

EXPANDABLE STENT AND METHOD FOR MANUFACTURING SAME

Field of the Invention

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This application relates to an expandable stent for deployment in a body lumen, such as a blood vessel. The stent is useful in the treatment of atherosclerotic stenosis.

Background of the Invention

Cardiovascular disease is the leading cause of death in the United States and Canada. The disease state is commonly caused by the deposition of fatty plaque within the coronary arteries, which is termed
15 atherosclerosis. Atherosclerosis gradually results in a narrowing of the coronary arteries and a corresponding decrease in blood flow to heart muscles. Eventually this may trigger serious clinical complications, such as angina or myocardial infarction.

20 Stents are small tubular devices, typically constructed from biocompatible metal, which are inserted in blood vessels and the like to maintain the patency of the vessel lumen. Once deployed, stents radially support a segment of the vessel wall and help prevent atherosclerotic plaque from occluding the lumen.

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Stents are commonly deployed by means of a thin-walled intravascular balloon dilation catheter. This procedure involves mounting a compressed stent around an expandable balloon positioned at the distal end of the catheter. The catheter is carefully guided by a physician to the

desired location while monitoring the procedure on a video screen. For example, the catheter may be inserted into the femoral artery of the patient and progressively advanced into the iliac artery, ascending aorta and finally into a coronary artery. Once the catheter is advanced to the desired
5 location, the physician dilates the balloon to flatten plaque deposits and expand the stent from the compressed configuration to a fully expanded configuration supporting the vessel wall. The balloon is then deflated and the catheter is withdrawn from the patient.

10 In order to be effective, stents must exhibit both longitudinal flexibility and radial rigidity. Flexibility is necessary to permit the physician to readily guide the catheter through the twists and turns of blood vessel passageways when deploying the stent. Radial rigidity is desired to ensure that, once deployed, the stent will have the mechanical
15 rigidity to maintain the patency of the vessel lumen. In other words, the stent must be capable of effectively resisting restenosis (i.e. the chronic or acute occlusion of the coronary arteries following balloon angioplasty).

Various expandable stents have been proposed in the past
20 which have attempted to satisfy these requirements. For example, United States Patent No. 5,514,154 issued 7 May, 1996 to Lau et al. discloses stents comprising a plurality of radially expandable cylindrical elements which are connected together and aligned on a common longitudinal axis. Each individual element may be formed in an undulating or serpentine pattern
25 and includes edges which project outwardly when the stent is expanded. While the Lau et al. stents exhibit good longitudinal flexibility, the projecting edges have the capacity to damage tissue when they are embedded in the vascular wall at the lesion site to maintain the stent in

position. The Lau et al. stent elements are preferably formed from stainless steel tubing which is subjected to chemical etching and laser patterning. Such manufacturing processes require costly equipment, such as machine-controlled lasers.

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Canadian Patent No. 2,202,476 published 2 May, 1996 to Birdsall et al. is also representative of the prior art. This patent relates to a connected stent apparatus comprising a plurality of stent segments formed from wires arranged in an undulating pattern. The stent segments
10 are connected together by a series of small welds which restrict the stent's overall longitudinal flexibility. Further, the need to make a large number of welds increases production costs and restricts the capacity to make low profile (i.e. very small size) stents.

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It is also known in the prior art to use stents in combination with graft material. For example, United States Patent No. 5,683,448 issued 4 November, 1997 discloses a combination intraluminal stent and graft. The graft is positioned around the outside or within the interior of the stent and is fastened to the stent's wire body with a plurality of hoop
20 members. Other existing prior art stents also typically have single wire walls which are not adapted for easily clamping graft material to the wire body.

The need has therefore arisen for an expandable stent having
25 improved longitudinal flexibility and radial strength characteristics which may be manufactured in an automated process using inexpensive equipment. There is also a need for a stent specifically designed for delivering drug-coated graft material to the site of a target lesion by

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clamping the graft material between multiple wire wall sections of the stent.

