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(54) **EXPANDABLE SLEEVED STENT AND METHOD OF MAKING SUCH STENT**

(71) Applicant: **Strait Access Technologies Holdings (PTY) LTD**, Cape Town (ZA)

(72) Inventors: **Bruce De Jongh**, Hout Bay (ZA); **Deon Bezuidenhout**, Cape Town (ZA); **Peter Zilla**, Cape Town (ZA); **Carel Sebastiaan Van Heerden**, Meadowridge (ZA); **Johan Coetzee**, Newlands (ZA)

(73) Assignee: **STRAIT ACCESS TECHNOLOGIES HOLDINGS (PTY) LTD**, Cape Town (ZA)

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,330,528 A 7/1994 Lazim
5,449,385 A * 9/1995 Religa A61F 2/2412 623/2.19

(Continued)

FOREIGN PATENT DOCUMENTS

DE 102014102653 9/2015
EP 2749254 7/2014

(Continued)

OTHER PUBLICATIONS

International search report and written opinion dated Oct. 30, 2019 in international patent application No. PCT/ZA2019/050052.

Primary Examiner — Jacqueline Woznicki
(74) *Attorney, Agent, or Firm* — Billion & Armitage

(57) **ABSTRACT**

An expandable sleeved stent comprises a stent and a sleeve. The stent comprises a tubular body with: first and second axial ends; a latticed peripheral wall; and at least two arms that, upon radial expansion of the tubular body from a crimped condition to an expanded condition, protrude radially from the latticed peripheral wall, the free end of each arm being radially displaceable relative to the adjacent latticed peripheral wall. The sleeve: (a) extends from the first axial end of the tubular body and circumferentially covers at least a portion of the radial outer surface of the latticed peripheral wall between the free ends of the arms and the first axial end of the tubular body; (b) bridges the spaces between the portions of the latticed peripheral wall adjacent

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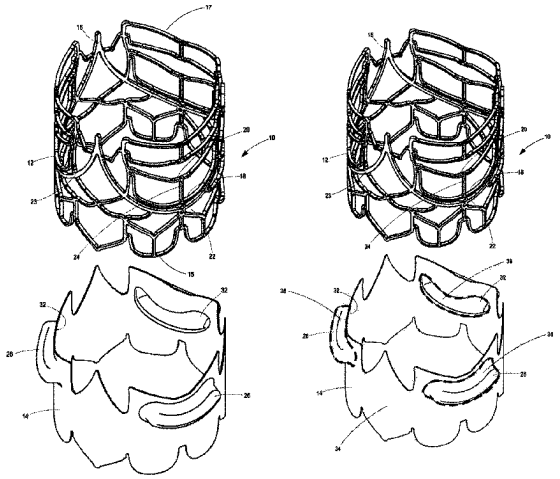

the arms; and the free ends of the arms; and (c) is secured to either: (i) the arms; or (ii) the tubular body in the vicinity between the free ends of the arms and the second axial end of the tubular body. Upon radial expansion of the tubular body towards the expanded condition and consequent protrusion of the arms radially from the latticed peripheral wall, the portions of the sleeve that bridge the latticed peripheral wall and the arms flare radially outwards.

7 Claims, 7 Drawing Sheets

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,549,665	A *	8/1996	Vesely	A61F 2/2409 623/2.14
5,665,117	A	9/1997	Rhodes	
5,693,088	A	12/1997	Lazarus	
7,044,962	B2	5/2006	Elliott	
7,445,642	B2	11/2008	Amos et al.	
7,803,178	B2	9/2010	Whirley	
10,456,245	B2 *	10/2019	Nguyen	A61L 31/10
10,631,978	B2 *	4/2020	Park	A61F 2/2406
2001/0021872	A1 *	9/2001	Bailey	A61F 2/2469 623/2.18
2002/0169497	A1	11/2002	Wholey et al.	
2003/0028244	A1 *	2/2003	Bates	A61L 31/16 623/1.42
2004/0044358	A1	3/2004	Khosravi et al.	
2004/0082989	A1	4/2004	Cook et al.	
2004/0098096	A1	5/2004	Eton	
2004/0176836	A1	9/2004	Kari et al.	
2005/0137692	A1 *	6/2005	Haug	A61F 2/2439 623/2.11
2005/0137699	A1 *	6/2005	Salahieh	A61F 2/2418 623/2.11
2005/0228484	A1	10/2005	Stephens et al.	
2006/0025853	A1	2/2006	Evans et al.	
2006/0271172	A1	11/2006	Tehrani	
2006/0292206	A1	12/2006	Kim et al.	
2008/0058920	A1	3/2008	Kari	
2008/0082166	A1 *	4/2008	Styrc	A61F 2/2418 623/2.18
2008/0234809	A1	9/2008	Greenan	
2008/0255661	A1 *	10/2008	Straubinger	A61F 2/2427 623/2.36
2009/0112305	A1	4/2009	Goldmann et al.	
2010/0070027	A1 *	3/2010	Bonhoeffer	A61F 2/2436 623/2.11
2011/0295363	A1 *	12/2011	Girard	A61F 2/2412 623/1.26
2012/0165917	A1	6/2012	Schreck et al.	
2012/0316656	A1	12/2012	Deal et al.	
2013/0274873	A1 *	10/2013	Delaloye	A61F 2/2469 623/2.18
2013/0304200	A1	11/2013	Mclean et al.	
2014/0018915	A1 *	1/2014	Biadillah	A61F 2/2418 623/2.17
2014/0058436	A1	2/2014	Rosenbluth et al.	
2014/0222136	A1	8/2014	Geist et al.	
2014/0296975	A1	10/2014	Tegels et al.	
2014/0358216	A1	12/2014	Schreck et al.	
2015/0142103	A1	5/2015	Vidlund	
2015/0148894	A1 *	5/2015	Damm	A61F 2/2436 623/2.11
2015/0289973	A1 *	10/2015	Braido	A61F 2/2412 623/2.17
2016/0038280	A1	2/2016	Morriss et al.	
2016/0213465	A1 *	7/2016	Girard	A61F 2/2409
2016/0220366	A1 *	8/2016	Burriesci	A61F 2/2418
2016/0338823	A1	11/2016	Akingba	
2017/0071734	A1	3/2017	Delaloye et al.	
2018/0147061	A1 *	5/2018	Drasler	A61F 2/2412
2018/0206982	A1 *	7/2018	Haivatov	A61F 2/2418
2018/0221146	A1	8/2018	Jana et al.	
2018/0289476	A1 *	10/2018	Vyas	A61F 2/2418
2018/0303612	A1 *	10/2018	Pasquino	A61F 2/2448
2019/0099266	A1 *	4/2019	Nelson	A61F 2/2418
2019/0336283	A1 *	11/2019	Le Cerf	A61F 2/2418
2020/0163760	A1 *	5/2020	Hariton	A61F 2/2418
2020/0306037	A1 *	10/2020	Siegel	A61M 25/0045 264/269
2021/0145572	A1 *	5/2021	Dasi	A61L 27/20
2021/0212820	A1 *	7/2021	De Jongh	A61F 2/2415
2022/0192824	A1 *	6/2022	Vidlund	A61F 2/2418

