



(43) International Publication Date
7 February 2013 (07.02.2013)

(51) International Patent Classification:
A61F 2/06 (2013.01)

(21) International Application Number: PCT/US2012/048912

(22) **International Filing Date:** 31 July 2012 (31.07.2012)

(25) **Filing Language:** English

(26) **Publication Language:** English

(30) Priority Data:
61/513,631 31 July 2011 (31.07.2011) US

(71) **Applicant:** **SCANLON, John, James** [US/US]; 1308 Hillside Boulevard, Wilmington, DE 19803 (US).

(72) **Inventor:** SCANLON, Catherine, Ann; 1308 Hillside Boulevard, Wilmington, DE 19803 (US).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP,

KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD,
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI,
NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW,
SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM,
ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— without international search report and to be republished upon receipt of that report (Rule 48.2(g))

(54) Title: FILAMENTOUS BIORESORBABLE STENT

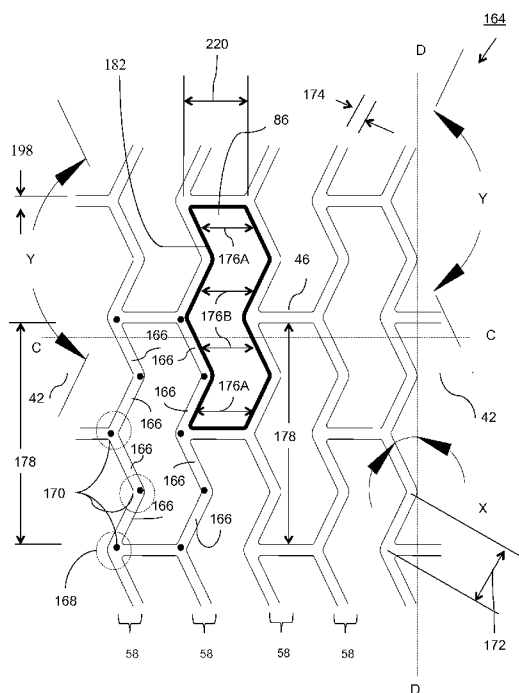


FIG. 11

(57) Abstract: Disclosed herein is a high radial strength, filament-reinforced bioresorbable stent comprising extruding a polymer into one or more small diameter filaments; stretching the extruded filaments to an optimum longer length; organizing one or more of the stretched filaments into a tubular shape; thermoforming the tubular shaped filaments to substantially retain a tubular shape; binding the filaments together with one or more bioresorbable polymers to produce a filament-reinforced tube; fabricating a stent from the filament-reinforced tube by cutting a strut pattern in the wall thickness of the tube; covering the stent with coating to delay hydrolysis and/or deliver an active ingredient to minimize the risk of restenosis; crimping the stent onto a balloon catheter assembly; delivering the stent into an anatomical lumen via percutaneous methods to a treatment location; expanding the stent at the treatment location wherein the stent temporarily supports the anatomical lumen; and removing the catheter from the lumen.

Title of Invention

FILAMENTOUS BIORESORBABLE STENT

Technical Field

The present invention relates to polymeric scaffolds that are expanded by a delivery balloon.

Background Art

Stents are endoprostheses that are generally cylindrical in shape and function to hold open and sometimes expand a segment of an anatomical lumen. The structure of a stent is typically composed of scaffolding that includes a pattern of interconnecting structural elements referred to in the art as struts. The scaffolding is designed so that the stent can be radially compressed (to allow crimping) and radially expanded (to allow deployment). In many treatment applications, the presence of a stent in a body may be necessary for a limited period of time until its intended function, for example, maintaining vascular patency and/or drug delivery is accomplished. Thus stents are sometimes fabricated from biodegradable, bioabsorbable, and/or bioresorbable ("bioresorbable") materials such that they completely erode only after the clinical need for them has ended. It is believed that bioresorbable stents allow for improved healing of the anatomical lumen as compared to a metal stent, which may lead to a reduced incidence of late stage thrombosis.

However, a shortcoming of polymer stents of bioresorbable material compared to metal stents of the same dimension is that the polymer stents typically have less radial strength. Relatively low radial strength potentially contributes to relatively high recoil of polymer stents after implantation into an anatomical lumen. In addition, the polymer stents of the prior art generally have twice the stent-to-artery coverage of metal stents, which may increase the probability of invoking restenosis or thrombosis. The polymeric struts are also more prone to cracking during crimping of a stent on a delivery catheter and during the treatment time when exposed to physiological conditions. Finally, the polymer stents of the prior art can expose the anatomical lumen to spikes in acidity when the polymer material degrades into byproducts over a short time period.

Summary of Invention

The present invention solves the aforementioned shortcomings of bioresorbable polymeric stents. Strengthening the struts and delaying the degradation of the polymer solve the fundamental problem of bioresorbable stents having insufficient radial strength. The struts are strengthened by cutting a strut pattern in a tube comprised of oriented, high tensile strength filaments optionally at least partially covered by a binder material. By covering the struts with a coating that protects the stent from the physiological conditions, the onset of degradation or slowing of the degradation of the polymer enables the stent of the present invention to provide sufficient support to the anatomical lumen for the entire treatment time. In addition, these improvements enable a stent of the present invention to have thinner struts, which enables flow through the stent with less resistance and to have a lower stent-to-artery coverage. Furthermore, the stent of the present invention is less prone to strut fractures during crimping, deployment, and treatment time. Finally, by varying the composition and thickness of the filaments, the

filaments are designed to degrade at various time intervals to avoid spikes in acidity when the polymer material degrades.

Brief Description of Drawings

FIG 1 is a perspective view of a portion of a stent.

FIG 2 is a cross-sectional view of a stent.

FIG 3 is a perspective view of a tubular precursor construct for a polymer stent.

FIG 4 is a perspective view of another tubular precursor construct for a polymer stent.

FIG 5 is a side view and cross-sectional view of another tubular precursor construct for a polymer stent.

FIG 6 is a braiding machine that is orienting and weaving filaments into a braided structure for use in a tubular precursor construct for a polymer stent.

FIG 7 is an example of braided filaments in tubular shape for use in a tubular precursor construct for a polymer stent.

FIG 8 is a winding machine that is orienting filaments into a wound structure for use in a tubular precursor construct for a polymer stent.

FIG 9 is a cross-sectional view of a strut including a coating containing active ingredients.

FIG 10 depicts a strut pattern viewed in a flat or planar state.

FIG 11 is a detailed view of an intermediate portion of the strut pattern of FIG 28.

Priority Claim

This application claims benefit of U.S. provisional patent application Ser. No. 61/513,631 filed on 31 July 2011 entitled "FILAMENTOUS SCAFFOLD HAVING STRUTS WITH HIGH SURFACE AREA."

Description of Embodiments

FIG. 1 shows a partial perspective view of an exemplary stent 40 in un-crimped or expanded state that includes a pattern of a plurality of interconnecting struts.

Stent 40 has a cylindrical shape with a central axis 42 and includes a pattern with a number of interconnecting struts 44,46 separated by openings 48. Central axis 42 extends through the center of the cylindrical shape. The stent 40 has an overall body having a tube shape with a central passageway 56 passing through the entire length of the stent. The term "tube" refers to a hollow elongated cylinder such as a channel, conduit, duct, or pipe. The central passageway has two circular openings, there being one opening at each of the distal 54 and proximal ends 52 of the overall body. In general, a strut pattern 60 (FIG 10) is designed so that the stent can be radially compressed to allow for percutaneous delivery through an anatomical lumen, and then deployed for implantation at the desired treatment site of the anatomical lumen. The strut pattern can have any geometrical configuration and is not limited to what is illustrated in FIG 1 or FIG 28. The possible variations of the strut pattern is virtually unlimited.

FIG 2 is an exemplary cross-sectional view of the stent 40 along line A-A in FIG 1. There can be any number of struts 44,46 along line A-A. In FIG 2 the cross-section of seven struts 44 are shown for ease of illustration. The struts 44 in cross-section are arranged in a circular pattern having an outer diameter 62 and inner diameter 64. The circular pattern encircles the central axis 42. A portion of the surface of each strut 44,46 faces radially inward in a direction 66 facing toward the central axis 42. A portion of the surface of each strut 44,46 faces radially outward in a direction 68 facing away from the

central axis 42. The various strut 44,46 surfaces that face radially outward collectively form the outer surface 70 of the stent 40. The various strut 44,46 surfaces that face radially inward collectively form the inner surface 72 of the stent 40.

Shown in FIG 3 is a tube 74 that serves as a stent precursor construct in the sense that further processing is performed on the tube before the pattern of stent struts is cut from the tube. The present invention is different than the prior art because the tube 74 is comprised of a wall thickness 76 including at least one high strength filament 78, multi-filament, or combinations thereof that dramatically improves the radial strength and crack resistance of the stent 40.

The filament 78 or multi-filaments are preferably comprised of a bioresorbable material 82. The term "bioresorbable" refers to any material 82 that is: biodegradable; bioabsorbable; bio-adsorbable; dissolvable; degradable; soluble; metabolizable; degradable via hydrolytic mechanism; able to disappear via chemical breakdown by physiological conditions; a macromolecule that experiences cleavage of the main chain and is broken down into by-products and can be eliminated by biological pathways such as through the kidneys or lungs; or any substance that partially or fully disappears in the living body after installation. For simplicity the terms "biodegradable," "bioresorbable," "bioabsorbable", and "bioadsorbable" are used interchangeably and synonymously in this application.

After further processing of the tube 74, a pattern of struts 44, 46 is formed on the resultant tube by removing portions of the wall thickness 76 by chemical etching, mechanical cutting, or laser cutting material away from the tube 74 wall thickness 76. Representative examples of lasers that may be used include without limitation excimer, carbon dioxide, YAG, diode lasers, ultra short pulse lasers, Er/YB-doped cw fiber lasers, pulsed Nd:YAG lasers, athermal ablation, femto second laser, lasers which emit optical pulses with a duration below 1 ps, bulk lasers (pulses with durations between 30 fs and 30 ps, fiber lasers, dye lasers, semiconductor lasers, color center lasers, free electron lasers, solid state lasers, ultra fast lasers, other equipment know by those skilled in the art of manufacturing stents.

