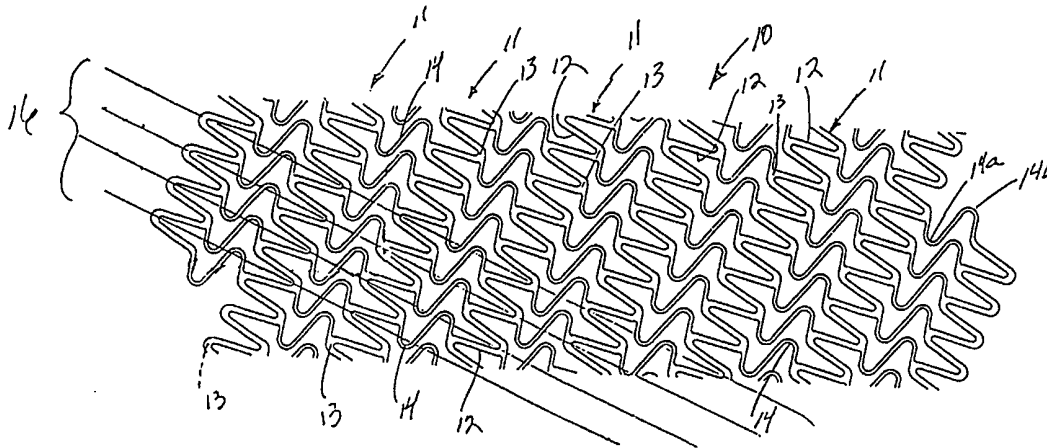




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁷ : A61F 2/06</p>	<p>A1</p>	<p>(11) International Publication Number: WO 00/24340</p> <p>(43) International Publication Date: 4 May 2000 (04.05.00)</p>
<p>(21) International Application Number: PCT/US99/23797</p> <p>(22) International Filing Date: 12 October 1999 (12.10.99)</p> <p>(30) Priority Data: 09/178,457 23 October 1998 (23.10.98) US</p> <p>(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One SCIMED Place, Maple Grove, MN 55311 (US).</p> <p>(72) Inventors: KVEEN, Graig, L.; 14125 - 74th Place North, Maple Grove, MN 55311 (US). DORAN, Burns, P.; 11421 - 80th Street N.E., Albertville, MN 55301 (US). JUDNITCH, Robert, T.; 6620 - 57th Avenue North, Crystal, MN 55428 (US).</p> <p>(74) Agent: ARRETT, Oliver, F.; VIDAS, ARRETT & STEINKRAUS, Suite 2000, 6109 Blue Circle Drive, Minnetonka, MN 55343 (US).</p>		<p>(81) Designated States: CA, JP, 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>

(54) Title: HELICAL STENT DESIGN



(57) Abstract

An expandable tubular reinforcing member used for body lumens such as vessels, the reinforcing member being formed of a continuous elongated helical element comprised of spaced undulating portions forming end loop portions and including a plurality of curvilinear connector elements extending between and interconnecting at least some of the adjacent undulating portions of the helical element over its length.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

HELICAL STENT DESIGN

BACKGROUND OF THE INVENTION

The present invention relates to stents. A stent, generally speaking, is
5 a device that can be placed within a body lumen or interior space for supporting and
assuring patency of a lumen. Patency refers to the state of being freely open and is
particularly important in the vascular system. The field of angioplasty is concerned
with the reconstruction of blood vessels and stents are used, for example, for holding
blood vessels open or for back tacking intimal flaps inside the vessels after
10 angioplasty. More generally, however, stents can be used inside the lumina of any
physiological conduit including arteries, veins, vessels, the biliary tree, the urinary
tract, the elementary tract, the tracheal bronchial tree, the genitourinary system, and
the cerebral aqueduct. Stents can be used inside lumina of animals and/or humans.

Stents are generally tubular in structure and are radially expandable
15 between an unexpanded insertion size or circumference and an expanded implantation
size or circumference which is greater than the unexpanded insertion size.

An important attribute of a stent is that it be radially compressible and
expandable so that it will easily pass through a blood vessel or the like when collapsed
and will expand or can be expanded to its implanted size after the implantation
20 location has been reached. It is also desirable that a stent be generally flexible
throughout its length so that it is easily maneuverable through bends and curves of the
vascular system or the like to reach the implantation site and that the stent be
conformable to the vascular site when expanded. It is also typically desirable that a
stent have a substantial amount of open space so as to allow for endothelialization
25 along its length to minimize foreign body response and to minimize interference with
collateral blood vessels and the like.

There have been introduced various types of stents and various stent
designs. Stents are generally categorized as being self-expandable, i.e., which expand
by themselves and balloon expandable, i.e., expanded by a balloon inserted inside the
30 stent.

From the view point of materials, stents can be categorized as being
made from various metals such as stainless steel, nitinol and from various plastics.

