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(54) STENT HAVING A MULTIPLICITY OF UNDULATING LONGITUDINALS

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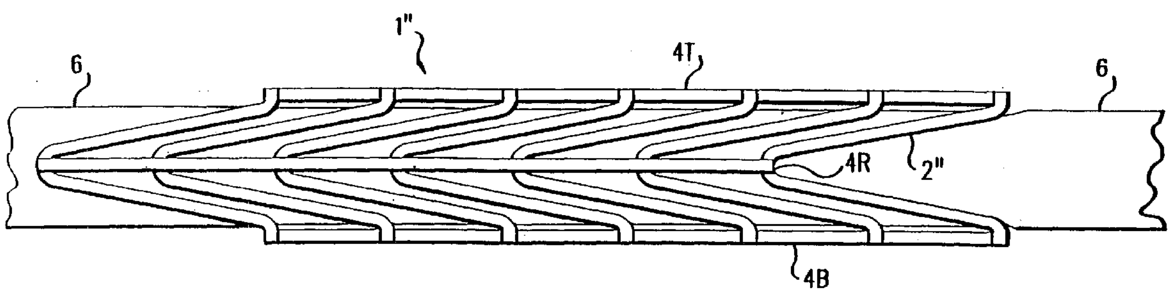
(57) ABSTRACT

A method for implanting a balloon expandable stent at a site within a passageway of a curved coronary article. The stent includes at least two longitudinally spaced apart circumferential rings. At least one longitudinally extending connector extends between adjacent rings. The connector has at least one turn back portion that can expand or contract in length while being passed through a curved passageway. The stent is disposed on a stent delivery catheter having an inflatable balloon. The stent delivery catheter and the stent is delivered through the passageway to the site of implementation with the connector member expanding or contracting in length to facilitate delivery and placement of the stent. The stent is expanded at the site of implantation by inflating the balloon to force the stent radially outward against the wall of the coronary artery.



