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Method and apparatus for covering a stent

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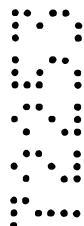
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(56) Related Art
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ABSTRACT

An expandable stent (22) suitable for implantation in a lumen is covered with a biological material. In one embodiment (20), biological fibers are interwoven to form a stent covering (24). The fibers are disposed at an angle (28) with
5 respect to the longitudinal axis of the stent so that when the stent is expanded, the angle increases. In another embodiment, a strip of pericardium is helically wound around a supporting stent while the stent is in a compressed state. When the stent is expanded, the strip unwinds, but maintains full coverage of the stent. Interlocking edges may be formed on the strip of pericardium to
10 maintain full coverage of the stent.



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COMPLETE SPECIFICATION

FOR A STANDARD PATENT

ORIGINAL

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Invention Title: 'METHOD AND APPARATUS FOR COVERING A STENT'

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

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METHOD AND APPARTUS FOR COVERING A STENT

FIELD OF THE INVENTION

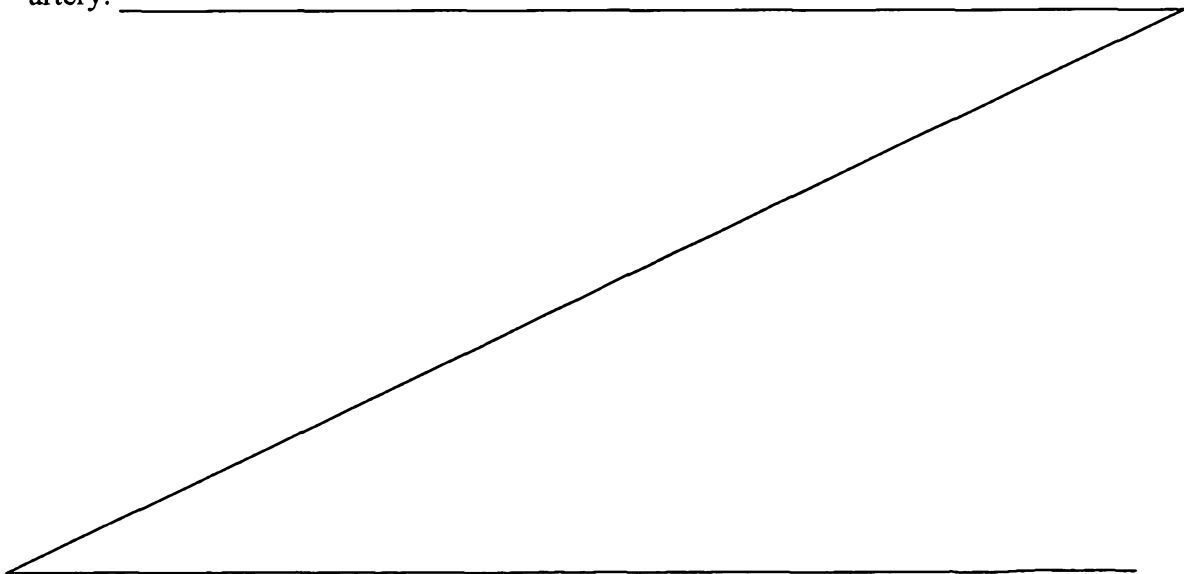
The present invention relates generally to stents for implanting into a living body.

5 In particular, the present invention relates to a biological covering for a stent suitable for implanting into a variety of lumens.

BACKGROUND OF THE INVENTION

10 Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

15 In an attempt to prevent restenosis, metallic vascular stents have been permanently implanted in coronary or peripheral vasculature. These stents are typically delivered intraluminally by a catheter and expanded in place to support a diseased portion of an artery.



One shortcoming of these conventional stents is that even after stent implantation, restenosis can still occur. Another shortcoming is that during the implantation of the stent, the stent may cause particles to discharge from the artery wall through the open cell. These dislodged particles can embolize in the bloodstream, and may cause catastrophic effects.

In an attempt to reduce these problems, coverings have been proposed for stents. These coverings have been made from artificial materials, such as PTFE. As of yet, however, coverings made from artificial materials have not proven successful. This may be because of the poor biocompatibility of such materials.