Stents can be made from tubular stock structures from which a desired design may be cut or etched. Also they may be made from wire. Both of these types are well known.

Details of prior art stents can be found in U.S. Patent No. 5,562,697,
5 U.S. Patent No. 5,540,713, U.S. Patent No. 5,575,816, U.S. Patent No. 5,569,295,
U.S. Patent No. 5,496,365, U.S. Patent No. 5,344,426, U.S. Patent No. 5,139,480,
U.S. Patent No. 5,135,536, U.S. Patent No. 5,810,872, U.S. Patent No. 5,226,913,
U.S. Patent No. 5,716,396, and U.S. Patent No. 5,370,683.

This invention relates to all of the above-discussed types of stents and
10 incorporates herein by reference all of the above patents specifically identified herein.

It is an object of the invention to provide, as a preferred embodiment, a
stent comprised of a helically wound serpentine or undulating structure including
curved connecting elements, i.e., curvilinear, which produces closed flexible cells in
the expanded form. In combination the flexible cells yield a flexible, conformable
15 stent which expands uniformly and provides good radial strength, scaffolding and
fatigue characteristics when expanded.

Stents incorporating the design of the invention are preferably made
from wire windings as in the prior art or from tubes such as metal tubes which are
etched or laser cut to obtain the desired configuration of the stent in accordance with
20 the invention.

The art referred to and/or described above is not intended to constitute
an admission that any patent, publication or other information referred to herein is
"prior art" with respect to this invention. In addition, this section should not be
construed to mean that a search has been made or that no other pertinent information
25 as defined in 37 C.F.R. §1.56(a) exists.

BRIEF SUMMARY OF THE INVENTION

Generally speaking the present invention provides a stent comprised of
two major structural elements, the first being a continuous elongated helical element
30 preferably comprised of spaced undulating portions forming periodic end loop
portions, i.e., a serpentine configuration, the helical element extending substantially
over the length of the stent body to create a cylindrical stent configuration. The

second element comprises a plurality of curvilinear, most preferably sinusoidal, connectors extending between and interconnecting at least some of the adjacent undulating portions, preferably connected to the end loop portions, of the helical element over its length. A double parallel helix or multiple parallel helices may also
5 be used but the single helix as described hereinbelow is preferred.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view of a stent extended in a flat form according to a first embodiment of the invention;

10 Figure 1a is a front view of a stent before it is expanded;

Figure 1b is a front view of a stent after it is expanded;

Figure 2 is a view similar to Figure 1 of another embodiment of the invention;

15 Figure 3 is a similar view according to a third embodiment of the invention;

Figure 4 is again a similar view of yet another embodiment of the invention;

Figure 5 is a similar view of a further embodiment of the invention;

Figure 6 is a similar view of still another embodiment of the invention;

20 Figure 7 is a fragmentary flat form view of another stent embodiment;

Figure 8 is a fragmentary flat form view of yet another stent embodiment, and

Figure 9 is a fragmentary flat form view of another stent embodiment.

25 DETAILED DESCRIPTION OF THE INVENTION

While this invention may be embodied in many different forms, there are described in detail herein specific preferred embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

30 A stent 10 of a first embodiment the invention as shown in Figure 1.

The stent 10 is formed of a diagonally arranged helical band 11 which is arranged spirally in a cylindrical shape. The band 11 includes undulating portions 12 over its

entire continuous length to provide a serpentine configuration. As can be seen in the Figure, each of the undulating portions includes loop end portions 13. Each loop end portion 13 is interconnected with an adjacent longitudinally spaced end portion 13 by a curvilinear connector element 14 which, in this embodiment, includes two bends or
5 U-shaped portions 14a and 14b to form a connector having a preferred sinusoidal shape. Also as can be seen from Figure 1 in this embodiment the interconnecting elements 14 preferably join end portions 13 at their extreme ends and extend directly between longitudinally spaced adjacent end portions. The connectors may be attached to other locations on the undulations other than the extreme ends. Also, with respect
10 to the stent of Figure 1, it should be noted that the undulations are out of phase as indicated by lines 16.

In this embodiment as in all of the embodiments disclosed, the stent is preferably formed from a tubular stock material by laser cutting. However, a tube may be etched as well. It is possible to form a desired configuration from flat sheet
15 stock which is then bent into the desired cylindrical configuration. This is a procedure which is known in the art.

When a stent such as that shown in Figure 1 is implanted in a body lumen, such as an artery, with the stent having an initial diameter D_1 as shown in Figure 1a as delivered into the lumen to the desired location, the stent can be flexed
20 and bent easily in a meandering lumen during delivery. Then, the stent is expanded to have a second diameter D_2 as shown in Figure 1b which is larger than the initial diameter D_1 whereby the stent is implanted.

