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<p>(21) International Application Number: PCT/US00/02886</p> <p>(22) International Filing Date: 2 February 2000 (02.02.00)</p> <p>(30) Priority Data: 60/118,269 2 February 1999 (02.02.99) US 09/408,890 29 September 1999 (29.09.99) US</p> <p>(71) Applicant: IMPRA, INC. [US/US]; 1625 West 3rd Street, P.O. Box 1740, Tempe, AZ 85280-1740 (US).</p> <p>(72) Inventor: LAYNE, Richard; 1717 Woodland Avenue #314, E. Palo Alto, CA 94308 (US).</p> <p>(74) Agents: KIRCHANSKI, Stefan, J. et al.; Graham & James LLP, 14th Floor, 801 S. Figueroa Street, Los Angeles, CA 90017-5554 (US).</p>	<p>(81) Designated States: CA, JP, MX, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>	
<p>(54) Title: PARTIAL ENCAPSULATION OF STENTS USING STRIPS AND BANDS</p> <p>(57) Abstract</p> <p>Partially encapsulated stents are made using strips and bands of covering material. In one embodiment ringed stents are placed over an inner ePTFE tube (e.g., supported on a mandrel) and are covered by a series of longitudinal strips. A series of spaced apart ePTFE circumferential bands can then be placed over the top of the longitudinal strips and ringed stents; alternatively bands alone or strips alone may be employed. All of the components of the structure are then laminated to the inner ePTFE tube to capture the stents. By selecting the size and position of the ePTFE bands, it is possible to leave critical parts of the stent unencapsulated to facilitate flexibility and expansion. The longitudinal strips can be woven about the stent or later laminated into position to provide an anti-compression function as well as overall structural stability. Although a single stent can be used, these approaches lend themselves to use of a plurality of individual ring stents spaced apart along the inner ePTFE tube.</p>		

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of PTFE into ePTFE. This expansion represents a controlled longitudinal stretching in which the PTFE is stretched to several hundred percent of its original length.

If stents could be enclosed in ePTFE, cellular infiltration could be prevented, hopefully preventing restenosis. Early attempts to produce a stent enshrouded with ePTFE focused around use of adhesives or physical attachment such as suturing. However, such methods are far from ideal and suturing, in particular, is very labor intensive. More recently methods have been developed for encapsulating a stent between two tubular ePTFE members whereby the ePTFE of one-member touches and bonds with the ePTFE of the other member through the mesh opening in the stent. Unfortunately, such a monolithically encapsulated stent tends to be rather inflexible. In particular, radial expansion of the stent may stress and tear the ePTFE cover. Therefore, there is a need for a stent that is encapsulated to provide a smooth inner surface for the flow of blood and yet still allows expansion of the stent without tearing or delaminating, providing a relatively flexible device.

SUMMARY OF THE INVENTION

The present invention is directed to partially encapsulating stents wherein flexibility of the stent is retained, despite encapsulation. This can be done by placing a plurality of longitudinal strips over the stent or series of stents rings made of ePTFE and/or placing a plurality of circumferential ePTFE bands over the stent(s).

It is an object of this invention to provide a stent device that has improved flexibility, yet maintains its shape upon expanding or contracting.

It is also an object of this invention to provide a stent encapsulated to prevent cellular infiltration, wherein portions of the stent can move during radial expansion without stressing or tearing the encapsulating material.

These and additional objects are accomplished by embedding or encapsulating only a portion of the stent. In this way, the unencapsulated portion of the stent is free to move during expansion without compromising the ePTFE covering. The most straightforward way of achieving partial encapsulation is to place the stent(s) over an inner ePTFE tubular member (e.g., supported on a mandrel) and then to cover the outer surface of the stent(s) with a series

of spaced apart longitudinal ePTFE strips, which are then laminated to the inner ePTFE to capture the stent. These strips (e.g., cut from an extension of the inner ePTFE tube) can be woven about the stent(s) and later laminated into position to provide an anti-compression function as well as overall structural stability. Beside strips of ePTFE it is also possible to use
5 circumferential ePTFE bands to further or alternatively capture the stent(s). By selecting the size and position of the bands it is possible to leave critical parts of the stent unencapsulated to facilitate flexibility and expansion. Although a single stent can be used, these approaches lend themselves to use of a plurality of individual ring stents spaced apart along the inner ePTFE tube.

