



(22) Date de dépôt/Filing Date: 2005/08/02

(41) Mise à la disp. pub./Open to Public Insp.: 2006/02/04

(30) Priorité/Priority: 2004/08/04 (10/911,265) US

(51) Cl.Int./Int.Cl. *A61F 2/04* (2006.01),
A61F 2/06 (2006.01)

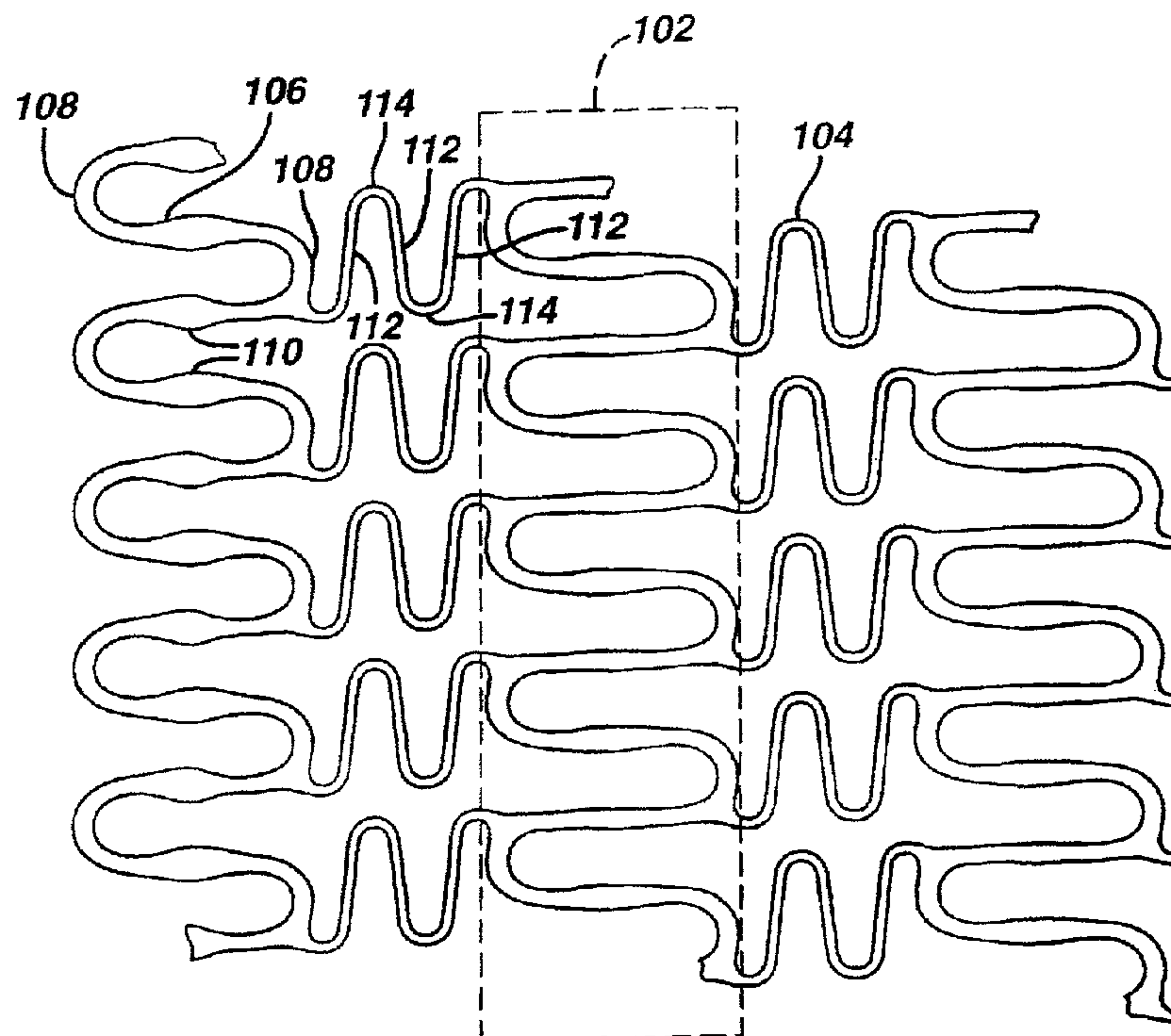
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(54) Titre : CONCEPTION RADIALE AMELIOREE POUR ENDOPROTHESE A FORTE RESISTANCE, GRANDE SOUPLESSE ET RECUIL CONTROLE

(54) Title: IMPROVED RADIAL DESIGN FOR HIGH STRENGTH, HIGH FLEXIBILITY, CONTROLLED RECOIL STENT



(57) **Abrégé/Abstract:**

A biocompatible metallic material may be configured into any number of implantable medical devices including intraluminal stents. The biocompatible metallic material comprises a unique composition and designed-in properties that enable the fabrication of intraluminal stents that are able to withstand a broader range of loading conditions than currently available stents. More particularly, the microstructure designed into the biocompatible metallic material facilitates the design of stents with a wide range of geometries that are adaptable to various loading conditions.



ABSTRACT OF THE INVENTION

A biocompatible metallic material may be configured into any number of implantable medical devices including intraluminal stents. The biocompatible
5 metallic material comprises a unique composition and designed-in properties that enable the fabrication of intraluminal stents that are able to withstand a broader range of loading conditions than currently available stents. More particularly, the microstructure designed into the biocompatible metallic material facilitates the design of stents with a wide range of geometries that are adaptable to various
10 loading conditions.

IMPROVED RADIAL DESIGN FOR HIGH STRENGTH, HIGH FLEXIBILITY, CONTROLLED RECOIL STENT

5 BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to novel geometries for use in implantable medical devices, and more particularly, to novel stent designs manufactured or
10 fabricated from alloys that provide high strength, high flexibility, high expansion capability, high fatigue resistance and controlled recoil.

2. Discussion of the Related Art

15 Currently manufactured intravascular stents do not adequately provide sufficient tailoring of the microstructural properties of the material forming the stent to the desired mechanical behavior of the device under clinically relevant in-vivo loading conditions. Any intravascular device should preferably exhibit certain characteristics, including maintaining vessel patency through a chronic outward
20 force that will help to remodel the vessel to its intended luminal diameter, preventing excessive radial recoil upon deployment, exhibiting sufficient fatigue resistance and exhibiting sufficient ductility so as to provide adequate coverage over the full range of intended expansion diameters.

25 Accordingly, there is a need to develop precursory materials and the associated processes for manufacturing intravascular stents that provide device designers with the opportunity to engineer the device to specific applications.

SUMMARY OF THE INVENTION

30 The present invention overcomes the limitations of applying conventionally available materials to specific intravascular therapeutic applications as briefly

described above. The present invention also overcomes the limitations associated with conventionally configured stent geometry.

