

## FIELD OF THE INVENTION

The invention relates generally to stents, which are endoprotheses implanted into vessels within the body, such as blood vessels, to support and hold open the vessels, or to secure and support other endoprotheses in the vessels.

## BACKGROUND OF THE INVENTION

Various stents are known in the art. Typically stents are generally tubular in shape, and are expandable from a relatively small, unexpanded diameter to a larger, expanded diameter. For implantation, the stent is typically mounted on the end of a catheter, with the stent being held on the catheter at its relatively small, unexpanded diameter. By the catheter, the unexpanded stent is directed through the lumen to the intended implantation site. Once the stent is at the intended implantation site, it is expanded, typically either by an internal force, for example by inflating a balloon on the inside of the stent, or by allowing the stent to self-expand, for example by removing a sleeve from around a self-expanding stent, allowing the stent to expand outwardly. In either case, the expanded stent resists the tendency of the vessel to narrow, thereby maintaining the vessel's patency.

Some examples of patents relating to stents include U.S. Patent No. 4,553,545 to Maass et al.; U.S.



Patent No. 4,733,665 to Palmaz; U.S. Patent Nos. 4,800,882  
and 5,282,824 to Gianturco; U.S. Patent Nos. 4,856,516,  
4,913,141, 5,116,365 and 5,135,536 to Hillstead; U.S. Patent  
Nos. 4,649,922, 4,886,062, 4,969,458 and 5,133,732 to  
5 Wiktor; U.S. Patent No. 5,019,090 to Pinchuk; U.S. Patent  
No. 5,102,417 to Palmaz and Schatz; U.S. Patent No.  
5,104,404 to Wolff; U.S. Patent No. 5,161,547 to Tower; U.S.  
Patent No. 5,383,892 to Cardon et al.; U.S. Patent No.  
5,449,373 to Pinchasik et al.; and U.S. Patent No. 5,733,303  
10 to Israel et al.

U.S. Patent No. 4,553,545 to Maass et al. (the  
"Maass '545 patent"), the disclosure of which is hereby  
expressly incorporated by reference into this application,  
shows various stents in the form of coiled springs. Figures  
15 1 through 7 of that patent illustrate coiled spring stents  
formed of helically wound wire wherein the diameters of the  
stents are contracted and expanded by rotating the spring  
ends. Such coiled spring stents are very flexible, such  
that they can be tracked easily down tortuous lumens and  
20 such that they conform relatively closely to the compliance  
of the vessel after deployment. However, while these stents  
are very flexible, they also lend relatively unstable  
support after expansion. The individual windings of the  
coil may move relative to each other, causing sometimes  
25 significant gaps between adjacent windings, which could  
cause significant portions of the vessel wall to be left



unsupported. Also, the windings of the coil may bend or tilt somewhat, potentially obstructing and seriously compromising the lumen. Figure 10 of the Maass '545 patent illustrates an example of tilted windings in these coiled  
5 spring stents.

The Maass '545 patent discloses various mechanisms designed to address the instability of these coiled spring stents. For example, Figures 11 through 14 show the use of rigidifying devices in the form of axial support members  
10 that extend along a side of the stent and maintain the relative positioning of the windings. Figure 22 shows a stent constructed of a coiled band, wherein the band has openings in it so that it takes the shape of a ladder. Figure 23 shows another coiled ladder stent, wherein the  
15 ladder is formed by two wires attached to each other by transverse elements. Each of these coiled ladder stents provides improved stability when compared to the single strand coiled spring stents.

Despite these modifications, one problem with each  
20 of the coiled spring and coiled ladder stents disclosed in the Maass '545 patent is that expansion of the stent results in an unwinding of the coil. This unwinding causes twisting of the stent, including rotation of the stent ends, which is potentially harmful to the vessel wall. In addition, the  
25 expansion and twisting causes the number of individual windings to lessen, resulting in less windings to support



the vessel wall. The reduction in windings also means either that the length of the stent will foreshorten significantly, in order to maintain the spacing of the windings, or that the spacing between the windings will increase significantly, in order to maintain the length of the stent, or in some instances a combination of both. The foreshortening results in less lengthwise coverage of the vessel wall in the deployed stent as well as lateral movement during deployment which may be harmful to the vessel wall. The increase in the spacing between windings could result in significant portions of the vessel wall being left unsupported. Both are potential disadvantages of the coiled spring and coiled ladder stents disclosed in the Maass '545 patent.