When the stent is delivered and expanded, a delivery catheter assembly with an expandable member, such as a balloon, is preferably used as is known in the
25 art. When the catheter assembly with a balloon is used to deliver the stent, the stent is mounted on the balloon and the catheter assembly is pushed into the implantation site. Then, the balloon is inflated, radially applying a force inside the stent and the stent is expanded to its expanded diameter.

Referring now to Figure 2, a second embodiment of the invention is
30 shown which is similar in most respects to the embodiment shown in Figure 1 with the exception that the sinusoidal connector elements 14 extend between end portions 13

which are not only longitudinally adjacent but are spaced upwardly or downwardly with respect to each other. Again, the serpentine configuration is out of phase.

Referring now to Figure 3, another embodiment of the invention is shown which is comprised of similar undulating structural elements 11 as is described with reference to Figures 1 and 2. However, in this embodiment the connecting elements 14 are of a different configuration in the sense that the two U-shaped bends 14a and 14b are closer together, the resulting configuration not being strictly speaking "sinusoidal" but being curvilinear.

Other curvilinear configurations may also be used for the connector elements. For example, spiral configurations may be used such as those disclosed in U.S. Patent application Serial No. 08/846,164 filed April 25, 1997, entitled "*Improved Stent Configurations Including Spirals*", which application is incorporated herein by reference in its entirety.

Referring now to the embodiment of Figure 4, it can be seen that this embodiment is also somewhat similar to that of Figure 1. However, in this embodiment the ends of the stent rather than being diagonal as shown in Figure 1 are squared off with respect to the longitudinal axis of the stent 40.

Referring now to Figure 5, another embodiment of a stent 50 according to this invention is shown. Again, the basic elements of this stent are similar to those of the preceding embodiments with the exception that the helical elements 11 are not merely diagonal in arrangement but are curvilinear as well. This is demonstrated by reference to lines 18.

Referring now to the embodiment shown in Figure 6, it can be seen that the undulations of the helical element 11 can be arranged so as to be in phase as is shown by lines 20.

Referring now to Figures 7, 8 and 9, a fragment of a stent 10 is shown in each Figure including helical bands 11. In Figures 7 and 9 the bands are made up of interconnected rectangular cells and in Figure 8 the cells are joined serpentine or diamond shaped cells. In these Figures the curvilinear connector elements 14 are the preferred sinusoidal configuration.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and

alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached

5 hereto.

WHAT IS CLAIMED IS:

1. A stent for implantation in a body lumen, the stent having an open-ended tubular shape defined by a structure comprising:
at least one continuous elongated helical band element comprised of
5 spaced undulating portions forming end loop portions the helical element extending substantially over the length of the stent body, and
a plurality of curvilinear elements extending between and interconnecting at least some of the adjacent, undulating portions of the helical element over its length.
- 10 2. The stent of claim 1 in which the undulating portions are in a sinusoidal pattern.
3. The stent of claim 1 in which the curvilinear elements extend between the loops of the undulating portions.
4. The stent of claim 1 in which the curvilinear elements include at
15 least one bend.
5. The stent of claim 4 in which the bend is U-shaped.
6. The stent of claim 1 in which the curvilinear elements include at least two bends.
7. The stent of claim 6 in which the bends are U-shaped.
- 20 8. The stent of claim 6 in which the bends open in substantially opposite directions.
9. The stent of claim 1 wherein adjacent undulating portions of the helical element are in phase.
10. the stent of claim 1 wherein adjacent undulating portions of the
25 helical element are out of phase.
11. The stent of claim 1 wherein the interconnecting elements extend between longitudinally spaced loop end portions.
12. The stent of claim 1 wherein the interconnecting elements extend between longitudinally spaced helical portions from and to loop end portions
30 which are diagonally spaced from each other.
13. A stent for implantation in a body lumen, the stent having an open-ended tubular shape defined by a structure comprising:

at least one helically arranged band element forming a tubular configuration, the band being made up of a plurality of closed, interconnected cells;

5 a plurality of curvilinear connector elements extending between and interconnecting longitudinally spaced portions of the band over its tubular length.

14. The stent of claim 13 in which the cells of the band are rectangular.

10 15. The stent of claim 13 in which the curvilinear connectors are sinusoidal.

