e. it occurs at both ureters, a renal failure, which is incompatible with the patient survival, takes place if no operation for substituting the renal function is effected, for instance extra-corporeal dialysis or a kidney transplantation.

When the cause of the ureter occlusion is determined by advanced neoplastic processes, such as relapses of tumors of the colon or rectum, of the prostate or of the bladder, gynecologic tumors (uterus or ovaries), or periaortic lymphadenopathies, i.e. it is due to clinic situations wherein the basic disease cannot be radically treated anymore, the patient cannot obviously undergo a transplantation and is universally excluded from any program of extra-corporeal dialysis. However, the solution of the occlusive problem can improve the life quality of the patient and/or lengthen his survival, so that a few so-called endourologic procedures are practiced, which allow the occlusive problem to be solved with a palliative and without surgical access (open surgery).

In the practice, through an endoscopic access by means of retrograde cystoscopy or, in case of failure, by means of an anterogradous nephrostomic per cutem access, that is, from the top by passing through the dilated intrarenal excretories, the urologist positions a plastic pipe, for instance made with

polyurethane or silicone and generally known with the English name *plastic stent*, through the urethral occlusion by techniques which are derived from the intervention radiology. Said plastic endoprosthesis has a diameter generally from 8 to 12 frenches (1 french = 0,33 mm) and is provided with curl-shaped ends which protrude into the renal pelvis and into the bladder.

The occlusion is thus solved, nevertheless complications and problems are frequent, particularly with the need of substituting every 4/6 months the plastic endoprosthesis, always under complete anesthesia, before that deposits, further occlusions or other problems may occur. It is important to consider that said endoprosthesis is able to solve also situations of renal occlusions which are not due to malignant processes, such as retroperitoneal fibrosis or post-surgical stenosis of ureteroileal anastomosis, wherein the risk-benefit ratio is strongly shifted in favor of the endourological procedures with respect to the complex and delicate corrective surgical operations.

Further, a second kind of tubular endoprosthesis is known, commonly known with the English name *metal stent*, which comprise a tubular metal net made with stainless steel or nitinol, a particular elastic nickel-titanium alloy. These prostheses, which are self-expansible or expansible by means of a ball catheter, have been found to be useful in the treatment of stenosis and occlusions.

The advantage of this kind of prosthesis consist in their considerable compressibility in the insertion into an even small access hole, thereby obtaining in any case through the stenosis an end lumen which is greater than that obtainable by plastic endoprosthesis. Once it is introduced, the endoprosthesis metal net is passed through by the hyperplastic reaction of the urothelium that actively proliferates in response to the extension. However, the urothelium response can often be excessive, thus determining the endoprosthesis occlusion. From published researches, only the 67% of 95 ureters provided with this endoprosthesis have been found to be accessible for a significant period of time. The endoprosthesis occlusion can also occur by proliferation through the metal net meshes of tumor tissue or inflammatory granulation tissue or by extension of the tumor to the ureter segments which are not provided with the endoprosthesis. On

the other side, the reaction of the urothelium through the endoprosthesis is considered to be a positive phenomenon because at the end it is incorporated and fixed to the urothelium, without deposit and migration risks.

Altogether, the use of metal endoprostheses in the treatment of the urethral or biliary stenosis has been very limited with the publication of about ten small case-reports, because of the high incidence of subsequent occlusions. In the literature, not more than 150 cases are reported, with respect to tens of thousands which are treated in other fields with metal endoprostheses.

A third kind of tubular endoprostheses is known, commonly called with the English name *stent-graft*, wherein the metal net is still self-expansible or expansible with a ball, and is externally or sometimes internally covered by a biocompatible fabric, for instance one made with polyester or polyurethane. The *stent-grafts*, born for applications in blood vessel, for example for the treatment of aneurysms or arterovenous fistulae, have never been used in the urethral ducts, although the covering of the tubular metal net with the biocompatible fabric is capable of impeding the passage of the urothelium, of the tumor tissue or of the granulation tissue through said net, thus providing for a remedy for the drawbacks of the purely metal endoprosthesis.