U.S. Patent Nos. 4,886,062 and 5,133,732 to Wiktor (the "Wiktor '062 patent" and the "Wiktor '732 patent"), the disclosures of which are hereby expressly incorporated by reference into this application, show stents formed of wire wherein the wire is initially formed into a band of zig-zags forming a serpentine pattern, and then the zig-zag band is coiled into a helical stent. The stents are expanded by an internal force, for example by inflating a balloon. Another example of a similar coiled zig-zag stent is the Crossflex stent marketed by Cordis Corporation.

The coiled zig-zag stents that are illustrated in Figures 1 through 6 of the Wiktor '062 and '732 patents are



very flexible, but, again, they are relatively unstable.  
The Wiktor '732 patent discloses alternative constructions  
of these coiled zig-zag stents to address their instability.  
In one example, illustrated in Figure 7 of that patent, a  
5 straight longitudinal wire extends along a side of the stent  
and is connected to the windings to fix them relative to  
each other. In another example, illustrated in Figure 8 of  
that patent, in various locations around the helix of the  
stent, a bend in the zig-zag wire is made longer than other  
10 bends, so that it can reach and hook around a bend in an  
adjacent winding of the helix. Each of these constructions  
results in increased stability of the stent, but each also  
results in some reduction in the flexibility of the stent.

#### SUMMARY OF THE INVENTION

15 An object of the invention is to provide a stent  
that is longitudinally flexible such that it can easily be  
tracked down tortuous lumens and does not significantly  
change the compliance of the vessel after deployment,  
wherein the stent is relatively stable so that it avoids  
20 bending or tilting in a manner that would potentially  
obstruct the lumen and so that it avoids leaving significant  
portions of the vessel wall unsupported.

Another object of the present invention is to  
provide a stent that has little or no twisting or rotation  
25 of its ends upon expansion, and that also undergoes little



or no foreshortening upon expansion and simultaneously does not result in significant gaps being created between adjacent windings of the stent upon expansion.

In accordance with one embodiment of the invention, a stent is configured as a coiled stent in which the coil is formed from a wound strip of cells, wherein the sides of the cells are serpentine. Thus, the stent is comprised of a strip helically wound into a series of coiled windings, wherein the strip is formed of at least two side bands connected to each other, for example by a series of cross struts. Each side band is formed in a serpentine pattern comprising a series of bends, wherein upon expansion of the stent, the bends of the side bands open to increase the length of each of the individual cells in the helical direction, thereby lengthening the strip in the helical direction to allow the stent to expand without any significant unwinding of the strip.

A serpentine coiled ladder stent according to the invention retains the flexibility associated with coiled spring stents, yet has windings which are relatively stable and insusceptible to displacement or tilt. A serpentine coiled ladder stent according to the invention thus provides continuous support of the vessel tissue without disadvantageously obstructing the lumen.

In addition, the serpentine coiled ladder stent substantially avoids the problems of twisting, end rotation,



foreshortening and the creation of significant gaps upon expansion. When the serpentine coiled ladder stent is expanded, the outward radial force on the stent causes the bends in the serpentine sides to open up and become  
5 straighter, thereby causing the overall length of the strip in the helical direction to increase. By providing a serpentine strip that allows the strip itself to lengthen in the helical direction as the stent is expanded, the increase in the diameter of the stent is accommodated by a  
10 lengthening of the strip, rather than by an unwinding of the strip. Thus, the number of windings may be maintained, and rotation of the ends and foreshortening or the opening of gaps between windings can be substantially reduced or avoided. In fact, the serpentine coiled ladder stent may be  
15 constructed so that adjacent points on adjacent windings remain adjacent to each other as the stent is expanded. Thus, the two ends of the strip at the ends of the stent may be joined, for example by welding, to the respective adjacent windings, thereby creating smooth ends and assuring  
20 no relative rotation.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a schematic diagram of three coiled wire  
stents as in the prior art, the first having  
equally spaced windings, the second having  
25 unevenly spaced windings, and the third have some



tilted windings;

