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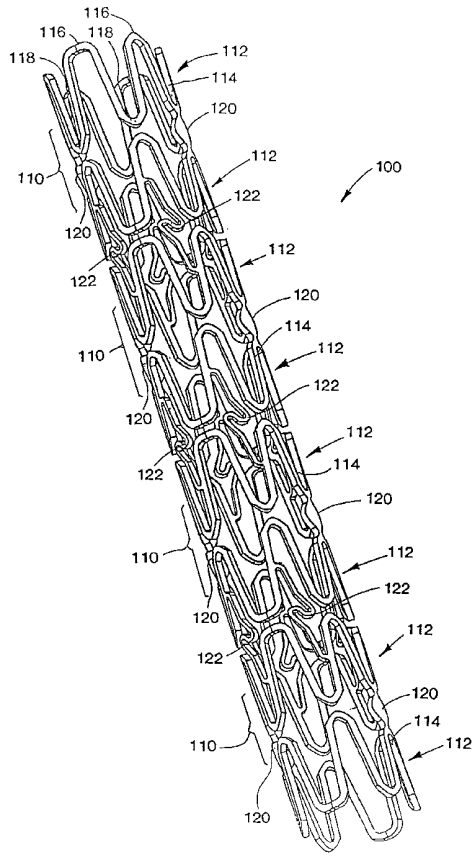
(54) Title: IMPLANTABLE INTRAVASCULAR STENT



(57) Abstract: An improved implantable intravascular stent is disclosed comprising a plurality of expandable stent modules. Each of the modules preferably comprises first and second annular elements each comprising thin filaments formed in an undulating pattern consisting of alternating peaks and troughs. A plurality of first connectors secure the first and annular second elements together in radial alignment to define a cylindrical opening. A plurality of second connectors are also provided for joining adjacent pairs of stent modules together at radially spaced locations. The second connectors are extensible between contracted and extended configurations to allow the stent to conform to curves in the vessel wall during deployment of the stent and to prevent foreshortening. The second connectors also inhibit prolapse of atherosclerotic plaque or vascular tissue at locations between the modules.

WO 02/051335 A1

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IMPLANTABLE INTRAVASCULAR STENT

Field of the Invention

This application relates to an improved intravascular 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 gradual deposition of fatty plague within the coronary arteries , resulting in a narrowing of the coronary arteries and a corresponding decrease in blood flow to heart muscles. Narrowing of the coronary arteries is termed "atherosclerosis" and may trigger serious clinical complications, such as angina or myocardial infarction.

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 plague from occluding the lumen.

Stents are commonly deployed by means of a coronary balloon dilation catheter. This procedure involves mounting a compressed stent around an expandable balloon positioned at the distal end of a thin-walled intravascular catheter. The catheter is 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 the coronary artery. Once the catheter is advanced to the desired location, the physician dilates the balloon to flatten plague 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.

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 splint. Radial rigidity is desired to ensure that, once deployed, the splint will have the mechanical rigidity to maintain the patency of the vessel lumen. In other words, the splint must be capable of effectively resisting stenosis which is the chronic or acute occlusion of the coronary arteries following balloon angioplasty.

Various expandable stents have been proposed in the past which have attempted to satisfy these requirements. An earlier stent design of the applicant is the subject of a Patent Cooperation Treaty application PCT/CA99/0039 published on 18 May, 2000 under No. WO 00/27306 (the '306 application). The '306 application describes a modular stent which is fabricated from wire strands. Each module includes first and second wire segments which are annular in shape and are formed in a sinusoidal pattern. In a preferred embodiment, the wire segments of each module are fastened together at two opposed locations by metal clips.

The modules are connected together by connecting elements which extend between the clips of adjacent modules.

While the '306 stent is a significant improvement over conventional stent designs, it suffers from several shortcomings. Since the stent modules are joined by only one or two connecting elements, small gaps are present between the modules. These gaps in the stent scaffold permit prolapse of plaque deposits in some patients, which may lead to restenosis. The gaps are particularly problematic at locations where the stented blood vessel curves (and hence the length between adjacent modules is increased).

The use of metal clips to secure the two annular segments of each stent module together can also be problematic. Since the clips project outwardly a short distance from the remainder of the stent outer surface, there is a risk that the clips will tear vascular tissue during deployment of the stent within a vessel lumen. Also, during expansion of the stent at the target site, the edges of the clips may puncture the balloon used in the balloon dilation catheter procedure. Moreover, since the clips increase the effective diameter of the stent, they also impede its "trackability", namely the capacity of a physician to safely guide the stent through tortuous blood vessels to the target site. Many clinically significant lesions occur in blood vessels having a very small effective diameter and hence it is desirable to minimize the cross-sectional profile of the stent wherever possible.

The size and position of the clip connectors also prevents the stent from expanding symmetrically, resulting in a deployed stent which is not perfectly cylindrical. This can adversely affect the hemodynamics

of the rehaped blood vessel in question and cause the gradual formation of fibrines.