Said lack of use is due to the fact that, according to clinical tests, the *stent-grafts* present an elevated risk of migration, resulting in a recidivation of the occlusion in patients affected by urethroenteral stenosis, since the urothelium is not capable of anchoring to the metal net in a correct way. Similar migration problems are found also with the *stent-grafts* inserted into biliary ducts, as well as into the esophagus, particularly next to the gastroesophageous junction.

Object of the present invention is therefore to provide an endoprosthesis which is free from said drawbacks, that is an endoprosthesis which remains easily in its position and which cannot be obstructed. Said object is obtained by an endoprosthesis whose main features are specified in the first claim and other features are specified in the following claims.

Thanks to the loops which it is provided with, the endoprosthesis according to the present invention remains stably positioned, because the internal walls of

the duct wherein it is placed are capable of anchoring themselves stably by going through and incorporating said loops, thus avoiding possible migrations which may damage the patient. Further, said loops are obtained by suitably bending some portions of the tubular net meshes, with following advantageous economicity in the manufacture and simplicity in use.

Another advantage of the endoprosthesis according to the present invention consists in the particular shapes that the meshes of the tubular net can take depending on the kind of required application, by obtaining anyway a plurality of loops for the fastening to the internal walls of the patient's ducts.

A further advantage of the endoprosthesis according to the present invention is that, according to the physical features of the metallic material which the tubular net is made with, the shape and the arrangement of the loops are permanently and perfectly correct even after the endoprosthesis compression, which is necessary for the installation thereof.

Further advantages and features of the endoprosthesis according to the present invention will appear to those which are skilled in the art from the following detailed description of some embodiments thereof with reference to the accompanying drawings, wherein:

- figure 1 shows a front view of a first embodiment of the endoprosthesis according to the present invention;
- figure 2 shows a partial side view of the endoprosthesis of figure 1;
- figure 3 shows a partial view of the metal wire used for the tubular net of the endoprosthesis of figure 1;
- figure 4 shows a front view of a second embodiment of the endoprosthesis according to the present invention;
- figure 5 shows a partial side view of the endoprosthesis of figure 4;
- figure 6 shows a front view of a third embodiment of the endoprosthesis according to the present invention;
- figure 7 shows a partial side view of the endoprosthesis of figure 6;
- figure 8 shows a front view of a fourth embodiment of the endoprosthesis according to the present invention;

- figure 9 shows a partial side view of the endoprosthesis of figure 8;
- figure 10 shows a front view of a fifth embodiment of the endoprosthesis according to the present invention;
- figure 11 shows a partial side view of the endoprosthesis of figure 10;
- figure 12 shows a partial view of the metal wire used for the tubular net of the endoprosthesis of figure 10;
- figure 13 shows a front view of a sixth embodiment of the endoprosthesis according to the present invention;
- figure 14 shows a partial side view of the endoprosthesis of figure 13;
- figure 15 shows a partial view of the metal wire used for the tubular net of the endoprosthesis of figure 13; and
- figure 16 shows a partial side view of the endoprosthesis of figure 1, in the condition of compression into a tubular container.

Referring to figures 1 and 2, the first embodiment of the endoprosthesis according to the present invention comprises in a known way at least one cylindrical tube 1 made with a biocompatible fabric, particularly with a fabric in a synthetic material having low porosity, having a diameter, in the extended condition, comprised between 5 and 10 mm. On the external surface of tube 1 one tubular net 2 is fastened, having substantially the same diameter, which is preferably made with a nickel-titanium alloy known with the name nitinol. Besides being biocompatible, this particular alloy is characterized by high elasticity as well as by the so-called "shape-memory" which enables the structure made with this alloy to take again a predetermined shape depending on the temperature whereat said structure was manufactured, for instance 37° C, corresponding to human body temperature.

In order to favor adhesion to the internal walls of the duct wherein the endoprosthesis is inserted, some portions of the meshes of tubular net 2 are suitably bent outwards, so that they form a multiplicity of loops 3 wherein the epithelium of said duct, particularly the ureter epithelium, can get inserted. For a correct adhesion, loops 3 preferably protrude of at least 1 mm out of fabric tube 1.

