(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) **EP 4 031 023 B9**

(12) **CORRECTED EUROPEAN PATENT SPECIFICATION**

(15) Correction information:
Corrected version no 1 (W1 B1)
Corrections, see
Description Paragraph(s) 19, 44

(48) Corrigendum issued on:
24.04.2024 Bulletin 2024/17

(45) Date of publication and mention of the grant of the patent:
12.07.2023 Bulletin 2023/28

(21) Application number: **20765037.5**

(22) Date of filing: **08.09.2020**

(51) International Patent Classification (IPC):
A61B 17/12 *(2006.01)* ***A61F 2/07*** *(2013.01)*
A61F 2/06 *(2013.01)*

(52) Cooperative Patent Classification (CPC):
A61F 2/07; A61F 2002/065; A61F 2002/077; A61F 2210/0076; A61F 2240/001; A61F 2250/0051; A61F 2250/0056

(86) International application number:
PCT/EP2020/074991

(87) International publication number:
WO 2021/052803 (25.03.2021 Gazette 2021/12)

(54) ENDOPROSTHESIS AND A METHOD OF PRODUCING AN ENDOPROSTHESIS

ENDOPROTHESE UND VERFAHREN ZUR HERSTELLUNG EINER ENDOPROTHESE

ENDOPROTHÈSE ET PROCÉDÉ DE PRODUCTION D'UNE ENDOPROTHÈSE

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **19.09.2019 EP 19315116**

(43) Date of publication of application:
27.07.2022 Bulletin 2022/30

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(56) References cited:
WO-A1-2009/149294 WO-A2-2006/111801

EP 4 031 023 B9

Description

[0001] The invention relates to an endoprosthesis and a method to produce an endoprosthesis, in particular a vascular or a heart stent, according to the preamble of the independent claims. Endoprostheses, in particular vascular and heart stents, are used to support blood vessels in the human body. For example, occlusions or aneurysms can be treated by placing such an endoprosthesis at the respective treatment site. In the treatment of an occlusion, the endoprosthesis keeps the vessel open for unhindered blood flow. In the case of an aneurysm, the endoprosthesis can prevent circulation of blood in the aneurysm and thus lower the risk of rupture or further growth of the aneurysm.

[0002] It is known in the prior art to use thrombogenic elements on endoprostheses. For example, WO 2013/182614 A1 discloses an endoprosthesis with thrombogenic elements that extend away from a body of the endoprosthesis and promote thrombosis. This allows for the occlusion of an aneurysm to enhance the above-mentioned treatment effect. WO 2006/111801 A2 discloses a covered endoprosthetic device,comprising an endoprosthesis and a sheath. Blood flow can be reduced by the central portion of the sheath by varying the permeability of the sheath or by having projections on the sheath that slow blood flow. Permeability may be provided by perforations in the material of the sheath.

[0003] However, currently known methods do not provide a simple way of post-production arrangement of thrombogenic elements on an endoprosthesis. Fixation and attachment of thrombogenic elements is usually cumbersome and difficult, and not typically versatile. Thus, the object of the present invention is to overcome the drawbacks of the prior art, in particular to provide an endoprosthesis and a method to produce an endoprosthesis wherein thrombogenic elements can easily be added to a surface of the endoprosthesis, in particular in a versatile manner and at selected locations on the endoprosthesis surface.

[0004] This and other objects are achieved by the endoprosthesis and the methods according to the characterizing portion of the independent claims of the invention.

[0005] The endoprosthesis, in particular the vascular stent or the heart stent, according to the invention has a longitudinal axis and comprises at least one body part, and a first cover sheet. The body part preferably comprises a scaffold, in particular a scaffold arranged within the first cover sheet. Additionally, the endoprosthesis comprises at least one thrombogenic fiber. Furthermore, the endoprosthesis comprises at least one fixation layer which attaches, preferably permanently, the at least one thrombogenic fiber to the endoprosthesis. The at least one thrombogenic fiber and/or a support structure for the thrombogenic fiber is at least partially arranged between the fixation layer and the first cover sheet.

[0006] For example, a support structure for the at least one thrombogenic fiber may be a support strip to which the fiber is attached. If no support structure is used, at least a portion of the fiber is arranged in a sandwich-like structure between the fixation layer and the first cover sheet. If the at least one fiber is attached to a support structure, only the support structure may be arranged between the first cover sheet and the fixation layer. However, it is also possible to arrange both the at least one fiber and the support structure in that way, for example if the fixation layer extends over the support structure and covers the at least one fiber as well. Alternatively, the at least one fiber may be arranged above or below the support structure, the two of which are arranged between the fixation layer and the first cover sheet.

[0007] In a preferred embodiment, the at least one thrombogenic fiber has at least one part, in particular a free end, extending from the fixation layer and the first cover sheet. For example, the fixation layer may cover a segment of the fiber, but not cover another segment of it.

[0008] In another preferred embodiment, the endoprosthesis comprises at least one support strip and the at least one thrombogenic fiber is attached to the at least one support strip. The attachment of the at least one fiber may include knitting, threading, stitching and/or gluing. The separate attachment of the fibers to a support strip in particular enables easy production of preassembled parts and ultimately easier production of the endoprosthesis.

