US 20190110884A1

(19) **United States**

(12) **Patent Application Publication**

Perkins et al.

(10) **Pub. No.: US 2019/0110884 A1**

(43) **Pub. Date: Apr. 18, 2019**

(54) STENT GRAFT WITH EXTERNAL SCAFFOLDING AND METHOD

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(21) Appl. No.: **16/219,312**

(22) Filed: **Dec. 13, 2018**

Related U.S. Application Data

(62) Division of application No. 15/043,246, filed on Feb. 12, 2016, now Pat. No. 10,188,500.

Publication Classification

(51) **Int. Cl.**

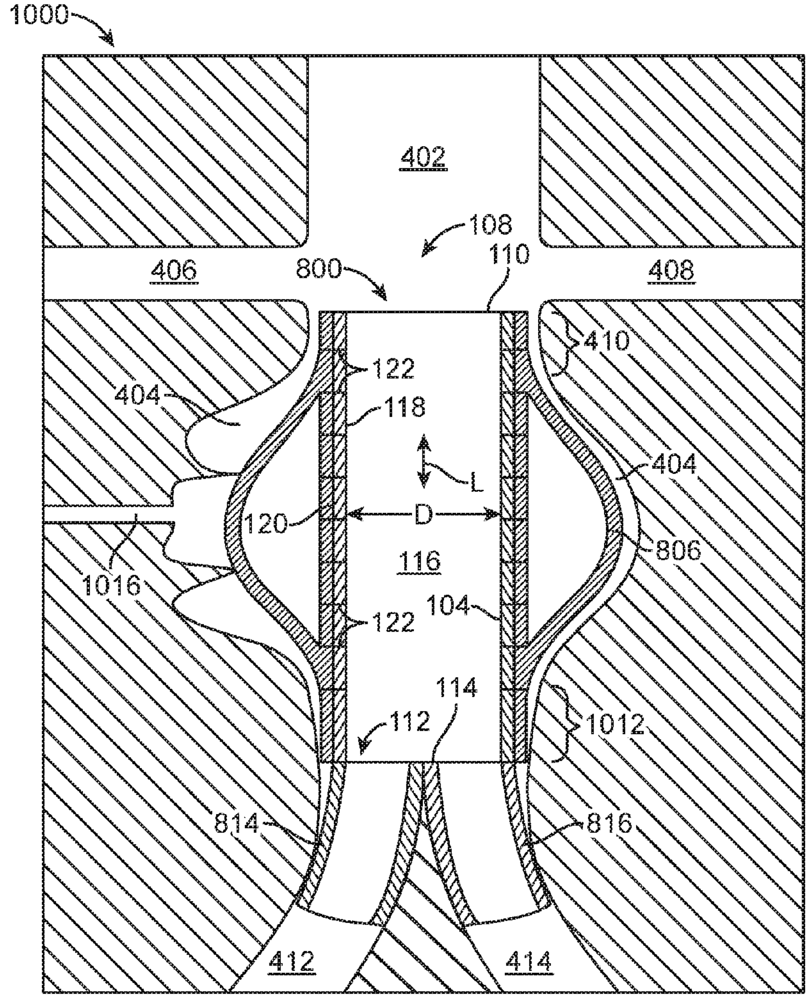
A61F 2/07	(2006.01)
A61F 2/00	(2006.01)

(52) **U.S. Cl.**

CPC ***A61F 2/07*** (2013.01); ***A61F 2/0077*** (2013.01); *A61F 2002/068* (2013.01); *A61F 2230/0065* (2013.01); *A61F 2002/075* (2013.01); *A61F 2250/0051* (2013.01)

(57) ABSTRACT

A scaffolded stent-graft includes a graft material comprising an inner surface and an outer surface. The inner surface defines a lumen within the graft material. The scaffolded stent-graft further includes a scaffold comprising a mesh coupled to the graft material at the outer surface. The scaffold is configured to promote tissue ingrowth therein. In this manner, the scaffold enhances tissue integration into the scaffolded stent-graft. The tissue integration enhances biological fixation of the scaffolded stent-graft in vessels minimizing the possibility of endoleaks and migration.



