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(54) **CONTROLLED INGROWTH FEATURE FOR ANTIMIGRATION**

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(57)

**ABSTRACT**

A tubular prosthesis that includes a scaffolding formed by at least one scaffolding filament; a cover; and at least one controlled ingrowth feature constructed and arranged to abut an inner surface of a lumen wall when the prosthesis is implanted in the body lumen.

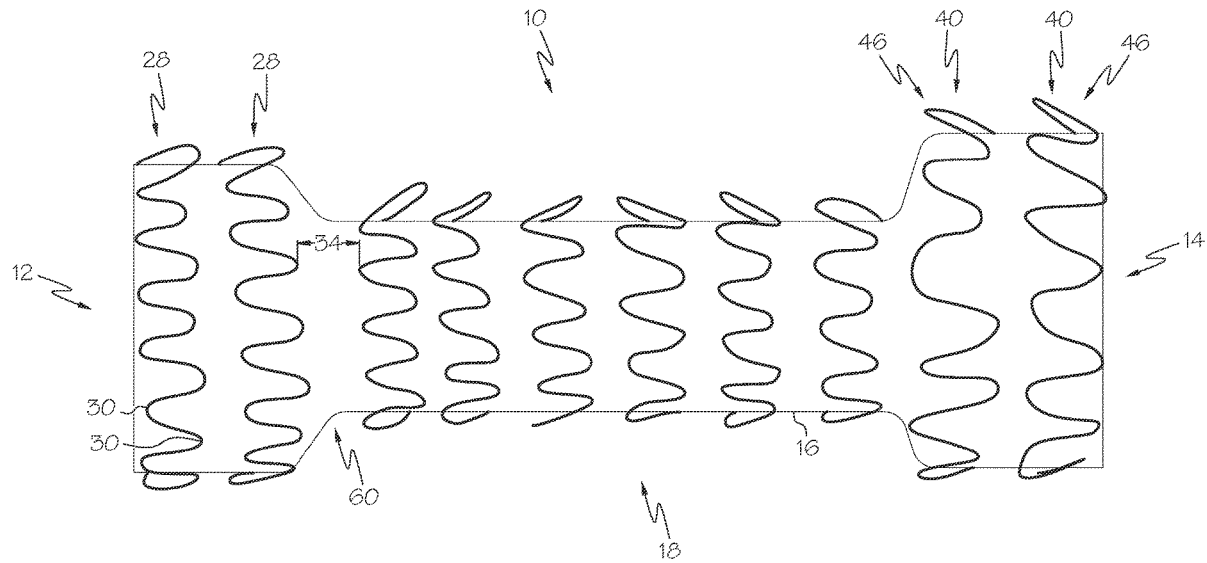
The controlled ingrowth feature may extend inwards or outwards from the prosthesis outer surface. The controlled ingrowth feature may be formed by a scaffolding filament; by a separate filament; by the cover; and combinations thereof

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**Related U.S. Application Data**

(63) Continuation of application No. 16/263,353, filed on Jan. 31, 2019, now Pat. No. 11,590,008, which is a continuation of application No. 14/873,833, filed on Oct. 2, 2015, now Pat. No. 10,219,921.