Figure 2 shows a coiled ribbon stent in an unexpanded condition;

5 Figure 3 shows the coiled ribbon stent of Figure 2 in an expanded condition;

Figure 4 shows a prior art coiled ladder stent, similar to those shown and described in U.S. Patent No. 4,553,545 to Maass et al.;

10 Figure 5 shows a serpentine coiled ladder stent in accordance with the invention, in an expanded condition;

Figure 6 shows a strip used to form a serpentine coiled ladder stent in accordance with the invention; and

15 Figure 7 shows a serpentine coiled ladder stent in accordance with the invention, in an unexpanded condition.

#### DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

Figure 1 shows a schematic diagram of cross-sections through three prior art stents, each formed of a helically wound wire. The top coiled wire stent A is in its  
20 optimal, desired condition, with each of the windings 1' evenly spaced from the next. Thus, the gaps 2' between the adjacent windings 1' are relatively uniform, such that a relatively uniform support is provided to the vessel wall,  
25 should the windings 1' remain evenly spaced as shown.



In practice, though, a coiled wire stent as shown in Figure 1 sometimes tends to change configuration, particularly during and after implantation when it is subjected to various stresses in the vessel. Thus, some of the windings may tend to separate somewhat, as shown in the middle coiled wire stent B in Figure 1. In the middle coiled wire stent B, the windings 1'' are spaced unevenly, sometimes leaving significant gaps 2''.

Alternatively or additionally, the windings of the traditional coiled wire stent may bend or tilt while in the vessel. In the bottom coiled wire stent C in Figure 1, some of the windings 1''' have tilted somewhat. These tilted windings not only fail to provide proper support to the vessel, but they also enter and partially obstruct the passageway through the stent, thus seriously compromising the lumen.

One way to overcome the instability problems of the coiled wire stent is to replace the wire with a ribbon having a width substantially larger than its thickness. Figure 2 shows an unexpanded coiled ribbon stent 10 mounted on a catheter 15. As shown in Figure 2, the coiled ribbon stent is formed as a helically wound ribbon strip. Because the width of the ribbon in the coiled ribbon stent 10 as shown in Figure 2 is greater than the width of the wire in the coiled wire stent A as shown in Figure 1, the windings 11 of the coiled ribbon stent 10 are relatively resistant to



longitudinal displacement or tilting.

Figure 3 shows the coiled ribbon stent 10 of Figure 2 in an expanded condition. Expansion may be accomplished, for example, by inflating a balloon 16 on the catheter 15, with the outward force of the balloon 16 acting on the inside of the stent 10 and causing the stent 10 to expand. When the coiled ribbon stent 10 is expanded as shown in Figure 3, the diameter of the individual windings 11 increases. However, because the length of the ribbon strip is constant, the increase in diameter causes the ribbon strip to unwind somewhat, in order to accommodate the expansion. In doing so, the ends 13 of the stent 10 rotate, the number of windings 11 decreases, and the overall length of the stent foreshortens and/or gaps are formed between adjacent windings 11. The rotation of the stent, particularly of the stent ends, is potentially harmful to the vessel, and the decrease in windings and the decrease in length of the stent or the opening of significant gaps between windings results in less of the vessel wall being supported and unpredictable lesion coverage.

In addition to these disadvantages, the coiled ribbon stent 10 is also somewhat disadvantageous in that the metal of the ribbon strip covers a high percentage of the surface area of the stented vessel wall. This high percentage of metal coverage inhibits or slows down the healing response of the vessel wall to the trauma of



stenting. This problem of the high percentage of metal coverage in the coiled ribbon stent 10 may be solved by modifying the ribbon strip to a ladder strip, in which the strip coiled to form the stent has a series of openings in it, resembling a ladder. Figure 4 shows an example of a coiled ladder stent 20, similar to the prior art coiled ladder stents shown and described in U.S. Patent No. 4,553,545 to Maass et al.