Other potential problems with the '397 design have been identified. Since the clip connectors define a very small cavity surrounding the coupled wire filaments, they may trap bacteria or chemicals during the manufacturing process, potentially resulting in adverse complications *in vivo*. Further, the crimped clip connectors are sensitive to metal fatigue over time which may compromise the functional longevity of the stent scaffold.

The need has therefore arisen for a stent design having improved connecting elements for overcoming the various limitations apparent in the prior art.

Summary of the Invention

In accordance with the invention, a stent is disclosed comprising a plurality of expandable stent modules. Each of the modules preferably comprises first and second annular elements each comprising thin filaments formed in an undulating pattern comprising alternating peaks and troughs. A plurality of first connectors secure the first and annular second elements together in radial alignment to define a cylindrical opening. A plurality of second connectors are also provided for joining adjacent pairs of stent modules together at radially spaced locations. The second connectors are extensible between contracted and extended configurations to allow the stent to conform to curves in the vessel wall during deployment of the stent and prevent foreshortening.

Preferably the second connectors are serpentine-shaped in the contracted configuration. Each second connector has a first end and a second end which are joined to the module filaments mid-way between one of the peaks and one of the troughs.

In one embodiment, each stent module may include a pair of first connectors located on opposite sides of the module. The first connectors do not deform when the stent is expanded and they may be used as substrate for delivery of drugs to the target lesion. The first connectors have a relatively large surface area for drug delivery and enhanced radiopacity. Both the first and second connectors are flush with the cylindrical profile of the remainder of the stent for improved trackability and deployment.

Brief Description of the Drawings

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

Figure 1 is first perspective view of the applicant's stent comprising four separate stent modules;

Figure 2 is a second perspective view thereof showing the stent rotated approximately 45 degrees relative to the view of Figure 1;

Figure 3 is a third perspective view thereof showing the stent rotated approximately 90 degrees relative to the view of Figure 1;

Figure 4 is an enlarged perspective end view of the stent of Figure 3;

Figure 5 is a plan view of the applicant's stent showing the stent cut lengthwise and laid in a flat configuration for the purpose of clarity; and

Figures 6A - 6D are side elevational views, in three dimensions, of semi-cylindrical portions of the applicant's stent wrapped around a cylinder for the purposes of clarity.

Detailed Description of the Preferred Embodiment

An earlier stent design of the applicant is the subject of a Patent Cooperation Treaty application PCT/CA99/0039 published on 18 May, 2000 under No. WO 00/27306 (the '306 application). The '306 application, the text of which is incorporated herein by reference, describes a modular stent which is fabricated from wire strands. In the preferred manufacturing process, the wire strands are bent in a flat configuration and are then expanded to a generally cylindrical configuration.

With reference to Figure 1, stent 100 of the present application is preferably formed from small diameter biocompatible steel tubing by a laser cutting manufacturing process rather than by wire forming. As a result, stent 100 has smooth, cylindrical inner and outer surfaces which define an opening 102 having a consistent diameter.

As in the '306 invention, stent 100 comprises a plurality of interconnected modules 110 defining opening 102. Each module 110 consists of a pair of generally annular elements 112 comprising thin metal filaments 114. Filaments 114 are preferably formed in an undulating pattern, such as a sinusoidal wave pattern comprising alternating peaks 116 and troughs 118. Elements 112 are disposed such that the peaks 116 of one element 112 are located adjacent the troughs 118 of the other element 112 (and vice versa).

Within each module 110 elements 112 are joined by a pair of opposed first connectors 120. In the illustrated embodiment, each first connector 120 is generally disk-shaped. As a result of the laser cutting process described above, connectors 120 are the same thickness as filaments 114 and hence they do not protrude from the inner or outer surfaces of modules 110. This ensures that each stent module has a consistent cross-sectional profile which is important for ease of deployment.

Although the shape of first connectors 120 is not critical, it preferable that they have a relatively large, non-deformable surface area to serve as a substrate for delivery of drugs to the site of the target lesion. For example, connectors 120 could be coated with anti-restenosis drugs. Since connectors 120 are not stretchable, such coatings will not splinter or peel when stent 100 is expanded at the site of the target lesion unlike some prior art drug delivery systems. In alternative embodiments of the invention, additional first connectors 120 could be distributed at different locations in stent 100 for targeted drug delivery or homogenous diffusion of drugs along the vessel wall.

First connectors 120 may also function as improved radio-opaque markers enabling physicians to better visualize the position of stent 100 during deployment within vascular or other body lumens. In order to enhance their radiopacity, connectors 120 may be plated with a dense material easily visible using fluroscopy.

Modules 110 are interconnected by a plurality of extensible second connectors 126. Each second connector 126 is serpentine in shape in its contracted configuration comprising generally linear end portions 122 and a generally S-shaped central portion 124. In the preferred embodiment, each end portion 122 is connected to a filament 114 mid-way between a peak 116 and trough 118 and central portion 124 is disposed in the space between adjacent modules 110. When stent 100 is deployed at the site of the target lesion, second connectors 126 are moveable to an extended configuration. For example, if stent 100 is deployed at a curve in the vessel lumen, some of the second connectors 126 will extend in length to enable stent 100 to conform to the contour of the vessel. Each module 112 is independently expandable to conform to the particular anatomy of the target site. Since second connectors 126 are extensible, they prevent foreshortening of stent 100 (i.e. a reduction in the overall length of stent 100 as individual modules 112 are radially expanded).