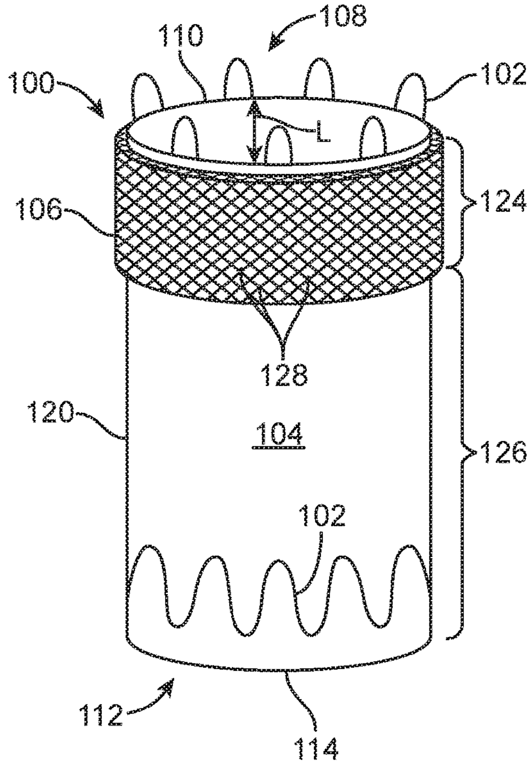


FIG. 1

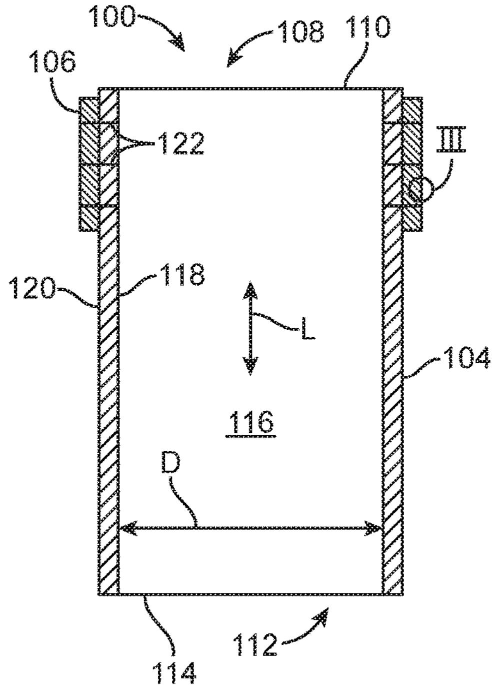


FIG. 2

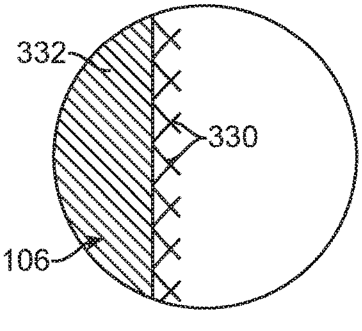


FIG. 3A

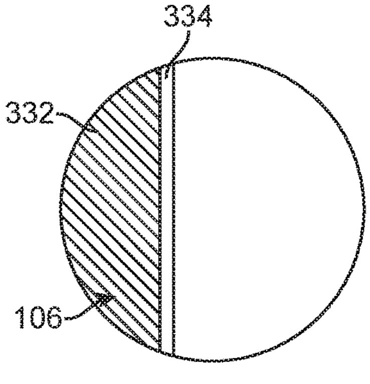


FIG. 3B

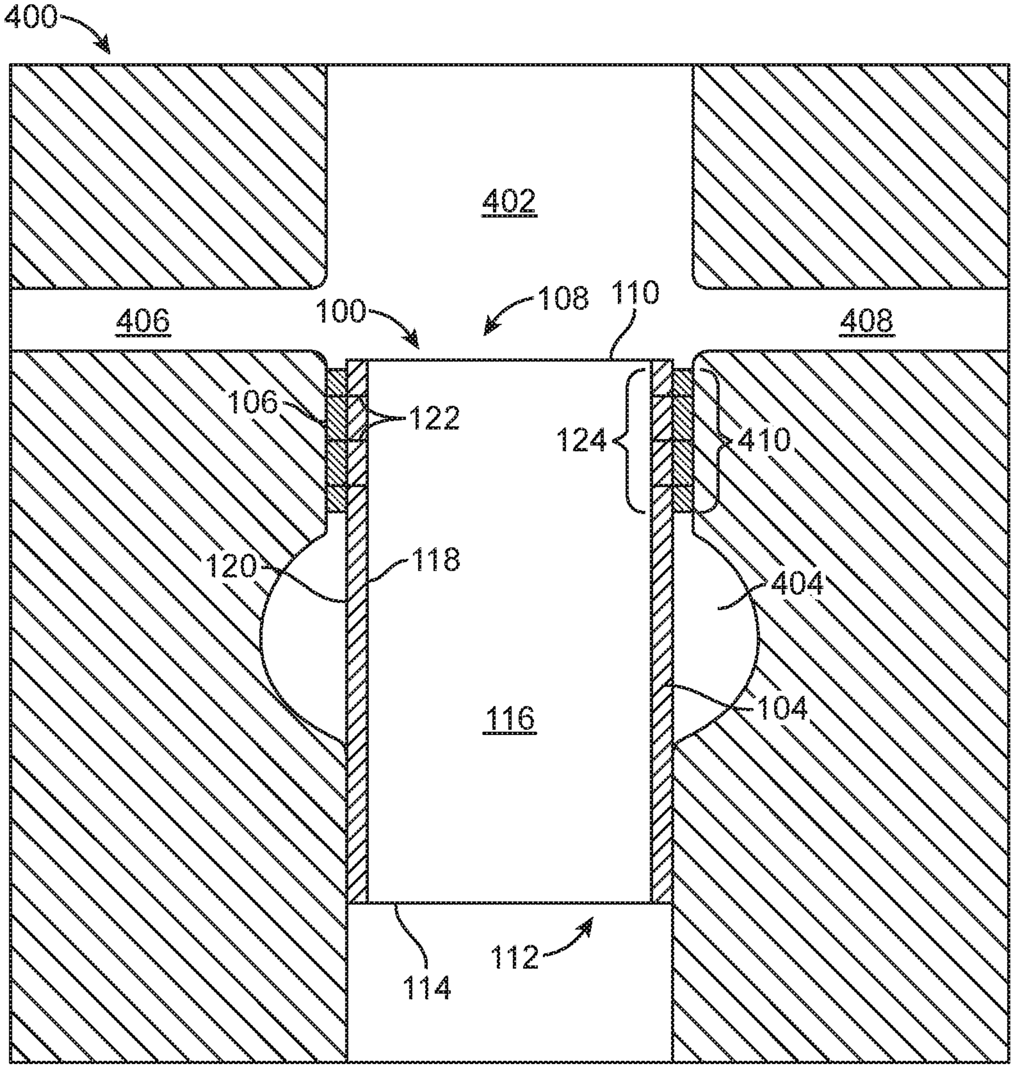

400
402
406
100
108
110
408
106
122
124
410
120
118
404
116
104
114
112

FIG. 4

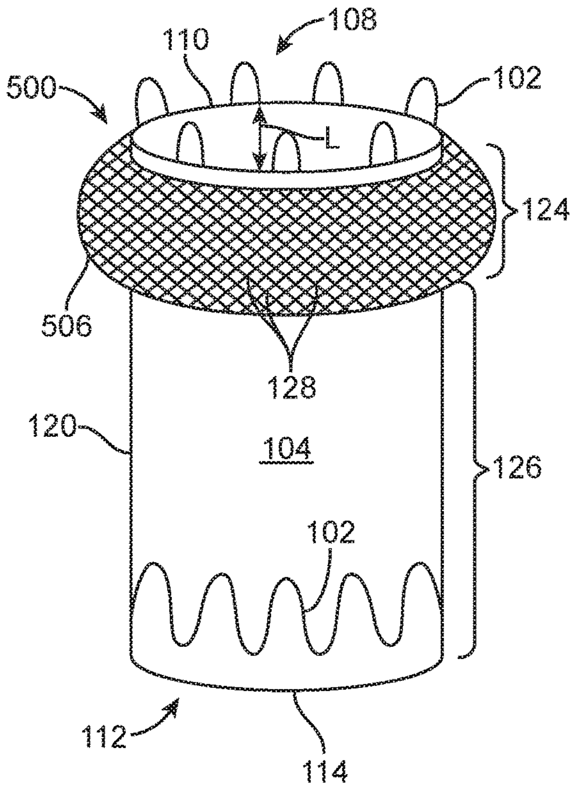

108
110
500
102
L
124
506
128
120
104
126
102
112
114

FIG. 5

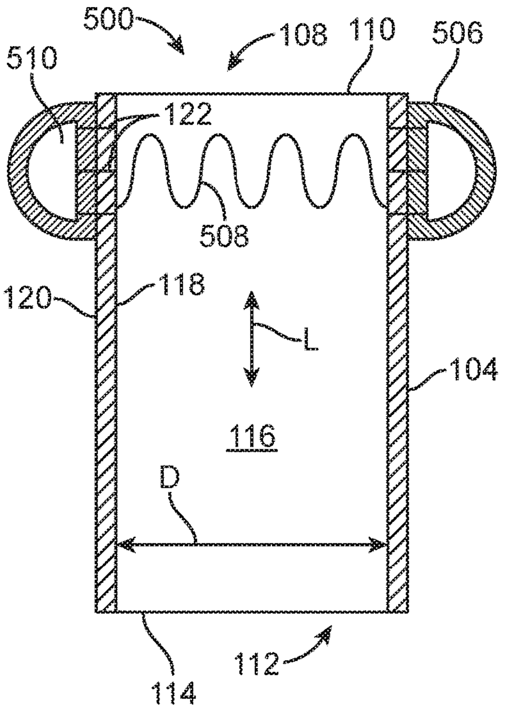

500
108
110
506
510
122
508
120
118
L
104
116
D
114
112

FIG. 6

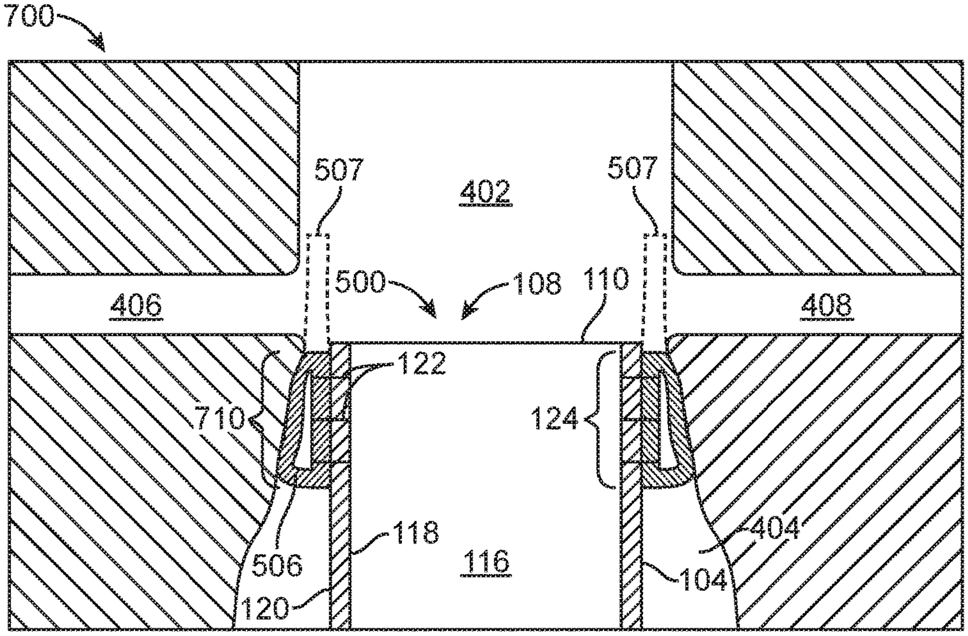

700
507
402
507
500
108
110
406
408
122
710
124
118
404
116
506
104
120

FIG. 7

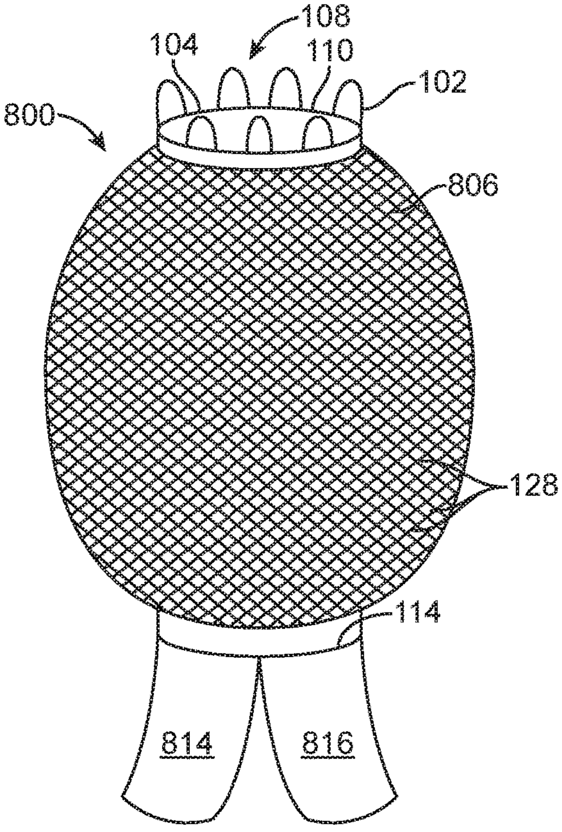

108
104
110
102
800
806
128
114
814
816

FIG. 8

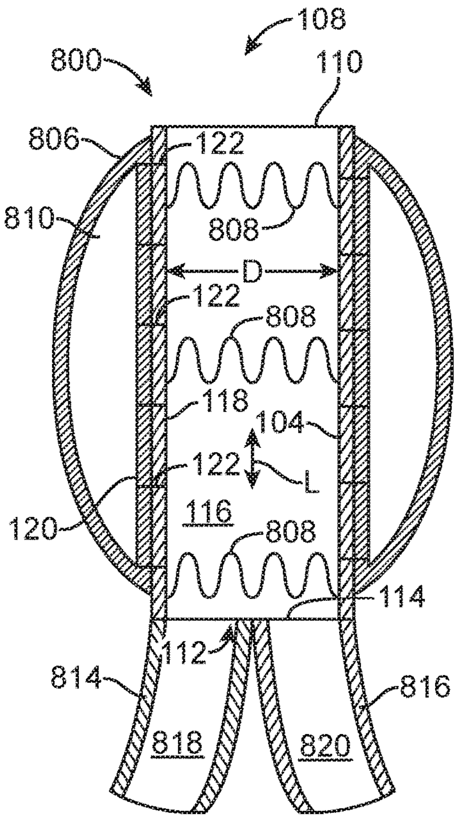

108
800
110
806
122
810
808
D
122
808
118
104
122
L
120
116
808
114
112
814
816
818
820

FIG. 9

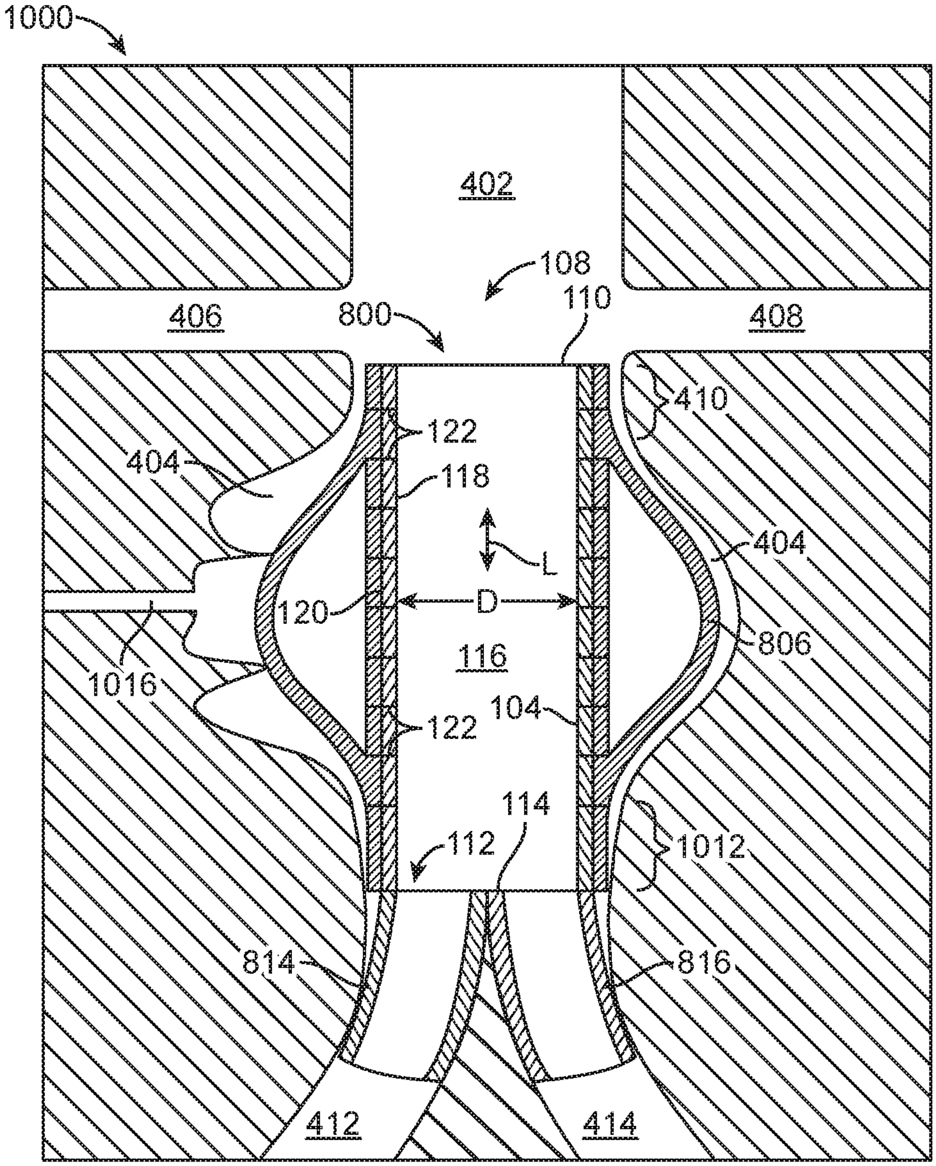

1000
402
108
406
800
110
408
410
122
404
118
L
404
120
D
806
116
1016
104
122
114
1012
112
814
816
412
414

FIG. 10

STENT GRAFT WITH EXTERNAL SCAFFOLDING AND METHOD

RELATED APPLICATIONS

[0001] This application is a divisional of pending U.S. patent application Ser. No. 15/043,246, entitled "STENT GRAFT WITH EXTERNAL SCAFFOLDING AND METHOD", filed Feb. 12, 2016, which is incorporated herein by reference in its entirety.