10 In the present invention, individual ring stents are partially encapsulated using the procedure outlined above. Preferably, ring stents of zigzag sinusoidal structure are placed "in phase" on the outside surface of a tubular ePTFE graft supported by a mandrel. Separate bands of ePTFE are placed over the stent rings, so that some portion of the stent rings is covered. In addition, longitudinal strips of ePTFE can be woven (e.g., over and under) about
15 the ring stents, either before or after the bands are applied. The resulting structure is then subjected to heat and pressure so that the regions of ePTFE become laminated or fused together. In addition, the ends of the stent can be completely encapsulated, by known methods, to stabilize the overall structure.

A more complete understanding of the partial encapsulation of stents will be afforded
20 to those skilled in the art, as well as a realization of additional advantages and objects thereof, by a consideration of the following detailed description of the preferred embodiment. Reference will be made to the appended sheets of drawings, which will first be described briefly.

BRIEF DESCRIPTION OF THE DRAWINGS

25 Fig. 1 is a perspective view of a tubular ePTFE member with individual ring stents arranged over the outside;

Fig. 2 is a sectional view of the device in Fig.1 with longitudinal strips of ePTFE interwoven between the ring stents;

Fig. 3 is a sectional view of the device in Fig. 2 with circumferential strips of ePTFE placed over the top.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention satisfies the need for an encapsulated stent device to prevent
5 restenosis that is flexible upon expansion and contraction so that the general structural form is retained. This is accomplished by partially encapsulating a stent or stent rings using connected strips and bands of ePTFE.

Referring now to the drawings, in which like reference numbers represent similar or
10 identical structures throughout, Fig. 1 illustrates an initial step in constructing the partially encapsulated stent of the present invention. A tubular ePTFE graft **20** is placed over a mandrel for the assembly of a device **10** (Fig. 2). A stent is then placed over the graft **20**. In the preferred embodiment, as shown in Fig. 1, a series of zigzag sinusoidal ring stents **30** are placed over the outer surface of the graft **20**. These ring stents **30** can be made of any material, but a preferred material is metal. The zigzag ring stents **30** may be assembled “in
15 phase” with each adjacent ring stent having peaks and valleys aligned. Alternatively, the individual stents **30** can be “out of phase” to different degrees. It will be apparent that the phase relation of adjacent stents **30** will alter the lateral flexibility as well as the longitudinal compressibility of the structure. The phase relationship can be varied along the length of the device **10**, thereby altering the physical properties in different portions of the device **10**.
20 Having individual ring stents **30**, as opposed to a single tubular stent, provides the advantage that the periodicity, or the number and precise shape of the zigzags per ring, can readily be varied along the length of the graft to influence flexibility and stability properties of the structure. Also, spacing of the individual stents (number of stents per unit length) as well as the phase relationship of stent to stent can be varied to produce stent grafts with desired
25 properties. By placing the ring stents **30** over the outer surface of the tubular ePTFE graft **20**, the resulting structure has an inner (luminal) surface that is completely smooth to facilitate the flow of blood. However, there may be instances where the ring stents **30** or other tubular stents are advantageously placed on the inner graft surface or on both the inner and outer

surfaces, as one of ordinary skill in the art will readily appreciate.

A preferred embodiment of the present invention can be seen in Fig. 2. The ring stents 30 are longitudinally stabilized by strips of ePTFE 50 that are woven between the adjacent ring stents 30 and the underlying graft 20. These anti-compression strips 50 are woven so that
5 a given strip 50 passes over one ring stent 30 and under an adjacent stent 30 and so on. Just as in actual weaving, a complex pattern can be developed with a given strip 50 passing over several stents 30 before passing under one or more stents 30. Thus a "twill" or other weave can be implemented with significant effects on flexibility and similar physical properties. This woven pattern can vary from strip to strip so that each ring stent 30 is held down by at
10 least one strip 50.