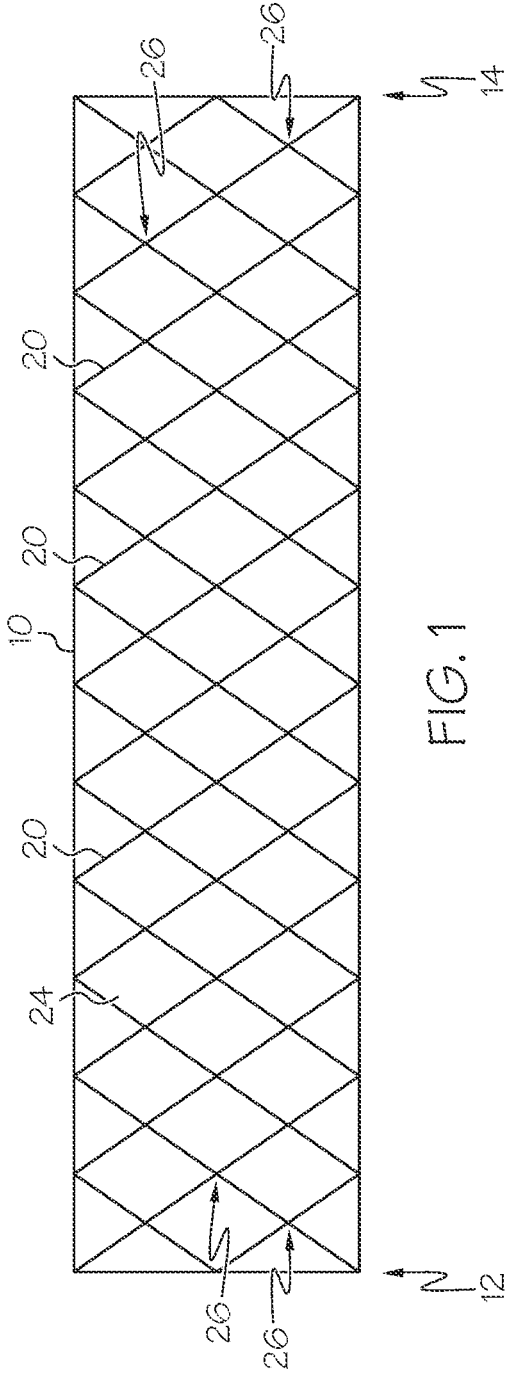


FIG. 1

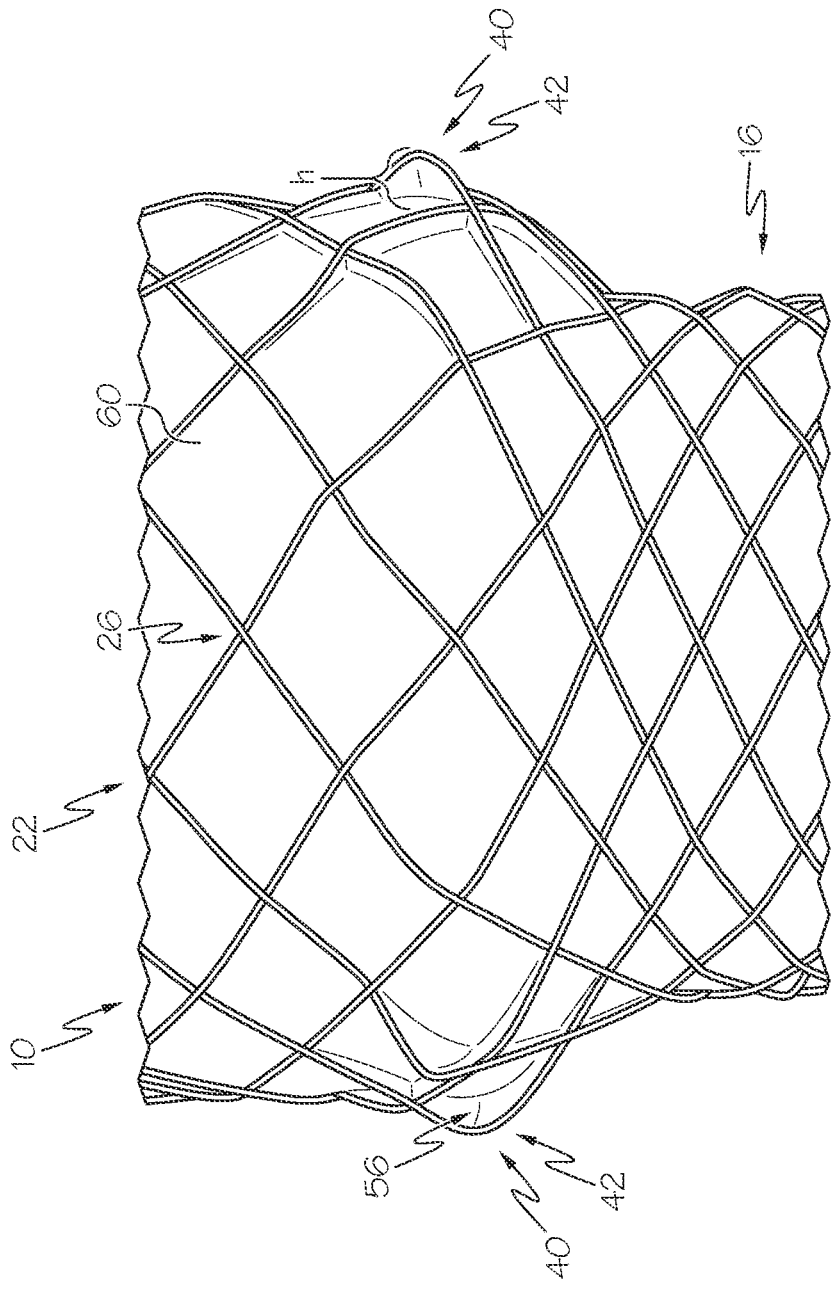


FIG. 2

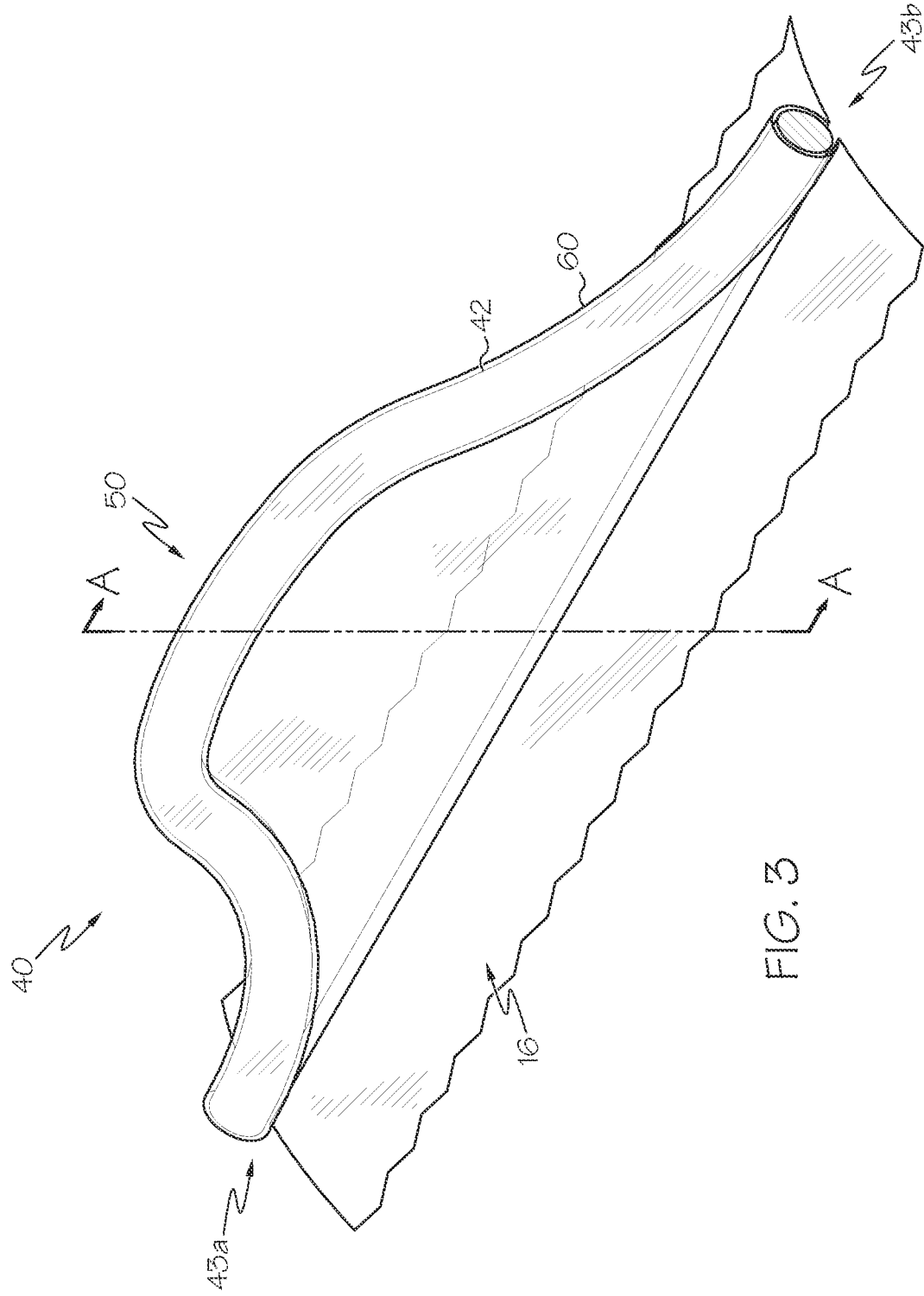


FIG. 3

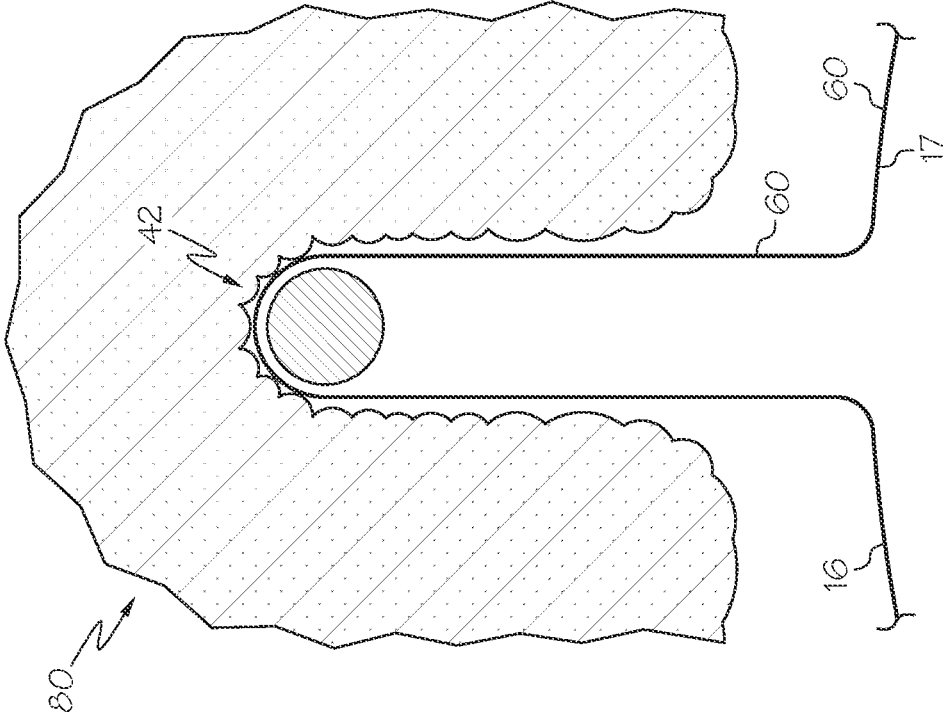


FIG. 5

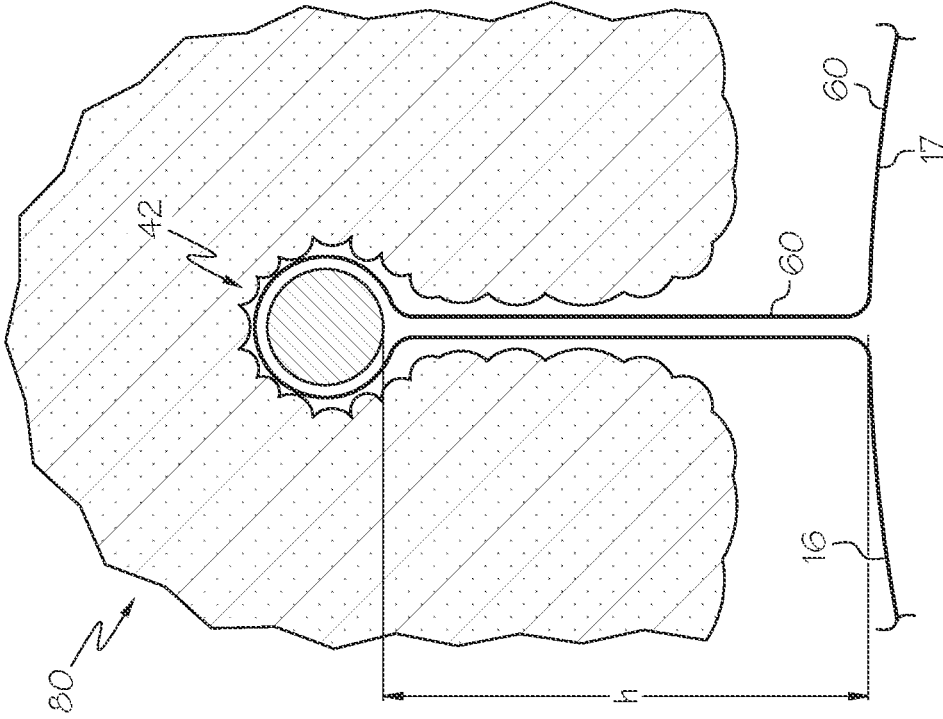


FIG. 4

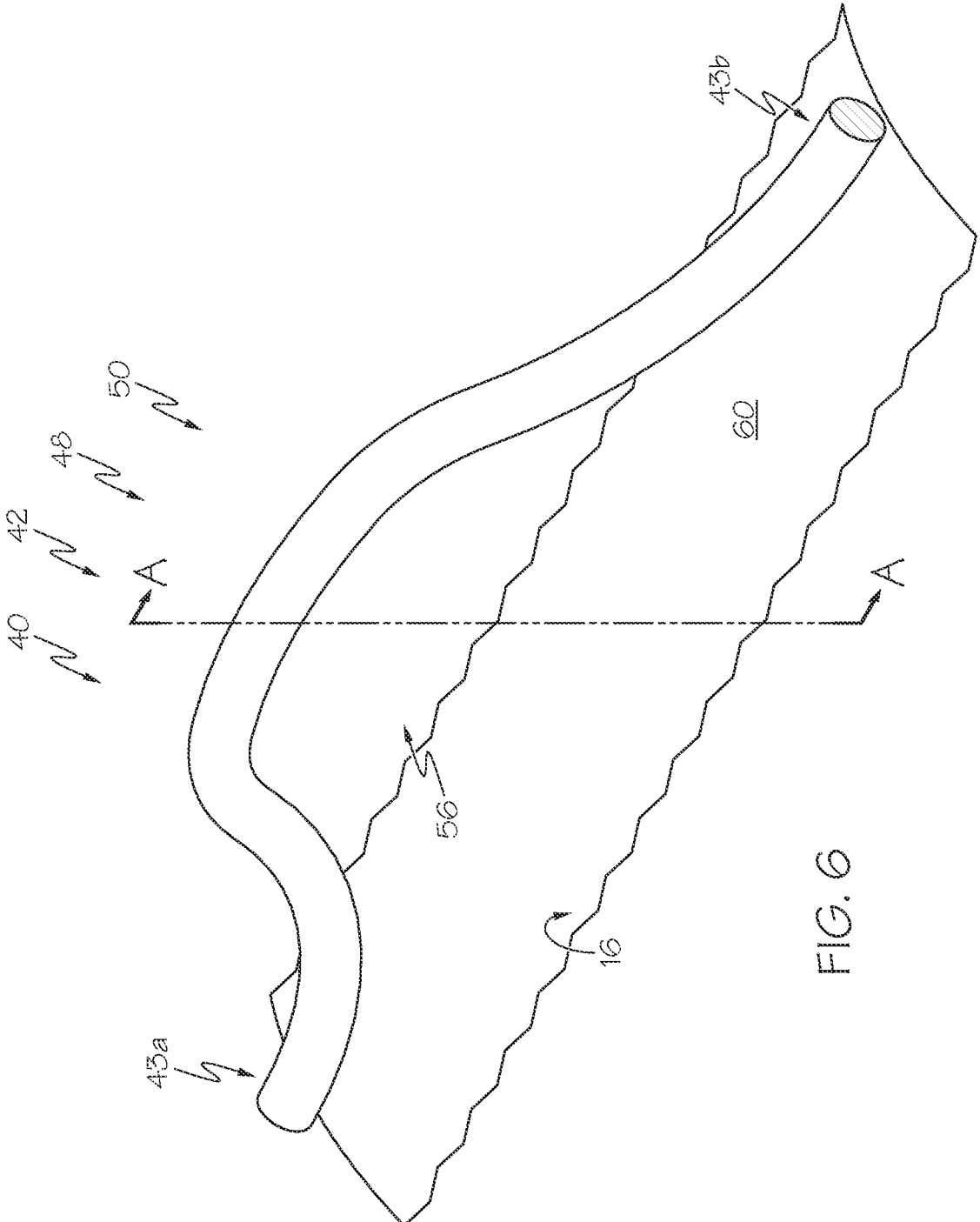
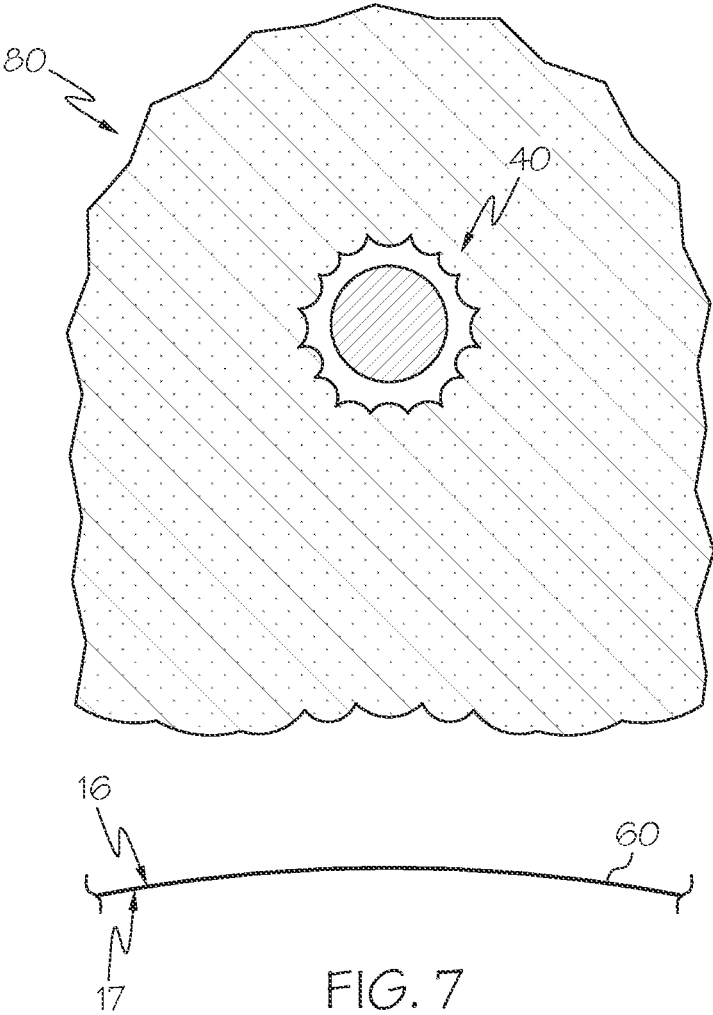
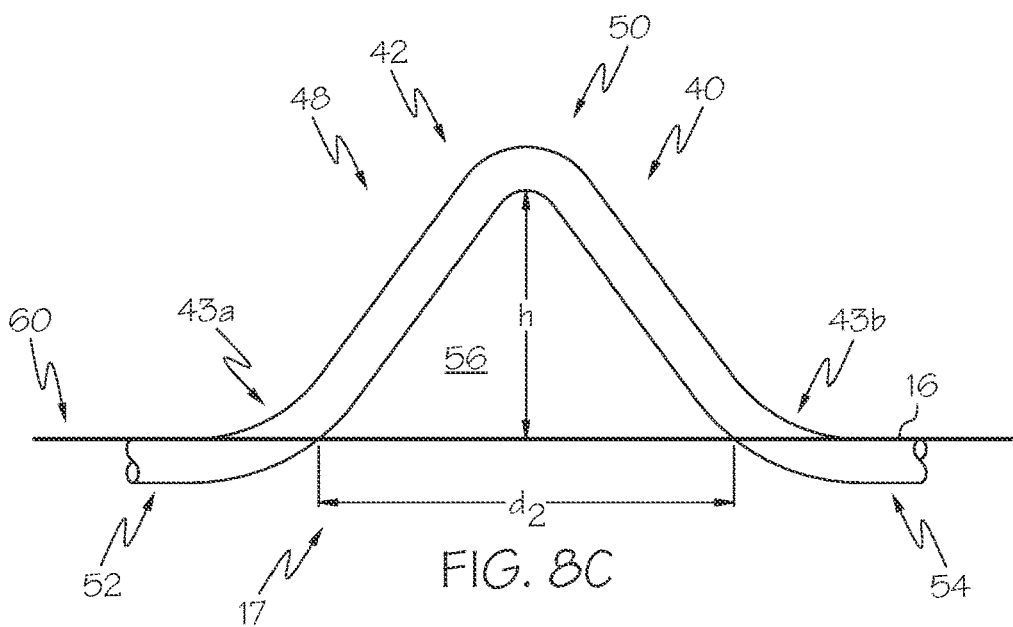
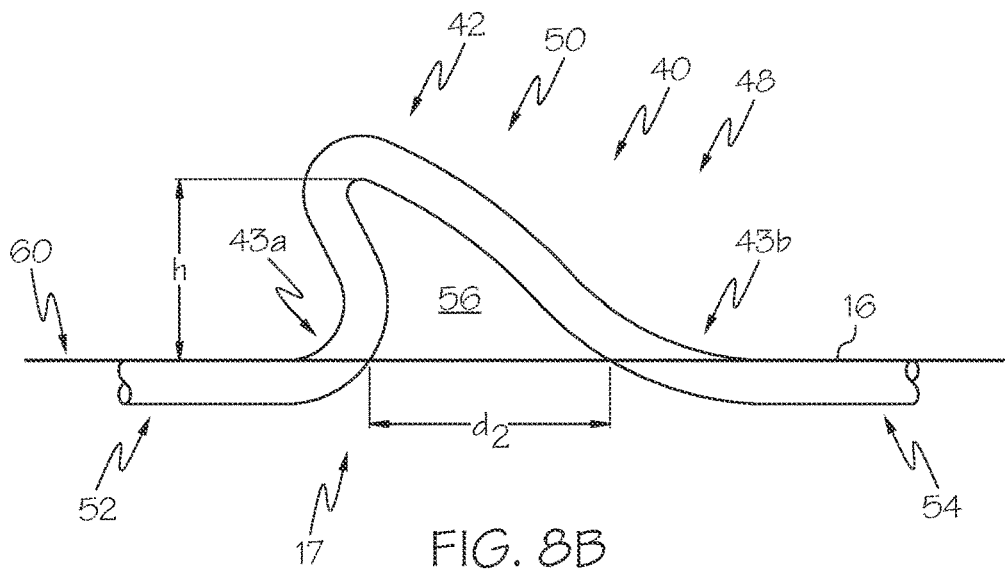
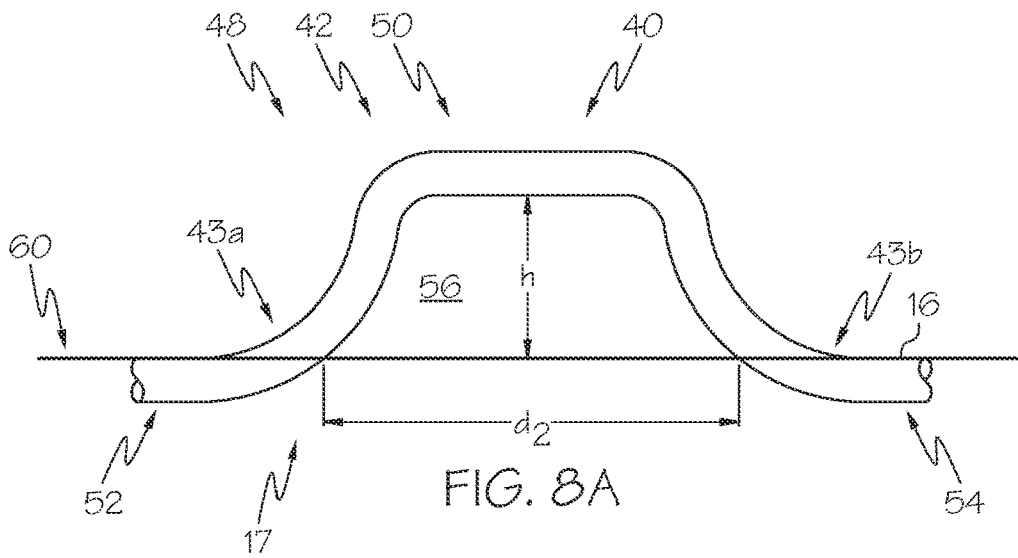