In an embodiment as shown in FIGS 10 and 11, the strut pattern 60 includes at least a partial thermal fusion of the ends of the filaments 78, multi-filaments, or combinations thereof at the location wherein the wall thickness is cut from the tube 74. At the cutting edges 182 there is sufficient heat generated during cutting that the ends of the filaments 78 located at the cutting edges 182 are at least partially thermally fused together to connect the severed ends of the filaments in the wall thickness 76 at the juncture between the struts 44, 46 and the openings 48. For easy identification of the cutting edges 182, the lines illustrating the cutting edges are shown in bold in FIG 10 and 11.

The struts 44,46 are of any shape, width, cross section, or thickness that enables the stent 40 to have the functionality described herein. In some embodiments the cross section of the struts 44, 46 includes one or more void 84 spaces between the filaments or within the cross section of the filaments 78. Void spaces reduce the amount of material 82 to be resorbed during the treatment time and stop cracks from propagating through the wall thickness 76 should they be initiated.

As illustrated in FIG 3, the tube 74 is cylindrically shaped with an outer diameter 62, an inner diameter 64, an outer surface 70, an inner surface 72, a wall thickness 76, and a central axis 42. The cutting of the material 82 from the wall thickness 76 of the tube 74 removes sections of the wall thickness 76 in the shape of a closed cell 86 as shown in FIG 10. In other embodiments of the stent 40 of the present invention the wall thickness 76 includes open cells or hybrids of open and closed cells 86. A closed cell 86 is completely surrounded by one or more struts 44,46 and one or more struts 44,46

incompletely surround an open cell.

Without intent on limiting, the term “filament” in the present invention refers to any filaments, belts, monofilaments, multi-filaments, fibers, strands, strips, straps, tapes, threads, twine, wires, or yarns. A multi-filament is a bundle of more than one filament 78. The filaments 78 and multi-filaments are optionally individually or collectively twisted or braided prior to usage during the fabrication of the tube 74. Moreover, the tension of the filaments can be variable or constant within a single embodiment having low tension, medium tension, high tension, or combinations thereof.

Braiding, winding, or knitting one or more coated or uncoated filaments 78, multi-filaments, or combinations thereof into the shape of a tube, forms the tube 74. The preferred embodiment the tube 74 includes at least one layer 106 of the filament 78, multi-filament, or combinations thereof. The filaments comprising the wall thickness 76 are comprised of material 82 having the same or different chemical composition, the same or different molecular weight, the same or different thickness, the same or different coating, the same or different cross sectional shape, or combinations thereof.

The filaments 78, multi-filaments, or combinations thereof are optionally connected together or partially or fully encapsulated with one or more binders 108 such as a coating, adhesive, prepeg, resin, polymer, biodegradable polymer, bioresorbable polymer, or bioabsorbable polymer. The term “encapsulated” refers to the filament being substantially enclosed or surrounded by the binder 108. In other embodiments the filaments 78, multi-filaments, or combinations thereof are connected together using a fusion, a thermal weld, a solvent weld, an ultrasonic weld, a friction weld, or a weld. The binder 108 can be located on the outer surface 70, inner surface 72, between multiple layers 106 of filaments 78, between multiple layers 106 of multi-filaments, between adjacent filaments 78, between adjacent multi-filaments, or combinations thereof.

Referring to FIG 4, an example of a multi-layer embodiment of tube 74 is shown in exploded isometric view. Starting at the inner diameter, the tube 74 is comprised of an interior (“luminal”) binder layer 108A that surrounds the central passageway 56. Positioned at a farther radial distance from the central axis 42 and in direct contact with the interior layer 108A is a first layer of reinforcing filament 78A, multi-filament, or combinations thereof oriented in an axial, radial, or angled configuration. Positioned at an even farther radial distance from the central axis 42 and in direct contact with the first layer of filaments is a second layer of reinforcing filament 78B, multi-filament, or combinations thereof oriented in an axial, radial, or angled configuration. Positioned at the farthest radial distance from the central axis 42 and in direct contact with the second layer of filaments is an exterior (“abluminal”) binder layer 108B. These two layers of binder 108A, 108B and two layers of filament 78, multi-filament, or combinations thereof, are sandwiched together to form a high-strength, integrally connected network of filaments bound together in the form of a tube.

The binder 108 is applied to the oriented filaments 78, in any method that produces a tube 74 having the physical and performance specifications described herein. Without intent on limiting, the binder 108 is applied to the filaments 78, by coating, molding, or casting the binder 108 on the interior and/or exterior surface of the filament 78. Depending on the size of the tube, the thickness of the binder 108 layer preferably ranges from about 0.0001 mm to 0.2000 mm, more preferably from about 0.001 mm to 0.0800 mm, and most preferably from about 0.0010 mm to 0.0500 mm.

Without intent on limiting one possible method of positioning the binder 108 on the oriented filaments 78 first involves the step of forming a tube of oriented filaments as examples are shown in FIGs

6 and 8 by winding, braiding, knitting, and other processes. The layer or layers of binder 108 are added to tube shaped filaments. For example, a bioresorbable material 82 is dissolved in a solvent and the solution is applied to the tube shaped filaments by spraying the solution onto the surfaces of the tube. As the solvent evaporates the polymer forms a film on the surface of the filaments binding them together or encapsulating them. The solution is sprayed on the tube until the desired thickness of binder 108 is obtained.

In another possible method, the binder 108 layer is added to the filaments by solvent casting. The filaments 78 that are oriented on a mandrel are inserted into a mold having a cavity wherein there is clearance between the outside surface of the mandrel 118 and the interior of the mold. The cavity is filled with a solution of material 82 dissolved in solvent. As the solvent evaporates it forms a film of material 82 surrounding the filaments 78 on the mandrel 118 forming a binder 108 layer.

In one more possible method, the binder 108 is added to the filaments 78 by dipping the filamentous tube 74 in a vessel containing polymer material 82 dissolved in solvent. As the tube is dipped in the solution and removed the solvent evaporates leaving a film of polymer material 82 on the surface of the filaments forming a layer of the binder 108. The process is repeated until the desired thickness of the binder 108 is obtained.

In yet one more possible method, the binder 108 is added to the filaments by molding or extruding a thickness of binder on the tube formed of filaments. The binder 108 of the present invention can be added to the filaments in any way that produces a filament-reinforced tube 74 as described herein. Since the filaments are bioresorbable material 82, care must be taken not to weaken or destroy the mechanical integrity of the filaments 78 while forming the tube of filaments 78 and binder 108. The applicants found that using a lower polymer concentration in solvent produced a lower viscosity solution that was useful for penetrating the crevices of the filamentous tube and this improved adhesive strength of the tubular network. Moreover, the applicants found that using higher polymer concentrations in solvent enabled building of the thickness of the binder 108 layer to be less time consuming. Therefore, it is preferable to apply the binder 108 to the surface of the filamentous tube in layers wherein the first layer penetrates the filament crevices and the second layer builds film thickness.

The selection of solvents suitable for applying a binder 108 to the tube 74 including filaments 78 is important. The applicants found that it is important to check the compatibility of the solvent used to manufacture the binder 108 solution to ensure it does not dissolve the filaments. For example, chloroform, methylene chloride, and hexafluoroisopropanol (HFIP) are useful for making a binder solution including PLLA for application to a filament comprised of polyglycolide because PLLA is soluble in these solvents but polyglycolide is not soluble. As another example, acetone, ethyl acetate, and tetrahydrofuran (THF) are useful for making a binder solution including poly(DL-lactide) for application to a filament comprised of PLLA because poly(DL-Lactide) is soluble in these solvents, but PLLA is not soluble in these solvents. Depending on the process to apply the binder 108 to the filaments 78 one may use fast evaporating or slow evaporating solvents. A solvent chart is a useful tool for determining alternative solvents. For example, if it is found that acetone evaporates too quickly because the solution creates a stringy consistency during spray application of the solution on the tube, then a slower solvent in the same "ketone family of solvents" like methyl ethyl ketone can be tried to see if a slower evaporating solvent processes better than acetone. Solvent selection is possible by those skilled in the art of manufacturing and applying solvent based coatings.

The tube 74 can have a wall thickness 76 comprised of any configuration of layers of filament 78, multi-filaments, binder 108, or combinations thereof to achieve the performance of the stent 40 as described in this application. The variations in number of binder layers, number of filament layers, number of multi-filament layers, number of filament and multi-filament layers, orientation of filaments or multi-filaments, thickness of binder layer, thickness of filament or multi-filaments layers, materials of binder, materials of filament or multi-filaments, molecular weight of material comprising filaments, multi-filaments, and binder, is virtually unlimited and all such combinations are within the scope of the present invention.

The filament 78 and multifilament are manufactured of any material 82 providing the performance described herein. In the present invention, it is preferred that the filaments 78 and multi-filaments are comprised of one or more biodegradable materials 82 and most preferred that they are comprised of one or more bioresorbable or bioabsorbable materials. The preferred material 82 initially loses strength and then loses mass after stent 40 is implanted at the treatment location.

The filaments 78 and multi-filaments of the present invention can be of any thickness that provides the functionality described herein. However, it is preferred that the thickness of the filaments 78 be less than about 150 microns (0.0059 inch), more preferred less than about 75 microns (0.003 inch), and most preferably be less than about 50 microns (0.002 inch). The thickness of the multi-filaments depends on the number of monofilaments 78 utilized in the fabrication of the multi-filament. The multi-filaments have a tendency to flatten when tension is applied to them during formation of the tube 74. Therefore, it is difficult to specify the exact overall thickness of a multi-filament. In the present invention the multi-filament is comprised of any number of monofilaments of any thickness that produces a stent 40 having the performance described herein. However, it is preferred in the present invention to utilize multi-filaments comprised of about two to seventy-five monofilaments 78 having an average thickness of about one to fifty microns, more preferred to use multi-filaments comprised of about five to fifty monofilaments 78 having an average thickness of about one to twenty five microns, and most preferred to use multi-filaments comprised of about five to thirty monofilaments 78 having an average thickness of about one to fifteen microns.