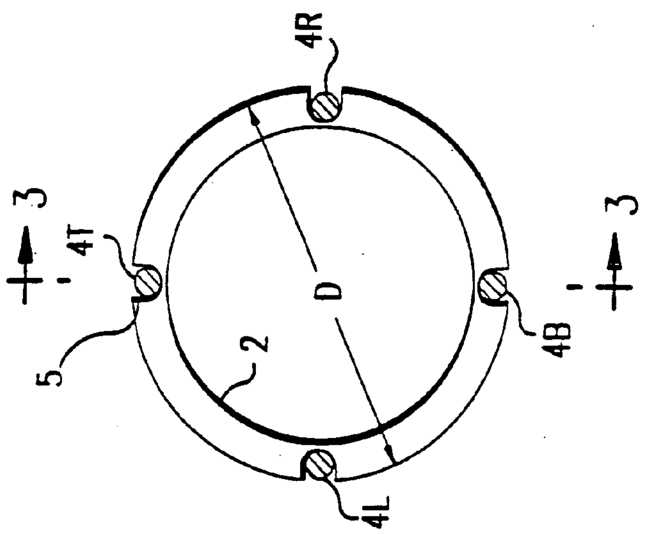


FIG.2

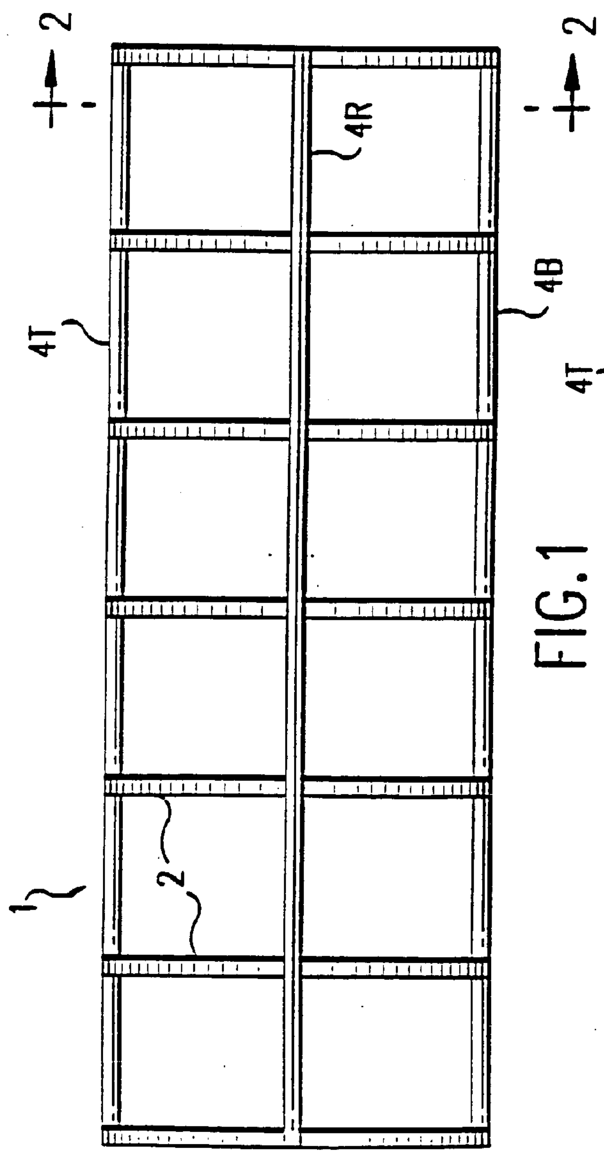


FIG.1

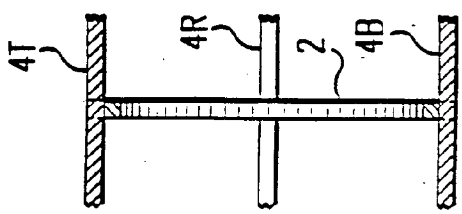


FIG.3

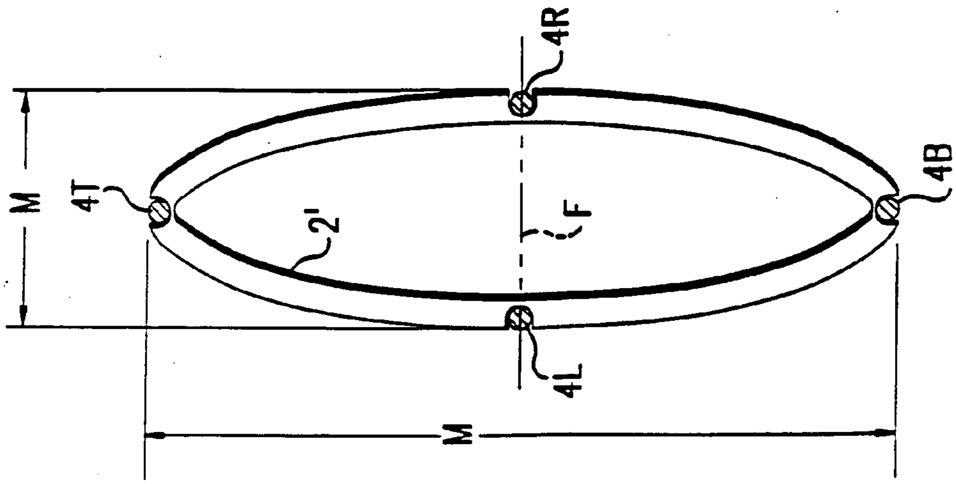


FIG.5

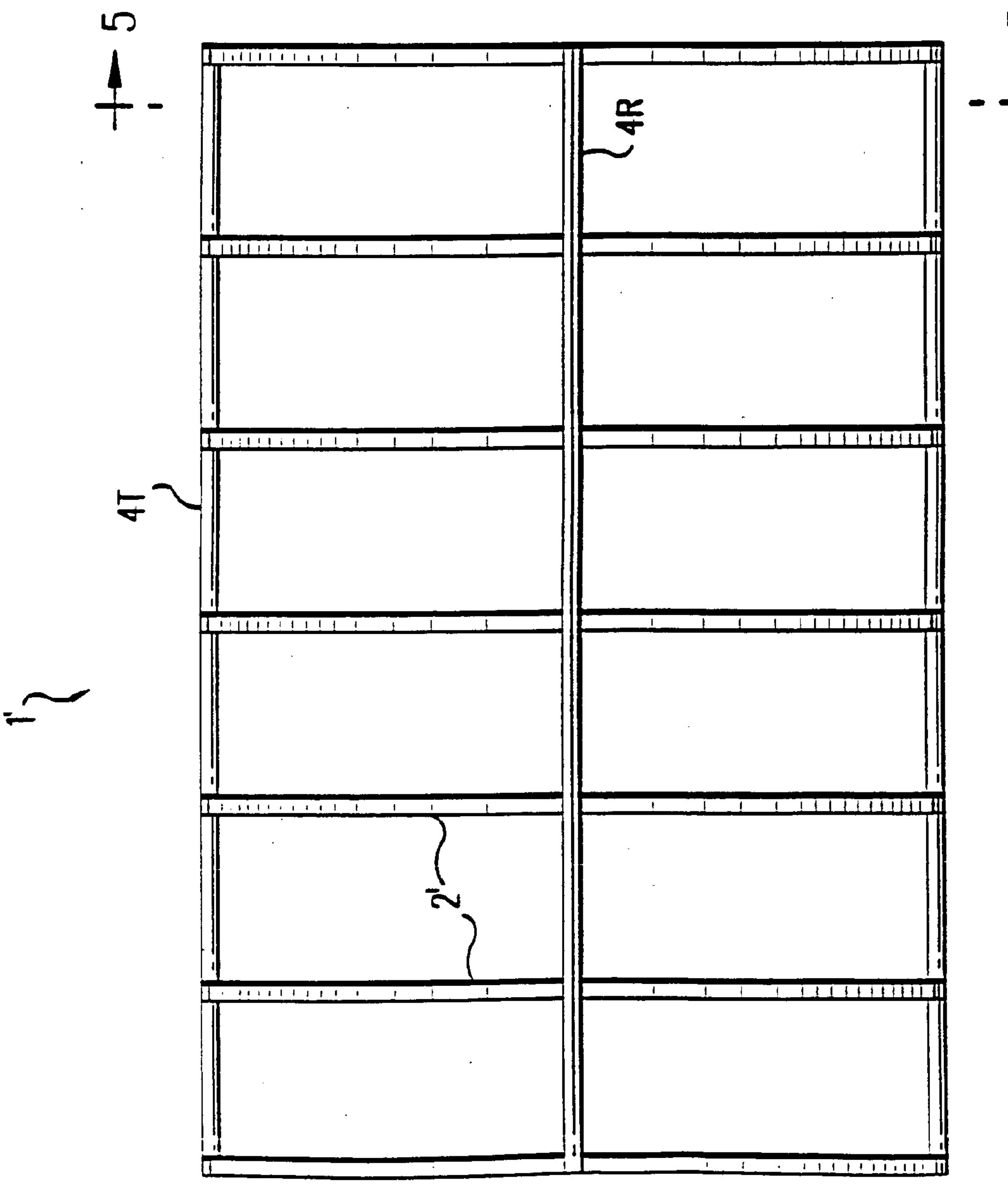


FIG.4

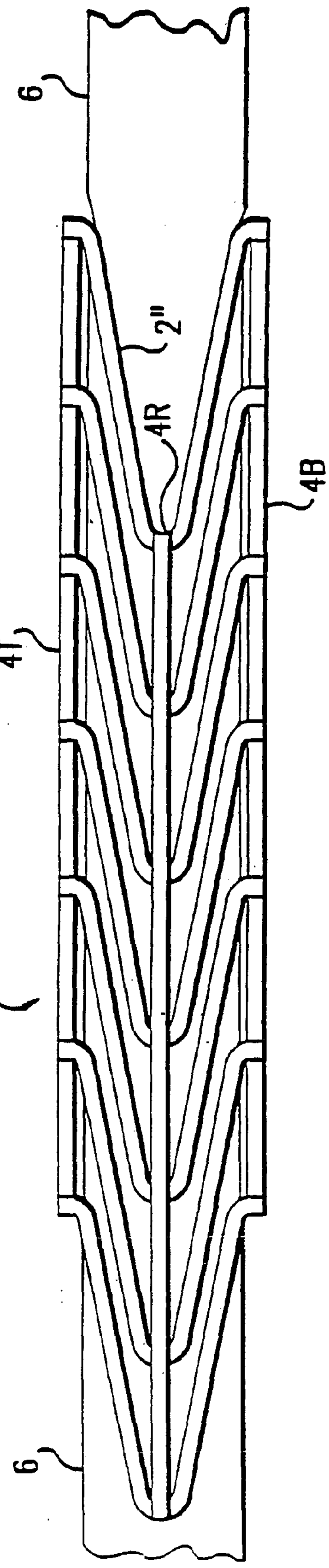


FIG.6

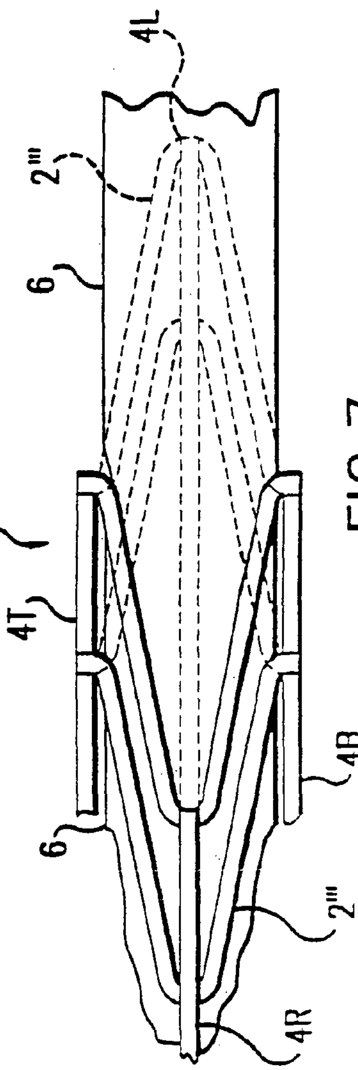


FIG.7

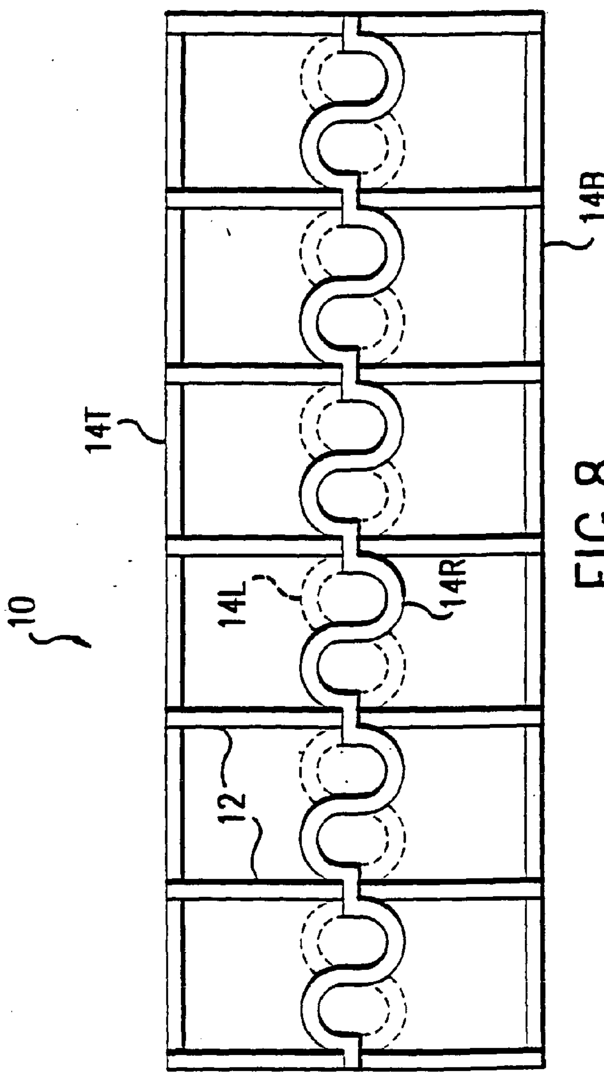


FIG.8

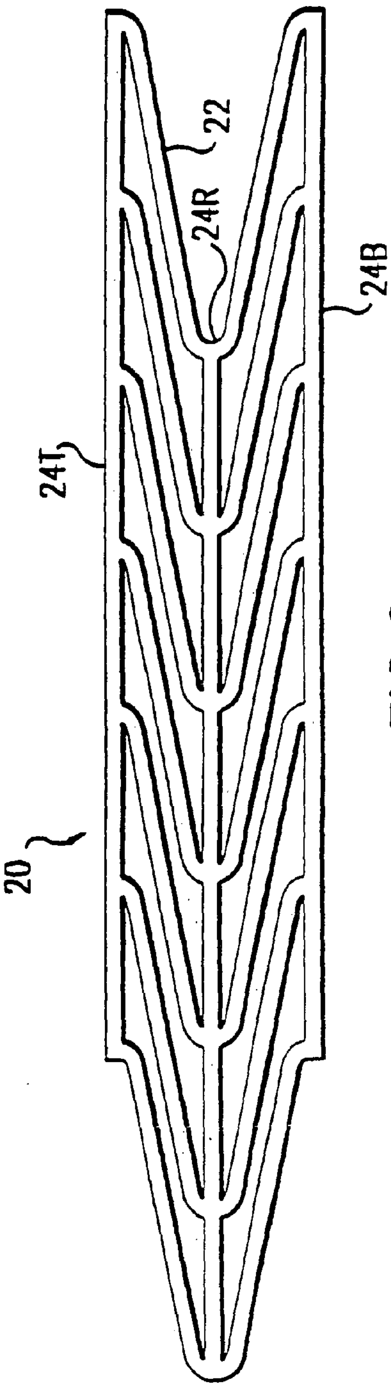


FIG.9

STENT HAVING A MULTIPLICITY OF UNDULATING LONGITUDINALS

FIELD OF THE INVENTION

[0001] This invention is in the field of stents for maintaining patency of any one of a multiplicity of vessels of the human body.

BACKGROUND OF THE INVENTION

[0002] In the last decade, many different designs of stents have been used to maintain patency of arteries and other vessels of the human body. In all such devices, hoop strength is an important characteristic. Specifically, the stent must have enough hoop strength to resist the elastic recoil exerted by the vessel into which the stent is placed. The Mass stent described in the U.S. Pat. No. 4,553,545 and the Dotter stent described in U.S. Pat. No. 4,503,569 are each open helical coils. The Palmaz stent described in the U.S. Pat. No. 4,733,665 is of the "chinese