Summary of the Invention

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In accordance with the invention, a stent is disclosed comprising a plurality of separate stent modules. Each module includes a first element comprising a first flexible wire strand and a second flexible wire strand; a second element comprising a third flexible wire strand and
10 a fourth flexible wire strand; and fastening means for joining the first and second elements together. The fastening means comprises a first connector for joining the first and second elements at a first location; and a second connector for joining the first and second elements at a second location opposite the first location. The first and second elements are formed in
15 a sinusoidal wave pattern having alternating peaks and troughs. Preferably the peaks on the first element are aligned with the troughs on the second element, and the troughs on the first element are aligned with the peaks on the second element.

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The first and second elements are moveable between a substantially flattened position and a cylindrical expanded position. In the flattened position, the first and second elements extend in a substantially common plane. In the expanded position, the first and second elements are annular in shape and are aligned to define a cylindrical opening.

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Preferably the first, second, third and fourth strands are of substantially equal length and each strand is semi-cylindrical in shape in the expanded position. The first and second elements may comprise equal

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length segments of a multi-stranded flexible wire. Preferably the first and second elements each comprise $2(n)$ wire strands where n is an integer greater than or equal to 1.

- 5 The application also relates to an elongated stent comprising a plurality of stent modules connected together along a common longitudinal axis by fastening one of the first and second connectors on one of the modules to one of the first and second connectors on an adjacent module. In one embodiment, the modules are fastened together on
- 10 alternating sides of the stent.

A method of forming a stent module is also disclosed which includes the steps of

- 15 (a) providing a first flexible wire strand bent in a loop and a second flexible wire strand bent in a loop;
- (b) connecting the first and second wire strands together at a first location with a first connector;
- 20 (c) connecting the first and second wire strands together at a second location diametrically opposite the first location with a second connector, wherein the first and second connectors subdivide the strands into first and second segments of
- 25 substantially equal length; and
- (d) forming the first and second segments into a sinusoidal waveform pattern having alternating peaks and troughs.



A method of forming an elongated stent is also disclosed which includes the steps of:

- 5 (a) forming a stent module by following the method described above;
- (b) fastening an interconnection element to one of the connectors on the stent module;
- 10 (c) forming a further stent module by repeating the steps of subparagraphs (a) and (b) above;
- (d) aligning the stent modules adjacent one another such that the first and second connectors on each of the modules are
15 longitudinally aligned;
- (e) fastening the interconnection element to one of the connectors on the further stent module; and
- 20 (f) repeating steps (c) - (e) until a stent of a desired length is formed.

Brief Description of the Drawings

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In drawings which illustrate embodiments of the invention, but which should not be construed as restricting the spirit or scope of the invention in any way,

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Figure 1 is an enlarged, fragmented sectional view of a portion of blood vessel showing the applicant's stent mounted on a balloon catheter;

Figure 2 is an isometric view of a single stent module;

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Figure 3 is an isometric view of a stent comprising a plurality of interconnected stent modules as illustrated in Figure 2;

Figure 4 is an isometric view illustrating a method for
10 manufacturing a stent module in accordance with the applicant's invention;

Figure 5 is an isometric view of a method step for adjusting a stent module derived from the process of Figure 4 from a flattened to an
15 expanded configuration;

Figure 6 is an isometric view of a stent in its flattened configuration comprising a plurality of interconnected stent modules as illustrated in Figure 5;

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Figure 7 is an isometric view of an alternative stent module having closely-spaced wire walls; and

Figure 8 is a fragmented, isometric view of a stent suitable for
25 holding graft material which comprises a plurality of stent modules as illustrated in Figure 7.

Detailed Description of the Preferred Embodiment

Figure 1 illustrates the applicant's stent 10 in its expanded configuration within a blood vessel 4 or other body lumen. Stent 10 is
5 deployed in vessel 4 by mounting it on an expandable balloon 6 of a flexible catheter 8. As described further below, after balloon 6 is deflated and catheter 8 is withdrawn, stent 10 remains in place within vessel 4 to radially support a segment of the inner vessel wall 9.