FIG. 6







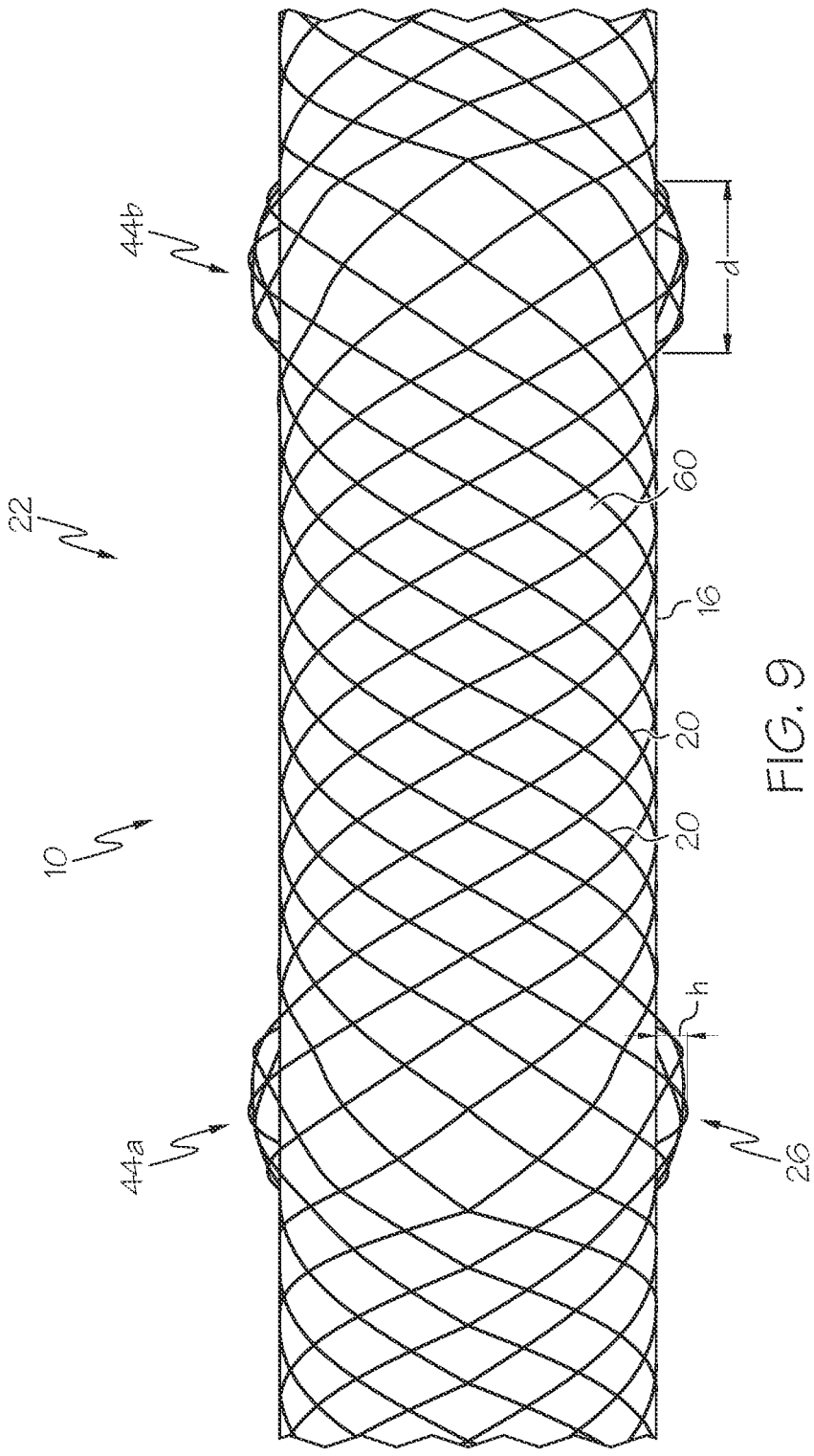


FIG. 9

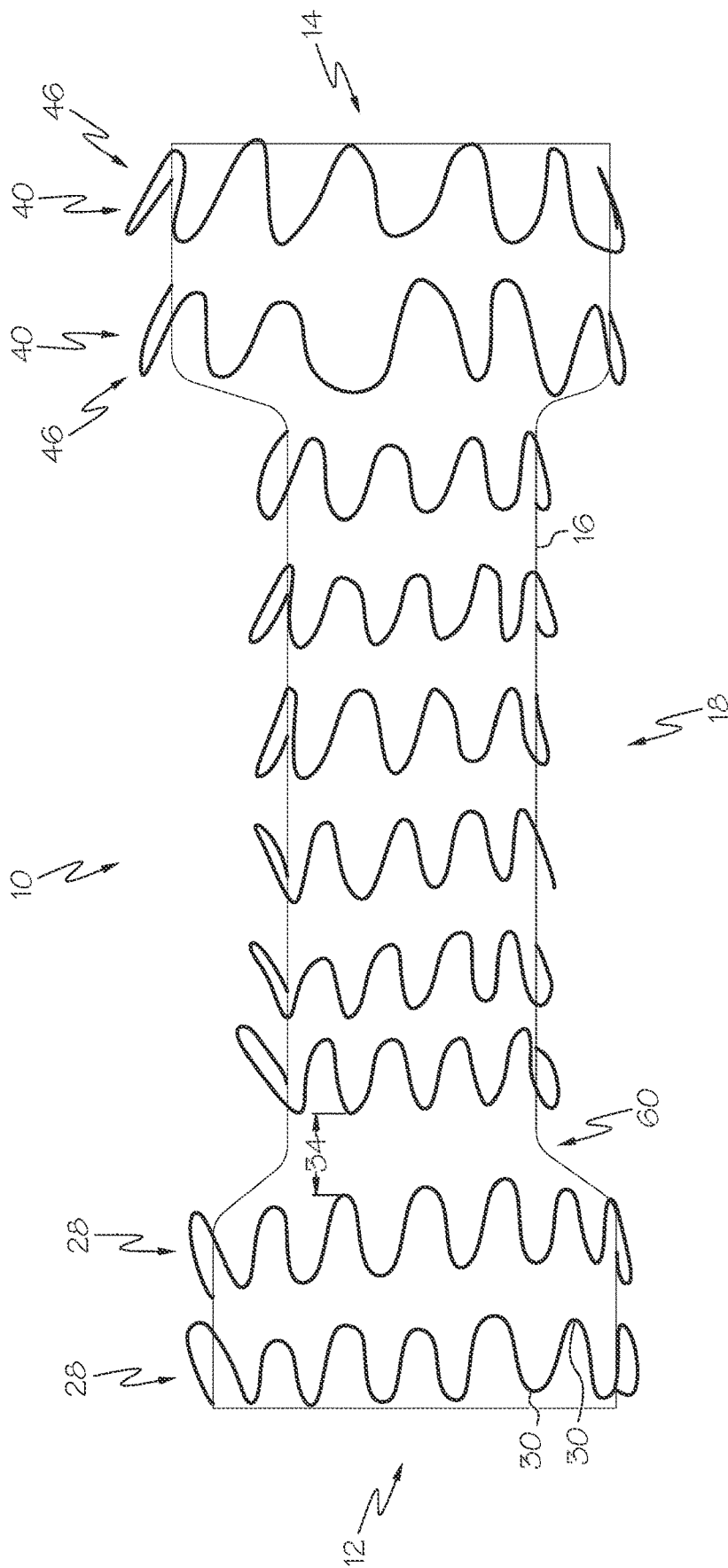


FIG. 10

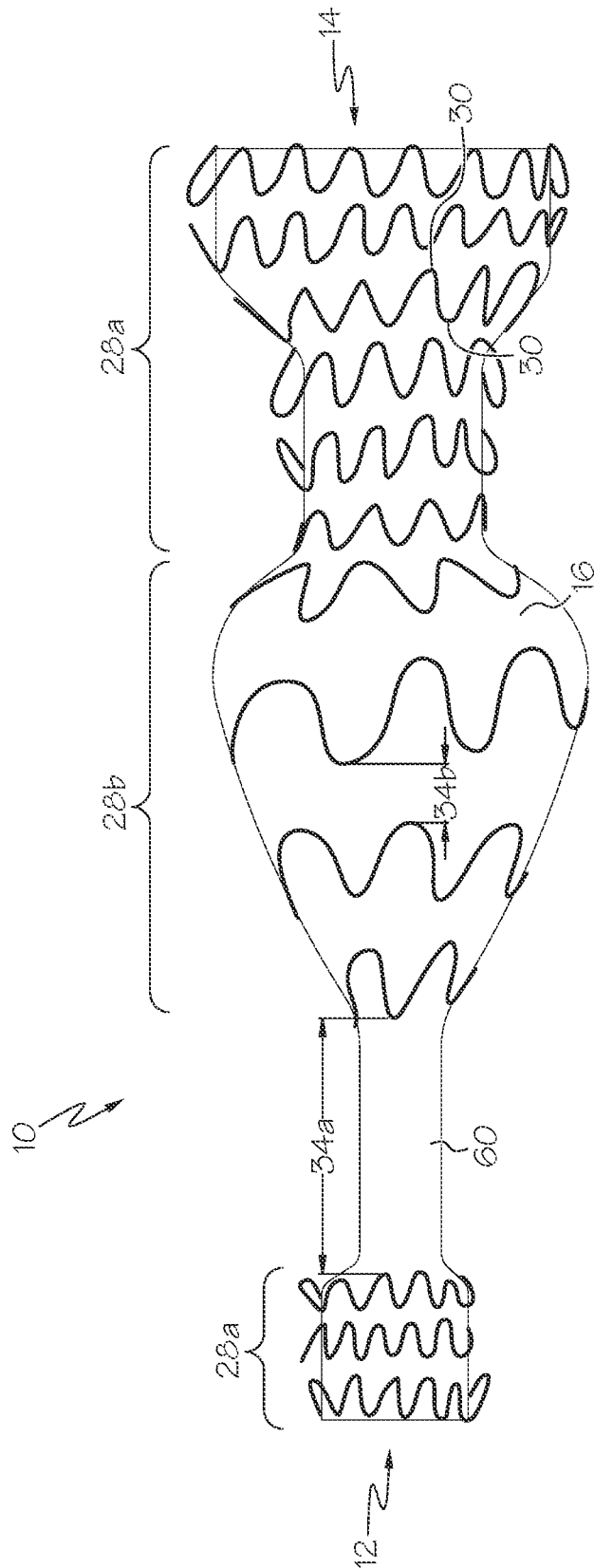


FIG. 11

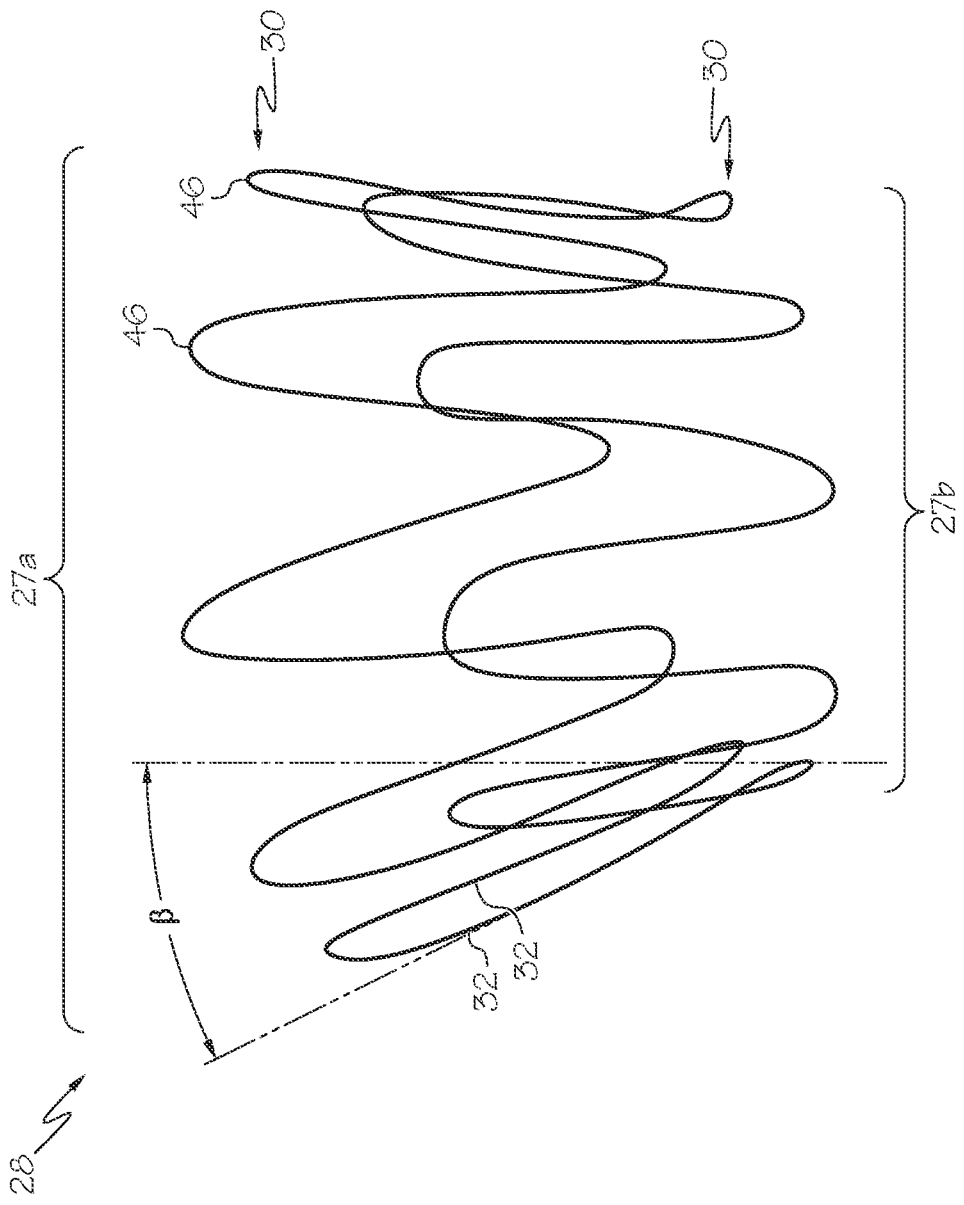


FIG. 12

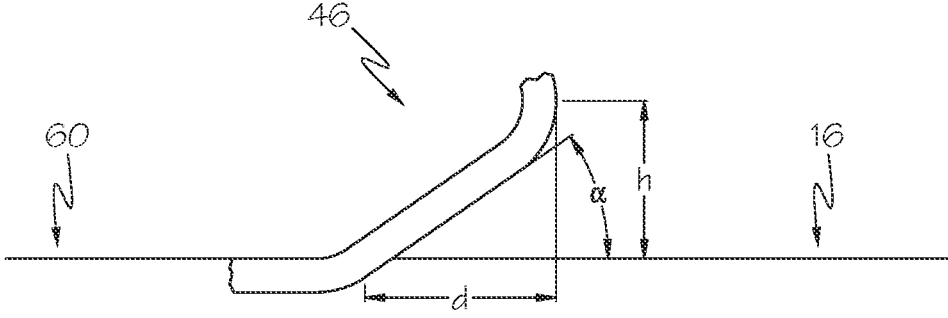


FIG. 13A

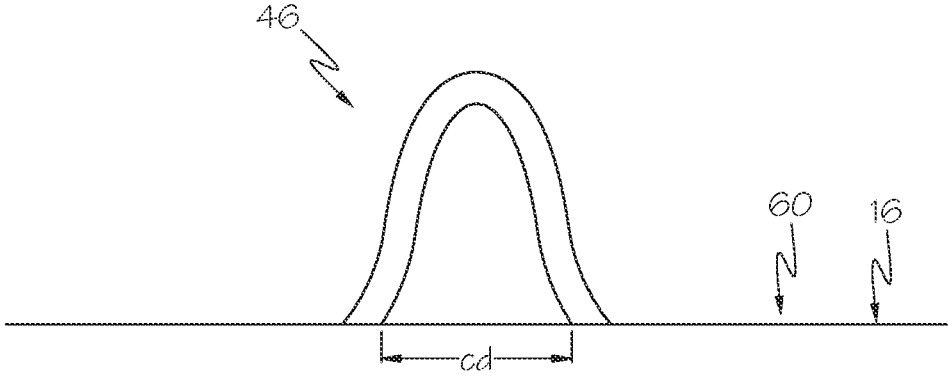


FIG. 13B

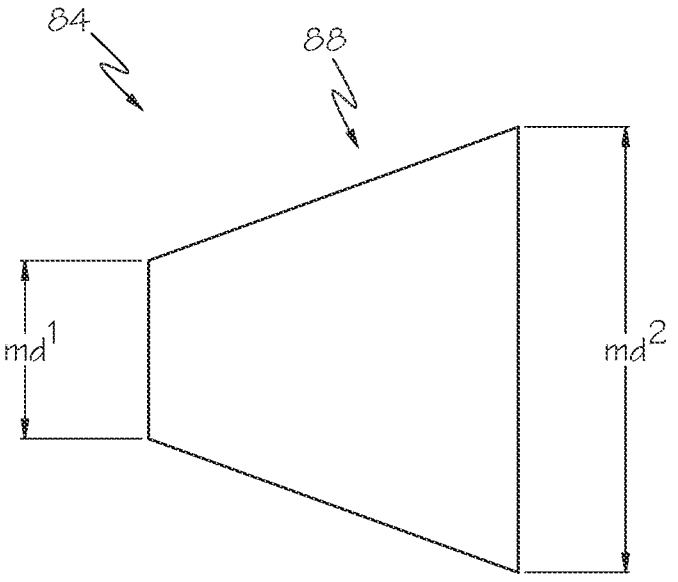


FIG. 14

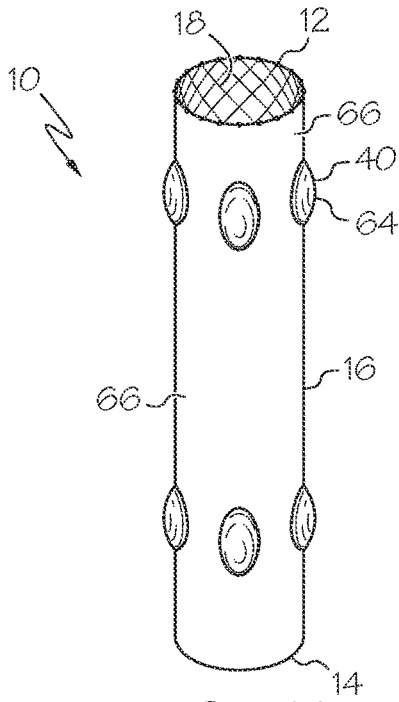


FIG. 15A

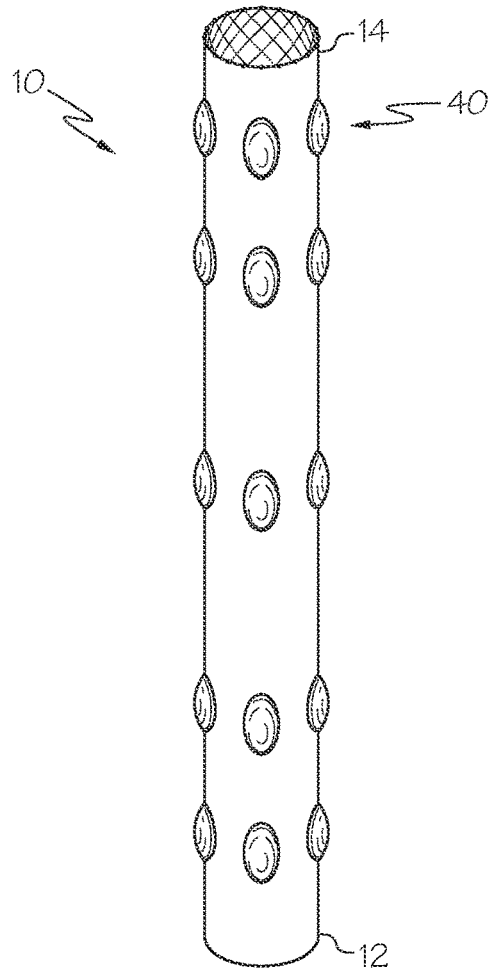


FIG. 15C

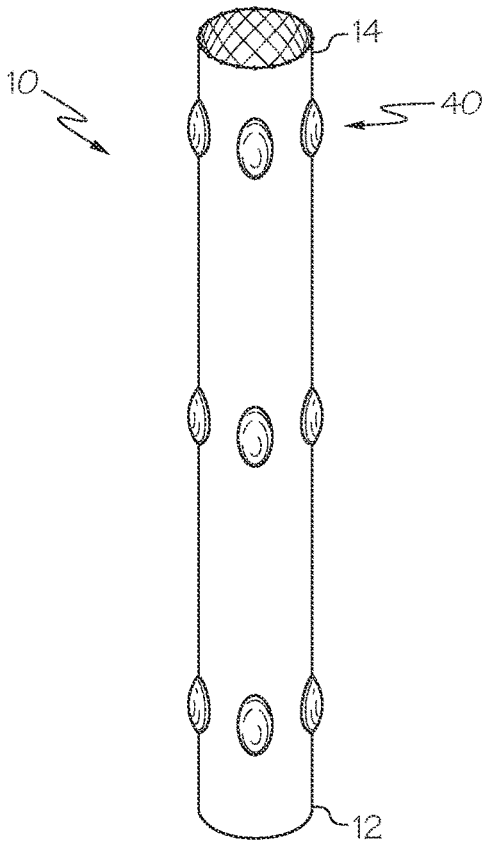


FIG. 15B

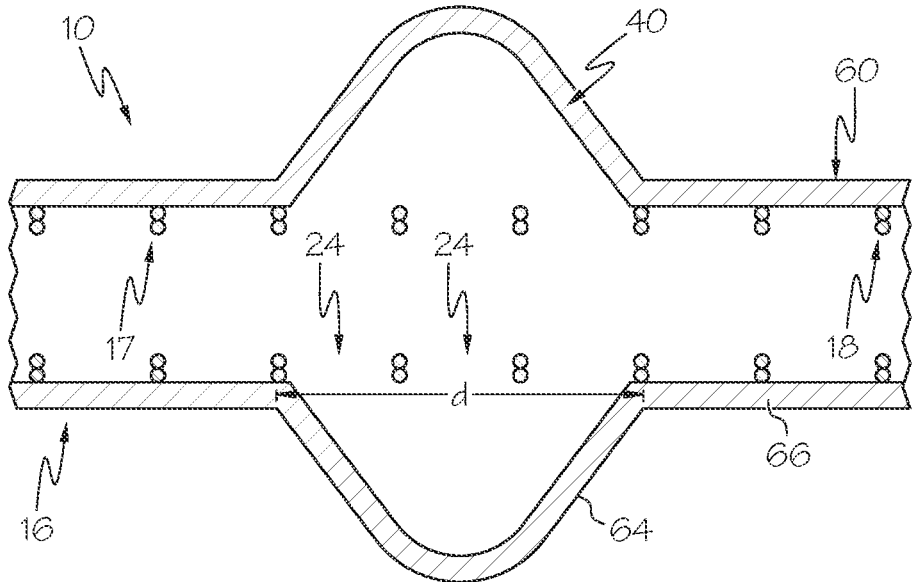


FIG. 16A

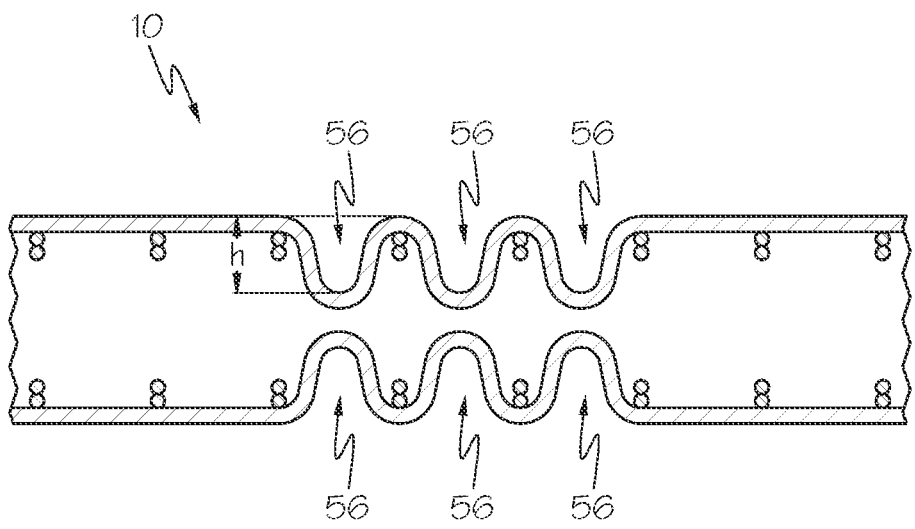


FIG. 16B

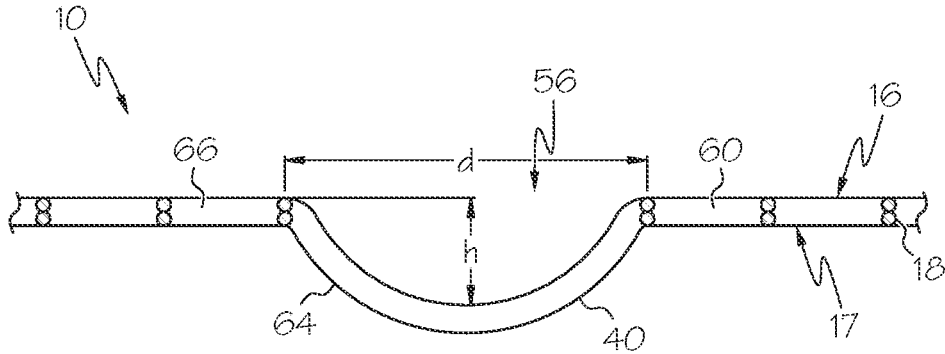


FIG. 17

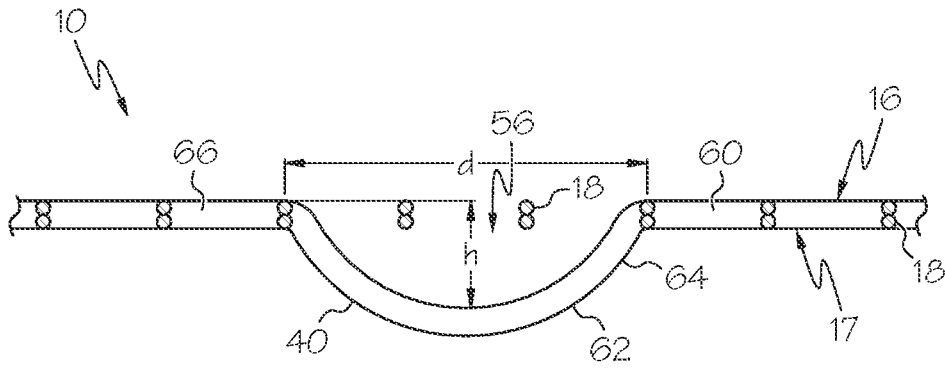


FIG. 18



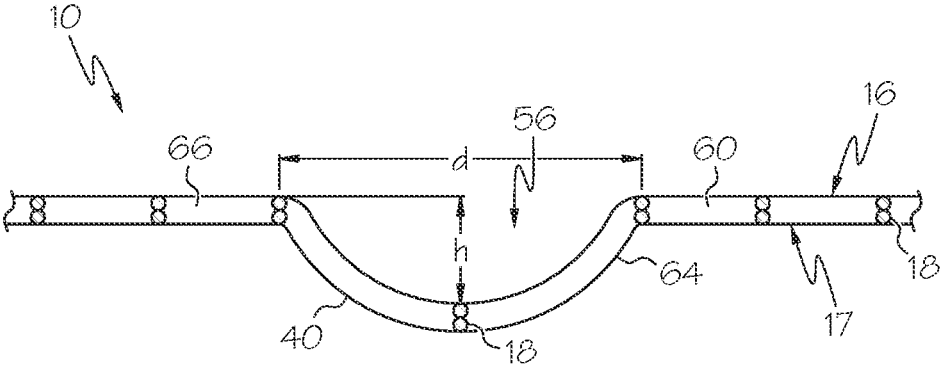


FIG. 19

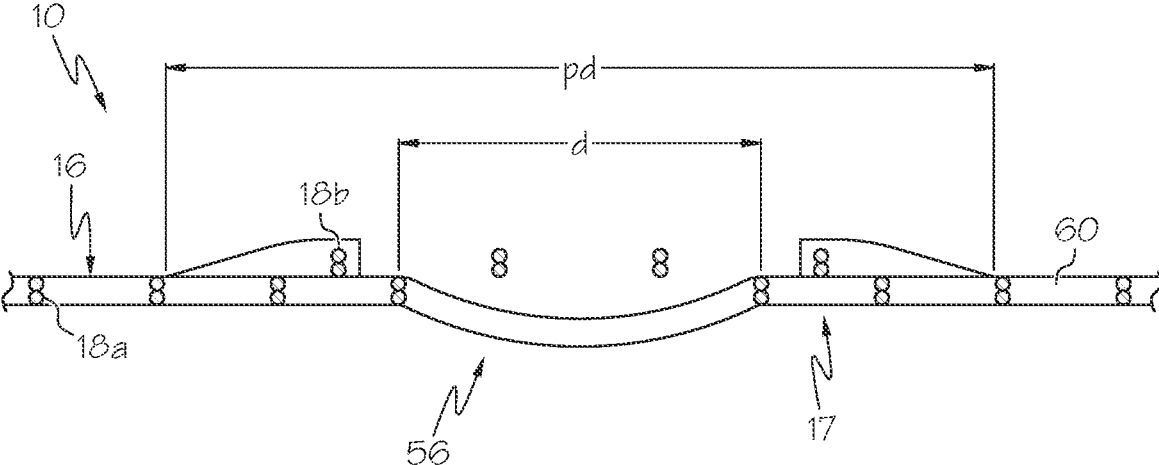


FIG. 20

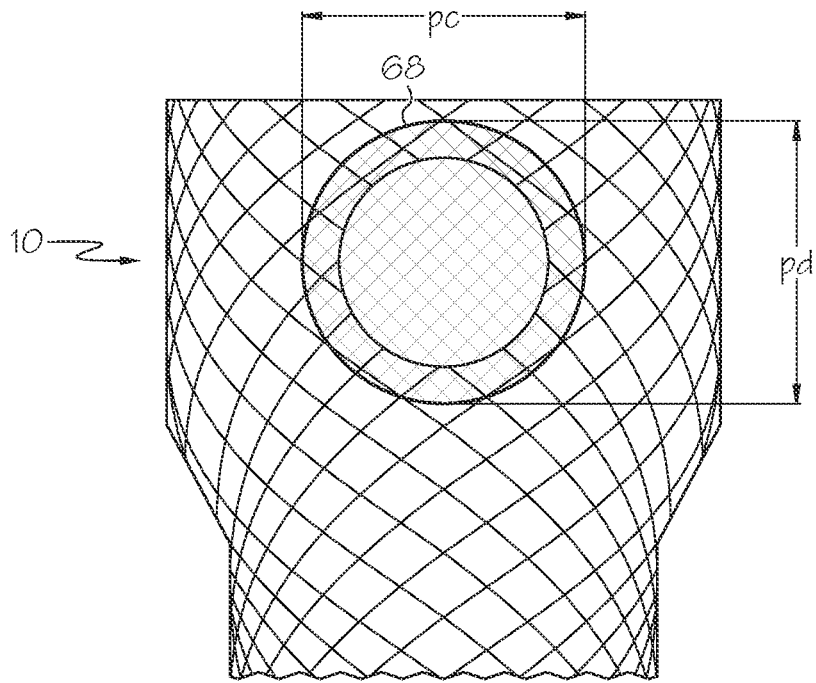


FIG. 21A

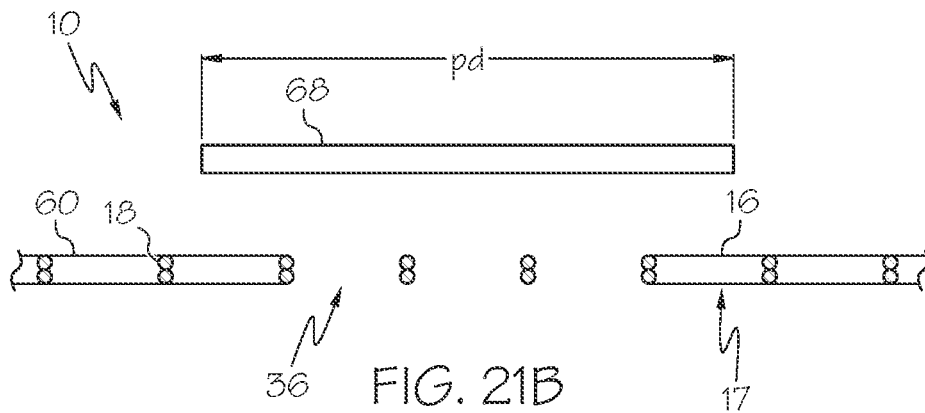


FIG. 21B

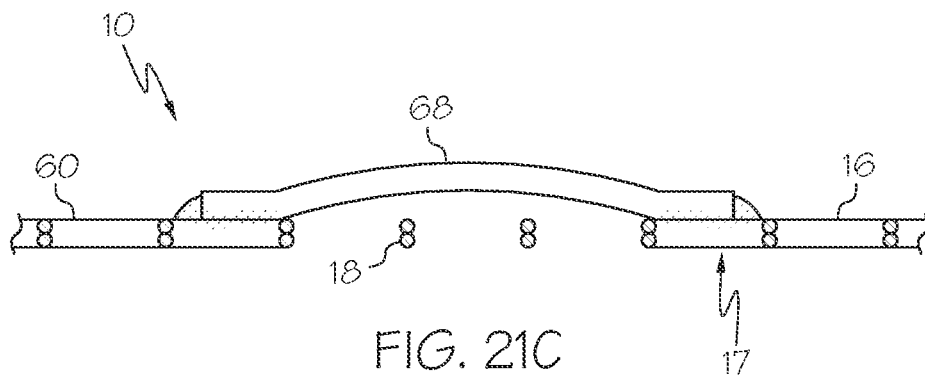


FIG. 21C

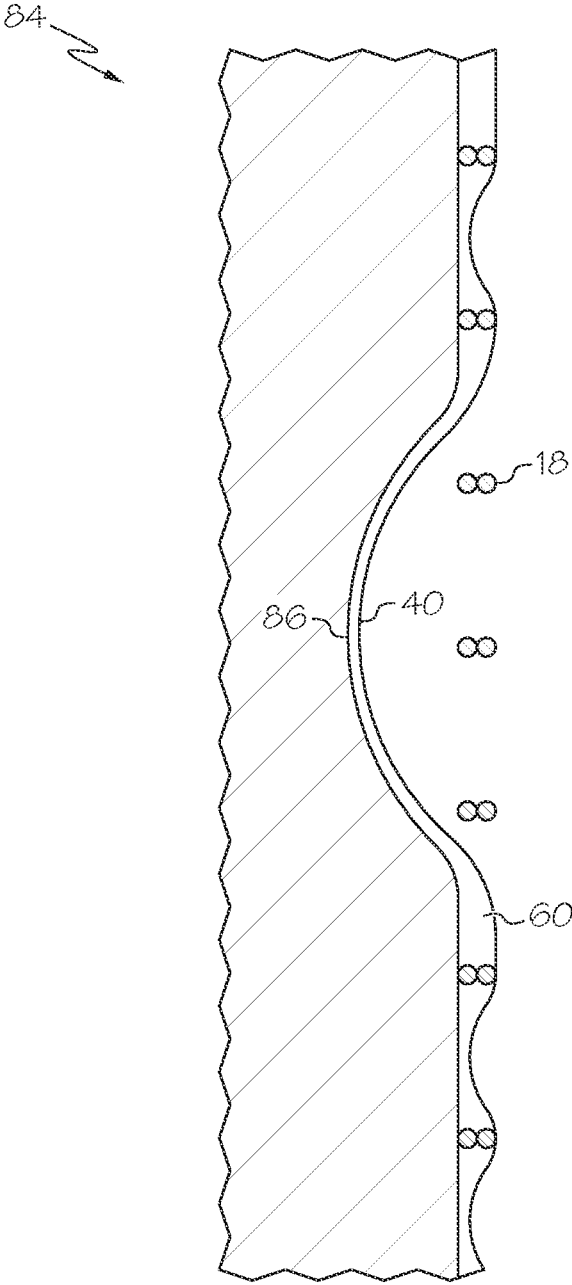


FIG. 22

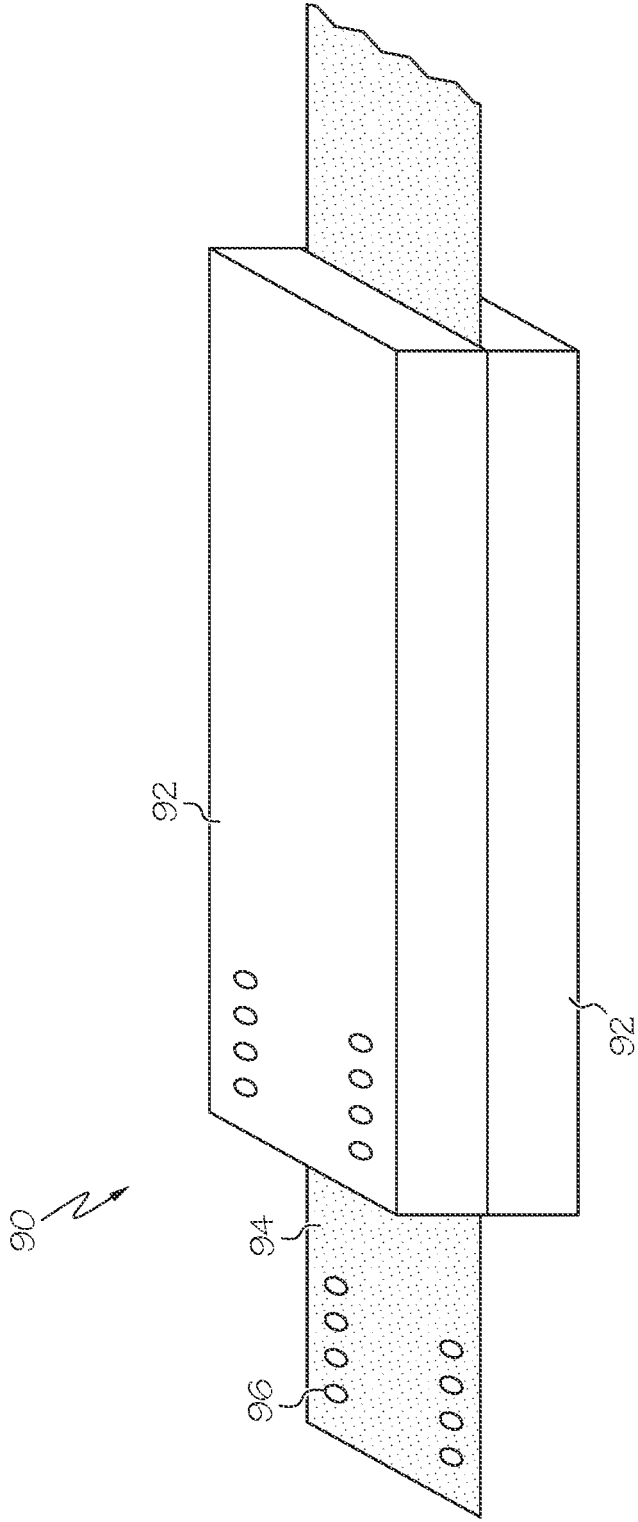


FIG. 23

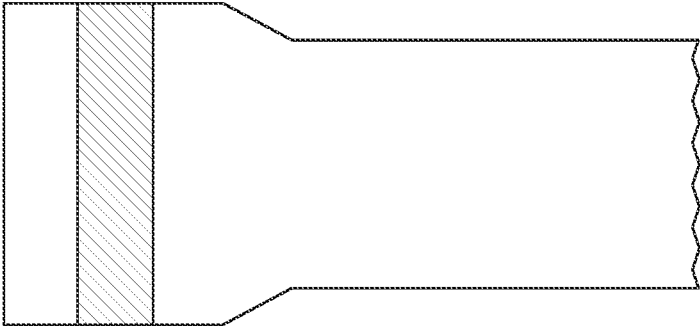


FIG. 24C

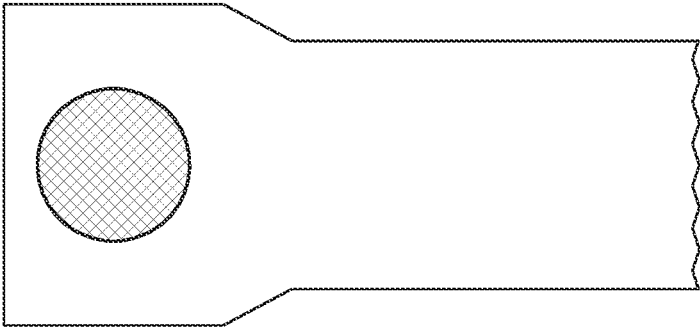


FIG. 24B

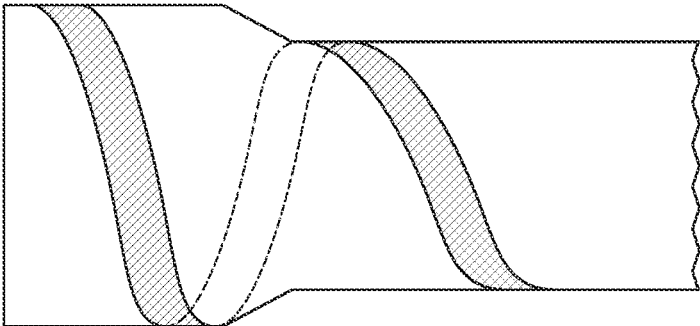


FIG. 24A

## CONTROLLED INGROWTH FEATURE FOR ANTIMIGRATION

### CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application is a continuation of U.S. application Ser. No. 16/263,353, filed Jan. 31, 2019, which is a continuation of U.S. application Ser. No. 14/873,833, filed Oct. 2, 2015, now U.S. Pat. No. 10,219,921, which claims priority under 35 U.S.C. § 119 to U.S. Provisional Application Ser. No. 62/058,821, filed Oct. 2, 2014, the entirety of which is incorporated herein by reference.

### BACKGROUND

**[0002]** Stents may be implanted in a variety of body lumens or vessels such as within the vascular system, urinary tracts, gastrointestinal tracts, fallopian tubes, coronary vessels, secondary vessels, airways, structural heart (valve frame), etc. They may be self-expanding, expanded by an internal radial force, such as when mounted on a balloon, or a combination of self-expanding and balloon expandable (hybrid expandable). Some stents are partially or fully covered. Migration of the stent from its initial site of implantation can be undesirable.

**[0003]** Without limiting the scope of the invention a brief summary of some of the claimed embodiments of the disclosure is set forth below. Additional details of the summarized embodiments of the disclosure and/or additional embodiments of the disclosure may be found in the Detailed Description of the Invention below.