finger" design. The Gianturco-Rubin stent currently sold by Cook, Inc, is another stent design which like the stents of Mass, Dotter and Palmaz does not have any closed circular member to optimize hoop strength.

[0003] The ideal arterial stent utilizes a minimum wire size of the stent elements to minimize thrombosis at the stent site after implantation. The ideal arterial stent also possess sufficient hoop strength to resist elastic recoil of the artery. Although the optimum design for maximizing hoop strength is a closed circular structure, no prior art stent has been described which has a small diameter when percutaneously inserted into a vessel and which expands into the form of multiplicity of closed circular structures (i.e. rings) when expanded outward against the vessel wall.

BRIEF SUMMARY OF THE PRESENT INVENTION

[0004] The present invention is an expandable stent that can be used in an artery or any other vessel of the human body which, when expanded, forms a multiplicity of generally circular rings whose closed structure optimizes hoop strength so as to minimize elastic recoil of the vessel into which the stent is inserted. Furthermore, the structure of the stent in the present invention is initially in the form of folded ellipses or ovals which can be formed to a small diameter for percutaneous insertion by means of a stent delivery catheter. The ovals are joined to each other by either a straight or undulating shaped wires which are called "longitudinals" which serve to space the deployed rings within the vessel. Straight longitudinals are used in straight vessels and undulating longitudinals can be employed in either straight or highly curved vessels such as some coronary arteries.

[0005] Thus, an object of this invention is to provide a stent having a maximum hoop strength by the employment of closed, generally circular structures which are in fact rings.

[0006] Another object of this invention is that the rings are initially in the form of ovals that can be folded to fit onto a cylindrical structure at a distal portion of a stent delivery catheter.

[0007] Still another object of this invention is that the fully deployed rings are spaced apart by means of longitudinals which are either straight of undulating wires that are placed to be generally parallel to the longitudinal axis of the vessel into which the stent is deployed.

[0008] Still another object of this invention is that the pre-deployment stent structure is formed as a single piece out of a metal tube having a smaller inside diameter as compared to the outside diameter of an expandable balloon onto which the pre-deployment stent is mounted.

[0009] These and other important objects and advantages of this invention will become apparent from the detailed description of the invention and the associated drawings provided herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] **FIG. 1** is a side view of the stent after it has been deployed; i.e., in its post-deployment form.

[0011] **FIG. 2** is a transverse cross section of section **2-2** of **FIG. 1** illustrating how the longitudinals are joined to the rings.

[0012] **FIG. 3** is a cross section at section **3-3** of **FIG. 2** showing the joining of a single ring to the longitudinals.

[0013] **FIG. 4** is a side view of the stent prior to being mounted onto a stent delivery catheter, i.e., in the form of an initial structure.

[0014] **FIG. 5** is a transverse cross section of section **5-5** of **FIG. 4** illustrating how the longitudinals are joined to the ovals.

[0015] **FIG. 6** is a side view of a pre-deployment form of the stent structure in which the ovals have been folded into a small diameter cylinder that is placed around a deflated balloon situated near the distal end of a stent delivery catheter.