10 Stent 10 ordinarily comprises a plurality of separate stent modules 12 which are fastened together (although stent 10 could comprise a single module 12). As shown in Figure 2, each module 12 consists of a first segment 14 and a second segment 16 which are joined on opposite
15 sides of each module 12 by means of a first connector 18 and a second connector 20. In the expanded configuration shown in Figure 2, segments 14 and 16 are annular in shape and are longitudinally aligned to define a cylindrical opening 17 for permitting blood flow through the interior of
20 stent 10. Preferably segments 14, 16 comprise flexible wire elements which are formed in a sinusoidal pattern comprising a plurality of peaks 43 and troughs 45 as illustrated in Figures 1 and 2 and described below.

Each stent module 12 is individually expandable to conform to the internal anatomy of vessel wall 9. Connectors 18, 20 provide enhanced vessel wall support and are radio-opaque for easy visualization
25 under fluoroscopy. As shown best in Figures 1, the peaks 43 and troughs 45 of module segments 14, 16 are aligned in the direction of the vessel 4 to be stented (i.e. along the longitudinal axis of cylindrical opening 17 in the direction of blood flow). Each individual module 12 is relatively short in

length and is radially rigid. The combination of a plurality of modules 12 having these design characteristics provides stent 10 with a high degree of radial strength.

5 As shown in Figures 1 and 3, the various modules 12 comprising stent 10 are joined together by interconnection elements 22. Interconnection elements 22 extend between connectors 18, 20 on adjacent modules 12 and may comprise, for example, strands or loops of flexible wire. In the illustrated embodiment, interconnection elements 22 alternate
10 on opposite sides of stent 10 so each pair of adjacent modules 12 are coupled by a single interconnection element 22. This provides stent 10 with a high degree of longitudinal flexibility which facilitates its insertion inside a tortuous body lumen. However, as will be apparent to someone skilled in the art, each pair of adjacent modules 12 could alternatively be
15 coupled by two interconnection elements 22 (i.e. one element 22 extending between adjacent connectors 18 aligned on one side of stent 10 and a second connector 22 extending between adjacent connectors 20 aligned on an opposite side of stent 10). Other alternative fastening combinations could also be envisaged provided that each pair of adjacent modules 12 is
20 coupled together by at least one interconnection element 22.

 Figures 4 and 5 illustrate method steps for fabricating a stent module 12. A length of flexible wire 24 having a first strand 26 and a second strand 28 is provided. As shown in Figure 4, wire 24 is bent until
25 a first wire end 30 is juxtaposed with a second wire end 32. Wire ends 30, 32 are coupled together with first connector 18. Second connector 20 is then secured to wire 24 at a location directly opposite connector 18.

Connectors 18, 20 therefore subdivide module 12 into first segment 14 and second segment 16 which are of substantially equal length.

Connectors 18 and 20 and wire strands 26 and 28 are preferably constructed from medical grade stainless steel. Optionally other biocompatible materials could be employed.

In one embodiment of the invention, connectors 18, 20 may comprise small metal tubes which encircle wire 24 and are mechanically crimped to hold connectors 18, 20 in place. Other equivalent means for securing wire strands 26, 28 together on opposite sides of stent module 12 may be substituted. For example, connectors 18, 20 could comprise clips, welds, or the like.

As will be apparent to someone skilled in the art, in an alternative embodiment, module 12 could be fabricated from two separate wire strands 26 and 28 each formed in an endless loop. Such wire strands 26, 28 could be aligned in parallel planes in a manner similar to that shown in Figure 4 and joined together at diametrically opposite locations with connectors 18 and 20, thereby defining module segments 14 and 16 of substantially equal length.

The next step in the manufacturing process involves forming segments 14, 16 of each module 12 into a sinusoidal wave pattern while module 12 remains in a flattened configuration. As shown in Figure 4, this may be achieved by bending the wire strands 26, 28 comprising segments 14, 16 using a template having first and second sections 36 and 38. Each template section 36, 38 includes one or more protruding fingers 40.