There is also some experience using biological tissue such as bovine pericardium to build a covering for a stent that is more biocompatible than coverings made from artificial materials. Preliminary results with bovine pericardium have been encouraging from the point of view of biocompatibility.

The current method, however, of creating a covering using biological tissue is simplistic. A rectangular piece of pericardium is harvested from a bovine source. The pericardium is then, after being prepared so that it is suitable for implantation, rolled into a cylinder. The

abutting edges of the pericardium are sewn together to create a covering. This covering is then placed over a stent.

There is an inherent disadvantage in this cut and sew approach to creating a covering. Biological tissue has a very small expansion range. Therefore, the diameter of the cut and sewn cylinder of tissue is limited to a very small range. This limits the stent to a very small range of expansion diameters, limiting the utility of the stent. This also limits the difference in diameter between the stent as delivered and the stent at its expanded state, increasing significantly the profile of the delivery system required for a given supported diameter.

It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.

SUMMARY OF THE INVENTION

According to first aspect, the present invention provides a covered stent comprising:

an expandable stent with a longitudinal axis, the stent being expandable from a first diameter to a second diameter;

a covering affixed to the stent, the cover being formed of linear fibers of biological material, selected from the group consisting of: bovine pericardium, ovine pericardium, porcine pericardium, wherein in the first diameter, the biological fibers form a first angle with respect to the longitudinal axis of the stent, and in the second diameter, the biological fibers form a second angle with respect to the longitudinal axis of the stent.

Unless the context clearly requires otherwise, throughout the description and the claims, the words 'comprise', 'comprising', and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to".

5 According to a second aspect, the present invention provides a method of covering a stent comprising the steps of:

 providing pericardium tissue;

 providing an expandable stent with a longitudinal axis, the stent being expandable from a first diameter to a second diameter;

10 dissolving the pericardium tissue into fiber groups;

 interweaving the fiber groups into a cylindrical covering so that in the first diameter, the interwoven fiber groups are oriented at an angle with respect to the longitudinal axis of the stent, the angle being less than approximately 45 degrees when in the first diameter;

15 affixing the covering to the stent while the stent is in its first diameter.

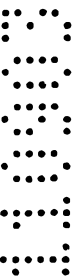
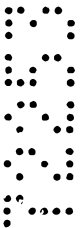
 Preferably, the interwoven threads are arranged with an acute angle between the interwoven threads while the stent is unexpanded. Advantageously, when the stent is expanded, the angle between the interwoven threads increases. More advantageously, this allows the stent covering to be expanded to a variety of diameters.

20 According to a third aspect, the present invention provides a method of making an intraluminal stent comprising the steps of:

 providing a stent with a first diameter and a second diameter;

 providing a strip of pericardium with lateral edges;

 folding the pericardium to form locking edges; and



helically winding the pericardium around the stent while the stent is in its first diameter so that the lateral edges of adjacent windings overlap.

According to a fourth aspect, the present invention provides an intraluminal stent, comprising:

5 a tubular support member with a longitudinal axis; the member being expandable from a first diameter to a second diameter;

an expandable covering applied over the tubular support member, the expandable covering being made from pericardium fibres, the fibers arranged so that in the first diameter, the threads are at an angle of less than 45 degrees with respect to the
10 longitudinal axis of the tubular support member.

According to another aspect, the present invention provides an intraluminal stent, comprising:

a tubular support member, the member being expandable from a first diameter to a second diameter;

15 an expandable covering applied over the tubular support member, the expandable covering being formed by a strip of pericardium, having locking edges, helically wound around the tubular support member, the strip having lateral edges which overlap in the first diameter.

Advantageously, during expansion to a second expanded diameter, the strips will
20 slide over the stent and unwrap for a smaller number of loops, but will still completely cover the stents. In a further preferred enhancement to this embodiment, the edges of the spiral wrapping are formed into locking folds to prevent the spiral loops from separating during expansion of the stent and covering.

Advantageously, at least in a preferred form, the current invention provides an improved biological tissue covering for a stent, and a method for producing the same.

BRIEF DESCRIPTION OF THE DRAWINGS

5 A preferred embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Fig. 1 shows an interwoven stent covering in an unexpanded state.

Fig. 2 shows an interwoven stent covering in an expanded state.

Fig. 3 shows a strip of pericardium used to form a stent covering.