[0016] **FIG. 7** is a partial side view of a pre-deployment stent structure showing only two of a multiplicity of folded ovals formed around an expandable balloon in which the ovals are folded in an alternative manner as compared with **FIG. 6**.

[0017] **FIG. 8** is a side view of a post-deployment stent structure which utilizes two undulating longitudinals on opposite sides of the stent for improved placement in curved vessels.

[0018] **FIG. 9** is a side view of a stent as etched out of a small diameter metal cylinder as a single piece of metal.

DETAILED DESCRIPTION OF THE DRAWINGS

[0019] **FIG. 1** is a side view of the cylindrical stent **1** of the present invention shown in its post-deployment configuration. The stent **1** has a multiplicity of rings **2** which are spaced apart by four wires called longitudinals. As seen in **FIGS. 1 and 2**, at the top of the stent is longitudinal **4**T, at the bottom is longitudinal **4**B, at the left side is longitudinal **4**L and at the right side is longitudinal **4**R. Although **FIGS. 1 and 2** show 7 rings and 4 longitudinals, it is apparent that the stent can be made longer by adding rings or increasing the separation between rings. In a similar manner, the stent can be made shorter by reducing the number of rings or decreasing the spacing between rings. Also variable spacing of the rings is envisioned for accomplishing a variety of purposes including increased hoop strength at a particular section of the stent. Also, it is envisioned that the two or more longitudinals could be utilized for this stent design with a maximum number being **32**.

[**0020**] **FIGS. 2 and 3** illustrate the joining of the longitudinals to the rings. Specifically the longitudinals can be placed into cutouts in the form of notches **5** located on the outside perimeter of the ring **2**. The longitudinals can then be spot welded, adhesively bonded or joined by any variety of means to the rings **2**. It is also envisioned that the longitudinals could be placed on the inside perimeter of the ring **2**, or holes could be mechanically or laser drilled through the ring **2** for placement therethrough of the longitudinals.

[**0021**] **FIGS. 4 and 5** illustrate a stent **1**' shown in one particular form in which it could be fabricated; i.e., in an initial structure form. Specifically, **FIGS. 4 and 5** show that this initial form of the stent **1**' is a multiplicity of parallel ellipses or ovals **2**" each oval having the same minor axis dimension m and major axis dimension M. The oval's minor axis passes through the center of the longitudinals **4**L and **4**R. The oval's major axis passes through the center of the longitudinals **4**T and **4**B. It is important to note that, if it is desired to have a final outside diameter D (as seen in **FIG. 2**) of the ring **2** after it is fully deployed, then it can be shown that D is given by the equation $D^2=\frac{1}{2}(m^2+M^2)$.

[**0022**] To place the stent design of **FIGS. 4 and 5** onto a balloon that is mounted near the distal end of a stent delivery catheter, it is necessary to fold the ovals **2**' around that balloon. Specifically, the pre-deployment cylindrical stent **1**" can be formed onto an expandable balloon **6** as shown in **FIG. 6** by folding the ovals **2**' about the dotted line F (which is the minor axis of the oval **2**') as shown in **FIG. 5** Specifically, as seen in **FIG. 4**, the top and bottom of the ovals **2**' could be held stationery while the side longitudinals **4**R and **4**L are pushed to the left which results in the pre-deployment structure which is shown as the stent **1**" in **FIG. 6**. An optimum design has the folded ovals **2**" as shown in **FIG. 6** with the stent **1**" being a cylinder whose outside diameter is equal in size to the minor axis dimension m. When the balloon **6** of **FIG. 6** is expanded, the pre-deployment stent **1**" structure forms the post-deployment stent **1** structure having circular rings **2** as shown in **FIGS. 1 and 2**.

[**0023**] The stent **1**'" is an alternative embodiment for a pre-deployment structure of the stent of the present invention as it is placed onto a balloon. Specifically, **FIG. 7** shows 2 folded rings **2**'" of a multiple ring stent **1**'". The stent **1**'" being formed by holding the top and bottom of the stent **1**' of **FIG. 4** stationery while pushing the longitudinal **4**R to the left and pushing the longitudinal **4**L to the right. Like the stent **1**" of **FIG. 6**, when mounted onto a balloon, the stent **1**'" has cylindrical shape with a diameter equal to the dimension m.