5 In accordance with one aspect, the present invention is directed to an intraluminal stent. The intraluminal stent comprising a plurality of hoop components being formed as a continuous series of substantially circumferentially oriented radial strut members and alternating radial arc members, wherein the continuous path from a midpoint of a radial strut member to an equivalent midpoint of an adjacent radial strut member through a radial arc member defines a single loop, and wherein a series of interconnected single loops comprise a single hoop component, wherein the number of circumferentially adjacent single loops are geometrically configured to substantially minimize crossing profile, and the total number of single loops define a total path-length, as measured along the centroidal axis of each radial strut and arc member, of the hoop component, and one or more flexible connectors being formed as a continuous series of substantially longitudinally oriented flexible strut members and alternating flexible arc members, the one or more flexible connectors connecting adjacent hoop components to form a substantially tubular structure having a luminal surface and an abluminal surface, 20 wherein a wall thickness is defined as the radial distance between the luminal surface and the abluminal surface of the substantially tubular structure, the single loop components are configured into a hoop component with a ratio of expanded circumferential distance to total path-length greater than about 0.25 and fabricated from a metallic material processed to have a microstructure, in at least 25 the radial arc members, with a granularity of about 32 microns or less and comprise from about 2 to about 10 substantially equiaxed grains as measured across the wall thickness.

30 In accordance with another aspect, the present invention is directed to an intraluminal stent. The intraluminal stent comprising one or more support structures defining a predetermined path-length, wherein the ratio of vessel

luminal perimeter to path-length is greater than about 0.25 and the one or more support structures being fabricated from a metallic material processed to have a microstructure with a granularity of about 32 microns or less and comprises from about 2 to about 10 substantially equiaxed grains as measured across the wall thickness.

The biocompatible material for implantable medical devices of the present invention offers a number of advantages over currently utilized materials. The biocompatible material of the present invention is magnetic resonance imaging compatible, is less brittle than other metallic materials, has enhanced ductility and toughness, and has increased durability. The biocompatible material also maintains the desired or beneficial characteristics of currently available metallic materials, including strength and flexibility.

The biocompatible material for implantable medical devices of the present invention may be utilized for any number of medical applications, including vessel patency devices such as vascular stents, biliary stents, ureter stents, vessel occlusion devices such as atrial septal and ventricular septal occluders, patent foramen ovale occluders and orthopedic devices such as fixation devices.

The biocompatible material of the present invention is simple and inexpensive to manufacture. The biocompatible material may be formed into any number of structures or devices. The biocompatible alloy may be thermomechanically processed, including cold-working and heat treating, to achieve varying degrees of strength and ductility. The biocompatible material of the present invention may be age hardened to precipitate one or more secondary phases.

The intraluminal stent of the present invention may be specifically configured to optimize the number of discrete equiaxed grains that comprise the

wall dimension so as to provide the intended user with a high strength, controlled recoil device as a function of expanded inside diameter.

The biocompatible material of the present invention comprises a unique composition and designed-in properties that enable the fabrication of stents that are able to withstand a broader range of loading conditions than currently available stents. More particularly, the microstructure designed into the biocompatible material facilitates the design of stents with a wide range of geometries that are adaptable to various loading conditions.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other features and advantages of the invention will be apparent from the following, more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings.

Figure 1 is a graphical representation of the transition of critical mechanical properties as a function of thermomechanical processing for Cobalt- Chromium alloys in accordance with the present invention.

Figure 2 is a graphical representation of the endurance limit chart as a function of thermomechanical processing for a Cobalt-Chromium alloy in accordance with the present invention.

Figure 3 is a planar representation of an exemplary stent fabricated from the biocompatible alloy in accordance with the present invention.

Figure 4 is a detailed planar representation of a hoop of an exemplary stent fabricated from the biocompatible alloy in accordance with the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Biocompatible, solid-solution strengthened alloys such as iron-based alloys, cobalt-based alloys and titanium-based alloys as well as refractory metals and refractory-based alloys may be utilized in the manufacture of any number of implantable medical devices. The biocompatible alloy for implantable medical devices in accordance with the present invention offers a number of advantages over currently utilized medical grade alloys. The advantages include the ability to engineer the underlying microstructure in order to sufficiently perform as intended by the designer without the limitations of currently utilized materials and manufacturing methodologies.

For reference, a traditional stainless steel alloy such as 316L (i.e. UNS S31603) which is broadly utilized as an implantable, biocompatible device material may comprise Chromium (Cr) in the range from about 16 to 18 wt.%, nickel (Ni) in the range from about 10 to 14 wt.%, molybdenum (Mo) in the range from about 2 to 3 wt.%, manganese (Mn) in the range up to 2 wt.%, silicon (Si) in the range up to 1 wt.%, with iron (Fe) comprising the balance (approximately 65 wt.%) of the composition.

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Additionally, a traditional Cobalt-based alloy such as L605 (i.e. UNS R30605) which is also broadly utilized as an implantable, biocompatible device material may comprise Chromium (Cr) in the range from about 19 to 21 wt.%, tungsten (W) in the range from about 14 to 16 wt.%, nickel (Ni) in the range from about 9 to 11 wt.%, iron (Fe) in the range up to 3 wt.%, manganese (Mn) in the range up to 2 wt.%, silicon (Si) in the range up to 1 wt.%, with Cobalt (cobalt) comprising the balance (approximately 49 wt.%) of the composition.

In general, elemental additions such as Chromium (Cr), nickel (Ni), tungsten (W), manganese (Mn), silicon (Si) and molybdenum (Mo) where added to iron- and/or Cobalt-based alloys, where appropriate, to increase or enable desirable

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performance attributes, including strength, machinability and corrosion resistance within clinically relevant usage conditions.

In accordance with one exemplary embodiment, a cobalt-based alloy may
5 comprise from about nil to about metallurgically insignificant trace levels of elemental iron (Fe) and elemental silicon (Si), elemental iron only, or elemental silicon only. For example, the cobalt-based alloy may comprise Chromium in the range from about 10 weight percent to about 30 weight percent, Tungsten in the range from about 5 weight percent to about 20 weight percent, Nickel in the range
10 from about 5 weight percent to about 20 weight percent, Manganese in the range from about 0 weight percent to about 5 weight percent, Carbon in the range from about 0 weight percent to about 1 weight percent, Iron in an amount not to exceed 0.12 weight percent, Silicon in an amount not to exceed 0.12 weight percent, Phosphorus in an amount not to exceed 0.04 weight percent, Sulfur in an amount
15 not to exceed 0.03 weight percent and the remainder Cobalt. Alternately, the cobalt-based alloy may comprise Chromium in the range from about 10 weight percent to about 30 weight percent, Tungsten in the range from about 5 weight percent to about 20 weight percent, Nickel in the range from about 5 weight percent to about 20 weight percent, Manganese in the range from about 0 weight percent to
20 about 5 weight percent, Carbon in the range from about 0 weight percent to about 1 weight percent, Iron in an amount not to exceed 0.12 weight percent, Silicon in an amount not to exceed 0.4 weight percent, Phosphorus in an amount not to exceed 0.04 weight percent, Sulfur in an amount not to exceed 0.03 weight percent and the remainder Cobalt. In yet another alternative composition, the cobalt-based alloy
25 may comprise Chromium in the range from about 10 weight percent to about 30 weight percent, Tungsten in the range from about 5 weight percent to about 20 weight percent, Nickel in the range from about 5 weight percent to about 20 weight percent, Manganese in the range from about 0 weight percent to about 5 weight percent, Carbon in the range from about 0 weight percent to about 1 weight
30 percent, Iron in an amount not to exceed 3 weight percent, Silicon in an amount not to exceed 0.12 weight percent, Phosphorus in an amount not to exceed 0.04 weight

percent, Sulfur in an amount not to exceed 0.03 weight percent and the remainder Cobalt.