In a preferred embodiment, several second connectors 126 (e.g. four) extend between stent modules 110 at spaced locations. Connectors 126 strengthen the overall stent scaffold and help prevent prolapse of atherosclerotic plaque or vascular tissue at locations between the modules 110.

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.

WHAT IS CLAIMED IS:

1. A stent comprising:

(a) a plurality of expandable stent modules, each of said modules comprising:

(i) first and second annular elements each comprising thin filaments formed in an undulating pattern comprising alternating peaks and troughs; and

(ii) a plurality of first connectors for securing said first and annular second elements together in radial alignment to define a cylindrical opening; and

(b) a plurality of second connectors extensible between contracted and extended configurations, wherein said second connectors extend between adjacent pairs of said modules at spaced radial locations.

2. The stent of claim 1, wherein said second connectors are serpentine-shaped in said contracted configuration.

3. The stent of claim 2, wherein each of said connectors has a first end and a second end and wherein said first and second ends are joined to said module filaments mid-way between one of said peaks and one of said throughs.

4. The stent of claim 1, wherein each of said modules comprises a pair of said first connectors located on opposite sides of said module.

5. The stent of claim 4, wherein said first connectors do not deform when said stent modules are expanded.

6. The stent of claim 5, wherein said first connectors are coated with pharmaceutically active compositions.

7. The stent of claim 4, wherein said first connectors are disk-shaped.

8. The stent of claim 1, wherein said filaments are produced by laser cuttting of a metal tube.

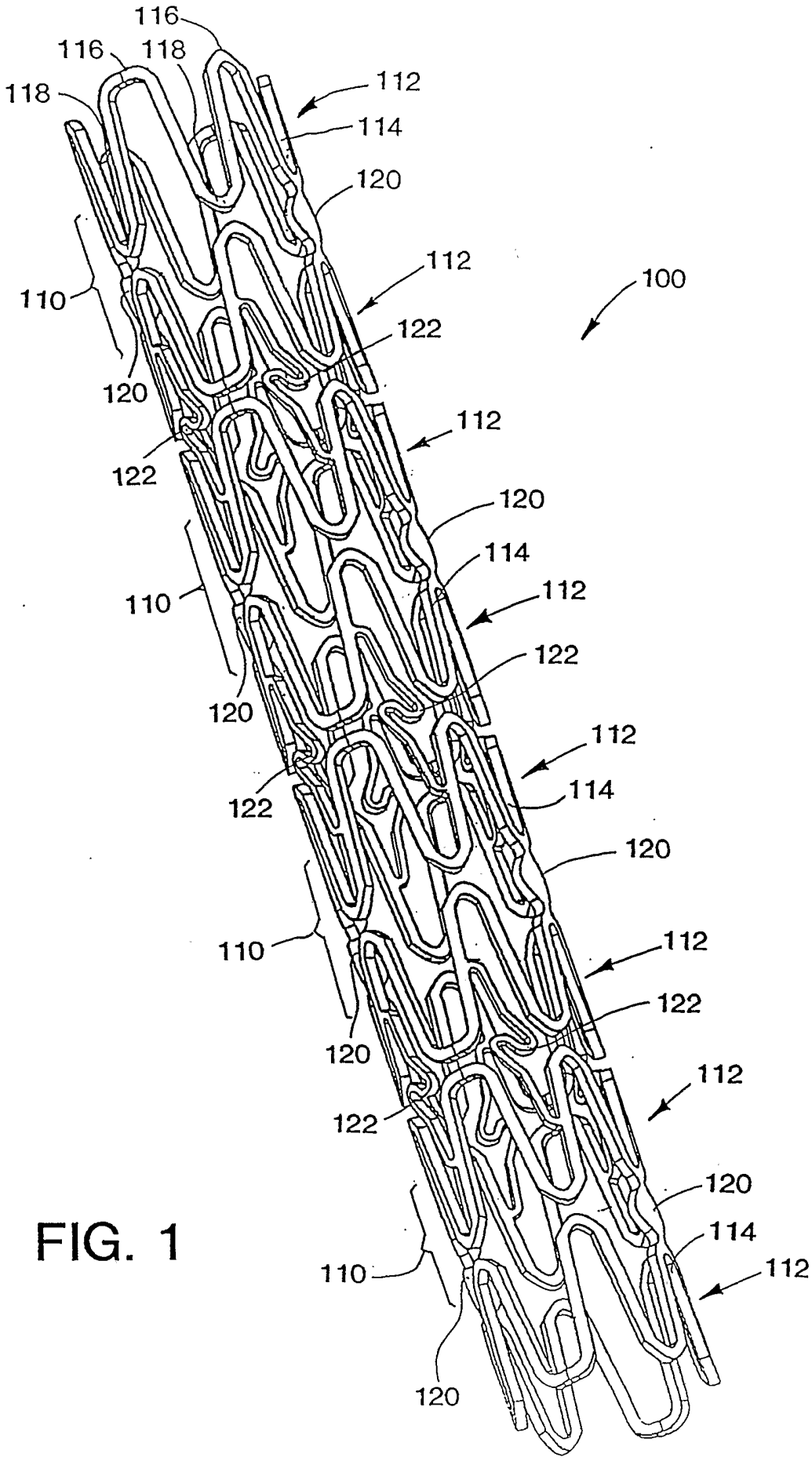
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FIG. 1