[**0024**] FIGS. **1** to **7** inclusive illustrate stents that employ longitudinals that are formed from generally straight wires. **FIG. 8** shows an alternative embodiment of a stent **10** that has two undulating longitudinals. Specifically, the left side longitudinal **14**L (shown as dotted lines) and the right side longitudinal **14**R are each undulating shaped longitudinals. A stent such as stent **10** could have two or more undulating longitudinals. Such a stent would bend more easily during insertion into a vessel and would be more readily adaptable for placement in curved vessels such as some coronary arteries.

[**0025**] Typically, the rings and longitudinals of the stents would be made of the same material. Typical metals used for such a stent would be stainless steel, tantulum, titanium, or a shape memory metal such as Nitinol. If Nitinol is used, the stent would be heat treated into the shape at body temperature having circular rings **2** as shown in **FIGS. 1 and 2**. The rings could then be distorted into ovals as shown in **FIGS. 4 and 5** and then mounted onto a stent delivery catheter which does not employ a balloon but is of the more general shape described in the previously cited U.S. Pat. No. 4,553,545 by C. T. Dotter. Such a design would provide the desired stent structure having a multiplicity of generally circular rings instead of the Dotter design of a helical spring which inherently has a lesser hoop strength as compared to the present invention.

[**0026**] It should be understood that once the ovals are folded onto a stent delivery catheter, when they fully deploy, they do not form perfectly circular rings as shown in **FIG. 2**, but rather they are of a generally circular shape. Such comparatively small deviations form an exactly circular shape do not appreciably decrease hoop strength because they are in fact closed structures that are almost exactly circular.

[**0027**] It should also be understood that at least part of the end rings of the stent could be fabricated from or coated with a radiopaque metal such as tantalum or gold to provide a fluoroscopic indication of the stent position within a vessel. However, the other rings and the longitudinals could be made from a much less dense metal which would provide less obscuration of the central region within the stent. For example, the stent rings and longitudinals could all be fabricated from titanium or a titanium alloy except the end rings which could be formed from gold which is then plated with titanium. Thus, the entire outside surface of the stent would be titanium, which is known to be a comparatively non-thrombogenic metal while the gold in the end rings provides an improved fluoroscopic image of the stent extremities.

[**0028**] The dimensions of stent rings are typically 0.1 to 0.3 mm thick, with a width of 0.1 to 0.5 mm and an outside diameter D between 2.0 and 30.0; mm depending on the luminal diameter of the vessel into which it is inserted. The length of the stent could be between 1 and 10 cm. The wire diameter for the longitudinals would typically be between 0.05 and 0.5 mm.

[**0029**] Although the designs of **FIGS. 1 through 7** inclusive illustrate separate longitudinals attached to a multiplicity of rings, this invention also contemplates an initial stent structure which is chemically etched from thin-walled tubing having an oval transverse cross section. Thus the oval and longitudinals would be formed from a single piece of metal thus precluding the need for attaching the longitudinals to the rings. In a similar manner laser or EDM machining could be used to form the stent from a thin-walled tube.

[**0030**] It is further anticipated that a pre-deployment stent structure **20** as shown in **FIG. 9** could be formed from a thin-walled cylindrical tube whose inside diameter is slightly smaller than the outside diameter of the balloon **6** shown in **FIG. 6**. A pattern such as that shown in either **FIG. 6** or **FIG. 7** could be photoetched onto a tin-walled metal cylinder. The one piece structure **20** shown in **FIG. 9** has folded ovals **22** and longitudinals **23**T, **24**B, **24**R and (not shown) **24**L. This pre-deployment stent structure **20** could then be mounted onto the expandable balloon; the stent having sufficient elastic recoil to firmly grasp down onto the balloon. Another method to form the pre-deployment stent is by etching the correct pattern onto a thin, flat metal plate, then forming a tube from the plate and then making a longitudinal weld to form a cylindrically shaped structure which is, in fact, the pre-deployment stent structure **20** shown in **FIG. 9**.

[**0031**] Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings. Therefore, it should be understood at this time that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

1-35 (Cancelled)

36: A generally cylindrical stent for delivery to a coronary artery, said stent having a first pre-deployment diameter and a second deployed diameter, said stent being cut from a pre-existing metal tube and having a circumference and a longitudinal axis, said stent having sufficient flexibility to permit percutaneous delivery to a curved coronary artery; said stent in its first diameter comprising:

at least two longitudinally spaced apart circumferential rings, each of said circumferential rings defining a portion of the circumference of the stent, each of said circumferential rings having at least two peak segments and at least two valley segments; and

at least one connector having a first end portion and a second end portion, said first end portion being fixedly connected to a peak segment of a first of said circumferential rings and said second end portion being fixedly connected to a valley segment of a circumferential ring adjacent to said first circumferential ring, at least one of said first and second end portions of said connector including a straight segment that is substantially parallel to the longitudinal axis of the stent, said connector having at least one circumferentially extending generally U-shaped turn back portion between its first and second end portions that can expand or contract in length, as measured by the straight line distance between its first and second end portions, while being passed through a curved coronary artery.