### BRIEF SUMMARY

**[0004]** A prosthesis for controlled tissue ingrowth may comprise a scaffolding extending from a first prosthesis end to a second prosthesis end; a cover; and a controlled tissue ingrowth feature constructed and arranged to abut an inner surface of a lumen wall when the prosthesis is implanted in the body lumen, the controlled ingrowth feature selected from the group consisting of protruding elements and dimples; wherein the controlled ingrowth feature is formed by a scaffolding filament; by a separate filament; by the cover; and combinations thereof.

**[0005]** The prosthesis may be a fully covered prosthesis. The prosthesis has a first prosthesis end and a second prosthesis end. The prosthesis may have a longitudinal length measured from the first prosthesis end to the second prosthesis end of about 40 mm to about 400 mm, preferably about 60 mm to about 200 mm.

**[0006]** The scaffolding may be selected from the group consisting of: a mesh; a plurality of spaced apart rings; laser cut from a tube; and laser cut from a sheet of material formed into a tube. The scaffolding may be a single layer. The scaffolding may extend from a first prosthesis end to a second prosthesis end. The scaffolding has a scaffolding outer surface. The scaffolding may have a longitudinal length of about 40 mm to about 400 mm, preferably about 60 mm to about 200 mm. The scaffolding defines a plurality of scaffolding openings. The scaffolding openings may have a size of about 1×1 mm to about 5×5 mm.

**[0007]** The scaffolding may be formed by a scaffolding filament. The scaffolding filament may have a diameter of 0.06 mm to 0.60 mm. The scaffolding filament may be

bioabsorbable. The scaffolding filament may comprise nitinol, polyethylene terephthalate (PET), or a bioabsorbable material.

**[0008]** The scaffolding may be a mesh. The mesh may be an interwoven mesh. The scaffolding filament may be interwoven at a uniform angle to form the mesh. The interwoven mesh has a plurality of scaffolding filament crossings.

**[0009]** The cover may be non-porous. The cover may be attached to the scaffolding outer surface. The cover may have a length equal to the longitudinal length of the scaffolding. The cover may form the prosthesis outer surface. The cover may have a thickness of about 10 μm to about 400 μm preferably about 50 μm to about 200 μm more preferably about 100 μm to about 150 μm most preferably about 100 μm. The cover may have a variable thickness or a uniform thickness.