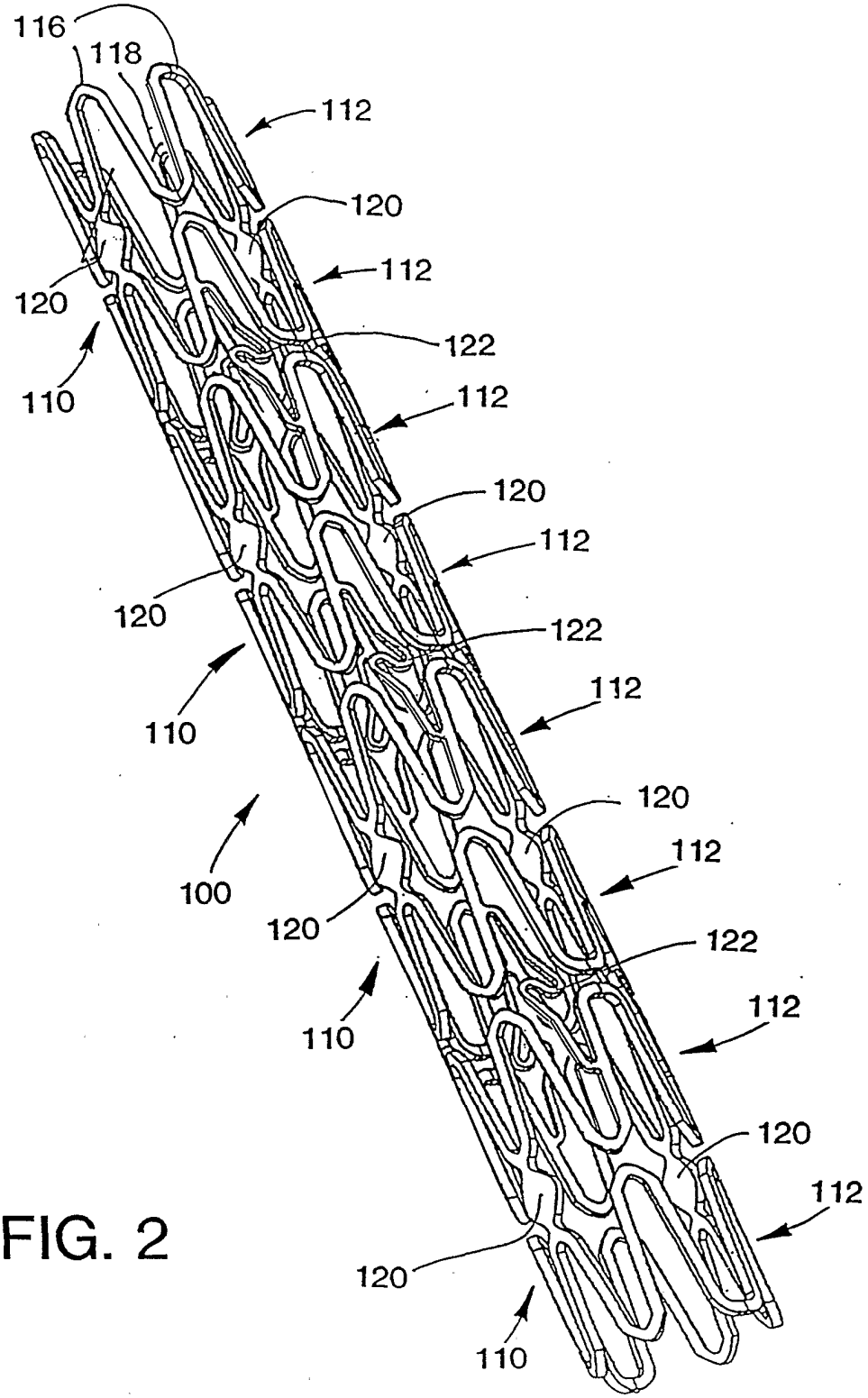
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FIG. 2