Without intent on limiting, the filaments 78, multi-filaments, and binder 108 are comprised of one or more materials 82 selected from the following group: alpha-hydroxyesters; aliphatic polyesters; asymmetrically 3,6-substituted poly-1,4-dioxane-2,5-diones, asymmetrically 3,6-substituted poly-1,4-dioxane-2,5-diones; chitin polymers; copolymer DL-lactide/glycolide; copolymer L-lactide/epsilon-caprolactone; copolymer L-lactide/glycolide; cross linked hyaluronic acid; degradable polycarbonates; degradable polycarboxylates; desaminotyrosyl-tyrosine alkyl ester; desaminotyrosyl-tyrosine ethyl ester; homopolymer of L-lactide; hydrolyzable polyesters; iodinated poly(DTE carbonate); lactide based polymers; magnesium; magnesium based alloys; materials broken down by proteolytic enzyme process; materials susceptible to hydrolytic breakdown; poly (1,3-dioxane-2-one); poly (1,4-dioxane-2,3 dione); poly (1,5-dioxepan-2-one); poly (4 hydroxy butyrate)[P4BH]; methylmethacrylate-N-vinylpyrrolidone copolymers; poly (beta-alkanoic acid); poly (beta-dioxanone) (PDS); poly (beta-hydroxybutyrate-co-beta-hydroxyvalerate); poly (beta-hydroxybutyrate) (PHBA); poly (beta-hydroxypropionate) (PHPA); poly (beta-maleic acid) (PMLA); poly (delta-valerolactone); poly (dioxanone); poly (DL-lactide-co-glycolide) [DLPLG]; poly (DL-lactide); poly (epsilon-caprolactone); poly (ethylene oxide) (PEO); poly (glycine-co-DL-lactide); poly (glycolic acid) [PGA]; poly (glycolide-co-lactide) (PGLA); poly (glycolide-co-trimethylene

carbonate (PGA/TMC); poly (glycolide); poly (hydroxyacids); poly (hydroxybutyrate/hydroxyvalerate) [PHBV]; poly (L-lactic acid) [PLLA]; poly (L-lactide); poly (lactic acid-coglycolic acid) [PLGA]; poly (lactic acid) [PLA]; poly (lactide-co-delta-valerolactone); poly (lactide-co-epsilon-caprolactone); poly (lactide-co-ethylene oxide); poly (lactide-co-glycolide); poly (lactide-co-tetramethylene glycolide); poly (lactide-co-trimethylene carbonate); poly (orthoester) [POE]; poly (para-dioxanone); poly (trimethylene carbonate); poly (tyrosine carbonates); poly (urethane-based); poly (β -R,S-malic acid); poly-D-lactide (PDLA); poly-DL-lactide (PDLLA); poly-L-lactide (PLLA); poly(α -malic acid); polyanhydrides; polyarylates; polydihydropyranes; poly(alkyl-2-cyanoacrylate); polydioxanone polymers; polyesters of oxalic acid; polygluconate; polylactide anhydride; polymers and copolymers of glycolide; polymers and copolymers of polylactide (PLA); polymers manufactured by ring-opening polymerization; polypeptides; polyphosphoester; polysaccharides; polyvalerolactone [PVL]; polyvinyl alcohol (PVA); salicylate based polymers; salicylate-based polyanhydrides; tyrosine-derived polycarbonate; their functional equivalents, analogs, or combinations thereof.

Employing very thin filaments or monofilaments enables the material 82 to be substantially increased in strength by orienting or extending the molecular chains of material 82. For example, the tensile strength of PURASORB PLG 1017 a copolymer of L-lactide and glycolide in a 10/90 molar ratio (available from Purac as PLG 1017) can be increased in strength from about 70 MPa (10,152 psi) to about 620-930 MPa (89,923-135,00 psi) when the filament 318 is reduced to the thickness range of about 25 microns (0.001 inch) to 125 microns (0.005 inch). This strengthening process makes filaments 78 comprised of bioresorbable material 82 approximately the same or greater tensile strength as 316L stainless steel, which is commonly used in the construction of durable metallic stents. For reference, 316 stainless steel has a tensile strength of about 619 MPa (89,900 psi).

Moreover, using thin filaments 78 increases the surface area of the struts 44,46 to help manage the rate of degradation and resorption of material 82 by the living body. For example, a thick filament 78 will degrade and be resorbed slower than thin filaments 78. Therefore, in the stent 40 of the present invention in some embodiments includes filaments 78 of multiple thicknesses 92 so that the degradation of the strut 44,46 wall thickness 76 is staged to occur over different time intervals so that the thinnest filaments 78 degrade first and the thickest filaments 78 degrade last. The benefit of this embodiment is that the majority of the mass of material 82 does not have to be resorbed all at one time. This innovation is important because the hydrolysis of many bioabsorbable polymers, including lactide and glycolide-based chemistries results in the formation of carboxylic acid and alcohol groups for every bond cleaved. This build up of end groups can lead to local drops in pH. If too many of these groups form too quickly, the surrounding tissue is unable to manage the built-up of acidity and inflammation results. The present inventive stent 40 provides a solution to this problem by staging the cleavage of the molecules over time to minimize the risk of inflammation. As mentioned, the degradation and resorption rate can also be staged to occur at different periods during the treatment time by selecting materials 82 having shorter or longer degradation times or materials 82 having a higher or lower molecular weight. The time for degradation and resorption is dependant on the end use application.

As previously mentioned, an embodiment of the tube 74 consists of the steps of winding, braiding, weaving, crocheting, interlacing, or knitting the filament 78, multi-filament or combinations thereof into a tube shape. Referring to FIG 5, which is an embodiment of the tube 74 shown in cross sectional and side views, the wall thickness 76 is at least partially comprised of multiple layers 106 of

filament 78. The tube is formed of circumferential filaments 110 which are axially displaced in relation to each other and have a central axis 42 of the tube 74 as a common axis. The bottom layer 112 of filaments 78 forms the inner surface 72 and the top layer 114 of filaments 78 forms the outer surface 70 of the tube 74. The middle layer 116 of filaments 78 separates the top layer and bottom layer of filaments. The outside surface of each filament 78 at least partially touches the outside surface of each adjacent filament 78 except for in embodiments wherein the optional binder 108 may be located between filaments and partially or fully secures the filaments 78 in a tubular configuration.

An embodiment is shown in FIG 8 wherein the filament 78, multi-filament, or combinations thereof are positioned using a helical winding process 122. In this embodiment the wall thickness 76 of tube 74 is comprised of one or more angled filaments 134. The angled filaments 134 can range from zero to three hundred sixty degrees from the central axis 42. In an embodiment it is preferred that the angle 130 of at least one the filaments substantially matches the angle of the struts 44,46 to maximize the length of the remaining filaments after cutting the strut pattern 60 into the tube 74. For example, if the Y angle shown in FIG 11 is about 125 degrees, then the filament 78 or multi-filament is preferably wound at about 62.5 degrees from the central axis 42. When the angled filaments cross over each other they form a node 142, which is at least double the thickness of filaments 78, multi-filaments, or combination thereof. As previously mentioned, the process of positioning filaments 78, multi-filaments, or combination thereof oriented on the mandrel 118 at an angle can be optionally adapted to include at least one binder 108 to substantially stabilize a tube shape.

In a preferred embodiment, as shown in FIG 6, one or more filaments 78, multi-filaments, or combinations thereof are laid down on a mandrel 118 to form tube 74 having a braided wall thickness 76. The term "braid" refers to interweaving multiple filaments 76, multi-filaments, or combinations thereof into a wall thickness 78 having a tubular shape. A tubular braid is formed by crossing a number of filaments 78, multi-filaments, or combinations thereof in such a way that single or multiple filaments pass alternatively over and under filaments laid up in the opposite direction. Without intent on limiting, a braid configuration suitable for use in the present invention can be selected from the group of: (1) one over, two under, (2) two over, two under, (3) one over, two under, or (4) any suitable braid pattern or interlacements known by those skilled in the art of braiding tubes.

Still referring to FIG 6, a plurality of bobbins 126 are wound with one or more filaments 78 or multi-filaments. The filaments feeding the braiding machine may be material 82 of the same chemical composition, different chemical composition, same thickness, different thickness, material of different molecular weights, or material of same molecular weight, or combinations thereof.

Referring to FIG 7, which illustrates a side view of tube 74 having a braided wall thickness 76, the filaments 78 or multi-filaments are interlaced using a braiding machine. The filaments are interlaced so that they are oriented having a braid angle 130 in relation to the central axis 42. The braid angle 130 of the tube 74 used to fabricate stent 40 can range from zero to ninety degrees from the central axis 42. Depending on the diameter of the stent 40, there can be a wide range in the number of filaments 78 or multi-filaments employed to construct the wall thickness of the tube 76. The number of individual filaments, multi-filaments, or combinations thereof used to construct the wall thickness can range from one to about three hundred or more.

As shown in FIG 7, in some embodiments of the wall thickness 76 of the braided tube 74 the filaments are closely packed together so that the surface of each filament is at least partially touching the

surface of the adjacent filaments. In other embodiments of the braided wall thickness of tube 74 there are one or more spaces between the filaments. As known by those skilled in the art the density of the braid can be low or high by changing the tension of the filaments or by changing the take-up rate of the braiding machine. For example, slow take-up rate produces a close braid with tight plait spacing while rapid take-up creates a loose braid with more open plait spacing.

In one more embodiment the braids may include one or more additional strands called warp threads. The warp threads can be utilized to improve dimensional stability, compressive strength, crimpability, foreshortening, or expandability. The warp threads lie parallel to the central axis 42 and are generally interwoven with the diagonal tubular braid strands.

In other embodiments not shown, the wall thickness 76 is prepared of filaments by a weaving process, circumferential winding process, polar winding process, knitting process, crocheting process, nonwoven process, spun bond process, fibrillation processes, or flash spun process.

The mandrel 118 is either temporary or permanent. If the mandrel is permanent, it is tubular shape. The term "temporary" refers to a mandrel that is only utilized during the braiding, winding, weaving, knitting, or crocheting processes or during the cutting of the strut pattern 60 into the wall thickness 76 of the tube 74 to convert the tube into a stent 40. The term "permanent" refers to a mandrel 118 that is generally positioned at or near the inner diameter 64 and remains with the tube 74 and becomes incorporated into the wall thickness 76 of stent 40. The permanent mandrel 118 is made of materials 82 exactly the same or similar to that of the filaments 78, multi-filaments, or combinations thereof. The mandrel 118 provides an accurate diameter, assures even tension on the filaments or multi-filaments, and offers rigidity during fabrication of the tube 74.