**[0010]** The controlled ingrowth feature may form a maximum of about 30% of an outer surface area of the prosthesis. The controlled ingrowth feature may be positioned about 5 mm to about 25 mm from the closest prosthesis end; preferably about 10 mm to about 20 mm from the closest prosthesis end; more preferably about 12 mm to about 15 mm from the closest prosthesis end; and most preferably about 15 mm from the closest prosthesis end. The controlled ingrowth feature may be constructed and arranged to abut an inner surface of the lumen wall when the prosthesis is implanted in a body lumen. The controlled ingrowth feature may be constructed and arranged not to penetrate the lumen wall when the prosthesis is implanted in a body lumen.

**[0011]** The controlled ingrowth feature may be a protruding element. The protruding element may be selected from the group consisting of a protruding scaffolding filament section; a separate filament attached to the scaffolding; a protruding mesh region; and a protruding ring turn. The protruding element is positioned above the scaffolding. The protruding element may define a gap with a gap height of about 0.25 mm to about 4.0 mm, preferably about 0.25 mm to about 2 mm. The gap may be an open gap or a closed gap. The prosthesis may have only open gaps; only closed gaps; or a combination of open gaps and closed gaps.

**[0012]** The protruding element may be a plurality of protruding elements.

**[0013]** The protruding scaffolding filament section may form about 2.5% to about 20% of the outer surface area of the prosthesis. The protruding scaffolding filament section may extend between two scaffolding filament crossings immediately adjacent one another, or may extend over a scaffolding filament crossing. The protruding scaffolding filament section has a first end and a second end. The first and second ends of the protruding scaffolding filament section may be separated by a distance of 1.5 mm to 7.5 mm. The protruding scaffolding filament section may have a rounded shape, a square shape, or a triangular shape. The protruding scaffolding filament section may have no sharp bends. The protruding scaffolding filament section may have a rounded shape. The protruding scaffolding filament section may be oriented at a non-parallel angle to a longitudinal axis of the prosthesis.

**[0014]** The separate filament may form about 2.5% to about 20% of the outer surface area of the prosthesis. The separate filament may extend between two scaffolding filament crossings immediately adjacent one another, or may extend over a scaffolding filament crossing. The separate filament has a first end and a second end. The first and second ends of the separate filament may be separated by a

distance of 1.5 mm to 7.5 mm. The separate filament may have a rounded shape, a square shape, or a triangular shape. The separate filament may have no sharp bends. The separate filament may be oriented at a non-parallel angle to a longitudinal axis of the prosthesis.

**[0015]** The protruding mesh region may define an open gap with a maximum gap height of 0.50 mm to 2 mm. The protruding mesh region has a first edge and a second edge. The first and second edges may be separated by a longitudinal distance of 2 mm to 10 mm. The protruding mesh region may form about 2.5% to about 20% of the outer surface area of the prosthesis.

**[0016]** The ring may be formed by a scaffolding filament. Each ring has interconnected ring turns. The ring turns include first ring turns forming the first ring end and second ring turns forming the second ring end. The rings may include a first ring with a variable diameter and a second ring with a uniform diameter. The first ring has a first ring end with a first diameter and a second ring end with a second diameter greater than the first diameter, wherein the second ring end is the protruding element. The second ring end may be positioned above the cover and define a gap therebetween. About 25-75% of the longitudinal length of the first ring, as measured from the first and second ring ends, may be positioned above the outer surface of the cover. The gap may have a maximum gap height of 0.25 mm to 4 mm.

**[0017]** The first ring may either have a truncated cone shape with a single uniform slope or angle  $\beta$ ; or a cylindrical section with a uniform diameter and a truncated cone section with a single uniform slope or angle  $\beta$  extending from the cylindrical section.

**[0018]** The prosthesis may include a second ring with a first end having a first diameter and a second end having the first diameter. The prosthesis may have only first rings. The prosthesis may have first and second rings. The rings may be interconnected only by the cover.

**[0019]** The controlled ingrowth feature may be a dimple. The prosthesis may have a single dimple or a plurality of dimples. The dimple may be selected from the group consisting of a dimple cover section of the cover; a reinforced dimple comprising a dimple cover section and a section of the scaffolding; a dimple patch; and combinations thereof.

**[0020]** The prosthesis with a dimple may have a single layer of scaffolding, or two layers of scaffolding with only one of the two layers of scaffolding extending from the first prosthesis end to the second prosthesis end. The second layer of scaffolding is a scaffolding patch.

**[0021]** The dimple may span a single scaffolding opening or a plurality of scaffolding openings. The dimple may span a scaffolding opening having a larger size than the other scaffolding openings. The dimple may define a dimple gap with a maximum gap height of about 3 mm. The dimple may have a maximum longitudinal extent of 1 mm to 10 mm. The maximum longitudinal extent of the dimple may be less than the longitudinal length of the prosthesis. The dimple may have a maximum circumferential extent of 1 mm to 10 mm. The maximum circumferential extent may be equal to or less than the circumference of the prosthesis.

**[0022]** The cover may comprise a non-dimple cover section and a dimple cover section. The dimple cover section may be entirely surrounded by the non-dimple cover section. The dimple cover section may form a dimple gap. The

dimple gap may have a gap height of about 0.25 mm to about 2.0 mm. The dimple may define a single dimple gap or a plurality of dimple gaps.

**[0023]** The dimple is sized so as not to exert a suction force on the lumen wall when the prosthesis is implanted. The dimple may have a longitudinal extent of about 1 mm to about 10 mm; a circumferential extent of about 1 mm to about 10 mm; an area of about 1 mm<sup>2</sup> to 100 mm<sup>2</sup>, preferably 5 mm<sup>2</sup> to about 50 mm<sup>2</sup>, and most preferably 25 mm<sup>2</sup>; and combinations thereof. The dimple may form about 1% to about 30% of the outer surface area of the prosthesis, preferably 5% to 20% of the outer surface area of the prosthesis, and most preferably 10% of the outer surface area of the prosthesis.

**[0024]** Scaffolding may extend over the dimple gap. The scaffolding extending over the dimple gap may be either a portion of the scaffolding or a scaffolding patch attached to the prosthesis outer surface. A portion of the mesh scaffolding may extend over the dimple gap.

**[0025]** A scaffolding patch may extend over the dimple gap and be secured to the non-dimple cover section.

**[0026]** The dimple gap may span a scaffolding opening having a larger size than other scaffolding openings.

**[0027]** These and other aspects of a prosthesis of the present disclosure are pointed out with particularity in the detailed description and the claims annexed hereto and forming a part hereof. However, for further understanding of the invention reference can be made to the drawings which form a further part hereof and the accompanying descriptive matter, in which there is illustrated and described embodiments of the invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

**[0028]** A detailed description of the invention is hereafter described with specific reference being made to the drawings.

**[0029]** FIG. 1 is a flat view of an exemplary interwoven prosthesis.

**[0030]** FIG. 2 is a view of a portion of an exemplary prosthesis with a raised filament section.

**[0031]** FIG. 3 is a perspective view a raised filament section with a closed gap.

**[0032]** FIGS. 4-5 are cross-sectional views of the raised filament section of FIG. 3 at line A-A showing no controlled tissue ingrowth.

**[0033]** FIG. 6 is a perspective view of a raised filament section with an open gap.

**[0034]** FIG. 7 is a cross-section view of the raised filament section of FIG. 6 at line A-A showing controlled tissue ingrowth.

**[0035]** FIGS. 8A-C show exemplary shapes for a protruding element formed by a scaffolding filament or a separate filament.

**[0036]** FIG. 9 is a view of a portion of an exemplary prosthesis with protruding mesh regions.

**[0037]** FIG. 10 is a view of an exemplary prosthesis with protruding ring turns.

**[0038]** FIG. 11 is a view of another exemplary prosthesis with protruding ring turns.

**[0039]** FIG. 12 is a view of an exemplary pre-formed ring.

**[0040]** FIGS. 13A-B show schematic views of a protruding ring turn.

**[0041]** FIG. 14 is a schematic view of a tapered mandrel section for forming a ring.

[0042] FIGS. 15A-C are schematic views of exemplary prostheses with dimples

[0043] FIGS. 16-20 are schematic partial cross-sectional views of a dimple.

[0044] FIGS. 21A-C are views of an exemplary method of forming a dimple.

[0045] FIG. 22 is a schematic cross-sectional view of an exemplary coating mandrel.

[0046] FIG. 23 is view of an exemplary device for forming dimples in a cover.

[0047] FIGS. 24A-C are exemplary configurations of a controlled ingrowth feature.

#### DETAILED DESCRIPTION

[0048] While this disclosure may be embodied in many different forms, there are described in detail herein specific embodiments of the disclosure. This description is an exemplification of the principles of the disclosure and is not intended to limit the disclosure to the particular embodiments illustrated.

[0049] For the purposes of this disclosure, like reference numerals in the figures shall refer to like features unless otherwise indicated.

[0050] As used in this disclosure, the terms “connect” or “engage” do not include “indirect” connection or engagement.

[0051] As used in this disclosure, “thickness” is measured radially from the prosthesis outer surface 16 to the prosthesis inner surface 17; “width” is measured in a circumferential direction; and “length” is measured in a longitudinal direction.

[0052] As used in this disclosure, an “end” is the last part or extremity of an element, while an “end region” is a region adjacent to, and includes, the “end.”

#### Prosthesis

[0053] A tubular prosthesis or stent 10 as described herein provides for controlled tissue ingrowth (see e.g. FIGS. 1-13 and 15-21). Thus, the prosthesis 10 may be described as a “controlled tissue ingrowth prosthesis”. “Controlled tissue ingrowth” as used herein means that the prosthesis is constructed and arranged for a pre-determined amount of tissue ingrowth when the prosthesis 10 is implanted.

[0054] The prosthesis 10 includes a first prosthesis end 12; a second prosthesis end 14; a prosthesis outer surface 16; a prosthesis inner surface 17 opposite the prosthesis outer surface 16, the prosthesis inner surface 17 defining the prosthesis lumen; a scaffolding 18; a cover 60 and a controlled ingrowth feature 40. The pre-determined amount of tissue ingrowth depends in part on the cover 60 and in part on the controlled ingrowth feature 40.

[0055] The prosthesis outer surface 16 may be defined by the cover 60 and the controlled ingrowth feature 40 (see e.g. FIG. 9), or entirely by the cover 60 (see e.g. FIGS. 2 and 16B). The prosthesis outer surface 16 has an outer surface area. The prosthesis inner surface 17 may be defined by the cover 60 and by the scaffolding 18 (see e.g. FIGS. 2, 9, and 16B). The prosthesis inner surface 17 has an inner surface area.

[0056] The prosthesis 10 is expandable from a compressed delivery diameter to an expanded implanted diameter. As is known in the art the prosthesis 10 may self-expand from the compressed delivery diameter to the expanded implanted

diameter, or may be expanded by a balloon from the compressed delivery diameter to the expanded implanted diameter. For this disclosure, a “diameter” of the prosthesis 10 does not take into account the overall height of the controlled ingrowth feature 40. In other words the diameter of the prosthesis is based on the diameter measured from the outer surface of the cover 60. As used in this disclosure, “diameter” is the distance of a straight line extending between two points and does not indicate a particular cross-sectional shape.

[0057] A prosthesis 10 as described herein may have a substantially constant diameter (see e.g. FIGS. 9 and 15-18); prosthesis end regions with a greater diameter than the prosthesis middle region (see e.g. FIGS. 2 and 10); or a variable diameter (see e.g. FIGS. 11 and 19). The prosthesis 10 may have a minimum diameter of about 15 mm and a maximum diameter of about 40 mm. The prosthesis end regions may have a diameter of about 15 mm to about 35 mm, while the prosthesis middle region may have a diameter of about 15 mm to about 25 mm.

[0058] The prosthesis 10 may have a longitudinal length measured from the first prosthesis end 12 to the second prosthesis end 14 of about 40 mm to about 400 mm, preferably about 60 mm to about 200 mm.

[0059] The prosthesis 10 can be implanted in any suitable body lumen including the gastrointestinal system (e.g. colon, esophagus), the hepatobiliary system (e.g. biliary tract), the respiratory system (e.g. trachea), the cardiovascular system, and elsewhere in the body.

#### A. Scaffolding

[0060] The prosthesis 10 has a tubular scaffolding 18 that extends from the first prosthesis end 12 to the second prosthesis end 14. The scaffolding 18 has a scaffolding outer surface, a scaffolding inner surface, and a thickness measured from the scaffolding outer surface to the scaffolding inner surface. The scaffolding 18 may have a longitudinal length of about 40 mm to about 400 mm, preferably about 60 mm to about 200 mm; a thickness of about 0.06 mm to about 0.60 mm; and combinations thereof. The scaffolding 18 defines a plurality of scaffolding openings 24 (see e.g. FIGS. 1-2, 9, and 15-22). The scaffolding openings 24 may have a size of about 1×1 mm to about 5×5 mm.

[0061] The scaffolding 18 may be in the form of a mesh 22 (see e.g. FIGS. 1-2, 9, and 14-20C); a plurality of longitudinally spaced apart rings 28 (see e.g. FIGS. 10-11); laser cut from a tube; or laser cut from a sheet of material that is welded to form a tube.

[0062] The prosthesis 10 may have a single layer of scaffolding 18 (e.g. FIGS. 2-13, 15-19, and 21-22), or two layers of scaffolding 18 (e.g. FIG. 20). As discussed below in greater detail, where the prosthesis 10 has two layers of scaffolding, only one layer of scaffolding 18 extends from the first prosthesis end 12 to the second prosthesis end 14.

[0063] The scaffolding 18 is expandable from a compressed delivery diameter to an expanded implanted diameter. Suitable materials for the scaffolding 18 are provided below. The structures forming the scaffolding 18 may have any suitable cross-sectional shape, for example but not limited to a round cross-sectional shape (see e.g. FIG. 3), or a rectangular cross-sectional shape (not shown). A scaffolding structure, e.g. a scaffolding filament 20, may have a



diameter of about 0.06 mm to about 0.60 mm. The scaffolding filament 20 can be a monofilament or a multifilament.

[0064] A “mesh” 22 as used in the present disclosure has at least one scaffolding filament 20; a plurality of scaffolding filament crossings 26; defines a plurality of scaffolding openings 24; and may be formed by any suitable method, including but not limited to braiding, weaving, and knitting. A prosthesis 10 with a mesh scaffolding may be described as an interwoven prosthesis. A scaffolding filament 20 forming the mesh scaffolding 22 may have a length equal to or greater than the longitudinal length of the mesh scaffolding 22.

[0065] A “ring” 28 as used in the present disclosure extends around the entire circumference of the prosthesis 10; and has a plurality of interconnected ring turns 30, with some ring turns 30 facing the first prosthesis end 12, and other ring turns 30 facing the second prosthesis end 14 (see e.g. FIGS. 10-11). A ring 28 may be formed by a scaffolding filament 20. Thus the scaffolding filament 20 has sections forming the ring turns 30 and sections 32 interconnecting the ring turns 30. Sections 32 extending between, and connecting, two ring turns 30 may be straight or include at least one bend. The scaffolding filaments 20 forming the rings 28 of a prosthesis 10 may have the same diameter or different diameters.

[0066] The ring 28 has a longitudinal length measured from the first and second ring ends of about 1 mm to about 30 mm, preferably about 5 mm to about 15 mm, most preferably about 10 mm. A prosthesis 10 may have rings 28 with different longitudinal lengths or rings 28 with the same longitudinal length.

[0067] A prosthesis 10 formed of rings 28 has at least two rings 28 connected to one another only by the cover 60 (see e.g. FIGS. 10-11).

[0068] A prosthesis 10 may have rings 28 formed of the same material or rings 28 formed of different materials.

[0069] A prosthesis 10 may have rings 28 with the same radial strength or rings 28 of different radial strengths.

[0070] A prosthesis 10 may have rings 28 with the same diameter (see e.g. the rings forming middle section of the prosthesis 10 shown in FIG. 10), or rings with different diameters (see e.g. FIGS. 10-11).

[0071] The rings 28 of a prosthesis 10 may be separated by a substantially constant longitudinal distance 34 (see e.g. FIG. 10) or by different longitudinal distances 34 (see e.g. 34a and 34b of FIG. 11). The longitudinal distance 34 between adjacent rings 28 may be about 0 mm to about 50 mm. Where the longitudinal distance is about 0 mm, the rings are in phase and the proximal turns of one ring and the distal turns of the adjacent ring are aligned on a line perpendicular to the longitudinal axis of the prosthesis.

[0072] As is known in the art, scaffolding that is formed by laser cutting a tube or a sheet of material typically has a plurality of interconnected struts that defines a plurality of scaffolding openings. The interconnected struts may be arranged in any pattern.

#### B. Cover

[0073] As discussed above, the pre-determined amount of tissue ingrowth depends in part on the cover 60. The cover 60 is constructed and arranged to prevent tissue from growing through the scaffolding openings 24 and into the

lumen of the prosthesis 10. Examples of suitable materials for the cover 60 are provided below.

[0074] To prevent tissue from growing into the lumen of the prosthesis 10, the prosthesis 10 is a fully covered prosthesis. As used in this disclosure, a “fully covered prosthesis” has a cover 60 that extends over the scaffolding outer surface at least from the first prosthesis end 12 to the second prosthesis end 14 and occludes the scaffolding openings 24. Therefore, the cover 60 has a length equal to, or greater than, the longitudinal length of the prosthesis 10. About 80% of the cover 60 may be supported by and/or secured to the scaffolding 18. The prosthesis 10 may further include a cover extending over the inner surface of the scaffolding 18.

[0075] The cover 60 may be non-porous. Alternatively, the cover 60 may be porous. For example if the cover 60 is porous, the pore size and/or pores location may be constructed and arranged so that there is no tissue growth through the cover 60 and into the lumen of the prosthesis 10; the inner surface of the cover 60 may have a impermeable layer the prevents tissue growth therethrough; and combinations thereof.

[0076] The cover 60 may have a thickness of about 10  $\mu\text{m}$  to about 400  $\mu\text{m}$ , preferably about 50  $\mu\text{m}$  to about 200  $\mu\text{m}$ , more preferably 100  $\mu\text{m}$  to about 150  $\mu\text{m}$ , most preferably about 100  $\mu\text{m}$ . The cover 60 may have a variable thickness (see e.g. FIG. 22) or a uniform thickness (see e.g. FIG. 17). Although the cover 60 typically has a thickness less than the diameter of the scaffolding filament 20, the cover 60 may have a thickness equal to or greater than the diameter of the scaffolding filament 20. Where the cover 60 has a thickness greater than the diameter of the scaffolding filament 20 the cover 60 extends over the outer surface of the scaffolding 18. Where the cover has a thickness less than the diameter of the scaffolding filament 20, the scaffolding filament 20 may protrude slightly outward from outer surface of the cover 60. The height of the slight outward protrusion of the scaffolding filament 20 is minimal (e.g. a height of about 0.5 mm). Thus, the prosthesis outer surface 16 is substantially uniform.