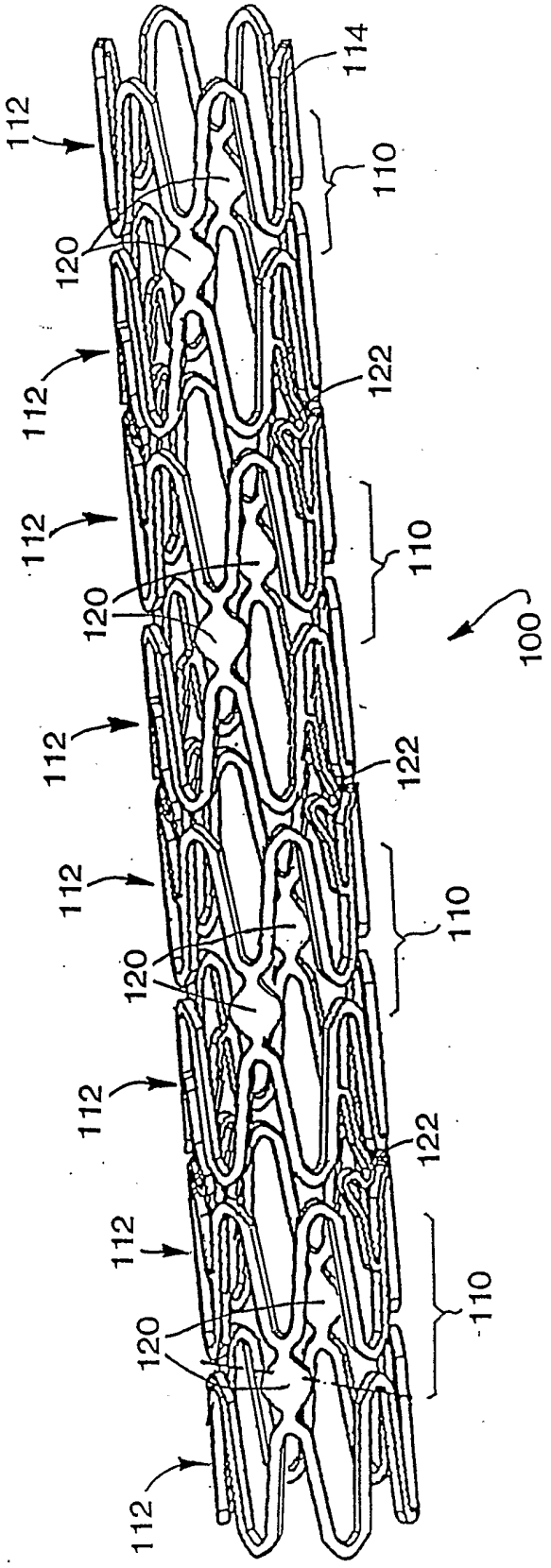
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FIG. 3

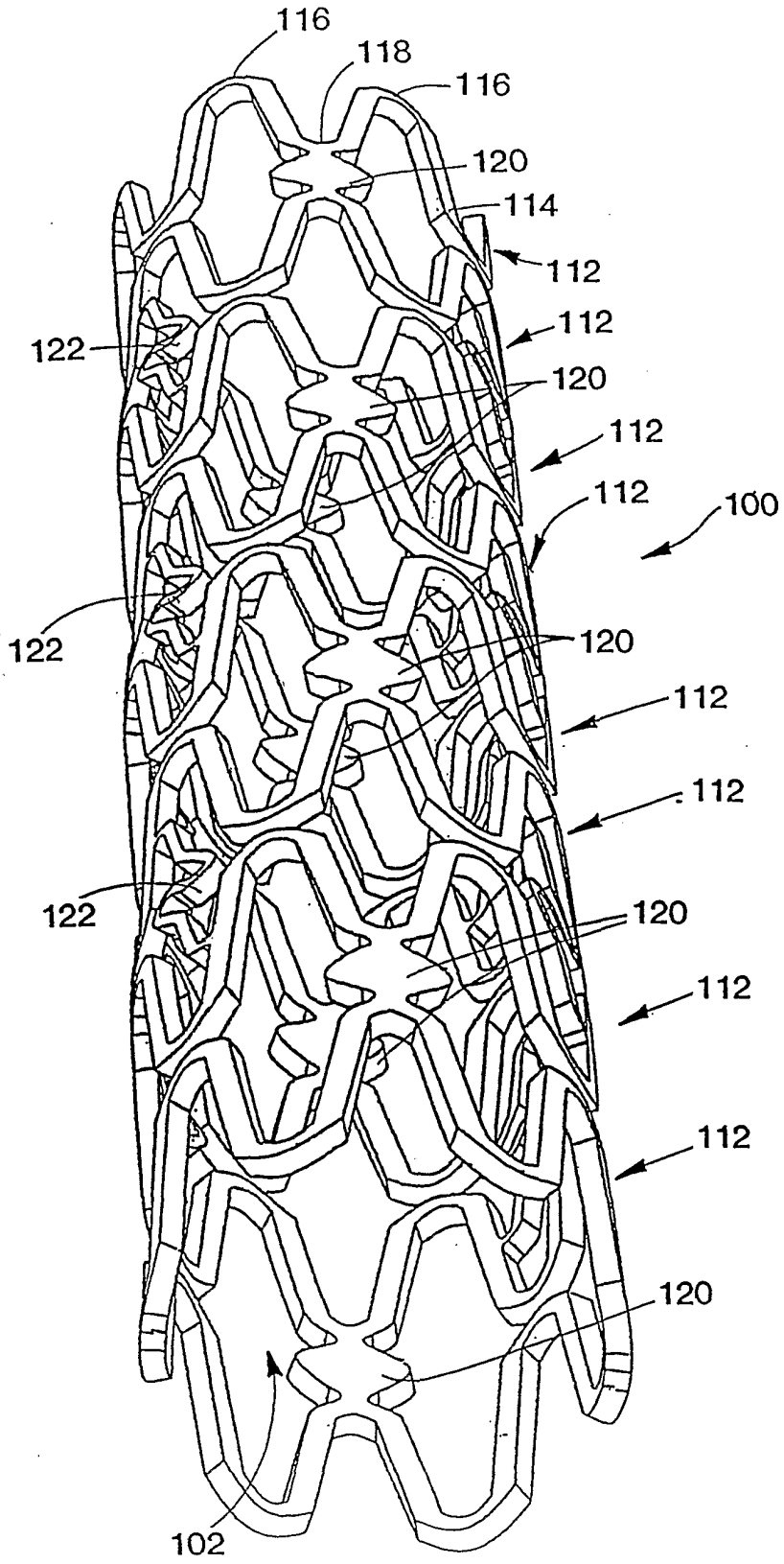
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FIG. 4