10 Fig. 4 shows a spiral wrapped stent covering in an unexpanded state.

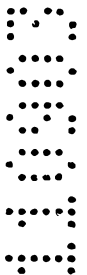
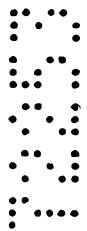
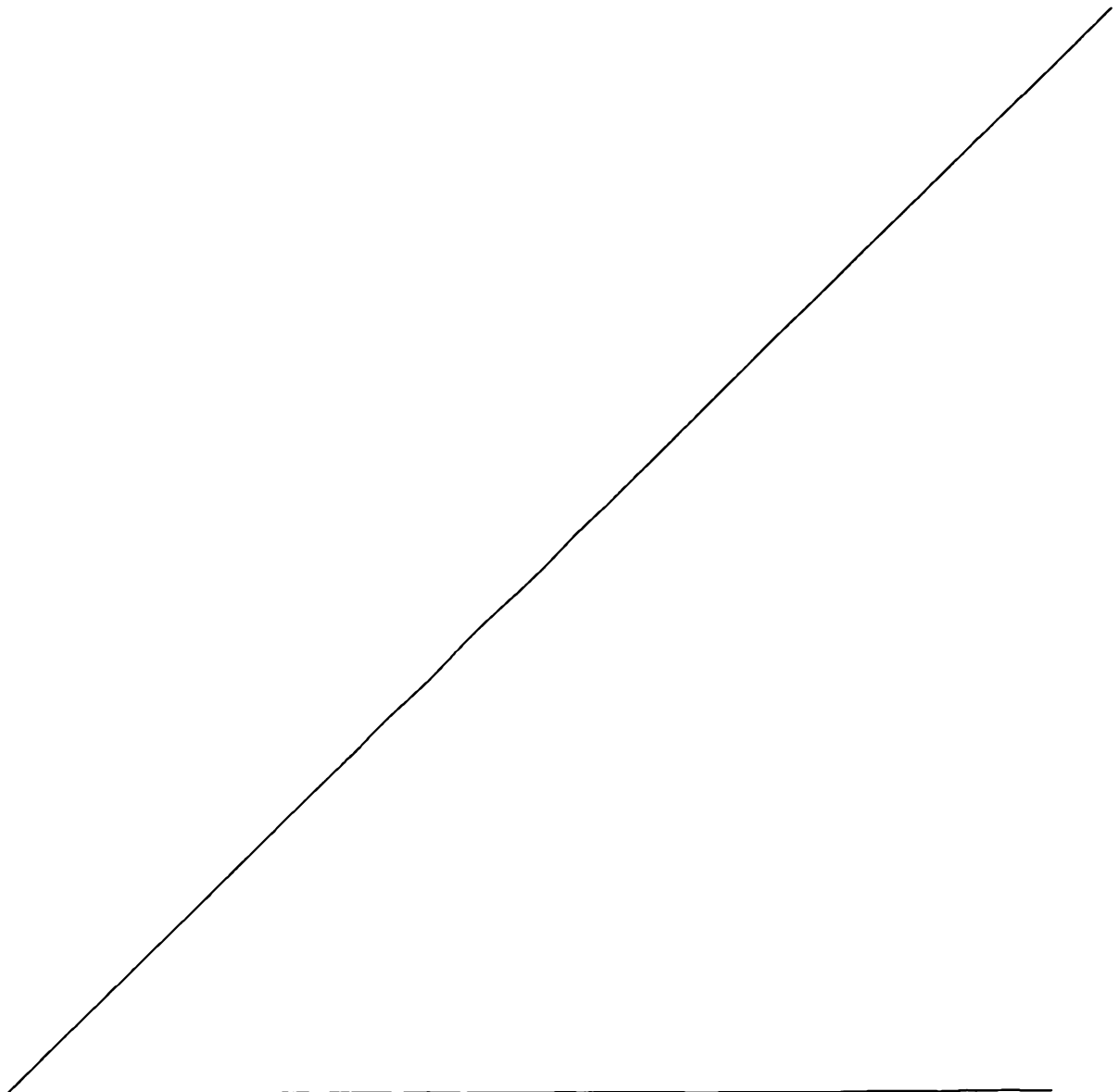


Fig. 5 shows a spiral wrapped stent covering in an expanded state.