#### C. Controlled Ingrowth Feature

[0077] As discussed above, the pre-determined amount of tissue ingrowth when the prosthesis 10 is implanted depends in part on the controlled ingrowth feature 40. Some features of the controlled ingrowth feature that affect the pre-determined amount of tissue ingrowth include the amount of the prosthesis outer surface 16 that is formed by the controlled ingrowth feature 40; the gap height h and overall height of the controlled ingrowth feature; and combinations thereof.

[0078] As discussed below in greater detail, the controlled ingrowth feature 40 may form a maximum of about 30% of the prosthesis outer surface 16.

[0079] Each controlled ingrowth feature 40 defines a gap 56 between the controlled ingrowth feature 40 and the prosthesis outer surface 16. The gap 56 has a maximum extent or height h measured from the prosthesis outer surface 16 (hereinafter “gap height h”; see e.g. FIGS. 2, 4, 8A-C, 9, 13A, and 16B-19). Depending on the type of controlled ingrowth feature 40, the controlled ingrowth feature 40 may have maximum gap height h of about 0.25 mm to about 4 mm, or about 0.5 mm to about 2 mm.

[0080] The controlled ingrowth feature 40 is positioned between the first and second prosthesis ends 12, 14, and may be parallel, or non-parallel, to the longitudinal axis of the

prosthesis 10. Exemplary configurations of the placement of the controlled ingrowth feature(s) 40 along the longitudinal length of the prosthesis 10 are shown in FIGS. 2, 9-11, 14, and 22A-E. A longitudinal distance separates the controlled ingrowth feature 40 from each prosthesis end 12, 14. In other words, a section of the prosthesis 10 separates the controlled ingrowth feature 40 and the closest prosthesis end 12, 14. The controlled ingrowth feature may be positioned about 5 mm to about 25 mm from the closest prosthesis end 12,14; preferably about 10 mm to about 20 mm from the closest prosthesis end 12,14; more preferably about 12 mm to about 15 mm from the closest prosthesis end 12,14; and most preferably about 15 mm from the closest prosthesis end 12,14. For example, as shown in FIG. 2, the closest prosthesis end to the controlled ingrowth feature 40 is a distance beyond the top edge of the figure and the end of the controlled ingrowth feature 40 closest to the top edge of the figure is a distance from that closest prosthesis end. Without being bound by theory, having a longitudinal distance separating an end or edge of a controlled ingrowth feature 40 from the closest prosthesis end 12, 14 mitigates granulation tissue formation at or near the prosthesis end 12, 14 when the prosthesis 10 is implanted in a body lumen.

[0081] Forming the controlled ingrowth feature 40 is part of the method of forming the prosthesis 10 so that, once formation of the prosthesis 10 is completed, the prosthesis 10 has a controlled ingrowth feature 40. In other words, the prosthesis has a controlled ingrowth feature 40 at all times and the presence of the controlled ingrowth feature is not dependent on the prosthesis being in a particular state, e.g. a compressed delivery state or an expanded deployed state.

[0082] A controlled ingrowth feature 40 may extend outwardly from the prosthesis outer surface 16 of the prosthesis 10 (see e.g. FIGS. 2-11), or may extend inwardly from the prosthesis outer surface 16 (see e.g. FIGS. 14-19). The controlled ingrowth feature 40 may be formed by a scaffolding filament 20; by a separate filament 48; by the cover 60, and combinations thereof.

#### C.1. Outwardly Extending Controlled Ingrowth Feature/Protruding Element

[0083] As discussed above, the controlled ingrowth feature 40 may extend outwardly. A controlled ingrowth feature 40 that extends outwardly can be described as an outwardly extending controlled ingrowth feature or as a protruding element (hereinafter “protruding element”). Thus, as used in this disclosure, a “protruding element” extends outwardly and has a first end/edge and a second end/edge positioned at the outer surface of the cover 60.

[0084] A prosthesis 10 with a protruding element 40 has a single layer of scaffolding 18 (see e.g. FIGS. 2-13). The protruding element 40 may be formed by a part of the scaffolding 18 (see e.g. FIGS. 2 and 9-11), or by a separate filament 48 incorporated into the scaffolding 18 (see e.g. FIGS. 6). Examples of a part of the scaffolding 18 forming a protruding element 40 include: a section of a scaffolding filament 20 forming the mesh 22 (see e.g. FIG. 2; referred hereinafter as a protruding scaffolding filament section 42); a region of the mesh 22 (see e.g. FIG. 9; referred hereinafter as a protruding mesh region 44); and a ring turn 30 that protrudes (see e.g. FIGS. 10-11; referred hereinafter as a protruding ring turn 46).

[0085] As discussed above, the pre-determined amount of tissue ingrowth depends in part on the amount of the

prosthesis outer surface that is formed by the protruding element 40. For protruding elements 40 that are a part of the scaffolding 18, a separate filament 48 incorporated into the scaffolding, or a protruding scaffolding filament section 42, a maximum of about 20% of the prosthesis outer surface 16 is formed by the protruding elements 40 (see e.g. FIGS. 2-9). Thus for these embodiments, about 80% of the cover is supported by and/or secured to the scaffolding 18. These types of protruding elements 40 may form about 2.5% to about 20% of the prosthesis outer surface 16. Without being bound by theory, having a maximum of about 20% of the prosthesis outer surface 16 with protruding elements 40 may maintain adhesion between the cover 60 and the scaffolding 18, thereby preventing tissue ingrowth through the scaffolding 18; may prevent the cover 60 from being pulled away from the scaffolding 18 by tissue ingrowth; may prevent collapse of the cover 60 into the lumen of the prosthesis; and combinations thereof.

[0086] For protruding elements 40 that are protruding ring turns 46, a maximum of about 75% of the prosthesis outer surface 16 is formed by the protruding elements 40. As discussed below in greater detail, this type of protruding element 40 may form about 25% to about 75% of the prosthesis outer surface 16.

[0087] The pre-determined amount of tissue ingrowth depends in part on the gap height  $h$  of the protruding element 40 and the overall height of the protruding element 40. The gap height  $h$  is measured from the prosthesis outer surface 16 to the protruding element 40. The gap height  $h$  does not include the diameter of the protruding element 40. The combination of the gap height  $h$  and the diameter of the protruding element 40 is a measure of the overall height of the protruding element 40.

[0088] The overall height of the protruding element 40 is constructed and arranged so that the protruding element 40 does not puncture or jab into the lumen wall after the prosthesis 10 is implanted in a body lumen. In other words, when the prosthesis 10 is implanted the protruding element 40 abuts/contacts the lumen wall 80 but does not penetrate the lumen wall 80. The contact of the protruding element 40 against the lumen wall irritates the tissue of the lumen wall 80, which induces tissue growth around the protruding element 40 (see e.g. FIGS. 4-5 and 7).

[0089] The gap height  $h$  and the overall height are substantially fixed because the protruding element 40 has limited flex. Because the protruding element 40 has limited flex, the gap height  $h$  and the overall height of the protruding element 40 is substantially uniform. In other words, because the movement of the protruding element 40 up or down relative to the cover 60 is minimized, the protruding element 40 has a substantially uniform gap height  $h$  and a substantially uniform overall height. A prosthesis 10 with protruding elements 40 with a uniform gap height  $h$  and overall height has controlled tissue ingrowth. In contrast, a prosthesis with outwardly extending features that flex up or down relative to a covering would have uncontrolled tissue ingrowth. For protruding elements 40 that are a part of the scaffolding 18, a separate filament 48 incorporated into the scaffolding, or a protruding scaffolding filament section 42, the gap height  $h$  and the overall height are substantially fixed because the protruding element 40 has a preset curvature that limits flex of the protruding element 40.

[0090] Depending on the configuration of the protruding element 40, the gap height may be uniform or variable (see

e.g. FIGS. 8-11). Where the gap height  $h$  is variable, the gap height  $h$  is the maximum gap height  $h$ . Depending on the type of protruding element 40, the maximum gap height  $h$  may be about 0.25 mm to about 4 mm, or about 0.50 mm to about 2 mm.

[0091] As discussed above, prosthesis outer surface 16 is considered to be substantially uniform even though the scaffolding filament 20 may protrude slightly from the outer surface of the cover 60. Thus, the height of the outward protrusion from the outer surface of the cover 60 is not considered for the purpose of measuring the gap height  $h$  and the overall height of a protruding element 40.

[0092] The protruding element 40 may have a diameter of about 0.06 mm to about 0.6 mm. Thus, the overall height of the protruding element may be about 0.56 mm to about 2.6 mm. The overall height of the protruding element 40 may be described with reference to the diameter of the protruding element 40. The overall height of the protruding element 40 may be about 4× to about 9× the diameter of the protruding element 40. For example, where the protruding element 40 has a diameter of 0.06 mm and an overall height of 0.56 mm the overall height is about 9.3 times the diameter of the protruding element 40. Similarly, where the protruding element 40 has a diameter of 0.6 mm and an overall height of 2.6 mm, the overall height is about 4.33 times the diameter of the protruding element 40.

[0093] The gap height  $h$  and overall height of the protruding element 40 may depend on the intended implantation site. For example when the prosthesis 10 is constructed for implantation in the esophagus, the overall height of the protruding element 40 is between about 0.1 mm and about 2 mm because the lumen wall in the esophagus varies from 1.5 mm to 4 mm, depending on location and state of swallowing. The range for the overall height allows for tissue growth around the protruding element 40 without a risk of eroding completely through the lumen wall of the esophagus. Where the prosthesis 10 is constructed for implantation in anatomy further down the gastrointestinal tract, such as the large and small bowel, the protruding element 40 may have a smaller overall height, between about 0.5 mm and about 1 mm, as the lumen wall is thinner in these regions.

[0094] For a protruding element 40, the pre-determined amount of tissue ingrowth also depends on whether tissue grows entirely or partially around the protruding element 40 (see e.g. FIGS. 4-5 and 7). Tissue grows entirely around a protruding element 40 with a gap 56 that is open (an “open gap”), while tissue grows partially around a protruding element 40 with a gap 56 that is closed (a “closed gap”). As used in this disclosure an “open gap” is not enclosed by, or filled with, the material forming the cover 60 (see e.g. FIG. 7), while a “closed gap” is enclosed by, or filled with, the material forming the cover 60 (see e.g. FIGS. 4-5). It is noted that the gap height  $h$  does not depend on whether the gap 56 is to be an open gap or a closed gap.

[0095] Although a prosthesis 10 with an open gap 56 may be removed after implantation, less trauma to the lumen wall 80 occurs if the prosthesis has closed gaps 56 because the cover material around the protruding element 40 provides for a passageway for removal of the protruding element 40 from the lumen wall. A prosthesis 10 may have only protruding elements 40 with open gaps 56; only protruding elements 40 with closed gaps 56; or a combination of

protruding elements 40 open gaps 56 and protruding elements 40 with closed gaps 56.

[0096] A closed gap 56 may be described as being defined by a section the cover 60 extending up from the prosthesis outer surface 16, around the protruding element 40, and down to the prosthesis outer surface 16, or as a film of covering material that goes up and connects to the underside of the protruding element 40 (see e.g. FIGS. 4-5). This section of the cover 60 can be described as a gap section.

[0097] Alternatively, a closed gap 56 may be described as being formed by a layer of cover material that extends up from the prosthesis outer surface 16, around the protruding element 40, and down to the prosthesis outer surface 16. This layer of cover material forming the closed gap 56 may have a thickness less than the thickness of the cover 60.

[0098] The cover material forming a closed gap 56 may have a thickness less than the diameter of the protruding element 40 (see e.g. FIG. 4); greater than the diameter of the protruding element (see e.g. FIG. 5); and combinations thereof (see e.g. FIG. 5). As used in this disclosure, a closed gap is an “enclosed closed gap” if there is a space between the material forming the cover 60 on either side of the protruding element 40, (see e.g. FIG. 4), whereas a closed gap is a “filled closed gap” if the cover material on both sides of the protruding element 40 are in contact so that there is no space therebetween (see e.g. FIG. 5).

[0099] The protruding element 40 is also constructed so that the protruding element 40 does not include any sharp turns or bends. The sharpness of a turn or bend may be described by referring to the curvature of the turn/bend. Curvature is a measure of how quickly a tangent line turns on a curve. A curve with a larger curvature bends more sharply (e.g. inside lane of a track) than another curve with a smaller curvature (e.g. outside lane of a track). Curvature is also the reciprocal of radius. Thus a small curvature implies a large radius. The turn of a protruding element 40 may have a radius of curvature of about 0.254 mm to about 0.00254 mm (0.010 inches to about 0.0001 inches). The radius of curvature is a measure of the radius of a circular arc which best approximates the curve at a particular point. An example of a “sharp” turn is a turn greater than 45° (0.785 radians) that has a radius less than 0.010 inches (0.254 mm).

#### C.1.a. Scaffolding Filament/Separate Filament

[0100] As discussed above, the protruding element 40 may be a protruding scaffolding filament section 42 of a scaffolding filament 20 forming the mesh 22 (see e.g. FIG. 2), or a separate filament 48 incorporated into a mesh scaffolding 18 (see e.g. FIG. 6). In either case the protruding element 40 is formed by a single filament 20, 48. Some exemplary shapes for the protruding scaffolding filament section 42 and the separate filament 48 include rounded (see e.g. FIGS. 3 and 6); square shape (see e.g. FIG. 8A); wave shaped (see e.g. FIG. 8B); and triangular shaped (see e.g. FIG. 8C).

[0101] An individual scaffolding filament 20 of the mesh scaffolding 18 may have no protruding scaffolding filament section 42; one (1) protruding scaffolding filament section 42; or a plurality (2+) of protruding scaffolding filament sections 42. Each protruding scaffolding filament section 42 extends from a first end 43a to a second end 43b (see e.g. FIGS. 8A-C). In one aspect, each end of a protruding scaffolding filament section 42 is located at a scaffolding filament crossing 26 (see e.g. FIG. 2). The scaffolding filament crossings 26 may be positioned immediately adja-

cent one another (see e.g. the two scaffolding filament crossings **26** identified at the left end region of the prosthesis **10** of FIG. 1); or may be separated by at least one scaffolding filament crossing **26** (see e.g. the two scaffolding filament crossings **26** identified at the right end region of the prosthesis **10** of

**[0102]** FIG. 1; in other words, the protruding scaffolding filament section **42** extends over, or positioned above, at least one scaffolding filament crossing **26**).

**[0103]** The two ends **43a**, **43b** of a protruding scaffolding filament section **42** are separated by a distance  $d_2$  measured along the prosthesis outer surface **16** (see e.g. FIGS. 8A-C). The protruding scaffolding filament section **42** is constructed and arranged to that the distance  $d_2$  provides the cover **60** with sufficient support to withstand pressure applied by tissue ingrowth so that the cover **60** is not damaged or broken by tissue ingrowth when the prosthesis **10** is implanted. The distance  $d_2$  does not include the diameter of the scaffolding filament **20** and may be about 1.5 mm to about 7.5 mm. Where the ends **43a**, **43b** are located at scaffolding filament crossings **26** positioned immediately adjacent one another, the distance  $d_2$  is equal to the length of the cell/opening **24** of the braided scaffolding **18**.

**[0104]** Each protruding scaffolding filament section **42** defines a gap **56** with a height  $h$  of about 0.5 mm to about 2 mm measured from the outer surface of the cover **60**; a distance  $d_2$  from the first end **43a** to the second end **43b** of about 1.5 mm to about 7.5 mm; and combinations thereof.

**[0105]** The prosthesis **10** may have at least one separate filament **48** (see e.g. FIG. 6). Each separate filament **48** has a first end region **52** forming a first filament end, a second end region **54** forming a second filament end, and a protruding section **50** with a first end **43a** connected to the first end region **52** and a second end **43b** connected to the second end region **54** (see e.g. FIGS. 8A-C).

**[0106]** The separate filament **48** may have any suitable cross-sectional shape, for example but not limited to a round cross-sectional shape or a rectangular cross-sectional shape (not shown). The separate filament **48** may have a diameter of about 0.06 mm to about 0.6 mm. The separate filament **48** has a length less than the longitudinal length of the scaffolding **18**. The separate filament **48** may have a length less than the length of the scaffolding filament **20** forming the scaffolding to which the separate filament **48** is secured.

**[0107]** The separate filament **48** may be parallel to a scaffolding filament **20** (not shown). The end regions **52**, **54** of the separate filament **48** are secured to the scaffolding **18** by any suitable manner. For example the separate filament **48** can be secured to the scaffolding **18** by interweaving the end regions **52**, **54** into the scaffolding **18**; by bonding the end regions **52**, **54** to the scaffolding **18**; by welding the end regions **52**, **54** to the scaffolding **18**; and/or by wrapping the end regions **52**, **54** around a scaffolding filament **20**. Thus, the ends of the separate filament **48** are free ends until the end regions **52**, **54** are secured to the scaffolding **18**. Although the separate filament **48** is secured to the scaffolding **18**, the separate filament **48** is not a layer of scaffolding **18** as used herein. Thus, a prosthesis **10** with a separate filament **48** has a single layer of scaffolding **18**.

**[0108]** Each protruding section **50** defines a gap **56** with a height  $h$  of about 0.5 mm to about 2 mm measured from the outer surface of the cover **60**; a distance  $d_2$  from the first end **43a** to the second end **43b** of about 1.5 mm to about 7.5 mm measured along the prosthesis outer surface **16**, not includ-

ing the diameter of the separate filament **48**; has an overall height of about 0.56 mm to about 2.6 mm; and combinations thereof

**[0109]** Where a prosthesis has more than one scaffolding filament section or separate filament, the protruding scaffolding filament sections **42** or protruding sections **50** may have the same orientation, for example a right hand orientation (see e.g. FIG. 2). Further, the protruding scaffolding filament sections **42** or protruding sections **50** may be substantially aligned about the circumference of the prosthesis **10** (see e.g. FIG. 2 where the protruding scaffolding filament sections **42** have substantially the same longitudinal position but different circumferential positions).

#### C.1.b. Mesh Regions

**[0110]** As discussed above, the protruding element **40** may be a protruding mesh region **44** (see e.g. FIG. 9). The scaffolding filament(s) **20** forming the mesh **22** and the protruding mesh region **44** may have a uniform braid angle. In other words, the braid angle of the scaffolding filament(s) **20** in the protruding mesh region **44** is the same as the braid angle of the scaffolding filament(s) **20** in the rest of the mesh **22**. An example of a suitable uniform braid angle is 100°.