Now, with reference also to figure 3, tubular net 1 can be seen to be

preferably obtained by zigzag bending a single metal wire so as to form a substantially triangular wave having alternated crests and valleys of two different heights. Further, the upper and lower profile of said triangular wave are provided with a whole periodical height increase, for instance every 24 crests, so that said wire can be easily winded around fabric tube 1 by following a helicoidal profile, so that tubular net 2 is obtained. For this purpose, crests 4 and valleys 5 which are arranged along the external profiles of the triangular wave are joined, for instance by microscopic sutures, to valleys 6 and crests 7 respectively of the adjacent portions included in a wave period, as well as possibly fastened to fabric tube 1, again with said sutures. The points of crests 8 and valleys 9 included between the external wave profiles are bent outwards, so that a multiplicity of loops 3 having triangular shape is formed when the metal wire is winded around fabric tube 1.

Now, with reference to figures 4 and 5, the second embodiment of the endoprosthesis according to the present invention comprises again one tubular net 2 fastened outside one fabric tube 1. Again, in this embodiment tubular net 2 is preferably made with a single metal wire which is zigzag bent so as to form a substantially triangular wave, which is though provided with the crests and the valleys arranged only along the lower profile and the upper profile of the wave. In this case, loops 3 are obtained by bending outwards only the points of the crests of a portion comprised in a wave period and the corresponding points of the valleys of the adjacent wave portion, which are reciprocally fixed, again with microscopical sutures, at a certain distance from the fabric tube 2.

Now, with reference to figures 6 and 7, in the third embodiment of the endoprosthesis according to the present invention, tubular net 2 can be seen to be again formed of a single metal wire zigzag bent so as to form a substantially triangular wave, but in this case loops 3 are obtained by bending outwards, with the shape of a triangle, a portion of the wire segments included between one crest and one valley.

With reference to figures 8 and 9, it can be seen that in the fourth embodiment of the endoprosthesis according to the present invention, substantially equal to the first embodiment, tubular net 2 is arranged inside fabric

tube 1, while loops 3 protrude outwards crossing a multiplicity of through holes made in the tube itself.

With reference to figures 10 and 12, it can be seen that in the fifth embodiment of the endoprosthesis according to the present invention tubular net 2 is again obtained by zigzag bending a single metal wire so as to form a substantially triangular wave, which is though provided with alternated crests and valleys having the same height. In order to obtain loops 3, the points of valleys 5 are bent outwards about by half in the direction of crests 4, so that they are arranged as in the dotted lines 10 of figure 12.

Now, with reference to the figures 13 to 15, it can be seen that in the sixth embodiment of the endoprosthesis according to the present invention tubular net 2 is obtained by zigzag bending a single metal wire with alternated crests and valleys having the same heights, as in the fifth embodiment. However, in order to obtain loops 3, not only the points of the valleys 5, but also the points of the crests 4 are bent outwards about by half, with alternated groups of valleys and crests, in the direction of the crests 4 and valleys 5 respectively, so that they are arranged as in the dotted lines of figure 15.

Finally, with reference to figure 16, it can be seen that during use, before being inserted into a duct of the patient, the endoprosthesis according to the present invention is compressed as in the figure and arranged in a known way into a suitable tubular container 11, which has the function of bringing the endoprosthesis in the desired position. Once in position, the endoprosthesis is taken out from the tubular container, thus being free to expand inside the duct, possibly with the help of a ball catether, and taking the former shape with the loops protruding outwards.

In further embodiments of the present invention, not shown in the figures but having anyway an appearance similar to that of the preceding embodiments, crests 4 are fastened to valleys 5 not through microscopic sutures, but by means of weldings with supply of metallic material preferably equal to that of the whole tubular net 2, for example the same nitinol. By this measure a slightly harder tubular net is obtained, but still flexible, which can be used in operations wherein

an endoprosthesis having an elasticity similar to that of a helicoidal spring is required.

Obviously, other embodiments of the present invention can comprise more than one biocompatible fabric tubes and/or tubular nets, for instance a external tubular net for anchorage and an internal tubular net supporting the fabric tube.

Further variants and additions can be made by those which are skilled in the art to the embodiments here described and illustrated by remaining within the scope of the invention itself.