It is important to note that any number of alloys and engineered metals, including iron-based alloys, cobalt-based alloys, refractory-based alloys, refractory metals, and titanium-based alloys may be used in accordance with the present invention. However, for ease of explanation, a detailed description of a cobalt-based alloy will be utilized in the following detailed description.

An exemplary embodiment may be processed from the requisite elementary raw materials, as set-forth above, by first mechanical homogenization (i.e. mixing) and then compaction into a green state (i.e. precursory) form. If necessary, appropriate manufacturing aids such as hydrocarbon based lubricants and/or solvents (e.g. mineral oil, machine oils, kerosene, isopropanol and related alcohols) be used to ensure complete mechanical homogenization. Additionally, other processing steps such as ultrasonic agitation of the mixture followed by cold compaction to remove any unnecessary manufacturing aides and to reduce void space within the green state may be utilized. It is preferable to ensure that any impurities within or upon the processing equipment from prior processing and/or system construction (e.g. mixing vessel material, transfer containers, etc.) be sufficiently reduced in order to ensure that the green state form is not unnecessarily contaminated. This may be accomplished by adequate cleaning of the mixing vessel before adding the constituent elements by use of surfactant-based cleaners to remove any loosely adherent contaminants.

Initial melting of the green state form into a ingot of desired composition, is achieved by vacuum induction melting (VIM) where the initial form is inductively heated to above the melting point of the primary constituent elements within a refractory crucible and then poured into a secondary mold within a vacuum environment (e.g. typically less than or equal to 10^{-4} mmHg). The vacuum process ensures that atmospheric contamination is significantly minimized. Upon

solidification of the molten pool, the ingot bar is substantially single phase (i.e. compositionally homogenous) with a definable threshold of secondary phase impurities that are typically ceramic (e.g. carbide, oxide or nitride) in nature. These impurities are typically inherited from the precursor elemental raw materials.

A secondary melting process termed vacuum arc reduction (VAR) is utilized to further reduce the concentration of the secondary phase impurities to a conventionally accepted trace impurity level (i.e. < 1,500 ppm). Other methods maybe enabled by those skilled in the art of ingot formulation that substantially embodies this practice of ensuring that atmospheric contamination is minimized. In addition, the initial VAR step may be followed by repetitive VAR processing to further homogenize the solid-solution alloy in the ingot form. From the initial ingot configuration, the homogenized alloy will be further reduced in product size and form by various industrially accepted methods such as, but not limited too, ingot peeling, grinding, cutting, forging, forming, hot rolling and/or cold finishing processing steps so as to produce bar stock that may be further reduced into a desired raw material form.

In this exemplary embodiment, the initial raw material product form that is required to initiate the thermomechanical processing that will ultimately yield a desired small diameter, thin-walled tube, appropriate for interventional devices, is a modestly sized round bar (e.g. one inch in diameter round bar stock) of predetermined length. In order to facilitate the reduction of the initial bar stock into a much smaller tubing configuration, an initial clearance hole must be placed into the bar stock that runs the length of the product. These tube hollows (i.e. heavy walled tubes) may be created by 'gun-drilling' (i.e. high depth to diameter ratio drilling) the bar stock. Other industrially relevant methods of creating the tube hollows from round bar stock may be utilized by those skilled-in-the-art of tube making.

Consecutive mechanical cold-finishing operations such as drawing through a compressive outer-diameter (OD), precision shaped (i.e. cut), circumferentially complete, diamond die using any of the following internally supported (i.e. inner diameter, ID) methods, but not necessarily limited to these conventional forming methods, such as hard mandrel (i.e. relatively long traveling ID mandrel also referred to as rod draw), floating-plug (i.e. relatively short ID mandrel that 'floats' within the region of the OD compressive die and fixed-plug (i.e. the ID mandrel is 'fixed' to the drawing apparatus where relatively short workpieces are processed) drawing. These process steps are intended to reduce the outer-diameter (OD) and the corresponding wall thickness of the initial tube hollow to the desired dimensions of the finished product.

When necessary, tube sinking (i.e. OD reduction of the workpiece without inducing substantial tube wall reduction) is accomplished by drawing the workpiece through a compressive die without internal support (i.e. no ID mandrel). Conventionally, tube sinking is typically utilized as a final or near-final mechanical processing step to achieve the desired dimensional attributed of the finished product.

Although not practically significant, if the particular compositional formulation will support a single reduction from the initial raw material configuration to the desired dimensions of the finished product, in process heat-treatments will not be necessary. Where necessary to achieve intended mechanical properties of the finished product, a final heat-treating step is utilized.

Conventionally, all metallic alloys in accordance with the present invention will require incremental dimensional reductions from the initial raw material configuration to reach the desired dimensions of the finished product. This processing constraint is due to the material's ability to support a finite degree of induced mechanical damage per processing step without structural failure (e.g. strain-induced fracture, fissures, extensive void formation, etc.).

In order to compensate for induced mechanical damage (i.e. cold-working) during any of the aforementioned cold-finishing steps, periodic thermal heat-treatments are utilized to stress-relieve (i.e. minimization of deleterious internal residual stresses that are the result of processes such as cold-working) thereby increasing the workability (i.e. ability to support additional mechanical damage without measurable failure) the workpiece prior to subsequent reductions. These thermal treatments are typically, but not necessarily limited to, conducted within a relatively inert environment such as an inert gas furnace (e.g. nitrogen, argon, etc.), a oxygen rarified hydrogen furnace, a conventional vacuum furnace and under less common process conditions, atmospheric air. When vacuum furnaces are utilized, the level of vacuum (i.e. subatmospheric pressure), typically measured in units of mmHg or torr (where 1 mmHg is equal to 1 unit torr), shall be sufficient to ensure that excessive and deteriorative high temperature oxidative processes are not functionally operative during heat treatment. This process may usually be achieved under vacuum conditions of 10^{-4} mmHg (0.0001 torr) or less (i.e. lower magnitude).