FOREIGN PATENT DOCUMENTS

EP	2815723	12/2014
EP	2926766	10/2015
WO	9528899	11/1995
WO	2007098937	9/2007
WO	2010008548	1/2010
WO	2016073189	5/2016
WO	2017081679	5/2017
WO	2017101232	6/2017
WO	2017163247	9/2017
WO	2017190161	11/2017

* cited by examiner

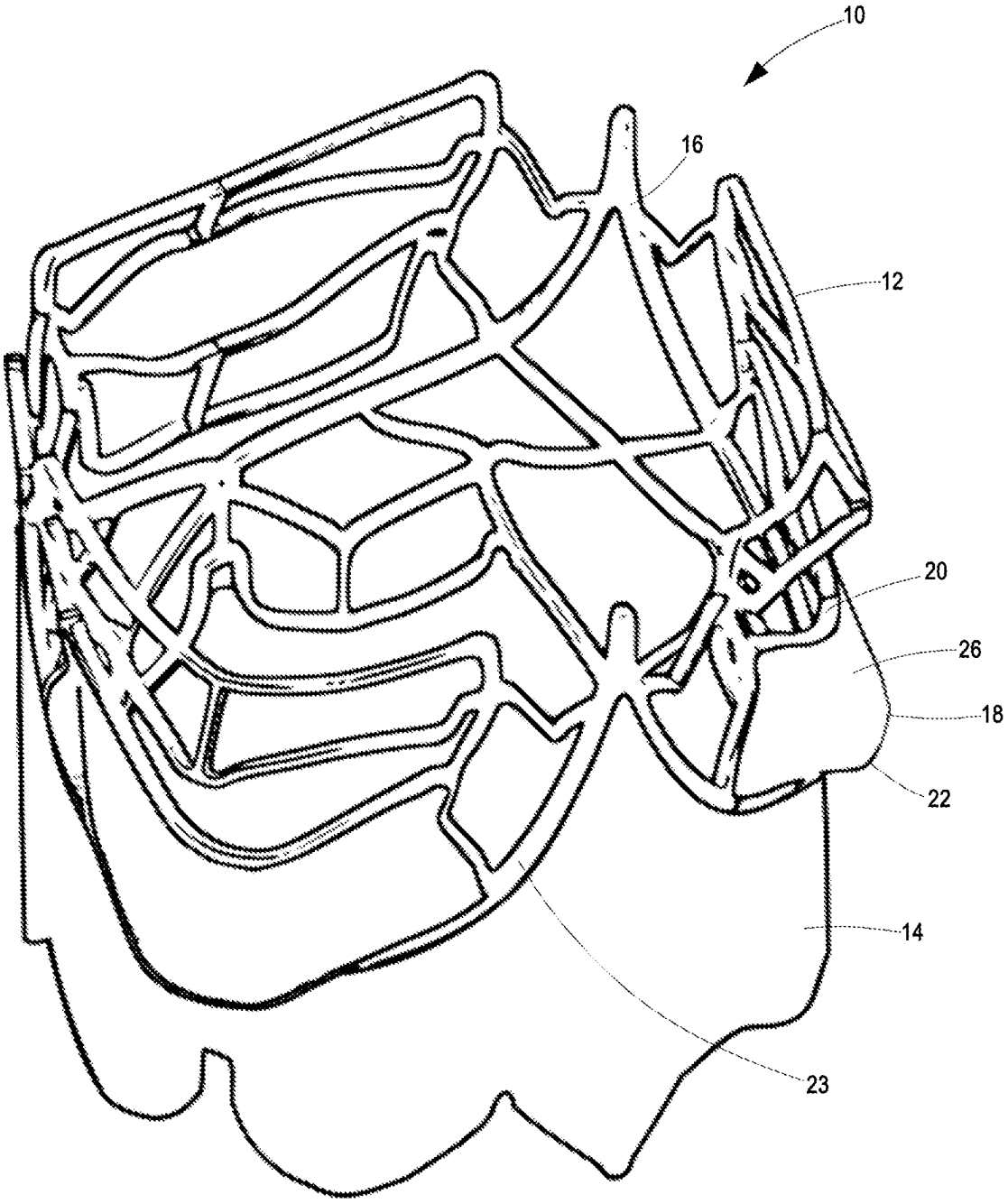

Figure 1

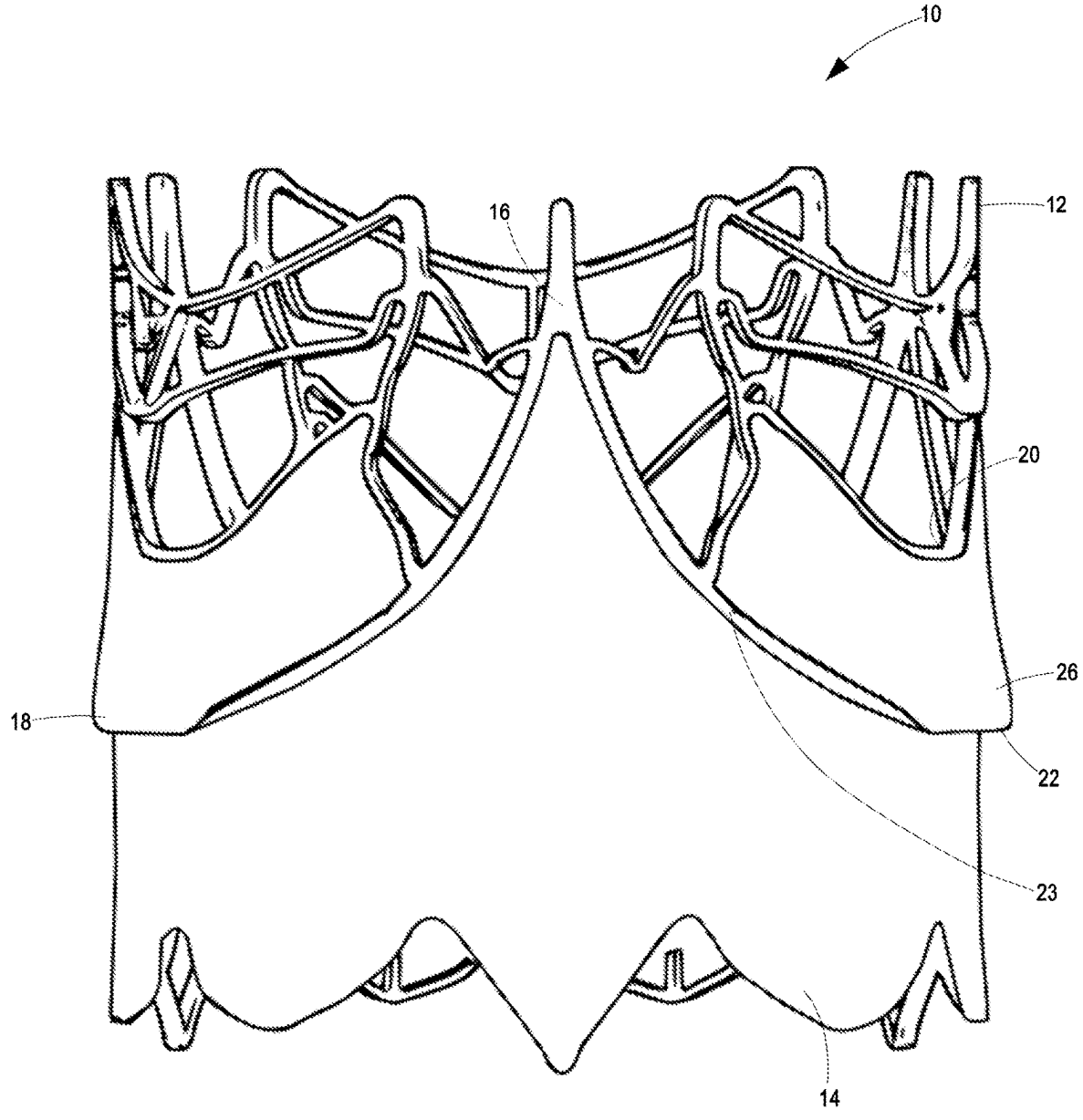

Figure 2

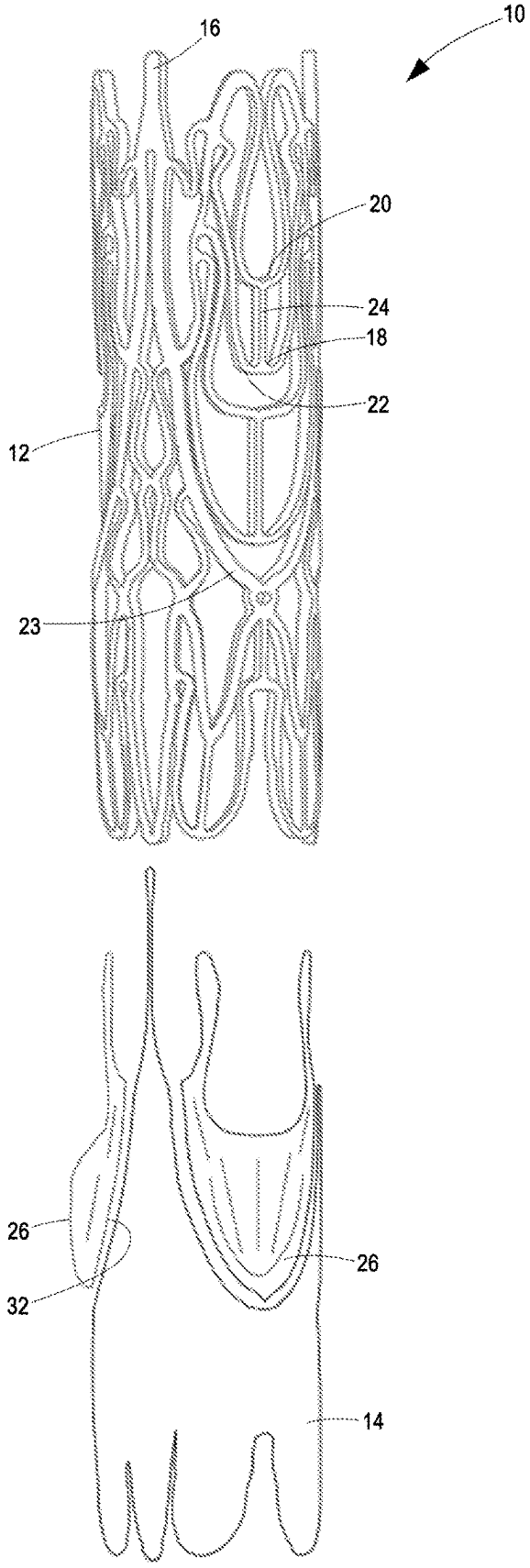

Figure 3

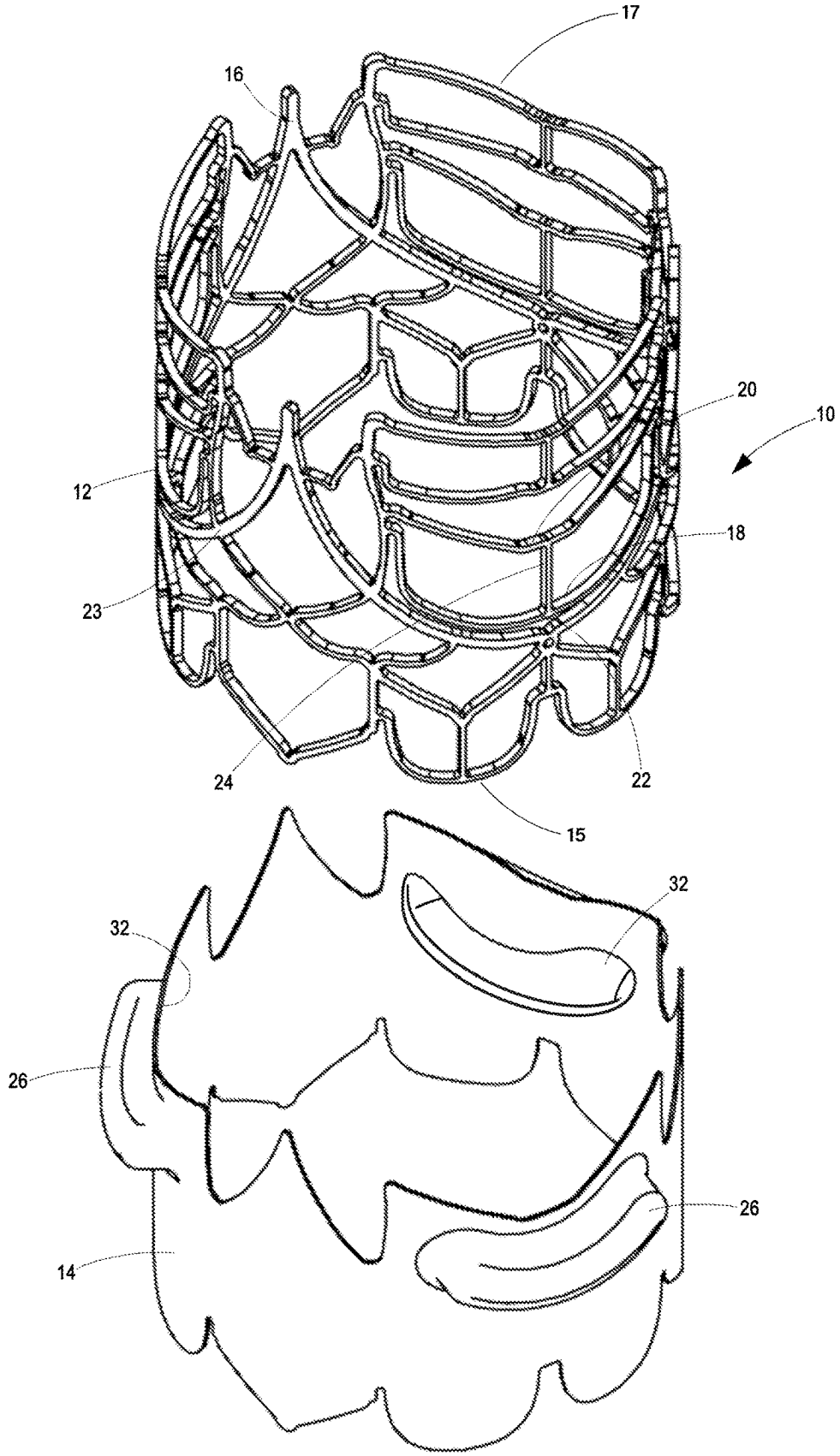