In the coiled ladder stent 20, the strip has side bands 24, 25 bridged by cross struts 26. The side bands 24, 25 and the cross struts 26 form a series of openings 27, in which each opening 27 is bounded by the two side bands 24, 25 and two cross struts 26. Similarly to the coiled wire and the ribbon strip, the ladder strip is wound helically, forming a series of windings 21.

The coiled ladder stent 20 retains the rigidity and stability associated with the coiled ribbon stent 10, since the individual windings 21 of the ladder strip, like the windings 11 of the ribbon strip, have increased width as compared to the individual windings of the coiled wire. In addition, because of the openings 27, the coiled ladder stent 20 yields a reduced area of metal coverage as compared to the coiled ribbon stent 10, without compromising support of the tissue.

The coiled ladder stent 20, however, still has some of the same disadvantages associated with the coiled



wire and ribbon stents. Most significantly, the ladder strip unwinds somewhat upon expansion, resulting in twisting of the stent and rotation of the stent ends 23, as well as foreshortening of the stent or the opening of significant  
5 gaps between adjacent windings.

Figure 5 shows a serpentine coiled ladder stent 30 constructed in accordance with the invention. The serpentine coiled ladder stent 30 in Figure 5 is shown mounted on a catheter 15, in an expanded condition.

10 The serpentine coiled ladder stent 30 illustrated in Figure 5 is configured as a coiled stent in which the coil is formed from a wound strip of cells 37, wherein the sides of the cells 37 are serpentine. Thus, the stent is comprised of a strip helically wound into a series of coiled  
15 windings 31, wherein the strip is formed of two side bands 34, 35 connected to each other, for example by a series of cross struts 36. Each side band 34, 35 is formed in a serpentine pattern comprising a series of bends 38, wherein upon expansion of the stent, the bends 38 of the side bands  
20 34, 35 open to increase the length of each of the individual cells 37 in the helical direction, thereby lengthening the strip in the helical direction to allow the stent 30 to expand without any significant unwinding of the strip. In this illustrated embodiment, the bends in the side bands 34,  
25 35 occur in a periodic pattern. The bends 38 may be arranged, for example, in the pattern of a sine wave, or in



any other suitable configuration.

In the illustrated embodiment, the cross struts 36 joining the side bands 34, 35 to each other are straight and extend in a direction generally perpendicular to the helical direction in which the strip is wound. Alternatively, the cross struts may have one or more bends, and/or they may extend between the two side bands at other angles. In the illustrated embodiment, the cross struts 36 join oppositely facing bends 38 on the side bands 34, 35, and they are attached to the side bands 34, 35 at every second bend 38. Alternatively, the cross struts 36 may be joined in other places, and may occur with more or less frequency, without departing from the general concept of the invention. The stent alternatively may be made without cross struts 36, by having the two serpentine side bands 34, 35 periodically joined to each other at adjacent points.

As shown in Figure 5, the ends 33 of the serpentine ladder strip may be tapered. The tapering of the ends 33 of the strip allows the ends of finished stent to be straight, i.e., it allows the stent to take the form of a right cylinder, with each of the ends of the cylindrical stent lying in a plane perpendicular to the longitudinal axis of the stent. The ends 33 of the strip may be joined, for example by welds, to respective adjacent windings 31.

Figure 6 shows a strip 40 used to form a serpentine coiled ladder stent in accordance with the



invention. The strip 40 has serpentine side bands 44, 45, joined by cross struts 46. The strip 40 is tapered at its ends, such that the serpentine side bands 44, 45 converge at ends 43.

5           Figure 7 shows a serpentine coiled ladder stent 50 in accordance with the invention, in an unexpanded condition. As shown in Figure 7, the tapered ends 43 may be joined to the respective adjacent windings.