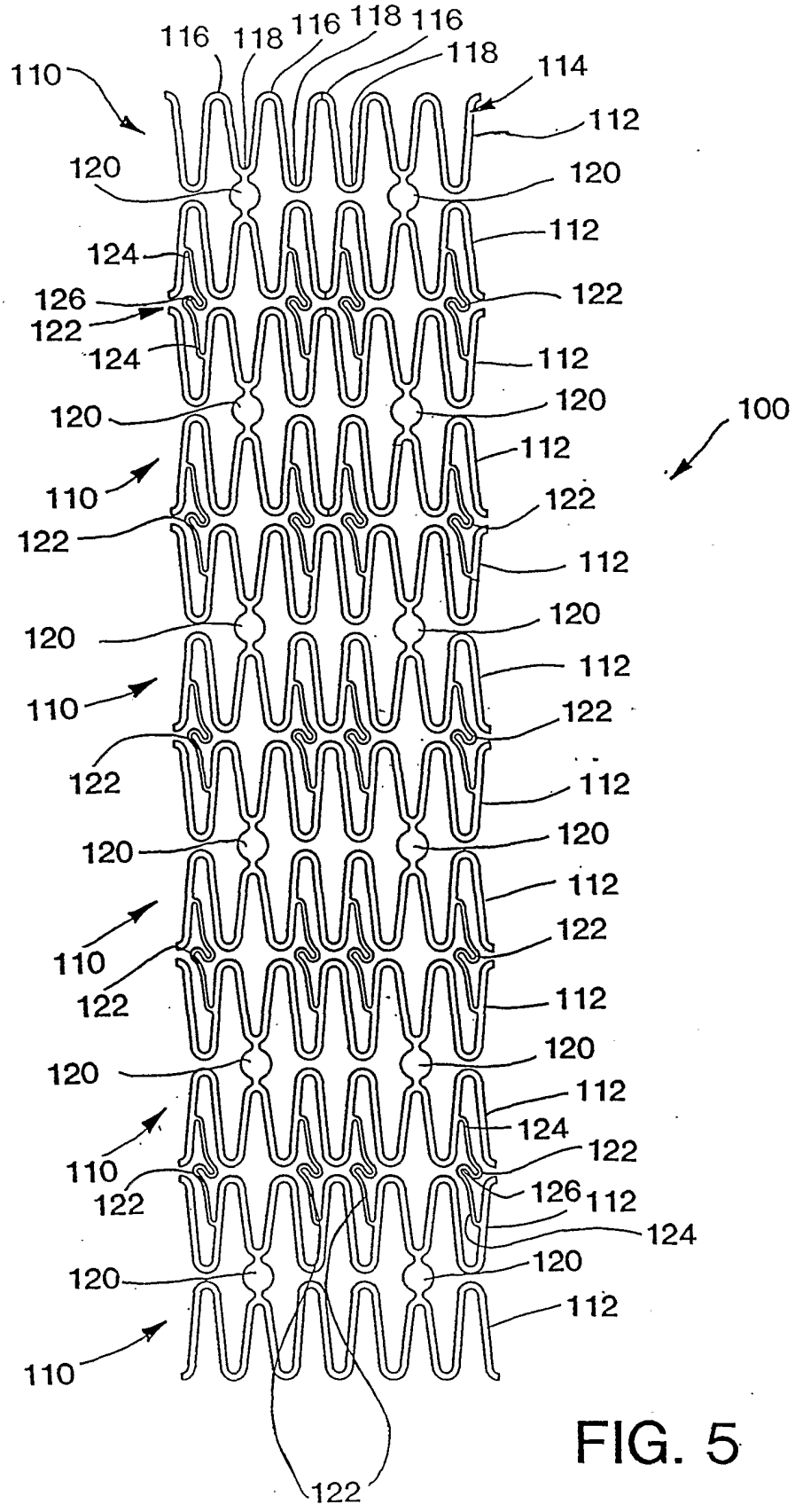
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FIG. 5