The stress relieving heat treatment temperature is typically held constant between 82 to 86% of the conventional melting point (i.e. industrially accepted liquidus temperature, 0.82 to 0.86 homologous temperatures) within an adequately sized isothermal region of the heat-treating apparatus. The workpiece undergoing thermal treatment is held within the isothermal processing region for a finite period of time that is adequate to ensure that the workpiece has reached a state of thermal equilibrium and for that sufficient time is elapsed to ensure that the reaction kinetics (i.e. time dependent material processes) of stress-relieving and/or process annealing, as appropriate, is adequately completed. The finite amount of time that the workpiece is held within the processing is dependent upon the method of bringing the workpiece into the process chamber and then removing the working upon completion of heat treatment. Typically, this process is accomplished by, but not limited to, use of a

conventional conveyor-belt apparatus or other relevant mechanical assist devices. In the case of the former, the conveyor belt speed and appropriate finite dwell-time, as necessary, within the isothermal region is controlled to ensure that sufficient time at temperature is utilized so as to ensure that the process is
5 completed as intended.

When necessary to achieve desired mechanical attributes of the finished product, heat-treatment temperatures and corresponding finite processing times may be intentionally utilized that are not within the typical range of 0.82 to 0.86
10 homologous temperatures. Various age hardening (i.e. a process that induces a change in properties at moderately elevated temperatures, relative to the conventional melting point, that does not induce a change in overall chemical composition change in the metallic alloy being processed) processing steps may be carried out, as necessary, in a manner consistent with those previously
15 described at temperatures substantially below 0.82 to 0.86 homologous temperature. For cobalt-based alloys in accordance with the present invention, these processing temperatures may be varied between and inclusive of approximately 0.29 homologous temperature and the aforementioned stress relieving temperature range. The workpiece undergoing thermal treatment is held
20 within the isothermal processing region for a finite period of time that is adequate to ensure that the workpiece has reached a state of thermal equilibrium and for that sufficient time is elapsed to ensure that the reaction kinetics (i.e. time dependent material processes) of age hardening, as appropriate, is adequately completed prior to removal from the processing equipment.

25 In some cases for cobalt-based alloys in accordance with the present invention, the formation of secondary-phase ceramic compounds such as carbide, nitride and/or oxides will be induced or promoted by age hardening heat-treating. These secondary-phase compounds are typically, but not limited to, for cobalt-
30 based alloys in accordance with the present invention, carbides which precipitate along thermodynamically favorable regions of the structural crystallographic planes

that comprise each grain (i.e. crystallographic entity) that make-up the entire polycrystalline alloy. These secondary-phase carbides can exist along the intergranular boundaries as well as within each granular structure (i.e. intragranular). Under most circumstances for cobalt-based alloys in accordance with the present invention, the principal secondary phase carbides that are stoichiometrically expected to be present are M_6C where M typically is Cobalt (cobalt). When present, the intermetallic M_6C phase is typically expected to reside intragranularly along thermodynamically favorable regions of the structural crystallographic planes that comprise each grain within the polycrystalline alloy in accordance with the present invention. Although not practically common, the equivalent material phenomena can exist for a single crystal (i.e. monogranular) alloy.

Additionally, another prominent secondary phase carbide can also be induced or promoted as a result of age hardening heat treatments. This phase, when present, is stoichiometrically expected to be $M_{23}C_6$ where M typically is Chromium (Cr) but is also commonly observed to be Cobalt (cobalt) especially in cobalt-based alloys. When present, the intermetallic $M_{23}C_6$ phase is typically expected to reside along the intergranular boundaries (i.e. grain boundaries) within a polycrystalline alloy in accordance with the present invention. As previously discussed for the intermetallic M_6C phase, the equivalent presence of the intermetallic $M_{23}C_6$ phase can exist for a single crystal (i.e. monogranular) alloy, albeit not practically common.

In the case of the intergranular $M_{23}C_6$ phase, this secondary phase is conventionally considered most important, when formed in a manner that is structurally and compositionally compatible with the alloy matrix, to strengthening the grain boundaries to such a degree that intrinsic strength of the grain boundaries and the matrix are adequately balanced. By inducing this equilibrium level of material strength at the microstructural level, the overall mechanical

properties of the finished tubular product can be further optimized to desirable levels.

5 In addition to stress relieving and age hardening related heat-treating steps, solutionizing (i.e. sufficiently high temperature and longer processing time to thermodynamically force one of more alloy constituents to enter into solid solution – ‘singular phase’, also referred to as full annealing) of the workpiece may be utilized. For cobalt-based alloys in accordance with the present invention, the typical solutionizing temperature can be varied between and inclusive of
10 approximately 0.88 to 0.90 homologous temperatures. The workpiece undergoing thermal treatment is held within the isothermal processing region for a finite period of time that is adequate to ensure that the workpiece has reached a state of thermal equilibrium and for that sufficient time is elapsed to ensure that the reaction kinetics (i.e. time dependent material processes) of solutionizing, as
15 appropriate, is adequately completed prior to removal from the processing equipment.

The sequential and selectively ordered combination of thermomechanical processing steps that may comprise but not necessarily include mechanical cold-
20 finishing operations, stress relieving, age hardening and solutionizing can induce and enable a broad range of measurable mechanical properties as a result of distinct and determinable microstructural attributes. This material phenomena can be observed in Figure 1. which shows a chart that exhibits the affect of thermomechanical processing (TMP) such as cold working and in-process heat-
25 treatments on measurable mechanical properties such as yield strength and ductility (presented in units of percent elongation) in accordance with the present invention. In this example, thermomechanical (TMP) groups one (1) through five (5) were subjected to varying combinations of cold-finishing, stress relieving and age hardening and not necessarily in the presented sequential order. In general,
30 the principal isothermal age hardening heat treatment applied to each TMP group varied between about 0.74 to 0.78 homologous temperatures for group (1), about

0.76 to 0.80 homologous temperatures for group (2), about 0.78 to 0.82 homologous temperatures for group (3), about 0.80 to 0.84 homologous temperatures for group (4) and about 0.82 to 0.84 homologous temperatures for group (5). The each workpiece undergoing thermal treatment was held within the isothermal processing region for a finite period of time that was adequate to ensure that the workpiece reached a state of thermal equilibrium and to ensure that sufficient time was elapsed to ensure that the reaction kinetics of age hardening was adequately completed.

More so, the effect of thermomechanical processing (TMP) on cyclic fatigue properties is on cobalt-based alloys, in accordance with the present invention, is reflected in Figure 2. Examination of Figure 2, shows the affect on fatigue strength (i.e. endurance limit) as a function of thermomechanical processing for the previously discussed TMP groups (2) and (4). TMP group (2) from this figure as utilized in this specific example shows a marked increase in the fatigue strength (i.e. endurance limit, the maximum stress below which a material can presumably endure an infinite number of stress cycles) over and against the TMP group (4) process.