[0009] In particular, the support strip may be arranged between the first cover sheet and the at least one fixation layer.

[0010] In particularly preferred embodiment, at least one of the support strip and the fixation layer comprises an adhesive. The adhesive enables easy attachment of the support structure to the the first cover sheet of the endoprosthesis.

[0011] In particular, the support strip and/or the fixation layer may comprise a hot melt adhesive that, in its molten state, has a contact angle on polytetrafluoroethylene (PTFE) of less than 45°, preferably less than 30°. Additionally or alternatively, the adhesive may also be adapted to be curable by electromagnetic radiation, in particular UV light, heat, or oxygen.

[0012] Most preferably, the adhesive is adapted such as to, in particular in its molten state, penetrate at least one of the first cover sheet and the fixation layer. In particular, the contact angle of the adhesive in a liquid state (prior to a hardening, annealing, or drying step) on the first cover sheet material is adapted such that it can fill percolating pores in the first cover sheet.

[0013] Preferably, the adhesive is provided as an adhesive layer on the fixation layer. For example, the adhesive may be provided as a layer of poly urethane on a fixation layer.

[0014] In another preferred embodiment, at least one of the first cover sheet and the at least one fixation layer comprise PTFE, in particular a plurality of electrospun fibers of PTFE.

[0015] In a preferred embodiment, the first cover sheet and the at least one fixation layer consist of the same material.

[0016] In preferred embodiment, the endoprosthesis comprises at least one protection strip which is releasably attached to the endoprosthesis. In its attached state, the protection strip retains the at least one thrombogenic fiber on a surface of the first cover sheet.

[0017] In a particularly preferred embodiment, the scaffold comprises a metallic material, in particular a shape memory metal, preferably an alloy comprising nickel and/or titanium.

[0018] In a preferred embodiment, the endoprosthesis comprises at least two body parts. The at least two body parts may, for example, be adapted to treat different parts of a vessel with different diameters. Such endoprostheses with more than one body part are disclosed in WO 2013/182614 A1.

[0019] In another preferred embodiment, the total thickness of the endoprosthesis wall can typically be less than 120 μm and/or greater than 115 μm.

[0020] In a preferred embodiment, a first and a second end portion of the at least one thrombogenic fiber extends from the fixation layer and the first cover sheet.

[0021] In an alternative embodiment, a first end portion of the at least one thrombogenic fiber is arranged between the fixation layer and the first cover sheet. A second end portion of the at least one thrombogenic fiber extends from the fixation layer the first cover sheet.

[0022] In yet another preferred embodiment, at least one of the fixation layers is arranged such that a first and a second end portion of the at least one thrombogenic fiber extends from the fixation layer the first cover sheet.

[0023] In yet another preferred embodiment, a first end portion of at least one of the thrombogenic fibers is arranged between the fixation layer and the first cover sheet. A second end portion of said at least one of the thrombogenic fibers extends from the fixation layer the first cover sheet.

[0024] In a preferred embodiment, the endoprosthesis comprises at least two fixation layers. The at least two fixation layers are separated by a space along the surface of the first cover sheet.

[0025] In a preferred embodiment, the at least one fixation layer has an elongated shape running in a direction parallel to the longitudinal axis of the endoprosthesis.

[0026] The invention further relates to a method of producing an endoprosthesis, in particular an endoprosthesis as described herein.

[0027] The method according to the invention comprises, in a first step, providing an endoprosthesis frame having a first cover sheet. In other steps, a thrombogenic fiber and a fixation layer are provided. The thrombogenic fiber is arranged on the first cover sheet. The thrombogenic fiber is attached on the first cover sheet by fixing the fixation layer on the first cover sheet, wherein, preferably, the at least one thrombogenic fiber is arranged at least partially between the fixation layer the first cover sheet.

[0028] In preferred embodiment, the method further comprises providing a mandrel which is provided with a first cover sheet and a scaffold. In particular, the scaffold may be arranged in the first cover sheet.

[0029] In a preferred embodiment, at least one support strip, with the at least one thrombogenic fiber attached thereto, is provided.

[0030] In a preferred embodiment, the at least one of the at least one support strip and the at least one fixation layer comprises an adhesive, preferably a hot melt adhesive. The step of fixing the fixation layer comprises an activation of the adhesive, preferably melting of the hot melt adhesive. Alternatively, the activation of the adhesive may also comprise exposure to electromagnetic radiation, in particular UV light, heat, or oxygen.

[0031] In a preferred embodiment, the method further comprises the step of providing at least one protection strip which is releasably attached to the endoprosthesis. In its attached state, the protection strip retains the at least one thrombogenic fiber on a surface of the first cover sheet.

[0032] In a preferred embodiment, the step of providing a first cover sheet comprises coating with a plurality of electrospun fibers. In a preferred embodiment, the step of providing a fixation layer comprises coating with a plurality of electrospun fibers. Alternatively, the fixation layer may also be provided as a pre-cut patch comprising a plurality of electron-spun fibers. Preferably, such pre-cut patch comprises an adhesive layer.

[0033] In particular, the electrospun fibers comprise, preferably consist of, PTFE.