BACKGROUND

Field

[0002] The present application relates to an intra-vascular device and method. More particularly, the present application relates to a device for treatment of intra-vascular diseases.

DESCRIPTION OF THE RELATED ART

[0003] A conventional stent-graft typically includes a radially expandable reinforcement structure, formed from a plurality of annular stent rings, and a cylindrically shaped layer of graft material defining a lumen to which the stent rings are coupled. Stent-grafts are well known for use in tubular shaped human vessels.

[0004] To illustrate, endovascular aneurysmal exclusion is a method of using a stent-graft to exclude pressurized fluid flow from the interior of an aneurysm, thereby reducing the risk of rupture of the aneurysm and the associated invasive surgical intervention.

[0005] The graft material of traditional stent-grafts is extremely hydrophobic and presents a hostile environment for the recruitment and proliferation of cells. The inability of tissue to integrate into the graft material prevents the biological fixation of the stent-graft in vessels and makes the stent-graft susceptible to endoleaks and migration.

SUMMARY

[0006] In accordance with one embodiment, a scaffolded stent-graft includes a graft material comprising an inner surface and an outer surface. The inner surface defines a lumen within the graft material. The scaffolded stent-graft further includes a scaffold comprising a mesh coupled to the graft material at the outer surface.

[0007] The scaffold is configured to promote tissue ingrowth therein. In this manner, the scaffold enhances tissue integration into the scaffolded stent-graft. The tissue integration enhances biological fixation of the scaffolded stent-graft in vessels minimizing the possibility of endoleaks and migration.

BRIEF DESCRIPTION OF DRAWINGS

[0008] FIG. **1** is a perspective view of a scaffolded stent-graft in accordance with one embodiment.

[0009] FIG. **2** is a cross-sectional view of the scaffolded stent-graft of FIG. **1** in accordance with one embodiment.

[0010] FIG. **3**A is an enlarged view of the region III of the scaffolded stent-graft of FIG. **2** in accordance with one embodiment.

[0011] FIG. **3**B is an enlarged view of the region III of the scaffolded stent-graft of FIG. **2** in accordance with another embodiment.

[0012] FIG. **4** is a cross-sectional view of a vessel assembly including the scaffolded stent-graft of FIGS. **1** and **2** in accordance with one embodiment.