Figure 4a

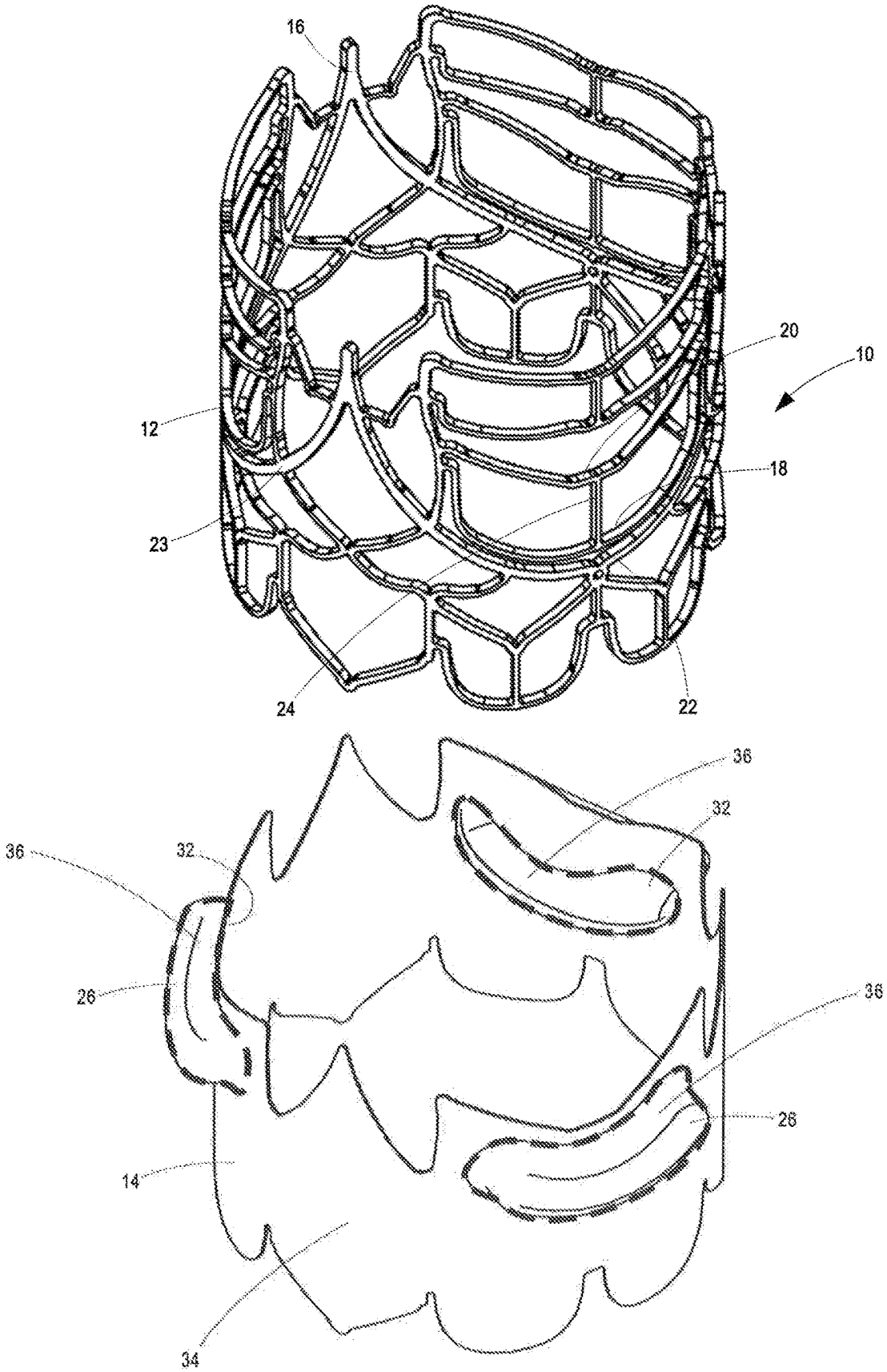

Figure 4b

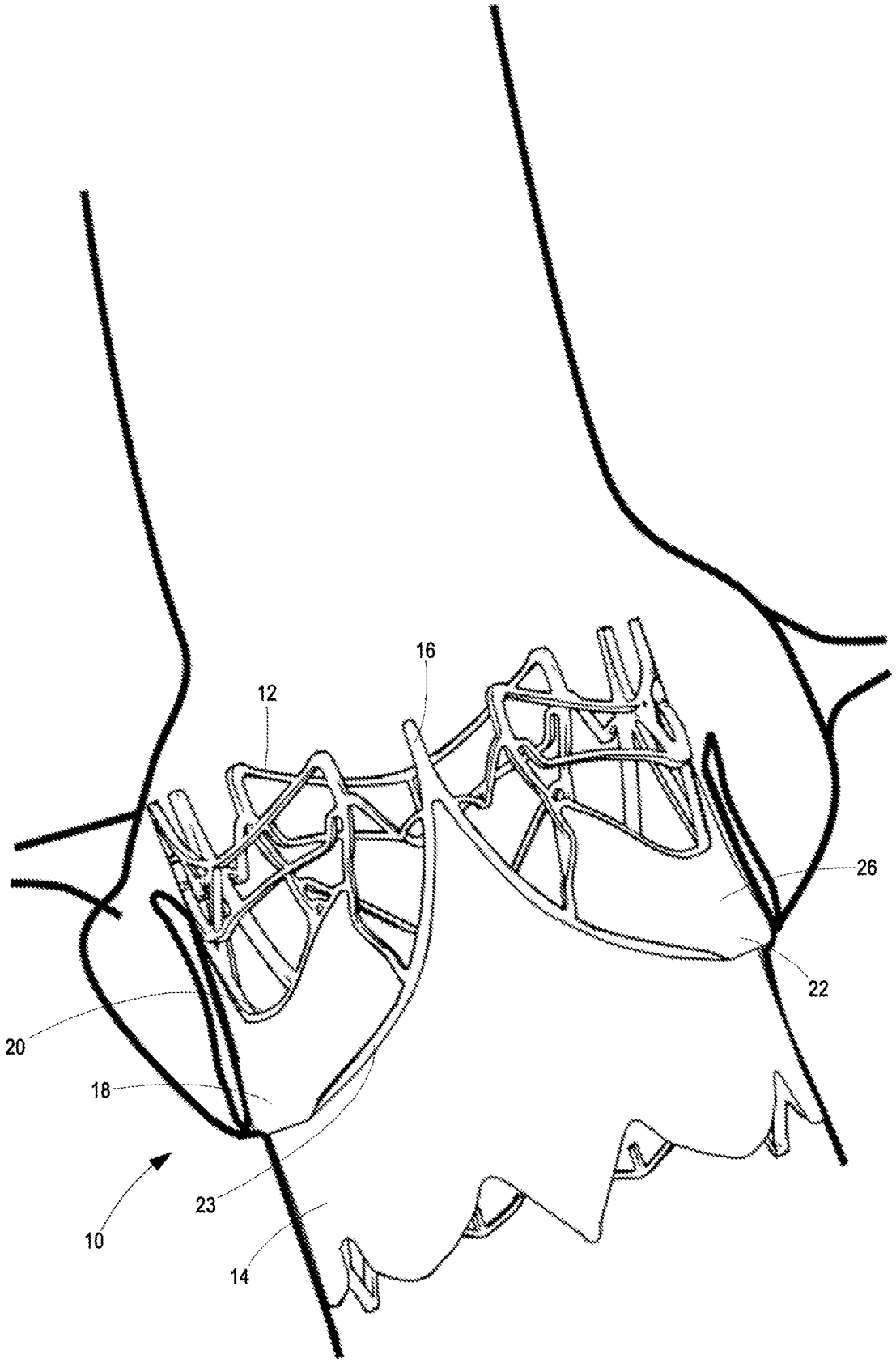

Figure 5

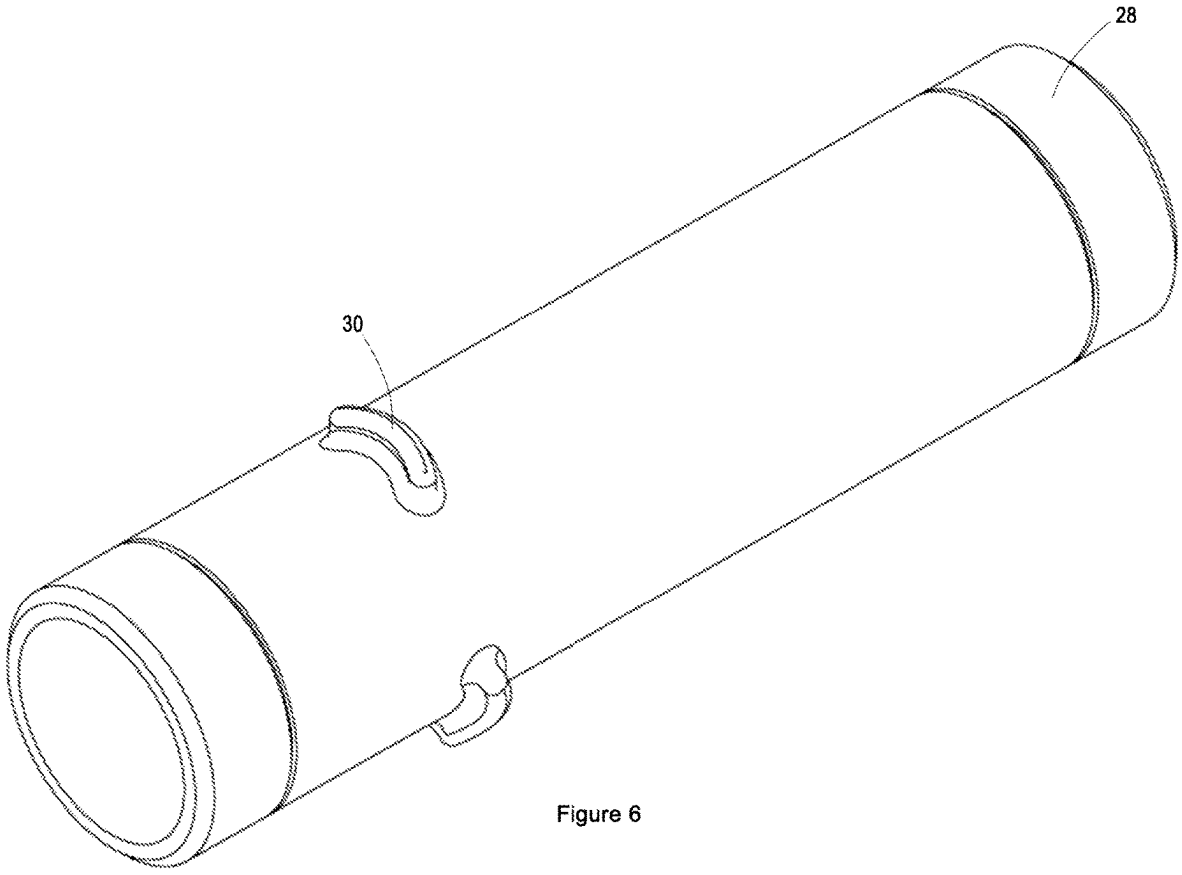

Figure 6

EXPANDABLE SLEEVED STENT AND METHOD OF MAKING SUCH STENT

BACKGROUND

The present invention relates to an expandable sleeved stent. More particularly, the present invention relates to an expandable sleeved stent including: (i) a tubular body comprising a latticed peripheral wall and arms that protrude radially from the latticed peripheral wall upon radial expansion of the tubular body; and (ii) a sleeve that extends circumferentially along a portion of both the latticed peripheral wall and the arms. Even more particularly, the present invention relates to an expandable sleeved stent including radially extendable arms and a sleeve, wherein the sleeve bridges the free ends of the arms and adjacent portions of the latticed peripheral wall, such that, upon protrusion of the arms radially from the latticed peripheral wall, the bridging portions of the sleeve flare radially. The present invention also relates to an expandable sleeved stent, wherein the sleeve defines radially outwards extending humps for receiving radially protruding stent arms therein upon radial expansion of the stent. Furthermore, the present invention relates to a method of making an expandable sleeved stent.