[0034] The endoprosthesis and the method described herein are particularly suited to be combined with the endoprostheses disclosed in WO 2013/182614 A1,

[0035] In the following, the invention is described in detail with reference to the following figures:

Fig. 1:	shows schematically an endoprosthesis according to the invention
Fig. 2a-2b:	show a top view of a support strip and a side view when attached to an endoprosthesis
Fig. 3a-3b:	show a top view of another support strip and a side view when attached to an endoprosthesis
Fig. 4:	show different embodiments of fiber attachments
Fig. 5:	schematically shows the method according to the invention
Fig. 6:	shows a detailed illustration of an endoprosthesis

[0036] Fig. 1 shows an endoprosthesis 1 according to the invention comprising a body part 2 and a first cover sheet 4. A plurality of fibers 5 is attached to the first cover sheet 4 by means of a support strip (not shown) and a fixation strip 7. The support strips and the fixation layers

exhibit an elongated shape and are running in the direction of the longitudinal axis L of the endoprosthesis 1.

[0037] Fig. 2a shows a support strip 6 with a plurality of fibers 5 attached thereto. The support strip comprises a polyurethane as an adhesive composition. In this particular embodiment, the support strip has an elongated shape and the fibers are only extending on one side of the support strip.

[0038] Fig. 2b shows the support strip 6 of Fig. 2a in a cross-sectional side view when fixed on the first surface 4 with a fixation layer 7. Because the fibers 5 are only attached on one side of the support strip 6, the fibers 5 only extend on one side of the fixation layer 7 as well.

[0039] Fig. 3a shows an alternative embodiment of a support strip 6. This support strip 6 exhibits an elongated shape with fibers 5 extending from both sides.

[0040] Fig. 3b shows the support strip 6 of Fig. 3a when fixed on the first cover sheet 4 by means of a fixation layer 7. The fibers 5 extend from the fixation layer 7 on both sides, corresponding to the fiber arrangement of the support strip.

[0041] Fig. 4a shows an embodiment of the endoprosthesis in a side view. In this particular embodiment, no support strip is used. Instead, the fiber 5 is arranged directly on the first cover sheet 4. The fixation layer is arranged over a first end portion 9 of the fiber 5, whereas a second end portion 10 of the fiber 5 extends from the fixation layer 7.

[0042] Fig. 4b shows an alternative embodiment of the endoprosthesis. In this particular embodiment, no support strip is used. Instead, the fiber 5 is arranged directly on the first cover sheet 4. A middle portion 11 of the fiber 5 is arranged between the first cover sheet 4 and the fixation layer 7. The first and second end portions 9,10 of the fiber 5 extend away from the fixation layer.

[0043] Fig. 5 schematically shows the steps of the method according to the invention. In a first step (A), an endoprosthesis is provided. For simplicity, only the first cover sheet 4 is shown. Here, the first cover sheet consists of electrospun PTFE fibers. In another step (B), a support strip 6 that has fibers 5 attached to it on both sides is provided and arranged on the first cover sheet 4. Another step (C) comprises arranging protection strips 8 on the first cover sheet 4 and the fibers 5. The fibers 5 are retained close to the surface of the first cover sheet 4 and completely covered by the protection strips 8. The support strip 6 is not covered by the protection strips 8. In a next step (D), the endoprosthesis is provided with the fixation layer (7). Here, the fixation layer 7 consists of a pre-cut patch of electrospun PTFE fibers with an adhesive layer 7a of polyurethane. The fixation layer 7 is arranged on the support strip 6. The side of the fixation layer 7 with the adhesive layer 7a is oriented towards the support strip 6 and the first cover sheet 4. Finally (E), the protection strips 8 are removed. This releases the fibers 5 that now extend freely from the support strip 6 and the fixation layer 7. At this point, a heating and pressing step is used to press the fixation layer 7 towards the first cover sheet 4 and partially melt the adhesive layer of the fixation layer 7, which penetrates into the support strip 6, the first cover sheet 4, and the fixation layer 7, leading to enhanced fixation. Because of the melting and penetration of other layers, the adhesive layer 7a is no longer visible after this step.

[0044] Fig. 6 shows a particular embodiment of the endoprosthesis. This illustration corresponds to step E in Fig. 5. Here, the endoprosthesis frame comprises a metallic scaffold 3 that is arranged within the first cover sheet 4. In this particular embodiment, the endoprosthesis has several body elements 2,13a,13b, wherein two body elements 13a,13b have a smaller diameter than another body part 2. The endoprosthesis 1 exhibits a Y-shape. The scaffold 3 consists of an interconnected grid made of a Nitinol shape memory metal. It is encapsulated by electrospun PTFE fibers that make up the first cover sheet. The fibers 5 are provided on a support strip 6 that is arranged on the first cover sheet 4. After the coating with another layer of electrospun PTFE fibers and the removal of the protection strips (not shown here), the support strip 6 is encapsulated in a sandwich-like structure in between the first cover sheet 4 and the fixation layer 7. The total thickness T of the endoprosthesis wall, comprising the first cover sheet 4, the scaffold 3, the support strip 6, and the fixation layer 7 is between 115 and 120 μm.