During the wire bending process, module 12 is supported on a plurality of spaced-apart cylindrical pins 39 which extend from a plate 41. When template segments 36, 38 are moved toward one another as shown in Figure 4, fingers 40 pass between stationary pins 39 to bend segments 14, 16 into a sinusoidal pattern comprising a plurality of peaks 43 and troughs 45. Pins 39 function as stoppers which define the peaks 43 in first segment 14 and troughs 45 in second segment 16. Preferably template sections 36, 38 and pins 39 are configured so that peaks 43 formed in segment 14 are aligned with the troughs 45 of segment 16, and the troughs 45 formed in stent segment 14 are similarly aligned with the peaks 43 of segment 16 (Figure 4). As will be apparent to someone skilled in the art, the number of peaks and troughs 43, 45 formed during this wire bending process may vary and is not a critical feature of the invention (each wire strand 26, 28 of each element 14, 16 has at least one peak 43 or trough 45).

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The method steps of Figure 4 yield a flattened stent module 12 as illustrated in Figure 5 having bent wire strands 26 and 28 which extend in substantially parallel planes. In order to adjust module 12 from this flattened configuration to the expanded configuration of Figure 2, a mandrel 42 having a tapered conical end 44 is inserted between wire strands 26 and 28 (Figure 5) to form each segment 14, 16 into an annular shape defining cylindrical opening 17 (Figure 2).

If stent 10 comprises a plurality of modules 12, wire interconnection elements 22 may be secured to connectors 18, 20 on adjacent modules 12 during the manufacturing process to yield a flattened stent 10 as shown in Figure 6. For example, if connectors 18, 20 consist of small tubes, then an end portion of an interconnection element 22 may be

inserted within one of the connectors 18, 20 before it is crimped. The other end of the interconnection element 22 may be similarly joined to a connector 18, 20 on another stent module 12 fabricated in accordance with the method steps illustrated in Figure 4, and so on, to produce a stent 10 comprising a plurality of modules 12.

As will be apparent to a person skilled in the art, if stent 10 comprises a plurality of aligned modules 12, then each of the modules 12 may be adjusted from the flattened configuration (Figure 6) to the expanded configuration (Figure 3) in a single step using mandrel 42. This will yield a cylindrical stent 10 as shown in Figure 3 where modules 12 share a common longitudinal axis.

The applicant's manufacturing method as illustrated in Figures 4 and 5 and described above may be automated to decrease the cost of production. The method is readily reproducible and is economical as compared to conventional stent machining techniques employing costly laser cutting, etching and welding equipment. One important advantage of the applicant's method is that stent segments 14, 16 may be shaped into the desired sinusoidal pattern using inexpensive equipment while module 12 is in a flattened configuration (Figure 4).

In alternative embodiments, stent 10 may comprise modules 12 arranged in diverging branches for supporting portions of blood vessels 4 or other body lumens which do not share a common axis. This can easily be achieved by connecting each branching segment to one connector 18, 20 on opposite sides of a single linking module 12.

Figure 7 and 8 illustrate a further alternative embodiment of the invention wherein each module 12 is fabricated according to the method of Figure 4 from four separate flexible wire strands 26a, 26b, 28a and 28b. In order to adjust such a module 12 from the flattened configuration to the expanded configuration, a mandrel 42 may be passed between the innermost wire strands 26b and 28a. This results in a stent module 12 where, in the expanded configuration, wire strands 26a and 26b are closely spaced together and wire strands 28a and 28b are similarly closely spaced together (Figure 7). A plurality of modules 12 formed in this manner may be joined together with interconnection elements 22 as described above and shown in Figure 8.