**[0111]** The protruding mesh region **44** includes a plurality of scaffolding filament crossings **26** positioned above the prosthesis outer surface **16** which is defined by the cover **60** (see e.g. FIG. 9). The protruding mesh region **44** has a rounded shape with no sharp bends or turns (see e.g. FIG. 9). Attributes of bends/turns that are not sharp are discussed above.

**[0112]** The protruding mesh region **44** has a longitudinal extent/distance  $d$  measured from a first end/edge of the protruding mesh region **44** to a second end/edge of the protruding mesh region **44**. The longitudinal distance  $d$  of the protruding mesh region **44** is sized so that the mesh scaffolding provides the cover **60** with sufficient support to withstand pressure applied by tissue ingrowth so that the cover **60** is not damaged or broken by tissue ingrowth when the prosthesis **10** is implanted. The longitudinal distance  $d$  may be about 2 mm to about 10 mm. The gap height  $h$  of the protruding mesh region **44** is variable. The maximum gap height  $h$  of the protruding mesh region is about 0.5 mm to about 2 mm. The area of the gap **56** defined by a protruding mesh region **44** depends on the diameter of the prosthesis **10**, the gap height  $h$ , and the longitudinal distance  $d$  of the protruding mesh region **44**.

**[0113]** A prosthesis **10** may have one or a plurality of protruding mesh regions **44**. For a prosthesis **10** with a plurality of protruding mesh regions **44**, adjacent protruding mesh regions **44** are separated by a minimum longitudinal distance of about 20 mm.

#### C.1.c. Ring Turns

**[0114]** As discussed above, the prosthesis **10** may have a single layer of scaffolding **18** and a protruding element **40** (see e.g. FIGS. 10-11). The protruding element **40** may be a protruding ring turn **46** of a ring **28**. Where the protruding element **40** is a protruding ring turn **46**, the cover **60** may have a thickness of about 40  $\mu\text{m}$  to about 400  $\mu\text{m}$ .

**[0115]** A ring **28** with a protruding ring turn **46** may be described as having a first diameter  $27a$  at a first ring end and a second, greater, diameter  $27b$  at a second ring end (see e.g.

FIG. 12). When a ring 28 with a larger diameter at the second ring end than the first ring end is incorporated into a prosthesis 10, the ring turns 30 at the second ring end are protruding ring turns 46 (see e.g. FIG. 12). Thus, the entire second ring end may be described as a protruding element 40.

[0116] A ring 28 with a protruding ring turn 46 may have a single, uniform slope or angle  $\beta$  from the first ring end to the second ring end. This type of ring 28 can be described as a truncated cone (see e.g. FIG. 12). It is noted that even when a section 32 of the scaffolding filament 20 includes a bend, the ring 28 has a single uniform slope or angle  $\beta$  because the bend does not affect the distance of the protruding ring turn from the outer surface of the cover 60. Alternatively a ring 28 with a protruding ring turn 46 may have a cylindrical section and a truncated cone section, where the cylindrical section forms one end of the ring 28 and has a uniform diameter, and the truncated cone section forms the other end of the ring 28 and has a single, uniform slope or angle from the cylindrical section to the end of the ring 28. A ring 28 with either of these two configurations has protruding ring turns 46 that extend outwardly at a single uniform slope or angle  $\beta$ .

[0117] As discussed above, the ring 28 has a longitudinal length. About 25-75% of the longitudinal length of the ring 28, as measured from the first and second ring ends, may be positioned above the outer surface of the cover 60. Thus for a ring 28 in the shape of a truncated cone, a protruding ring turn 46 may include a portion of each of the two sections 32 connected the protruding ring turn 46 (see e.g. FIG. 13A). For a ring 28 with a cylindrical section and a truncated cone section, the truncated cone section is constructed and arranged to be positioned above the outer surface of the cover 60. Thus, the truncated cone section may have a length of about 25% to about 75% of the longitudinal length of the ring 28.

[0118] The protruding ring turn 46 has a gap height  $h$  of about 0.25 mm to about 4 mm, preferably about 0.25 mm to about 2 mm (see e.g. FIGS. 13A-B). For a given uniform slope  $\beta$ , the gap height  $h$  correlates either to the percentage of the longitudinal length of the ring 28 or to the percentage of the truncated cone section that is positioned above the outer surface of the cover 60. For example, for a given uniform slope  $\beta$ , the greater the percentage of the ring or truncated cone section that is positioned above the outer surface of the cover, the greater the gap height  $h$ . In other words, the gap height  $h$  at 25% is greater than the gap height  $h$  at 75%. For a given gap height  $h$ , the uniform slope  $\beta$  correlates to the percentage of the longitudinal length of the ring 28 or the percentage of the truncated cone section that is positioned above the outer surface of the cover 60. For example, for a given gap height  $h$ , the greater the percentage of the ring or truncated cone section that is positioned above the outer surface of the cover, the greater the uniform slope  $\beta$ . In other words, a greater uniform slope  $\beta$  is needed to obtain a given gap height when 75% is positioned above the outer surface of the cover than when 25% is positioned above the outer surface of the cover.

[0119] A prosthesis 10 has at least one ring 28 with a protruding ring turn 46. A prosthesis 10 may comprise only rings 28 having at least one protruding ring turn 46 (see e.g. FIG. 10); or a combination of rings 28a having at least one protruding ring turn 46, and rings 28b having no protruding ring turns (see e.g. FIG. 11). The protruding ring turns 46 of

a prosthesis 10 may be oriented toward the same prosthesis end 12, 14, or may be oriented towards both prosthesis ends 12, 14 (see e.g. FIGS. 10-11). An individual ring 28 may have protruding ring turns 46 facing toward only one prosthesis end 12, 14, or protruding ring turns 46 facing both prosthesis ends 12, 14.

### C.2. Inwardly Extending Controlled Ingrowth Feature/Dimple

[0120] A controlled ingrowth feature 40 that extends inwardly can be described as an inwardly extending controlled ingrowth feature or as a dimple (hereinafter referred to as a “dimple”). In other words, a dimple 40 is positioned a smaller distance from, or is closer to, the longitudinal axis of the prosthesis than the prosthesis outer surface 16 (see e.g. FIGS. 15-21C). As used in this disclosure, a “dimple” extends inwardly from a prosthesis outer surface 16 of an implanted prosthesis and has an edge positioned at the prosthesis outer surface 16. For a prosthesis 10 comprising a dimple 40, the prosthesis outer surface 16 is defined by the cover 60.

[0121] A dimple 40 may be entirely formed by a portion of the cover 60 extending over the outer surface of the scaffolding 18 (see e.g. FIGS. 15-18 and 20); may be formed by a portion of the cover 60 and a portion of the scaffolding 18 (see e.g. FIG. 19); may be formed by a dimple patch 68 (see e.g. FIGS. 21A-C); and combinations thereof.

[0122] A dimple 40 has a longitudinal extent (distance  $d$ ) measured along the prosthesis outer surface 16 of about 1 mm to about 10 mm; a circumferential extent measured along the prosthesis outer surface 16 of about 1 mm to about 10 mm; an area of about 1 mm<sup>2</sup> to 100 mm<sup>2</sup>, preferably about 5 mm<sup>2</sup> to about 50 mm<sup>2</sup>, most preferably 25 mm<sup>2</sup>; and combinations thereof. Where the longitudinal or circumferential extent is variable, the longitudinal/circumferential extent refers to the maximum extent.

[0123] As discussed above, the pre-determined amount of tissue ingrowth depends in part on the amount of the prosthesis outer surface 16 that is formed by the dimple(s) 40. The dimple(s) cover a maximum of about 30% of the scaffolding outer surface. The dimple(s) 40 may cover about 1% to about 30% of the scaffolding outer surface, preferably about 5% to about 20% of the scaffolding outer surface, and most preferably 10% of the scaffolding outer surface.

[0124] When the prosthesis 10 expands to an implanted diameter, the dimple 40 defines a gap 56 for tissue ingrowth (see e.g. FIGS. 16B and 17-19). The gap 56 of a dimple 40 may also be described as a dimple gap or dimple recess. It is noted that the dimple 40 may or may not extend inward into the prosthesis lumen at other times (e.g. during delivery). A dimple 40 may define one (1) dimple gap 56 (see e.g. FIGS. 17-19); or a plurality of dimple gaps 56 (see e.g. FIG. 16B). The dimple gap 56 is constructed and arranged so that the dimple 40 does not exert suction on the lumen wall when the prosthesis 10 is implanted. A dimple gap 56 may extend inward through a single scaffolding opening 24 (see e.g. FIG. 16B) or span several scaffolding openings (see e.g. FIGS. 18 and 20-21). The scaffolding opening 24 into which the dimple 40 extends may have a size equal to the other scaffolding openings 24 (see e.g. FIG. 16B), or greater than the other scaffolding openings 24 (see e.g. FIG. 17).

[0125] The dimple gap 56 has a maximum gap height  $h$  measured from the outer surface of the cover 60 to the bottom of the dimple gap 56 (see e.g. FIGS. 16B-19). The

maximum gap height  $h$  is about 0.5 mm to about 3 mm, preferably about 1 mm to about 2 mm, and most preferably about 1.5 mm. The overall size of the dimple gap **56** depend at least in part on the size of the scaffolding openings **24**; the gap height  $h$ ; and combinations thereof (see e.g. FIGS. **16** and **21**).

**[0126]** A prosthesis **10** with a dimple **40** may have a single layer of scaffolding **18** (see e.g. FIGS. **16-19** and **21-22**) or two layers of scaffolding **18** (see e.g. FIG. **20**). The prosthesis **10** may have a single (1) dimple **40** or a plurality of dimples **40**. The dimple(s) **40** may be arranged in a circumferential ring (see e.g. FIGS. **15A-C** and **24 C**); helically (see e.g. FIG. **24A**); an island surrounded by a non-dimple portion of the prosthesis (see e.g. FIGS. **15A-C** and **24A-C**); and combinations thereof. Where the dimple **40** forms a circumferential ring, the ring may extend around the entire circumference of the prosthesis **10** or only a portion of the circumference of the prosthesis **10**. For each of these arrangements the dimple **40** covers only a portion of the outer surface area of the prosthesis **10** and only a portion of the inner surface area of the prosthesis **10**.

#### C.2.a. Inwardly Extending Controlled Ingrowth Feature/Dimple Entirely Formed by Cover

**[0127]** As discussed above, a dimple **40** may be entirely formed by the cover **60** (see e.g. FIGS. **15-18** and **20**). Thus the cover **60** has at least one dimple cover section **64** forming a dimple **40**. Each dimple cover section **64** is entirely surrounded by a non-dimple cover section **66** of the cover **60** (see e.g. FIG. **15A**). As used herein a “non-dimple cover section” is a section of the cover **60** that has a size equal to the size of the scaffolding covered thereby, and a “dimple cover section” is a section of the cover **60** that has a size greater than the size of the scaffolding covered thereby.

**[0128]** A cover **60** with a dimple cover section **64** and a non-dimple cover section **66** may have a uniform thickness. In other words, the thickness of the dimple cover section **64** is equal to the thickness of the non-dimple cover section **66**.

**[0129]** Scaffolding **18** may extend over a gap **56** formed by the dimple **40** (see e.g. FIG. **20**). The scaffolding extending over the gap **56** may be a portion of the scaffolding **18** forming the prosthesis (see e.g. FIG. **18**), or a scaffolding patch **18b** attached to the prosthesis outer surface **16** (see e.g. FIG. **20**). Where the scaffolding extending over the gap is a portion of the scaffolding **18**, the prosthesis **10** has a single layer of scaffolding **18**.

**[0130]** Where the scaffolding extending over the gap **56** is a scaffolding patch **18b**, the prosthesis **10** may be described as having two layers of scaffolding. However, only one of the two layers of scaffolding extends from the first prosthesis end **12** to the second prosthesis end **14**. The other layer of scaffolding **18**, the scaffolding patch **18b**, has a patch longitudinal extent  $pd$  and a patch circumferential extent that is sufficiently large to cover the gap **56** but extends over only a portion of the scaffolding **18**. In other words, the area of the scaffolding patch **18b** is less than the outer surface area of the prosthesis **10**. A scaffolding patch may be attached to the prosthesis outer surface **16** by any suitable means.

#### C.2.b. Inwardly Extending Controlled Ingrowth Feature/Dimple Formed by Cover and Scaffolding

**[0131]** As discussed above, a dimple **40** may be formed by a portion of the cover **60** and a portion of the scaffolding **18**

(see e.g. FIG. **19**). Hereinafter, this type of dimple is referred to as a reinforced dimple **40**. Because the scaffolding **18** forms a part of the reinforced dimple **40**, the prosthesis **10** has a variable diameter.

**[0132]** The scaffolding **18** of a reinforced dimple **40** may be positioned between the outer and inner surface of the reinforced dimple, or may form a part of the inner surface of the reinforced dimple.

#### C.2.c. Inwardly Extending Controlled Ingrowth Feature/Dimple Patch

**[0133]** As discussed above, a dimple **40** may be formed by a dimple patch **68** (see e.g. FIGS. **21A-C**). The dimple patch **68** may cover an area **36** with no cover (see e.g. FIG. **21B**). The size of the area **36** may be greater than the size of the scaffolding openings **24**. The size of the dimple patch **68** is greater than the size of the area **36** but less than the size of the cover **60**. In other words, the surface area covered by the dimple patch **68** is less than outer surface area of the cover **60**. The size of the dimple patch **68** is also sufficiently large to form a dimple **40** when the prosthesis is implanted.

**[0134]** The area **36** may include scaffolding **18** (portion of scaffolding with no cover, see e.g. FIGS. **21B-C**); or no scaffolding. Any suitable means can be used to form an area **36** with no scaffolding. For example, a region of the scaffolding **18** may be removed leaving an opening with a greater size than the scaffolding openings **24**; or formation of the area **36** may be a part of forming the scaffolding, e.g. forming the scaffolding includes forming a scaffolding opening **24** that is larger than other scaffolding openings **24**.

**[0135]** As can be seen in FIGS. **21A-C**, the dimple patch **68** is attached to the prosthesis outer surface **16**. The dimple patch **68** may be attached to the prosthesis outer surface **16** by any suitable means.

**[0136]** A scaffolding patch may be combined with a dimple patch **68**. The scaffolding patch has a size equal to or less than the size of the dimple patch. The scaffolding patch may be positioned over the dimple patch **68**. This configuration may look similar to that shown in FIG. **20** except that the wall of the prosthesis will have three layers, an inner layer of scaffolding; a middle layer formed by the dimple patch **68** extending over an area **36**; and an outer layer formed by the scaffolding patch. This type of dimple patch can be described as a reinforced dimple patch. Alternatively, the scaffolding patch may be positioned between the inner and outer surfaces of the dimple patch.

#### D. Optional Prosthesis Features

**[0137]** A prosthesis **10** as described above may include one or more areas, bands, coatings, members, etc. that is (are) detectable by imaging modalities such as X-Ray, MRI, ultrasound, etc. In one aspect at least a portion of the prosthesis **10** is at least partially radiopaque.

**[0138]** A prosthesis **10** as described above may be configured to include one or more mechanisms for the delivery of a therapeutic agent. As used in this disclosure, a “therapeutic agent” is a drug or other pharmaceutical product used to treating, preventing, or alleviating the symptoms of disease, and is not a cover **60** as disclosed herein. Therapeutic agents include non-genetic agents, genetic agents, cellular material, etc. Often the agent will be in the form of a coating or other layer (or layers) of material placed on a surface region of the prosthesis, which is adapted to be

released at the site of the prosthesis' implantation or areas adjacent thereto. In some embodiments, the controlled ingrowth feature **40** has a therapeutic agent deposited thereon.

#### Prosthesis Examples

[0139] Exemplifications of a prosthesis **10** as described above are provided by the following non-limiting examples.

##### Example 1

[0140] FIG. 2 shows an example of a prosthesis **10** with at least protruding element **40**. Specifically, the prosthesis **10** has a single layer of scaffolding **18** in the form of a mesh **22** with a protruding scaffolding filament section **42**; and a cover **60**.

[0141] The prosthesis has a longitudinal length of 102 mm. The end regions of the prosthesis **10** have a greater diameter than the middle region, with the end regions having a diameter of 30 mm, and the middle region having a diameter of 23 mm.

[0142] The scaffolding **18** is formed from **24** scaffolding filaments **20** each having a diameter of 0.009 mm, and comprises Nitinol. The scaffolding filaments **20** are braided at a uniform braiding angle.

[0143] The cover **60** is non-porous.

[0144] In this example, each scaffolding filament **20** with a right hand orientation has a protruding scaffolding filament section **42** extending between two scaffolding filament crossings **26** immediately adjacent one another, and each protruding scaffolding filament section **42** has a closed gap **56** and a rounded shape with no sharp bends. Further, the protruding scaffolding filament sections **42** are substantially aligned about the circumference of the prosthesis **10**. As can be seen a right hand orientation is non-parallel to the longitudinal axis of the prosthesis.

##### Example 2

[0145] FIG. 9 shows another example of a prosthesis **10** with at least one controlled tissue ingrowth feature **40**. Specifically, the prosthesis **10** has a single layer of scaffolding **18** in the form of a mesh **22** with two protruding mesh regions **44a**, **44b**; and a cover **60**.

[0146] The prosthesis **10** has a diameter of 23 mm and a longitudinal length of 150 mm. The prosthesis **10** may have a uniform diameter except for the protruding mesh regions **44**. However, the ends of the prosthesis, not shown in FIG. 9, may have a greater diameter than the uniform diameter section shown in FIG. 9. The scaffolding **18** is formed from **24** scaffolding filaments **20** each having a diameter of 0.008 mm and comprises Nitinol.

[0147] The cover **60** is non-porous and has a thickness of 40  $\mu\text{m}$ .

[0148] Each protruding mesh region **44a**, **44b** forms a circumferential ring that extends around the entire circumference of the prosthesis; has a gap height  $h$  of 1 mm; and a longitudinal distance  $d$  of 10 mm. A longitudinal distance of 40 mm separates the two protruding mesh regions **44a**, **44b** and each protruding mesh region **44a**, **44b** is 45 mm from the closest prosthesis end **12**, **14**.

##### Example 3

[0149] FIG. 10 shows another example of a prosthesis **10** with at least one protruding element **40**. The prosthesis **10** shown in FIG. 10 is constructed and arranged for implantation in the esophagus.

[0150] The prosthesis has a longitudinal length, and prosthesis end regions with a greater diameter than the prosthesis middle region.

[0151] The prosthesis **10** has a single layer of scaffolding **18** consisting of rings **28** with protruding ring turns **46**; and a cover **60**.