The tube 74 manufactured according to the embodiments described herein optionally includes enhancements. Compressing the wall thickness 76 optionally densifies the wall thickness 76. Densification is preferably performed at a temperature between the melting temperature of the material 82 and ambient temperature and more preferably between the glass transition temperature and ambient temperature to reduce or eliminate the void spaces such as those sometimes found between the filaments 78, multi-filaments, or combinations thereof. Moreover, in another embodiment the tube 74 is at least partially constructed of filaments or multi-filaments comprised of a bioresorbable metal to enable the stent 40 to be more malleable or ductile so that it can be adjusted in size after deployment with a balloon catheter. For example, the wall thickness 76 includes at least one filament of magnesium or alloys of magnesium. A stent 40 having one or more malleable wires included in the wall thickness 76 produces a stent 40 suitable for enhanced plastic deformation similar to that of a metallic balloon expandable stent but it has the benefit of being resorbed after the treatment time. The tube 74 is also optionally enhanced by including one or more additives 150 or nano sized additives 152 in the material 82 prior to, during, or after extrusion of filaments to improve the mechanical properties of the stent 40.

Without intent on limiting, a few examples of additives 150 and nano-size 152 additives that are useful in the present invention include: agents that increase porosity, barium sulfate, bicarbonates, bismuth sub-carbonate, bismuth trioxide, buffering salts, calcium carbonate, calcium phosphates, carbon, ceramics, chalk, clay, disintegrants, excipients, glass, gold, hydrophobic modifiers, iodine, lime, minerals, monosodium phosphates, multi-wall carbon nano tubes, nano tubes, oxides, pH modifiers, phosphates, platinum, proteins, titanium dioxide, silica, tri-calcium phosphate, tungsten, combinations thereof, or other materials that improve the functionality of stent 40.

As previously discussed, the orientation of the filaments 78, multi-filaments or combinations thereof in the wall thickness 76 of the tube 74 can be circumferential (ninety degrees from the central axis 42) as shown in FIG 5. In some embodiments the filaments are oriented at an angle from the central axis ranging from zero to three-hundred-sixty degrees as examples are shown in FIGS 8. In addition to these previously discussed orientations, in an embodiment of the tube 74 it has a wall thickness 76 including one or more axial filaments wherein the filaments 78, multi-filaments, or combinations thereof are positioned in the axial direction or parallel to the central axis 42.

In another embodiment of tube 74, the wall thickness 76 includes one or more bent filaments or curved filaments. The circumferential, angled, axial, bent, or curved filaments are used in combination or independently in the same layer 106 or in different layers 106 of the wall thickness 76. The filaments 78 or multi-filaments of the tube 74 may have a bi-axial or multi-axial orientation in some embodiments wherein the some filaments are oriented in the axial direction, some in the radial direction, and some in the angled direction. The different filament orientations are sometimes on the same layer 106 and in other cases in different layers 106 of the wall thickness 76.

After organizing the filaments 78, multi-filaments, or combinations thereof into the tube shape, the tube 74 in some embodiments is thermoformed. The term "thermoform" refers to a process where the filaments, multi-filaments, or combinations thereof are heated to a pliable forming temperature, formed into a tube shape, and cooled to a finished tube shape. Thermoforming of bioresorbable materials 82 is better performed near the glass transition temperature of the material 82. For example, filaments 78 comprised of a copolymer of L-lactide and glycolide in a 10/90 molar ratio is thermoformed in the temperature range of about 35-45 degree Celsius. Higher temperature and long exposure time may have a detrimental impact on the mechanical properties of the material.

During extrusion, a polymer melt of is conveyed through an extruder, which is then formed into a filament 78. Extrusion tends to impart large forces on the material 82 molecules in the longitudinal direction of the filament due to shear forces on the material 82 melt. The shear forces arise from forcing the material 82 melt through an opening of a die at the end of an extruder. Additional shear forces may arise from any pulling and forming of the material 82 melt upon exiting the die, such as may be performed in order to bring the extruded material to the desired dimensions of a finished filament 78. As a result, the filaments 78 formed by some extrusion methods tend to possess a significant degree of molecular and/or crystal orientation in the direction that the material 82 is extruded, thereby affecting the mechanical properties, such as strength and toughness, of the extruded filament 78.

After forming the filaments 78, multi-filaments, or combinations thereof into the shape of a tube, pieces of the wall thickness 76 are cut away, leaving stent struts having the pattern 60 shown in FIG. 10. The strut pattern 60 is illustrated in a planar or flattened view for ease of illustration and clarity, and is representative of the pattern of struts before the stent is crimped or after the stent is deployed. The strut pattern 60 actually forms a tubular stent structure, as shown in FIG. 1, so that line C-C is parallel to the central axis 42 of the stent 40. FIG. 1 shows the stent in a state prior to crimping or after deployment. As can be seen from FIG. 1, the stent 40 comprises an open framework of struts that define a generally tubular body.

As shown in FIG 10, the strut pattern 60 includes various struts 44, 46 oriented in different directions and openings between the struts. Each opening and the struts 44, 46 immediately surrounding the opening defines a closed cell 86. At the proximal 52 and distal 54 ends of the stent 40, a marker strut

154 includes depressions, blind holes, or through holes adapted to hold a radiopaque marker that allows the position of the stent inside of a patient to be determined. One of the closed cells 86 is shown with cross-hatch lines to illustrate the shape and size of the cells.

The strut pattern 60 is illustrated with a bottom edge 156 and a top edge 158. On the stent 40, the bottom edge 156 meets the top edge 158 so that line D-D forms a circle around the stent central axis 42. In this way, the strut pattern 60 forms sinusoidal hoops or rings 58 that include a group of struts arranged circumferentially. The rings 58 include a series of crests 160 and troughs 162 that alternate with each other. All points on the outer surface of each ring 58 are at the same or substantially the same radial distance away from the central axis 42 of the stent 40.

In an embodiment, the stent preferably has a stent-to-anatomical lumen coverage in the range of about one to seventy-five percent, more preferably in the range of about one to twenty-five percent, and most preferably in the range of one to ten percent.

Still referring to FIG. 10, the rings 58 are connected to each other by another group of link struts 46 that have individual lengthwise axes parallel or substantially parallel to line C-C. The rings 58 are capable of being collapsed to a smaller diameter during crimping and expanded to their original diameter or to a larger diameter during deployment in a vessel.

FIG. 11 shows a detailed view of an intermediate portion 164 of the strut pattern 60 of FIG. 10. The intermediate portion 164 is located between the distal 54 and proximal 52 end rings of the stent. The rings 58 include linear ring struts 166 and curved hinge elements 168. The ring struts 166 are connected to each other by the hinge elements 168.

The hinge elements 168 are adapted to flex, which allows the rings 58 to move from a non-deformed configuration to a deformed configuration. As used herein in connection with the strut pattern 60, "non-deformed configuration" refers to the state of the rings prior to being crimped to a smaller diameter for delivery through an anatomical lumen. As used herein in connection with the strut pattern 60, "deformed configuration" refers to the state of the rings upon some type of deformation, such as crimping or deployment to a diameter greater than the original diameter prior to crimping.

Still referring to FIG 11, line D-D lies perpendicular to the central axis 42. When the rings 58 are in the non-deformed configuration, as shown in FIG 11, each ring strut 166 is oriented at an angle X. The angle X is between 20 degrees and 30 degrees, and more narrowly at or about 25 degrees. In other embodiments, the angle X can have other values.

Also, the ring struts 166 are oriented at an interior angle Y relative to each other prior to crimping. The interior angle Y is between 120 degrees and 130 degrees, and more narrowly at or about 125 degrees. In combination with other factors such as radial expansion, having the interior angle be at least 120 degrees results in high hoop strength when the stent is deployed. Having the interior angle be less than 180 degrees allows the stent to be crimped while minimizing damage to the stent struts during crimping, and may also allow for expansion of the stent to a deployed diameter that is greater than its initial diameter prior to crimping. In other embodiments, the interior angle Y can have other values.

While continuing to refer to FIG 11, the stent 40 also includes link struts 46 connecting the rings 58 together. The link struts 46 are oriented parallel or substantially parallel to line C-C and the central axis 42. The ring struts 166, hinge elements 168, and link struts 46 define a plurality of closed cells 86. The boundary or perimeter of one closed cell 86 is darkened in FIG 11 for clarity.

Still referring to FIG 11, the perimeter of each closed cell 86 includes eight of the ring struts 166,

two of the link struts 46, and ten of the hinge elements 168. Four of the eight ring struts form a proximal side of the cell perimeter and the other four ring struts form a distal side of the cell perimeter. The opposing ring struts on the proximal and distal sides are parallel or substantially parallel to each other.

Within each of the hinge elements 168 there is an intersection point 170 toward which the ring struts 166 and link struts 46 converge. There is an intersection point 170 adjacent each end of the ring struts 166 and link struts 46. A radius is preferably located near the junction of a ring strut 166 and a ring strut 166 and a ring strut 166 and link strut 46 to minimize stress concentration or crack tip initiators during crimping and deployment. Distances 172 between the intersection points adjacent the ends of rings struts 166 are the same or substantially the same for each ring strut 166 in the intermediate portion 164 of the strut pattern 60. The distances 220 are the same or substantially the same for each link strut 46 in the intermediate portion 164.

The ring struts 166 have widths 174 that are uniform in dimension along the individual lengthwise axis of the ring strut. The ring strut widths 174 are between 0.07 mm and 0.25 mm, and more narrowly at or below about 0.165 mm. The link struts 46 have widths 198 that are also uniform in dimension along the individual lengthwise axis of the link strut. The link strut widths 196 are between 0.07 mm and 0.25 mm, and more narrowly at or below about 0.127 mm. The ring struts 166 and link struts 46 have the same or substantially the same thickness 76 (FIG. 2) in the radial direction, which is between 0.08 mm and 0.20 mm, and more narrowly at or below about 0.152 mm.

As shown in FIG. 11, the interior space of each closed cell 86 has an axial dimension 176 parallel to line C-C and a circumferential dimension 178 parallel to line D-D. The axial dimension 176 is constant or substantially constant with respect to circumferential position within each closed cell 86 of the intermediate portion 164. That is, axial dimensions 176A adjacent the top and bottom ends of the cells 86 are the same or substantially the same as axial dimensions 176B further away from the ends. The axial and circumferential dimensions 176, 178 are the same among the closed cells 86 in the intermediate portion 164.

It will be appreciated that FIG. 11 that the strut pattern 60 for a stent 40 that comprises linear ring struts 166 and linear link struts 46 is formed from a tube comprised of a wall thickness 76 including at least one layer of filaments 78, multi-filaments, or combinations thereof. The ring struts 166 define a plurality of rings 58 capable of moving from a non-deformed configuration to a deformed configuration. Each ring has a center point, and at least two of the center points define the stent 40 central axis 42. The link struts 46 are oriented parallel or substantially parallel to the stent 40 central axis 42. The link struts 46 connect the rings 58 together. The link struts 46 and the ring struts 166 define closed cells 86. Each closed cell 86 abuts other closed cells. The ring struts 166 and hinge elements 168 on each ring 58 define a series of crests 160 and troughs 162 (FIG. 10) that alternate with each other. Each crest 160 on each ring 58 is connected by one of the link struts 46 to another crest on an immediately adjacent ring, thereby forming an arrangement of the closed cells.