Stents are used to treat aneurysms and to anchor and support replacement valves. When secured in a patient's vascular system, the radial outer surface of the stent is preferably sealed against the wall of the vascular system. Failure to create such seal permits blood flow between the radial outer surface of the stent and the wall of the vascular system, which in turn may apply pressure to the aneurism or cause paravalvular leakage. To improve the seal between the stent and the wall of the vascular system, various bladders, sleeves, skirts or formations have been added to stents, which added features protrude radially beyond the radial outer surface of the stent. For instance:

US2006/0271172 "Minimally invasive aortic valve replacement" describes a stent with deformable rings on the radial outer surface of the stent.

US2006/0292206 "Devices and methods for treatment of vascular aneurysms" and EP2815723 "Collapsible and re-expandable prosthetic heart valve cuff designs and complementary technological applications" describe a stent with an expandable material on the radial outer surface of the stent.

US2009/0112305 "Stent-graft prosthesis" and US2014/0058436 "Blood flow disruption devices and methods for the treatment of vascular defects" describe a stent with a radially expandable sleeve about the radial outer surface of the stent.

US2004/0044358 "Methods and apparatus for treating aneurysms and arterio-venous fistulas", US2004/0098096 "Endograft device to inhibit endoleak and migration", US2004/0176836 "Kink resistant endovascular graft", US2005/0228484 "Modular endovascular graft", US2006/0025853 "Methods and systems for endovascular aneurysm treatment", US2008/0058920 "Dual chamber cuff structure", US2008/0234809 "Stent graft system with injection tube", US2012/0316656 "Balloon expandable stent", US2012/0165917 "Stent graft", US2014/358216 "Stent graft", U.S. Pat. No. 5,330,528 "Vascular surgical devices", U.S. Pat. No. 5,665,117 "Endovascular prosthesis with improved sealing means for aneurysmal arterial disease and method of use", U.S. Pat. No. 5,693,088 "Intraluminal vascular graft", U.S. Pat. No. 7,445,642 "Agent eluting stent and catheter", U.S. Pat. No. 7,803,178 "Inflatable porous implants and methods for drug delivery" and WO95/28899 "Stented bioprosthetic heart valve" describe a stent (or other carrier) including a double-walled bladder that is inflated to expand radially from the radial outer surface of the stent by the introduction of fluid (e.g. blood) between the bladder walls.

EP2926766 "Repositionable heart valve" describes a stent with inflatable sacs on the radial outer surface of the stent.

US2014/0296975 "Inflatable annular sealing device for prosthetic mitral valve" describes a stent with a skirt and a shell that expands from the radial outer surface of the stent.

US2002/0169497 "Endovascular stent system and method of providing aneurysm embolization", US2004/0082989 "Stent graft with improved proximal end", WO2016/073189 "Transcatheter valve prosthesis having an external skirt for sealing and preventing paravalvular leakage" and EP2749254 "Repositionable heart valve" describe a stent with a sleeve circumferentially covering a portion of the stent.

U.S. Pat. No. 7,044,962 "Implantable prosthesis with displaceable skirt" describes a stent including a skirt on the radial outer surface of the stent, the skirt having a free peripheral edge that can be deployed into a flared condition.

US2015/0142103 "Multi-component designs for heart valve retrieval device, sealing structures and stent assembly", US2016/0338823 "Jaxtarenal stent and methods", US2017/0071734 "Transcatheter stent-valves and methods, systems and devices for addressing para-valve leakage", WO2017/081679 "Stent-grafts systems with skirt" and WO2017/101232 "Artificial heart valve stent, artificial heart valve and implantation method" describe: (i) a stent having a peripheral wall and arms that extend radially from the peripheral wall; and (ii) a sleeve that extends over a portion of the peripheral wall and that radiates along the stent arms to form a skirt. In each instance, the skirt extends from the peripheral wall and along the stent arms from the hinged connection of the stent arms to the peripheral wall to the free ends of the stent arms. Neither the sleeve, nor the skirt bridges the gap between the free ends of the stent arms and the peripheral wall.

An object of the present invention is to provide a sleeved stent, wherein radial expansion of the stent causes the sleeve to expand radially and form (in axial cross-section) a cylindrical sleeve with at least two humps supported by radially extending stent arms.

SUMMARY OF THE INVENTION

According to a first aspect of the invention, there is provided an expandable sleeved stent that comprises:

- a tubular body with: first and second axial ends; a latticed peripheral wall; and at least two arms that, upon radial expansion of the tubular body from a crimped condition to an expanded condition, protrude radially from the latticed peripheral wall, the free end of each arm being radially displaceable relative to the adjacent latticed peripheral wall;
- a sleeve that:
  - extends from the first axial end of the tubular body and circumferentially covers at least a portion of the radial outer surface of the latticed peripheral wall between the free ends of the arms and the first axial end of the tubular body;
  - bridges the spaces between: the portions of the latticed peripheral wall adjacent the arms; and the free ends of the arms; and
  - is secured to either: (i) the arms; or (ii) the tubular body in the vicinity between the free ends of the arms and the second axial end of the tubular body,

such that, upon radial expansion of the tubular body towards the expanded condition and consequent protrusion of the arms radially from the latticed peripheral wall, the portions of the sleeve that bridge the latticed peripheral wall and the arms flare radially outwards.

Typically, when the tubular body is in the crimped condition, the sleeve: (i) in the region that radially overlaps the latticed peripheral wall is right circular cylindrical in shape; and (ii) in the regions that radially overly the arms define radially outward extending humps.

Generally, when the tubular body is in the crimped condition, the humps defined by the sleeve provide pockets between the sleeve and associated arms, into which pockets the arms may extend upon radial expansion of the tubular body towards the expanded condition.

Preferably:

each arm includes: (i) a first arm lattice member; (ii) a generally U-shaped second arm lattice member; and (iii) a third arm lattice member bridging the first and second arm lattice members; and

the sleeve extends to, and is secured to the first arm lattice member of each arm.

Typically, in respect of each arm, the second arm lattice member is not secured to the sleeve, permitting sliding movement of the second arm lattice member along the sleeve in the region of the corresponding hump defined by the sleeve upon radial expansion of the tubular body towards the expanded condition.