One way of achieving this effect is to pull a tubular graft member onto a mandrel, leaving a terminal overhang at least as long as the portion on the mandrel. This overhang is then slit into a number (e.g., four) of strips. The strips are folded over and laid along the mandrel. Two opposite strips are lifted while a first ring stent is slid over the mandrel (and
15 two of the strips) and brought to rest at the end of the mandrel nearest the origin of the strips. Then the previously lifted strips are laid along the mandrel and the other two strips are lifted. A second ring stent is slid onto the mandrel over the strips that were lifted for the first ring stent. This weaving process is continued until a full compliment of stents is on the mandrel. At this time, the resulting structure is subjected to heat and pressure to laminate the woven
20 strips to the underlying ePTFE graft. Obviously, any number of strips can be employed and the pattern of lifted strips can be varied to create any of a number of woven patterns. Alternatively, each adjacent strip could alternate between going over all of the stents and under all of the stents.

In Fig. 3, a second embodiment is illustrated, utilizing longitudinal ePTFE strips 50
25 for stabilizing the structure 60 and circumferential ePTFE bands 52 for holding the ring stents 30 in place. In addition, an end ePTFE ring is used to fully encapsulate each longitudinal end of structure 60 for further stability. It should be appreciated that the bands of ePTFE 52 that are placed over the top of the ring stents 30 can encompass many different designs. The spaces between the bands of ePTFE 52 can be altered to control the degree of flexibility and

stability desired. In the preferred embodiment shown in Fig. 3, the bands **52**, placed over the center portion of each ring stent **30** are intended to cover the circumference of each ring stent **30**, leaving the ends of the zigzags uncovered. By circumferentially covering a portion of each ring stent **30**, the maximum amount of lateral flexibility is provided. However, circumferentially covering the individual ring stents **30** without any longitudinal support would result in a structure with little longitudinal strength and stability that would be prone to “telescoping”. Thus, the longitudinal strips **50** that are incorporated under the bands of ePTFE **52** are important, making the preferred design in Fig. 3 optimal. The longitudinal strips **50** are completely laminated to the underlying graft **20** and act as “anti-compression” devices by resisting the shortening of the structure **60**. The width of the bands **52** and the anti-compression strips **50** control longitudinal strength and stability versus lateral flexibility. By adjusting these parameters, grafts can be made more or less flexible with greater or lesser anti-compression strength. In a preferred embodiment, four longitudinal strips **50** are used and the ends of the structure **60** are completely encapsulated for greater stability. Of course, a larger number of anti-compression strips **50** can be employed. Also, the strips **50** may themselves zigzag or may be helically arranged. Each different structure has different properties. Similarly, the bands **52** can have different forms and may be undulating (sinusoidal) in form. In fact, there is nothing to preclude a structure including a complex pattern where individual bands **52** and strips **50** are difficult to discern.

After the strips **50** and/or bands **52** are configured in the desired pattern onto each of the structures **10** and **60**, the structures are exposed to heat and pressure, such as that caused by wrapping with PTFE tape, thereby causing the ePTFE regions of the strips **50** and/or bands **52** to fuse or laminate to the tubular graft **20**. Of course, depending on the desired properties the numbers of strip **50** and bands **52** may be varied greatly. The inventor specifically contemplates devices with no bands **52** or devices with no strips **50**.

Having thus described a preferred embodiment of the partial encapsulation of stents using strips and bands, it will be apparent by those skilled in the art how certain advantages of the present invention have been achieved. It should also be appreciated that various modifications, adaptations, and alternative embodiments thereof may be made within the

scope and spirit of the present invention. For example, zigzag stent rings have been illustrated, but it should be apparent that the inventive concepts described above would be equally applicable to sinusoidal and other stent designs. Moreover, the words used in this specification to describe the invention and its various embodiments are to be understood not
5 only in the sense of their commonly defined meanings, but to include by special definition in this specification structure, material or acts beyond the scope of the commonly defined meanings. Thus, if an element can be understood in the context of this specification as including more than one meaning, then its use in a claim must be understood as being generic to all possible meanings supported by the specification and by the word itself. The definitions
10 of the words or elements of the following claims are, therefore, defined in this specification to include not only the combination of elements which are literally set forth, but all equivalent structure, material or acts for performing substantially the same function in substantially the same way to obtain substantially the same result. The described embodiments are to be considered illustrative rather than restrictive. The invention is further
15 defined by the following claims.