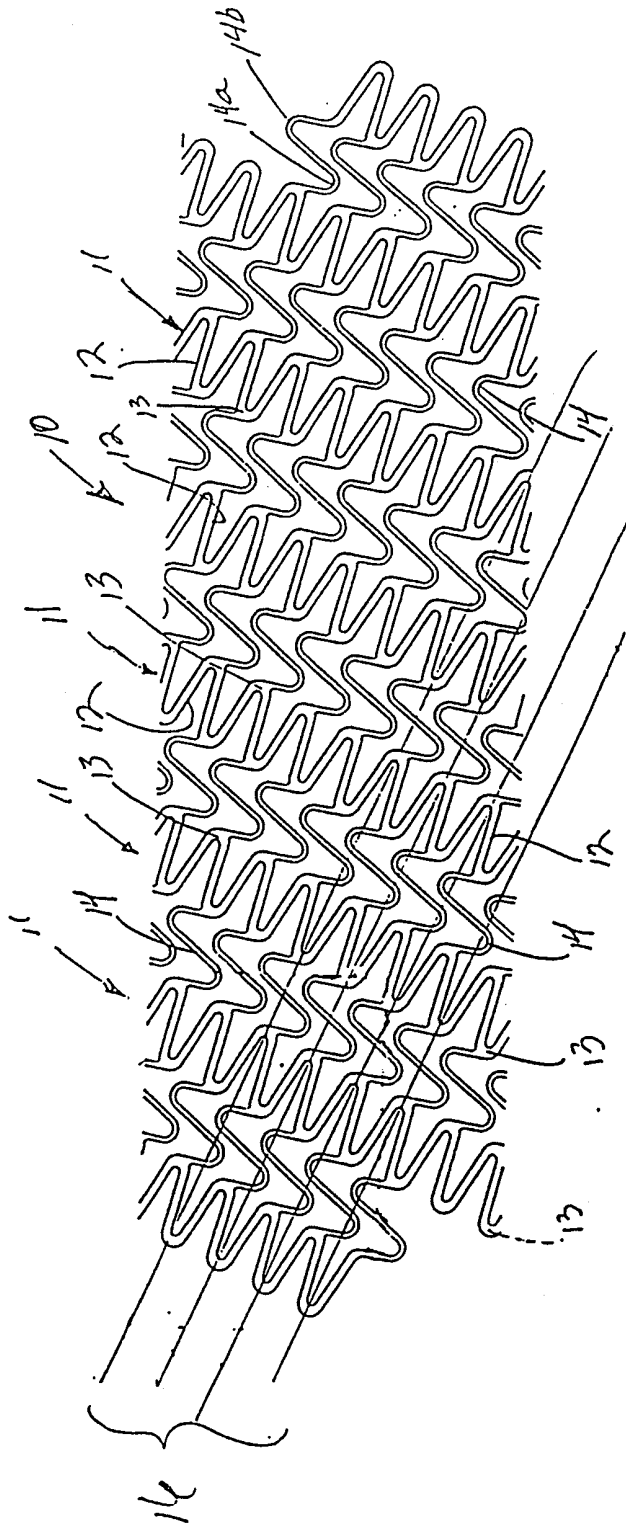


Fig 1

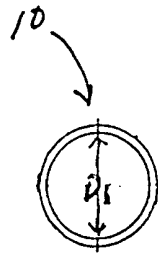


Fig 1a

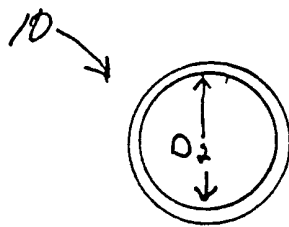