CLAIMS

1. Tubular endoprosthesis comprising at least one tube (1) of biocompatible fabric integral with at least one tubular net (2) having substantially the same diameter, characterized in that some portion of the meshes of the tubular net (2) are bent so as to form a multiplicity of loops (3) protruding out of the tube (1) of biocompatible fabric.
2. Tubular endoprosthesis according to the preceding claim, characterized in that said tubular net (2) comprises at least one metal wire, which is bent so as to form a substantially triangular wave, is winded along a helicoidal profile and is provided with some crest (4, 7) and some valley (5, 6) joined to each other.
3. Tubular endoprosthesis according to the preceding claim, characterized in that said crests (4, 7) and said valleys (5, 6) are welded to each other.
4. Tubular endoprosthesis according to claim 2 or 3, characterized in that the point of some crest (8) and some valley (9) is bent outwards so as to form a multiplicity of loops (3) protruding out of the tube (1) of biocompatible fabric when the metal wire is winded.
5. Tubular endoprosthesis according to the preceding claim, characterized in that said metal wire is bent so as to form a substantially triangular wave having alternated crests (4, 7, 8) and valleys (5, 6, 9) with two different heights, wherein the lower profile and the upper profile of said triangular wave are provided with a whole periodic increment of the height.
6. Tubular endoprosthesis according to one of claims 2 to 5, characterized in that the crests (4) and the valleys (5) arranged along the external profiles of the triangular wave are joined to the valleys (6) and to the crests (7) respectively of the adjacent portions included in a wave period.
7. Tubular endoprosthesis according to claim 2, characterized in that said loops (3) are obtained by bending outwards a portion of the segment of the metal wires of the tubular net (2) included between one crest (4) and one valley (5).
8. Tubular endoprosthesis according to one of the preceding claims, characterized in that said tubular net (2) is arranged outside the tube (1) of biocompatible fabric.

9. Tubular endoprosthesis according to one of claims 1 to 7, characterized in that the tubular net (2) is arranged inside the tube (1) of biocompatible fabric and the loops (3) protrude outwards by passing through a multiplicity of through holes which are made in said tube (1).
10. Tubular endoprosthesis according to one of the preceding claims, characterized in that said tubular net (2) is made with a nickel-titanium alloy.
11. Use of the tubular endoprosthesis according to one of the preceding claims for the treatment of the stenosis or occlusion of the urethral duct.
12. Use of the tubular endoprosthesis according to one of claims 1 to 10 for the treatment of the stenosis or occlusion of the biliary duct.
13. Use of the tubular endoprosthesis according to one of claims 1 to 10 for the treatment of the stenosis or occlusion of the esophagus.