Fig. 6 shows a partial cross-sectional view of one embodiment of a spiral wrapped stent covering in an unexpanded state.

Fig. 7 shows a partial cross-sectional view of one embodiment of a spiral wrapped stent covering in an expanded state.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The subject invention will now be described in detail for specific preferred embodiments of the invention, it being understood that these embodiments are intended only as illustrative examples and the invention is not to be limited thereto.

Figs. 1 and 2 show an endoprosthesis according to this invention. A luminal endoprosthesis 20 has a tubular stent 22 expandable from a first diameter D shown in Fig. 1 to a second diameter D' shown in Fig. 2. Stent 1 may be a self-expanding stent or a balloon expandable stent. One example of a suitable balloon expandable stent is illustrated in U.S. Patent No. 5,807,404, the disclosure of which is hereby incorporated by reference.

The stent has a covering 24 formed of biological fibers. The biological fibers may be obtained by dissolving any suitable biological tissue, such as bovine, ovine, or porcine pericardium tissue. Alternatively, the fibers can be
5 formed from other material, such as Cut-Gut collagen threads.

As shown in Fig. 1, the individual fibers 26 are interwoven, and form an angle 28 with respect to the longitudinal axis 30 of the stent 22. When the stent is at
10 the unexpanded diameter D, the angle 28 is approximately 30°.

Typically, the endoprotheses will be implanted using a conventional balloon angioplasty procedure. In this procedure, the stent 22 and associated covering 24 are placed
15 onto the balloon at the end of a balloon catheter and delivered to the site of the restricted or diseased portion of an artery. The stent and covering are then expanded into contact with the lumen by inflating the balloon. The catheter can then be deflated and withdrawn, leaving the stent and
20 covering at the treatment site. As shown in Fig. 2, upon expansion from the first diameter D to the second diameter D', the fibers of the expandable coating change orientation so that they are at a greater angle 28 with respect to the longitudinal axis 30 of the stent 20 then when they are in the
25 first diameter D. The angle 28 at the expanded diameter D' is dependent upon the amount of expansion of the stent. Therefore, depending on the size of the lumen which the stent is inserted into, the angle 28 varies from 30° to 90°.

Another embodiment of the biological stent covering is shown in FIGS. 3-5. In this embodiment, pericardium tissue is collected and prepared in a manner known to those skilled in the art. The pericardium tissue is then cut into a single strip 50 with lateral edges 52. A supporting stent 54 with an unexpanded diameter of D and an expanded diameter of D' is provided. The strip 50 is helically wound around a supporting stent 54 while the stent is in a collapsed state with a diameter of D to form a series of helical windings 56. The lateral edges 52 of adjacent helically windings 56 are arranged so that the lateral edge 52 of one winding overlaps the adjacent winding.

Upon expansion of the stent from the diameter D to D' , the helically wound strip of pericardium unwinds. However, because of the overlap between adjacent strips, no area of the stent is uncovered during and after expansion of the stent and covering. The ratio between the maximal expanded diameter without causing gaps, and that of the unexpanded stent equals the overlap ratio of the stent.

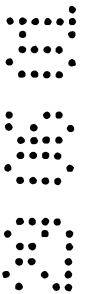
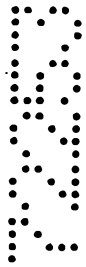
An alternative embodiment of the spiral wrapped stent is shown in FIGS. 6 and 7. In this embodiment, the edges 52 of the pericardium strip 50 are provided with interlocking edges 60, 62. The right interlocking edge 62 is formed by folding the edge of the pericardium strip over itself. The left interlocking edge 64 is formed by folding

the edge of the pericardium strip over itself; the left edge is folded in the opposite direction as the right edge.

The strip with the interlocking edges is helically wound around the stent in the same manner as described above with respect to the embodiment illustrated in FIGS. 4 and 5. Special care is taken to make sure that the right interlocking edge 62 is placed between the right edge 66 and the left interlocking edge 64 of the adjacent spiral wrap. Upon expansion of the stent, the right and left interlocking edges mate together. In this manner, the interlocking edges assure that there are no gaps in the coverage of the expanded stent, as illustrated in Fig. 7.