CLAIMS

1. A vascular graft, comprising:
a first expanded polytetrafluoroethylene layer;
a support layer comprising at least one stent, wherein said support
5 layer is placed around said first expanded
polytetrafluoroethylene layer; and
a second expanded polytetrafluoroethylene layer comprising a plurality
of longitudinal strips.

2. The vascular graft of Claim 1, wherein said second expanded
10 polytetrafluoroethylene layer secures said support layer to said first expanded
polytetrafluoroethylene layer and wherein portions of the support layer remain
exposed.

3. The vascular graft of Claim 1, further comprising a third
expanded polytetrafluoroethylene layer comprising a plurality of circumferential
15 bands spaced so that portions of the support layer are exposed.

4. The vascular graft of Claim 3, wherein said second and third
expanded polytetrafluoroethylene layers secure said support layer to said first
expanded polytetrafluoroethylene layer.

5. The vascular graft of Claim 1, wherein said support layer
20 comprises a plurality of ringed stents.

6. The vascular graft of Claim 5, wherein said ringed stents are
formed in a zigzag pattern of alternating peaks and valleys.

7. The vascular graft of Claim 6, wherein said zigzag ringed stents are placed around said first expanded polytetrafluoroethylene layer with the alternating peaks and valleys in phase.

8. The vascular graft of Claim 1, wherein said stent is made of
5 metal.

9. The vascular graft of Claim 5, wherein said longitudinal strips of material are alternatingly woven over and under each successive ringed stent.

10. The vascular graft of Claim 9, wherein said longitudinal strips of material are cut from a distal end of said first expanded polytetrafluoroethylene layer
10 of material with a proximal end of said longitudinal strips attached to said first expanded polytetrafluoroethylene layer of material.

11. The vascular graft of Claim 9, wherein a first longitudinal strip is woven over a first ringed stent, wherein a second longitudinal strip, adjacent to said first longitudinal strip, is woven under a first ringed stent, and wherein each
15 successive adjacent odd numbered longitudinal strip is woven over a first ringed stent and each successive adjacent even numbered longitudinal strip is woven under a first ringed stent.

12. The vascular graft of Claim 10, wherein a first longitudinal strip is woven over a first ringed stent, wherein a second longitudinal strip, adjacent to
20 said first longitudinal strip, is woven under a first ringed stent, and wherein each successive adjacent odd numbered longitudinal strip is woven over a first ringed stent and each successive adjacent even numbered longitudinal strip is woven under a first ringed stent.

13. The vascular graft of Claim 1, wherein both a proximal and a distal end of said vascular graft are fully encapsulated.

14. A vascular graft, comprising:

a first expanded polytetrafluoroethylene layer;

5 a support layer comprising at least one stent, wherein said support layer is placed around said first expanded polytetrafluoroethylene layer; and

10 a second expanded polytetrafluoroethylene layer comprising a plurality of circumferential bands spaced so that portions of the support layer are exposed.

15 15. The vascular graft of Claim 14, wherein said second expanded polytetrafluoroethylene layer secures said support layer to said first expanded polytetrafluoroethylene layer .

16 16. The vascular graft of Claim 14, further comprising a third expanded polytetrafluoroethylene layer comprising a plurality of longitudinal strips of material.

17. The vascular graft of Claim 16, wherein said second and third expanded polytetrafluoroethylene layers secure said support layer to said first expanded polytetrafluoroethylene layer .

20 18. The vascular graft of Claim 14, wherein said support layer comprises a plurality of ringed stents.

19. The vascular graft of Claim 18, wherein said ringed stents are formed in a zigzag pattern of alternating peaks and valleys.

20. The vascular graft of Claim 19, wherein said zigzag ringed stents are placed around said first expanded polytetrafluoroethylene layer with the
5 alternating peaks and valleys in phase.

21. The vascular graft of Claim 14, wherein said stent is made of metal.

22. The vascular graft of Claim 16, wherein said longitudinal strips of material are alternatingly woven over and under each successive ringed stent.