Once the all intended processing is complete, the tubular product may be configured into any number of implantable medical devices including intravascular stents, filters, occlusionary devices, shunts and embolic coils. In accordance with the present invention, the tubular product is configured into a stent. Preferred material characteristics of a stent include strength, fatigue robustness and sufficient ductility.

Strength is an intrinsic mechanical attribute of the raw material. As a result of prior thermomechanical processing, the resultant strength attribute can be assigned primarily to the underlying microstructure that comprises the raw material. The causal relationship between material structure, in this instance, grain size, and the measurable strength, in this instance yield strength, is explained by the classical

Hall-Petch relationship where strength is inversely proportional the square of grain size as given by,

$$\sigma_y \propto \frac{1}{\sqrt{G.S.}}, \quad (1)$$

wherein σ_y is the yield strength as measured in MPa and G.S. is grain size as measured in millimeters as the average granular diameter. The strength attribute specifically affects the ability of the intravascular device to maintain vessel patency under in-vivo loading conditions.

The causal relationship between balloon-expandable device recoil (i.e. elastic “spring-back” upon initial unloading by deflation of the deployment catheter’s balloon) and strength, in this instance yield strength, is principally affected by grain size. As previously described, a decrement in grain-size results in higher yield strength as shown above. Accordingly, the measurable device recoil is inversely proportional to the grain size of the material.

The causal relationship between fatigue resistance, in this instance endurance limit or the maximum stress below which a material can presumably endure an infinite number of stress cycles, and strength, in this instance yield strength, is principally affected by grain size. Although fatigue resistance is also affected by extrinsic factors such as existing material defects, for example, stable cracks and processing flaws, the principal intrinsic factor affecting fatigue resistance for a given applied load is material strength. As previously described, a decrement in grain-size results in higher yield strength as shown above. Accordingly, the endurance limit (i.e. fatigue resistance) is inversely proportional to the grain size of the material.

The causal relationship between ductility, in this instance the material’s ability to support tensile elongation without observable material fracture (i.e. percent elongation), is significantly affected by grain size. Typically, ductility is inversely proportional to strength that would imply a direct relationship to grain size.

In accordance with the exemplary embodiment described wherein, microstructural attributes, in this instance, grain-size, may be configured to be equal to or less than about 32 microns in average diameter. In order to ensure that all of the measurable mechanical attributes are homogenous and isotropic within the intended stent, an equiaxed distribution of granularity is preferable. So as to ensure that the structural properties of the intended stent are configured in the preferred manner, a minimum of about two structurally finite intergranular elements (i.e. grains) to a maximum of about ten structurally finite intergranular elements shall exist within a given region of the stent. In particular, the number of grains may be measured as the distance between the abluminal and the luminal surface of the stent (i.e. wall thickness). While these microstructural aspects may be tailored throughout the entirety of the stent, it may be particularly advantageous to configure the deformable regions of the stent with these microstructural aspects as described in detail below.

Referring to Figure 3, there is illustrated a partial planar view of an exemplary stent 100 in accordance with the present invention. The exemplary stent 100 comprises a plurality of hoop components 102 interconnected by a plurality of flexible connectors 104. The hoop components 102 are formed as a continuous series of substantially circumferentially oriented radial strut members 106 and alternating radial arc members 108. Although shown in planar view, the hoop components 102 are essentially ring members that are linked together by the flexible connectors 104 to form a substantially tubular stent structure. The combination of radial strut members 106 and alternating radial arc members 108 form a substantially sinusoidal pattern. Although the hoop components 102 may be designed with any number of design features and assume any number of configurations, in the exemplary embodiment, the radial strut members 106 are wider in their central regions 110. This design feature may be utilized for a number of purposes, including, increased surface area for drug delivery.

The flexible connectors 104 are formed from a continuous series of substantially longitudinally oriented flexible strut members 112 and alternating flexible arc members 114. The flexible connectors 104, as described above, connect adjacent hoop components 102 together. In this exemplary embodiment, the flexible connectors 104 have a substantially N-shape with one end being connected to a radial arc member on one hoop component and the other end being connected to a radial arc member on an adjacent hoop component. As with the hoop components 102, the flexible connectors 104 may comprise any number of design features and any number of configurations. In the exemplary embodiment, the ends of the flexible connectors 104 are connected to different portions of the radial arc members of adjacent hoop components for ease of nesting during crimping of the stent. It is interesting to note that with this exemplary configuration, the radial arcs on adjacent hoop components are slightly out of phase, while the radial arcs on every other hoop component are substantially in phase. In addition, it is important to note that not every radial arc on each hoop component need be connected to every radial arc on the adjacent hoop component.

The substantially tubular structure of the stent 100 provides the scaffolding for maintaining the patency of substantially tubular organs, such as arteries. The stent 100 comprises a luminal surface and an abluminal surface. The distance between the two surfaces defines the wall thickness as is described in detail above. The stent 100 has an unexpanded diameter for delivery and an expanded diameter which roughly corresponds to the normal diameter of the organ into which it is delivered. As tubular organs such as arteries may vary in diameter, different size stents having different sets of unexpanded and expanded diameters may be designed without departing from the spirit of the present invention. As described herein, the stent 100 may be formed from any number of metallic materials, including cobalt-based alloys, iron-based alloys, titanium-based alloys, refractory-based alloys and refractory metals.

In the exemplary stent described above, a number of examples may be utilized to illustrate the relationship of equiaxed granularity to wall thickness. In the first example, the wall thickness may be varied in the range from about 0.0005 inches to about 0.006 inches for a stent having an expanded inside diameter of less than about 2.5 millimeters. Accordingly, for a maximal number of equiaxed grains, which in the exemplary embodiment is substantially not more than ten (10) discrete grains across the thickness of the wall, the equiaxed grain size shall be equal to or greater than substantially 1.25 microns. This dimensional attribute may be arrived at by simply dividing the minimal available wall thickness by the maximal number of available equiaxed grains. In another example, the wall thickness may be varied in the range from about 0.002 inches to about 0.008 inches for a stent having an expanded inside diameter from about 2.5 millimeters to about 5.0 millimeters. Accordingly, for a maximal number of equiaxed grains, which in the exemplary embodiment is substantially not more than ten (10) discrete grains across the thickness of the wall, the equiaxed grain size shall be equal to or greater than substantially 5.0 microns. In yet another example, the wall thickness may be varied in the range from about 0.004 inches to about 0.012 inches for a stent having an expanded inside diameter from about 5.0 millimeters to about 12.0 millimeters. Accordingly, for a maximal number of equiaxed grains, which in the exemplary embodiment is substantially not more than ten (10) discrete grains across the thickness of the wall, the equiaxed grain size shall be equal to or greater than substantially 10.0 microns. In yet still another example, the wall thickness may be varied in the range from about 0.006 inches to about 0.025 inches for a stent having an expanded inside diameter from about 12.0 millimeters to about 50.0 millimeters. Accordingly, for a maximal number of equiaxed grains, which in the exemplary embodiment is substantially not more than ten (10) discrete grains across the thickness of the wall, the equiaxed grain size shall be equal to or greater than substantially 15.0 microns. In making the above calculations, it is important to maintain rigorous consistency of dimensional units.