[0152] The prosthesis **10** has rings **28** with protruding ring turns **46**. Half of the rings **28** have protruding ring turns **46** oriented towards the second prosthesis end **14**, and half of the rings **28** have protruding ring turns **46** oriented towards the first prosthesis end **12**. Adjacent rings **28** are separated by a uniform longitudinal distance **34**.

[0153] The cover **60** is non-porous and comprises silicone.

##### Example 4

[0154] FIG. 11 shows another example of a prosthesis **10** with at least one protruding element **40**. The prosthesis **10** shown in FIG. 11 is constructed and arranged for implantation in the stomach.

[0155] The prosthesis **10** has a single layer of scaffolding **18** formed of rings **28** where at least some of the rings **28** have protruding ring turns **46**; and a cover **60**.

[0156] The prosthesis **10** has a longitudinal length and a variable diameter with a minimum diameter of 15 mm, and a maximum diameter of 40 mm. Adjacent rings **28** are separated by a variable longitudinal distance (e.g. distances **34a**, **34b**). The rings **28** include rings **28a** with a protruding ring turn **46**, and rings **28b** with no protruding ring turns **46**. The rings **28a** with protruding ring turns **46** are arranged in two groups. Within each group the protruding ring turns **46** of an individual ring **28a** are oriented towards one prosthesis end and the adjacent ring **28a** is oriented toward to other prosthesis end **12**, **14**. In other words, within a group of rings **28a**, the orientation of the protruding ring turns **46** alternates.

[0157] Each ring **28** is formed by a scaffolding filament **20** comprising Nitinol.

[0158] The cover **60** is non-porous.

##### Example 5

[0159] FIGS. 15A-C show examples of a prosthesis with a dimple **40**. Specifically, the prosthesis **10** has a single layer of scaffolding **18** in the form of a mesh **22**, and a cover defining at least one dimple **40**.

[0160] The prosthesis has a longitudinal length of 100 mm and a diameter of 24 mm. The cover **60** has a thickness of 0.05-0.15 mm and forms the prosthesis outer surface **16**. The cover **60** has a plurality of dimple sections **64** each forming a dimple **40**; and a non-dimple section **66**.

[0161] Each dimple **40** is positioned at least 15 mm from the closest prosthesis end **12**, **14**; has a maximum longitudinal extent of 12.7 mm; a maximum circumferential extent of 6 mm; and define a gap of 2 mm. The dimples **40** are aligned circumferentially and longitudinally. For the prosthesis **10** shown in FIG. 15A, longitudinally adjacent dimples **40** are positioned 44.6 mm apart.

## Methods of Manufacture

[0162] In general, forming a prosthesis as described above includes: forming the scaffolding; forming a controlled ingrowth feature; and applying a cover to the scaffolding. Forming the controlled ingrowth feature may be a part of forming the scaffolding; a part of forming the cover; or a separate step. Thus, when the prosthesis is formed, the prosthesis has a scaffolding; a cover; and a controlled ingrowth feature. Manufacturing or formation of the prosthesis is completed before the prosthesis is engaged to a delivery device.

## Method 1

[0163] An exemplary method of forming a prosthesis 10 with a protruding element 40 formed by a separate filament 48 includes one or more of the following: forming the scaffolding 18 by interweaving a scaffolding filament 20 into a mesh; securing a separate filament 48 to the scaffolding 18; forming a protruding element 40 from the separate filament 48, the protruding element 40 being a section 50 of the separate filament 48; applying a cover 60 to the scaffolding 18; wherein securing the separate filament 48 to the scaffolding 18 further comprises securing each end region 52, 54 of the separate filament 48 to the scaffolding 18; wherein the end regions 52, 54 may be secured by interweaving into the scaffolding 18; by bonding to the scaffolding 18; by welding to the scaffolding 18; by wrapping the end regions 52, 54 around a scaffolding filament 20; and combinations thereof; wherein the scaffolding 18 is formed before the separate filament 48 is secured to the scaffolding 18; wherein the scaffolding filament 20 is interwoven on a mandrel; wherein the mandrel has a constant diameter; wherein the mandrel has end mandrel regions with a greater diameter than a middle mandrel region; and combinations thereof.

## Method 2

[0164] An exemplary method of forming a prosthesis 10 with a protruding element 40 formed by a scaffolding filament 20 includes one or more of the following: forming the scaffolding 18 by interweaving a scaffolding filament 20 into a mesh; forming a protruding element 40 from a section 42 of the scaffolding filament 20; applying a cover 60 to the scaffolding 18; wherein the scaffolding filament is interwoven on a mandrel; wherein the mandrel has a constant diameter; wherein the mandrel has end mandrel regions with a greater diameter than a middle mandrel region; and combinations thereof.

[0165] A prosthesis formed by this method can have only protruding elements 40 with open gaps; only protruding elements with closed gaps; or a combination of protruding elements 40 with open gaps and protruding elements 40 with closed gaps.

## Method 3

[0166] An exemplary method of forming a prosthesis 10 with a protruding mesh region 44 includes one or more of the following: forming the scaffolding 18 by interweaving a scaffolding filament 20 into a mesh; forming a protruding mesh region 44; and applying a cover 60 to the scaffolding 18, wherein the protruding element 40 is positioned above the cover 60; removing the covered prosthesis from the mandrel; interweaving the scaffolding filament 20 on a

mandrel; wherein the mandrel has a constant diameter; wherein the mandrel has end mandrel regions with a greater diameter than a middle mandrel region; and combinations thereof.

## Method 4

[0167] In one aspect, a method of forming a ring 28 with protruding ring turns 46 includes one or more of the following: forming a ring with a plurality of interconnected ring turns 30; wherein forming the ring with the plurality of interconnected ring turns 30 comprises winding a single (1) scaffolding filament 20 around a mandrel and securing the ends of the scaffolding filament 20; wherein securing the ends of the scaffolding filament 20 comprises welding, joining by clips, applying adhesive, and combinations thereof; wherein the mandrel 84 includes a tapered section with a first mandrel diameter  $md1$  and a second mandrel diameter  $md2$  greater than the first diameter, and a slope from the first mandrel diameter to the second mandrel diameter (see e.g. FIG. 14); wherein the slope from the first mandrel diameter to the second mandrel diameter provides for the uniform angle  $\beta$  of the ring 28 from the first diameter 27a to the second diameter 27b; wherein the mandrel further includes a cylindrical section with a second uniform mandrel diameter; wherein the slope of the tapered section of the mandrel from the cylindrical section to the second mandrel diameter provides for the uniform angle  $\beta$  of the ring from the cylindrical section of the ring to the second diameter of the ring; wherein the ring turns 30 formed at the second mandrel diameter will be protruding ring turns 46 when incorporated into a prosthesis 10; wherein the mandrel includes protrusions extending outwardly from the outer surface of the mandrel 84; wherein the single scaffolding filament 20 further forms a plurality of sections 32, each section 32 extending between two ring turns 30; wherein forming the ring with the plurality of interconnected ring turns 30 comprises injection molding a filament material into a mold with a desired shape for the ring; wherein the filament material is polymeric; wherein the prosthesis 10 has a single layer of scaffolding 18; and combinations thereof

## Method 5

[0168] An exemplary method of forming a prosthesis 10 includes one or more of the following: mounting the rings 28 onto a mandrel, each ring 28 comprising a plurality of interconnected ring turns 30, at least one of the rings 28 has a first end with a smaller diameter than a second end; applying a cover 60, the cover 60 interconnecting the rings 28; wherein the mandrel has a constant diameter; removing the prosthesis 10 from the mandrel; wherein the mandrel has end regions with a greater diameter than a mandrel middle region; wherein all of the rings have a first end with a smaller diameter than a second end; wherein dip-coating is used for applying the cover; wherein spray-coating is used for applying the cover; wherein the cover comprises silicone; and combinations thereof.

## Method 6

[0169] An exemplary method of forming a cover 60 with a dimple cover section 64 comprises one or more of the following: forming a cover template 94 with a dimple; mounting a film in dimple forming device 90; forming a dimple 40 in the film; wherein the dimple forming device



comprises a plate **92** with a surface defining an indentation; wherein the pattern of the indentation corresponds to a predetermined pattern for the cover **60**; wherein forming a dimple in the film comprises pressing the film into the indentation; wherein the film comprises polytetrafluoroethylene; and combinations thereof.

[0170] An exemplary cover template **94** with template dimples **96** is shown in FIG. **23**. An exemplary device for forming a cover template **94** is the device **90** shown in FIG. **23**. Although the device **90** shown in FIG. **23** has two plates **92**, a single plate **92** may be used. One plate **92** has at least one plate dimple or indentation in the surface of the plate.

#### Method 7

[0171] An exemplary method of forming a prosthesis **10** with at least one dimple **40** comprises one or more of the following: mounting the scaffolding **18** on a mandrel **84** with a recess **86**; applying coating material to the mounted scaffolding; wherein the scaffolding is positioned a distance above the recess **86**; wherein the scaffolding **18** conforms to the recess **86**; wherein dip-coating is used for applying the material of the cover **60**; wherein spray-coating is used for applying the material of the cover **60**; wherein the material of the cover **60** comprises silicone; and combinations thereof.

[0172] A schematic example of a mandrel **84** with a recess **86** is provided in FIG. **22**.

#### Method 8

[0173] An exemplary method of forming a prosthesis **10** with a dimple **40** comprises one or more of the following: securing a cover **60** with a dimple **40** to an expandable prosthesis **10**, the expandable prosthesis defining a plurality of scaffolding openings **24**; wherein the cover **60** forms a prosthesis outer surface **16**; wherein the cover **60** is secured to the prosthesis by an adhesive; wherein the cover **60** is secured to the prosthesis by a suture; wherein the scaffolding **18** has a uniform diameter; and combinations thereof.

#### Method 9

[0174] An exemplary method of forming a prosthesis **10** with a reinforced dimple **40** comprises one or more of the following: forming a scaffolding **18** comprising a first region with a first diameter and a second region with a second diameter greater than the first diameter; applying a cover material to the scaffolding; wherein the coated first region is a reinforced dimple; wherein the first region extends around the circumference of the prosthesis.

#### Method 10

[0175] An exemplary method of forming a prosthesis **10** with a dimple patch **68** comprises one or more of the following: forming an opening in a side wall of an expandable prosthesis **10**; and attaching a dimple patch **68** to the expandable prosthesis so that the dimple patch covers the opening formed in the side wall, wherein the dimple patch is sized to extend inward into the opening of the side wall when the prosthesis is implanted; wherein forming the opening in the side wall is part of forming the scaffolding of the expandable prosthesis; wherein forming the opening in the side wall comprises removing a part of a scaffolding of the prosthesis; wherein the expandable prosthesis is selected from the group consisting of stents; covered stents; and

stent-grafts; wherein the dimple patch is reinforced with a secondary scaffolding, the secondary scaffolding positioned between an inner surface and an outer surface of the dimple patch; wherein the dimple patch comprises silicone; and combinations thereof.

### Materials

#### Cover/Dimple Patch

[0176] Suitable materials for the cover **60** and the dimple patch include any other type of material that prevents tissue ingrowth therethrough. In one aspect, the cover **60** is non-porous. Non-limiting examples include silicone elastomers, polyurethane, polystyrene-polyisobutylene-polystyrene triblock copolymer (SIBS), polytetrafluoroethylene (PTFE), expanded polytetrafluoroethylene (ePTFE), and combinations thereof

#### Scaffolding/Separate Filament/Scaffolding Patch

[0177] The scaffolding **18**, the separate filament **48**, and scaffolding patch may be balloon expandable or self-expandable, and may be made from any suitable biocompatible materials including one or more polymers, one or more metals or combinations of polymer(s) and metal(s). Examples of suitable metals include, but are not limited to, stainless steel, titanium, tantalum, platinum, tungsten, gold and alloys of any of the above-mentioned metals. Examples of suitable alloys include platinum-iridium alloys; cobalt-chromium alloys including Elgiloy and Phynox; nickel-cobalt-chromium-molybdenum alloy such as MP35N; and nickel-titanium alloys, for example, Nitinol; and doped ternary alloys such as NiTiCo and NiTiCr.

[0178] The scaffolding **18** may be made of shape memory materials (metallic such as Nitinol; or polymeric, e.g. polyethylene terephthalate (PET)); or may be made of materials which are plastically deformable. Shape memory materials may be processed to have a shape memory effect or super-elasticity. In the case of shape memory materials with a shape memory effect, the prosthesis may be processed to have a memorized shape, and then deformed to a reduced diameter shape for delivery to a body lumen. The prosthesis may restore itself to its memorized shape in a body lumen upon being heated to a transition temperature and having any restraints removed therefrom.

[0179] The scaffolding **18** may be made of biodegradable or bioabsorbable materials will undergo breakdown or decomposition into harmless compounds as part of a normal biological process. Suitable biodegradable or bioabsorbable materials include polylactic acid, polyglycolic acid (PGA), collagen or other connective proteins or natural materials, polycaprolactone, hyaluric acid, adhesive proteins, co-polymers of these materials as well as composites and combinations thereof and combinations of other biodegradable polymers. Other polymers that may be used include polyester and polycarbonate copolymers.

#### Therapeutic Agents

[0180] Some examples of suitable non-genetic therapeutic agents include but are not limited to: anti-thrombogenic agents such as heparin, heparin derivatives, vascular cell growth promoters, growth factor inhibitors, Paclitaxel, etc. Where an agent includes a genetic therapeutic agent, such a genetic agent may include but is not limited to: DNA, RNA

and their respective derivatives and/or components; hedgehog proteins, etc. Where a therapeutic agent includes cellular material, the cellular material may include but is not limited to: cells of human origin and/or non-human origin as well as their respective components and/or derivatives thereof. Where the therapeutic agent is delivered by a polymer agent, the polymer agent may be a polystyrene-polyisobutylene-polystyrene triblock copolymer (SIBS), polyethylene oxide, silicone rubber and/or any other suitable substrate.

**[0181]** The above disclosure is intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in this art. The various elements shown in the individual figures and described above may be combined or modified for combination as desired. All these alternatives and variations are intended to be included within the scope of the claims where the term “comprising” means “including, but not limited to”.

**[0182]** Further, the particular features presented in the dependent claims can be combined with each other in other manners within the scope of the disclosure such that the disclosure should be recognized as also specifically directed to other embodiments having any other possible combination of the features of the dependent claims. For instance, for purposes of claim publication, any dependent claim which follows should be taken as alternatively written in a multiple dependent form from all prior claims which possess all antecedents referenced in such dependent claim if such multiple dependent format is an accepted format within the jurisdiction (e.g. each claim depending directly from claim 1 should be alternatively taken as depending from all previous claims). In jurisdictions where multiple dependent claim formats are restricted, the following dependent claims should each be also taken as alternatively written in each singly dependent claim format which creates a dependency from a prior antecedent-possessing claim other than the specific claim listed in such dependent claim below.

**[0183]** This completes the description of the disclosure. Those skilled in the art may recognize other equivalents to the specific embodiment described herein which equivalents are intended to be encompassed by the claims attached hereto.

What is claimed is:

1. A stent, comprising:
  - a tubular scaffolding having an outer surface and an inner surface defining a lumen extending therethrough, wherein the tubular scaffolding is configured to radially expand from a delivery configuration to a deployed configuration; and
  - a protruding element extending radially outward from the outer surface in the deployed configuration;
    - wherein the tubular scaffolding is formed from at least one filament interwoven about a central longitudinal axis of the stent;
    - wherein the protruding element is formed from a portion of the at least one filament.
2. The stent of claim 1, further comprising a cover secured to the tubular scaffolding.
3. The stent of claim 2, wherein the tubular scaffolding includes a plurality of scaffold openings extending through the tubular scaffolding from the outer surface to the inner surface and the cover spans at least some of the plurality of openings.

4. The stent of claim 2, wherein the cover is configured to prevent tissue ingrowth into the lumen.

5. The stent of claim 1, wherein protruding element is configured to engage a wall of a body lumen when the tubular scaffolding is in the deployed configuration within the body lumen.

6. The stent of claim 1, wherein the protruding element defines a gap between the protruding element and the outer surface.

7. The stent of claim 1, wherein the protruding element defines a maximum radial extent measured radially outward from the outer surface, the maximum radial extent being in a range of about 0.25 millimeters to about 4 millimeters.

8. The stent of claim 7, wherein the range of the maximum radial extent is about 0.5 millimeters to about 2 millimeters.

9. The stent of claim 1, wherein the protruding element is oriented non-parallel to the central longitudinal axis of the stent.

10. A stent, comprising:

- a tubular scaffolding having an outer surface and an inner surface defining a lumen extending therethrough, wherein the tubular scaffolding is configured to radially expand from a delivery configuration to a deployed configuration; and

- a plurality of protruding elements extending radially outward from the outer surface in the deployed configuration;

- wherein the tubular scaffolding is formed from at least one filament interwoven about a central longitudinal axis of the stent;

- wherein each of the plurality of protruding elements is formed from the at least one filament.

11. The stent of claim 10, wherein the plurality of protruding elements is disposed between a first end of the tubular scaffolding and a second end of the tubular scaffolding opposite the first end.

12. The stent of claim 10, wherein the plurality of protruding elements is configured to engage a wall of a body lumen when the tubular scaffolding is in the deployed configuration within the body lumen.

13. The stent of claim 12, wherein the plurality of protruding elements permits tissue ingrowth between the plurality of protruding elements and the outer surface when engaged with the wall of the body lumen.

14. The stent of claim 12, wherein the plurality of protruding elements is configured to prevent axial migration of the stent within the body lumen in the deployed configuration.

15. The stent of claim 10, further comprising a cover extending along at least a portion of the tubular scaffolding to prevent tissue ingrowth into the lumen.

16. A stent, comprising:

- a tubular scaffolding having an outer surface and an inner surface defining a lumen extending therethrough, wherein the tubular scaffolding is configured to radially expand from a delivery configuration to a deployed configuration; and

- a protruding element extending radially outward from the outer surface in the deployed configuration;

- wherein the tubular scaffolding is formed from at least one filament interwoven about a central longitudinal axis of the stent;

wherein the protruding element is formed from a separate filament distinct from the at least one filament forming the tubular scaffolding.

**17.** The stent of claim **16**, further comprising a cover extending along at least a portion of the tubular scaffolding to prevent tissue ingrowth into the lumen.

**18.** The stent of claim **16**, wherein the separate filament is oriented parallel to one or more of the at least one filament.

**19.** The stent of claim **16**, wherein the separate filament is secured to the tubular scaffolding.

**20.** The stent of claim **16**, wherein the separate filament is interwoven into the tubular scaffolding.

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