[0013] FIG. **5** is a perspective view of a scaffolded stent-graft in accordance with another embodiment.

[0014] FIG. **6** is a cross-sectional view of the scaffolded stent-graft of FIG. **5** in accordance with one embodiment.

[0015] FIG. **7** is a cross-sectional view of a vessel assembly including the scaffolded stent-graft of FIGS. **5** and **6** in accordance with one embodiment.

[0016] FIG. **8** is a perspective view of a scaffolded stent-graft in accordance with another embodiment.

[0017] FIG. **9** is a cross-sectional view of the scaffolded stent-graft of FIG. **8** in accordance with one embodiment.

[0018] FIG. **10** is a cross-sectional view of a vessel assembly including the scaffolded stent-graft of FIGS. **8** and **9** in accordance with one embodiment.

[0019] Common reference numerals are used throughout the drawings and detailed description to indicate like elements.

DETAILED DESCRIPTION

[0020] As an overview and in accordance with one embodiment, a scaffolded stent-graft includes a graft material and an external scaffold. The graft material provides a barrier to tissue integration. The external scaffold is more suited to promote tissue integration and is mechanically attached to the graft material. Tissue incorporation into the external scaffold creates a biological fixation with the native vessel, thus minimizing the possibility of endoleaks and migration.

[0021] More particularly, FIG. **1** is a perspective view of a scaffolded stent-graft **100**, e.g., an abdominal aortic stent-graft, in accordance with one embodiment. Referring now to FIG. **1**, scaffolded stent-graft **100** includes one or more stent rings **102**. Illustratively, stent rings **102** are self-expanding stent rings, e.g., nickel titanium alloy (NiTi), sometimes called Nitinol. The inclusion of stent rings **102** is optional and in one embodiment stent rings **102** are not included.

[0022] FIG. **2** is a cross-sectional view of scaffolded stent-graft **100** of FIG. **1** in accordance with one embodiment. In FIG. **2**, stent rings **102** are not illustrated for clarity of presentation.

[0023] Referring now to FIGS. **1** and **2** together, scaffolded stent-graft **100** includes a graft material **104** and a scaffold **106**. In accordance with this embodiment, graft material **104** includes a proximal opening **108** at a proximal end **110** of graft material **104** and a distal opening **112** at a distal end **114** of graft material **104**.

[0024] Further, scaffolded stent-graft **100** includes a longitudinal axis L. A lumen **116** is defined by graft material **104**, and generally by scaffolded stent-graft **100**. Lumen **116** extends generally parallel to longitudinal axis L and between proximal opening **108** and distal opening **112** of scaffolded stent-graft **100**.

[0025] As used herein, the proximal end of a prosthesis such as a stent-graft is the end closest to the heart via the path of blood flow whereas the distal end is the end furthest away from the heart during deployment. In contrast and of note, the distal end of the catheter is usually identified to the end that is farthest from the operator (handle) while the proximal end of the catheter is the end nearest the operator (handle).

[0026] For purposes of clarity of discussion, as used herein, the distal end of the catheter is the end that is farthest from the operator (the end furthest from the handle) while the distal end of the prosthesis is the end nearest the operator (the end nearest the handle), i.e., the distal end of the catheter and the proximal end of the stent-graft are the ends furthest from the handle while the proximal end of the catheter and the distal end of the stent-graft are the ends nearest the handle. However, those of skill in the art will understand that depending upon the access location, the stent-graft and delivery system description may be consistent or opposite in actual usage.

[0027] Graft material **104** is cylindrical having a substantially uniform diameter D. However, in other embodiments, graft material **104** varies in diameter and/or is bifurcated at distal end **114**. Graft material **104** includes a cylindrical inner surface **118** and an opposite outer surface **120**.

[0028] In one embodiment, graft material **104** is hydrophobic, e.g., is polyester terephthalate (PET), expanded polyester terephthalate (ePET), or other graft material. As graft material **104** is hydrophobic, graft material **104** presents a hostile environment for the recruitment and the proliferation of cells.

[0029] In one embodiment, to enhance tissue integration, scaffold **106** is attached to outer surface **120** of graft material **104** by an attachment means **122**. Illustratively, attachment means **122** is stitching, adhesive, thermal bonding, or other attachment between scaffold **106** and graft material **104**.

[0030] In accordance with this embodiment, scaffold **106** is attached to graft material **104** at or adjacent proximal end **110** of graft material **104**. The region **124** of graft material **104** which is covered by scaffold **106** is referred to as a seal zone **124** of graft material **104**. The region **126** of graft material **104** which is uncovered by scaffold **106** is referred to as a bare zone **126** of graft material **104**. Seal zone **124** extends distally from proximal end **110** to bare zone **126**. Bare zone **126** extends distally from seal zone **124** to distal end **114**.

[0031] In accordance with this embodiment, scaffold **106** is a mesh. In one embodiment, a mesh is an interlaced or solid structure defining a plurality of openings **128** therein. For example, a network of wires or threads are interlaced, e.g., woven, to form scaffold **106** having openings **128**. In another example, a tube or sheet is laser cut to form openings **128** therein and thus scaffold **106** is integral, i.e., is a single piece and not a plurality of pieces coupled together.

[0032] Openings **128** in scaffold **106** are optimized to promote maximum tissue integration in one embodiment. In one embodiment, openings **128** are entirely surrounded by scaffold **106**, i.e., are discrete openings. Scaffold **106** is sometimes called a tissue integration scaffold **106**.

[0033] Scaffold **106** is a metallic material in one of embodiment. For example, scaffold **106** is formed of Nitinol, although is formed from other metallic materials in other embodiments. In another embodiment, scaffold **106** is a polymeric material. Generally, scaffold **106** is formed of a material that supports good tissue integration and incorporation into the vascular wall of the anatomy that scaffolded stent-graft **100** is implanted into.

[0034] In one embodiment, scaffold **106** is physically coupled to graft material **104**, e.g., using suturing techniques. Accordingly, mechanical advantage provided by integration of scaffold **106** into the vessel wall is directly transferred to scaffolded stent-graft **100** enhancing migration resistance and sealing.

[0035] In accordance with this embodiment, scaffold **106** is cylindrical. Scaffold **106** is flexible and of sufficiently low profile that it does not significantly impact the packing density of scaffolded stent-graft **100**.