Generally, the sleeve is made of an electrospun polymer.

Preferably, each hump defined by the sleeve is kidney-shaped, curving between the axial ends of the second arm lattice member.

Typically, the tubular body is coated in a polymer and the sleeve is bonded to the tubular body.

Optionally, the tubular body is bonded to scalloped members forming part of the latticed peripheral wall adjacent the second arm lattice members.

Generally: the tubular body includes three arms; and the sleeve defines three humps.

Preferably: a first portion of the sleeve is made of single layered polymer material; and second portions of the sleeve are made of double-layered polymer material.

According to a second aspect of the invention, there is provided an expandable sleeved stent that comprises:

a tubular body with: first and second axial ends; a latticed peripheral wall; and at least two arms that, upon radial expansion of the tubular body from a crimped condition to an expanded condition, protrude radially from the latticed peripheral wall, the free end of each arm being radially displaceable relative to the adjacent latticed peripheral wall; and

a sleeve that:

extends from the first axial end of the tubular body and circumferentially covers at least a portion of the radial outer surface of the latticed peripheral wall between the free ends of the arms and the first axial end of the tubular body;

bridges the spaces between the portions of the latticed peripheral wall adjacent the arms; and the free ends of the arms;

covers the arms; and

when the tubular body is in the crimped condition:

in the region of the sleeve that radially overlaps the latticed peripheral wall, is right circular cylindrical in shape; and

in the regions of the sleeve that radially overly the arms, define radially outward extending humps, providing pockets between the sleeve and associated arms,

such that, upon protrusion of the arms radially from the latticed peripheral wall, the arms extend into the pockets provided by the humps.

Typically, in respect of each arm, the free end of the arm is not secured to the sleeve, permitting sliding movement of the free end of the arm along the sleeve in the region of the corresponding hump defined by the sleeve upon radial expansion of the tubular body towards the expanded condition.

Generally: the tubular body includes three arms; and the sleeve defines three humps.

According to a third aspect of the invention, there is provided a method of making an expandable sleeved stent, including the steps of:

providing an expandable stent comprising a tubular body with: first and second axial ends; a latticed peripheral wall; and at least two arms that, upon radial expansion of the tubular body from a crimped condition to an expanded condition, protrude radially from the latticed peripheral wall, the free end of each arm being radially displaceable relative to the adjacent latticed peripheral wall;

electrospinning a polymer onto a first cylindrical mandrel to create a sleeve;

stretching the sleeve over a second cylindrical mandrel that defines at least two radially outward extending humps symmetrically spaced about the second cylindrical mandrel;

heating the sleeve to cause the sleeve to assume the shape of the second cylindrical mandrel with humps; and

placing the sleeve over the stent, with the humps formed in the sleeve radially overlying the stent arms.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in more detail, by way of example only, with reference to the accompanying drawings in which:

FIG. **1** is a perspective view of an expandable sleeved stent according to a preferred embodiment of first and second aspects of the invention, with the sleeved stent in an expanded condition;

FIG. **2** is a side view of the expandable sleeved stent in FIG. **1**, in an expanded condition;

FIG. **3** is an exploded perspective view of the expandable sleeved stent in FIG. **1**, in a crimped condition;

FIGS. **4***a* and **4***b* are exploded perspective views of the expandable sleeved stent in FIG. **1**, in a nascent condition;

FIG. **5** is a side view of the expandable sleeved stent in FIG. **1** in an expanded condition, with the expandable sleeved stent located within an aortic root; and

FIG. **6** is a perspective view of a second cylindrical mandrel used to form a sleeve forming part of the expandable sleeved stent in FIG. **1**.

DESCRIPTION OF THE INVENTION

With reference to FIGS. **1** to **5** of the drawings, an expandable sleeved stent **10** includes a stent **12** and a sleeve **14**.

The stent **12** is a tubular body that is laser cut from a single right circular cylindrical tube (typically between 18 mm and 30 mm in outer diameter) to integrally form a

latticed peripheral wall **16** having first and second axial ends **15**, **17** and arms **18**. Preferably, the stent **12** is coated with a polymer. FIG. **4***a* shows the stent **12** in a nascent condition (i.e. after being laser-cut, but before being crimped).

The latticed peripheral wall **16** permits the stent **12** to be: crimped (i.e. radially compressed) under the influence of an enveloping external radially compressive force to a crimped condition shown in FIG. **3**; and radially expanded under the influence of an internal radially expansive force to an expanded condition shown in FIG. **1**.

Three arms **18** are symmetrically arranged about the stent **12**. Each arm **18** comprises: a first arm lattice member **20**; a generally U-shaped second arm lattice member **22**; and a third arm lattice member **24** bridging the first and second arm lattice members **20** and **22**.

The latticed peripheral wall **16** includes a scalloped member **23** adjacent each second arm lattice member **22** (i.e. neighbouring the second arm lattice member **22** in the direction towards the first axial end **15** of the stent **12** tubular body).

The stent **12** is described in more detail in co-pending patent application no. PCT/ZA2017/050025 (published as WO/2017/190161), which application is incorporated herein by reference.

Each arm **18** is hingedly movable relative to the latticed peripheral wall **16** between:

- an initial configuration (i.e. when the stent **12** tubular body is in the crimped condition) in which the arms **18** are aligned with the adjacent latticed peripheral wall **16**; and
- a radially protruding configuration in which the arms **18** protrude radially from the adjacent latticed peripheral wall **16**—the free ends of the arms **18** (i.e. the second arm lattice members **22**) displaced radially outwards relative to the adjacent latticed peripheral wall **16**.

Expansion of the stent **12** from the crimped condition to the expanded condition causes the arms **18** to move from the initial configuration towards the radially protruding configuration.

The sleeve **14** is generally right circular cylindrical in shape and defines three radially outwards extending humps **26**.

The sleeve **14** is formed by:

- electrospinning a polymer onto a first cylindrical mandrel (not shown);
- stretching the sleeve **14** over a second cylindrical mandrel **28** (shown in FIG. **6**) that defines three radially outward extending kidney-shaped humps **30** symmetrically spaced about the second cylindrical mandrel **28**; and
- heating the sleeve **14** to cause the sleeve **14** to assume the shape of the second cylindrical mandrel **28** (with kidney-shaped humps).

The sleeve **14** is placed over the stent **12** (when the stent **12** tubular body is in the nascent condition shown in FIG. **4***a*), with the humps **26** formed in the sleeve **14** radially overlying the stent **12** arms **18**. More particularly, with reference to FIG. **4***b*, the sleeve **14**:

(i) in the region **34** (i.e. region outside the dashed lines) that radially overlaps the latticed peripheral wall **16** is right circular cylindrical in shape; and

(ii) in the regions **36** (i.e. regions within the dashed lines) that radially overly the arms **18** define: (a) radially outward extending kidney-shaped humps **26** curving between the axial ends of the second arm lattice members **22**; and (b) pockets **32** between the humps **26** and the corresponding arms **18**.