Claims

1. An endoprosthesis (1), in particular a vascular stent or a heart stent, having a longitudinal axis (L), comprising

   - at least one body part (2), a first cover sheet (4),
   - at least one thrombogenic fiber (5)

   characterized in that

   the endoprosthesis (1) further comprises at least one fixation layer (7) which attaches, preferably permanently, the at least one thrombogenic fiber (5) to the endoprosthesis (1), wherein at least one of

   - the at least one thrombogenic fiber (5), and
   - a support structure (6) for the thrombogenic fiber (5) is at least partially arranged between the fixation layer (7) and the first cover sheet (4).

2. The endoprosthesis (1) according to claim 1, wherein the at least one thrombogenic fiber (5) has at least one part, particularly a free end, extending from the fixation layer (7) and the first cover sheet (4).

3. The endoprosthesis (1) according to one of the

claims 1 or 2, further comprising at least one support strip (6), wherein the at least one thrombogenic fiber (5) is attached to the at least one support strip (6).

4. The endoprosthesis (1) according to claim 3, wherein the at least one support strip (6) is arranged between the first cover sheet (4) and the at least one fixation layer (7).

5. The endoprosthesis (1) according to one of the claims 3 or 4, wherein at least one of the support strip (6) and the fixation layer (7) comprises an adhesive,
in particular a hot melt adhesive that, in its molten state, has a contact angle on PTFE of less than 45°, preferably less than 30°.

6. The endoprosthesis (1) according to claim 5, wherein the adhesive is adapted such as to, in particular in its molten state, penetrate at least one of the first cover sheet and the fixation layer (4).

7. The endoprosthesis (1) according to one of the claims 5 or 6, wherein the adhesive is provided as an adhesive layer (7a) on the fixation layer (7).

8. The endoprosthesis (1) according to any one of the preceding claims, wherein at least one of the first cover sheet (4) and the at least one fixation layer (7) comprise PTFE, in particular a plurality of electrospun fibers of PTFE.

9. The endoprosthesis (1) according to any one of the preceding claims, wherein the first cover sheet (4) and the at least one fixation layer (7) consist of the same material.

10. The endoprosthesis (1) according to any one of the preceding claims, wherein the at least one fixation layer (7) is arranged such that a first and a second end portion (9,10) of the at least one thrombogenic fiber (5) extend from the fixation layer (7) and the first cover sheet (4).

11. The endoprosthesis (1) according to any one of the preceding claims, wherein a first end portion (9) of the at least one thrombogenic fiber (5) is arranged between the fixation layer (7) and the first cover sheet (4) and a second end portion (10) of the at least one thrombogenic fiber (5) extends from the fixation layer (7) and the first cover sheet (4) .

12. The endoprosthesis (1) according to any one of the preceding claims, comprising at least two fixation layers (7), wherein the at least two fixation layers are separated by a space along the surface of the first cover sheet (4).

13. The endoprosthesis (1) according to any one of the preceding claims, wherein the at least one fixation layer (7) has an elongated shape running in a direction parallel to the longitudinal axis (L) of the endoprosthesis (1).

14. A method of producing an endoprosthesis (1), preferably an endoprosthesis (1) according to one of the preceding claims, comprising the steps:

- Providing an endoprosthesis frame comprising a first cover sheet (4)
- Providing at least one thrombogenic fiber (5)
- Providing at least one fixation layer (7)
- Arranging the at least one thrombogenic fiber (5) on the first cover sheet (4)
- Attaching the thrombogenic fiber (5) on the first cover sheet (4) by fixing the fixation layer (7) on the first cover sheet (4), wherein at least one of the at least one thrombogenic fiber (5) and a support structure for the thrombogenic fiber is arranged at least partially between the fixation layer (7) and the first cover sheet (4).

15. The method according to any one of the preceding claims,
wherein at least one support strip (6) with the at least one thrombogenic fiber (5) attached thereto is provided.

16. The method according to claim 14, wherein at least one of the at least one support strip (6) and the at least one fixation layer comprises an adhesive, preferably a hot melt adhesive, and the step of fixing the fixation layer (7) comprises an activation of the adhesive, preferably melting the hot melt adhesive.

17. The method according to any one of the preceding claims, further comprising the step of providing at least one protection strip (8), releasably attaching it to the endoprosthesis (1), wherein, in its attached state, the protection strip (8) retains the at least one thrombogenic fiber (5) on a surface of the first cover sheet (4).

Patentansprüche

1. Endoprothese (1), insbesondere Gefäßstent oder Herzstent, mit einer Längsachse (L), bestehend aus

- mindestens ein Körperteil (2), ein erstes Deckschicht (4),
- mindestens einer thrombogenen Faser (5)

dadurch gekennzeichnet, dass

die Endoprothese (1) weiterhin mindestens eine

Fixierungsschicht (7) aufweist, die die mindestens eine thrombogene Faser (5), vorzugsweise dauerhaft, an der Endoprothese (1) befestigt, wobei
mindestens eines aus

- der mindestens einen thrombogenen Faser (5), und
- eine Halterungsanordnung (6) für die thrombogene Faser (5)

zumindest teilweise zwischen der Fixierungsschicht (7) und der ersten Deckschicht (4) angeordnet ist.