Although the invention has been described with reference to specific examples, it will be appreciated by those skilled in the art that the invention may be embodied in many other forms.

15



THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A covered stent comprising:
 - an expandable stent with a longitudinal axis, the stent being expandable from a
 - 5 first diameter to a second diameter;
 - a covering affixed to the stent, the cover being formed of linear fibers of biological material, selected from the group consisting of: bovine pericardium, ovine pericardium, porcine pericardium, wherein in the first diameter, the biological fibers form a first angle with respect to the longitudinal axis of the stent, and in the second
 - 10 diameter, the biological fibers form a second angle with respect to the longitudinal axis of the stent.
2. The stent according to claim 1, wherein the first angle is approximately 30°.
3. The stent according to claim 1, wherein the second angle is dependent upon the amount of expansion of the stent.
- 15 4. A method of covering a stent comprising the steps of:
 - providing pericardium tissue;
 - providing an expandable stent with a longitudinal axis, the stent being expandable from a first diameter to a second diameter;
 - dissolving the pericardium tissue into fiber groups;
 - 20 interweaving the fiber groups into a cylindrical covering so that in the first diameter, the interwoven fiber groups are oriented at an angle with respect to the longitudinal axis of the stent, the angle being less than approximately 45 degrees when in the first diameter;
 - affixing the covering to the stent while the stent is in its first diameter.
- 25 5. A method of making an intraluminal stent comprising the steps of:

providing a stent with a first diameter and a second diameter;

providing a strip of pericardium with lateral edges;

folding the pericardium to form locking edges; and

helically winding the pericardium around the stent while the stent is in its first

5 diameter so that the lateral edges of adjacent windings overlap.

6. The method of claim 5, wherein the pericardium tissue is selected from the group consisting of: bovine pericardium, ovine pericardium, and porcine pericardium.

7. An intraluminal stent, comprising:

10 a tubular support member with a longitudinal axis; the member being expandable from a first diameter to a second diameter;

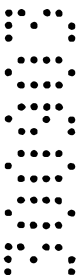
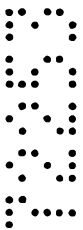
an expandable covering applied over the tubular support member, the expandable covering being made from pericardium fibres, the fibres arranged so that in the first diameter, the threads are at an angle of less than 45 degrees with respect to the longitudinal axis of the tubular support member.

15 8. An intraluminal stent, comprising:

a tubular support member, the member being expandable from a first diameter to a second diameter;

20 an expandable covering applied over the tubular support member, the expandable covering being formed by a strip of pericardium, having locking edges, helically wound around the tubular support member, the strip having lateral edges which overlap in the first diameter.

9. A covered stent substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying drawings.



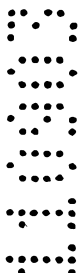
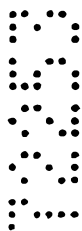
10. A method of covering a stent, said method substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying drawings and/or examples.

5 11. A method of making an intraluminal stent, said method substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying drawings and/or examples.

12. An intraluminal stent substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying drawings and/or

10 examples.

DATED this 11th Day of September, 2003
BALDWIN SHELSTON WATERS
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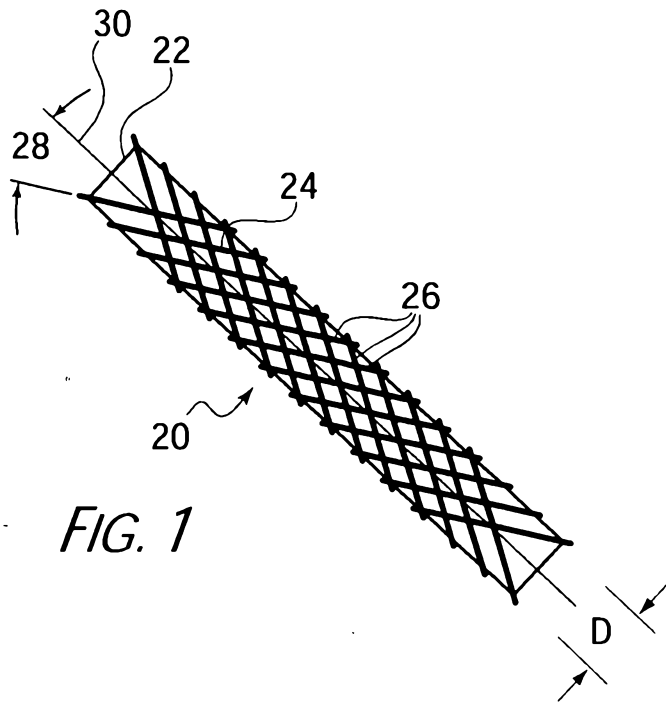