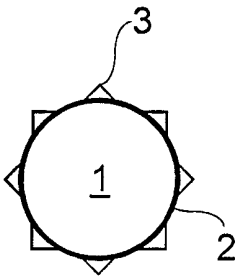

Fig.1

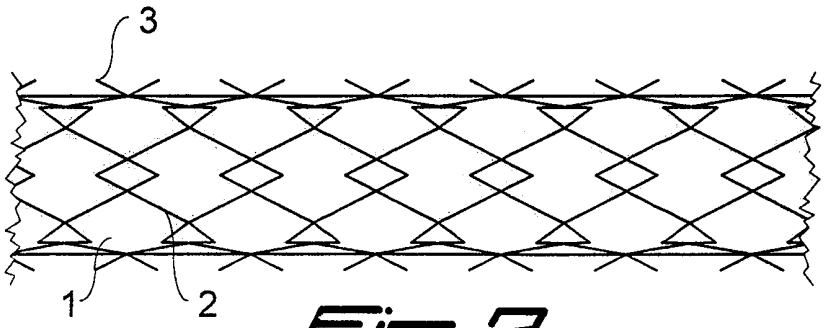

Fig.2

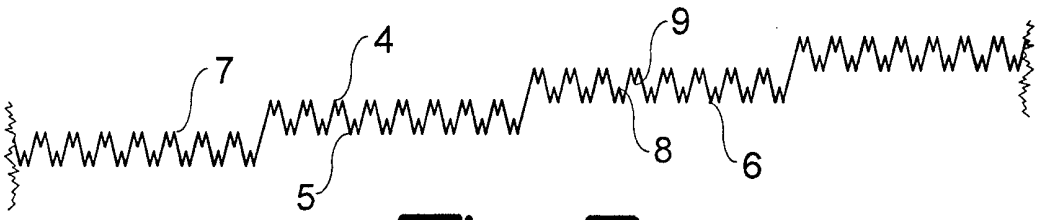

Fig.3

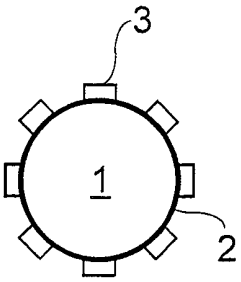

Fig.4

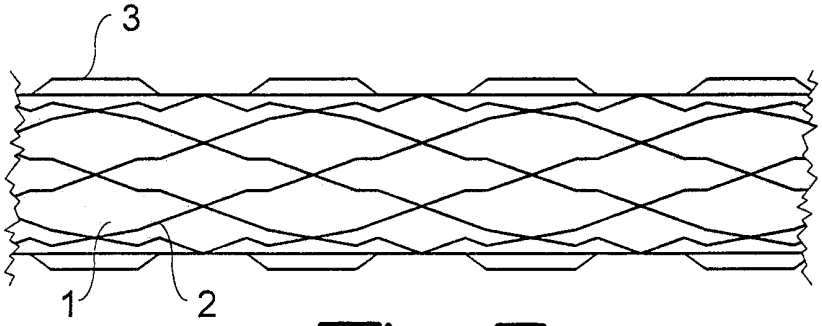

Fig.5

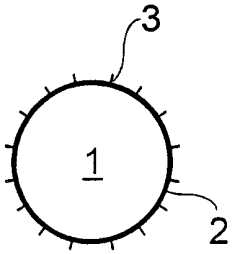

Fig.6

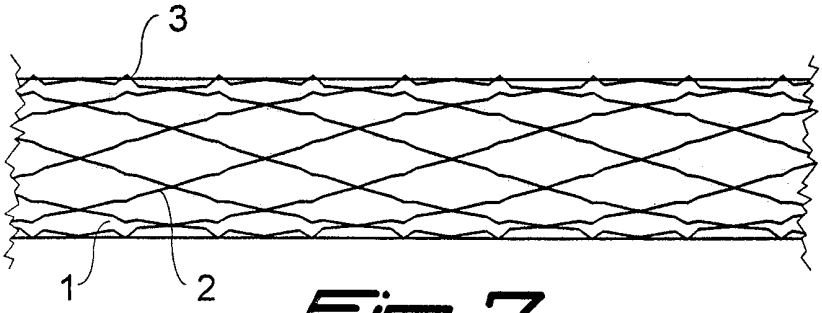

Fig.7

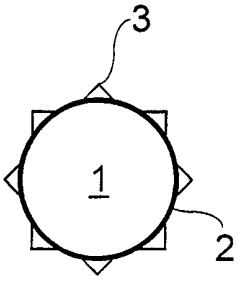

Fig.8

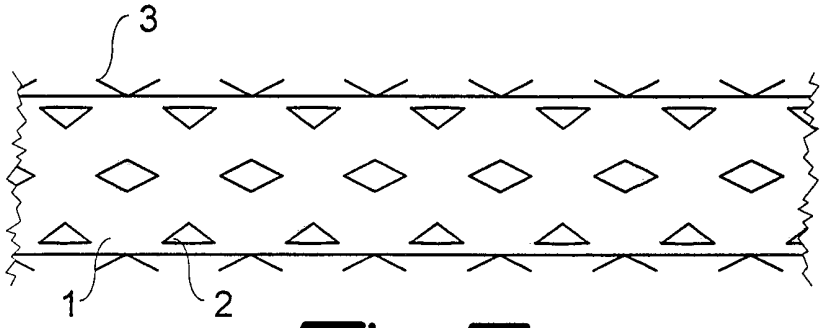

Fig.9

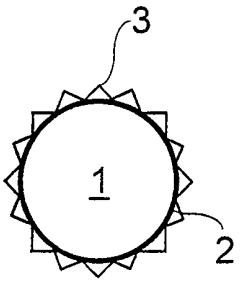

Fig.10

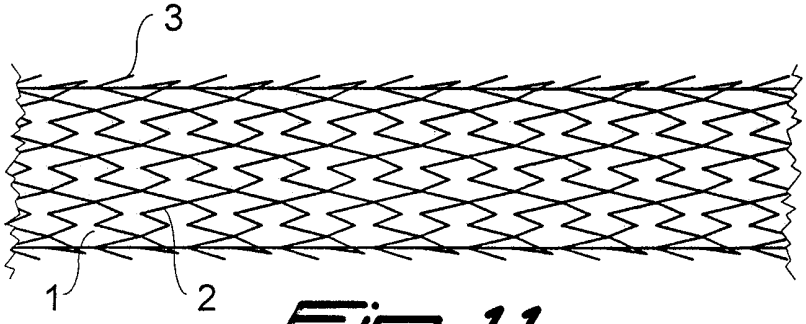

Fig.11

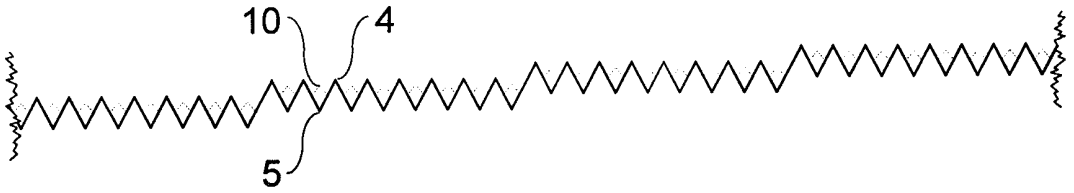

Fig.12

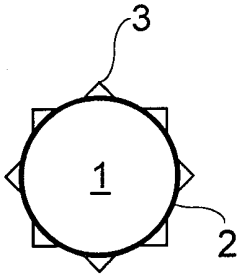

Fig.13

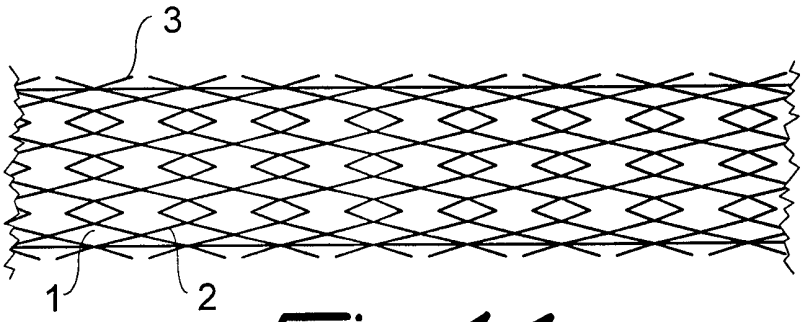

Fig.14

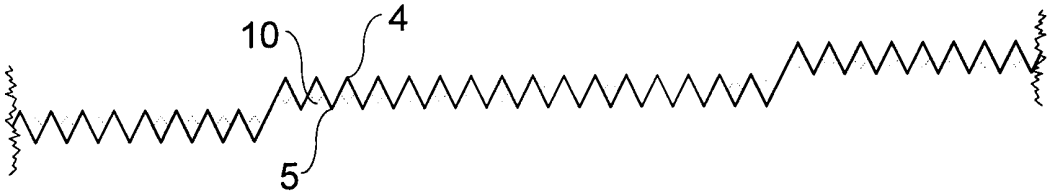

Fig.15

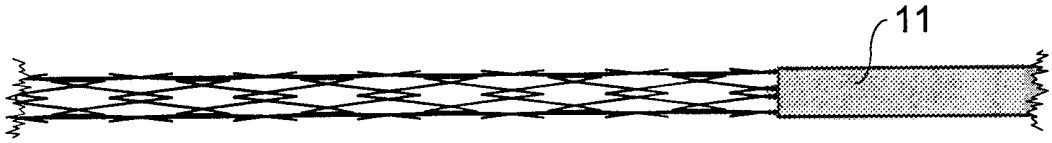

Fig.16

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IT 00/00032

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 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)
IPC 7 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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 575 818 A (PINCHUK) 19 November 1996 (1996-11-19) the whole document	1,2,4,6, 7,11-13 10
Y A	WO 98 19631 A (VASCULAR SCIENCE INC.) 14 May 1998 (1998-05-14) page 6, line 17 - line 21 page 7, line 9 - line 19 figures	10 1
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☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
15 May 2000	26/05/2000

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, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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