In other embodiments, adjustments to the above specified stent design may be made to compensate for unique characteristics of materials 82 used to construct the stent 40, manufacturing processes used to produce the stent 40, or equipment utilized to deploy the stent 40. For example, in another embodiment of the stent 40 the perimeter of closed cell 86 may include a discontinuity to make the cell an open cell. As another embodiment, some of or all of the lengths of ring struts 166 or link struts 46, may be equal, unequal, or combinations thereof. In other embodiments some or all the crests 160

may be connected to a troughs 162 of adjacent rings 58 with link struts 46, some or all the crests 160 may be connected to crests 160 of adjacent rings 58 with the link struts 46, some or all the troughs 162 may be connected to troughs 162 of adjacent rings 58 with the link struts 46, or combinations thereof. In yet more embodiments some or all the ring struts 166 or link struts 46 may include curved or bent portions. Moreover, in other embodiments some or all of the ring struts 166, link struts 46, or hinged elements 168 may include one or more features such as and without limitation indentations, radii, grooves, cuts, and other features that enhance operability during crimping and deployment. In another embodiment the shape of the cells are a mixture of different shapes and configurations. In one more embodiment there can be more or less than eight ring struts 166 and more or less than two link struts 46 to form cells. In yet one more embodiment, the size and shape of the cells vary. For example, the cells are different near the proximal and distal ends than near the central portion of the stent 40. And, in other embodiments the width 174, 196 and thickness 76 of the ring struts 166 and link struts 46 vary in one or more portions of the stent 40. In an embodiment, the thickness 76 of the stent 40 is thinner near the proximal and distal ends than near the center portion of the length 50 so that stress concentrations do not develop at the intersection of the stent and the lumen.

As shown in FIG 9, which is a cross-sectional view of the strut 44, 46 of stent 40, in this embodiment the strut includes one or more layers of a coating 180. The coating or coatings 180 are positioned on the outer surface 70, inner surface 72, cutting edges 182, or combinations thereof. In other embodiments, the coating or coatings 180 are positioned on the outside surface of one or more filaments 78, on the outside surface of one or more multi-filaments, or combinations thereof. The purpose of the coating 180 is to improve the patency of the lumen after deployment of the stent 40.

Without intent on limiting a few useful materials for use as a coating 180 in the present invention include: acrylate-based, acrylic, alkyds, amorphous polymers, C10 polymer, C19 polymer, collagen, crystalline polymers, epoxy-based, fluropolymers, heparin, high molecular weight polymers, hydrophilic materials, hydrophobic materials, hydroxyapatite, Lactide-based, light curing materials, low molecular weight polymers, materials 82 listed herein, moisture curing materials, olefins; oxides, phosphorylcholine, poly (n-butyl methacrylate), polycaprolactone copolyglycolic acid, polycaprolactone glycerylmonostearate, polyethylene co-vinyl acetate, polyethylene glycol, styrene-based, urethane-based, vinyl-based, wax, combinations thereof, derivatives, analogs, and functional equivalents.

In some embodiments the coating or coatings 180 or material 82 includes one or more additives 150, nano size additives 152, or combinations thereof. In an embodiment, the additives and nano size additives are one or more active ingredients. The term "active ingredient" refers to any substance that is biologically active, therapeutically active, or an active pharmaceutical ingredient (API). The term "nano" refers to any substance that has one dimension in the size range of about one to one hundred nanometers.

Without intent on limiting, a few examples of the active ingredients suitable for inclusion in the stent 40 are selected from the group of: agents that reduce neointimal hyperplasia, Biolimus A9, everolimus, limus drugs, paclitaxel, pimecrolimus, rapamycin derivatives, sirolimus, sirolimus salicylate, tacrolimus, zotarolimus, their derivatives, analogs, and functional equivalents.

In an embodiment the coating 180 delays or controls the onset or rate of degradation and/or resorption of material 82. Delaying the onset of degradation improves patency by enabling the stent 40 to substantially maintain its strength for a longer period of time than an uncoated stent. It is important, for

example, for the stent 40 to provide support to a vascular lumen until the struts 44,46 are partially or fully covered with endothelial cells and until the lumen remodels and becomes self-supporting.

To avoid a vascular lumen from experiencing stenosis, studies have found that a stent should substantially support the lumen for a minimum of about one to six months to stabilize the luminal diameter. Seventy to ninety percent of the decrease in arterial lumen is the result of negative remodeling with only twenty to thirty percent attributable to neointimal cellular proliferation and plaque growth. Therefore, the stent 40 must provide two functions: (1) provide mechanical support until healing occurs and (2) deliver active ingredients to control neointimal cellular growth. The problem is that these two functions are interrelated. For example, the length of time required to mechanically support the lumen is directly related to the active ingredient employed, the dosage of active ingredient, and the rate in which the active ingredient is eluted from the stent. The influence of the active ingredient on the healing process overall is positive but it creates unique challenges to employing bioresorbable stents because the healing process can take longer due to usage of active ingredients which means that the bioresorbable stent has to provide mechanical support longer than the currently available bioresorbable materials are capable of providing.

The present invention provides a solution to this challenging engineering problem. In an embodiment, one or more layers of the coating 180 controls the rate at which water penetrates the outside surface of the material 82. As an example, an embodiment of the an uncoated stent having a wall thickness of a homopolymer of L-lactide (PLLA) starts to lose mechanical strength several weeks after deployment and all its strength about three months after deployment because the polymer undergoes hydrolysis upon exposure to water in the living body. By employing a coating 180 on the surface of the polymer between the material 82 and the living body, the water uptake by the polymer can be partially or fully delayed or reduced to increase the period of time when the bioresorbable stent provides mechanical stability to the lumen.

In an embodiment, the stent 40 preferably has a radial strength in the range of about 0.053 to 0.24 MPa (400 to 1800 mmHg), more preferably in the range of about 0.107 to 0.24 MPa (800 to 1800 mmHg), and most preferably in the range about 0.12- 0.16 MPa (900 to 1200 mmHg) during the healing period.

Without intent on limiting, the delay in the onset of hydrolysis or delay in the onset of loss of radial strength of a vascular stent 40 by substantially preventing water from hydrating the material 82 is preferably in the range of about one week to one year, more preferably in the range of about one week to six months, and most preferably in the range of about one to three months. So for example, if a stent comprised of PLLA has a nominal duration of radial support of the lumen of three months, then employing the coating 180 of the present invention would increase the nominal duration of support preferably to be in the range of about three months and one week to one year and three months, more preferably to be in the range of about three months and one week to nine months, and most preferably to be in the range of about four to six months. At some time after deployment, the stent degrades and loses sufficient strength that the lumen in which the stent 40 is implanted is free to expand and contract thus restoring vasomotion to the lumen.

Without intent on limiting, the slowing of the rate of hydrolysis or slowing of the decrease in radial strength by limiting the amount of water hydrating the material 82 is such that the radial strength is preferably maintained in the range of about one to three hundred percent longer, more preferably in the

range of about 10 to 100 percent longer, and most preferably in the range of about 30 and 100 percent longer. So for example if a bioresorbable stent comprised of PLLA having a nominal radial strength of 0.133 MPa (1000 mmHg) for thirteen weeks after deployment, the stent 40 having controlled hydrolysis my reducing or metering the volume of water available to hydrate the material 82 through use of, for example, a porous coating 180 would maintain this radial strength preferably in the range of about 13.1 to 39 weeks, more preferably in the range of about 14.3 to 26 weeks, and most preferably in the range of about 16.9 to 26 weeks.

Slowing the rate of hydrolysis or reduction in radial strength is controlled by durability of the coating 180 under physiological conditions, thickness of the coating 180, hydrophilicity, hydrophobicity, of the coating 180, porosity of the coating 180, or combinations thereof.

An embodiment of the stent 40 includes one or more layers of a coating 180 that contains and delivers one or more beneficial active ingredient ingredients to the lumen. This coating 180 can be multifunctional in that it manages the onset and rate of hydrolysis and also functions as a drug storage area and delivers the active ingredient to the lumen. Or in other embodiments the coating 180 has single functionality and only serves as an active ingredient storage location and drug delivery mechanism or serves only as a means to manage the onset and rate of hydrolysis. The coating 180 preferably delivers the active ingredient in a period of time in the range of about one minute to six months, more preferably in a range of about one day to 4 months, and most preferably in a range of about one day to three months after deployment. The beneficial active ingredients, for example, reduce the risk of neointimal hyperplasia and restenosis.

The active ingredients are partially or fully encapsulated in another embodiment of stent 40 and feature the capability of controlled release of the active ingredients so that for example drug delivery kinetics can be customized.

One significant factor that controls the degradation rate of the stent 40 upon deployment in a living body is the surface area of the struts 44, 46. If, for example, the struts 44, 46 are comprised of many relatively thin filaments 78 the stent 40 has a relatively higher surface area and it degrades more quickly. Conversely, if the struts 44, 46 are comprised of few relatively thick filaments 78 then the stent 40 has a lower surface area and it degrades more slowly.

To avoid large spikes in degradative byproducts, in an embodiment of stent 40, filaments 78 having different diameters are employed in the fabrication of wall thickness 76 of tube 74 to stage the degradation of the filaments 78 in stent 40 over time.

The rate at which degradative byproducts are generated during the degradation of stent 10 can be managed by selecting materials 82 having different degradation rates. For example, in an embodiment the wall thickness 76 is comprised partially of slow degrading filaments 78 comprised of a homopolymer of L-lactide (PLLA) and partially of faster degrading polyglycolide (PG) filaments 78. In another embodiment, the degradation rate is managed by using filaments 78 comprised of blends of polymers or copolymers. For example, a wall thickness includes filaments 78 comprised of co-polymers of L-lactide (PLLA) and polyglycolide (PG) wherein the PLLA is slower to degrade and the PG is faster to degrade. The degradation rate can be fine tuned to achieve the performance specifications of stent 40 as described herein, for example, by varying the molar ratio from ten percent L-lactide and ninety percent glycolide to ninety percent L-lactide to ten percent glycolide.