10 23. The vascular graft of Claim 22, wherein said longitudinal strips of material are cut from a distal end of said first expanded polytetrafluoroethylene layer of material with a proximal end of said longitudinal strips attached to said first expanded polytetrafluoroethylene layer of material, and wherein a distal end of said longitudinal strips is alternatingly woven over and under each successive ringed
15 stent.

24. The vascular graft of 22, wherein a first longitudinal strip is woven over a first ringed stent, wherein a second longitudinal strip, adjacent to said first longitudinal strip, is woven under a first ringed stent, and wherein each successive adjacent odd numbered longitudinal strip is woven over a first ringed
20 stent and each successive adjacent even numbered longitudinal strip is woven under a first ringed stent.

25. The vascular graft of 23, wherein a first longitudinal strip is woven over a first ringed stent, wherein a second longitudinal strip, adjacent to said first longitudinal strip, is woven under a first ringed stent, and wherein each successive adjacent odd numbered longitudinal strip is woven over a first ringed stent and each successive adjacent even numbered longitudinal strip is woven under a first ringed stent.

26. The vascular graft of Claim 14, wherein both a proximal and a distal end of said vascular graft are fully encapsulated.

27. A vascular graft, comprising:
a first expanded polytetrafluoroethylene layer;
a support layer comprising at least one stent with said support layer placed around said first expanded polytetrafluoroethylene layer;
a second expanded polytetrafluoroethylene layer comprising a plurality of longitudinal strips of material; and
a third expanded polytetrafluoroethylene layer comprising a plurality of circumferential bands spaced apart to cover a portion of an outer surface of the at least one stent, wherein said second and third expanded polytetrafluoroethylene layers secure said support layer to said first expanded polytetrafluoroethylene layer.

28. The vascular graft of Claim 27, wherein said support layer comprises a plurality of ringed stents.

29. The vascular graft of Claim 28, wherein said ringed stents are formed in a zigzag pattern of alternating peaks and valleys.

30. The vascular graft of Claim 29, wherein said zigzag ringed stents are placed around said first expanded polytetrafluoroethylene layer with the alternating peaks and valleys in phase.

5 31. The vascular graft of Claim 27, wherein said at least one stent is made of metal.

32. The vascular graft of Claim 27, wherein said longitudinal strips of material are alternatingly woven over and under each successive ringed stent.

10 33. The vascular graft of Claim 32, wherein said longitudinal strips of material are cut from a distal end of said first expanded polytetrafluoroethylene layer of material with a proximal end of said longitudinal strips attached to said first expanded polytetrafluoroethylene layer of material.

15 34. The vascular graft of 32, wherein a first longitudinal strip is woven over a first ringed stent, wherein a second longitudinal strip, adjacent to said first longitudinal strip, is woven under a first ringed stent, and wherein each successive adjacent odd numbered longitudinal strip is woven over a first ringed stent and each successive adjacent even numbered longitudinal strip is woven under a first ringed stent.

20 35. The vascular graft of 33, wherein a first longitudinal strip is woven over a first ringed stent, wherein a second longitudinal strip, adjacent to said first longitudinal strip, is woven under a first ringed stent, and wherein each successive adjacent odd numbered longitudinal strip is woven over a first ringed stent and each successive adjacent even numbered longitudinal strip is woven under a first ringed stent.

36. The vascular graft of Claim 27, wherein both a proximal and a distal end of said vascular graft are fully encapsulated.

37. A vascular graft, comprising:

a first expanded polytetrafluoroethylene layer of material;

5 a support layer having a plurality of ringed stents evenly spaced, wherein said support layer is placed around said first expanded polytetrafluoroethylene layer; and

10 a second expanded polytetrafluoroethylene layer comprising a plurality of longitudinal strips of material that are alternatingly woven over and under each successive ringed stent; and

15 a third expanded polytetrafluoroethylene layer comprising a plurality of circumferential bands spaced apart to cover a portion of an outer surface of the at least one stent, wherein said second and third expanded polytetrafluoroethylene layers secure said support layer to said first expanded polytetrafluoroethylene layer.

38. The vascular graft of Claim 37, wherein said longitudinal strips of material are cut from a distal end of said first expanded polytetrafluoroethylene layer of material, wherein a proximal end of said longitudinal strips is attached to said
20 first expanded polytetrafluoroethylene layer of material.