2. Endoprothese (1) nach Anspruch 1, wobei die mindestens eine thrombogene Faser (5) mindestens einen Teil aufweist, insbesondere ein freies Ende, das sich von der Fixierungsschicht (7) und der ersten Deckschicht (4) erstreckt.

3. Endoprothese (1) nach einem der Ansprüche 1 oder 2, ferner umfassend mindestens einen Stützstreifen (6), wobei die mindestens eine thrombogene Faser (5) mit dem mindestens einen Stützstreifen (6) verbunden ist.

4. Endoprothese (1) nach Anspruch 3, wobei der mindestens eine Stützstreifen (6) zwischen der ersten Deckschicht (4) und der mindestens einen Fixierungsschicht (7) angeordnet ist.

5. Endoprothese (1) nach einem der Ansprüche 3 oder 4, **dadurch gekennzeichnet, dass** mindestens eines aus Stützstreifen (6) und Fixierungsschicht (7) einen Klebstoff aufweist,
insbesondere einen Hotmelt-Klebstoff, der im geschmolzenen Zustand einen Kontaktwinkel auf PTFE von weniger als 45°, vorzugsweise weniger als 30°, aufweist.

6. Endoprothese (1) nach Anspruch 5, **dadurch gekennzeichnet, dass** der Klebstoff so beschaffen ist, dass er insbesondere im geschmolzenen Zustand mindestens eines von der Deckschicht und der Fixierungsschicht (4) durchdringt.

7. Endoprothese (1) nach einem der Ansprüche 5 oder 6, wobei der Klebstoff als Klebeschicht (7a) auf der Fixierungsschicht (7) vorgesehen ist.

8. Endoprothese (1) nach einem der vorhergehenden Ansprüche, wobei mindestens eines aus der ersten Deckschicht (4) und der mindestens einen Fixierungsschicht (7) PTFE, insbesondere eine Vielzahl von elektrogesponnenen PTFE-Fasern, aufweist.

9. Endoprothese (1) nach einem der vorhergehenden Ansprüche, wobei die erste Deckschicht (4) und die mindestens eine Fixierungsschicht (7) aus demselben Material bestehen.

10. Endoprothese (1) nach einem der vorhergehenden Ansprüche, wobei die mindestens eine Fixierungsschicht (7) so angeordnet ist, dass ein erster und ein zweiter Endabschnitt (9, 10) der mindestens einen thrombogenen Faser (5) von der Fixierungsschicht (7) und der ersten Deckschicht (4) ausgehen.

11. Endoprothese (1) nach einem der vorhergehenden Ansprüche, wobei ein erster Endabschnitt (9) der mindestens einen thrombogenen Faser (5) zwischen der Fixierungsschicht (7) und der ersten Deckschicht (4) angeordnet ist und ein zweiter Endabschnitt (10) der mindestens einen thrombogenen Faser (5) sich von der Fixierungsschicht (7) und der ersten Deckschicht (4) erstreckt.

12. Endoprothese (1) nach einem der vorhergehenden Ansprüche, umfassend mindestens zwei Fixierungsschichten (7), wobei die mindestens zwei Fixierungsschichten durch einen Zwischenraum entlang der Oberfläche der ersten Deckschicht (4) voneinander getrennt sind.

13. Endoprothese (1) nach einem der vorhergehenden Ansprüche, wobei die mindestens eine Fixierungsschicht (7) eine längliche Form aufweist, die in einer Richtung parallel zur Längsachse (L) der Endoprothese (1) verläuft.

14. Verfahren zur Herstellung einer Endoprothese (1), vorzugsweise einer Endoprothese (1) nach einem der vorhergehenden Ansprüche, umfassend die Schritte:

- Bereitstellung eines Endoprothesenrahmens mit einer ersten Deckschicht (4)
- Bereitstellen von mindestens einer thrombogenen Faser (5)
- Bereitstellen mindestens einer Fixierungsschicht (7)
- Anordnen der mindestens einen thrombogenen Faser (5) auf der ersten Deckschicht (4)
- Anbringen der thrombogenen Faser (5) auf der ersten Deckschicht (4) durch Fixieren der Fixierungsschicht (7) auf der ersten Deckschicht (4), wobei mindestens eines aus der mindestens einen thrombogenen Faser (5) und einer Halterungsanordnung für die thrombogene Faser mindestens teilweise zwischen der Fixierungsschicht (7) und der ersten Deckschicht (4) angeordnet ist.

15. Verfahren nach einem der vorhergehenden Ansprüche, wobei mindestens ein Trägerstreifen (6) mit der

mindestens einen daran befestigten thrombogenen Faser (5) vorgesehen ist.

16. Verfahren nach Anspruch 14, wobei mindestens einer von dem mindestens einen Trägerstreifen (6) und der mindestens einen Fixierungsschicht einen Klebstoff, vorzugsweise einen Schmelzklebstoff, umfasst und der Schritt des Fixierens der Fixierungsschicht (7) eine Aktivierung des Klebstoffs umfasst, vorzugsweise ein Schmelzen des Schmelzklebstoffs.