FIG. 1

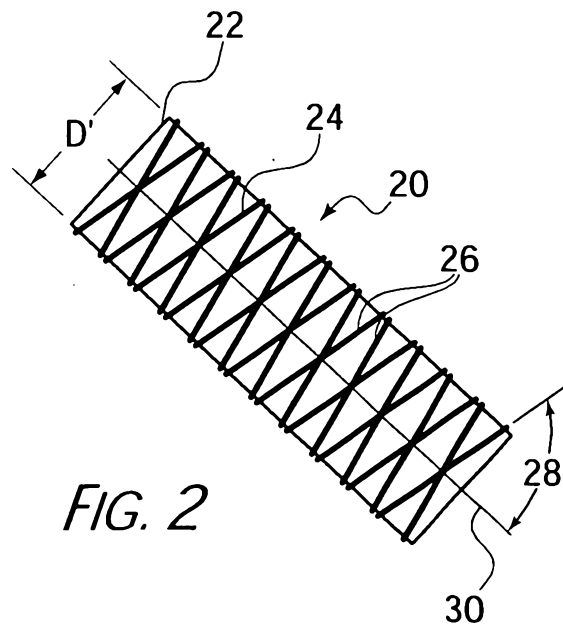
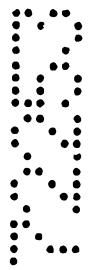


FIG. 2



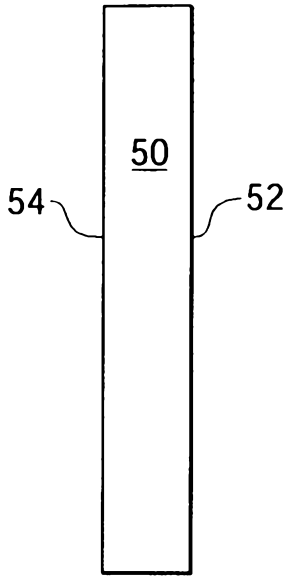


FIG. 3

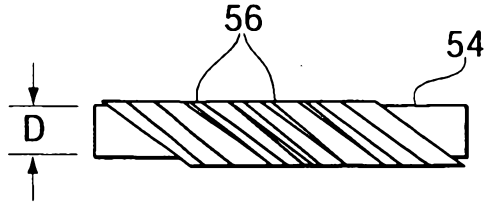


FIG. 4

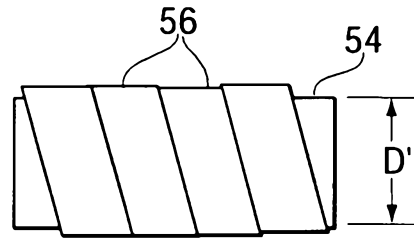


FIG. 5

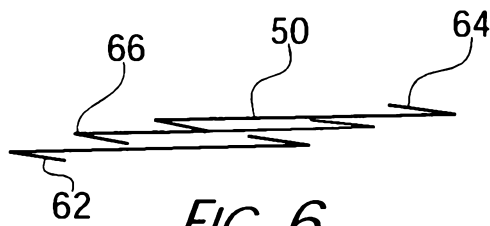


FIG. 6

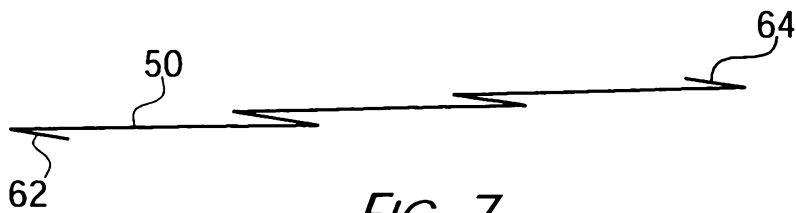


FIG. 7