          When the serpentine coiled ladder stent is  
10   expanded, as shown in Figure 5, the outward radial force on the stent causes the bends 38 in the serpentine sides 34, 35 to open, thereby causing the length of the cells 37 to increase in the helical direction. This feature of the expandable cells of the strip allows the overall length of  
15   the strip to increase in the helical direction. By the strip itself lengthening in the helical direction as the stent is expanded, the increase in the diameter of the stent is accommodated without the need for the strip to unwind. In this manner, the number of windings 31 is maintained, and  
20   rotation of the ends 33 is avoided. In fact, because the ends 33 do not rotate, they may be welded, as mentioned above, to the respective adjacent windings 31, thereby creating smooth ends. Other adjacent points on the stent windings 31 may similarly be joined, to increase stability  
25   of the stent at the expense of flexibility.



A serpentine coiled ladder stent according to the invention retains the flexibility associated with coiled wire stents, but avoids some of the problems associated with those stents. The windings of the serpentine coiled ladder  
5 stent are relatively stable and insusceptible to displacement or tilting, which has been associated not only with straight single strand coiled stents as in the Maass '545 patent but also with serpentine single strand coiled stents, such as in the Wiktor '062 and '732 patents and in  
10 the Cordis Crossflex stent. In addition, a serpentine coiled ladder stent according to the invention provides continuous support of the vessel tissue without a disadvantageously high percentage of metal coverage. Because the strip from which the stent is made can expand in  
15 length in the helical direction, the strip can lengthen on expansion to accommodate the increased diameter, thereby substantially avoiding the problems of end rotation and foreshortening or the opening of significant gaps between windings upon expansion.

20 The strip for forming the serpentine coiled ladder stent may be made, for example, of wire or flat metal. When flat metal is used, the pattern in the strip may be formed, for example, by laser cutting or chemical etching. The stent may be manufactured by first manufacturing the strip,  
25 then winding the strip in a helix to form the stent, and then, if desired, welding the ends of the strip to the



adjacent windings. Alternatively, the stent may be formed by forming the desired pattern directly out of a tube, by laser cutting or chemical etching, or by forming the desired pattern out of a flat sheet, by laser cutting or chemical etching, and then rolling that flat sheet into a tube and joining the edges, for example by welding. Any other suitable manufacturing method known in the art may be employed for manufacturing a stent in accordance with the invention.

10                   The embodiments described herein are examples only, as other variations are within the scope of the invention as defined by the appended claims.

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What is Claimed is:



1. A stent comprised of a strip helically wound into a series of coiled windings, wherein the strip has at least two side bands, wherein each of the at least two side bands is formed in a serpentine pattern comprising a series of bends, wherein the at least two side bands of the strip are connected to each other, and wherein upon expansion of the stent, the bends of the at least two side bands open to lengthen the strip in the helical direction to allow the stent to expand without any significant unwinding of the strip.
2. A stent as claimed in claim 1, wherein the at least two serpentine side bands are connected to each other by cross struts.
3. A stent as claimed in claim 2, wherein the cross struts connect adjacent bends on the at least two serpentine side bands.
4. A stent as claimed in claim 3, wherein the adjacent bends that are connected by each cross strut face in opposite directions.

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5. A stent as claimed in claim 3, wherein the cross struts connect the at least two serpentine side bands at periodic intervals, and wherein each of the at least two serpentine side bands has at least one bend between sequential cross struts.
6. A stent as claimed in claim 2, wherein the cross struts are straight.
7. A stent as claimed in claim 2, wherein the cross struts have bends.
8. A stent as claimed in claim 2, wherein the cross struts extend generally perpendicularly to the helical direction in which the strip is wound.
9. A stent as claimed in claim 1, wherein the strip has two ends, wherein the at least two side bands converge toward each other at the two ends of the strip, so that the two ends of the strip are tapered.
10. A stent as claimed in claim 1, wherein the strip has two ends, the first end of the strip being located at a first end of the stent and the second end of the strip being located at a second end of the stent, and wherein each end of the strip is joined to an adjacent winding



of the stent.



11. A stent as claimed in claim 10, wherein each end of the strip is joined to the adjacent winding by welding.
12. A stent as claimed in claim 1, wherein the strip is  
5 made of wire.
13. A stent as claimed in claim 1, wherein the strip is made from flat metal.
14. A stent as claimed in claim 1, wherein the stent is made by manufacturing the strip and then winding the  
10 strip in a helix to form the stent.

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