[0036] FIG. **3**A is an enlarged view of the region III of scaffolded stent-graft **100** of FIG. **2** in accordance with one embodiment. Referring to FIG. **3**A, in accordance with this embodiment, scaffold **106** includes tissue response enhancing fibers **330** embedded therein. For example, scaffold **106** includes a scaffold body **332**, e.g., formed of a mesh of metallic or polymeric materials as described above, and tissue response enhancing fibers **330** embedded within scaffold body **332**. Tissue response enhancing fibers **330** are sometimes called fibers of bioactive material.

[0037] Tissue response enhancing fibers **330** enhance the tissue response of tissue with scaffolded stent-graft **100**. In one embodiment, tissue response enhancing fibers **330** include tissue healing promoting materials, sometimes called scaffolding materials. The tissue healing promoting materials of tissue response enhancing fibers **330** serve to promote the healing process, e.g., the recruitment and proliferation of cells that drive the healing process. Examples of the tissue healing promoting materials of tissue response enhancing fibers **330** include polymer polyglycolic-lactic acid (PGLA), poly(glycerol sebacate) (PGS), animal derived decellularized scaffold, collagen scaffolds, and other tissue healing promoting materials.

[0038] In another embodiment, tissue response enhancing fibers **330** include tissue irritant materials that serve to actively drive an inflammatory response that results in a robust fibrocellular response. Examples of the irritant materials of tissue response enhancing fibers **330** include PGLA, polyglycolic acid (PGA), polylactic acid (PLA), silk, bacterial endotoxin, and other irritant materials.

[0039] In another embodiment, tissue response enhancing fibers **330** includes an absorbable polymeric material that allows for the elution of bioactive molecules that promote rapid healing and/or promote thrombus formation/maturation. Examples of the bioactive molecules include drugs, peptides, cytokine/chemokine.

[0040] FIG. 3B is an enlarged view of the region III of scaffolded stent-graft **100** of FIG. **2** in accordance with another embodiment. Referring to FIG. 3B, in accordance with this embodiment, scaffold **106** includes a tissue response enhancing coating **334**. For example, scaffold **106** includes scaffold body **332** and tissue response enhancing coating **334** coated on or impregnated within scaffold body **332**. Tissue response enhancing coating **334** enhances the tissue response of tissue with scaffolded stent-graft **100** in a manner similar to tissue response enhancing fibers **330** described above. Tissue response enhancing coating **334** is sometimes called a bioactive material coating.

[0041] More particularly, tissue response enhancing coating **334** includes material, e.g., tissue healing promoting materials or irritant materials. In one embodiment, tissue response enhancing coating **334** include tissue healing promoting materials that serve to promote tissue healing, e.g., the recruitment and proliferation of cells that drive the healing process. Examples of the tissue healing promoting materials of tissue response enhancing coating **334** include

PGLA, PGS, animal derived decellularized scaffold, collagen scaffolds, and other tissue healing promoting materials.

[0042] In another embodiment, tissue response enhancing coating **334** include tissue irritant materials that serve to actively drive an inflammatory response that results in a robust fibrocellular response. Examples of the irritant materials of tissue response enhancing coating **334** include PGLA, PGA, PLA, silk, bacterial endotoxin, and other irritant materials.

[0043] In another embodiment, tissue response enhancing coating **334** includes an absorbable polymeric material that allows for the elution of bioactive molecules that promote rapid healing and/or promote thrombus formation/maturation. Examples of the bioactive molecules include drugs, peptides, cytokine/chemokine.

[0044] FIG. **4** is a cross-sectional view of a vessel assembly **400** including scaffolded stent-graft **100** of FIGS. **1** and **2** in accordance with one embodiment. Referring now to FIG. **4**, a vessel **402**, e.g., the aorta, includes an aneurysm **404**. Scaffolded stent-graft **100** is deployed into vessel **402** to exclude aneurysm **404** using any one of a number of techniques well known to those of skill in the art.

[0045] Emanating from vessel **402** is a first branch vessel **406** and a second branch vessel **408**, sometimes called visceral branches of the abdominal aorta. The location of branch vessels **406**, **408** vary from patient to patient. Examples of branch vessels include the renal arteries (RA) and the superior mesenteric artery (SMA).

[0046] Scaffolded stent-graft **100** is deployed just distal of branch vessels **406**, **408**. Scaffold **106**, i.e., sealing zone **124**, is deployed in the landing zone **410** between branch vessels **406**, **408** and aneurysm **404**. Over time, tissue from vessel **402** will become integrated with scaffold **106** thus preventing leakage around sealing zone **124** and migration of scaffolded stent-graft **100**.

[0047] Landing zone **410** is sometimes call a proximal seal zone **410**. Although proximal seal zone **410** is discussed, in light of this disclosure, those of skill in the art will understand that generally scaffold **106** can be deployed in any seal zone, e.g., including a distal seal zone.

[0048] Once anchored within vessel **402**, blood flows through lumen **116** and more generally through scaffolded stent-graft **100** thus excluding aneurysm **404**.

[0049] FIG. **5** is a perspective view of a scaffolded stent-graft **500** in accordance with another embodiment. FIG. **6** is a cross-sectional view of scaffolded stent-graft **500** of FIG. **5** in accordance with one embodiment. In FIG. **6**, stent rings **102** are not illustrated for clarity of presentation. Scaffolded stent-graft **500** of FIGS. **5**, **6** is similar to scaffolded stent-graft **100** of FIGS. **1**, **2** and only the significant differences are discussed below.

[0050] Referring now to FIGS. **5** and **6** together, scaffolded stent-graft **500** includes graft material **104**, a scaffold **506**, and a scaffold opposition stent ring **508**.

[0051] In one embodiment, to enhance tissue integration, scaffold **506** is attached to outer surface **120** of graft material **104** by attachment means **122**. In accordance with this embodiment, scaffold **506** is attached to graft material **104** at or adjacent proximal end **110** of graft material **104**. The region **124** of graft material **104** which is covered by scaffold **506** is again referred to as seal zone **124** of graft material **104**. The region **126** of graft material **104** which is uncovered by scaffold **506** is again referred to as a bare zone **126** of graft material **104**.

[0052] In accordance with this embodiment, scaffold **506** is formed of the same materials as described above regarding scaffold **106**, including metallic materials, polymeric materials, tissue response enhancing fibers **330**, scaffold body **332**, tissue response enhancing coating **334**, and/or combination thereof. The metal to artery ratio of scaffold **506** it is optimized to create stasis of the blood resulting in thrombus formation that helps to promote acute seal. In one embodiment, the metal to artery ratio of scaffold **506** is greater than approximately 30-40% although other metal to artery ratios are used in other embodiments.