39. The vascular graft of 37, wherein a first longitudinal strip is woven over a first ringed stent, wherein a second longitudinal strip, adjacent to said first longitudinal strip, is woven under a first ringed stent, and wherein each successive adjacent odd numbered longitudinal strip is woven over a first ringed stent and each successive adjacent even numbered longitudinal strip is woven under a first ringed stent.

40. The vascular graft of 38, wherein a first longitudinal strip is woven over a first ringed stent, wherein a second longitudinal strip, adjacent to said first longitudinal strip, is woven under a first ringed stent, and wherein each successive adjacent odd numbered longitudinal strip is woven over a first ringed stent and each successive adjacent even numbered longitudinal strip is woven under a first ringed stent.

41. The vascular graft of Claim 37, wherein said ringed stents are formed in a zigzag pattern of alternating peaks and valleys.

42. The vascular graft of Claim 41, wherein said zigzag ringed stents are placed over said first expanded polytetrafluoroethylene layer with the alternating peaks and valleys of successive stents in phase.

43. The vascular graft of Claim 37, wherein said ringed stents are made of metal.

44. The vascular graft of Claim 37, wherein both a proximal and a distal end of said vascular graft are fully encapsulated.

45. A method for making a partially encapsulated vascular graft, comprising:

providing a generally tubular expanded polytetrafluoroethylene layer of material;

5 placing a support layer comprised of a plurality of ringed stents over said tubular layer;