The sleeve **14** is bonded to a first axial end **15** of the stent **12** tubular body, and extends from the first axial end **15** of the stent **12** tubular body, circumferentially covering at least a portion of the radial outer surface of the latticed peripheral wall **16** between the free ends of the arms **18** (i.e. the second arm lattice members **22**) and the first axial end **15** of the stent **12** tubular body. The sleeve **14** further extends along the stent **12** tubular body to bridge the spaces between: the portions of the latticed peripheral wall **16** adjacent the arms **18**; and the free ends of the arms **18** (i.e. the second arm lattice members **22**). The sleeve **14** may be secured (i.e. bonded) to the free ends of the arms **18** (i.e. the second arm lattice members **22**). Alternatively (as shown in the Figures), the sleeve **14** may be secured (i.e. bonded) to the first arm lattice members **20**. Further alternatively, the sleeve **14** may extend beyond the arms **18** and be secured (i.e. bonded) to the stent **12** tubular body in the vicinity between the free ends of the arms **18** (i.e. the second arm lattice members **22**) and the second axial end **17** of the stent **12** tubular body. Preferably, the sleeve **14** is also bonded to the scalloped members **23**.

Since the stent **12** is coated in a polymer, the sleeve **14** can be bonded to the polymer coating **19** on the stent **12** to secure the sleeve **14** to the stent **12**.

The stent **12** with sleeve **14** thereon is then crimped to a crimped condition shown in FIG. **3**.

Upon radial expansion of the expandable sleeved stent **10**:

The stent **12** tubular body expands radially.

The free ends of the arms **18** displace/protrude radially outwards from the adjacent latticed peripheral wall **16**. Preferably, the free ends of the arms **18** (i.e. the second arm lattice members **22**) are not secured (i.e. are not bonded) to the sleeve **14**, such that protrusion of the arms **18** radially from the adjacent latticed peripheral wall **16** causes: (i) the free ends of the arms **18** (i.e. the second arm lattice member **22**) to protrude into the pockets **32** defined by the sleeve **14** humps **26**, sliding along the radial inner surface of the humps **26** defined by the sleeve **14**; and (ii) the portions of the sleeve **14** that bridge the latticed peripheral wall **16** and the arms **18** to flare radially outwards.

When the stent **12** is in the expanded condition, the arms **18** provide support for the humps **26** defined by the sleeve **14**, resisting radial inward collapse of the humps **26**.

Although the sleeve **14** may be made of a single layered polymer material, portions of the sleeve **14** may be reinforced with a second polymer layer, in use, to withstand large surface areas of pressure differential across the sleeve **14**.

Optionally, the expandable sleeved stent **10** includes a valve axially within the stent **12**.

By extending the sleeve **14** from the first axial end **15** of the stent **12** beyond the free ends of the arms **18**, the expandable sleeved stent **10** increases the sleeved axial length for stents **12** with radially expanding arms **18**. Furthermore, by extending the arms **18** radially inwards of the sleeve **14** (i.e. within the humps **26** defined by the sleeve **14**), the expandable sleeved stent **10** increases the axial cross-sectional area sealed by the sleeve **14**. Even further, since the sleeve **14** in the vicinity of the humps **26** is expanded radially by the arms **18**, the portions of the sleeve **14** that extend into sinuses (i.e. the humps **26**) are mechanically supported in such radially extended condition by the radially protruding arms **18**. Furthermore, since the sleeve **14** bridges the gap between the free ends of the arms **18** and the adjacent latticed peripheral wall **16**, when viewed in axial cross-section in the vicinity of the humps **26**, an effective con-

tinuous non-circular seal (i.e. with added humps/lobes formed thereby) is provided by the sleeve **14**.

The combination of:

increasing the axial length of the sleeve **14** along the stent **12**;

mechanically supporting the humps **26** defined by the sleeve **14** in a radially protruding condition;

bridging the gap between the free ends of the arms **18** and adjacent latticed peripheral wall **16**; and

providing a continuous non-circular seal in axial cross-section (in the vicinity of the humps **26**),

renders the expandable sleeved stent **10** suited to address leakages (including paravalvular leakage) resulting from positioning and expanding the expandable sleeved stent **10**: too low within the cardiovascular system; or adjacent a large sinus or aneurysm.

The invention claimed is:

1. An expandable sleeved stent comprising:

a tubular body defined by a latticed peripheral wall having first and second axial ends and at least two arms that, upon radial expansion of the tubular body from a crimped condition to an expanded condition, protrude radially from the latticed peripheral wall, a free end of each arm being radially displaceable relative to the adjacent latticed peripheral wall;

a sleeve that:

extends from the first axial end of the tubular body and circumferentially covers at least a portion of a radial outer surface of the latticed peripheral wall between the free ends of the arms and the first axial end of the tubular body;

bridges spaces between portions of the latticed peripheral wall adjacent the arms; and the free ends of the arms;

is secured to either: (i) the arms; or (ii) the tubular body in a vicinity between the free ends of the arms and the second axial end of the tubular body;

is right circular cylindrical in a region that radially overlaps the latticed peripheral wall; and

defines humps radially overlying the arms such that, when the tubular body is in an uncrimped condition and the sleeve is secured to the tubular body, the humps define pockets between the humps and the corresponding arms,

wherein, upon radial expansion of the tubular body from the crimped condition towards the expanded condition, the free ends of the arms protrude radially outwardly into the pockets to mechanically support the humps and to radially outwardly flare

portions of the sleeve that bridge the latticed peripheral wall and the arms.

2. The expandable sleeved stent according to claim **1**, wherein:

each arm includes: (i) a first arm lattice member; (ii) a U-shaped second arm lattice member; and (iii) a third arm lattice member bridging the first and second arm lattice members; and

the sleeve extends to, and is secured to the first arm lattice member of each arm.

3. The expandable sleeved stent according to claim **2**, wherein, for each arm, the second arm lattice member is not secured to the sleeve, permitting sliding movement of the second arm lattice member along the hump.

4. The expandable sleeved stent according to claim **3**, wherein the sleeve is made of an electrospun polymer.

5. The expandable sleeved stent according to claim **4**, wherein the sleeve is bonded to the latticed peripheral wall.

6. The expandable sleeved stent according to claim **5**, wherein the sleeve is bonded to scalloped members forming part of the latticed peripheral wall adjacent the second arm lattice members.

7. The expandable sleeved stent according to claim **6**, wherein: the arms included in the tubular body are limited to three in number; and the humps defined by the sleeve are limited to three in number.

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