17. Verfahren nach einem der vorhergehenden Ansprüche, das ferner den Schritt des Bereitstellens mindestens eines Schutzstreifens (8) umfasst, der lösbar an der Endoprothese (1) befestigt wird, wobei der Schutzstreifen (8) in seinem befestigten Zustand die mindestens eine thrombogene Faser (5) auf einer Oberfläche der ersten Deckschicht (4) zurückhält.

Revendications

1. Une endoprothèse (1), en particulier une endoprothèse vasculaire ou une endoprothèse cardiaque, ayant un axe longitudinal (L), comprenant

- au moins une partie du corps (2), une première couverture (4),
- au moins une fibre thrombogénique (5)

caractérisé par le fait que

l'endoprothèse (1) comprend en outre au moins une couche de fixation (7) qui attache, de préférence de manière permanente, au moins une fibre thrombogène (5) à l'endoprothèse (1), dans laquelle

- au moins un de l'au moins une fibre thrombogène (5), et une structure de support (6) pour la fibre thrombogène (5)

est au moins partiellement disposée entre la couche de fixation (7) et la première couverture (4).

2. Endoprothèse (1) selon la revendication 1, dans laquelle la au moins une fibre thrombogène (5) présente au moins une partie, notamment une extrémité libre, s'étendant à partir de la couche de fixation (7) et de la première couverture (4) .

3. L'endoprothèse (1) selon l'une des revendications 1 ou 2, comprenant en outre au moins une bande de support (6), dans laquelle au moins une fibre thrombogène (5) est attachée à la au moins une bande de support (6).

4. Endoprothèse (1) selon la revendication 3, dans laquelle la au moins une bande de support (6) est disposée entre la première couverture (4) et la au moins une couche de fixation (7).

5. L'endoprothèse (1) selon l'une des revendications 3 ou 4, dans laquelle au moins l'une de la bande de support (6) et de la couche de fixation (7) comprend un adhésif,
en particulier un adhésif "hot melt" qui, à l'état fondu, a un angle de contact avec le PTFE inférieur à 45°, de préférence inférieur à 30°.

6. Endoprothèse (1) selon la revendication 5, dans laquelle l'adhésif est adapté pour, notamment à l'état fondu, pénétrer dans au moins l'une de la première couverture et de la couche de fixation (4).

7. L'endoprothèse (1) selon l'une des revendications 5 ou 6, dans laquelle l'adhésif est fourni sous forme de couche adhésive (7a) sur la couche de fixation (7).

8. L'endoprothèse (1) selon l'une quelconque des revendications précédentes, dans laquelle au moins l'une de la première couverture (4) et l'au moins une couche de fixation (7) comprennent du PTFE, en particulier une pluralité de fibres électrofilées de PTFE.

9. Endoprothèse (1) selon l'une quelconque des revendications précédentes, dans laquelle la première couverture (4) et la au moins une couche de fixation (7) sont constituées d'un même matériel.

10. L'endoprothèse (1) selon l'une quelconque des revendications précédentes, dans laquelle l'au moins une couche de fixation (7) est disposée de telle sorte qu'une première et une seconde portion d'extrémité (9,10) de l'au moins une fibre thrombogène (5) s'étendent à partir de la couche de fixation (7) et de la première couverture (4).

11. L'endoprothèse (1) selon l'une quelconque des revendications précédentes, dans laquelle une première partie d'extrémité (9) de l'au moins une fibre thrombogène (5) est disposée entre la couche de fixation (7) et la première couverture (4) et une deuxième partie d'extrémité (10) de l'au moins une fibre thrombogène (5) s'étend à partir de la couche de fixation (7) et de la première couverture (4).

12. L'endoprothèse (1) selon l'une quelconque des revendications précédentes, comprenant au moins deux couches de fixation (7), les au moins deux couches de fixation étant séparées par un espace le long de la surface de la première couverture (4).

13. L'endoprothèse (1) selon l'une quelconque des revendications précédentes, dans laquelle l'au moins une couche de fixation (7) a une forme allongée dans une direction parallèle à l'axe longitudinal (L) de l'endoprothèse (1).

14. Procédé de fabrication d'une endoprothèse (1), de préférence une endoprothèse (1) selon l'une des revendications précédentes, comprenant les étapes suivantes :

- Fournir un cadre d'endoprothèse comprenant une première couverture (4)
- Fournir au moins une fibre thrombogène (5)
- Fournir au moins une couche de fixation (7)
- Disposer la au moins une fibre thrombogène (5) sur la première couverture (4)
- Fixer la fibre thrombogène (5) sur la première couverture (4) en fixant la couche de fixation (7) sur la première couverture (4), dans laquelle au moins l'une des fibres thrombogènes (5) et une structure de support pour la fibre thrombogène sont disposées au moins partiellement entre la couche de fixation (7) et la première couverture (4) .

15. Procédé selon l'une quelconque des revendications précédentes, dans lequel au moins une bande de support (6) à laquelle est attachée au moins une fibre thrombogène (5) est fournie.

16. Procédé selon la revendication 14, dans lequel au moins une de la bande de support (6) et de la couche de fixation comprend un adhésif, de préférence un adhésif hot melt, et l'étape de fixation de la couche de fixation (7) comprend une activation de l'adhésif, de préférence en faisant fondre l'adhésif hot melt.