In accordance with another aspect of the present invention, the elements of the exemplary stent 100, illustrated in Figure 3, may be further defined in terms that may be utilized to describe the relationship between geometry, material and the effects of applied loading. Referring to Figure 4, there is illustrated, in planar view,
 5 a single hoop component 102. As described above, the hoop component 102 is formed as a series of substantially circumferentially oriented radial strut members 106 and alternating radial arc members 108. However, the hoop component 102 may also be defined as a number of interconnected loops 200, wherein a single loop is the element between point a and point b, as illustrated by line 202 in Figure
 10 4. In other words, each single loop comprises a portion of two radial strut members and an entire radial arc member. Formulaically, the linear length or path length of a single loop, L_L , may be given by

$$L_L = RS_L + RA_L, \quad (2)$$

15 wherein RS_L is the length of a strut member and RA_L is the linear length of the arc member as measured through its center line. Given that the hoop 102 may be defined as a number of interconnected loops, the total linear length or path-length of a hoop, H_L , may be given by

$$H_L = \sum L_L. \quad (3)$$

From the expressions represented by equations (2) and (3) a number of ratios may be developed that describe or define the relationship between geometry,
 25 material and the effects of applied load. More specifically, it is the unique material composition and built in properties, i.e. microstructure, that provide the means for fabricating a stent with various geometries that are able to withstand the various loading conditions as is described in detail subsequently. For example, a stent may be designed such that each radial strut's member is configured to exhibit
 30 substantially no permanent plastic deformation upon expansion while each radial arc member is configured to accommodate substantially all permanent plastic

deformation upon expansion. Alternately, a stent may be designed such that each radial arc member is configured to exhibit substantially no permanent plastic deformation upon expansion, while each radial strut member is configured to accommodate substantially all permanent deformation upon expansion. As these
 5 two examples represent the two extremes, it is important to note that the present invention also applies to the continuum between these extremes.

The material properties that are of importance relate to the microstructure as described in detail above. Specifically, the stents are fabricated from a metallic
 10 material processed to have a microstructure with a granularity of about thirty-two microns or less and comprise from about two to about ten substantially equiaxed grains as measured across the wall thickness of the stent. The ratios set forth below help describe the desirable properties of the stent.

15 The expansion efficiency ratio, H_{eff} , is given by

$$H_{\text{eff}} = C/H_L, \quad (4)$$

wherein C is the circumference of a fully expanded hoop (or stent) and H_L is the
 20 total path length of a hoop as set forth in equation (3). Due to the metallic materials and associated built-in properties thereof, the ratio of equation (4) that may be achieved is given by

$$H_{\text{eff}} = C/H_L > 0.25. \quad (5)$$

25 In other words, the ratio of the circumference of a fully expanded hoop to the total path of the hoop is greater than 0.25. Obviously, the maximum that this ratio may achieve is unity since the path length should not be greater than the circumference of the expanded hoop. However, it is this 0.25 expansion
 30 efficiency ratio that is important. In any stent design it is desirable to minimize the amount of structural metal within the vessel and to reduce the overall

complexity of fabrication. Expansion efficiency ratios of greater than 0.25 are achievable through the utilization of these new materials. It is important to note that the circumference of a fully expanded hoop should substantially correspond to the normal luminal circumference of the vessel into which the stent is placed.

5 In addition, if the lumen of the vessel is not substantially circular, perimeter may be substituted for circumference, C.

The loop efficiency ratio, L_{eff} , is given by

$$10 \quad L_{eff} = L_L / RA_L, \quad (6)$$

wherein L_L is the linear length or path-length of a single loop given by equation (2) and RA_L is the linear length or path-length of an arc member. Using the elementary rules of algebraic substitution while maintaining rigorous dimensional
15 integrity, Equation (6) may be rewritten as

$$L_{eff} = (RS_L + RA_L) / RA_L. \quad (7)$$

As may be easily seen from Equation (7), the loop efficiency ratio may never be
20 less than unity. However, because of the material properties, the linear length or path-length of the arc and the linear length or path-length of the struts may be manipulated to achieve the desired characteristics of the final product. For example, under the condition where the strain is primarily carried within the radial arc member, increasing the length of the radial strut for a fixed expansion diameter
25 (displacement controlled phenomena) reduces the magnitude of the non-recoverable plastic strain integrated across the entirety of the radial arc. Similarly, under the condition where the strain is primarily carried within the radial strut member, increasing the length of the radial strut for a fixed expansion diameter (displacement controlled phenomena) reduces the magnitude of the non-
30 recoverable plastic strain integrated across the entirety of the radial strut. In addition, under the condition where the strain is primarily carried within the radial

arc member, increasing the path-length of the radial arc for a fixed expansion diameter (displacement controlled phenomena) reduces the magnitude of the non-recoverable plastic strain integrated across the entirety of the radial arc. As these examples represent the extremes, it is important to note that the present invention
5 also applies to the continuum between these extremes.

Accordingly, since the material is able to withstand greater loading, various designs based upon the above ratios may be achieved.

10 It is important to note that no assumption is made as to the symmetry of the radial struts or radial arc that comprise each single loop and the hoops of the structure. Furthermore, these principals also apply to loops that are interconnected along the longitudinal axis but not necessarily along the radial axis, for example, loops configured into a helical structure. Although a single loop has been
15 illustrated with a single arc member, it obvious to those of ordinary skill in the art, a single loop may be comprise no radial arcs, a single radial arc (as illustrated in Figures 3 and 4) and/or multiple radial arcs and no radial strut, a single radial strut and/or multiple radial struts (as illustrated in Figure 3 and 4).

20 Although shown and described is what is believed to be the most practical and preferred embodiments, it is apparent that departures from specific designs and methods described and shown will suggest themselves to those skilled in the art and may be used without departing from the spirit and scope of the invention. The present invention is not restricted to the particular constructions described
25 and illustrated, but should be constructed to cohere with all modifications that may fall within the scope for the appended claims.