Referring back to FIG 5, which is a cross sectional view of an embodiment of the stent 40 of the

present invention, the degradation of stent 40 is managed by having a wall thickness 76 comprised of filaments 78 comprised of material 82 having the same chemical composition but having differing molecular weights. In one such embodiment the abluminal layer 114 is comprised of a higher molecular weight material 82 than the luminal layer 112. In another embodiment the molecular weight of the material 82 in the abluminal layer 114 is comprised of a lower molecular weight material than the luminal layer 112. In the case wherein there are one or more middle layers the filaments of these layers can be comprised of material 82 having molecular weight progressively higher to lower molecular weight from abluminal layer 114 to luminal layer 112 or comprised of material progressively decreasing in molecular weight from abluminal layer 114 to luminal layer 112.

An embodiment of bioresorbable stent 40 is crimped onto a balloon catheter. The stents of the prior art are difficult to crimp because the bioresorbable materials are weaker than metal and therefore have thicker struts, which are difficult to crimp. In addition, the bioresorbable materials are in many cases brittle and subject to cracking during crimping, especially when crimping is performed at temperatures below the glass transition temperature of the material. The stent 40 of the present invention is much easier to crimp without fracturing the struts because the high strength and flexible filaments 78 within the wall thickness enable the stent to be crimped without fracturing the struts 44, 46.

Although the above embodiments have been described in terms of a stent, it will be appreciated that the present invention can be applied to endoprostheses in general. An "endoprosthesis" corresponds to an artificial device that is placed inside the body, more particularly, within an anatomical lumen. An "anatomical lumen" refers to a cavity, duct, of a tubular organ such as a blood vessel, urinary tract, and bile duct. Devices to which the present invention may be applied include without limitation a coronary vascular stent, a peripheral vascular stent, a carotid stent, a renal stent, a iliac stent, a superficial femoral artery stent, a urethral stent, a biliary stent, a tracheal stent, a gastrointestinal stent, an esophageal stent, a drug delivery stent, a self-expandable stent, a balloon-expandable stent, a bifurcated stent, a stent-graft, a graft, an anatomical lumen repair or splicing device, a device for local delivery of active ingredients to tubular shaped lumen or organs for treatment of cancer, a device for treatment of colon or rectal cancer, and a device for the treatment of cancer.

The stent 40 of the present invention can be of any dimensions that meet the requirements of the application. For vascular stents the diameter will typically be in the range of 2.0 mm to 4.5 mm in diameter and length ranging from about 6 mm to 30 mm. These stent sizes generally incrementally increase in diameter in 0.5 mm increments and in length by 4 mm to 6 mm increments.

While several particular forms of the invention have been illustrated and described, it will also be apparent that various modifications can be made without departing from the scope of the invention. For example and without limitation, the strut pattern can have a lesser or greater number of rings 58 than what is shown in FIG 10. As a further non-limiting example, the strut pattern 60 can have any number of open or closed cells circumferentially arranged to encircle the stent central axis of other embodiments of the present invention. In FIG 10, there are three W-shape or other shape closed or open cells that are circumferentially arranged, although a lesser or greater number may be implemented in a strut pattern of other embodiments. In yet another non-limiting example, the strut pattern can have any number of W-shape or other shape open or closed cells arranged axially along the entire longitudinal length of a stent in other embodiments. In FIG. 10, there are eighteen W-shape closed cells axially arranged, although a lesser or greater number may be implemented in a strut pattern of other embodiments.

Claims

What is claimed is:

Claim 1. An endoprosthesis comprising:

A hollow elongated cylindrical shaped body including a wall thickness comprised of at least one layer of one or more filaments comprised of one or more materials of the same or different chemical composition or molecular weight, positioned in said wall thickness in an axial, a circumferential, or an angled orientation, or combination thereof relative to the central axis of the endoprosthesis;

Wherein said wall thickness includes a pattern of openings partially or fully surrounded by interconnecting struts of any repeating or non-repeating geometric shape;

Wherein said openings include cutting edges positioned around the perimeter of the openings and said filaments positioned within struts include severed ends; and

Wherein said material comprising said wall thickness includes sufficient radial strength to hold open an anatomical lumen from the time of deployment of said endoprosthesis until the end of treatment time, at which time said material or materials undergo degradation resulting in a loss of said radial strength and ultimately with longer time substantially all material is chemically broken down into byproducts that undergo resorption by a living body.

Claim 2. The endoprosthesis of claim 1 includes a coating on the abluminal surface, luminal surface, and cutting edges.

Claim 3. The endoprosthesis of claim 1 includes at least a partial thermal fusion between said severed filaments at a position near the cutting edges to at least partially attach the ends of the filaments together near the cutting edges.

Claim 4. The endoprosthesis of claim 1 includes one or more active ingredients.

Claim 5. The endoprosthesis of claim 1 includes at least one layer of a binding material that connects one or more filaments or layers of filaments wherein the binding material is positioned on the inner surface of a filament layer, outer surface of a filament layer, between filament layers, between adjacent filaments, between adjacent multi-filaments, or combinations thereof.

Claim 6. The endoprosthesis of claim 1 includes an application selected from the group of: coronary vascular stents, carotid stents, peripheral vascular stents, renal stents, iliac stents, superficial femoral artery stents, cerebral stents, urinary stents (urethral and ureteral stents), biliary stents, tracheal stents, gastrointestinal stents, esophageal stents, and drug delivery device.

Claim 7. The endoprosthesis of claim 1 includes a stent-to-anatomical lumen coverage ratio of less than 25 percent.

Claim 8. The endoprosthesis of claim 1 includes a strut thickness less than 0.15 mm.

Claim 9. The endoprosthesis of claim 1 includes a radial strength of greater than 0.05 MPa (400 mmHg).

Claim 10. The endoprosthesis of claim 1 includes filaments organized in said wall thickness by one or more processes selected from the group of: braiding, winding, weaving, crocheting, interlacing, or knitting said filaments.

Claim 11. The binding material of claim 5 has a thickness ranging from 0.0001 to 0.2000 mm.

Claim 12. The filament of claim 1 has a thickness ranging from 0.05 to 150 microns.

Claim 13. The filament of claim 1 has a tensile strength greater than 70 MPa (10,500 psi).

Claim 14. The endoprosthesis of claim 1 includes at least one malleable wire comprised of bioresorbable material.

Claim 15. The endoprosthesis of claim 1 includes filaments that degrade and lose mass at different rates.

Claim 16. The coating of claim 2 delays the onset of degradation of said material by greater than 1 week at physiological conditions.

Claim 17. The coating of claim 2 includes a storage and a delivery of at least one therapeutic drug to said anatomical lumen.

Claim 18. The endoprosthesis of claim 1 includes one or more additives, nano sized additives, or combinations thereof.

Claim 19. An endoprosthesis comprising:

A hollow elongated cylindrical shaped body including a wall thickness comprised of one or more layers of one or more materials of the same or different chemical composition or molecular weight;

Wherein said wall thickness includes a pattern of openings partially or fully surrounded by interconnecting struts of any repeating or non-repeating geometric shape;

Wherein said struts include one or more layers of a coating substantially preventing material comprising struts from being in direct contact with physiological conditions after deployment of endoprosthesis; and

Wherein said material comprising said wall thickness includes sufficient radial strength to hold open an anatomical lumen from the time of deployment of said endoprosthesis until the end of treatment time, at which time said coating at least partially allows material or materials comprising struts to be in direct contact with physiological conditions and undergo degradation resulting in a loss of said radial strength and ultimately with longer time substantially all material is chemically broken down into byproducts that undergo resorption by a living body.

Claim 20. The endoprosthesis of claim 19 includes an application selected from the group of: coronary vascular stents, carotid stents, peripheral vascular stents, renal stents, iliac stents, superficial femoral artery stents, cerebral stents, urinary stents (urethral and ureteral stents), biliary stents, tracheal stents, gastrointestinal stents, esophageal stents, and drug delivery device.