[0053] In accordance with this embodiment, scaffold **506** is a torus, e.g., shaped like a doughnut. Scaffold **506** is sometimes called a tubular mesh, e.g., includes a thin flexible mesh that will not adversely impact packing density. Scaffold **506** is packed flat in the delivery system to reduce the impact on delivery system packing density but is shape set to take a tubular form, for example, at 37° C. Note that in FIGS. **5** and **6**, scaffold **506** is shown in its expanded form and would be collapsed during delivery.

[0054] Due to the expansion of scaffold **506** to its tubular form, scaffold **506** applies an inward radial collapsing force on graft material **104**. To resist this force and prevent collapse of graft material **104**, scaffold opposition stent ring **508**, sometimes called a stent graft body spring, is coupled to inner surface **118** of graft material **104** directly opposite scaffold **506**. Scaffold opposition stent ring **508** provides an expanding outward radial force greater than the inward radial collapsing force of scaffold **506**. Accordingly, scaffold opposition stent ring **508** prevents collapse of graft material **104** from scaffold **506**. In one embodiment, due to the inertial properties of scaffold **506** along with blood pressure, scaffold opposition stent ring **508** can be soft, and so thin.

[0055] Although a single scaffold opposition stent ring **508** as illustrated, in other embodiments, more than one scaffold opposition stent ring **508** is provided. Further, in yet another embodiment, the inward radial collapsing force on graft material **104** by scaffold **506** is less than the the diastolic pressure, e.g., scaffold **506** has a “soft” construction. In accordance with this embodiment, a scaffold opposition stent ring **508** is unnecessary and not provided. The geometric design is such that scaffolded stent-graft **500** holds its shape in the wake of blood flow even absent scaffold opposition stent ring **508**.

[0056] In one embodiment, scaffold **506** is filled or coated with a moisture expanding material **510**, e.g., a hydrogel. For example, moisture expanding material **510** expands upon making contact with fluid, e.g., blood. The expansion of moisture expanding material **510** further enhances the seal of scaffolded stent-graft **500** within the vessel as described below in reference to FIG. **7**.

[0057] FIG. **7** is a cross-sectional view of a vessel assembly **700** including scaffolded stent-graft **500** of FIGS. **5** and **6** in accordance with one embodiment. Referring now to FIG. **7**, vessel assembly **700** is similar to vessel assembly **400** of FIG. **4** and includes vessel **402**, aneurysm **404**, and branch vessels **406**, **408**. Scaffolded stent-graft **500** is deployed into vessel **402** to exclude aneurysm **404** using any one of a number of techniques well known to those of skill in the art.

[0058] In accordance with this embodiment, the length of a neck **710** of aneurysm **404** is relatively short. Neck **710** is the area between aneurysm **404** and branch vessels **406**, **408**, sometimes also called a proximal seal zone **710**. Illustratively, the length of neck **710** is 10 mm or less and so is sometimes called a short neck **710**. As also illustrated in FIG. **7**, the diameter of neck **710** increases as the distal distance from branch vessels **406**, **408** increases. Due to the conical shape of neck **710**, neck **710** is also sometimes called a conical neck **710**.

[0059] Although conical short neck **710** is illustrated in FIG. **7** and discussed below, in light of this disclosure, those of skill in the art will understand that scaffolded stent-graft **500** can be deployed in any vessel regardless of the aneurysmal neck length and shape. Further, although proximal seal zone **710** is discussed, in light of this disclosure, those of skill in the art will understand that generally scaffold **506** can be deployed in any seal zone, e.g., including a distal seal zone.

[0060] As shown in FIG. **7**, scaffold **506** expands to make contact with the wall of neck **710**. Scaffold **506** has radial force such that scaffold **506** acts to stabilized scaffolded stent-graft **500** in the void of aneurysm **404**. Further, scaffold **506** creates stasis of the blood resulting in thrombus formation that promotes acute seal of scaffolded stent-graft **500** to vessel **402**. Scaffold **506** is rapidly integrated into the wall of vessel **402** providing for a permanent enhanced seal and migration resistance. Scaffold **506** is particularly well suited for stabilization in highly angled necks such as neck **710**.

[0061] Once anchored within vessel **402**, blood flows through lumen **116** and more generally through scaffolded stent-graft **500** thus excluding aneurysm **404**.

[0062] As shown in FIG. **7**, in another embodiment, scaffold **506** includes proximal segments **507** that extend proximally past proximal end **110** of graft material **104** and beyond branch vessels **406**, **408**. In accordance with this embodiment, scaffold **506** is sufficiently porous to not occlude branch vessels **406**, **408**.

[0063] FIG. **8** is a perspective view of a scaffolded stent-graft **800** in accordance with another embodiment. FIG. **9** is a cross-sectional view of scaffolded stent-graft **800** of FIG. **8** in accordance with one embodiment. In FIG. **9**, stent rings **102** are not illustrated for clarity of presentation. Scaffolded stent-graft **800** of FIGS. **8**, **9** is similar to scaffolded stent-graft **100** of FIGS. **1**, **2** and only the significant differences are discussed below.

[0064] Referring now to FIGS. **8** and **9** together, scaffolded stent-graft **800** includes graft material **104**, a scaffold **806**, and scaffold opposition stent rings **808**.

[0065] In one embodiment, to enhance tissue integration, scaffold **806** is attached to outer surface **120** of graft material **104** by attachment means **122**. In accordance with this embodiment, scaffold **806** is attached to graft material **104** along the entire length of graft material **104** and generally between proximal end **110** and distal end **114**.

[0066] In accordance with this embodiment, scaffold **806** is formed of the same materials as described above regarding scaffold **106**, including metallic materials, polymeric materials, tissue response enhancing fibers **330**, scaffold body **332**, tissue response enhancing coating **334**, and/or combination thereof. The metal to artery ratio of scaffold **806** it is optimized to create stasis of the blood in the sac of the aneurysm resulting in thrombus formation. In one embodiment, the metal to artery ratio of scaffold **806** is greater than approximately 30-40% although other metal to artery ratios are used in other embodiments.

[0067] In accordance with this embodiment, scaffold **806** is a torus, e.g., shaped like a doughnut. Scaffold **806** is sometimes called a tubular mesh. Scaffold **806** is packed flat, e.g., folded around graft material **104**, in the delivery system to reduce the impact on delivery system packing density but is shapes set to take a tubular form, for example, at 37° C. Note that in FIGS. **8** and **9**, scaffold **806** is shown in its expanded form and would be collapsed during delivery.