17. Procédé selon l'une quelconque des revendications précédentes, comprenant en outre l'étape de fournir au moins une bande de protection (8), de la fixer de manière détachable à l'endoprosthèse (1), dans lequel, dans son état fixé, la bande de protection (8) retient la au moins une fibre thrombogénique (5) sur une surface de la première couverture (4).

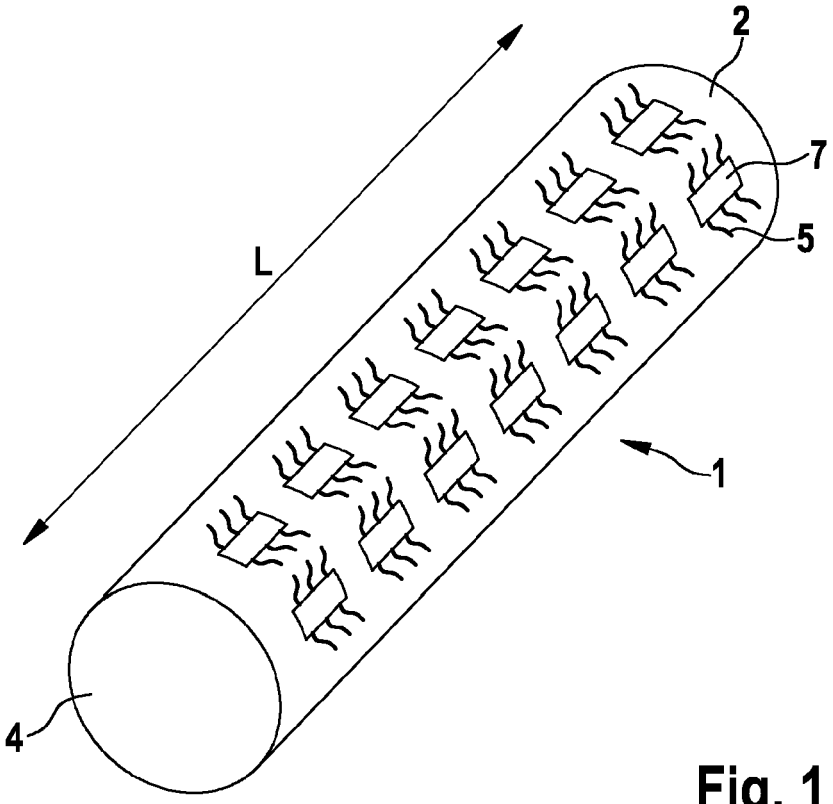


Fig. 1

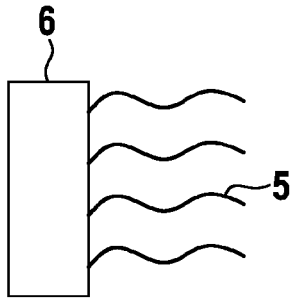


Fig. 2a

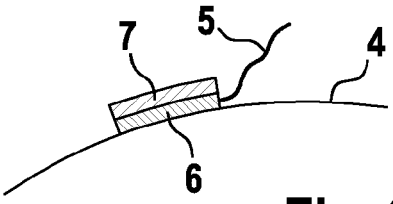


Fig. 2b

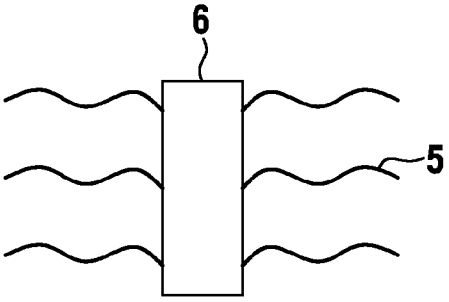


Fig. 3a

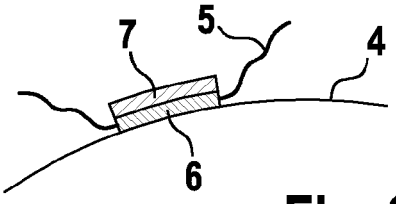


Fig. 3b

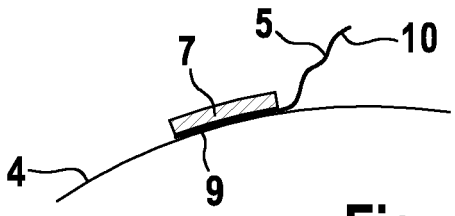


Fig. 4a

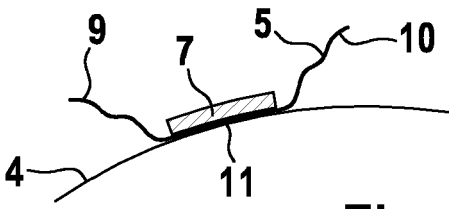
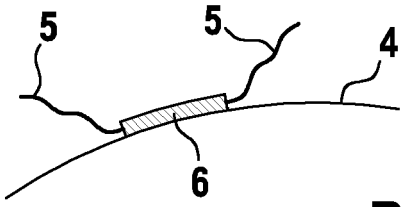
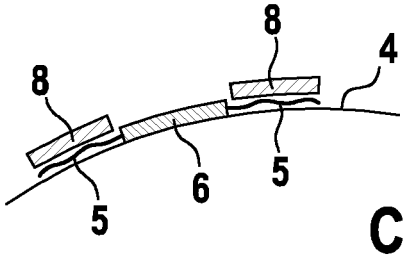