Fig 1b

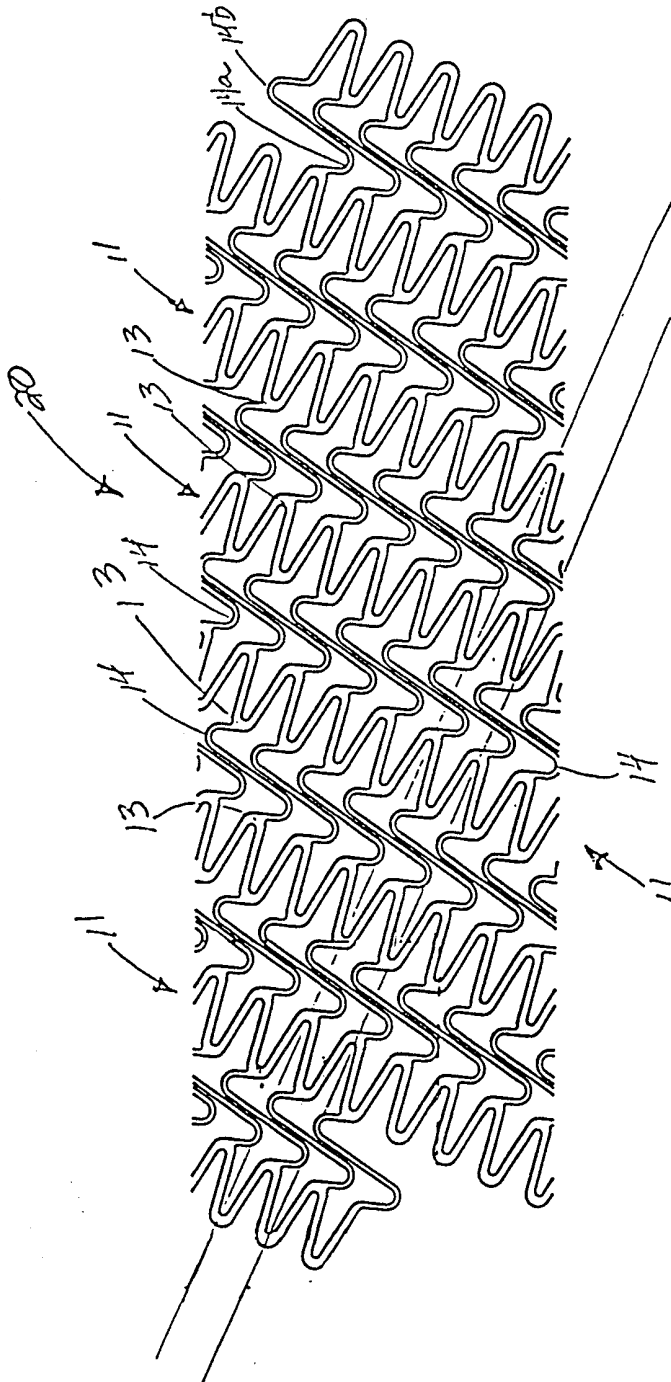


FIG 2

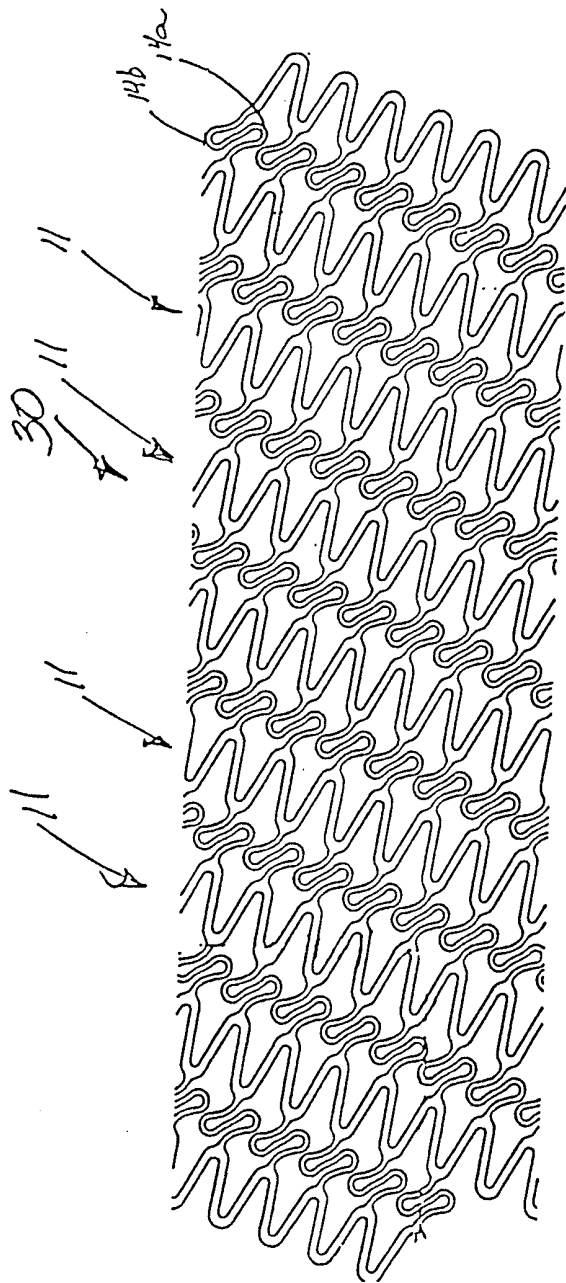


FIG 3