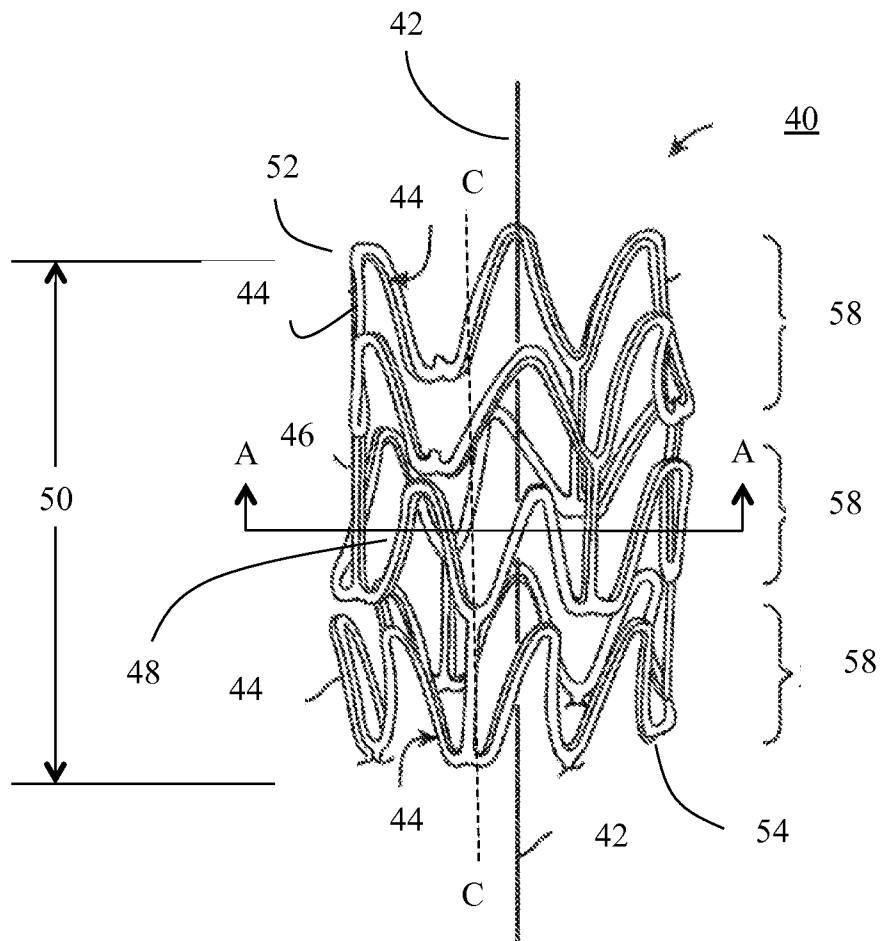


FIG. 1

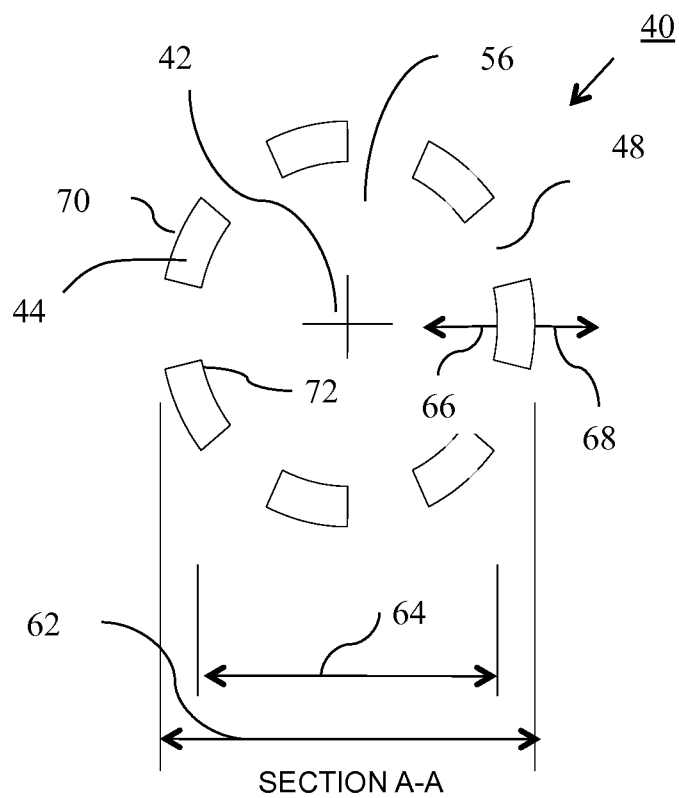
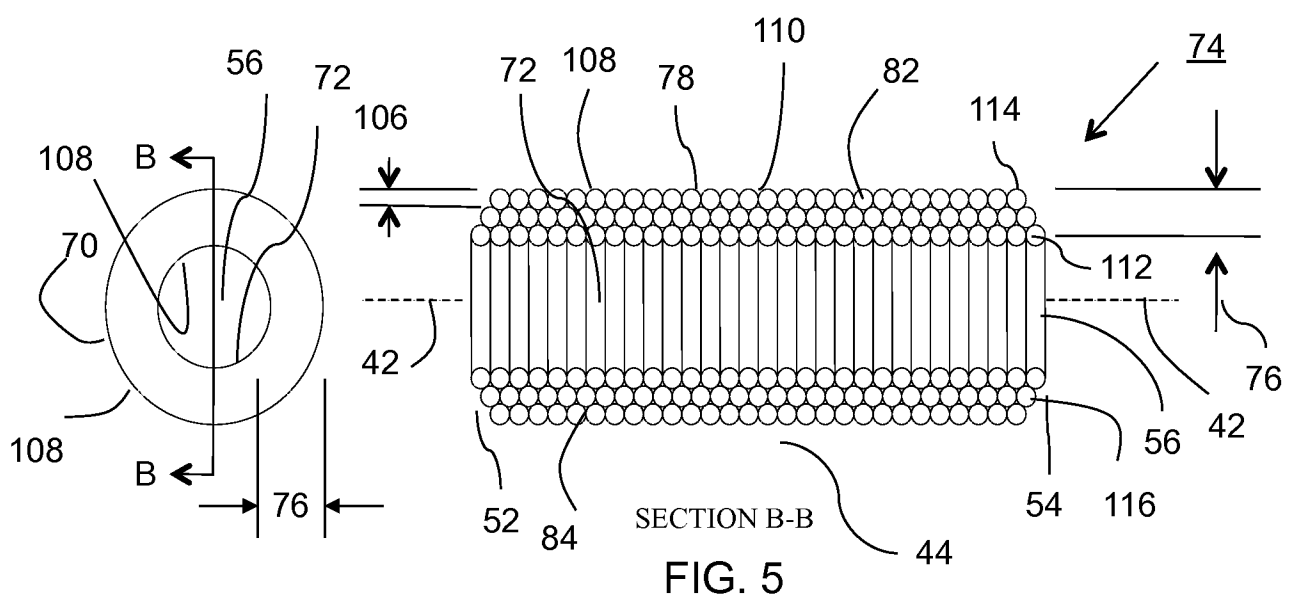
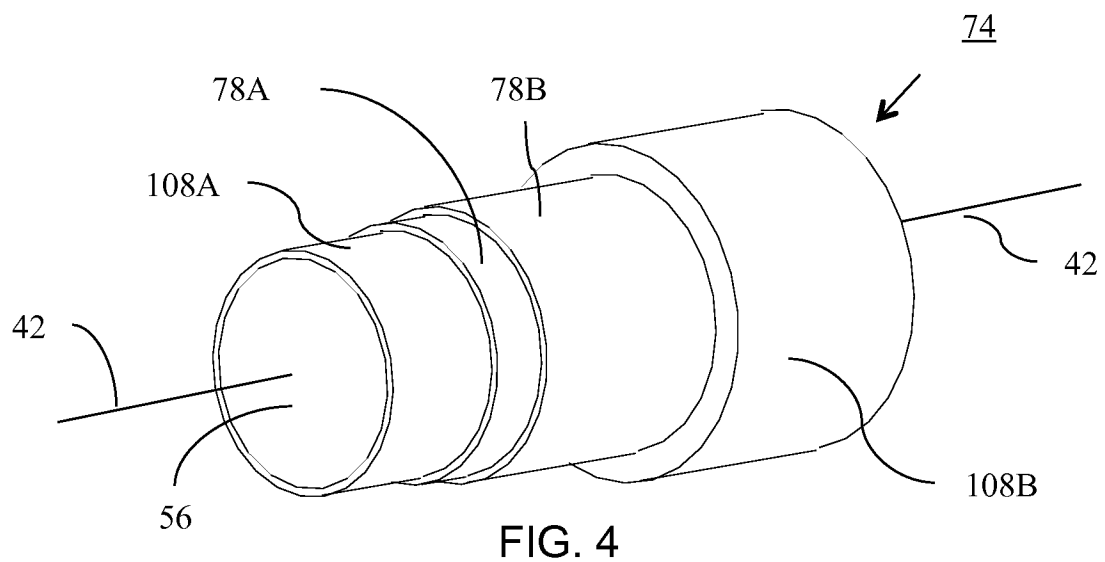
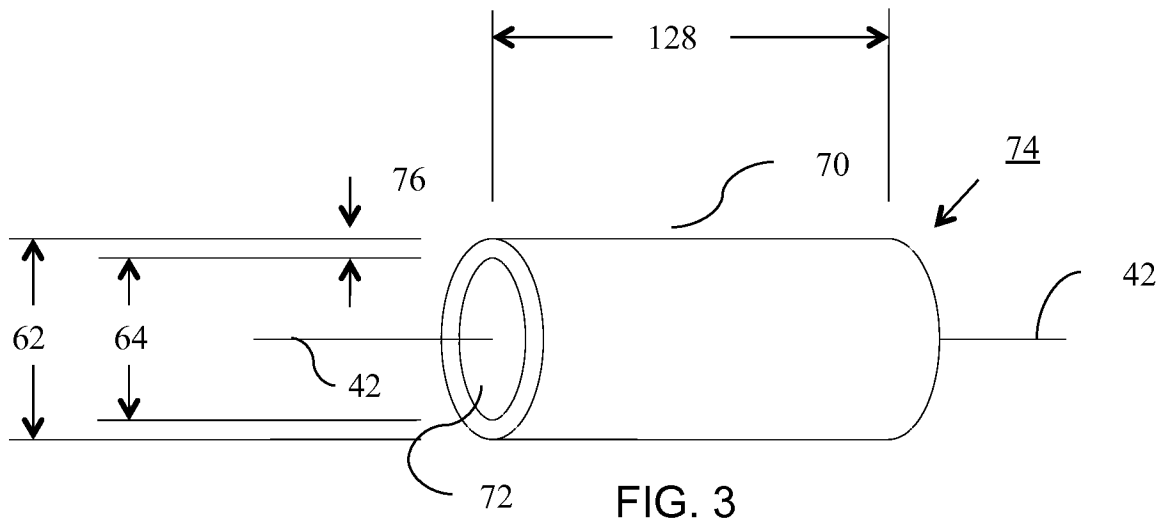