[0068] Due to the expansion of scaffold **806** to its tubular form, scaffold **806** applies an inward radial collapsing force on graft material **104**. To resist this force and prevent collapse of graft material **104**, scaffold opposition stent rings **808**, sometimes called stent graft body springs, are coupled to inner surface **118** of graft material **104** directly opposite scaffold **806**.

[0069] In accordance this embodiment, a plurality of scaffold opposition stent rings **808** are provided along the length of graft material **104**. Scaffold opposition stent rings **808** provide an expanding outward radial force greater than the inward radial collapsing force of scaffold **806**. Accordingly, scaffold opposition stent rings **808** prevent collapse of graft material **104** from scaffold **806**. In one embodiment, due to the inertial properties of scaffold **806** along with blood pressure, scaffold opposition stent rings **808** can be soft, and so thin.

[0070] Further, in yet another embodiment, the inward radial collapsing force on graft material **104** by scaffold **806** is less than the the diastolic pressure, e.g., scaffold **806** has a “soft” construction. In accordance with this embodiment, a scaffold opposition stent rings **808** are unnecessary and not provided. The geometric design is such that scaffolded stent-graft **800** holds its shape in the wake of blood flow even absent scaffold opposition stent rings **808**.

[0071] In one embodiment, scaffold **806** is filled or coated with a moisture expanding material **810**, e.g., a hydrogel. For example, moisture expanding material **810** expands upon making contact with fluid, e.g., blood. The expansion of moisture expanding material **810** further enhances the seal of scaffolded stent-graft **800** within the vessel as described below in reference to FIG. **10**.

[0072] In accordance with this embodiment, scaffolded stent-graft **800** includes extension portions **814**, **816**. Extension portions **814**, **816** extend from distal end **114** of graft material **104**. In one embodiment, extension portions **814**, **816** are separate pieces, e.g., of graft material, connected to graft material **104**. Extension portions **814**, **816** are sometime called modular components. In another embodiment, extension portions **814**, **816** are integral with graft material **104**, e.g., a single piece of graft material is sewn or otherwise manipulated to define extension portions **814**, **816**.

[0073] Extension portions **814**, **816** bifurcate main lumen **116** into lumens **818**, **820**. For example, extension portions **814**, **816** are deployed into the iliac arteries. However, in another embodiment, scaffolded stent-graft **800** is formed without extension portions **814**, **816**. Further, scaffolded stent-grafts **100**, **500** as described above include extension portions **814**, **816** in other embodiments.

[0074] FIG. **10** is a cross-sectional view of a vessel assembly **1000** including scaffolded stent-graft **800** of FIGS. **8** and **9** in accordance with one embodiment. Referring now to FIG. **10**, vessel assembly **1000** is similar to vessel assembly **400** of FIG. **4** and includes vessel **402**, aneurysm **404**, and branch vessels **406**, **408**. In accordance with this embodiment, vessel assembly **1000** further includes distal iliac arteries **412**, **414**. Scaffolded stent-graft **800** is deployed into vessel **402** to exclude aneurysm **404** using any one of a number of techniques well known to those of skill in the art.

[0075] In accordance with this embodiment, as shown in FIG. **10**, scaffold **806** is deployed to fill the sac of aneurysm **404**. By being deployed within aneurysm **404**, scaffold **806** anchors scaffolded stent-graft **800** in position. This insures sealing in proximal seal zone **410** and in a distal seal zone **1012** as well as prevents separation of modular components such as extension portions **814**, **816**.

[0076] Further, scaffold **806** creates stasis of the blood in aneurysm **404** resulting in thrombus formation. The formation of the clot within aneurysm **404** minimizes the occurrence of type I and type II endoleaks. Further, scaffold **806** is rapidly integrated into the wall of vessel **402** providing for a permanent enhanced seal and migration resistance.

[0077] As illustrated at the left side of scaffolded stent-graft **800**, in one embodiment, aneurysm **404** is irregular in shape, e.g., including protrusions, thrombus in the sac of aneurysm **404**, and/or including one or more branch vessels **1016** extending thereto. In accordance with this embodiment, contact of scaffold **806** with the actual vessel is unlikely, if not impossible. Scaffold **806** creates stasis of blood and thrombus formation thus occluding branch vessel **1016** preventing filling of aneurysm **404** from branch vessel **1016** and the associated type II endoleaks.

[0078] Although branch vessel **1016** is illustrated, branch vessel **1016** is representative of any communication that sets the ground for type II endoleaks. For example, when there is active communication between the inferior mesenteric artery (IMA) and a lumbar artery, the ground is set for a type II endoleak. This communication takes place through a network of cannulae. Scaffold **806** pushes out against the thrombus in the sac and interrupts this path. Once this communication is limited, thrombus forms in the small lumen in the sac thrombus. In one embodiment, scaffold **806** includes thrombogenic material to aid in thrombosis within the sac.

[0079] Once anchored within vessel **402**, blood flows through lumen **116** and more generally through scaffolded stent-graft **800** thus excluding aneurysm **404**. In accordance with this embodiment, extension portions **814**, **816** are deployed into iliac arteries **412**, **414**.

[0080] This disclosure provides exemplary embodiments. The scope is not limited by these exemplary embodiments. Numerous variations, whether explicitly provided for by the specification or implied by the specification or not, such as variations in structure, dimension, type of material and manufacturing process may be implemented by one of skill in the art in view of this disclosure.

What is claimed is:

1. A scaffolded stent-graft comprising:

a graft material comprising an inner surface and an outer surface, the inner surface defining a lumen within the graft material; and

a scaffold comprising a mesh coupled to the graft material at the outer surface, the scaffold configured to promote tissue ingrowth therein, wherein the mesh is cylindrical.

2. A method comprising:

deploying a scaffolded stent-graft into a vessel to exclude an aneurysm comprising:

engaging a scaffold of the scaffolded stent-graft with a wall of the vessel, the scaffold comprising a mesh promoting tissue ingrowth from the wall into the scaffold; and

extending a graft material of the scaffolded stent-graft across the aneurysm.

3. The method of claim **2** further comprising:

filling the aneurysm with the scaffold.

4. The method of claim **3** wherein the scaffold is configured to occlude a branch vessel extending to the aneurysm.

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