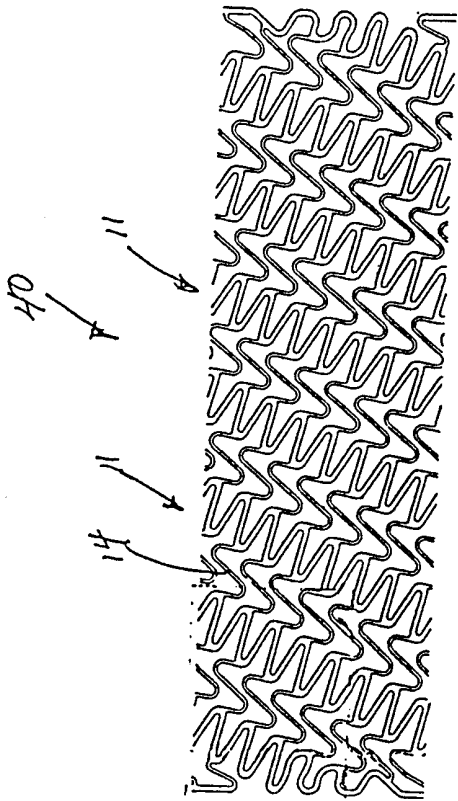


Fig. 4

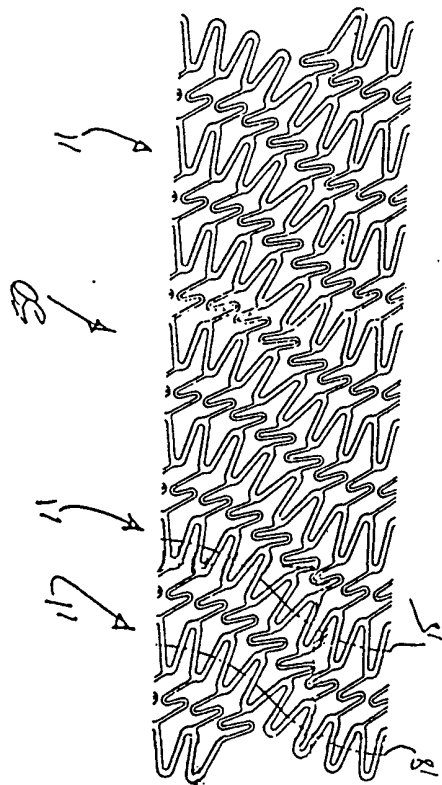


FIG 5

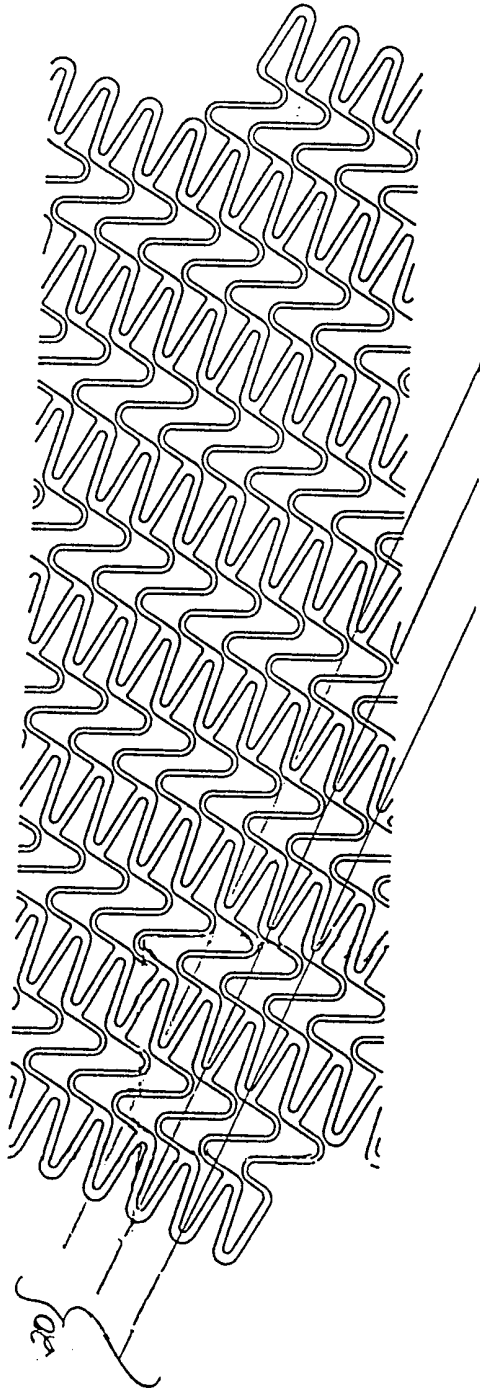


Fig 6