Fig. 4b

A



B



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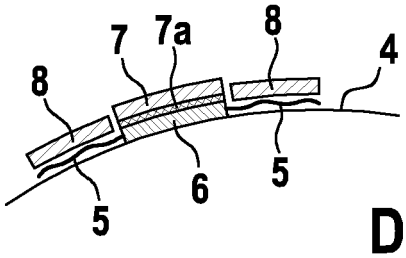
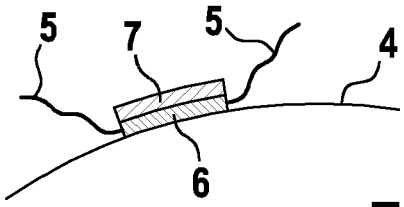


D



E

Fig. 5

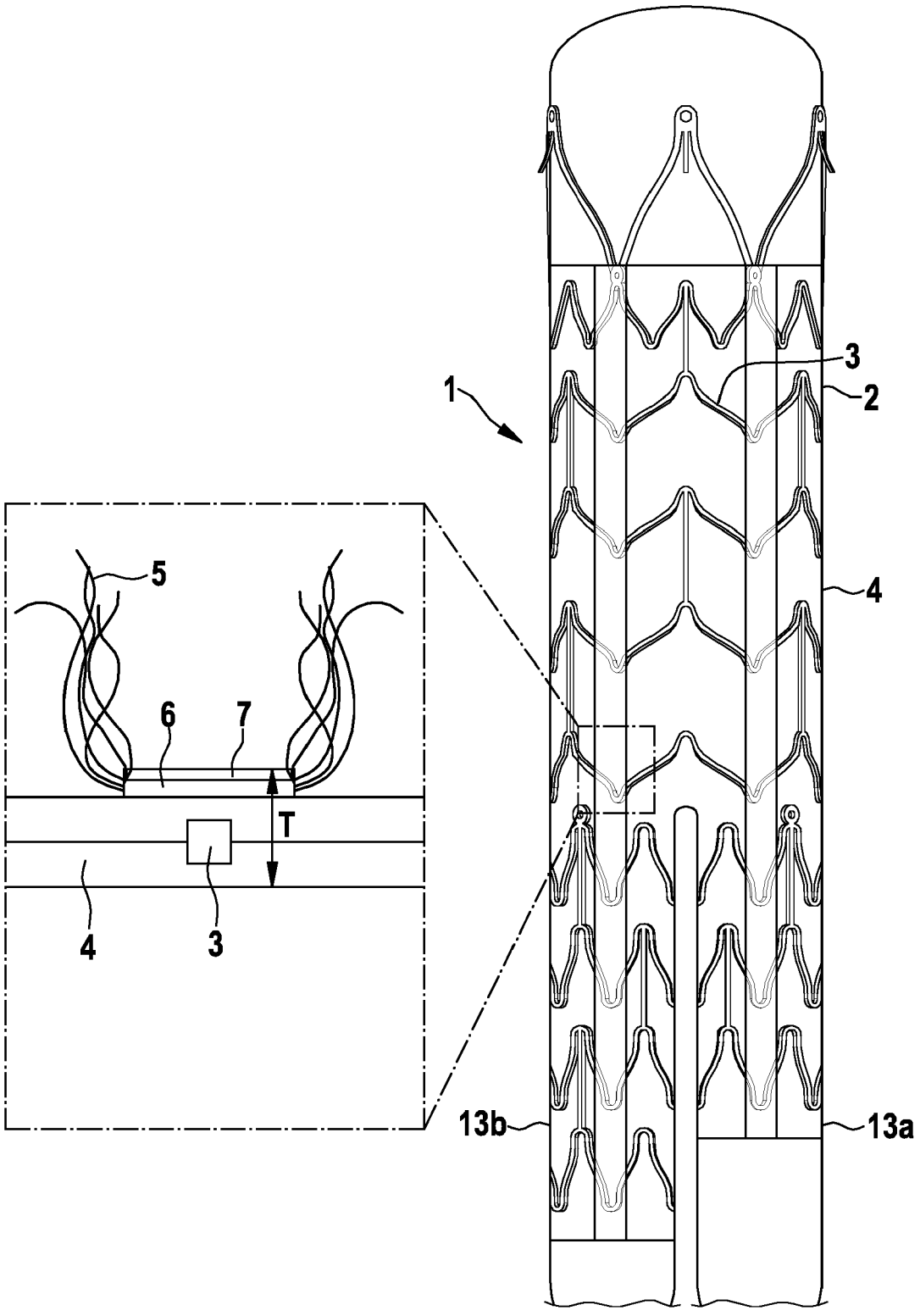


Fig. 6

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- WO 2013182614 A1 **[0002] [0018] [0034]**
- WO 2006111801 A2 **[0002]**