The alternative embodiment of Figures 7 and 8 provides an opportunity to clamp graft material 46 or other biocompatible substrates or barriers between respective pairs of wire strands 26a and 26b, and 28a and 28b. Such graft material 46 could be coated or impregnated, for example, with drugs for inhibiting restenosis or thrombosis. Thus, in this alternative embodiment, stent modules 12 have the added potential to function as a drug delivery apparatus. Optionally graft material 46 may also be used as an endovascular prosthesis or a barrier for sealing off aneurisms, thrombi, perforations or an entire vascular lesion. Graft material 46 may comprise one or more separate strips of material positionable side by side to extend between connectors 18, 20 around all or part of the circumference of stent 10 (in Figure 8 a fragment of a single strip of graft material 46 is shown).

As will be apparent to someone skilled in the art, in further alternative embodiments modules 12 may be fabricated from six, eight or

any other even number of wire strands of substantially equal length to provide further opportunities to clamp graft material 46 therebetween.

In use, a stent 10 may be fabricated in accordance with the method steps described above and adjusted from its flattened configuration (Figure 6) to its expanded configuration (Figure 3). Stent 10 is then radially compressed to be crimped on a deflated balloon 6 of a catheter 8 for delivery to a target site. The catheter 8 is inserted in a blood vessel or other body lumen of the patient undergoing treatment and carefully guided by the physician to the desired location while monitoring the procedure on a video screen. For example, the catheter may be inserted into the femoral artery of the patient and progressively advanced into the iliac artery, ascending aorta and finally into a coronary artery. Since interconnection elements 22 permit each stent module 12 to flex relative to an adjacent module 12, stent 10 has sufficient longitudinal flexibility to facilitate easy passage through tortuous blood vessels and the like.

An important advantage of the applicant's invention is that stent 10 exhibits excellent radiopacity. In particular, connectors 18, 20 of each stent module 12 are radio-opaque and easily visible to the physician during the stent deployment procedure using fluoroscopy. This ensures that the physician can accurately deliver stent 10 to the target site.

Once stent 10 has been positioned at the target site, balloon 6 is dilated causing stent 10 to expand until it contacts the vessel inner wall 9, as shown in Figure 1. Each module 12 is independently expandable for ease of deployment and to conform to the particular anatomy at the target

site. For example, a tapered balloon 6 may be employed to match the shape of a target blood vessel or other lumen. Once stent 10 has been expanded, balloon 6 is deflated and removed from vessel 4 together with catheter 8 leaving stent 10 in place. In this deployed position stent 10 remains set in place, each stent module 12 radially supporting a portion of the vessel inner wall 9. The provision of connectors 18, 20 on diametrically opposite sides of each module 12, and the sinusoidal waveform pattern of stent segments 14, 16, optimizes the radial strength and rigidity of stent 10 in the deployed position.

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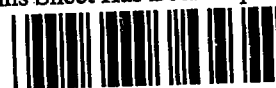
If the alternative stent 10 of Figures 7 and 8 is employed, graft material 46 may be deployed at the target site to provide further support for the vessel inner wall 9 and to serve as a substrate for the delivery of drugs as described above.

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As will be apparent to those skilled in the art in the light of the foregoing disclosure, many alterations and modifications are possible in the practice of this invention without departing from the spirit or scope thereof. Accordingly, the scope of the invention is to be construed in accordance with the substance defined by the following claims.

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WHAT IS CLAIMED IS:



1. A stent module comprising:

5 (a) a first element comprising a first flexible wire strand and a second flexible wire strand;

(b) a second element comprising a third flexible wire strand and a fourth flexible wire strand;

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(c) fastening means for joining said first and said second elements together, wherein said fastening means comprises:

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(i) a first connector for joining said first and second elements together at a first location; and

(ii) a second connector for joining said first and second elements together at a second location opposite said first location,

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wherein said first and second elements are formed in a sinusoidal wave pattern having alternating peaks and troughs.

25 2. The stent module of claim 1, wherein said peaks on said first element are aligned with said troughs on said second element, and wherein said troughs on said first element are aligned with said peaks on said second element.