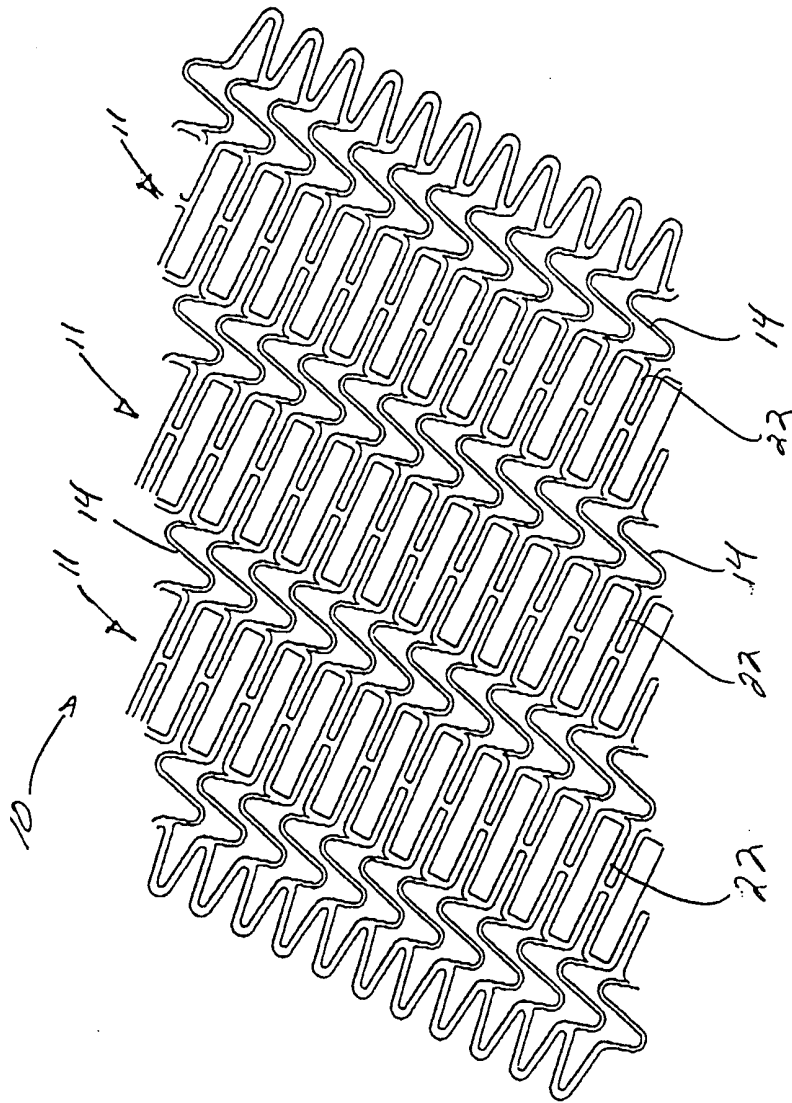


Fig. 7

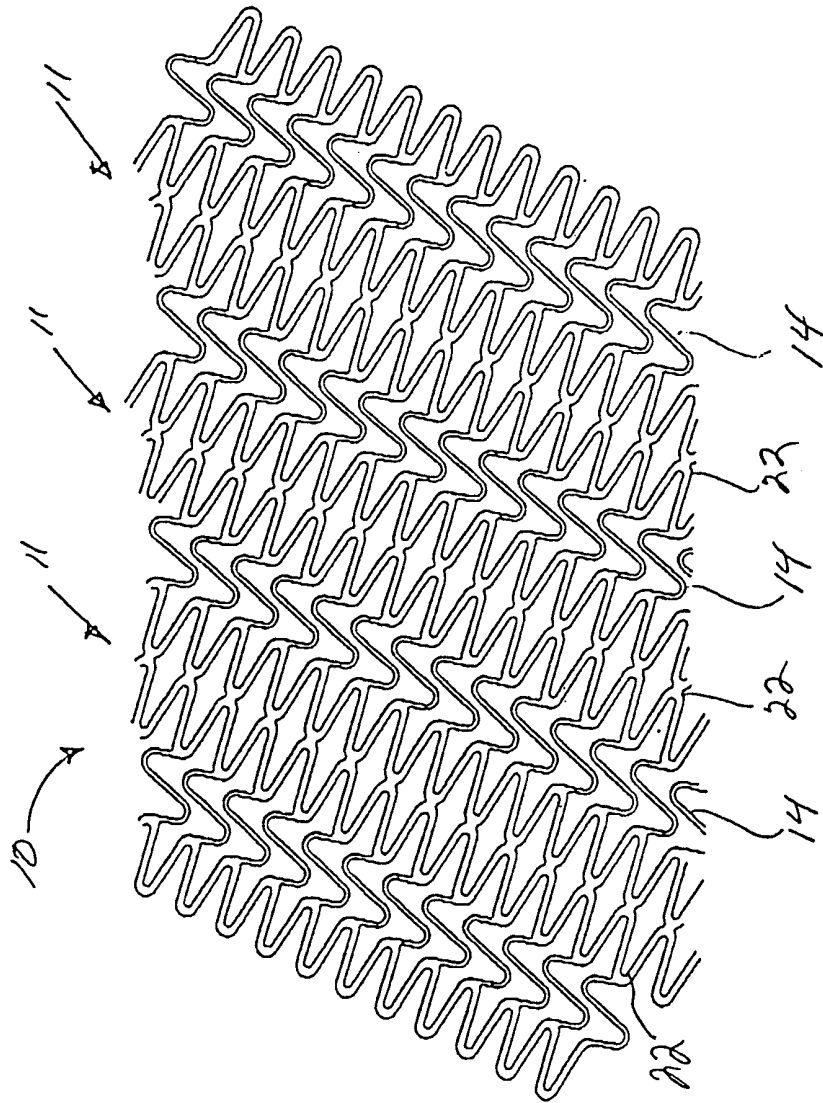
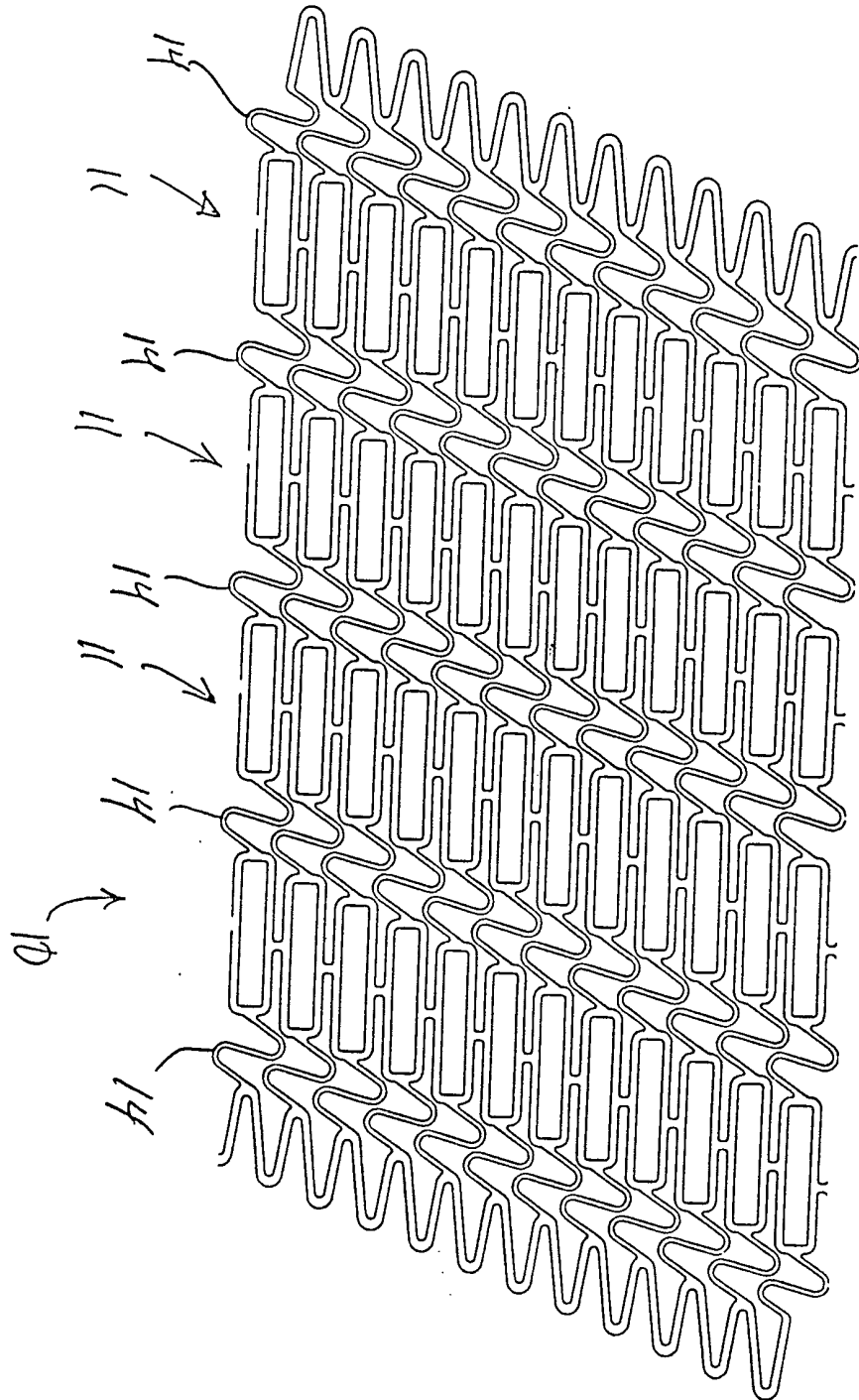