What is claimed:

1. An intraluminal stent comprising:

5 a plurality of hoop components being formed as a continuous series of substantially circumferentially oriented radial strut members and alternating radial arc members, wherein the continuous path from a midpoint of a radial strut member to an equivalent midpoint of an adjacent radial strut member through a radial arc member defines a single loop, and wherein a series of interconnected single loops comprise a single hoop component, wherein the number of
10 circumferentially adjacent single loops are geometrically configured to substantially minimize crossing profile, and the total number of single loops define a total path-length, as measured along the centroidal axis of each radial strut and arc member, of the hoop component; and,

one or more flexible connectors being formed as a continuous series of
15 substantially longitudinally oriented flexible strut members and alternating flexible arc members, the one or more flexible connectors connecting adjacent hoop components to form a substantially tubular structure having a luminal surface and an abluminal surface, wherein a wall thickness is defined as the radial distance between the luminal surface and the abluminal surface of the substantially
20 tubular structure, the single loop components are configured into a hoop component with a ratio of expanded circumferential distance to total path-length greater than about 0.25 and fabricated from a metallic material processed to have a microstructure, in at least the radial arc members, with a granularity of about 32 microns or less and comprise from about 2 to about 10 substantially
25 equiaxed grains as measured across the wall thickness.

2. The intraluminal stent according to claim 1, wherein each radial strut member is configured to exhibit substantially no permanent plastic deformation upon expansion.

30

3. The intraluminal stent according to claim 2, wherein each radial arc member is configured to accommodate substantially all permanent plastic deformation upon expansion.

5 4. The intraluminal stent according to claim 3, wherein the ratio of a length of a loop to a length of the radial arc member within any single loop is greater than or equal to unity.

10 5. The intraluminal stent according to claim 1, wherein each radial arc member is configured to exhibit substantially no permanent plastic deformation upon expansion.

15 6. The intraluminal stent according to claim 5, wherein each radial strut member is configured to accommodate substantially all permanent plastic deformation upon expansion.

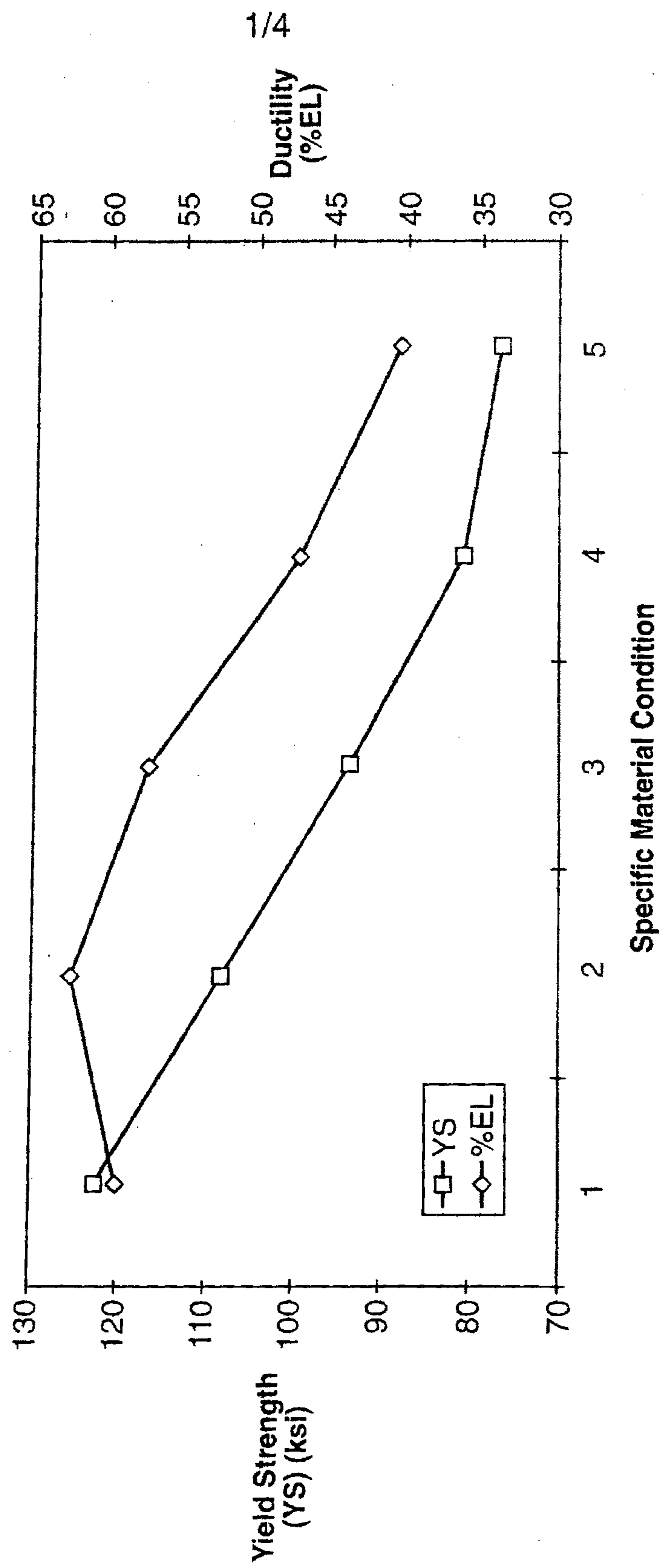
20 7. The intraluminal stent according to claim 6, wherein the ratio of a length of a loop to a length of the radial arc member within any single loop is greater than unity.

8. The intraluminal stent according to claim 1, wherein each radial arc member and each radial strut member are configured to accommodate permanent plastic deformation upon expansion.