37: The stent of claim 36, wherein the turn back portion has a first end point and a second end point, and a line drawn from the first end point to the second end point is generally parallel to the longitudinal axis of the stent.

38: The stent of claim 37, wherein said line drawn from the first end point to the second end point remains generally parallel to the longitudinal axis of the stent when the stent is expanded into its second deployed diameter.

39: The stent of claim 36, wherein the stent is laser-cut from a pre-existing metal tube.

40: The stent of claim 36, wherein at least three circumferentially spaced connectors connect said first circumferential ring and a circumferential ring adjacent to said first circumferential ring.

41: The stent of claim 36, wherein said connector has at least two turn back portions between its first and second end portions.

42: The stent of claim 36, wherein each of said first and second end portions of said connector includes a straight segment and a straight line drawn therethrough is substantially parallel to the longitudinal axis of the stent.

43: The stent of claim 36, wherein at least one turn back portion of said connector is located entirely within a valley segment of a circumferential ring.

44: The stent of claim 36, wherein said connector includes at least two generally U-shaped turn back portions that open in opposite directions.

45: A generally cylindrical stent for delivery to a coronary artery, said stent having a first pre-deployment diameter and a second deployed diameter, said stent being cut from a preexisting metal tube and having a longitudinal axis, said stent having sufficient flexibility to permit percutaneous delivery to a curved coronary artery; said stent in its first diameter comprising:

a multiplicity of closed perimeter cells, each of said cells including at least one generally U-shaped turn back portion having a first end point and a second end point wherein a line drawn from the first end point to the second end point is generally parallel to the longitudinal axis of the stent.

46: The stent of claim 45, wherein said line drawn from the first end point to the second end point remains generally parallel to the longitudinal axis of the stent when the stent is expanded into its second deployed diameter.

47: The stent of claim 45, wherein each of said cells has at least one circumferentially adjacent cell which shares one generally U-shaped turn back portion.

48: The stent of claim 45, wherein the stent includes at least two longitudinally spaced apart circumferential rings, each of said circumferential rings having at least two peak segments and at least two valley segments; and at least one connector having a first end portion and a second end portion, said first end portion being fixedly connected to a peak segment of a first of said circumferential rings and said second end portion being fixedly connected to a valley segment of a circumferential ring adjacent to said first circumferential ring, said connector having at least one of said generally U-shaped turn back portions, wherein each of said closed perimeter cells includes at least a portion of two circumferentially adjacent rings and at least one connector.

49: The stent of claim 45, wherein the stent is laser-cut from a pre-existing metal tube.

50: The stent of claim 45, wherein each of said cells includes at least two generally U-shaped turn back portions.

51: A generally cylindrical stent for delivery to a coronary artery, said stent having a first pre-deployment diameter and a second deployed diameter, said stent being cut from a pre-existing metal tube and having a longitudinal axis, said stent having sufficient flexibility to permit percutaneous delivery to a curved coronary artery; said stent in its first diameter comprising:

at least two longitudinally spaced apart circumferential rings and at least one connector, said connector having a first end portion fixedly connected to a first of said circumferential rings and a second end portion fixedly connected to a circumferential ring adjacent to said first circumferential ring, said connector including at least one generally U-shaped turn back portion having a first end point and a second end point so that a line drawn from the first end point to the second end point is generally parallel to the longitudinal axis of the stent so as to define a multiplicity of perimeter cells that include at least a portion of two circumferentially adjacent rings and at least one connector.

52: The stent of claim 51, wherein said line drawn from the first end point to the second end point remains generally parallel to the longitudinal axis of the stent when the stent is expanded into its second deployed diameter.

53: The stent of claim 51, wherein the stent is laser-cut from a pre-existing metal tube.

54: The stent of claim 51, wherein at least three circumferentially spaced connectors connect said first circumferential ring and a circumferential ring adjacent to said first circumferential ring.

55: The stent of claim 51, wherein said connector has at least two turn back portions between its first and second end portions.

56: The stent of claim 51, wherein said connector includes at least two generally U-shaped turn back portions that open in opposite directions.

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