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3. The stent module of claim 1, wherein said first and second elements are moveable between a substantially planar flattened position and a cylindrical expanded position.
- 5 4. The stent module of claim 3, wherein said first and second elements extend in a substantially common plane in said flattened position.
5. The stent module of claim 1, wherein said first, second, third and fourth strands are of substantially equal length.
- 10 6. The stent module of claim 1, wherein said first and second elements are annular in shape in said expanded position and are aligned to define a cylindrical opening.
- 15 7. The stent module of claim 6, wherein each of said first, second, third and fourth strands is semi-cylindrical in shape in said expanded position.
8. The stent module of claim 1, wherein each of said first and second
20 connectors comprise a tube encircling said first and second elements.
9. The stent module of claim 1, wherein said first and second elements comprise equal length segments of a multi-stranded flexible wire.
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10. The stent module of claim 1, wherein said first and second elements each comprise $2(n)$ wire strands where n is an integer greater than or equal to 1.
- 5 11. The stent module of claim 10, further comprising graft material clamped between said wire strands when n is greater than 1.
12. An elongated stent comprising a plurality of stent modules as defined in claim 1, wherein said modules are longitudinally aligned and connected together by fastening one of said first and second
10 connectors on one of said modules to one of said first and second connectors on an adjacent one of said modules.
13. The stent as defined in claim 12, wherein said modules are fastened
15 together on alternating sides of said stent.
14. A method of forming a stent module comprising:
- (a) providing a first flexible wire strand bent in a loop and a
20 second flexible wire strand bent in a loop;
- (b) connecting said first and second wire strands together at a first location with a first connector;
- 25 (c) connecting said first and second wire strands together at a second location diametrically opposite said first location with a second connector, wherein said first and second connectors





subdivide said strands into first and second segments of substantially equal length; and

(d) forming said first and second segments into a sinusoidal waveform pattern having alternating peaks and troughs.

15. The method of claim 14, wherein said first and second segments extend in the same plane when said segments are formed into said sinusoidal waveform pattern.

16. The method of claim 15, further comprising the step of separating said first and second flexible strands to form each of said first and second segments into an annular shape defining a cylindrical opening.

17. The method of claim 14, wherein said first and second strands are of substantially equal length.

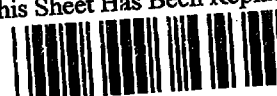
18. A method of forming an elongated stent, comprising

(a) forming a stent module by following the method of claim 14;

(b) fastening an interconnection element to one of said connectors on said stent module;

(c) forming a further stent module by repeating the steps of subparagraphs (a) and (b) above;

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- (d) aligning said stent modules adjacent one another such that said first and second connectors on each of said modules are longitudinally aligned;
- 5 (e) fastening said interconnection element to one of said connectors on said further stent module; and
- (f) repeating steps (c) - (e) until a stent of a desired length is formed.

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19. A method of forming an elongated stent, comprising

- (a) forming a plurality of stent modules by following the method of claim 14;
- 15 (b) aligning said stent modules adjacent one another such that said first and second connectors on each of said modules are longitudinally aligned; and
- 20 (c) fastening said stent modules together by joining at least one of said connectors on one of said modules to at least one of said connectors on an adjacent one of said modules.

20. A stent module comprising:

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- (a) a first flexible strand formed in a loop;
- (b) a second flexible strand formed in a loop;

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(c) a first connector for joining said first and second flexible strands together at a first location; and

5 (d) a second connector for joining said first and second strands together at a second location diametrically opposite said first location,

wherein said first and second connectors subdivide said strands into first and second segments of substantially equal length.

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21. The stent module of claim 20, wherein said first and second segments are each formed in a sinusoidal wave pattern.

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22. The stent module of claim 20, wherein said module is adjustable between a flattened configuration wherein said first and second strands extend in substantially parallel planes and an expanded position wherein said first and second strands are curved to define a cylindrical opening.

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23. The stent module of claim 20, wherein each of said first and second strands comprise an endless loop of wire.

24. A stent comprising at least one stent module as defined in claim 20.

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