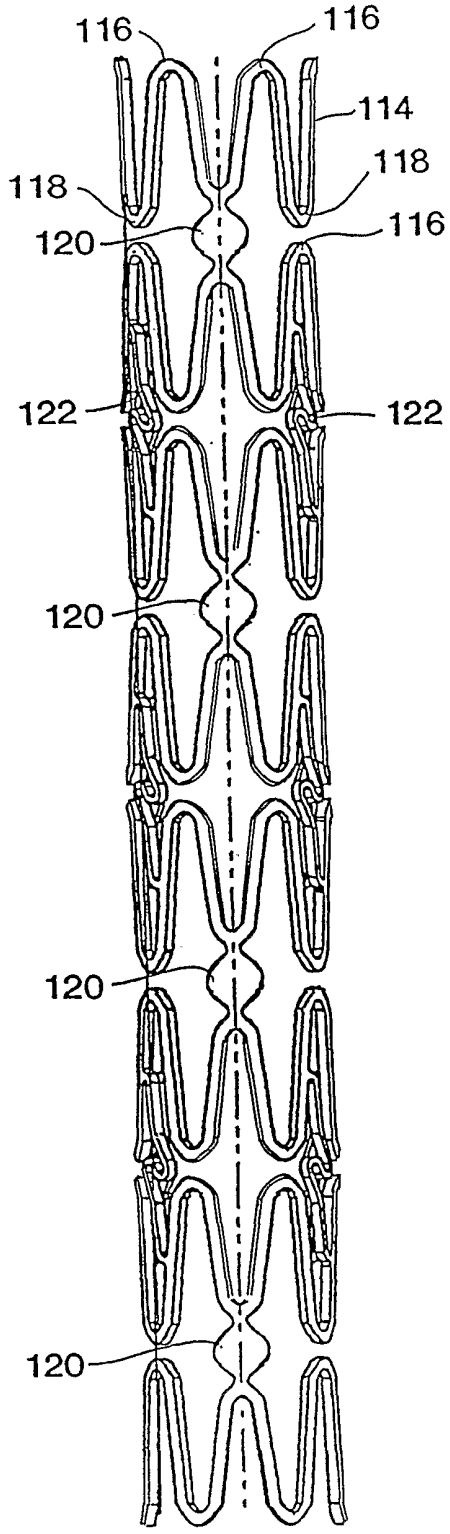
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FIG. 6A

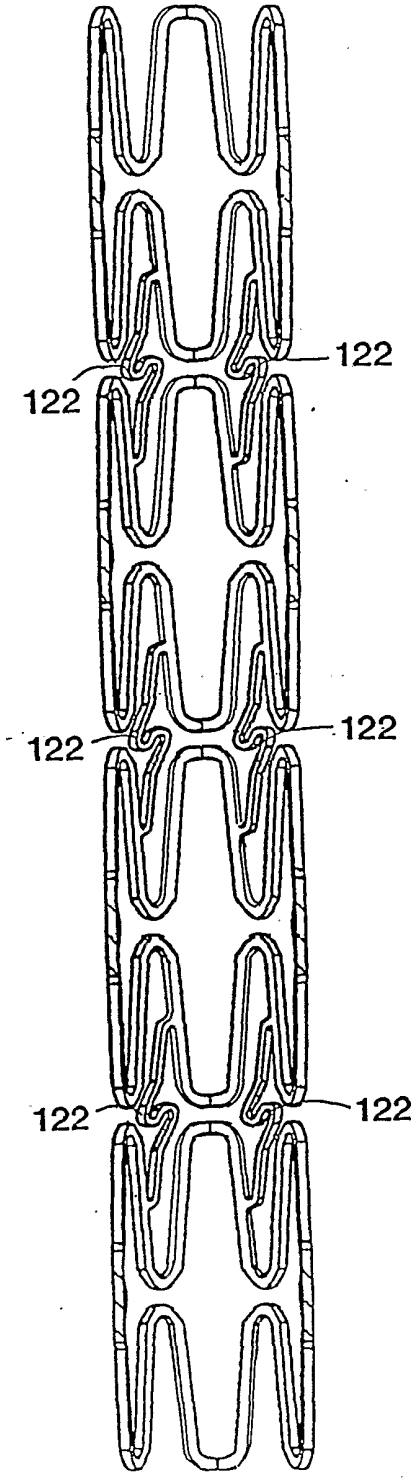
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FIG. 6B