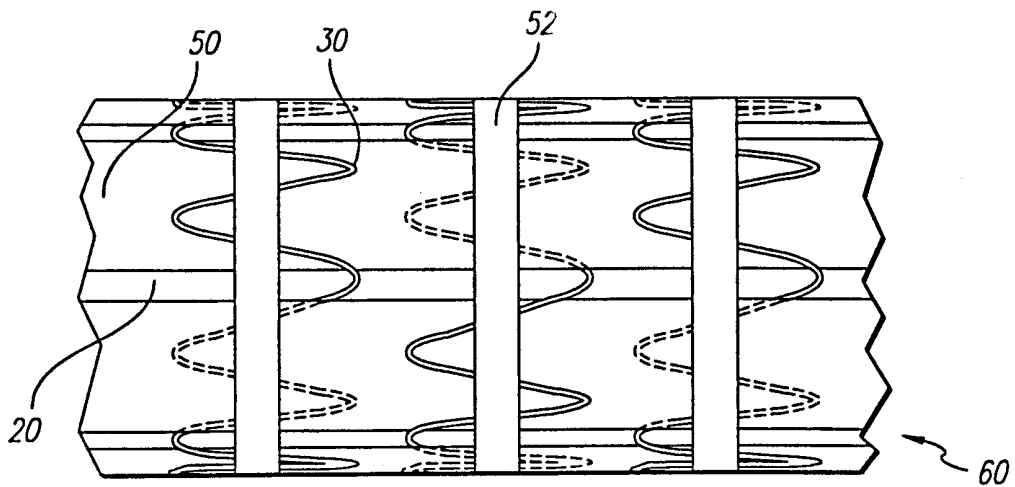
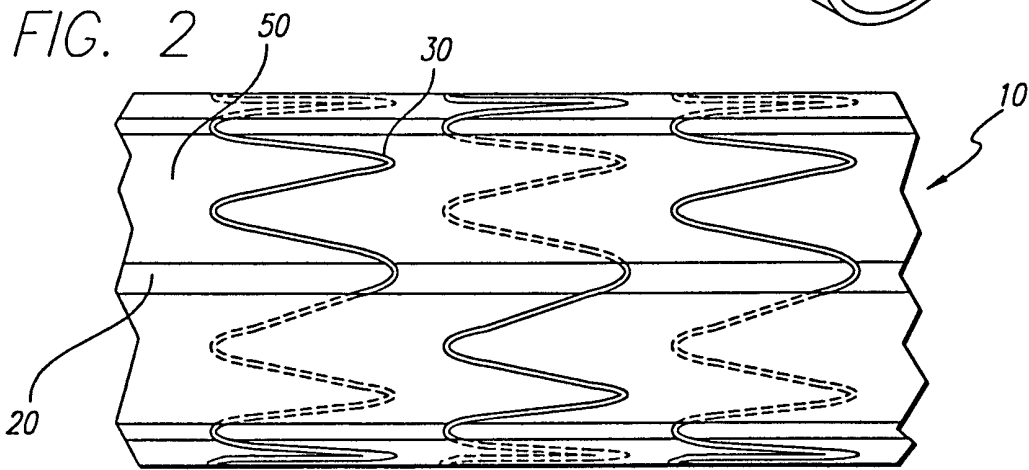
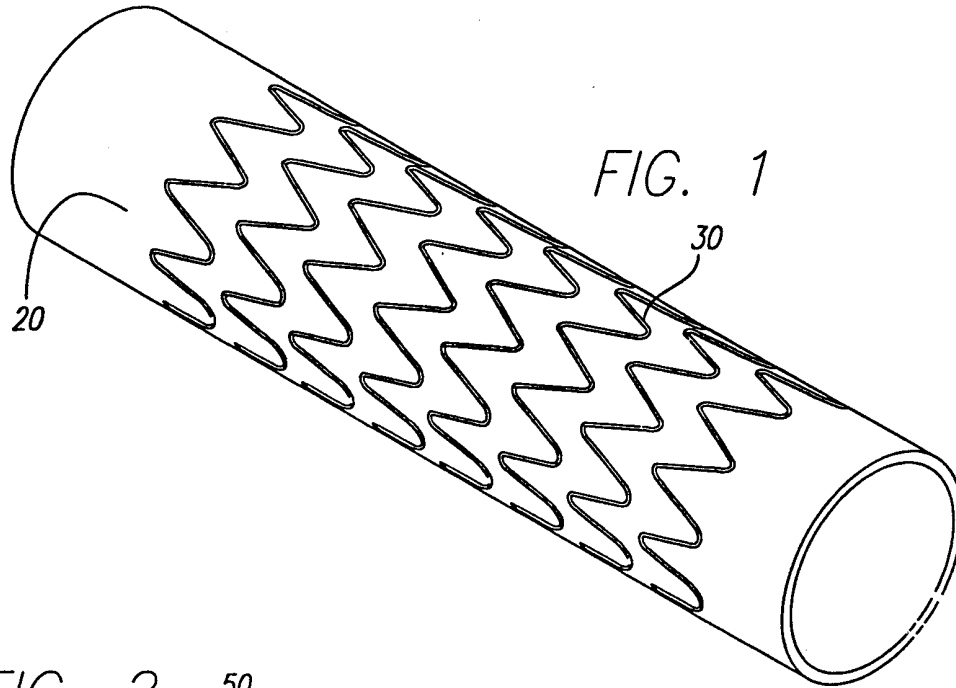
cutting a plurality of slits in a terminal portion of said tubular layer not covered by said stents, resulting in a plurality of longitudinal strips;

10 weaving said longitudinal strips alternately over and under each successive ringed stent, wherein a first longitudinal strip is woven over a first ringed stent, and wherein a second longitudinal strip is woven under the first ringed stent; and laminating said longitudinal strips to said tubular layer.

15 46. The method of Claim 45, further comprising the step of placing a plurality of expanded polytetrafluoroethylene circumferential bands over said support layer before said laminating step, wherein said plurality of circumferential bands are spaced apart so that each said circumferential band covers a portion of an outer surface of said ringed stents.

20 47. The method of Claim 45, further comprising the step of fully encapsulating both a proximal and a distal end of said vascular graft.

48. The method of Claim 45, wherein said ringed stents are formed in a zigzag pattern of alternating peaks and valleys and wherein said placing step further comprises placing said peaks and valleys of successive stents in phase.



INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	EP 0 893 108 A (GORE ENTERPRISE HOLDINGS, INC.) 27 January 1999 (1999-01-27) the whole document	14, 15, 18-21 1, 27, 37, 45
A	EP 0 792 627 A (CARDIOVASCULAR CONCEPTS, INC.) 3 September 1997 (1997-09-03) abstract; figures	1, 14, 27, 37, 45

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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