FIG. 2



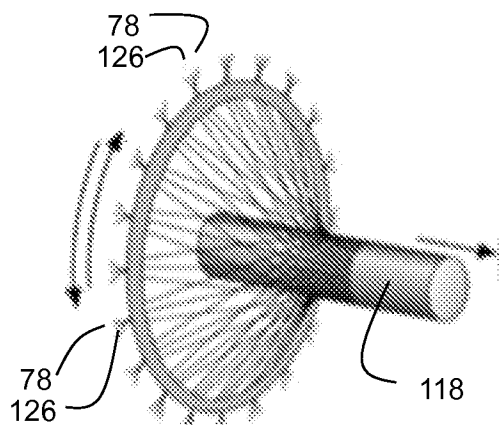


FIG. 6

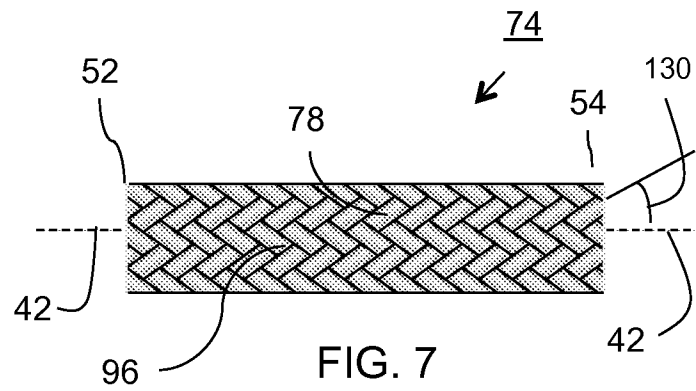


FIG. 7

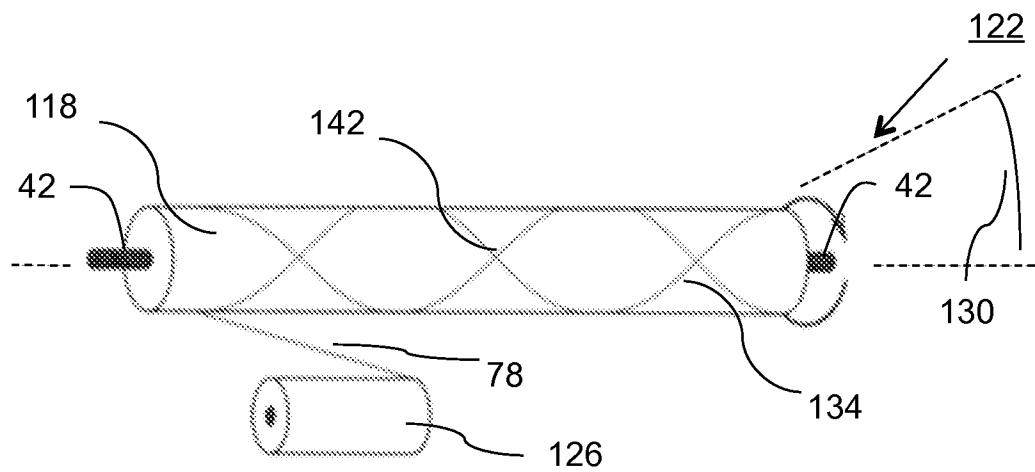


FIG. 8

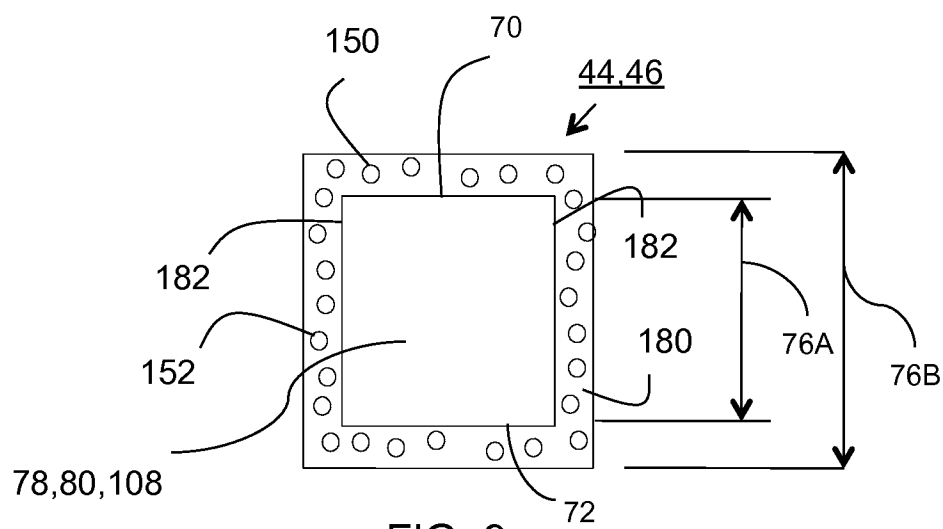


FIG. 9

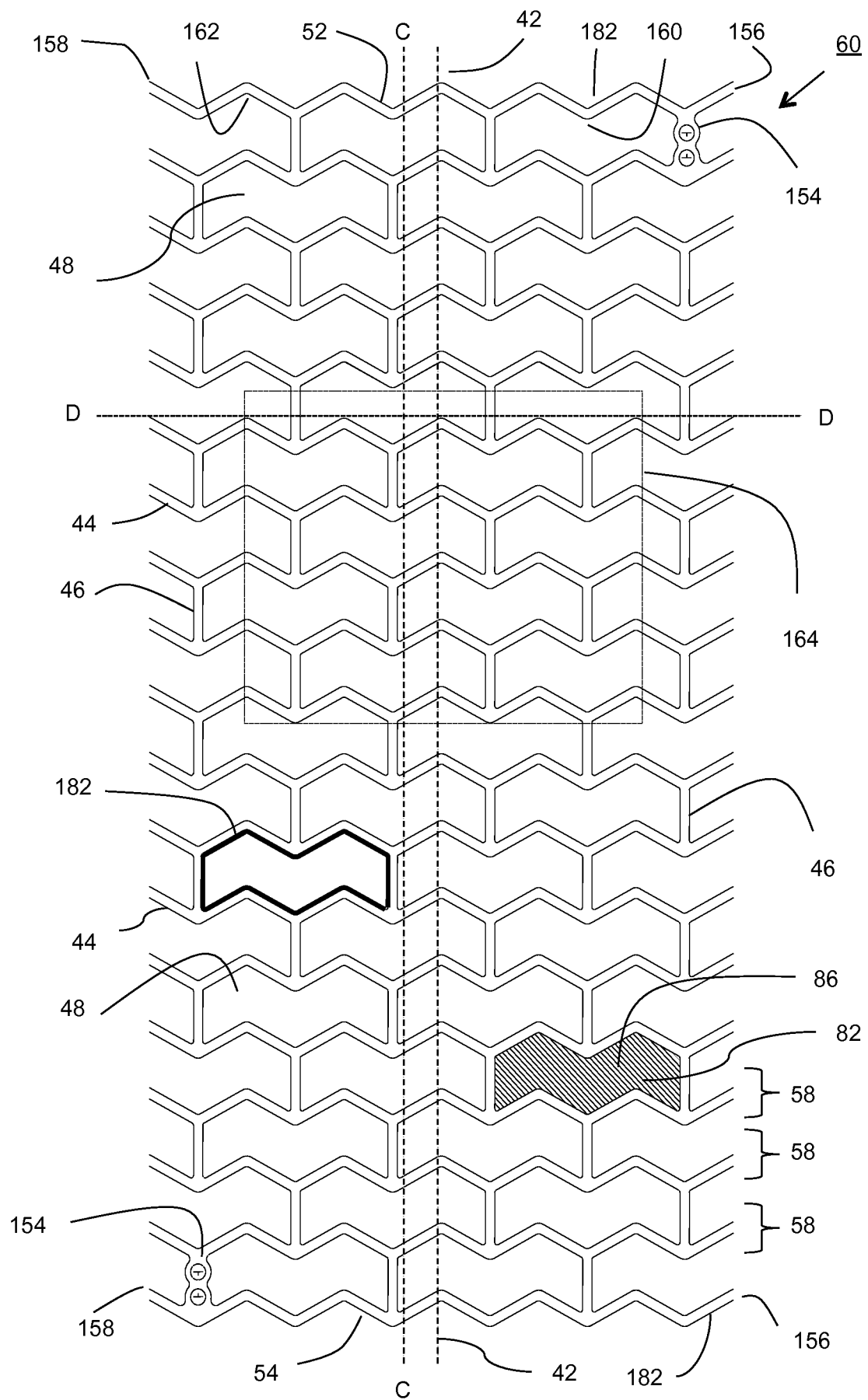


FIG. 10

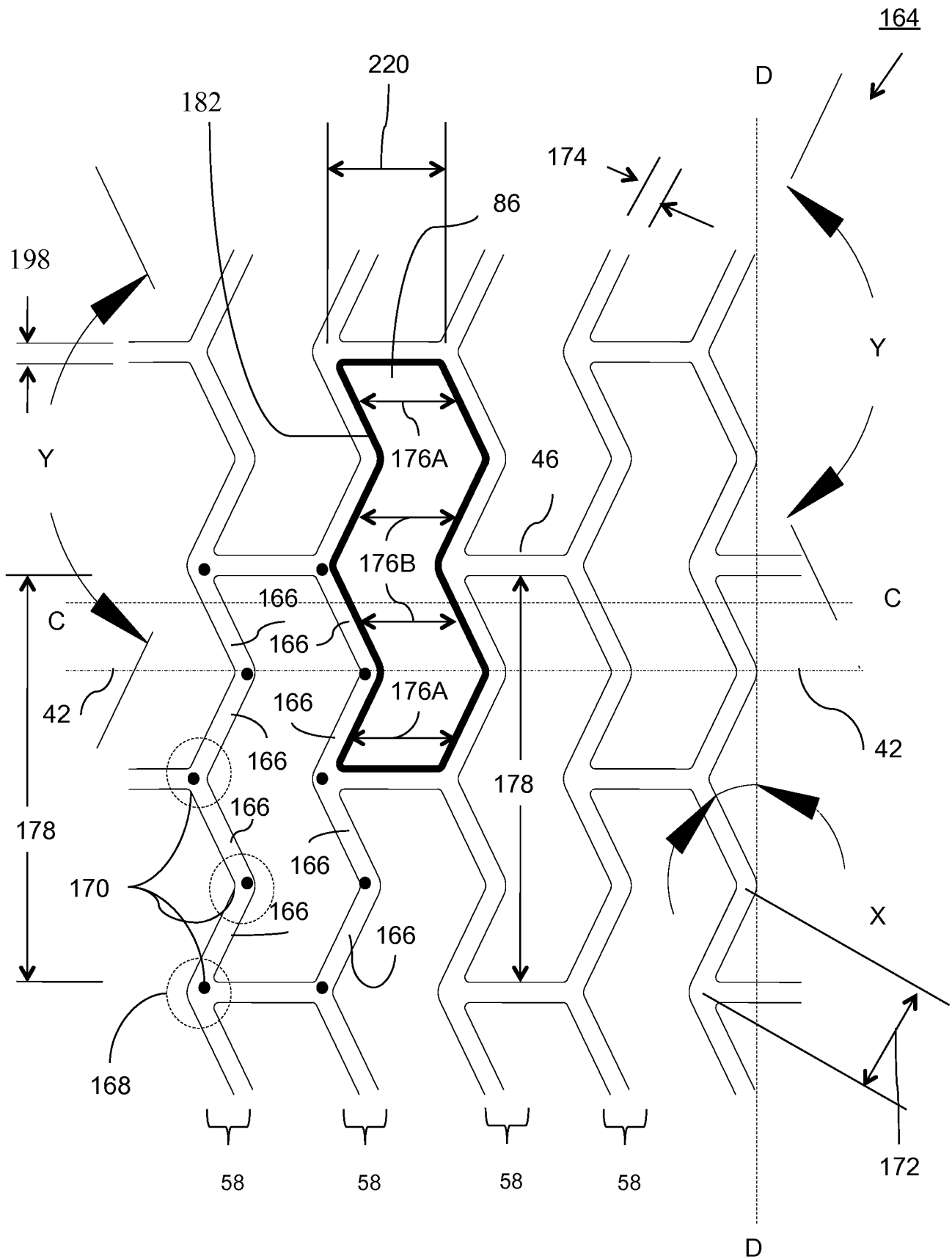


FIG. 11