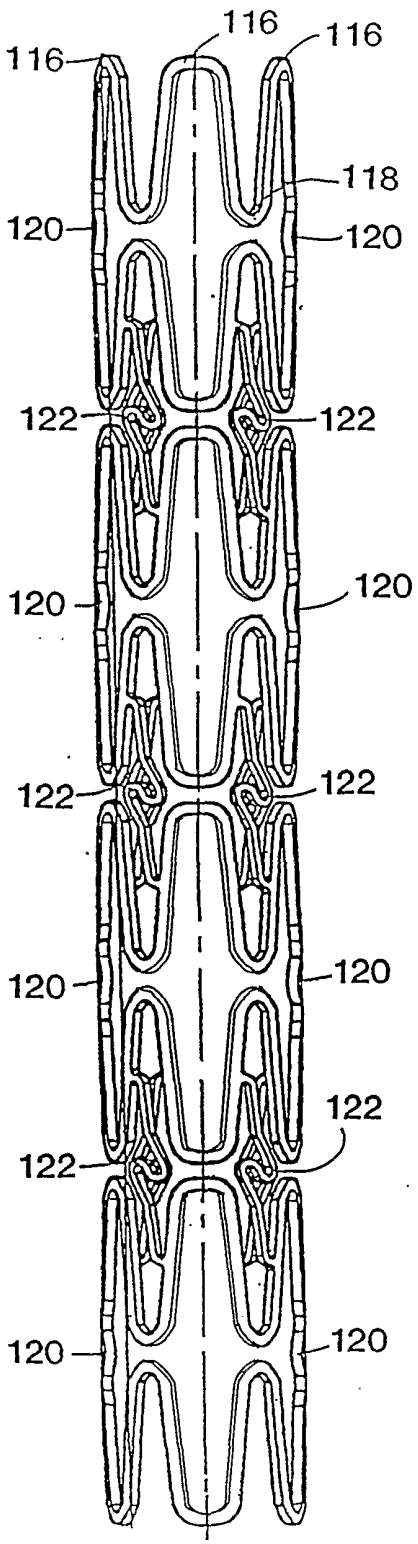
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FIG. 6C

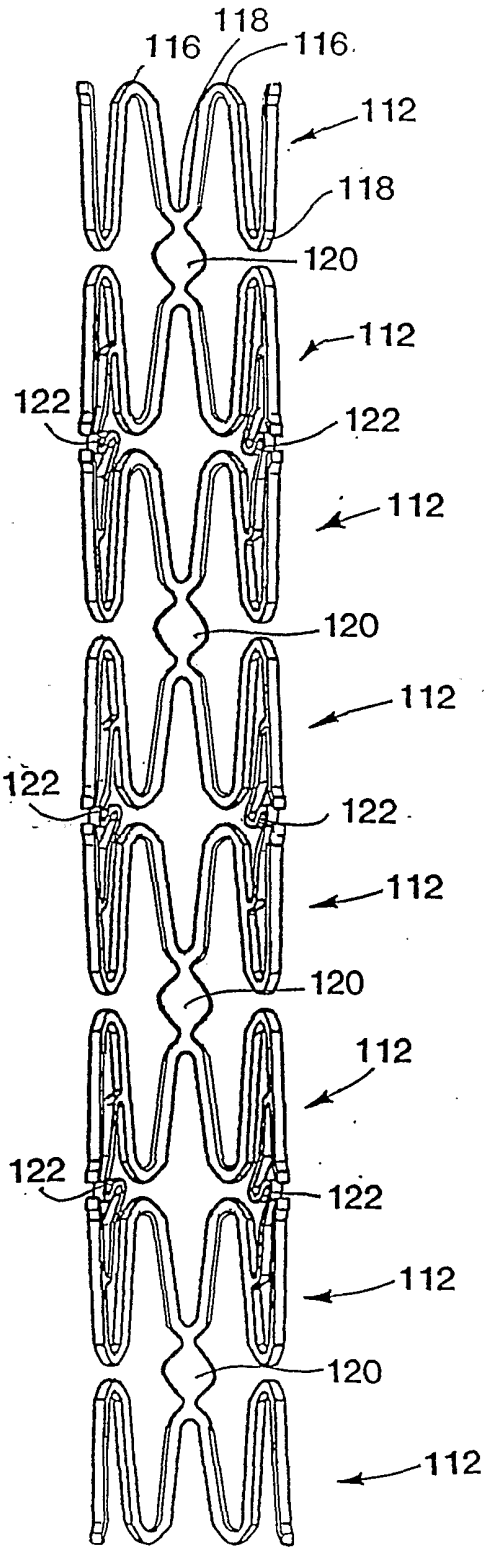
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FIG. 6D

INTERNATIONAL SEARCH REPORT

Int[illegible]onal Application No
PCT/CA 00/01577

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)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 083 259 A (FRANTZEN JOHN J) 4 July 2000 (2000-07-04) column 6, line 20 -column 7, line 13; figures	1,2,4,5, 8
X	EP 0 888 757 A (COROTEC MEDIZINTECHNIK GMBH) 7 January 1999 (1999-01-07) column 3, line 32 -column 4, line 13; figures	1,2,4,8
X	WO 99 17680 A (LOCALMED INC) 15 April 1999 (1999-04-15) figures 1-7; examples A-C	1,2,8
A	WO 00 45744 A (SCIMED LIFE SYSTEMS INC ;WANG LIXIAO (US); STANSLASKI JOEL (US); Y) 10 August 2000 (2000-08-10) abstract; figures	6

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 August 2001	28/08/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Neumann, E

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Int[illegible]nal Application No
PCT/CA 00/01577

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EP 0888757 A	07-01-1999	AU 8440198 A DE 19880840 D WO 9901086 A	25-01-1999 04-01-2001 14-01-1999
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