Fig. 8

Fig. 9



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/23797

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	WO 98 30173 A (GORE ENTERPRISE HOLDINGS INC.) 16 July 1998 (1998-07-16)	1-9
Y	the whole document	10-15
Y	US 5 810 872 A (KANESAKA ET AL) 22 September 1998 (1998-09-22) cited in the application abstract; figures	10, 12
Y	WO 98 40035 A (UNITED STATES SURGICAL CORPORATION) 17 September 1998 (1998-09-17) abstract; figures	11
Y	FR 2 758 253 A (LABORATOIRES NYCOMED) 17 July 1998 (1998-07-17) the whole document	13-15
<input type="checkbox"/> Further documents are listed in the continuation of box C.		
<input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents :		
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "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 "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family
Date of the actual completion of the international search 10 March 2000		Date of mailing of the international search report 16/03/2000
Name and mailing address of the ISA 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		Authorized officer Smith, C

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/23797

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9830173 A	16-07-1998	US 5925061 A	20-07-1999
		AU 5813798 A	03-08-1998
		EP 0951254 A	27-10-1999
US 5810872 A	22-09-1998	EP 0870483 A	14-10-1998
		JP 10258125 A	29-09-1998
WO 9840035 A	17-09-1998	AU 6464298 A	29-09-1998
FR 2758253 A	17-07-1998	EP 0951255 A	27-10-1999
		WO 9830172 A	16-07-1998