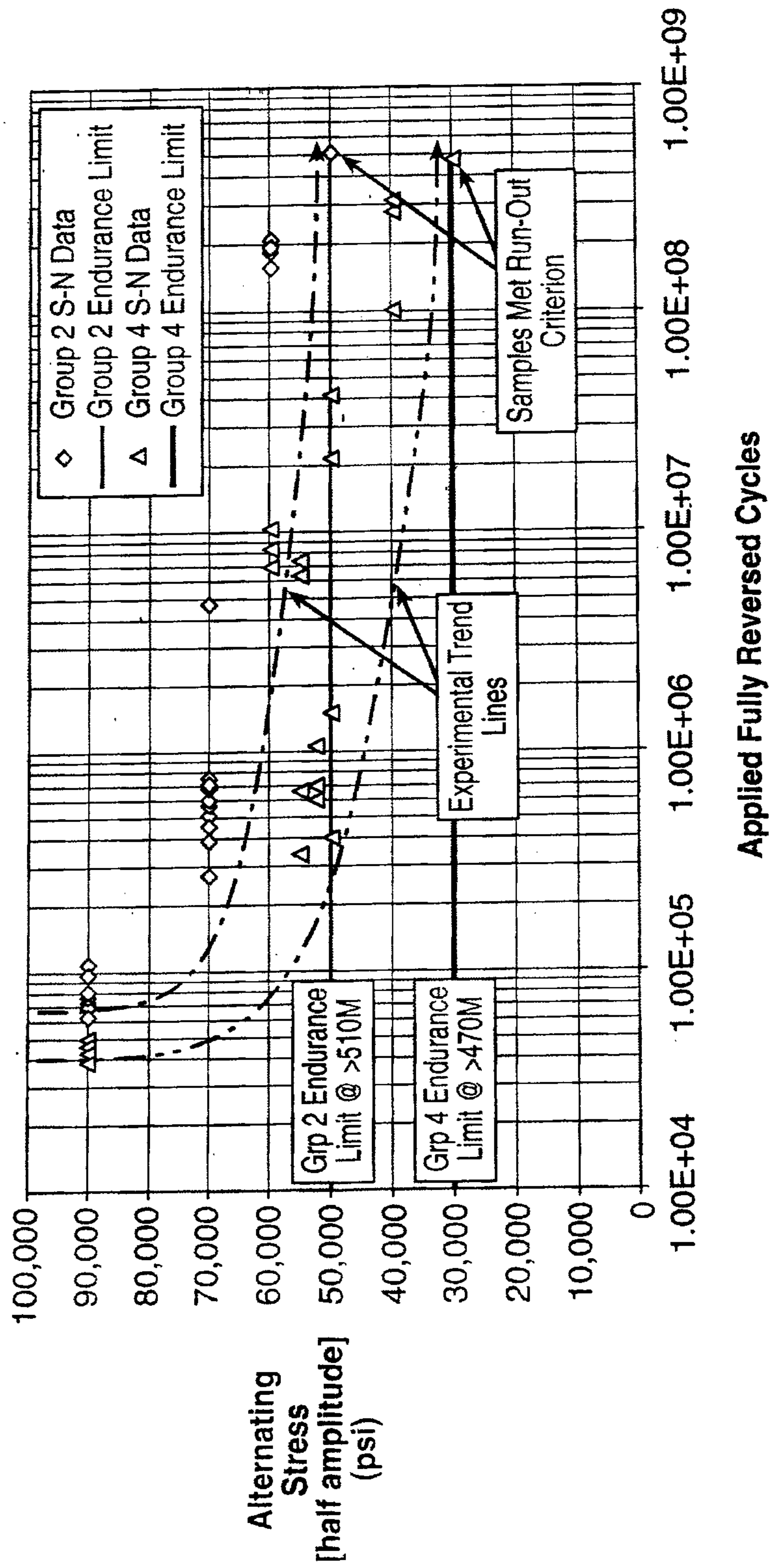
25 9. The intraluminal stent according to claim 8, wherein the ratio of a length of a loop to a length of the radial arc member within any single loop is greater than unity.

30 10. An intraluminal stent for placement within a vessel comprising one or more support structures defining a predetermined path-length, wherein the ratio of vessel luminal perimeter to path-length is greater than about 0.25 and the one

or more support structures being fabricated from a metallic material processed to have a microstructure with a granularity of about 32 microns or less and comprises from about 2 to about 10 substantially equiaxed grains as measured across the wall thickness.

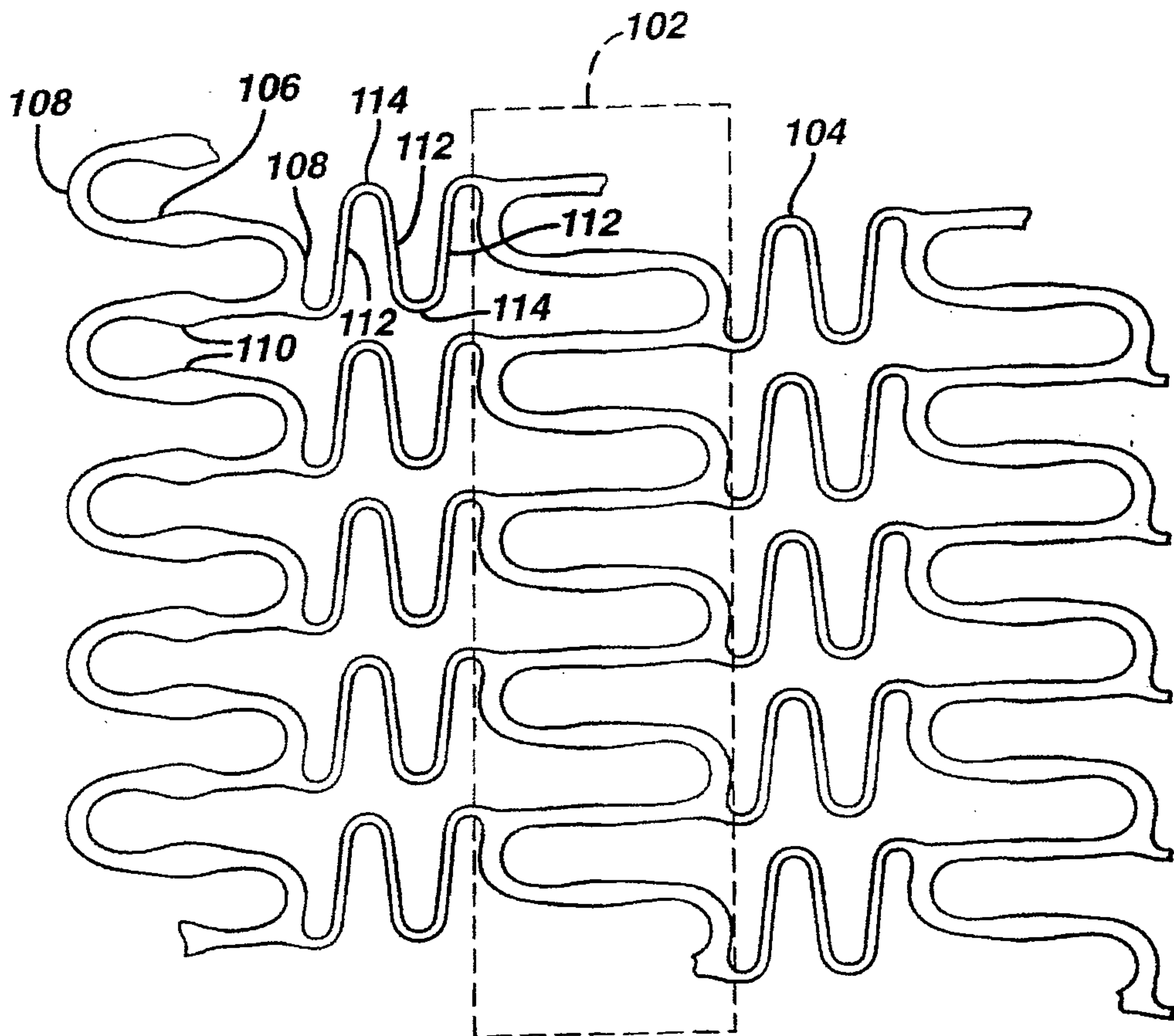
FIG. 1

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FIG. 2

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FIG. 3



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FIG. 4

